SOUTH CAROLINA STATE REGISTER DISCLAIMER

SOUTH CAROLINA STATE REGISTER

PART 1 OF 2
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This issue contains notices, proposed regulations, emergency regulations, final form regulations, and other documents filed in the Office of the Legislative Council, pursuant to Article 1, Chapter 23, Title 1, Code of Laws of South Carolina, 1976.

THE SOUTH CAROLINA STATE REGISTER

An official state publication, *The South Carolina State Register* is a temporary update to South Carolina's official compilation of agency regulations--the *South Carolina Code of Regulations*. Changes in regulations, whether by adoption, amendment, repeal or emergency action, must be published in the *State Register* pursuant to the provisions of the Administrative Procedures Act. The *State Register* also publishes the Governor's Executive Orders, notices or public hearings and meetings, and other documents issued by state agencies considered to be in the public interest. All documents published in the *State Register* are drafted by state agencies and are published as submitted. Publication of any material in the *State Register* is the official notice of such information.

STYLE AND FORMAT OF THE SOUTH CAROLINA STATE REGISTER

Documents are arranged within each issue of the *State Register* according to the type of document filed:

Notices are documents considered by the agency to have general public interest.
Notices of Drafting Regulations give interested persons the opportunity to comment during the initial drafting period before regulations are submitted as proposed.
Proposed Regulations are those regulations pending permanent adoption by an agency.
Pending Regulations Submitted to General Assembly are regulations adopted by the agency pending approval by the General Assembly.
Final Regulations have been permanently adopted by the agency and approved by the General Assembly.
Emergency Regulations have been adopted on an emergency basis by the agency.
Executive Orders are actions issued and taken by the Governor.

2001 PUBLICATION SCHEDULE

Documents will be accepted for filing on any normal business day from 8:30 A.M. until 5:00 P.M. All documents must be submitted in the format prescribed in the Standards Manual for Drafting and Filing Regulations.

To be included for publication in the next issue of the *State Register*, documents will be accepted no later than 5:00 P.M. on any closing date. The modification or withdrawal of documents filed for publication must be made **by 5:00 P.M.** on the closing date for that issue.

	Jan.	Feb.	Mar.	Apr.	May	June	July	Aug.	Sept.	Oct.	Nov.	Dec.
Submission Deadline	1/12	2/9	3/9	4/13	5/11	6/8	7/13	8/10	9/14	10/12	11/9	12/14
Publishing Date	1/26	2/23	3/23	4/27	5/25	6/22	7/27	8/24	9/28	10/26	11/23	12/28

REPRODUCING OFFICIAL DOCUMENTS

All documents appearing in the South Carolina *State Register* are prepared and printed at public expense. All media services are especially encouraged to give wide publicity to all documents printed in the *State Register*.

PUBLIC INSPECTION OF DOCUMENTS

A copy of each document filed with the Office of the State Register is available for public inspection during normal office hours, 8:30 A.M. to 5:00 P.M., Monday through Friday. The Office of the State Register is in the Legislative Council, Fourth Floor, Rembert C. Dennis Building, 1000 Assembly Street, in Columbia. Telephone inquiries concerning material in the *State Register* or the *South Carolina Code of Regulations* may be made by calling (803) 734-2145.

CERTIFICATE

Pursuant to Section 1-23-20, Code of Laws of South Carolina, 1976, this issue contains all previously unpublished documents required to be published and filed before the closing date of the issue.

Lynn P. Bartlett
Editor

ADOPTION, AMENDMENT AND REPEAL OF REGULATIONS

To adopt, amend or repeal a regulation, an agency must publish in the *State Register* a Notice of Drafting; a Notice of the Proposed Regulation that contains an estimate of the proposed action's economic impact; and, a notice that gives the public an opportunity to comment on the proposal. If requested by twenty-five persons, a public hearing must be held at least thirty days after the date of publication of the notice in the *State Register*.

After the date of hearing, the regulation must be submitted to the General Assembly for approval. The General Assembly has one hundred twenty days to consider the regulation. If no legislation is introduced to disapprove or enacted to approve before the expiration of the one-hundred-twenty-day review period, the regulation is approved on the one hundred twentieth day and is effective upon publication in the *State Register*.

EMERGENCY REGULATIONS

An emergency regulation may be promulgated by an agency if the agency finds imminent peril to public health, safety or welfare. Emergency regulations are effective upon filing for a ninety-day period. If the original filing began and expired during the legislative interim, the regulation can be renewed once.

REGULATIONS PROMULGATED TO COMPLY WITH FEDERAL LAW

Regulations promulgated to comply with Federal Law are exempt from General Assembly review. Following the notice of proposed regulation and hearing, regulations are submitted to the *State Register* and are effective upon publication.

EFFECTIVE DATE OF REGULATIONS

Final Regulations take effect on the date of publication in the *State Register* unless otherwise noted within the text of the regulation.
Emergency Regulations take effect upon filing with the Legislative Council and remain effective for ninety days. If the original ninety-day period begins and expires during legislative interim, the regulation may be renewable once.

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SUBSCRIPTIONS

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P.O. Box 11489
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Enclosed is my check or money order for $_____. Date _____

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Telephone _____

PART ONE

REGULATIONS SUBMITTED TO GENERAL ASSEMBLY

GOVERNOR'S EXECUTIVE ORDERS

NOTICES

NOTICES OF DRAFTING REGULATIONS

TABLE OF CONTENTS

PROPOSED REGULATIONS

EMERGENCY REGULATIONS

FINAL REGULATIONS

PART TWO

FINAL REGULATIONS

In order by General Assembly review expiration date
The history, status, and full text of these regulations are available on the
South Carolina General Assembly Home Page: www.scstatehouse.net

DOC NO.	RAT NO.	FINAL SR	SUBJECT	EXP. DATE	AGENCY
1981	SR25-1		Policy Development	1 12 01	Board of Education
1984	SR25-1		Principal Evaluation	1 12 01	Board of Education
2481	SR25-2		School Transportation	1 24 01	Board of Education
2504	SR25-2		Environmental Protection Fees	1 27 01	Department of Health and Envir Control
2502	SR25-2		Public Pupil Transportation Services	2 04 01	Board of Education
2485	SR25-3		(Repeal) Credit and Discount Plans	2 20 01	Department of Insurance
2487	SR25-3		(Repeal) Merit Rating Plan	2 20 01	Department of Insurance
2486	SR25-3		(Repeal) Refusal to Write, Cancellation	2 20 01	Department of Insurance
2511	SR25-3		Hunt Units and WMA's	2 20 01	Department Natural Resources
2503	SR25-3		Optional State Supplementation Prog	2 27 01	Health and Human Services Commission
2507	SR25-3		Student Loan Corp, Repayment	3 06 01	Commission on Higher Education
2514	SR25-4		LIFE, Palmetto Fellows Sch Appeals	3 12 01	Commission on Higher Education
2521	SR25-4		(Repeal) Loan Eligibility Requirements	3 24 01	Jobs-Economic Development Authority
2497	SR25-5		Quarantine of Garbage Fed Swine	4 22 01	Clemson University
2496	SR25-5		Brucellosis Testing	4 22 01	Clemson University
2530	SR25-5		Waste Disp Sites, Landfill Design, Const	5 09 01	Department of Health and Envir Control
2532	SR25-5		SWM: Off Site Treatment Contam Soil	5 09 01	Department of Health and Envir Control
2528	SR25-5		Adjustment of Dollar Amounts	5 09 01	Board of Financial Institutions
2548	SR25-5		Contact with Patients Before Prescribing	5 09 01	LLR: Board of Medical Examiners
2549	SR25-5		Registration of Licenses	5 09 01	LLR: Long Term Health Care Admin
2550	R35	SR25-4	Physician Supervision of Nurses	5 09 01	LLR: Board of Medical Examiners
2526	SR25-5		Licensure Requirements	5 09 01	LLR: Board of Professional Counselors…
2538	SR25-5		X-Rays (Title B)	5 09 01	Department of Health and Envir Control
2579	SR25-5		Practices of Real Estate Appraisers	5 09 01	LLR: Real Estate Appraisers Board
2575	SR25-5		Forms of Practice	5 09 01	LLR: Board of Accountancy
2531	SR25-5		Stds Lic Fac Chem Depend/Addicted Per	5 09 01	Department of Health and Envir Control
2576	SR25-5		Continuing Education	5 09 01	LLR: Board of Architectural Exam
2551	SR25-5		Valuation of Life Insurance Policies	5 09 01	Department of Insurance
2578	R34	SR25-4	Official Identification	5 09 01	LLR: Board of Nursing
2553	R26	SR25-4	Annuity Mortality Tables	5 09 01	Department of Insurance
2525	SR25-5		Adjustment of Dollar Amounts	5 09 01	Department of Consumer Affairs
2547	SR25-5		Seed Certification Standards	5 09 01	Clemson University/Crop Pest Comm
2585	SR25-5		Reduct, Expan, Consolid, Closure, Instit	5 09 01	Commission on Higher Education
2574	SR25-5		Practices of Auctioneers Comm	5 11 01	LLR: Auctioneers Commission
2559			STAR Diploma	5 16 01	Board of Education
2572			Water Classifications and Standards	5 18 01	Department of Health and Envir Control
2523			Sales Tax: Med, Prosthetic, Hearing Aids	5 23 01	Department of Revenue
2563			Definition of Facility Chap 6, Title 12	5 23 01	Department of Revenue
2561			Definition of Facility Chap 37 Title 12	5 23 01	Department of Revenue
2562			Definition of Facility Chap 117 Title 12	5 23 01	Department of Revenue
2552			Adjustment of Claims Unusual Circum	5 29 01	Department of Insurance
2568			Teaching Exp Acceptable for Credit	5 31 01	Board of Education
2571			Other Experience Acceptable for Credit	5 31 01	Board of Education
2565			Computing the Experience of Teachers	5 31 01	Board of Education
2570			Student Teachers	5 31 01	Board of Education
2595			Chapter Revision	6 01 01	LLR: Engineers & Land Surveyors

2596	R27 SR25-4	Port of Charleston: Short Branch Qualif	6 01 01 LLR: Commissioners of Pilotage
2597		Admission of Expert's Report as Evidence	6 05 01 Workers' Compensation Commission
2580		Service Contracts	6 05 01 Department of Insurance
2582		Captive Insurance Companies	6 05 01 Department of Insurance
2558		Principal Evaluation Program	6 05 01 Board of Education
2583		Reinsurance Facility Recoupment	6 06 01 Department of Insurance
2541		Lic Comm Residential Care Facilities	6 13 01 Department of Health and Envir Control
2567		Req for Additional Area of Certification	6 14 01 Board of Education
2581		Continuing Insurance Education	6 15 01 Department of Insurance
2600		Need-based Grants Program	6 22 01 Commission on Higher Education
2601		Palmetto Fellows Scholarship Program	6 22 01 Commission on Higher Education
2533		Criminal Justice Information System	6 27 01 Law Enforcement Division
2569		Types and Levels of Credential Classif	6 27 01 Board of Education
2577		Auth Prescriptions by Nurse Practitioner	7 04 01 LLR: Board of Nursing
2605		Physician Assistants	7 04 01 LLR: Board of Medical Examiners
2602		Hunt Units and Wildlife Management	7 05 01 Department of Natural Resources
2603		End-of-Course Tests	7 19 01 Board of Education
2609		State Human Resources	7 27 01 Budget and Control Board
2566		Graduation Requirements	8 07 01 Board of Education
2616		Well Standards	8 08 01 Department of Health and Envir Control
2518		Perinatal Care	8 14 01 Department of Health and Envir Control
2620		Percentage Storm or Wind/Hail Deduct	8 24 01 Department of Insurance
2613		Assessment Program	8 30 01 Board of Education
2618		Hunt Units and WMAs	8 30 01 Department of Natural Resources
2621		Retail Managers; Finance Managers	8 30 01 LLR: Manufactured Housing Board
2586		Definition of a Limousine	9 11 01 Public Service Commission

REQUEST FOR AN ASSESSMENT REPORT (120 DAY REVIEW PERIOD TOLLED)

DOC NO.	DATE	SUBJECT	AGENCY
2248	4 14 99	Primary and Substantial Portion (Video Game Machines)	Department of Revenue

REQUEST TO WITHDRAW (120 DAY REVIEW PERIOD TOLLED)

DOC NO.	DATE	SUBJECT	AGENCY
2457	1 23 01	Septic Tank Site Evaluation Fees	Department Health and Envir Control
2573	4 24 01	Food Stamp Program	Department of Social Services
2564	5 03 01	Accreditation Criteria	Board of Education

RESOLUTION INTRODUCED TO DISAPPROVE (120 DAY REVIEW PERIOD TOLLED)

DOC NO.	DATE	SUBJECT	AGENCY
2360	1 17 01	LIFE Scholarship	Commission on Higher Education

WITHDRAWN:

DOC NO.	DATE	SUBJECT	AGENCY
2433	1 31 01	Hearing Aids; Augmen Comm Devices	LLR: Speech-Language Path & Audio
2469	1 31 01	Volunteer Pharm Tech Free Med Clinics	LLR: Board of Pharmacy
2193	2 28 01	Video Poker; Def "Single Place" ...	Department of Revenue

No. 2001-10

WHEREAS, in Executive Order 2000-29, I established the Advisory Campaign Reform Study Commission and charged it with the responsibility of providing me with a final report and recommendation by April 16, 2001; and

WHEREAS, the Commission should have a full opportunity to evaluate the options available to our State in addressing the efforts to reform and improve South Carolina's election laws; and

WHEREAS, the Commission Chairman has indicated to me that the Commission needs a brief additional time period to complete the preparation of its report and recommendation.

NOW, THEREFORE, I hereby extend the time for the Commission to provide me with a final report from April 16, 2001 to April 25, 2001.

This Order shall take effect immediately.

GIVEN UNDER MY HAND AND THE GREAT SEAL OF THE STATE OF SOUTH CAROLINA, THIS 19th DAY OF APRIL, 2001.

JIM HODGES
GOVERNOR

No. 2001-11

WHEREAS, the environment and the health and welfare of citizens of South Carolina must be protected from pollutants generated by the growing or confining of swine, processing of swine waste, and land application of swine waste; and

WHEREAS, there are two permit applications pending before the Department of Health and Environmental Control for swine facilities; and

WHEREAS, these factory-style swine facilities would process as many as 31,000 animals; and

WHEREAS, additional, similar operations are anticipated to be proposed; and

WHEREAS, I have been contacted by legislators, officials, and constituents from Dillon, Marion and Marlboro counties expressing concern about the pending applications for the construction of swine operations and about the possibility that additional facilities will be proposed; and

WHEREAS, despite the existing regulations for the permitting of agricultural animal facilities, there is considerable concern for the environmental, health and social effects of these factory-style operations in the adjoining communities in the Pee Dee region and across the entire State, and the danger to state and local economic development efforts; and

WHEREAS, the General Assembly and the Department of Health and Environmental Control (DHEC) need time to consider the environmental and social effects of these large operations and the effect of the concentration of multiple facilities on the health and welfare of the citizens and natural resources of this State and the adequacy of the existing laws, regulations and procedures relating to the permitting of swine facilities and lagoons; and

WHEREAS, pursuant to Section 25-1-440 of the South Carolina Code of Laws, as amended, I hereby declare a State of Emergency due to the threat of a disaster within the State.

NOW, THEREFORE, by virtue of the power and authority vested in me as Governor pursuant to the Constitution and the laws of South Carolina, I hereby establish a moratorium on the construction or expansion of swine facilities and lagoons, and on the permitting of a waste management plan for swine facilities and lagoons.

For the duration of this Executive Order, neither DHEC nor any other state, county, or local agency or official shall issue a permit for the handling, storage, treatment and final disposal or utilization of swine waste from a new or existing swine facility or lagoon. I further order the Board of Health and Environmental Control to meet at the earliest possible time to consider an administrative moratorium on the issuance of permits for swine facilities, lagoons and associated waste management plans or other appropriate action that will allow sufficient time for thorough exploration and analysis of the issues associated with the handling, storage, treatment and final disposal or utilization of wastes created by these facilities.

The moratorium established under this Executive Order does not prohibit:

(1) Construction to repair a component of an existing swine farm or lagoon.

(2) Construction to replace a component of an existing swine farm or lagoon if the replacement does not result in an increase in swine population or waste, or

(3) Construction for the purpose of complying with applicable animal waste management rules and not for the purpose of increasing the swine population or waste.

For the purposes of this Executive Order, the terms "swine", "swine facility", "lagoon" and "waste management plan" shall have the same meanings set forth in Part 100.20 of DHEC Regulation 61-43.

This Executive Order shall take effect immediately.

GIVEN UNDER MY HAND AND THE GREAT SEAL OF THE STATE OF SOUTH CAROLINA, THIS 23rd DAY OF APRIL, 2001.

JIM HODGES
GOVERNOR

No. 2001-12

WHEREAS, the South Carolina State Grand Jury indicted Ricky Holland, Sr. on March 26, 2001, for one count of burglary, one count of assault and battery with intent to kill and one count of possession of a firearm or knife during the commission of a violent crime pursuant to the South Carolina Code of Laws, Sections 16-11-311, 16-3-620, and 16-23-490; and

WHEREAS, assault and battery with intent to kill and burglary are crimes of moral turpitude; and

WHEREAS, Ricky Holland, Sr. serves on the Town Council of Calhoun Falls, South Carolina; and

WHEREAS, Article VI, Section 8 of the South Carolina Constitution provides that "[a]ny officer of the State or its political subdivisions . . ., who has been indicted by a grand jury for a crime involving moral

turpitude or who has waived such indictment if permitted by law may be suspended by the Governor until he shall have been acquitted…."

NOW, THEREFORE, pursuant to the authority vested in me by the Constitution and Statutes of the State of South Carolina, I hereby suspend Ricky Holland, Sr. from the Town Council of Calhoun Falls.

GIVEN UNDER MY HAND AND THE GREAT SEAL OF THE STATE OF SOUTH CAROLINA, THIS 4th DAY OF MAY, 2001.

JIM HODGES
GOVERNOR

DEPARTMENT OF HEALTH AND ENVIRONMENTAL CONTROL

NOTICE OF PUBLIC HEARING

The South Carolina Department of Health and Environmental Control (SC DHEC) will conduct a public hearing concerning the 2002 Title V Maternal and Child Health Block Grant (MCHBG) on Monday, July 16, 2001. The hearing will be held in the Peeples Auditorium on the third floor of the Sims/Aycock Building located at 2600 Bull Street, Columbia, SC, from 6:00 p.m. to no later than 8:00 p.m.

The State of South Carolina receives MCHBG funds from the US Department of Health and Human Services, Maternal and Child Health Bureau under the authorization of Title V of the Social Security Act of 1935. The grant funds activities in the areas of access to quality maternal and child health services, prenatal, delivery, and post-partum care for at-risk, low income women, reduction of infant mortality and handicapping conditions among children, immunizations, rehabilitation services, and the promotion of family-centered, community-based, coordinated care for children with special health care needs.

The public is invited to attend the hearing and comment concerning proposed plans for utilization of these block grant funds. Comments received concerning the MCHBG will be submitted to the Maternal and Child Health Bureau as part of South Carolina's MCHBG application.

Copies of the MCHBG 2002 grant proposals will be available for public inspection from June 16, 2001 to July 16, 2001, during normal business hours at the SC Department of Health and Environmental Control, Maternal and Child Health Bureau, 0-426, Robert Mills Building, 1751 Calhoun Street, Columbia, SC.

DEPARTMENT OF HEALTH AND ENVIRONMENTAL CONTROL

NOTICE OF RESCHEDULING OF PUBLIC HEARING

Doc. No. 2623, Proposed New Regulation 61-109**,**
Standards for Licensing Body Piercing Facilities

The Department of Health and Environmental Control issued a Notice of Proposed New Regulation for R.61-109*, Standards for Licensing Body Piercing Facilities,* in the March 23, 2001, issue of the *State Register*, identified as Document No 2623. The Notice scheduled a Staff Informational Forum that was held on April 24, 2001, a write-in public comment period that closed April 24, 2001, and a public hearing before the Department's Board on May 17, 2001. The public hearing for May 17, 2001, has been cancelled. The next Department Board meeting and public hearing is scheduled for June 14, 2001. All public comments received through September 27, 2000, shall be submitted in a Summary of Public Comments and Department Responses for the Board's consideration at the public hearing.

The public hearing to be conducted by the Board of Health and Environmental Control for this proposed new regulation will be held at the regularly-scheduled meeting of the Board on June 14, 2001, in the Board Room of the Commissioner's Suite, Third Floor, Aycock Building of the Department of Health and Environmental Control, 2600 Bull St., Columbia, S.C. The Board meeting commences at 10:00 a.m. at which time the Board will consider items on its agenda in the order presented. The order of presentation for public hearing will be noticed in the Board's agenda to be published by the Department ten (10) days in advance of the meeting. Interested persons are invited to make oral or written comments on the proposed regulation at the public hearing. Persons desiring to make oral comments at the hearing are asked to limit their statements to five minutes and, as a courtesy, are asked to provide written copies of their presentations for the record. Any comments made at the public hearing will be given consideration in formulating the final version of the proposed New Regulation 61-109.

DEPARTMENT OF HEALTH AND ENVIRONMENTAL CONTROL

In accordance with Section 44-7-200(C), Code of Laws of South Carolina, the public is hereby notified that a Certificate of Need application has been accepted for filing and publication May 25, 2001, for the following project(s). After the application is deemed complete, affected persons will be notified that the review cycle has begun. For further information, please contact Mr. Albert N. Whiteside, Director, Division of Planning and Certification of Need, 2600 Bull St., Columbia, SC 29201 at (803) 737-7200.

Affecting Beaufort County

Construction of a freestanding oncology center on the campus of Beaufort Memorial Hospital with one (1) linear accelerator to provide radiation therapy services to inpatients and outpatients.
Beaufort Memorial Hospital
Beaufort, South Carolina
Project Cost: $ 5,084,058

Affecting Charleston County

Construction and renovation of Bon Secours St. Francis Hospital to accommodate sixty (60) medical/surgical beds transferred from Roper Hospital North, resulting in a total licensed capacity of 201general hospital beds at Bon Secours St. Francis and forty-four (44) alcohol and drug beds at Roper Hospital North.
Care Alliance Health Services
(Bon Secours St. Francis and Roper North)
Charleston, South Carolina
Project Cost: $ 18,058,472

Construction of an ambulatory surgery center with two (2) operating rooms.
Health First LLC
Charleston, South Carolina
Project Cost: $ 1,759,000

Affecting Darlington County

Expansion of current Surgical Services Department by adding two (2) new operating room suites, holding and PACU areas and waiting/reception space.
Carolina Pines Regional Medical Center
Hartsville, South Carolina
Project Cost: $ 3,653,397

Affecting Greenville County

Conversion of ten (10) institutional nursing home beds to community nursing home beds, which will not participate in the Medicaid (Title XIX) program, for a total of thirty-four (34) institutional nursing home beds which do not provide a community service and ten (10) community nursing home beds.
Rolling Green Village
Greenville, South Carolina
Project Cost: $ -0-

Affecting Greenville County

Replace one of the two (2) existing computed Tomography (CT) Scanners at the hospital.
St. Francis Hospital, Inc.
Greenville, South Carolina
Project Cost: $ 881,800

In accordance with S.C. DHEC Regulation 61-15, the public and affected persons are hereby notified that the review cycle has begun for the following project(s) and a proposed decision will be made within 60 days beginning May 25, 2001. "Affected persons" have 30 days from the above date to submit comments or requests for a public hearing to Mr. Albert N. Whiteside, Director, Division of Planning and Certification of Need , 2600 Bull Street, Columbia, S.C. 29201. For further information call (803) 737-7200.

Affecting Aiken County

Establishment of a diagnostic center to include a Spiral Computed Tomography (CT) Scanner and a Magnetic Resonance Imaging (MRI) Unit.
The Imaging Center of Aiken
Aiken, South Carolina
Project Cost: $ 1,803,670

Affecting Anderson County

Addition of one endoscopy suite for a total of five operating rooms and four endoscopy suites.
AnMed Health Outpatient Surgery Center
Anderson, South Carolina
Project Cost: $ 204,106

Affecting Barnwell County

Construction of a new forty (40) bed nursing home to replace the existing facility.
Barnwell County Nursing Home
Barnwell, South Carolina
Project Cost: $ 2,856,030

Affecting Charleston County

Purchase of a fixed Magnetic Resonance Imaging (MRI) unit to replace leased mobile MRI services.
Bon Secours St. Francis Hospital
Charleston, South Carolina
Project Cost: $ 1,958,145

Renovation of the existing ambulatory surgery center with the addition of three (3) new endoscopy rooms resulting in a total of four (4) operating rooms and three (3) endoscopy rooms.
HealthSouth Surgery Center of Charleston
Charleston, South Carolina
Project Cost: $1,800,571

Affecting Charleston County

Establishment of a freestanding ambulatory surgery center with two (2) endoscopy rooms, restricted to gastroenterology procedures only.
Palmetto Digestive Disease Endoscopy Center
Charleston, South Carolina
Project Cost: $ 1,549,688

Purchase of a Magnetic Resonance Imaging (MRI) unit for the Medical Arts Building for a total of three fixed MRI units on the campus of Trident Medical Center.
Trident Medical Center
Charleston, South Carolina
Project Cost: $ 1,787,106

Affecting Lancaster County

Renovation of existing space for the addition of a fixed cardiac catheterization laboratory to replace mobile catheterization services.
Springs Memorial Hospital
Lancaster, South Carolina
Project Cost: $2,586,900

Affecting Richland County

Development of an ambulatory surgery center with two (2) operating rooms for the single specialty of cataract surgery and eye surgery cases. The Center will be located within the Palmetto Surgery Center, LLC located at 109 Blarney Drive, Columbia, SC.
Huff and Milne Eye Surgery Center, LLC
Columbia, South Carolina
Project Cost: $ 228,091

DEPARTMENT OF HEALTH AND ENVIRONMENTAL CONTROL

NOTICE OF RESCHEDULING OF PUBLIC HEARING

Document No. 2622, Proposed Amendment of
Regulation *61-62.1, Definitions and General Requirements,*
of Regulation *61-62, Air Pollution Control Regulations and Standards*

On March 23, 2001, the Department of Health and Environmental Control issued a Notice of Proposed Regulation, identified as Document No. 2622, to amend Regulation *61-62.1, Definitions and General Requirements,* of Regulation 61-62, *Air Pollution Control Regulations and Standards*, and the *South Carolina Air Quality Implementation Plan (SIP)* to address "Credible Evidence." The Notice scheduled a staff-conducted informational forum that was held on April 23, 2001, a public comment period that has closed, and a public hearing before the Board of Health and Environmental Control at its regularly scheduled meeting on May 17, 2001. The public hearing for May 17, 2001, has been cancelled and rescheduled for June 14, 2001.

Interested members of the public and regulated community are invited to comment on the proposed amendment to Regulation *61-62.1, Definitions and General Requirements,* at a public hearing to be conducted by the Board of Health and Environmental Control at its regularly-scheduled meeting on June 14, 2001. The public hearing is to be held in room 3420 (Board Room) of the Commissioner's Suite, third floor, Aycock Building of the Department

of Health and Environmental Control, 2600 Bull Street, Columbia, SC. The Board meeting commences at 10:00 a.m. at which time the Board will consider items on its agenda in the order presented. The order of presentation for public hearings will be noted in the Board's agenda to be published by the Department ten days in advance of the meeting. Persons desiring to make oral comments at the hearing are asked to limit their statements to five minutes or less, and as a courtesy are asked to provide written copies of their presentation for the record.

DEPARTMENT OF HEALTH AND ENVIRONMENTAL CONTROL

PUBLIC NOTICE

Section IV of R.61-98, the State Underground Petroleum Environmental Response Bank (SUPERB) Site Rehabilitation and Fund Access Regulation, requires that the Department of Health and Environmental Control evaluate and certify site rehabilitation contractors to perform site rehabilitation of releases from underground storage tanks under the State Underground Petroleum Environmental Response Bank (SUPERB) Act. Pursuant to Section IV.B.1., the Department is required to place a list of those contractors requesting certification on public notice and accept comments from the public for a period of thirty (30) days. If you wish to provide comments regarding the companies and individuals listed below, please submit your comments in writing, no later than June 25, 2001 to:

Contractor Certification Program
South Carolina Department of Health and Environmental Control
Bureau of Underground Storage Tank Management
Attn: Barbara Boyd
2600 Bull Street
Columbia, SC 29201

The following companies and individuals have applied for certification as Underground Storage Tank Site Rehabilitation Contractors:

Class I	Class II
TAK Environmental Services, Inc.	

DEPARTMENT OF HEALTH AND ENVIRONMENTAL CONTROL

CHAPTER 61

Statutory Authority: 1976 Code Sections 48-1-30 and 47-20-165

Notice of Drafting:

The South Carolina Department of Health and Environmental Control proposes to amend Regulation 61-43, *Standards for the Permitting of Agricultural Animal Facilities*. Notices of Drafting for the proposed revisions were published in the State Register on November 26, 1999, July 28, 2000, and February 23, 2001. The Department is reissuing the Notice of Drafting to extend the time frame needed for development of the regulations and, as directed by the DHEC board, to get more public input on the appropriate regulatory requirements for larger swine facilities. Interested persons may submit written comments to Alton Boozer, Bureau Chief, Bureau of Water, SC Department of Health and Environmental Control, 2600 Bull Street, Columbia, SC 29201. To be considered, all written comments must be received no later than 5:00 p.m. on June 29, 2001, the close of the drafting comment period. Comments received from the previous three Notices of Drafting as well as this current reissuance will be considered.

Synopsis:

The Department is proposing to revise R.61-43 by replacing Part 100 (Swine Facilities) in its entirety and modifying Parts 200 (Other Animal Facilities) and Part 300 (innovative & Alternative Technology). The proposed amendments will address the permitting requirements for commercial agricultural animal production facilities, including the residual materials. The amended regulation will address the following:

1. Swine operations
2. New criteria and additional restrictions on larger swine facilities such as banning the use of traditional open (uncovered) anaerobic lagoons, specifying exact requirements for odor control, etc.
3. Poultry (including broiler, layer, turkey, quail, pigeon) operations.
4. Dairy and beef operations.
5. All other animal operations with a wet waste handling system.
6. All other animal operations with a dry waste handling system.
7. Manure broker operations.
8. Innovative and alternative technologies.
9. Integrator registration.
10. Co-permittee requirements on integrators
11. Responsible party
12. Financial assurance, including third-party liability.
13. Compliance history and repeat violators
14. Sanctions for certain violations

The amendments of the regulation will address methods of handling, treating, and disposing of residual material from animal production facilities. A new category of larger swine facilities requiring more protective criteria than presently found in the existing regulations will be considered. The amended regulation will include land application considerations such as agronomic rates for crop utilization. Also, minimum requirements for the location of facilities for production and residual material treatment and handling will be included. The administrative permitting process and technical criteria for permit issuance will be included. The amended Part 100 of these regulations will be the separate and distinct regulations for swine facilities as required by Title 47, Chapter 20, Confined Swine Feeding Operations Act. Legislative review of these proposed amendments will be required.

In addition to the proposed regulations as stated above, the public and regulated community is invited to recommend additional issues for consideration.

DEPARTMENT OF LABOR, LICENSING AND REGULATION
BOARD OF LONG TERM HEALTH CARE ADMINISTRATORS
CHAPTER 93
Statutory Authority: 1976 Code Section 40-35-230

Notice of Drafting:

The Board of Long Term Health Care Administrators is considering proposing an amendment to Chapter 93, Section 70, relating to other combinations of education and experience for the nursing home administrator license and the community residential care facility administrator license. The amendment would set standards in regulation for the Board's evaluation of combinations of education and experience for licensure other than the standards set in S.C. Code 40-35-230 and S.C. Regulation 93-70. Written comments can be submitted to Dana Welborn, Board Administrator, at P.O. Box 11329, Columbia, South Carolina 29211-1329.

Synopsis:

The purpose of the amendment is to set standards in regulation for the Board's evaluation of other combinations of education and experience to determine whether an applicant has gained the skills and knowledge appropriate for licensure as a nursing home administrator and community residential cares facility administrator.

DEPARTMENT OF REVENUE
CHAPTER 117
Statutory Authority: 1976 Code Section 12-4-320

Notice of Drafting:

The South Carolina Department of Revenue is considering adding a new regulation concerning the reduced sales tax rate on food items eligible for purchase with United States Department of Agriculture food coupons. This proposed regulation will establish certain rules and presumptions as to whether or not sales of certain foods qualify for the reduced sales tax rate. The department's employees will use these rules and presumptions in auditing and advising taxpayers. However, if a taxpayer can properly and sufficiently document that sales of certain foods are for home consumption (not merely off-premises consumption), then these sales may be eligible for the reduced sales tax rate.

Interested persons may submit written comments to Meredith F. Cleland, South Carolina Department of Revenue, Legislative Services, P.O. Box 125, Columbia, SC 29214. To be considered, comments must be received no later than 5:00 p.m. on June 27, 2001.

Synopsis:

The South Carolina Department of Revenue is considering adding a new regulation concerning the reduced sales tax rate on food items eligible for purchase with United States Department of Agriculture food coupons. This proposed regulation will establish certain rules and presumptions as to whether or not sales of certain foods qualify for the reduced sales tax rate. The department's employees will use these rules and presumptions in auditing and advising taxpayers. However, if a taxpayer can properly and sufficiently document that sales of certain foods are for home consumption (not merely off-premises consumption), then these sales may be eligible for the reduced sales tax rate.

DEPARTMENT OF REVENUE
CHAPTER 117
Statutory Authority: 1976 Code Section 12-4-320

Notice of Drafting:

The South Carolina Department of Revenue is considering repealing the following, sales tax, property tax, administrative, estate tax, license tax, video game and income tax regulations since they are no longer needed due to changes in the law.

Type Tax	Regulation	Regulation Title
Sales Tax	117-174.38	Automobile Dealer's Demonstrator
	117-174.221	Vendor's Discount
Property Tax	117-109	Determining the Fair Market Value of the Inventory Merchandise of Merchants
	117-124.14	Inventory Tax – Alcoholic Liquors
	117-121	Mobile Homes Located on Leased Land Assessed as Real Property
	117-107	Assessment of Manufacturers' Property
	117-108	Assessment of Property of Merchants
Administrative	117-5	Appeals Procedure by Which a Person May Contest the Authority of the Commission to Promulgate a Proposed Regulation.
	117-4	Procedure for Appeal to the Tax Commission from a County Board of Tax Appeals when the Statute Providing for such Appeal Fails to Specify the Manner in Which the Appeal is to be Made or the Grounds Therefore and Limits the Appeal to "Relief as Afforded by General Law".
	117-3	Appeal Procedure Before County Tax Board of Appeals.
Estate Tax	117-181.1	Rules and Regulations
	117-181.2	Transfer of Securities, Deposits or Other Assets
	117-181.3	Transfer of Contents of Safe Deposit Boxes.
Income Tax	117-60	Nonresidents Having Income from a Business in this State Subject to Tax.
	117-75	When Sales Allocated to State of the Purchaser.
	117-76	Nonresident Partners of a Partnership May File Single Return.
	117-77	Filing of a Consolidated Return for Two or More Corporations.
	117-79	Extension of Time for Filing and Tentative Returns Required.
	117-80	Application for Refund of Deceased.
	117-82	Income Tax in Another State Defined.
	117-84	Bond for Nonresidents Conducting a Temporary Business.
	117-85	Filing of Reports and Annual License Fees of Corporations.
	117-86	Foreign Corporation Defined.
	117-87.54	Definitions of "Taxable", "State" and "Net Income Tax" in

		Connection with the Allocation Formula.
	117-87.69	Allocation and Apportionment of Income.
	117-87.74	Nonresident Aliens
	117-87.78	Retirement Benefits Paid to Public School Teachers and State Employees Living in this State.
	117-89.3	License Fees--Professional Associations.
	117-91.2	Withholding on Casuals.
	117-91.3	Withholding of Rents
	117-91.4	Withholding on Rentals Paid to Nonresidents.
	117-91.5	Relieve Residents Working Without the State from Double Withholding.
	117-91.6	Agricultural Labor.
	117-91.8	Qualification to do Business.
	117-91.9	Credit for Tax Withheld by an Employee Even Though Not Paid to Tax Commission by Employer.
	117-91.11	When Federal Forms W-2, W-4 and 1099 are Acceptable by the South Carolina Tax Commission.
	117-95.1	Agreement for Withholding of Income Tax.
License Tax	117-32	Stamps Required on Certain Articles.
	117-33	Records.
	117-36	Cigarettes Displayed in Vending Machines.
	117-37	Cigars.
	117-44	Documentary Stamps--Sale of by Others.
	117-45.1	South Carolina Documentary Stamps must be Affixed before Instrument is Recorded.
	117-46	Base of the Documentary Stamp Tax When Consideration Received for Property Transferred Does Not Have a Readily Ascertainable Fair Market Value.
Video Game	117-191.1	Technical Standards for Video Game Machines.
	117-191.2	Technical Standards for Location Controller.
	117-191.3	Remote Shutdown of a Machine or Machines.

Interested persons may submit written comments to Meredith F. Cleland, South Carolina Department of Revenue, Legislative Services, P.O. Box 125, Columbia, SC 29214. To be considered, comments must be received no later than 5:00 p.m. on June 27, 2001.

Synopsis:

The South Carolina Department of Revenue is considering repealing various sales tax, property tax, administrative, estate tax, license tax, video game and income tax regulations since they are no longer needed due to changes in the law.

Document No. 2631
DEPARTMENT OF CONSUMER AFFAIRS
CHAPTER 28
Statutory Authority: 1976 Code Section 40-68-20

Staff Leasing Services.

Preamble:

Based on the Department of Consumer Affairs' review of the current Regulations for Staff Leasing Services and input from the regulated community, the Department proposes to amend the Regulations by revising existing Regulations 28-910, 28-920, 28-940, 28-955, and 28-990. The Department also proposes to amend the Regulations by adopting new Regulations 28-915, 28-933, 28-936, and 28-956. The proposed amendments are intended to update the Regulations in order to make them more effective in regulating the staff leasing services industry. The Notice of Drafting was published in the *State Register* on February 23, 2001. Written comments were received for Regulations 28-920, 28-933, 28-936, and 28-940. The comments received were used in formulating these Regulations.

The current Proposed Regulations cancel and supersede Document No. 2627 that was published in the *State Register* on April 27, 2001.

Section-by-Section Discussion

Existing Regulations

28-910. Application Procedure; Application Form; Confidential Information; Denial of Application; Request for Hearing; Positive Net Worth.

The Department proposes to amend Regulation 28-910 to change the Department's office address where applicants may visit to obtain application materials. The Department's new office address is 3600 Forest Drive, Third Floor, Columbia, S.C. 29204. The proposed amendments will also clarify the Department's procedures for handling incomplete/deficient applications by establishing a time limit of 90 days from the date of notification by the Department by which applicants must complete or correct application materials without penalty.

28-920. Annual Assessment on Gross South Carolina Payroll.

The Department proposes to amend Regulation 28-920 to change the type of documentation required from licensees to verify gross South Carolina payroll for annual assessment purposes. Under the proposed amendment, licensees will be required to submit to the Department copies of all South Carolina Department of Revenue "Fourth Quarter/Annual Reconciliation of Income Tax Withheld", form WH-1606, forms. Additionally, the proposed amendment will establish a late payment penalty of $150.00 for assessment fees submitted after the April 30 deadline.

R28-940. Quarterly Financial Reporting and Maintenance of Positive Working Capital.

The Department proposes to amend Regulation 28-940 to change the submission date for quarterly financial reports from 75 days to 45 days after the end of each quarter. Under the proposed amendment, quarterly reports that are submitted after the established deadlines may be assessed a late reporting fee of $50.00.

R28-955. Restricted License.

Amendments to Regulation 28-955 are proposed to exempt applicants who are qualified and approved for a restricted license from normal requirements for licensure. The proposed amendment will also clarify the term of the restricted license (1 year), and the corresponding licensing fees ($250.00 for a staff leasing services company and $500.00 for a staff leasing services group).

R28-990. Disciplinary Guidelines.

An amendment to Regulation 28-990 is proposed to establish disciplinary guidelines for client companies that do business with unlicensed staff leasing companies. Under the proposed amendment, client companies may be imposed a penalty of $50.00 per employee for each day the violation continues.

New Regulations

R28-915. License Renewal Procedures. Inactive License Renewal.

The Department proposes to draft Regulation 28-915 to establish license renewal procedures and to establish penalties for active licensees who fail to renew their license. The new regulation will require licensees to submit renewal applications within 60 days of the license's expiration date. A license that is not renewed shall automatically become delinquent. In addition, under Regulation 28-915, the period of time that a licensee can operate without renewing their license will be limited to 30 days from the license's expiration date. Licenses delinquent for a period of 30 days or less will be assessed a delinquent fee of $300.00. Licenses delinquent more than 30 days shall become void without further action by the Department.

R28-933. Annual Audited Financial Statements.

The Department also proposes to draft Regulation 28-933 to require annual audited financial statements be submitted to the Department for staff leasing companies with $2,500,000.00 or more in gross South Carolina payroll.

R28-936. Annual Reviewed Financial Statements.

The Department proposes to draft Regulation 28-936 to allow reviewed financial statements to be submitted for staff leasing companies with less than $2,500,000.00 in gross South Carolina payroll.

R28-956. Notification of Limited Operation.

The Department proposes to draft Regulation 28-956 to outline the requirements for certain staff leasing companies that meet specific requirements to operate in the State by notification only. In addition, this regulation will establish a notification service fee in the amount of $250.00 for those companies that are approved to operate in this capacity.

Notice of Public Hearing and Opportunity for Public Comment:

Should a public hearing be required, it will be conducted on June 28, 2001, at 10:00 a.m. at 3600 Forest Drive, Third Floor, Columbia, South Carolina. Written comments may be directed to Mr. Herbert Walker, Deputy Director for Administrative and Regulatory Services, Department of Consumer Affairs, Post Office Box 5757, Columbia, SC 29250-5757, or e-mail walker@dca.state.sc.us. Comments must received no later than 5:00 p.m. on June 25, 2001.

Preliminary Fiscal Impact Statement:

There will be no additional cost incurred by the State and its political subdivisions in complying with the proposed regulations.

Statement of Need and Reasonableness:

DESCRIPTION OF REGULATION: Staff Leasing Services.

Purpose:	The current Regulations for Staff Leasing Services are being amended. Existing Regulations 28-910, 28-920, 28-940, 28-955, and 28-990 are being revised and Regulations 28-915, 28-933, 28-936, and 28-956 are being drafted as new Regulations. The proposed amendments are intended to update the Regulations in order to make them more effective in regulating the staff leasing services industry. See Preamble and Discussion for details.
Legal Authority:	Section 40-68-20, S.C. Code of Laws
Plan for Implementation:	The proposed amendments and new regulations will take effect upon approval by the General Assembly and publication in the *State Register*. The proposed amendments will be implemented by providing the regulated community with copies of the regulations.

DETERMINATION OF NEED AND REASONABLENESS OF THE PROPOSED REGULATION BASED ON ALL FACTORS HEREIN AND EXPECTED BENEFITS:

Existing Regulations

Amendments to existing Regulation 28-910 will ensure that all applicants for a staff leasing services license complete the application process timely. Amendments to Regulation 28-920 will reduce the amount of documentation required from licensees as verification of their annual gross payroll by changing the type of documentation required to be submitted. Amendments to Regulation 28-940 will deter late submissions of quarterly reports and will enable the Department to perform more timely reviews of financial statements in order to identify and monitor those companies that may be in or have potential for financial distress. Amendments to Regulation 28-955 will exempt certain companies that apply for a restricted license from normal licensing requirements as the applicants have previously satisfied similar requirements during licensure from their state of residence (home state). Amendments to Regulation 28-990 will establish a form of prohibition to prevent client companies from contracting with unlicensed staff leasing companies and thus, becoming party to illegal activity.

New Regulations

Regulations 28-915 will ensure that all licenses are renewed before their expiration dates and that licensee's who continue to operate after a license expires are promptly identified and penalized. Regulation 28-933 will ensure that annual audited financial statements are received from licensees whose gross South Carolina payroll is $2,500,000.00 or more. The current Regulations require that audited financial statements be produced only at initial licensure and at renewal (every two years). Therefore, during the interim periods after initial licensure, audited financial information is not received and as a result, cannot be used to confirm that licensees have met the Department's working capital and net worth requirements. Regulation 28-936 will ensure that licensees with smaller gross South Carolina payrolls (less than $2,500,000.00) submit annual reviewed financial statements. Regulation 28-956 will address the concerns of those leasing companies that do not solicit business in the State but have clients desiring to relocate a small number of employees to the State. This regulation will allow such companies to operate in the State by notifying the Department in writing of their limited operations.

DETERMINATION OF COSTS AND BENEFITS: There will be a benefit to both the Department and the

licensed staff leasing services companies in that the regulations will allow for more effective monitoring and regulation of the staff leasing services industry in the State.

UNCERTAINTIES OF ESTIMATES: NONE

EFFECT ON ENVIRONMENT AND PUBLIC HEALTH: NONE

DETRIMENTAL EFFECT ON THE ENVIRONMENT AND PUBLIC HEALTH IF THE REGULATION IS NOT IMPLEMENTED: NONE

Text:

The full text of this regulation is available on the South Carolina General Assembly Home Page: www.scstatehouse.net If you do not have access to the Internet, the text may be obtained from the promulgating agency.

Document No. 2629
DEPARTMENT OF HEALTH AND ENVIRONMENTAL CONTROL
CHAPTER 30
Statutory Authority: S.C. Code Section 48-39-50

Preamble:

Pursuant to S.C. Code Section 1-23-110, the Department's Ocean and Coastal Resource Mangement proposed amendments of Regulations 30-1, 30-2, and 30-12 by publication of a Notice of Drafting in the State Register on July 28, 2000, and by publication of a Notice of Proposed Regulation in the State Register on February 23, 2001, identified as Document No. 2614. The Notice of Proposed Regulation provided notice of opportunity for interested persons to comment on the proposed regulations by attending an informational forum that was conducted on March 14, 2001, by submitting written comments during a public comment period that closed March 23, 2001, and by offering comments at a public hearing scheduled before the Board of Health and Environmental Control on April 12, 2001. Pursuant to S.C. Code Section 1-23-111, the Department's Board conducted a public hearing on April 12 and approved the proposed amendments of Regulations 30-1, 30-2, and 30-12 for submission to the General Assembly for review. At the conclusion of the public hearing the Board directed Department staff to separate the proposed amendments of Document 2614 into two separate packages for submission to the legislature for review.

The Legislative Council of the General Assembly requires that in order for the Department to submit two separate amendments at this stage of the Administrative Procedures process, separate document numbers for each amendment must be assigned. This Notice is being published so that two documents numbers can be assigned. The Department is submitting to the legislature under separate amendment Document No. 2614, which contains proposed amendments of Regulations 30-1, 30-2, and 30-12. The second package, containing a proposed amendment at Section 30-12.A(2)(1), is being submitted to the legislature as Document No. 2629.

Notice of Public Hearing and Opportunity for Public Comment Pursuant to S.C. Section 1-23-110 and 1-23-111:

A public hearing for proposed amendments of 30-1, 30-2, and 30-12, to include this proposed amendment at Section 30-12.A(2)(1), was conducted on April 12, 2001. Opportunity for public comment closed at the conclusion of the public hearing. An additional public hearing is not required.

Preliminary Fiscal Impact Statement:

SCDHEC/OCRM estimates there will be no significant economic impacts upon or incurred by the state or its political entities as a result of the promulgation, approval, and administration of the proposed Regulations. Existing staff and resources have been utilized in preparation and will further be utilized in additional regulatory administration resulting from the amendments.

Statement of Need and Reasonableness:

The text of this statement is incorporated herein as stated in the Notice of Proposed Regulation published as Document No. 2614 in the State Register on February 23, 2001.

Text of Proposed Amendment:

Replace 30-12.A(2)(l) to read:

R.30-12.A(2)(l) Private single-residence docks longer than 500 feet over the critical area are prohibited. This measurement is inclusive of pier heads, floats, boatlifts, ramps, mooring pilings, and other associated structures. Community docks over 750 feet over the critical area are prohibited.

Document No. 2632
DEPARTMENT OF INSURANCE
CHAPTER 69
Statutory Authority: 1976 Code Sections 38-3-110; 38-9-180; 1-23-10 et seq.

69-58. Privacy of Consumer Financial and Health Information

Preamble:

The South Carolina Department of Insurance proposes to draft Regulation 69-58 regarding the privacy of consumer financial and health information. The regulation will govern the treatment of nonpublic personal health information and nonpublic personal financial information about individuals by all licensees of the state insurance department. The regulation will require a licensee to provide notice to individuals about its privacy policies and practices. It will also describe the conditions under which a licensee may disclose nonpublic personal health information and nonpublic personal financial information about individuals to affiliates and nonaffiliated third parties as well as provide methods for individuals to prevent a licensee from disclosing that information. This regulation will implement the requirements of the Gramm-Leach-Bliley Act and federal regulations on the privacy of consumer information.

Notice of Public Hearing:

The Administrative Law Judge Division will conduct a public hearing for the purpose of receiving oral comments on Monday, June 25, 2001 at 10:00 a.m. in the Administrative Law Judge Division Hearing Room, 1205 Pendleton Street, Suite 224, Columbia, South Carolina. Interested persons should submit their views in writing to: Melanie A. Joseph, South Carolina Department of Insurance, Post Office Box 100105, Columbia, South Carolina 29202-3105 on or before Thursday, June 14, 2001.

Preliminary Fiscal Impact Statement:

A fiscal impact statement is not required as this regulation is exempt from General Assembly review pursuant to S.C. Code Section 1-23-120 (G)(1).

Statement of Need and Reasonableness:

The purpose of this regulation will be to address the new rules regarding privacy established by Title V of the Gramm-Leach-Bliley Act. Issues that will be addressed include the scope of such privacy requirements (opt in/opt out), the institutions to which they apply, the information to which the requirements apply, disclosure and notice requirements and restrictions on the sharing of information.

Text:

The full text of this regulation is available on the South Carolina General Assembly Home Page: **www.scstatehouse.net** If you do not have access to the Internet, the text may be obtained from the promulgating agency.

Document No.2630
DEPARTMENT OF NATURAL RESOURCES
CHAPTER 121
Statutory Authority: 1976 Code Section 49-23-10 et seq.

Preamble:

The South Carolina Department of Natural Resources proposes to amend the regulations that will provide for the implementation of the South Carolina Drought Response Act. This legislation was originally enacted in 1985 and was amended in 2000. One new provision requires that the Department of Natural Resources, through regulation, establish specific numerical values for the indices that define each level of drought in order to provide for upgrading or downgrading drought declaration status. The proposed regulation establishes new drought management areas that will allow for more effective drought management. The new drought management areas are based on river basin and geopolitical boundaries instead of climate divisions and geopolitical boundaries. The regulation also streamlines the committee appointment process by only requiring the advice and consent of the Senate rather than recommendation by the legislative delegation in each drought management area.

The Notice of Drafting was published in the State Register on February 23, 2001

Section-by-Section Discussion

121-11.1-11.12	Change Water Resources Commission to South Carolina Department of Natural Resources
121-11.2.	Definitions included in the act are added to the regulation for clarification
121-11.3.	The jurisdiction is being changed to exclude any restriction in use of water during an incipient, moderate, and severe drought declaration injected into aquifer storage and recovery facilities or water stored in managed watershed impoundments.
121-11.4.	The proposed regulation establishes new drought management areas that will allow for more effective drought management. The new drought management areas are based on river basin and geopolitical boundaries instead of climate divisions and geopolitical boundaries.

121-11.5. Representation on the local drought response committee is increased to include power generation facilities, special purpose districts, and Soil and Water Conservation Districts. However, there may not be more than two members on a local committee from each county within the drought management area. Local committee members are appointed by the Governor with the advice and consent of the Senate. The designation was added for the Governor to appoint the chair of the Drought Response Committee. The years of service limit was omitted for persons appointed by the Governor over and beyond the designated committee members.

121-11.6 The regulation includes a new provision that the Drought Response Committee should also consult with public and private water suppliers, public service districts, power generation facilities, industries, and special purpose districts in addition to representatives of municipalities, counties, and commissions of public works in the affected drought management area while evaluating drought conditions.

121-11.8. Establishes specific numerical values for the indices that define each level of drought in order to provide for upgrading or downgrading drought declaration status.

121-11.9. At the inception of a moderate drought alert phase, the South Carolina Department of Natural Resources must notify all public water systems of the drought declaration. The previous regulation required notification of municipal and county governments.

121-11.11. A section was added so that any party affected by a declaration of the Drought Response Committee can appeal that action to the Administrative Law Judge Division.

Notice of Public Hearing and Opportunity for Public Comment:

Should a hearing be requested pursuant to Section 1-23-110(b) of the 1976 Code, as amended, such hearing will be conducted at 1000 Assembly Street on June 25, 2001, at 4:00 pm in room 335, third floor, Rembert C. Dennis Building. Written comments may be directed to Hope Mizzell, Drought Program Coordinator, S.C. Department of Natural Resources, 1201 Main Street, Suite 1100, Columbia, SC 29201.

Preliminary Fiscal Impact Statement:

During times of drought, this regulation may require water curtailment and any water dependent industry may be impacted. This regulation will assist in securing federal agricultural drought disaster money.

Statement of Need and Reasonableness:

The statement of need and reasonableness was determined based on staff analysis pursuant to S.C. Code Sections 1-23-115(C)(1) through (3) and (9) through (11).

DESCRIPTION OF REGULATION: Drought Planning Response

Purpose: The proposed regulation establishes procedures by which the State's water resources can be carefully and closely monitored, conserved, and managed in the best interests of all South Carolinians during periods of drought.

Legal Authority: The legal authority for the Regulation 121-11.1 - 121-11.12 is Section 49-23-10 et seq., S.C. Code of Laws.

Plan for Implementation: The proposed amendments will take effect upon approval by the General Assembly and publication in the *State Register*. The public will be notified through this publication and through news releases and other Department media outlets and publications.

DETERMINATION OF NEED AND REASONABLENESS OF THE PROPOSED REGULATION BASED ON ALL FACTORS HEREIN AND EXPECTED BENEFITS:

More modern indices are available to better reflect the drought status and the South Carolina Drought Response Act was amended to reflect these changes. The existing regulation uses the Palmer Drought Index as the primary trigger for drought declaration; therefore, a new regulation must be filed to establish specific numerical values for the new indices that define each level of drought. The proposed regulation also establishes new drought management areas which will allow for more effective drought management. Omitting the requirement for committee recommendations by the legislative delegation should limit the number of vacancies on the local committees. Members would now be appointed by the Governor with advice and consent of the Senate.

DETERMINATION OF COSTS AND BENEFITS:

During times of drought, implementation of the proposed regulation may impact any water dependent industry. This regulation will assist in securing federal agricultural drought disaster money.

UNCERTAINTIES OF ESTIMATES:

Staff does not anticipate any increased program costs with the promulgation of this regulation. Accordingly, no cost estimates and the uncertainties associated with them are provided.

EFFECT ON THE ENVIRONMENT AND PUBLIC HEALTH:

The promulgation of this regulation will help sustain the availability of water for current and future use.

DETRIMENTAL EFFECT ON THE ENVIRONMENT AND PUBLIC HEALTH IF THE REGULATIONS ARE NOT IMPLEMENTED:

Without this regulation, during severe and extreme drought periods there may be problems with water availability.

Fiscal Impact Statement:
This regulation may require water curtailment and any water dependent industry may be impacted during severe or extreme droughts.

TEXT:

The full text of this regulation is available on the South Carolina General Assembly Home Page: **www.scstatehouse.net** If you do not have access to the Internet, the text may be obtained from the promulgating agency.

Filed: April 23, 2001, 9am

Document No. 2628
DEPARTMENT OF INSURANCE
CHAPTER 69
Statutory Authority: 1976 Code Sections 38-3-110; 38-9-180; 1-23-10 et seq.

69-58. Privacy of Consumer Financial and Health Information

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Emergency Situation:

This regulation is needed to protect South Carolina consumers from release of non-public financial and health information. The regulation implements the requirements of the Gramm- Leach- Bliley Act and federal regulations on the privacy of consumer information.

Text:

Table of Contents

ARTICLE I. GENERAL PROVISIONS

Section 1. Authority

This regulation is promulgated pursuant to the authority granted by Sections 38-3-110 of the South Carolina Insurance Code and Title V of Pub. Law 102-106, the Gramm-Leach-Bliley Act.

Section 2. Purpose and Scope

A. Purpose.

This regulation governs the treatment of nonpublic personal health information and nonpublic personal financial information about individuals by all licensees of the state insurance department. This regulation:

(1) Requires a licensee to provide notice to individuals about its privacy policies and practices;

(2) Describes the conditions under which a licensee may disclose nonpublic personal health information and nonpublic personal financial information about individuals to affiliates and nonaffiliated third parties; and

(3) Provides methods for individuals to prevent a licensee from disclosing that information.

B. Scope.

This regulation applies to:

(1) Nonpublic personal financial information about individuals who obtain or are claimants or beneficiaries of products or services primarily for personal, family or household purposes from licensees. This regulation does not apply to information about companies or about individuals who obtain products or services for business, commercial or agricultural purposes; and

(2) All nonpublic personal health information.

C. Compliance.

A licensee domiciled in this state that is in compliance with this regulation in a state that has not enacted laws or regulations that meet the requirements of Title V of the Gramm-Leach-Bliley Act (PL 102-106) may nonetheless be deemed to be in compliance with Title V of the Gramm-Leach-Bliley Act in such other state.

Section 3. Rule of Construction

The examples in this regulation and the sample clauses in Appendix A of this regulation are not exclusive. Compliance with an example or use of a sample clause, to the extent applicable, constitutes compliance with this regulation.

Section 4. Definitions

As used in this regulation, unless the context requires otherwise:

A. "Affiliate" means any company that controls, is controlled by or is under common control with another company.

B. (1) "Clear and conspicuous" means that a notice is reasonably understandable and designed to call attention to the nature and significance of the information in the notice.

(2) Examples.

(a) Reasonably understandable. A licensee makes its notice reasonably understandable if it:

(i) Presents the information in the notice in clear, concise sentences, paragraphs, and sections;

(ii) Uses short explanatory sentences or bullet lists whenever possible;

(iii) Uses definite, concrete, everyday words and active voice whenever possible;

(iv) Avoids multiple negatives;

(v) Avoids legal and highly technical business terminology whenever possible; and

(vi) Avoids explanations that are imprecise and readily subject to different interpretations.

(b) Designed to call attention. A licensee designs its notice to call attention to the nature and significance of the information in it if the licensee:

(i) Uses a plain-language heading to call attention to the notice;

(ii) Uses a typeface and type size that are easy to read;

(iii) Provides wide margins and ample line spacing;

(iv) Uses boldface or italics for key words; and

(v) In a form that combines the licensee's notice with other information, uses distinctive type size, style, and graphic devices, such as shading or sidebars.

(c) Notices on web sites. If a licensee provides a notice on a web page, the licensee designs its notice to call attention to the nature and significance of the information in it if the licensee uses text or visual cues to encourage scrolling down the page if necessary to view the entire notice and ensure that other elements on the web site (such as text, graphics, hyperlinks or sound) do not distract attention from the notice, and the licensee either:

(i) Places the notice on a screen that consumers frequently access, such as a page on which transactions are conducted; or

(ii) Places a link on a screen that consumers frequently access, such as a page on which transactions are conducted, that connects directly to the notice and is labeled appropriately to convey the importance, nature and relevance of the notice.

C. "Collect" means to obtain information that the licensee organizes or can retrieve by the name of an individual or by identifying number, symbol or other identifying particular assigned to the individual, irrespective of the source of the underlying information.

D. "Company" means a corporation, limited liability company, business trust, general or limited partnership, association, sole proprietorship or similar organization.

E. (1) "Consumer" means an individual who seeks to obtain, obtains or has obtained an insurance product or service from a licensee that is to be used primarily for personal, family or household purposes, and about whom the licensee has nonpublic personal information, or that individual's legal representative.

(2) Examples.

(a) An individual who provides nonpublic personal information to a licensee in connection with obtaining or seeking to obtain financial, investment or economic advisory services relating to an insurance product or service is a consumer regardless of whether the licensee establishes an ongoing advisory relationship.

(b) An applicant for insurance prior to the inception of insurance coverage is a licensee's consumer.

(c) An individual who is a consumer of another financial institution is not a licensee's consumer solely because the licensee is acting as agent for, or provides processing or other services to, that financial institution.

(d) An individual is a licensee's consumer if:

(i) (I) the individual is a beneficiary of a life insurance policy underwritten by the licensee;

(II) the individual is a claimant under an insurance policy issued by the licensee;

(III) the individual is an insured or an annuitant under an insurance policy or an annuity, respectively, issued by the licensee; or

(IV) the individual is a mortgagor of a mortgage covered under a mortgage insurance policy; and

(ii) the licensee discloses nonpublic personal financial information about the individual to a nonaffiliated third party other than as permitted under Sections 14, 15 and 16 of this regulation.

(e) Provided that the licensee provides the initial, annual and revised notices under Sections 5, 6 and 9 of this regulation to the plan sponsor, group or blanket insurance policyholder or group annuity contract holder, workers' compensation plan participant, and further provided that the licensee does not disclose to a nonaffiliated third party nonpublic personal financial information about such an individual other than as permitted under Sections 14, 15 and 16 of this regulation, an individual is not the consumer of the licensee solely because he or she is:

(i) A participant or a beneficiary of an employee benefit plan that the licensee administers or sponsors or for which the licensee acts as a trustee, insurer or fiduciary;

(ii) Covered under a group or blanket insurance policy or group annuity contract issued by the licensee; or

A beneficiary in a workers' compensation plan.

Drafting Note: Regulators may wish to urge their workers' compensation state insurance fund (or other applicable agency) to promulgate a regulation similar to this regulation in order to ensure parity in treatment of workers' compensation plans and to ensure that all workers covered by such plans have privacy protections.

(f) (i) The individuals described in Subparagraph (e)(i) through (iii) of this Paragraph are consumers of a licensee if the licensee does not meet all the conditions of Subparagraph (e).

(ii) In no event shall the individuals, solely by virtue of the status described in Subparagraph (e)(i) through (iii) above, be deemed to be customers for purposes of this regulation.

(g) An individual is not a licensee's consumer solely because he or she is a beneficiary of a trust for which the licensee is a trustee.

(h) An individual is not a licensee's consumer solely because he or she has designated the licensee as trustee for a trust.

F. "Consumer reporting agency" has the same meaning as in Section 603(f) of the federal Fair Credit Reporting Act (15 U.S.C. 1681a(f)).

G. "Control" means:

(1) Ownership, control or power to vote twenty-five percent (25%) or more of the outstanding shares of any class of voting security of the company, directly or indirectly, or acting through one or more other persons;

(2) Control in any manner over the election of a majority of the directors, trustees or general partners (or individuals exercising similar functions) of the company; or

(3) The power to exercise, directly or indirectly, a controlling influence over the management or policies of the company, as the director determines.

H. "Customer" means a consumer who has a customer relationship with a licensee.

I. (1) "Customer relationship" means a continuing relationship between a consumer and a licensee under which the licensee provides one or more insurance products or services to the consumer that are to be used primarily for personal, family or household purposes.

(2) Examples.

(a) A consumer has a continuing relationship with a licensee if:

(i) The consumer is a current policyholder of an insurance product issued by or through the licensee; or

(ii) The consumer obtains financial, investment or economic advisory services relating toan insurance product or service from the licensee for a fee.

(b) A consumer does not have a continuing relationship with a licensee if:

(i) The consumer applies for insurance but does not purchase the insurance;

(ii) The licensee sells the consumer airline travel insurance in an isolated transaction;

(iii) The individual is no longer a current policyholder of an insurance product or no longer obtains insurance services with or through the licensee;

(iv) The consumer is a beneficiary or claimant under a policy and has submitted a claim under a policy choosing a settlement option involving an ongoing relationship with the licensee;

(v) The consumer is a beneficiary or a claimant under a policy and has submitted a claim under that policy choosing a lump sum settlement option;

(vi) The customer's policy is lapsed, expired, or otherwise inactive or dormant under the licensee's business practices, and the licensee has not communicated with the customer about the relationship for a period of twelve (12) consecutive months, other than annual privacy notices, material required by law or regulation, communication at the direction of a state or federal authority, or promotional materials;

(vii) The individual is an insured or an annuitant under an insurance policy or annuity, respectively, but is not the policyholder or owner of the insurance policy or annuity; or

(viii) For the purposes of this regulation, the individual's last known a ddress according to the licensee's records is deemed invalid. An address of record is deemed invalid if mail sent to that address by the licensee has been returned by the postal authorities as undeliverable and if subsequent attempts by the licensee to obtain a current valid address for the individual have been unsuccessful.

J. "Director" means the director of the South Carolina Department of Insurance.

K. (1)"Financial institution" means any institution the business of which is engaging in activities that are financial in nature or incidental to such financial activities as described in Section 4(k) of the Bank Holding Company Act of 1956 (12 U.S.C. 1843(k)).

(2) Financial institution does not include:

(i) Any person or entity with respect to any financial activity that is subject to the jurisdiction of the Commodity Futures Trading Commission under the Commodity Exchange Act (7 U.S.C. 1 *et seq.*);

(ii) The Federal Agricultural Mortgage Corporation or any entity charged and operating under the Farm Credit Act of 1971 (12 U.S.C. 2001 *et seq.*); or

(iii) Institutions chartered by Congress specifically to engage in securitizations, secondary market sales (including sales of servicing rights) or similar transactions related to a transaction of a consumer, as long as the institutions do not sell or transfer nonpublic personal information to a nonaffiliated third party.

L. (1) "Financial product or service" means any product or service that a financial holding company could offer by engaging in an activity that is financial in nature or incidental to such a financial activity under Section 4(k) of the Bank Holding Company Act of 1956 (12 U.S.C. 1843(k)).

(2) Financial service includes a financial institution's evaluation or brokerage of information that the financial institution collects in connection with a request or an application from a consumer for a financial product or service.

M. "Health care" means:

(1) Preventive, diagnostic, therapeutic, rehabilitative, maintenance or palliative care, services, procedures, tests or counseling that:

(a) Relates to the physical, mental or behavioral condition of an individual; or

(b) Affects the structure or function of the human body or any part of the human body, including the banking of blood, sperm, organs or any other tissue; or

(2) Prescribing, dispensing or furnishing to an individual drugs or biologicals, or medical devices or health care equipment and supplies.

N. "Health care provider" means a physician or other health care practitioner licensed, accredited or certified to perform specified health services consistent with state law, or a health care facility.

O. "Health information" means any information or data except age or gender, whether oral or recorded in any form or medium, created by or derived from a health care provider or the consumer that relates to:

(1) The past, present or future physical, mental or behavioral health or condition of an individual;

(2) The provision of health care to an individual; or

(3) Payment for the provision of health care to an individual.

P. (1) "Insurance product or service" means any product or service that is offered by a licensee pursuant to the insurance laws of this state.

(2) Insurance service includes a licensee's evaluation, brokerage or distribution of information that the licensee collects in connection with a request or an application from a consumer for a insurance product or service.

Q. (1) "Licensee" means all licensed insurers, producers and other persons licensed or required to be licensed, or authorized or required to be authorized, or registered or required to be registered pursuant to the Insurance Law of this state.

(2) (a) A licensee is not subject to the notice and opt out requirements for nonpublic personal financial information set forth in Articles I, II, III and IV of this regulation if the licensee is an employee, agent or other representative of another licensee ("the principal") and:

(b) The principal otherwise complies with, and provides the notices required by, the provisions of this regulation; and

(c) The licensee does not disclose any nonpublic personal information to any person other than the principal or its affiliates in a manner permitted by this regulation.

(3) (a) Subject to Subparagraph (b), "licensee" shall also include an unauthorized insurer that accepts business placed through a licensed excess lines broker in this state, but only in regard to the excess lines placements placed pursuant to Section [insert section] of this state's laws.

(b) An excess lines broker or excess lines insurer shall be deemed to be in compliance with the notice and opt out requirements for nonpublic personal financial information set forth in Articles I, II, III and IV of this regulation provided:

(i) The broker or insurer does not disclose nonpublic personal information of a consumer or a customer to nonaffiliated third parties for any purpose, including joint servicing or marketing under Section 14 of this regulation, except as permitted by Section 15 or 16 of this regulation; and

(ii) The broker or insurer delivers a notice to the consumer at the time a customer relationship is established on which the following is printed in 16-point type:

PRIVACY NOTICE

"NEITHER THE U.S. BROKERS THAT HANDLED THIS INSURANCE NOR THE INSURERS THAT HAVE UNDERWRITTEN THIS INSURANCE WILL DISCLOSE NONPUBLIC PERSONAL INFORMATION CONCERNING THE BUYER TO NONAFFILIATES OF THE BROKERS OR INSURERS EXCEPT AS PERMITTED BY LAW."

R. (1) "Nonaffiliated third party" means any person except:

(a) A licensee's affiliate; or

(b) A person employed jointly by a licensee and any company that is not the licensee's affiliate (but nonaffiliated third party includes the other company that jointly employs the person).

(2) Nonaffiliated third party includes any company that is an affiliate solely by virtue of the direct or indirect ownership or control of the company by the licensee or its affiliate in conducting merchant banking or investment banking activities of the type described in Section 4(k)(4)(H) or insurance company investment activities of the type described in Section 4(k)(4)(I) of the federal Bank Holding Company Act (12 U.S.C. 1843(k)(4)(H) and (I)).

S. "Nonpublic personal information" means nonpublic personal financial information and nonpublic personal health information.

T. (1) "Nonpublic personal financial information" means:

(a) Personally identifiable financial information; and

(b) Any list, description or other grouping of consumers (and publicly available information pertaining to them) that is derived using any personally identifiable financial information that is not publicly available.

(2) Nonpublic personal financial information does not include:

(a) Health information;

(b) Publicly available information, except as included on a list described in Subsection T(1)(b) of this section; or

(c) Any list, description or other grouping of consumers (and publicly available information pertaining to them) that is derived without using any personally identifiable financial information that is not publicly available.

(3) Examples of lists.

(a) Nonpublic personal financial information includes any list of individuals' names and street addresses that is derived in whole or in part using personally identifiable financial information that is not publicly available, such as account numbers.

(b) Nonpublic personal financial information does not include any list of individuals' names and addresses that contains only publicly available information, is not derived in whole or in part using personally identifiable financial information that is not publicly available, and is not disclosed in a manner that indicates that any of the individuals on the list is a consumer of a financial institution.

U. "Nonpublic personal health information" means health information:

(1) That identifies an individual who is the subject of the information; or

(2) With respect to which there is a reasonable basis to believe that the information could be used to identify an individual.

V. (1) "Personally identifiable financial information" means any information:

(a) A consumer provides to a licensee to obtain an insurance product or service from the licensee;

(b) About a consumer resulting from a transaction involving an insurance product or service between a licensee and a consumer; or

(c) The licensee otherwise obtains about a consumer in connection with providing an insurance product or service to that consumer.

(2) Examples.

(a) Information included. Personally identifiable financial information includes:

(i) Information a consumer provides to a licensee on an application to obtain an insurance product or service;

(ii) Account balance information and payment history;

(iii) The fact that an individual is or has been one of the licensee's customers or has obtained an insurance product or service from the licensee;

(iv) Any information about the licensee's consumer if it is disclosed in a manner that indicates that the individual is or has been the licensee's consumer;

(v) Any information that a consumer provides to a licensee or that the licensee or its agent otherwise obtains in connection with collecting on a loan or servicing a loan;

(vi) Any information the licensee collects through an Internet cookie (an information-collecting device from a web server); and

(vii) Information from a consumer report.

(b) Information not included. Personally identifiable financial information does not include:

(i) Health information;

(ii) A list of names and addresses of customers of an entity that is not a financial institution; and

(iii) Information that does not identify a consumer, such as aggregate information or blind data that does not contain personal identifiers such as account numbers, names or addresses.

W. (1) "Publicly available information" means any information that a licensee has a reasonable basis to believe is lawfully made available to the general public from:

(a) Federal, state or local government records;

(b) Widely distributed media; or

(c) Disclosures to the general public that are required to be made by federal, state or local law.

(2) Reasonable basis. A licensee has a reasonable basis to believe that information is lawfully made available to the general public if the licensee has taken steps to determine:

(a) That the information is of the type that is available to the general public; and

(b) Whether an individual can direct that the information not be made available to the general public and, if so, that the licensee's consumer has not done so.

(3) Examples.

(a) Government records. Publicly available information in government records includes information in government real estate records and security interest filings.

(b) Widely distributed media. Publicly available information from widely distributed media includes information from a telephone book, a television or radio program, a newspaper or a web site that is available to the general public on an unrestricted basis. A web site is not restricted merely because an Internet service provider or a site operator requires a fee or a password, so long as access is available to the general public.

(c) Reasonable basis.

(i) A licensee has a reasonable basis to believe that mortgage information is lawfully made available to the general public if the licensee has determined that the information is of the type included on the public record in the jurisdiction where the mortgage would be recorded.

(ii) A licensee has a reasonable basis to believe that an individual's telephone number is lawfully made available to the general public if the licensee has located the telephone number in the telephone book or the consumer has informed you that the telephone number is not unlisted.

ARTICLE II. PRIVACY AND OPT OUT NOTICES FOR FINANCIAL INFORMATION

Section 5. Initial Privacy Notice to Consumers Required

A. Initial notice requirement. A licensee shall provide a clear and conspicuous notice that accurately reflects its privacy policies and practices to:

(1) Customer. An individual who becomes the licensee's customer, not later than when the licensee establishes a customer relationship, except as provided in Subsection E of this section; and

(2) Consumer. A consumer, before the licensee discloses any nonpublic personal financial information about the consumer to any nonaffiliated third party, if the licensee makes a disclosure other than as authorized by Sections 15 and 16.

B. When initial notice to a consumer is not required. A licensee is not required to provide an initial notice to a consumer under Subsection A(2) of this section if:

(1) The licensee does not disclose any nonpublic personal financial information about the consumer to any nonaffiliated third party, other than as authorized by Sections 15 and 16, and the licensee does not have a customer relationship with the consumer; or

(2) A notice has been provided by an affiliated licensee, as long as the notice clearly identifies all licensees to whom the notice applies and is accurate with respect to the licensee and the other institutions.

C. When the licensee establishes a customer relationship.

(1) General rule. A licensee establishes a customer relationship at the time the licensee and the consumer enter into a continuing relationship.

(2) Examples of establishing customer relationship. A licensee establishes a customer relationship when the consumer:

(a) Becomes a policyholder of a licensee that is an insurer when the insurer delivers an insurance policy or contract to the consumer, or in the case of a licensee that is an insurance producer or insurance broker, obtains insurance through that licensee; or

(b) Agrees to obtain financial, economic or investment advisory services relating to insurance products or services for a fee from the licensee.

D. Existing customers. When an existing customer obtains a new insurance product or service from a licensee that is to be used primarily for personal, family or household purposes, the licensee satisfies the initial notice requirements of Subsection A of this section as follows:

(1) The licensee may provide a revised policy notice, under Section 9, that covers the customer's new insurance product or service; or

(2) If the initial, revised or annual notice that the licensee most recently provided to that customer was accurate with respect to the new insurance product or service, the licensee does not need to provide a new privacy notice under Subsection A of this section.

E. Exceptions to allow subsequent delivery of notice.

(1) A licensee may provide the initial notice required by Subsection A(1) of this section within a reasonable time after the licensee establishes a customer relationship if:

(a) Establishing the customer relationship is not at the customer's election; or

(b) Providing notice not later than when the licensee establishes a customer relationship would substantially delay the customer 's transaction and the customer agrees to receive the notice at a later time.

(2) Examples of exceptions.

(a) Not at customer's election. Establishing a customer relationship is not at the customer's election if a licensee acquires or is assigned a customer's policy from another financial institution or residual market mechanism and the customer does not have a choice about the licensee's acquisition or assignment.

(b) Substantial delay of customer's transaction. Providing notice not later than when a licensee establishes a customer relationship would substantially delay the customer's transaction when the licensee and the individual agree over the telephone to enter into a customer relationship involving prompt delivery of the insurance product or service.

(c) No substantial delay of customer's transaction. Providing notice not later than when a licensee establishes a customer relationship would not substantially delay the customer's transaction when the relationship is initiated

in person at the licensee's office or through other means by which the customer may view the notice, such as on a web site.

F. Delivery. When a licensee is required to deliver an initial privacy notice by this section, the licensee shall deliver it according to Section 10. If the licensee uses a short-form initial notice for non-customers according to Section 7D, the licensee may deliver its privacy notice according to Section 7D(3).

Section 6. Annual Privacy Notice to Customers Required

A. (1) General rule. A licensee shall provide a clear and conspicuous notice to customers that accurately reflects its privacy policies and practices not less than annually during the continuation of the customer relationship. Annually means at least once in any period of twelve (12) consecutive months during which that relationship exists. A licensee may define the twelve-consecutive-month period, but the licensee shall apply it to the customer on a consistent basis.

(2) Example. A licensee provides a notice annually if it defines the twelve-consecutive-month period as a calendar year and provides the annual notice to the customer once in each calendar year following the calendar year in which the licensee provided the initial notice. For example, if a customer opens an account on any day of year 1, the licensee shall provide an annual notice to that customer by December 31 of year 2.

B. (1) Termination of customer relationship. A licensee is not required to provide an annual notice to a former customer. A former customer is an individual with whom a licensee no longer has a continuing relationship.

(2) Examples.

(a) A licensee no longer has a continuing relationship with an individual if the individual no longer is a current policyholder of an insurance product or no longer obtains insurance services with or through the licensee.

(b) A licensee no longer has a continuing relationship with an individual if the individual's policy is lapsed, expired or otherwise inactive or dormant under the licensee's business practices, and the licensee has not communicated with the customer about the relationship for a period of twelve (12) consecutive months, other than to provide annual privacy notices, material required by law or regulation, or promotional materials.

(c) For the purposes of this regulation, a licensee no longer has a continuing relationship with an individual if the individual's last known address according to the licensee's records is deemed invalid. An address of record is deemed invalid if mail sent to that address by the licensee has been returned by the postal authorities as undeliverable and if subsequent attempts by the licensee to obtain a current valid address for the individual have been unsuccessful.

(d) A licensee no longer has a continuing relationship with a customer in the case of providing real estate settlement services, at the time the customer completes execution of all documents related to the real estate closing, payment for those services has been received, or the licensee has completed all of its responsibilities with respect to the settlement, including filing documents on the public record, whichever is later.

D. Delivery. When a licensee is required by this section to deliver an annual privacy notice, the licensee shall deliver it according to Section 10.

Section 7. Information to be Included in Privacy Notices

A. General rule. The initial, annual and revised privacy notices that a licensee provides under Sections 5, 6 and 9 shall include each of the following items of information, in addition to any other information the licensee wishes to provide, that applies to the licensee and to the consumers to whom the licensee sends its privacy notice:

(1) The categories of nonpublic personal financial information that the licensee collects;

(2) The categories of nonpublic personal financial information that the licensee discloses;

(3) The categories of affiliates and nonaffiliated third parties to whom the licensee discloses nonpublic personal financial information, other than those parties to whom the licensee discloses information under Sections 15 and 16;

(4) The categories of nonpublic personal financial information about the licensee's former customers that the licensee discloses and the categories of affiliates and nonaffiliated third parties to whom the licensee discloses nonpublic personal financial information about the licensee's former customers, other than those parties to whom the licensee discloses information under Sections 15 and 16;

(5) If a licensee discloses nonpublic personal financial information to a nonaffiliated third party under Section 14 (and no other exception in Sections 15 and 16 applies to that disclosure), a separate description of the categories of information the licensee discloses and the categories of third parties with whom the licensee has contracted;

(6) An explanation of the consumer's right under Section 11A to opt out of the disclosure of nonpublic personal financial information to nonaffiliated third parties, including the methods by which the consumer may exercise that right at that time;

(7) Any disclosures that the licensee makes under Section 603(d)(2)(A)(iii) of the federal Fair Credit Reporting Act (15 U.S.C. 1681a(d)(2)(A)(iii)) (that is, notices regarding the ability to opt out of disclosures of information among affiliates);

(8) The licensee's policies and practices with respect to protecting the confidentiality and security of nonpublic personal information; and

(9) Any disclosure that the licensee makes under Subsection B of this section.

B. Description of parties subject to exceptions. If a licensee discloses nonpublic personal financial information as authorized under Sections 15 and 16, the licensee is not required to list those exceptions in the initial or annual privacy notices required by Sections 5 and 6. When describing the categories of parties to whom disclosure is made, the licensee is required to state only that it makes disclosures to other affiliated or nonaffiliated third parties, as applicable, as permitted by law.

C. Examples.

(1) Categories of nonpublic personal financial information that the licensee collects. A licensee satisfies the requirement to categorize the nonpublic personal financial information it collects if the licensee categorizes it according to the source of the information, as applicable:

(a) Information from the consumer;

(b) Information about the consumer's transactions with the licensee or its affiliates;

(c) Information about the consumer's transactions with nonaffiliated third parties; and

(d) Information from a consumer reporting agency.

(2) Categories of nonpublic personal financial information a licensee discloses.

(a) A licensee satisfies the requirement to categorize nonpublic personal financial information it discloses if the licensee categorizes the information according to source, as described in Paragraph (1), as applicable, and provides a few examples to illustrate the types of information in each category. These might include:

(i) Information from the consumer, including application information, such as assets and income and identifying information, such as name, address and social security number;

(ii) Transaction information, such as information about balances, payment history and parties to the transaction; and

(iii) Information from consumer reports, such as a consumer's creditworthiness and credit history.

(b) A licensee does not adequately categorize the information that it discloses if the licensee uses only general terms, such as transaction information about the consumer.

(c) If a licensee reserves the right to disclose all of the nonpublic personal financial information about consumers that it collects, the licensee may simply state that fact without describing the categories or examples of nonpublic personal information that the licensee discloses.

(3) Categories of affiliates and nonaffiliated third parties to whom the licensee discloses.

(a) A licensee satisfies the requirement to categorize the affiliates and nonaffiliated third parties to which the licensee discloses nonpublic personal financial information about consumers if the licensee identifies the types of businesses in which they engage.

(b) Types of businesses may be described by general terms only if the licensee uses a few illustrative examples of significant lines of business. For example, a licensee may use the term financial products or services if it includes appropriate examples of significant lines of businesses, such as life insurer, automobile insurer, consumer banking or securities brokerage.

(c) A licensee also may categorize the affiliates and nonaffiliated third parties to which it discloses nonpublic personal financial information about consumers using more detailed categories.

(4) Disclosures under exception for service providers and joint marketers. If a licensee discloses nonpublic personal financial information under the exception in Section 14 to a nonaffiliated third party to market products or services that it offers alone or jointly with another financial institution, the licensee satisfies the disclosure requirement of Subsection A(5) of this section if it:

(a) Lists the categories of nonpublic personal financial information it discloses, using the same categories and examples the licensee used to meet the requirements of Subsection A(2) of this section, as applicable; and

(b) States whether the third party is:

(i) A service provider that performs marketing services on the licensee's behalf or on behalf of the licensee and another financial institution; or

(ii) A financial institution with whom the licensee has a joint marketing agreement.

(5) Simplified notices. If a licensee does not disclose, and does not wish to reserve the right to disclose, nonpublic personal financial information about customers or former customers to affiliates or nonaffiliated third parties except as authorized under Sections 15 and 16, the licensee may simply state that fact, in addition to the information it shall provide under Subsections A(1), A(8), A(9), and Subsection B of this section.

(6) Confidentiality and security. A licensee describes its policies and practices with respect to protecting the confidentiality and security of nonpublic personal financial information if it does both of the following:

(a) Describes in general terms who is authorized to have access to the information; and

(b) States whether the licensee has security practices and procedures in place to ensure the confidentiality of the information in accordance with the licensee's policy. The licensee is not required to describe technical information about the safeguards it uses.

D. Short-form initial notice with opt out notice for non-customers.

(1) A licensee may satisfy the initial notice requirements in Sections 5A(2) and 8C for a consumer who is not a customer by providing a short-form initial notice at the same time as the licensee delivers an opt out notice as required in Section 8.

(2) A short-form initial notice shall:

(a) Be clear and conspicuous;

(b) State that the licensee's privacy notice is available upon request; and

(c) Explain a reasonable means by which the consumer may obtain that notice.

(3) The licensee shall deliver its short-form initial notice according to Section 10. The licensee is not required to deliver its privacy notice with its short-form initial notice. The licensee instead may simply provide the consumer a reasonable means to obtain its privacy notice. If a consumer who receives the licensee's short-form notice requests the licensee's privacy notice, the licensee shall deliver its privacy notice according to Section 10.

(4) Examples of obtaining privacy notice. The licensee provides a reasonable means by which a consumer may obtain a copy of its privacy notice if the licensee:

(a) Provides a toll-free telephone number that the consumer may call to request the notice; or

(b) For a consumer who conducts business in person at the licensee's office, maintains copies of the notice on hand that the licensee provides to the consumer immediately upon request.

E. Future disclosures. The licensee's notice may include:

(1) Categories of nonpublic personal financial information that the licensee reserves the right to disclose in the future, but does not currently disclose; and

(2) Categories of affiliates or nonaffiliated third parties to whom the licensee reserves the right in the future to disclose, but to whom the licensee does not currently disclose, nonpublic personal financial information.

F. Sample clauses. Sample clauses illustrating some of the notice content required by this section are included in Appendix A of this regulation.

Section 8. Form of Opt Out Notice to Consumers and Opt Out Methods

A. (1) Form of opt out notice. If a licensee is required to provide an opt out notice under Section 11A, it shall provide a clear and conspicuous notice to each of its consumers that accurately explains the right to opt out under that section. The notice shall state:

(a) That the licensee discloses or reserves the right to disclose nonpublic personal financial information about its consumer to a nonaffiliated third party;

(b) That the consumer has the right to opt out of that disclosure; and

(c) A reasonable means by which the consumer may exercise the opt out right.

(2) Examples.

(a) Adequate opt out notice. A licensee provides adequate notice that the consumer can opt out of the disclosure of nonpublic personal financial information to a nonaffiliated third party if the licensee:

(i) Identifies all of the categories of nonpublic personal financial information that it discloses or reserves the right to disclose, and all of the categories of nonaffiliated third parties to which the licensee discloses the information, as described in Section 7A(2) and (3), and states that the consumer can opt out of the disclosure of that information; and

(ii) Identifies the insurance products or services that the consumer obtains from the licensee, either singly or jointly, to which the opt out direction would apply.

(b) Reasonable opt out means. A licensee provides a reasonable means to exercise an opt out right if it:

(i) Designates check-off boxes in a prominent position on the relevant forms with the opt out notice;

(ii) Includes a reply form together with the opt out notice;

(iii) Provides an electronic means to opt out, such as a form that can be sent via electronic mail or a process at the licensee's web site, if the consumer agrees to the electronic delivery of information; or

(iv) Provides a toll-free telephone number that consumers may call to opt out.

(c) Unreasonable opt out means. A licensee does not provide a reasonable means of opting out if:

(i) The only means of opting out is for the consumer to write his or her own letter to exercise that opt out right; or

(ii) The only means of opting out as described in any notice subsequent to the initial notice is to use a check-off box that the licensee provided with the initial notice but did not include with the subsequent notice.

(d) Specific opt out means. A licensee may require each consumer to opt out through a specific means, as long as that means is reasonable for that consumer.

B. Same form as initial notice permitted. A licensee may provide the opt out notice together with or on the same written or electronic form as the initial notice the licensee provides in accordance with Section 5.

C. Initial notice required when opt out notice delivered subsequent to initial notice. If a licensee provides the opt out notice later than required for the initial notice in accordance with Section 5, the licensee shall also include a copy of the initial notice with the opt out notice in writing or, if the consumer agrees, electronically.

D. Joint relationships.

(1) If two (2) or more consumers jointly obtain an insurance product or service from a licensee, the licensee may provide a single opt out notice. The licensee's opt out notice shall explain how the licensee will treat an opt out direction by a joint consumer (as explained in Paragraph (5) of this subsection).

(2) Any of the joint consumers may exercise the right to opt out. The licensee may either:

(a) Treat an opt out direction by a joint consumer as applying to all of the associated joint consumers; or

(b) Permit each joint consumer to opt out separately.

(3) If a licensee permits each joint consumer to opt out separately, the licensee shall permit one of the joint consumers to opt out on behalf of all of the joint consumers.

(4) A licensee may not require all joint consumers to opt out before it implements any opt out direction.

(5) Example. If John and Mary are both named policyholders on a homeowner's insurance policy iss ued by a licensee and the licensee sends policy statements to John's address, the licensee may do any of the following, but it shall explain in its opt out notice which opt out policy the licensee will follow:

(a) Send a single opt out notice to John's address, but the licensee shall accept an opt out direction from either John or Mary.

(b) Treat an opt out direction by either John or Mary as applying to the entire policy. If the licensee does so and John opts out, the licensee may not require Mary to opt out as well before implementing John's opt out direction.

(c) Permit John and Mary to make different opt out directions. If the licensee does so:

(i) It shall permit John and Mary to opt out for each other;

(ii) If both opt out, the licensee shall permit both of them to notify it in a single response (such as on a form or through a telephone call); and

(iii) If John opts out and Mary does not, the licensee may only disclose nonpublic personal financial information about Mary, but not about John and not about John and Mary jointly.

E. Time to comply with opt out. A licensee shall comply with a consumer's opt out direction as soon as reasonably practicable after the licensee receives it.

F. Continuing right to opt out. A consumer may exercise the right to opt out at any time.

G. Duration of consumer's opt out direction.

(1) A consumer's direction to opt out under this section is effective until the consumer revokes it in writing or, if the consumer agrees, electronically.

(2) When a customer relationship terminates, the customer's opt out direction continues to apply to the nonpublic personal financial information that the licensee collected during or related to that relationship. If the individual subsequently establishes a new customer relationship with the licensee, the opt out direction that applied to the former relationship does not apply to the new relationship.

H. Delivery. When a licensee is required to deliver an opt out notice by this section, the licensee shall deliver it according to Section 10.

Section 9. Revised Privacy Notices

A. General rule. Except as otherwise authorized in this regulation, a licensee shall not, directly or through an affiliate, disclose any nonpublic personal financial information about a consumer to a nonaffiliated third party other than as described in the initial notice that the licensee provided to that consumer under Section 5, unless:

(1) The licensee has provided to the consumer a clear and conspicuous revised notice that accurately describes its policies and practices;

(2) The licensee has provided to the consumer a new opt out notice;

(3) The licensee has given the consumer a reasonable opportunity, before the licensee discloses the information to the nonaffiliated third party, to opt out of the disclosure; and

(4) The consumer does not opt out.

B. Examples.

(1) Except as otherwise permitted by Sections 14, 15 and 16, a licensee shall provide a revised notice before it:

(a) Discloses a new category of nonpublic personal financial information to any nonaffiliated third party;

(b) Discloses nonpublic personal financial information to a new category of nonaffiliated third party; or

(c) Discloses nonpublic personal financial information about a former customer to a nonaffiliated third party, if that former customer has not had the opportunity to exercise an opt out right regarding that disclosure.

(2) A revised notice is not required if the licensee discloses nonpublic personal financial information to a new nonaffiliated third party that the licensee adequately described in its prior notice.

C. Delivery. When a licensee is required to deliver a revised privacy notice by this section, the licensee shall deliver it according to Section 10.

Section 10. Delivery

A. How to provide notices. A licensee shall provide any notices that this regulation requires so that each consumer can reasonably be expected to receive actual notice in writing or, if the consumer agrees, electronically.

B. (1) Examples of reasonable expectation of actual notice. A licensee may reasonably expect that a consumer will receive actual notice if the licensee:

(a) Hand-delivers a printed copy of the notice to the consumer;

(b) Mails a printed copy of the notice to the last known address of the consumer separately, or in a policy, billing or other written communication;

(c) For a consumer who conducts transactions electronically, posts the notice on the electronic site and requires the consumer to acknowledge receipt of the notice as a necessary step to obtaining a particular insurance product or service;

(d) For an isolated transaction with a consumer, such as the licensee providing an insurance quote or selling the consumer travel insurance, posts the notice and requires the consumer to acknowledge receipt of the notice as a necessary step to obtaining the particular insurance product or service.

(2)Examples of unreasonable expectation of actual notice. A licensee may not, however, reasonably expect that a consumer will receive actual notice of its privacy policies and practices if it:

(a) Only posts a sign in its office or generally publishes advertisements of its privacy policies and practices; or

(b) Sends the notice via electronic mail to a consumer who does not obtain an insurance product or service from the licensee electronically.

C. Annual notices only. A licensee may reasonably expect that a customer will receive actual notice of the licensee's annual privacy notice if:

(1) The customer uses the licensee's web site to access insurance products and services electronically and agrees to receive notices at the web site and the licensee posts its current privacy notice continuously in a clear and conspicuous manner on the web site; or

(2) The customer has requested that the licensee refrain from sending any information regarding the customer relationship, and the licensee's current privacy notice remains available to the customer upon request.

D. Oral description of notice insufficient. A licensee may not provide any notice required by this regulation solely by orally explaining the notice, either in person or over the telephone.

E. Retention or accessibility of notices for customers.

(1) For customers only, a licensee shall provide the initial notice required by Section 5A(1), the annual notice required by Section 6A, and the revised notice required by Section 9 so that the customer can retain them or obtain them later in writing or, if the customer agrees, electronically.

(2) Examples of retention or accessibility. A licensee provides a privacy notice to the customer so that the customer can retain it or obtain it later if the licensee:

(a) Hand-delivers a printed copy of the notice to the customer;

(b) Mails a printed copy of the notice to the last known address of the customer; or

(c) Makes its current privacy notice available on a web site (or a link to another web site) for the customer who obtains an insurance product or service electronically and agrees to receive the notice at the web site.

F. Joint notice with other financial institutions. A licensee may provide a joint notice from the licensee and one or more of its affiliates or other financial institutions, as identified in the notice, as long as the notice is accurate with respect to the licensee and the other institutions. A licensee also may provide a notice on behalf of another financial institution.

G. Joint relationships. If two (2) or more consumers jointly obtain an insurance product or service from a licensee, the licensee may satisfy the initial, annual and revised notice requirements of Sections 5A, 6A and 9A, respectively, by providing one notice to those consumers jointly.

ARTICLE III. LIMITS ON DISCLOSURES OF FINANCIAL INFORMATION

Section 11. Limits on Disclosure of Nonpublic Personal Financial Information to Nonaffiliated Third Parties

A. (1) Conditions for disclosure. Except as otherwise authorized in this regulation, a licensee may not, directly or through any affiliate, disclose any nonpublic personal financial information about a consumer to a nonaffiliated third party unless:

(a) The licensee has provided to the consumer an initial notice as required under Section 5;

(b) The licensee has provided to the consumer an opt out notice as required in Section 8;

(c) The licensee has given the consumer a reasonable opportunity, before it discloses the information to the nonaffiliated third party, to opt out of the disclosure; and

(d) The consumer does not opt out.

(2) Opt out definition. Opt out means a direction by the consumer that the licensee not disclose nonpublic personal financial information about that consumer to a nonaffiliated third party, other than as permitted by Sections 14, 15 and 16.

(3) Examples of reasonable opportunity to opt out. A licensee provides a consumer with a reasonable opportunity to opt out if:

(a) By mail. The licensee mails the notices required in Paragraph (1) of this subsection to the consumer and allows the consumer to opt out by mailing a form, calling a toll-free telephone number or any other reasonable means within thirty (30) days from the date the licensee mailed the notices.

(b) By electronic means. A customer opens an on-line account with a licensee and agrees to receive the notices required in Paragraph (1) of this subsection electronically, and the licensee allows the customer to opt out by any reasonable means within thirty (30) days after the date that the customer acknowledges receipt of the notices in conjunction with opening the account.

(c) Isolated transaction with consumer. For an isolated transaction such as providing the consumer with an insurance quote, a licensee provides the consumer with a reasonable opportunity to opt out if the licensee provides the notices required in Paragraph (1) of this subsection at the time of the transaction and requests that the consumer decide, as a necessary part of the transaction, whether to opt out before completing the transaction.

B. Application of opt out to all consumers and all nonpublic personal financial information.

(1) A licensee shall comply with this section, regardless of whether the licensee and the consumer have established a customer relationship.

(2) Unless a licensee complies with this section, the licensee may not, directly or through any affiliate, disclose any nonpublic personal financial information about a consumer that the licensee has collected, regardless of whether the licensee collected it before or after receiving the direction to opt out from the consumer.

C. Partial opt out. A licensee may allow a consumer to select certain nonpublic personal financial information or certain nonaffiliated third parties with respect to which the consumer wishes to opt out.

Section 12. Limits on Redisclosure and Reuse of Nonpublic Personal Financial Information

A. (1) Information the licensee receives under an exception. If a licensee receives nonpublic personal financial information from a nonaffiliated financial institution under an exception in Sections 15 or 16 of this regulation, the licensee's disclosure and use of that information is limited as follows:

(a) The licensee may disclose the information to the affiliates of the financial institution from which the licensee received the information;

(b) The licensee may disclose the information to its affiliates, but the licensee's affiliates may, in turn, disclose and use the information only to the extent that the licensee may disclose and use the information; and

(c) The licensee may disclose and use the information pursuant to an exception in Sections 15 or 16 of this regulation, in the ordinary course of business to carry out the activity covered by the exception under which the licensee received the information.

(2) Example. If a licensee receives information from a nonaffiliated financial institution for claims settlement purposes, the licensee may disclose the information for fraud prevention, or in response to a properly authorized subpoena. The licensee may not disclose that information to a third party for marketing purposes or use that information for its own marketing purposes.

B. (1) Information a licensee receives outside of an exception. If a licensee receives nonpublic personal financial information from a nonaffiliated financial institution other than under an exception in Sections 15 or 16 of this regulation, the licensee may disclose the information only:

(a) To the affiliates of the financial institution from which the licensee received the information;

(b) To its affiliates, but its affiliates may, in turn, disclose the information only to the extent that the licensee may disclose the information; and

(c) To any other person, if the disclosure would be lawful if made directly to that person by the financial institution from which the licensee received the information.

(2) Example. If a licensee obtains a customer list from a nonaffiliated financial institution outside of the exceptions in Sections 15 or 16:

(a) The licensee may use that list for its own purposes; and

(b) The licensee may disclose that list to another nonaffiliated third party only if the financial institution from which the licensee purchased the list could have lawfully disclosed the list to that third party. That is, the licensee may disclose the list in accordance with the privacy policy of the financial institution from which the licensee received the list, as limited by the opt out direction of each consumer whose nonpublic personal financial information the licensee intends to disclose, and the licensee may disclose the list in accordance with an exception in Sections 15 or 16, such as to the licensee's attorneys or accountants.

C. Information a licensee discloses under an exception. If a licensee discloses nonpublic personal financial information to a nonaffiliated third party under an exception in Sections 15 or 16 of this regulation, the third party may disclose and use that information only as follows:

(1) The third party may disclose the information to the licensee's affiliates;

(2) The third party may disclose the information to its affiliates, but its affiliates may, in turn, disclose and use the information only to the extent that the third party may disclose and use the information; and

(3) The third party may disclose and use the information pursuant to an exception in Sections 15 or 16 in the ordinary course of business to carry out the activity covered by the exception under which it received the information.

D. Information a licensee discloses outside of an exception. If a licensee discloses nonpublic personal financial information to a nonaffiliated third party other than under an exception in Sections 15 or 16 of this regulation, the third party may disclose the information only:

(1) To the licensee's affiliates;

(2) To the third party's affiliates, but the third party's affiliates, in turn, may disclose the information only to the extent the third party can disclose the information; and

(3) To any other person, if the disclosure would be lawful if the licensee made it directly to that person.

Section 13. Limits on Sharing Account Number Information for Marketing Purposes

A. General prohibition on disclosure of account numbers. A licensee shall not, directly or through an affiliate, disclose, other than to a consumer reporting agency, a policy number or similar form of access number or access code for a consumer's policy or transaction account to any nonaffiliated third party for use in telemarketing, direct mail marketing or other marketing through electronic mail to the consumer.

B. Exceptions. Subsection A of this section does not apply if a licensee discloses a policy number or similar form of access number or access code:

(1) To the licensee's service provider solely in order to perform marketing for the licensee 's own products or services, as long as the service provider is not authorized to directly initiate charges to the account;

(2) To a licensee who is a producer solely in order to perform marketing for the licensee's own products or services; or

(3) To a participant in an affinity or similar program where the participants in the program are identified to the customer when the customer enters into the program.

C. Examples.

(1) Policy number. A policy number, or similar form of access number or access code, does not include a number or code in an encrypted form, as long as the licensee does not provide the recipient with a means to decode the number or code.

(2) Policy or transaction account. For the purposes of this section, a policy or transaction account is an account other than a deposit account or a credit card account. A policy or transaction account does not include an account to which third parties cannot initiate charges.

ARTICLE IV. EXCEPTIONS TO LIMITS ON DISCLOSURES OF FINANCIAL INFORMATION

Section 14. Exception to Opt Out Requirements for Disclosure of Nonpublic Personal Financial Information for Service Providers and Joint Marketing

A. General rule.

(1) The opt out requirements in Sections 8 and 11 do not apply when a licensee provides nonpublic personal financial information to a nonaffiliated third party to perform services for the licensee or functions on the licensee's behalf, if the licensee:

(a) Provides the initial notice in accordance with Section 5; and

(b) Enters into a contractual agreement with the third party that prohibits the third party from disclosing or using the information other than to carry out the purposes for which the licensee disclosed the information, including use under an exception in Sections 15 or 16 in the ordinary course of business to carry out those purposes.

(2) Example. If a licensee discloses nonpublic personal financial information under this section to a financial institution with which the licensee performs joint marketing, the licensee's contractual agreement with that institution meets the requirements of Paragraph (1)(b) of this subsection if it prohibits the institution from disclosing or using the nonpublic personal financial information except as necessary to carry out the joint marketing or under an exception in Sections 15 or 16 in the ordinary course of business to carry out that joint marketing.

B. Service may include joint marketing. The services a nonaffiliated third party performs for a licensee under Subsection A of this section may include marketing of the licensee's own products or services or marketing of financial products or services offered pursuant to joint agreements between the licensee and one or more financial institutions.

C. Definition of "joint agreement." For purposes of this section, "joint agreement" means a written contract pursuant to which a licensee and one or more financial institutions jointly offer, endorse or sponsor a financial product or service.

Section 15. Exceptions to Notice and Opt Out Requirements for Disclosure of Nonpublic Personal Financial Information for Processing and Servicing Transactions

A. Exceptions for processing transactions at consumer's request. The requirements for initial notice in Section 5A(2), the opt out in Sections 8 and 11, and service providers and joint marketing in Section 14 do not apply if the licensee discloses nonpublic personal financial information as necessary to effect, administer or enforce a transaction that a consumer requests or authorizes, or in connection with:

(1) Servicing or processing an insurance product or service that a consumer requests or authorizes;

(2) Maintaining or servicing the consumer's account with a licensee, or with another entity as part of a private label credit card program or other extension of credit on behalf of such entity;

(3) A proposed or actual securitization, secondary market sale (including sales of servicing rights) or similar transaction related to a transaction of the consumer; or

(4) Reinsurance or stop loss or excess loss insurance.

B. "Necessary to effect, administer or enforce a transaction" means that the disclosure is:

(1) Required, or is one of the lawful or appropriate methods, to enforce the licensee's rights or the rights of other persons engaged in carrying out the financial transaction or providing the product or service; or

(2) Required, or is a usual, appropriate or acceptable method:

(a) To carry out the transaction or the product or service business of which the transaction is a part, and record, service or maintain the consumer's account in the ordinary course of providing the insurance product or service;

(b) To administer or service benefits or claims relating to the transaction or the product or service business of which it is a part;

(c) To provide a confirmation, statement or other record of the transaction, or information on the status or value of the insurance product or service to the consumer or the consumer's agent or broker;

(d) To accrue or recognize incentives or bonuses associated with the transaction that are provided by a licensee or any other party;

(e) To underwrite insurance at the consumer's request or for any of the following purposes as they relate to a consumer 's insurance: account administration, reporting, investigating or preventing fraud or material misrepresentation, processing premium payments, processing insurance claims, administering insurance benefits (including utilization review activities), participating in research projects or as otherwise required or specifically permitted by federal or state law; or

(f) In connection with:

(i) The authorization, settlement, billing, processing, clearing, transferring, reconciling or collection of amounts charged, debited or otherwise paid using a debit, credit or other payment card, check or account number, or by other payment means;

(ii) The transfer of receivables, accounts or interests therein; or

(iii) The audit of debit, credit or other payment information.

Section 16. Other Exceptions to Notice and Opt Out Requirements for Disclosure of Nonpublic Personal Financial Information

A. Exceptions to opt out requirements. The requirements for initial notice to consumers in Section 5A(2), the opt out in Sections 8 and 11, and service providers and joint marketing in Section 14 do not apply when a licensee discloses nonpublic personal financial information:

(1) With the consent or at the direction of the consumer, provided that the consumer has not revoked the consent or direction;

(2) (a) To protect the confidentiality or security of a licensee's records pertaining to the consumer, service, product or transaction;

(b) To protect against or prevent actual or potential fraud or unauthorized transactions;

(c) For required institutional risk control or for resolving consumer disputes or inquiries;

(d) To persons holding a legal or beneficial interest relating to the consumer; or

(e) To persons acting in a fiduciary or representative capacity on behalf of the consumer;

(3) To provide information to insurance rate advisory organizations, guaranty funds or agencies, agencies that are rating a licensee, persons that are assessing the licensee's compliance with industry standards, and the licensee's attorneys, accountants and auditors;

(4) To the extent specifically permitted or required under other provisions of law and in accordance with the federal Right to Financial Privacy Act of 1978 (12 U.S.C. 3401 et seq.), to law enforcement agencies (including the Federal Reserve Board, Office of the Comptroller of the Currency, Federal Deposit Insurance Corporation, Office of Thrift Supervision, National Credit Union Administration, the Securities and Exchange Commission, the Secretary of the Treasury, with respect to 31 U.S.C. Chapter 53, Subchapter II (Records and Reports on Monetary Instruments and Transactions) and 12 U.S.C. Chapter 21 (Financial Recordkeeping), a state insurance authority, and the Federal Trade Commission), self-regulatory organizations or for an investigation on a matter related to public safety;

(5) (a) To a consumer reporting agency in accordance with the federal Fair Credit Reporting Act (15 U.S.C. 1681 et seq.); or

(b) From a consumer report reported by a consumer reporting agency;

(6) In connection with a proposed or actual sale, merger, transfer or exchange of all or a portion of a business or operating unit if the disclosure of nonpublic personal financial information concerns solely consumers of the business or unit;

(7) (a) To comply with federal, state or local laws, rules and other applicable legal requirements;

(b) To comply with a properly authorized civil, criminal or regulatory investigation, or subpoena or summons by federal, state or local authorities;

(c) To respond to judicial process or government regulatory authorities having jurisdiction over a licensee for examination, compliance or other purposes as authorized by law; or

(8) For purposes related to the replacement of a group benefit plan, a group health plan, a group welfare plan or a workers' compensation plan.

B. Example of revocation of consent. A consumer may revoke consent by subsequently exercising the right to opt out of future disclosures of nonpublic personal information as permitted under Section 8F.

ARTICLE V. RULES FOR HEALTH INFORMATION

Section 17. When Authorization Required for Disclosure of Nonpublic Personal Health Information

A. A licensee shall not disclose nonpublic personal health information about a consumer or customer unless an authorization is obtained from the consumer or customer whose nonpublic personal health information is sought to be disclosed.

B. Nothing in this section shall prohibit, restrict or require an authorization for the disclosure of nonpublic personal health information by a licensee for the performance of the following insurance functions by or on behalf of the licensee: claims administration; claims adjustment and management; detection, investigation or reporting of actual or potential fraud, misrepresentation or criminal activity; underwriting; policy placement or issuance; loss control; ratemaking and guaranty fund functions; reinsurance and excess loss insurance; risk management; case management; disease management; quality assurance; quality improvement; performance evaluation; provider credentialing verification; utilization review; peer review activities; actuarial, scientific, medical or public policy research; grievance procedures; internal administration of compliance, managerial, and information systems; policyholder service functions; auditing; reporting; database security; administration of consumer disputes and

inquiries; external accreditation standards; the replacement of a group benefit plan or workers compensation policy or program; activities in connection with a sale, merger, transfer or exchange of all or part of a business or operating unit; any activity that permits disclosure without authorization pursuant to the federal Health Insurance Portability and Accountability Act privacy rules promulgated by the U.S. Department of Health and Human Services; disclosure that is required, or is one of the lawful or appropriate methods, to enforce the licensee's rights or the rights of other persons engaged in carrying out a transaction or providing a product or service that a consumer requests or authorizes; and any activity otherwise permitted by law, required pursuant to governmental reporting authority, or to comply with legal process. Additional insurance functions may be added with the approval of the commissioner to the extent they are necessary for appropriate performance of insurance functions and are fair and reasonable to the interest of consumers.

Section 18. Authorizations

A. A valid authorization to disclose nonpublic personal health information pursuant to this Article V shall be in written or electronic form and shall contain all of the following:

(1) The identity of the consumer or customer who is the subject of the nonpublic personal health information;

(2) A general description of the types of nonpublic personal health information to be disclosed;

(3) General descriptions of the parties to whom the licensee discloses nonpublic personal health information, the purpose of the disclosure and how the information will be used;

(4) The signature of the consumer or customer who is the subject of the nonpublic personal health information or the individual who is legally empowered to grant authority and the date signed; and

(5) Notice of the length of time for which the authorization is valid and that the consumer or customer may revoke the authorization at any time and the procedure for making a revocation.

B. An authorization for the purposes of this Article V shall specify a length of time for which the authorization shall remain valid, which in no event shall be for more than twenty-four (24) months.

C. A consumer or customer who is the subject of nonpublic personal health information may revoke an authorization provided pursuant to this Article V at any time, subject to the rights of an individual who acted in reliance on the authorization prior to notice of the revocation.

D. A licensee shall retain the authorization or a copy thereof in the record of the individual who is the subject of nonpublic personal health information.

Section 19. Authorization Request Delivery

A request for authorization and an authorization form may be delivered to a consumer or a customer as part of an opt-out notice pursuant to Section 10, provided that the request and the authorization form are clear and conspicuous. An authorization form is not required to be delivered to the consumer or customer or included in any other notices unless the licensee intends to disclose protected health information pursuant to Section 17A.

Section 20. Relationship to Federal Rules

Irrespective of whether a licensee is subject to the federal Health Insurance Portability and Accountability Act privacy rule as promulgated by the U.S. Department of Health and Human Services 45 CFR Part 160 (the "federal rule"), if a licensee complies with all requirements of the federal rule except for its effective date provision, the licensee shall not be subject to the provisions of this Article V.

Section 21. Relationship to State Laws

Nothing in this article shall preempt or supercede existing state law related to medical records, health or insurance information privacy.

ARTICLE VI. ADDITIONAL PROVISIONS

Section 22. Protection of Fair Credit Reporting Act

Nothing in this regulation shall be construed to modify, limit or supersede the operation of the federal Fair Credit Reporting Act (15 U.S.C. 1681 et seq.), and no inference shall be drawn on the basis of the provisions of this regulation regarding whether information is transaction or experience information under Section 603 of that Act.

Section 23. Nondiscrimination

A. A licensee shall not unfairly discriminate against any consumer or customer because that consumer or customer has opted out from the disclosure of his or her nonpublic personal financial information pursuant to the provisions of this regulation.

B. A licensee shall not unfairly discriminate against a consumer or customer because that consumer or customer has not granted authorization for the disclosure of his or her nonpublic personal health information pursuant to the provisions of this regulation.

Section 24. Violation

Persons violating the provisions of this regulation shall have committed an unfair trade practice and shall be subject to the penalties set forth in Chapter 57 of Title 38.

Section 25. Severability

If any section or portion of a section of this regulation or its applicability to any person or circumstance is held invalid by a court of competent jurisdiction, the remainder of the regulation or the applicability of the provision to other persons or circumstances shall not be affected.

Section 26. Effective Date

A. Effective date. This regulation is effective upon publication of the final regulation in the State Register. In order to provide sufficient time for licensees to establish policies and systems to comply with the requirements of this regulation, the director has extended the time for compliance with this regulation until July 1, 2001. However, with respect to requirements related to the treatment of health information, the compliance deadline has been extended to January 1, 2003.

B. (1) Notice requirement for consumers who are the licensee's customers on the compliance date. By July 1, 2001, a licensee shall provide an initial notice, as required by Section 5, to consumers who are the licensee's customers on July 1, 2001.

(2) Example. A licensee provides an initial notice to consumers who are its customers on July 1, 2001, if, by that date, the licensee has established a system for providing an initial notice to all new customers and has mailed the initial notice to all the licensee's existing customers.

C. Two-year grandfathering of service agreements. Until July 1, 2002, a contract that a licensee has entered into with a nonaffiliated third party to perform services for the licensee or functions on the licensee's behalf satisfies the provisions of Section 14A(1)(b) of this regulation, even if the contract does not include a requirement that the

third party maintain the confidentiality of nonpublic personal information, as long as the licensee entered into the agreement on or before July 1, 2000.

APPENDIX A – SAMPLE CLAUSES

Licensees, including a group of financial holding company affiliates that use a common privacy notice, may use the following sample clauses, if the clause is accurate for each institution that uses the notice. (Note that disclosure of certain information, such as assets, income and information from a consumer reporting agency, may give rise to obligations under the federal Fair Credit Reporting Act, such as a requirement to permit a consumer to opt out of disclosures to affiliates or designation as a consumer reporting agency if disclosures are made to nonaffiliated third parties.)

A-1–Categories of information a licensee collects (all institutions)

A licensee may use this clause, as applicable, to meet the requirement of Section 7A(1) to describe the categories of nonpublic personal information the licensee collects.

Sample Clause A-1:

We collect nonpublic personal information about you from the following sources:

• Information we receive from you on applications or other forms;

• Information about your transactions with us, our affiliates or others; and

• Information we receive from a consumer reporting agency.

A-2–Categories of information a licensee discloses (institutions that disclose outside of the exceptions)

A licensee may use one of these clauses, as applicable, to meet the requirement of Section 7A(2) to describe the categories of nonpublic personal information the licensee discloses. The licensee may use these clauses if it discloses nonpublic personal information other than as permitted by the exceptions in Sections 14, 15 and 16.

Sample Clause A-2, Alternative 1:

We may disclose the following kinds of nonpublic personal information about you:

• Information we receive from you on applications or other forms, such as [provide illustrative examples, such as "your name, address, social security number, assets, income, and beneficiaries"];

• Information about your transactions with us, our affiliates or others, such as [provide illustrative examples, such as "your policy coverage, premiums, and payment history"]; and

• Information we receive from a consumer reporting agency, such as [provide illustrative examples, such as "your creditworthiness and credit history"].

Sample Clause A-2, Alternative 2:

We may disclose all of the information that we collect, as described [describe location in the notice, such as "above" or "below"].

A-3–Categories of information a licensee discloses and parties to whom the licensee discloses (institutions that do not disclose outside of the exceptions)

A licensee may use this clause, as applicable, to meet the requirements of Sections 7A(2), (3), and (4) to describe the categories of nonpublic personal information about customers and former customers that the licensee discloses and the categories of affiliates and nonaffiliated third parties to whom the licensee discloses. A licensee may use this clause if the licensee does not disclose nonpublic personal information to any party, other than as permitted by the exceptions in Sections 15 and 16.

Sample Clause A-3:

We do not disclose any nonpublic personal information about our customers or former customers to anyone, except as permitted by law.

A-4–Categories of parties to whom a licensee discloses (institutions that disclose outside of the exceptions)

A licensee may use this clause, as applicable, to meet the requirement of Section 7A(3) to describe the categories of affiliates and nonaffiliated third parties to whom the licensee discloses nonpublic personal information. This clause may be used if the licensee discloses nonpublic personal information other than as permitted by the exceptions in Sections 14, 15 and 16, as well as when permitted by the exceptions in Sections 15 and 16.

Sample Clause A-4:
We may disclose nonpublic personal information about you to the following types of third parties:
• Financial service providers, such as [provide illustrative examples, such as "life insurers, automobile insurers, mortgage bankers, securities broker-dealers, and insurance agents"];
• Non-financial companies, such as [provide illustrative examples, such as "retailers, direct marketers, airlines, and publishers"]; and
• Others, such as [provide illustrative examples, such as "non-profit organizations"].
We may also disclose nonpublic personal information about you to nonaffiliated third parties as permitted by law.

A-5–Service provider/joint marketing exception

A licensee may use one of these clauses, as applicable, to meet the requirements of Section 7A(5) related to the exception for service providers and joint marketers in Section 14. If a licensee discloses nonpublic personal information under this exception, the licensee shall describe the categories of nonpublic personal information the licensee discloses and the categories of third parties with which the licensee has contracted.
Sample Clause A-5, Alternative 1:
We may disclose the following information to companies that perform marketing services on our behalf or to other financial institutions with which we have joint marketing agreements:
• Information we receive from you on applications or other forms, such as [provide illustrative examples, such as "your name, address, social security number, assets, income, and beneficiaries"];
• Information about your transactions with us, our affiliates or others, such as [provide illustrative examples, such as "your policy coverage, premium, and payment history"]; and
• Information we receive from a consumer reporting agency, such as [provide illustrative examples, such as "your creditworthiness and credit history"].
Sample Clause A-5, Alternative 2:
We may disclose all of the information we collect, as described [describe location in the notice, such as "above" or "below"] to companies that perform marketing services on our behalf or to other financial institutions with whom we have joint marketing agreements.

A-6–Explanation of opt out right (institutions that disclose outside of the exceptions)

A licensee may use this clause, as applicable, to meet the requirement of Section 7A(6) to provide an explanation of the consumer's right to opt out of the disclosure of nonpublic personal information to nonaffiliated third parties, including the method(s) by which the consumer may exercise that right. The licensee may use this clause if the licensee discloses nonpublic personal information other than as permitted by the exceptions in Sections 14, 15 and 16.
Sample Clause A-6:
If you prefer that we not disclose nonpublic personal information about you to nonaffiliated third parties, you may opt out of those disclosures, that is, you may direct us not to make those disclosures (other than disclosures permitted by law). If you wish to opt out of disclosures to nonaffiliated third parties, you may [describe a reasonable means of opting out, such as "call the following toll-free number: (insert number)].

A-7–Confidentiality and security (all institutions)

A licensee may use this clause, as applicable, to meet the requirement of Section 7A(8) to describe its policies and practices with respect to protecting the confidentiality and security of nonpublic personal information.
Sample Clause A-7:
We restrict access to nonpublic personal information about you to [provide an appropriate description, such as "those employees who need to know that information to provide products or services to you"]. We maintain physical, electronic, and procedural safeguards that comply with federal regulations to guard your nonpublic personal information.

Document No. 2547
CLEMSON UNIVERSITY
CHAPTER 27
Statutory Authority: 1976 Code Section 46-21-620

R.27-190 General Certification Standards

Synopsis:

Clemson University proposes to amend its Seed Certification regulations as part of a general up-date. The amendments deal primarily with adapting to national standards as promulgated by the Association of Official Seed Certifying Agencies (AOSCA), standards which are promulgated in accordance with the Federal Seed Act. Some definitions are amended, and wording in some cases has been amended for clarity. Additionally, for lack of activity, standards for the following crops will be deleted from the South Carolina Seed Certification Standards in its 2001 revised publication: Cotton; Clover; Corn; Cowpeas; Grass Seed; Lespedeza; and Prunus Nursery Stock. Should applications for these crops be received in the future, the Department will apply the policy stated in Regulation 27-190.

Instructions:

A. Delete the following regulations: 27-191; 27-192; 27-193; 27-194; 27-197; 27-199; and 27-1005.
B. Delete and replace all regulations, sections and subsections in Article 14 which are the subject of an amendment with the amended regulation, section or subsection as indicated.

Text:

R.27-190. General Certification Standards.

In order to qualify as a seed certifying agency for purposes of section 101(a) (24) of the Federal Seed Act (7 U.S.C. 1551) the Department of Fertilizer & Seed Certification Services of Clemson University, hereinafter referred to as the Seed Certification Department, enforces standards and procedures, as conditions for its certification of seed, that meet or exceed the standards and procedures specified in sections 201.68-201.78 of Federal Seed Act Regulations.

The following are the minimum standards required for the certification of seed and vegetative propagating material for genetic purity and identity by the Seed Certification Department. This seed certification program shall cover planting stocks of varieties*, hybrids, multi-lines, synthetics, etc. produced, conditioned, sampled, tested and labeled in accordance with the standards of the Seed Certification Department.

Crops Without Published Standards

In the case of crops for which no standards have been published in South Carolina, standards of the Federal Seed Act or the Association of Official Seed Certifying Agencies (AOSCA) shall apply. If no Federal or AOSCA standards have been published for the crop, standards of an AOSCA member agency certifying the crop will be used until South Carolina Standards are published.

*In some cases certification will be as to kind, on an interim basis; for example, where varieties have not been developed.

R.27-190. I. Classes of Seed Recognized and Definition of Terms.

F. Off-type - a plant or seed not part of the variety in that it deviates in one or more characteristics from that which has been described by the breeder as being usual for the strain or variety.

K. Conditioning - the various procedures involved in the mechanical handling of seed after harvesting to prepare the seed for marketing.

L. Variants - seed of plants which are (a) distinct within the variety but occur naturally within the variety, (b) stable and predictable with a degree of reliability comparable to other varieties of the same kind, within recognized tolerances, when the variety is reproduced or reconstituted and (c) which were a part of the variety as

originally released. Variants are not to be considered off types.

M. Label - the term label as used herein shall be defined as an attachment to or printed area of a seed container which contains product identity and quality information as required by these standards and the SC Seed Law.

R.27-190. II. Eligibility Requirements For Certification of Varieties

A variety shall be eligible for certification in South Carolina only if it has been approved as meriting certification by the Seed Certification Department or one other agency which is a member of AOSCA, or by an appropriate national variety review board. The originator, developer, owner or agent must provide the following information when eligibility for certification is requested (this information may be submitted on forms provided by the Seed Certification Department or on an application for US Plant Variety Protection):

A. The name of the variety. This name must be the established name if the variety has previously been marketed.

C. A detailed description of the morphological, physiological and other characteristics of the plants and seed that distinguish it from other varieties, including variants and the frequency expected within the variety.

D. Evidence of performance of the variety, such as comparative yield data, insect and disease resistance, or other factors supporting the identity of the variety.

R.27-190. IV. Application For Certification

B. Establishing the Source of Seed.

In order to establish the source, class and quantity of seed used to plant each crop to be considered for certification, the applicant must submit with the application an invoice or bill of lading and one label from each lot of seed planted. In cases where growers plant eligible seed from their own production, lot numbers for the seed stock used must be provided with the application to allow for verification that an acceptable analysis report is on file with the Seed Certification Department. The applicant's signature on the application for certification is affidavit that the information submitted for verification of seed eligibility represents the total amount of seed used.

C. Certification Charges and Dates for Filing Applications.

Completed applications with accompanying seed documentary evidence specified in section B should be filed with the Seed Certification Department by the appropriate dates specified on the application and should be accompanied with applicable fees as indicated on the certification application form.

D. Late Application Fee

If an applicant fails to file application within 15 days of the deadline date for filing an application for certification of a crop, a late application fee plus an extra charge per acre will be added to regular certification charges.

E. Canceling Applications

To receive a full refund of all charges related to the application, applicants desiring to cancel applications for certification must inform the Seed Certification Department in sufficient time to notify the field inspector. If the inspector cannot be notified in time to prevent an unnecessary trip to the farm, the farm fee indicated on the application will be assessed.

R.27-190. V. Production of Seed

B. Unit of Certification

The unit of certification shall be a clearly defined area, which may be divided subject to specific crop standards.

C. Field Inspection

One or more field inspections shall be made each time a seed crop of any certified class is to be harvested and when genetic purity and identity or any other factor affecting seed certification can best be determined. The field shall be in such condition to permit an adequate inspection to determine genetic purity and identity. Weeds present in any field to the extent that genetic purity determination is not possible shall be sufficient cause for rejection of that field.

E. Seed-Borne Diseases and Seed Treatment

Every field for which certification is requested shall show evidence that reasonable precaution has been taken to control seed-borne diseases. The field at time of inspection shall not contain injurious seed-borne plant diseases beyond established tolerances specified in the individual crop seed standards. New diseases may create a need for new standards before they can be published. In such situations, the Seed Certification Department shall impose such standards as are deemed to be in the best interest of S. C. Certified seed. When seed of a variety without resistance to a seed-borne disease has been subjected to possible infection by the disease, it is desirable that such seed be treated with a recommended seed treatment.

F. Inspection of Harvested Seed.

Harvested lots of seed from inspected fields may be inspected at any time by representatives of the Seed Certification Department. Evidence that any lot of seed has not been protected from contamination which affects genetic purity, or is not properly identified, shall be cause for rejection of the seed for certification. Bins and other storage facilities must be labeled or marked to indicate crop, variety and class. Office records on identification of seed in storage must indicate variety, class, grower, approximate quantity and storage locations.

H. Bulk Shipment of Certified Seed for Conditioning.

When any class of certified seed is being transported in bulk for conditioning, the form Shipping, Receiving and Conditioning Report for Bulk Seed must be completed and filed with the Seed Certification Department. This form identifies the certifying agency, the crop and variety, class of seed, lot number, quantity, conditioner, etc. This form is also to be used to record change of ownership of seed.

R.27-190. VI. Conditioning of Seed.

B. 2. Identity of the seed must be maintained at all times.

a. Certified seed being delivered for conditioning must be adequately identified by the grower. All unconditioned certified seed stored in bins or other areas on the premises must be labeled or marked to indicate variety and class.

F. 5. Loss of Approved Conditioner Classification.

Loss of Approved conditioner classification may result from:

b. If, during any year in which a conditioner is classified Approved, more than ten percent (10%) of the samples of his certified seed are found out of tolerance in a percentage of purity, inert matter, weed seed or other crop seed, he will forfeit the Approved classification for no less than one year. This applies to all classes of certified seed on which the conditioner's name appears as seedsmen on the certification label or Bulk Conditioned Seed Sale Certificate for S.C. Registered or Certified Seed. Analyses of samples of certified seed conditioned for other growers shall be the basis for application of this standard to the conditioner who conditions no certified seed for himself. Determination of samples out of tolerance will be based on analyses of a combination of the samples of certified seed obtained by Seed Certification Department and S. C. Department of Agriculture inspectors as compared to analysis labels on the seed. No conditioner shall have his Approved classification withdrawn on the basis of analyses of less than fifty (50) samples annually unless the number of samples found out of tolerance at the end of the year exceeds five (5), (10% of 50). When less than fifty (50) samples of a conditioner's certified seed are drawn annually by Seed Certification and S. C. Department of Agriculture inspectors, and the number of samples found out of tolerance during the year has not exceeded five (5), the percentage of samples out of tolerance will be determined when fifty (50) such samples have been drawn and analyzed.

R.27-190. VII. Lot Size, Sampling, Seed Testing

A.

CROP	MAXIMUM LOT SIZE	SAMPLE SIZE
Clover	500 bags or 25,000 lbs.	5 oz.
Corn	500 bags or 25,000 lbs.	2 lb.
Cotton	500 bags or 25,000 lbs.	2 lb.
Fescue	500 bags or 25,000 lbs.	5 oz.
Lespedeza	500 bags or 25,000 lbs.	5 oz.

Okra	200 bags or 10,000 lbs.	4 oz.
Cowpeas	500 bags or 25,000 lbs.	2 lb.
Peanuts	500 bags or 25,000 lbs.	2 lb.
Small Grains:		
Barley	24,000 lbs.	2 lb.
Oats	32,000 lbs.	2 lb.
Rye	28,000 lbs.	2 lb.
Triticale	24,000 lbs.	2 lb.
Wheat	30,000 lbs.	2 lb.
Soybeans	30,000 lbs.	2 lb.

Note: Varietal purity determination is not possible on seed which has been treated with some pesticides. If a pesticide is to be used which coats or colors the seed, a sample of the conditioned, untreated seed must be submitted for purity analysis and a sample of the conditioned, treated seed must be submitted for the germination test.

R.27-190. VII. B. 2.

If seed is sampled after conditioning and closing of bags, a probe or trier long enough to reach all areas in the bag shall be used for free flowing seed. When sampling closed bags in quantities of one to six bags, a sample shall be composed of a core from each bag for a total of at least five cores for each sample. For lots of more than six bags, sample five bags plus at least 10% of the number of bags in the lot. Regardless of lot size, it is not necessary to sample more than thirty bags.

R.27-190. VII. B.3.

If seed is sampled after conditioning and is to remain in bulk, it shall be sampled by inserting a long probe into the seed at well distributed points throughout the bulk. Sufficient seed must be obtained from the bulk conditioned seed to provide the same number of samples required from the seed as if it were being bagged. (See VII. A.).

R.27-190. VII. D.1.

Each applicant whose fields meet certification standards will be furnished "Official Sample" stickers which must be attached to certified seed samples submitted to the SCDA for testing. The detailed "Official Sample" analysis must be performed on certified seed samples to determine that seed standards of the certification program are met.

R.27-190. VII. D.2.

Analyses performed on more than one sample taken from a given quantity of seed, without some form of reconditioning (re-cleaning, treating, etc.) shall be averaged to determine acceptance or rejection of the seed for certification.

R.27-190. VII. D.3

Note: It is a violation of the S.C. Seed Law to offer seed for sale or distribution before it has been analyzed in accordance with the provisions of the S. C. Seed Law.

R.27-190. IX. Labeling

Bag and Bulk Bin Labels

4.e. and f. (Deletion)

e. Special stapling devices, should they become available, may be used to both close the package and attach the certification label. Any such staple should be unique to certification, with distinctive design or lettering. If tags are stapled to bags special, heavy-duty stapling devices should be used and each tag should be stapled at least twice.

f. "Valve filled" paper bags shall be considered adequately closed and sufficiently tamper-proof.

B. Bags

2. When seed is bagged in official certified bags but found not meeting certification standards when analyzed, the seed must be re-bagged in non-certified bags, or the bag must be defaced to the extent that all mention of certification, the Seed Certification Department and Clemson University is obliterated.

Official Note: It is a violation of the SC Seed Law to offer for sale or distribution in official certification bags and bearing no official certification label, seed that fails to meet SC Certification Standards.

R.27-190. X. E.

Whenever a sale is to be made from bulk conditioned seed, a copy of the form Bulk Conditioned Seed Sale Certificate for S. C. Registered or Certified Seed must be obtained from the Seed Certification Department, completed, signed and issued to the purchaser to accompany the seed at the time of purchase. One copy must be retained in the conditioner's files and one copy must be mailed to the Seed Certification Department.

R.27-190. XIII. B.

Responsibility for compliance with certification requirements for seed to which a certification label or bulk sale certificate is attached, and responsibility for proper use of certification labels for bulk sale certificates rests, in all cases, with the seedsman whose name appears on the label or bulk sale certificate.

R.27-190. XIV. Producer Records

It is the responsibility of each grower of certified seed to maintain an accurate record of all sales including the name of purchaser and address, lot numbers, amount and date. The Seed Certification Department has the right to call for specific sales records and will periodically conduct random examinations of sales records. Failure to supply such records, when requested, or failure to give satisfactory reasons for being unable to supply such records, shall forfeit a grower's privilege to produce certified seed.

R.27-195. Vegetatively Propagated Forage Grass Certification Standards

R.27-196. Vegetatively Propagated Turf-grass Certification Standards

I. Application of General Certification Standards

A. The General Certification Standards, Clemson University Regulation 27-190, are basic and applicable.

The following specific standards constitute the standards for certification of vegetatively propagated turf-grasses including bermuda-grass, centipede, zoysia, St. Augustine and seashore paspalum.

B. The General Standards are modified as follows:

1. Foundation Turf - shall be the vegetative increase of Breeder or Foundation turf.

2. *Registered Turf - shall be the vegetative increase of Foundation turf.

3. Certified Turf - shall be the vegetative increase of Foundation or Registered turf.

4. Life of Stand: The life of the stand will continue for all classes of vegetatively propagated turf grasses as long as the varietal and mechanical purity for the class is maintained.

* A grower of Registered turf may increase his acreage of Registered turf from his own production provided the increase is adjacent and planted on land under the control of the grower. The size of such increase is not to exceed a total of ten (10) additional acres.

II. Land Requirement.

A. A field to be eligible for the production of Foundation, Registered or Certified turf must be free of contaminating grasses, weeds and other crops.

B. Land for production of Foundation or Registered sod shall be fumigated with a recommended soil

fumigant.

III. Field Inspection.

A. Handling the crop after planting and prior to inspection.

A field must be rogued and/or sprayed during the growing season to remove (1) other varieties, (2) other perennial grasses, (3) most common weeds, (4) objectionable and noxious weeds.

B. Time and number of inspections.

1. A minimum of three inspections will be required.

2. Fields must be inspected prior to planting to insure the field is free of contamination.

IV. Field Standards.

A. General

1. Unit of Certification.

A field or portion of a field may be certified.

2. Isolation requirements:

Plantings of vegetatively propagated turf grasses must be isolated from any other variety and other perennial grasses by an artificial barrier and/or strip at least six (6) feet wide to prevent mixing during the growing season and harvesting operation.

B. Specific Requirements.

Factor	Maximum Permitted in each class*** Foundation	Registered	Certified
*Other Varieties	None	None	1/acre
**Other Crops	None	None	None
Noxious/Objectionable Weeds	None	None	None
Other Living Plants (max.)	100	200	400

*Other varieties shall consist of all other varieties of the kind being produced.

**Other crops shall consist of all other kinds and varieties of perennial grasses.

***Should other varieties, other crops and/or noxious weeds be found in excess of standard, during field inspection, roguing and eradication by spot spraying will be permitted to bring turf in line with standards.

V. Turf Standards.

Objectionable or Noxious Weeds…..... None

INSTRUCTIONS AND PROCEDURES

1. An official certificate or label will accompany each shipment of certified sprigs, sod or plugs.

2. A complete record on the amount of certified turf sales will be maintained and made available to the official certifying agency. The record will include (a) class of certified turf sold (Foundation, Registered, or Certified), (b) Kind and Variety, (c) field number, (d) date of harvest, (e) amount of turf shipped (square feet, cubic feet, bushels, etc.).

R.27-1000. Peanut Seed Certification Standards.

II. Land Requirements.

Peanuts shall be planted on land on which the previous crop was of another kind or planted with certified seed of the same variety.

III. Field Inspection.

A field inspection shall be made at such time factors affecting certification can best be evaluated.

IV. Field Standards.

A. 1. Unit of Certification.

The unit of certification shall be a field or a portion of a field.

V. Seed Standards.

Factor	Standards for Each Class		
	Foundation	Registered	Certified
Pure seed (min.)	N.S.	97.00%	97.00%
*Inert Matter (max.)	N.S.	3.00%	3.00%
**Weed Seeds (max.)	0.01%	0.01%	0.01%
Objectionable or Noxious Weed Seeds	None	None	None
Other Crop Seeds	0.11%	.21%	.52%
***Other Kinds (max.)	0.01%	.01%	.02%
Other Varieties(max.)	0.10%	.20%	.50%
Germination & Hard Seed (min.)	N.S.	70.00%	70.00%

*Spanish-type, runner-type and Virginia-type seed peanuts may include an additional 3.0% inert or "bald head" (seed coat removed) seed.

**Total weed seeds shall not exceed 5 per lb.

***Other kinds shall not exceed 2 per lb. For Foundation and Registered, and 3 per lb. For Certified.

R.27-1001. Sweet Potato Certification Standards.

I. Application of General Certification Standards.

The General Certification Standards, Clemson University Regulation 27-190, are basic and applicable.

(All Section B Deleted)

B. The General Standards are modified as follows:

1. Classes of Certified Seed Recognized(I)

a. Breeder, Foundation, and Certified shall be the only classes recognized.

b. Foundation seed shall be the first increase of Breeder seed and produced under the jurisdiction of the South Carolina Experiment Station or by an approved agency.

2. Tags, Bulk Bin Labels and Bags (IX)

The use of a Blue Tag will be restricted to the first generation increase from Foundation Seed. The increase of Certified seed will not be eligible for further certification.

II. Land Requirements.

C. Plant Bed Requirements.

1. The plant bed must be located on well drained soil that has not produced sweet potatoes within the last three years unless disinfected by approved methods. The land must not be subject to drainage from barnyards or poultry yards or fields that are now or have grown sweet potatoes during the past three years.

2. Manure must not be used in the plant bed.

3. (Deleted)

Plant beds that have been used previously must be disinfected by approved methods.

4. (Renumbered as 3.)

3. Seed sweet potatoes must be treated with an approved pesticide prior to planting.

III. Field Inspection.

B. Field

At least two field inspections shall be made, one shortly after transplanting of sprouts cut from the bed or vine cuttings. The final field inspection shall be performed at least 21 days after the first inspection and when diseases and varietal mixtures can be most easily detected.

IV. Field Standards.

A. 1. Unit of certification.

A field or a portion of a field.

2. Isolation

All fields producing a class of certified seed potatoes shall be isolated from other sweet potato fields in such a manner as to prevent mechanical mixture.

B. Specific Requirements.

Factor	Maximum Permitted in Each Class Foundation	Registered	Certified
Plant Bed			
Blackrot	None	None	None
Wilt	None	None	None
Other Varieties	None	None	None
Scurf.	None	None	None
Field			
Wilt	None	None	5 plants/acre
Viruses	None	None	10 plants/acre
*Other Varieties	None	None	None

*Five plants current mutations allowed.

V. Seed and Storage Standards.

A. Seed

3. (Deleted)

Foundation and Certified seed shall have a minimum weight per bushel of 50 pounds net.

4. (Renumbered as 3.)

3. Root Standards.

Factor	Maximum Permitted Foundation	Registered	Certified
Common Storage Rots	None	None	None
Blackrot	None	None	None
Scurf	None	None	0.1%
Wilt	None	None	0.1%
Internal Cork	5.0%	5.0%	5.0%
*Nematode	None	None	0.5%
*Wireworm	1.0%	2.0%	5.0%
Sweet Potato Weevil	None	None	None
Other Varieties	None	None	0.1%

*Tolerance applied to severely infected roots.

B. Storage

1. Storage potatoes grown for certification shall be stored in new containers, or used containers that have been disinfected with an approved pesticide.

2. Sweet potatoes must be stored in a facility that has been cleaned and disinfected.

3. Each unit of sweet potatoes that passes field inspection shall be stored according to production unit and treated separately and distinctly at the time of storage inspection. Each crate shall be marked or labeled to correspond with the field unit that passed inspection.

R.27-1002. Small Grain Certification Standards (Wheat, Oats, Barley, Rye, and Triticale)

II. Land Requirements

A small grain crop shall be planted on land on which the last crop grown was of another crop kind other than small grains, or was planted with a class of certified seed of the same variety. A crop will not be eligible for certification if planted on land on which the same crop kind was grown the previous year, unless the previous crop was grown from a class of certified seed of the same variety.

IV. Field Standards.

A. 2. Isolation

b. Wheat for certification must be isolated from a field of rye by a distance of 660 feet.

(b. and c. renumbered as c. and d.)

c. All barley and wheat fields for the production of all classes of certified seed must be isolated by at least 990 feet from other fields which contain smut in excess of the tolerance indicated in the specific field standards.

d. A field producing any class of certified seed must be isolated by at least 660 feet from rye fields of any other variety or fields of the same variety that do not meet the varietal purity requirements of the class of seed inspected and are the same chromosome number. Isolation between diploid and tetraploid rye shall be at least 15 feet.

V. Seed Standards.

	Standards For Each Class		
	Foundation	Registered	Certified
Pure Seed (min.).....			
Wheat, Barley, Oats.....	-	98.00%	98.00%
Rye.....	-	97.00%	97.00%
Triticale	-	96.00%	96.00%
Inert Matter (max.)			
Wheat, Barley, Oats	-	2.00%	2.00%
Rye.....	-	3.00%	3.00%
Triticale	-	4.00%	4.00%
*Common Weed Seeds (max.).....	-	0.05%	0.05%
**Objectionable Weed Seeds (max.)	None	None	None
***Other Crop Seeds (max.)			
Other Varieties same crop	1 seed/lb.	2 seeds/lb.	5 seeds/lb.
****Other Small Grains.....	1 seed/lb.	2 seeds/lb.	5 seeds/lb.
Other Kinds of Crops	1 seed/lb.	2 seeds/lb.	5 seeds/lb.
Germination (min.) .			
Barley, Oats, Wheat, Triticale	-	85.00%	85.00%
Rye.....	-	75.00%	75.00%
*****Diseases.....	-	-	-

*For Common Weed Seeds, a maximum of 20 per pound must not be exceeded in any class.

**Objectionable weeds shall include all S. C. Noxious Weeds and others as designated by the Seed Certification Department.

***For Other Crop Seeds, no combination of components may exceed 2 per pound in Foundation, 5 per pound in Registered, or 10 per pound in Certified.

****For rye in Other Small Grains, standards shall be, 0 for Foundation, 1 for Registered and 2 for Certified.

*****If chemically controllable seed-borne diseases are noted upon field inspection or laboratory observation, seed treatment may be required.

VI. Size of Lots

For the purpose of issuing certification labels or bulk sale certificates, standard maximum lot sizes for small grains shall be as follows:

Barley	24,000 lbs. (500 bu.)
Oats	32,000 lbs. (1000 bu.)
Rye	28,000 lbs. (500 bu.)
Triticale	24,000 lbs. (500 bu.)
Wheat	30,000 lbs. (500 bu.)

R.27-1003. Soybean Certification Standards.

III. Field Inspections.

A field inspection shall be made after leaves have dropped and prior to harvest. For Foundation class, a flower color inspection shall also be made.

R.27-1004. Tobacco Seed (Including Hybrids) Certification Standards.

I. Application of General Certification Standards.

B. The General Standards are modified as follows:

Production of Seed (V).

(Numbering (a),(b),(c) corrected to 1.,2.,3.

Handling of Crop Prior to Inspection.

1. Plants of other varieties including off-type plants must be topped.
2. Plants affected with mosaic disease must be topped.
3. Plants affected with ring-spot disease must be topped as soon as found.

Labeling (IX)

Samples of all labels used on tobacco seed containers must be approved by and on file with the Seed Certification Department.

Fiscal Impact Statement: Clemson University believes that no increased costs will be incurred by the State or any of its subdivisions in complying with the amended regulations.

Document No. 2496
CLEMSON UNIVERSITY
CHAPTER 27
Statutory Authority S. C. Code Section 47-4-30

R27-1015C.9 Specific Requirements for Cattle

Synopsis:

The amended regulation will update the regulations to reflect changes in the Brucellosis status in the State of South Carolina.

Instructions:

Replace R27-1015.C.9 (a) with the following:

Text:

R27-1015.C.9 (a) Brucellosis Testing

When considered advisable by the State Veterinarian, the authorized representative of the State Veterinarian shall take a blood sample from cattle and shall test the blood in a manner approved by the State Veterinarian to determine if the cattle tested are free from serological evidence of the disease known as Brucellosis. This test will be a preliminary blood test and cattle sold as Brucellosis negative based upon the results of this test, will be sold as such subject to a re-test of the same blood by the Official State Brucellosis Laboratory.

Fiscal Impact Statement:

The Clemson University Livestock-Poultry Health Division estimates that there will be no anticipated additional costs incurred by the State and its political subdivisions as a result of this amendment.

Document No. 2497
CLEMSON UNIVERSITY
CHAPTER 27
Statutory Authority S. C. Code Section 47-4-30

R27-1026.2.C Quarantine of Garbage Fed Swine

Synopsis:

The regulation will narrow the definition of waste which may not be fed to swine.

Instructions:

Replace R27-1026.2.C with the following amendment.

Text:

R27-1026.2.C Quarantine of Garbage Fed Swine

"Garbage" means any animal wastes, including unprocessed dairy products, resulting from handling, preparation, cooking and consumption of foods, including animal carcasses and/or parts thereof or contents of offal.

Fiscal Impact Statement:

The Clemson University Livestock-Poultry Health Division estimates that there will be no anticipated additional costs incurred by the State and its political subdivisions as a result of this amendment.

Document No. 2525
DEPARTMENT OF CONSUMER AFFAIRS
CHAPTER 28
Statutory Authority: 1976 Code Section 37-1-109 and 37-6-104 (1) (e)

28-62 Adjustment of Dollar Amounts

Synopsis:

The proposed amendment indicates the dollar amounts in the South Carolina Consumer Protection Code Sections which shall change by increasing 10% with the exception of Sections 37-3-203 (2) and 37-3-203(2) which have a self-executing formula of 40%. These sections shall change as indicated on July 1, 2000 in accordance with Section 37-1-109.

Instructions: New regulation added. Delete old 28-62.

Text:

7/1/00 through 6/30/02

Consumer Protection Code Section	Section	Change Dollar Amount From	To
2.104(1)(e)	Consumer Credit Sale	65,000.00	67,500.00
2.106(1)(b)	Consumer Lease -	65,000.00	67,500.00
2.203(1)	Delinquency Charge-Sales	13.00	13.50
2.203(2)	Minimum Delinquency Charge-	5.20	5.40
2.407(1)	Security Interest-Sales	780.00 2,600.00	810.00 2,700.00
2.705(1)(a)	Delinquency Charge-Rental Purchase	7.20	7.60
2.705(1)(b)	Delinquency Charge-Rental Purchase	3.60	3.80
3.104(1)(d)	Consumer Loan	65,000.00	67,500.00
3.203(1)	Delinquency Charge-Loans	13.00	13.50
3.203(2)	Minimum Delinquency	5.20	5.40
3.510	Land as Security-Supervised Loans	2,600.00	2,700.00
3.511	Maximum Loan Term-	780.00 2,600.00	810.00 2,700.00
3.514	Attorney's Fees-	2,600.00	2,700.00

	Supervised Loans		
5.103(2), (3), & (4)	Deficiency Judgement	3,900.00	4,050.00

7/1/98 through 6/30/00

Consumer Protection Code Section	Section	Change Dollar Amount From	To
2.104(1)(e)	Consumer Credit Sale	62,500.00	65,000.00
2.106(1)(b)	Consumer Lease -	62,500.00	65,000.00
2.203(1)	Delinquency Charge-Sales	12.50	13.00
2.203(2)	Minimum Delinquency Charge-	5.00	5.20
2.407(1)	Security Interest-Sales	750.00 2,500.00	780.00 2,600.00
2.705(1)(a)	Delinquency Charge-Rental Purchase	6.80	7.20
2.705(1)(b)	Delinquency Charge-Rental Purchase	3.40	3.60
3.104(1)(d)	Consumer Loan	62,500.00	65,000.00
3.203(1)	Delinquency Charge-Loans	12.50	13.00
3.203(2)	Minimum Delinquency	5.00	5.20
3.510	Land as Security-Supervised Loans	2,500.00	2,600.00
3.511	Maximum Loan Term-	750.00 2,500.00	780.00 2,600.00
3.514	Attorney's Fees-Supervised Loans	2,500.00	2,600.00
5.103(2), (3), & (4)	Deficiency Judgement	3,750.00	3,900.00

7/1/96 through 6/30/98

Consumer Protection Code Section	Section	Change Dollar Amount From	To
2.104(1)(e)	Consumer Credit Sale	60,000.00	62,500.00
2.106(1)(b)	Consumer Lease -	60,000.00	62,500.00

2.203(1)	Delinquency Charge-Sales	12.00	12.50
2.203(2)	Minimum Delinquency Charge-	4.80	5.00
2.407(1)	Security Interest-Sales	720.00 2,400.00	750.00 2,500.00
2.705(1)(a)	Delinquency Charge- Rental Purchase	6.40	6.80
2.705(1)(b)	Delinquency Charge- Rental Purchase	3.20	3.40
3.104(1)(d)	Consumer Loan	60,000.00	62,500.00
3.203(1)	Delinquency Charge-Loans	12.00	12.50
3.203(2)	Minimum Delinquency	4.80	5.00
3.510	Land as Security- Supervised Loans	2,400.00	2,500.00
3.511	Maximum Loan Term-	720.00 2,400.00	750.00 2,500.00
3.514	Attorney's Fees- Supervised Loans	2,400.00	2,500.00
5.103(2), (3), & (4)	Deficiency Judgement	3,600.00	3,750.00

7/1/94 through 6/30/96

Consumer Protection Code Section	Subject	Change Dollar Amount From	To
2.104(1)(e)	Consumer Credit Sale	57,500.00	60,000.00
2.106(1)(b)	Consumer Lease	57,500.00	60,000.00
2.203(1)	Delinquency Charge- Sales	11.50	12.00
2.203(2)	Minimum Delinquency Charge-Credit Sales	4.60	4.80
2.407(1)	Security Interest-Sales	690.00 2,300.00	720.00 2,400.00
2.705(1)(a)	Delinquency Charge- Rental Purchase	6.00	6.40
2.705(1)(b)	Delinquency Charge- Rental Purchase	3.00	3.20

3.104(1)(d)	Consumer Loans	57,500.00	60,000.00
3.203(1)	Delinquency Charge-Loans	11.50	12.00
3.203(2)	Minimum Delinquence Charge-Loans	4.60	4.80
3.510	Land as Security-Supervised Loans	2,300.00	2,400.00
3.511	Maximum Loan Term-	690.00 2,300.00	720.00 2,400.00
3.514	Attorney's Fees-Supervised Loans	2,300.00	2,400.00
5.103(2), (3), & (4)	Deficiency Judgement	3,450.00	3,600.00

71/92 through 6/30/94

Consumer Protection Code Section	Subject	Change Dollar Amount From	To
2.104(1)(e)	Consumer Credit Sale	25,000.00	57,500.00
2.106(1)(b)	Consumer Lease	25,000.00	57,500.00
2.203(1)	Delinquency Charge-Sales	5.00	11.50
2.407(1)	Security Interest-Sales	300.00 1,000.00	690.00 2,300.00
2.705(1)(a)	Delinquency Charge-Rental Purchase	4.00	6.00
2.705(1)(b)	Delinquency Charge-Rental Purchase	2.00	3.00
3.104(1)(d)	Consumer Loans	25,000.00	57,500.00
3.203(1)	Delinquency Charge-Loans	5.00	11.50
3.510	Land as Security-Supervised Loans	1,000.00	2,300.00
3.511	Maximum Loan Term-	300.00 1,000.00	690.00 2,300.00
3.514	Attorney's Fees-		

	Supervised Loans	1,000.00	2,300.00
5.103(2), (3), &(4)	Deficiency Judgment	1,500.00	3,450.00

Effective Dollar Amounts
for Other Time Periods

Consumer Protection Code Section	Subject	7/1/80 6/30/82	7/1/82 6/30/84
2.104(1)(e)	Consumer Credit Sale	32,500.00	40,000.00
2.106(1)(b)	Consumer Lease	32,500.00	40,000.00
2.201(2)(a)	Graduated Rate Scale	390.00 1,300.00	_____ _____
2.203(1)	Delinquency Charge-	6.50	8.00
2.207(3)	Maximum Rates-Revolving	650.00	_____
2.407(1)	Security Interest-Sales	390.00 1,300.00	480.00 _____
3.104(1)(d)	Consumer Loan	32,500.00	40,000.00
3.201(2)(a)	Graduated Rate Scale- Supervised Loans	390.00 1,300.00	_____ _____
3.203(1)	Delinquency Charge-Loans	6.50	8.00
3.510	Land as Security-	1,300.00	1,600.00
3.511	Maximum Loan Term- Supervised Loans	390.00 1,300.00	480.00 1,600.00
3.514	Attorney's Fees- Supervised Loans	1,300.00	1,600.00
5.102(2), (3), & (4)*	Deficiency Judgement	1,950.00	2,400.00

*See Section 3 of Act 261
of 1984 effective 1/27/84

Effective Dollar Amounts
for Other Time Periods

Consumer Protection Code Section	Subject	7/1/84 6/30/86	7/1/86 6/30/88
2.104(1)(e)	Consumer Credit Sale	42,500.00	45,000.00
2.106(1)(b)	Consumer Lease	42,500.00	45,000.00

2.203(1)	Delinquency Charge-Sales	8.50	9.00
2.407(1)	Security Interest-Sales	510.00 1,700.00	540.00 1,800.00
3.104(1)(d)	Consumer Loan	42,500.00	45,000.00
3.203(1)	Delinquency Charge-Loans	8.50	9.00
3.510	Land as Security-Supervised Loans	1,700.00	1,800.00
3.511	Maximum Loan Term-Supervised Loans	510.00 1,700.00	540.00 1,800.00
3.514	Attorney's Fees Supervised Loans	1,700.00	1,800.00
5.102(2), (3), & (4)	Deficiency Judgment	2,550.00	2,700.00

Effective Dollar Amounts
for Other Time Periods

Consumer Protection Code Section	Subject	7/1/88 6/30/90	7/1/90 6/30/92
2.104(1)(e)	Consumer Credit Sale	47,500.00	50,000.00
2.106(1)(b)	Consumer Lease	47,500.00	50,000.00
2.203(1)	Delinquency Charge-	9.50	10.00
2.407(1)	Security Interest-Sales	570.00 1,900.00	600.00 2,000.00
2.705(1)(a)	Delinquency Charge Rental Purchase	4.40	4.80
3.103(1)(d)	Delinquency Charge Rental Purchase	2.20	2.40
3.104(1)(d)	Consumer Loan	47,500.00	50,000.00
3.203(1)	Delinquency Charge-Loans	9.50	10.00
3.510	Land as Security-Supervised Loans	1,900.00	2,000.00
3.511	Maximum Loan Term-	570.00	600.00

	Supervised Loans	1,900.00	2,000.00
3.514	Attorney's Fees- Supervised Loans	1,900.00	2,000.00
5.103(2), (3) & (4)	Deficiency Judgment	2,500.00	3,000.00

Fiscal Impact Statement: The Department does not anticipate any fiscal impact with the implementation of this Regulation.

Document No. 2528
BOARD OF FINANCIAL INSTITUTIONS
CHAPTER 15
Statutory Authority: 1976 Code Section 34-29-140(j); 37-1-109

15-63. Dollar Amount Changes.

Synopsis:

The dollar amount in the South Carolina Code Sections listed below shall change by increasing 10%. These sections shall change as indicated on July 1, 2000 in accordance with Section 37-1-109.

Instructions:

New regulation added. Delete old 15-63.

Text:

7/1/00 through 6/30/02

Consumer Finance Law Code Section		Subject	Change Dollar Amount From	To
34-29-140	(a)(2)	Loan Bracket	2,200.00	2,400.00
34-29-140	(a)(2)	Loan Bracket	1,100.00	1,200.00
34-29-140	(a)(2)	Loan Bracket	660.00	720.00
34-29-140	(a)(3)	Loan Bracket	2,200.00	2,400.00

Fiscal Impact Statement: The Board does not anticipate any fiscal impact with the implementation of this Regulation.

Document No. 2532
DEPARTMENT OF HEALTH AND ENVIRONMENTAL CONTROL
CHAPTER 61
Statutory Authority: 1976 Code Sections 44-96-260, 44-96-290, 44-96-300, 44-96-310, 44-96-360, and 44-96-450 (1991)

R.61-107.18 Solid Waste Management: Off-site Treatment of Contaminated Soil

Synopsis:

The Department proposes a new regulation that establishes minimum standards for the site selection, design, operation, and closure of facilities treating contaminated soil which is not hazardous waste as defined by Resource Conservation and Recovery Act (RCRA) and R.61-79, Hazardous Waste Management Regulations, that has been excavated and is being treated off-site. This regulation will allow and encourage the recycling/treatment of contaminated soil in lieu of landfilling. The regulation is not applicable to in-site treatment of contaminated soil, on-site ex-situ treatment of contaminated soil, nor treatment of soil contaminated with hazardous waste.

The regulation categorizes contaminated soil into three (3) classes based on the contaminants present in the soil. Treatment standards are based, in part, on the intended use of the soil after treatment. The regulation allows for innovative approaches regarding treatment of contaminated soil as well as utilization of readily available data on treatment methods.

Discussion:

Section A addresses the applicability of the regulation.

Section B addresses the definitions used in the regulation including the definitions of the three classes of soil.

Section C is an overview of the general provisions for the permitting of treatment facilities.

Section D addresses the administrative review, the first phase of the Department's review, of the permitting process and defines the documents required for submittal of this review.

Section E addresses the technical review and the design requirements for treatment facilities and includes operation standards and personnel training requirements.

Section F addresses the clean-up standards for the three classes of soil and the use of treated soil.

Section G addresses monitoring and reporting requirements.

Section H defines the closure and post-closure procedures that apply to all soil treatment facilities.

Section I addresses violations and penalties.

Section J addresses severability.

Instructions: Add new R.61-107.18 to Chapter 61 Regulations.
Text:
R.61-107.18 Solid Waste Management: Off-site Treatment of Contaminated Soil

Table of Contents:

C. General Provisions
D. Administrative Review
E. Technical Review
F. Standards
G. Monitoring Reporting Requirements
H. Closure & Post Closure
I. Violations and Penalties
J. Severability

A. Applicability.

1. This regulation establishes minimum standards for the procedures, documentation, and other requirements which must be met for the proper site selection, design, operation, and closure of facilities treating contaminated soil and soil-like materials, here in after referred to as soil, which is not hazardous waste as defined by Resource Conservation and Recovery Act (RCRA), Public Law 94-580, and R.61-79, Hazardous Waste Management Regulations promulgated pursuant to the South Carolina Hazardous Waste Management Act, (SCHWMA), as amended, S.C. Code Ann. Section 44-56-10 et seq., and that has been excavated and is being treated off-site. Off-site treatment processes include, but are not limited to: biological, low-temperature thermal desorption, composting, prepared beds, bioreactors, soil slurry reactors, chemical oxidation, soil washing, incineration, and biopile technology. Other Department or other agency laws and regulations may apply to the treatment or handling of soil not addressed in this regulation and to other entities who might handle the soil before or after treatment.

2. This regulation is not applicable to on-site treatment of contaminated soil of any kind.

3. A research, development, and demonstration (RD&D) permit, pursuant to R. 61-107.10, Solid Waste Management: Research, Development, and Demonstration Permit Criteria, may be required for the treatment of soil based on the contaminant and the proposed treatment technology, and at the discretion of the Department.

B. Definitions As Used In This Regulation.

1. "Aerobic" means able to live, grow, or take place only when free oxygen is present.

2. "Biological treatment" means the degradation of contaminants of concern in soil by increasing the microbial activity through the aeration and/or addition of minerals, nutrients, and/or moisture.

3. "Biopile technology" means heaping contaminated soil into piles (or cells) and stimulating microbial activity within the soil through aeration and/or addition of minerals, nutrients, and/or moisture.

4. "Bioreactor" means a contained vessel in which biological treatment takes place, e.g., fermentor.

5. "BTEX" means the total chemical constituents benzene, toluene, ethyl benzene, and total xylenes.

6. "Chemical oxidation" means a chemical reaction that increases the oxygen content in a compound or a reaction in which an element or ion loses electrons, resulting in a more positive valence.

7. "Class I soil" means soil contaminated with one or more of the following contaminants: gasoline, jet fuels, diesel fuels, kerosene, distillate fuel oils (number one and number two fuel oils), and other contaminants as approved by the Department for this classification.

8. "Class II soil" means soil contaminated with one or more of the following contaminants: combination fuel oils (number three and number four fuel oils), residual fuel oils (number five and number six fuel oils), virgin lubricating oils, used oils, weathered oils, other petroleum based products not listed in Class I, and other

contaminants as approved by the Department for this classification.

9. "Class III soil" means soil contaminated with any contaminant other than those listed under Class I or Class II.

10. "Composting" means treatment of contaminated soil by aerobic biodegradation of contaminants in an above ground, contained, or uncontained environment.

11. "Contaminated soil" means soil and soil-like material containing contaminants at a concentration that the Department has deemed poses a potential threat to human health and/or the environment and that does not constitute a hazardous waste, as defined by RCRA, the SCHWMA, and the Regulations promulgated pursuant thereto, as amended.

12. "Department" means the South Carolina Department of Health and Environmental Control.

13. "Existing facility" means those facilities in place and operating on the effective date of this regulation.

14. "Ex-situ" means the excavation of contaminated soil from its original location followed by treatment off-site.

15. "Facility" means all contiguous land, structures, other appurtenances and improvements on the land used for treating and storing waste. A facility may consist of several treatment, storage, or disposal operational units.

16. "Generator" means any person whose act or process produces or results in contaminated soil.

17. "Incineration" means an ex-situ technology that uses heating to volatilize and combust organic constituents.

18. "In-situ" means the treatment of contaminated soil on-site without excavation of the soil.

19. "Leachate" means a liquid that has passed through or emerged from contaminated soil and contains soluble, suspended, or miscible materials removed from such soil.

20. "Low-Temperature Thermal Desorption" (LTTD), also known as "low-temperature thermal volatilization," "thermal stripping," and "soil roasting," means the ex-situ technology that uses heat to physically separate contaminants from excavated soil. Vaporized hydrocarbons may require treatment in a secondary treatment unit, such as an afterburner, prior to atmospheric discharge.

21. "New facility" means those treatment facilities not in place and operating on the effective date of this regulation.

22. "Off-site" means a location other than the property on which the contamination of the soil occurred and any contiguous property under the same ownership.

23. "On-site" means the property on which the contamination of the soil occurred and all contiguous property under the same ownership.

24. "Open-dumping" means any unpermitted solid waste disposal activity.

25. "Owner/operator" means the person who owns the land on which a solid waste management facility is located or the person who is responsible for the overall operation of the facility, or both.

25. "PAH" means polynuclear aromatic hydrocarbons

26. "Person" means an individual, corporation, company, association, partnership, unit of local government, state agency, federal agency, or other legal entity.

27.“Prepared beds” means a contained area above ground where soil can be tilled or variously manipulated to increase biological treatment, i.e., contained land farming.

28.“RD&D Permit” means a research, development and demonstration permit issued pursuant to R.61-107.10.

29.“Residence” means any structure, all or part of which is designed or used for human habitation, that has received a final permit for electricity, permanent potable water supply, permanent sewage disposal, and a certificate of occupancy, if required by the local government.

30.“Road base” means that portion of road construction which is over-lain with a permanent impervious surface.

31.“Shipment” means all soil from the same release area.

32.“Soil-like material” means material, man-made or naturally occurring, that has good absorption capabilities and is used to absorb and bulk solid waste spills, e.g., kaolin clay, bentonite, kitty litter, sand, vermiculite.

33.“Soil slurry reactor” means biological or chemical treatment of soil by making a mixture with water and treating in a contained vessel.

34.“Soil treatment facility” means a facility that treats contaminated soil and soil-like material.

35.“Soil venting,” means a method to remove volatile and semi-volatile contaminants from soil. A positive or negative air pressure is applied either passively or actively to soil to remove vapors which are appropriately treated.

36.“Soil washing” means an ex-situ process to mechanically scrub soil to remove contaminants. Soft particles are separated from soil in an aqueous-based system. The wash water may be augmented with leaching agents, surfactants, pH adjustment or chelating agents.

37.“TCLP” means Toxicity Characteristic Leaching Procedure, a laboratory test used to determine if a substance is a hazardous waste due to leachability. The TCLP (Method 1311) is published in “Test Methods for Evaluating Solid Waste, Physical/Chemical Methods,” EPA Publication SW-846, as incorporated by reference in R.61-79.260.11.

38.“TPH” means total petroleum hydrocarbons.

39.“Treatment” means the off-site manipulation of contaminated soil in a confined and regulated environment to bring the soil into compliance with standards established in this regulation.

40.“Used Oil” means any oil that has been refined from crude oil or synthetic oil that has been used, and as a result of such use is contaminated by physical or chemical impurities.

41.“Virgin oil” means oil that has never been used or weathered.

42.“Waste profile sheet” means a form filled out by the waste generator outlining specific information regarding the generator, generator’s site location, generating process information, and a full waste characterization. This includes describing the chemical and physical (solid, liquid, or gas) characteristics of the solid waste, a description of the waste including a list of the chemical contaminants in the waste, analytical testing certification, quantity, and container size for proper disposal. The generator shall submit the waste profile sheet to the treatment facility for approval prior to shipment of soil pursuant to this regulation.

43.“Weathered oil” means oil that has been exposed to leaching and low-level biodegradation or

biotransformation and soil chemical reactions for extended periods of time, resulting in a contaminant chemical composition that is no longer virgin oil.

C. General Provisions.

1. The siting, design, construction, operation, and closure activities for facilities that treat contaminated soil shall conform to the standards set forth in this regulation, unless otherwise approved by the Department. Engineering plans, specifications, reports and other documents approved by the Department during the review process shall become enforceable documents upon issuance of a permit pursuant to this regulation. Facilities shall be constructed as approved and permitted.

2. Prior to the construction of a new soil treatment facility, a permit shall be obtained from the Department pursuant to this regulation. Prior to the modification of an existing soil treatment facility, as-built drawings of the existing facility which have current Department approval shall be submitted in addition to plans and specifications of proposed modifications to the facility. Any modification to the design/operation of a facility that would change the language of the permit shall receive prior Department approval.

3. Prior to operation of a new permitted soil treatment facility or a permitted modification to an existing facility, the facility shall be inspected by the Department and receive operational approval.

4. The Department reserves the right to require the soil treatment facility to acquire an RD&D permit pursuant to Regulation 61-107.10 for any process or compound for which the information provided is deemed insufficient to establish the efficacy of the proposed process to the Department's satisfaction. If, after the two (2) years expiration of the RD&D permit, the process is proved to be a viable method for treating soil, a permit pursuant to this regulation may be issued for the process. Petroleum and other compounds that have been shown to be highly degradable via the proposed treatment process will not generally require a RD&D permit. A permit requested pursuant to this regulation may be denied should the process not be determined to be acceptable to the Department's satisfaction.

5. No later than six (6) months from the effective date of this regulation, existing soil treatment facilities shall submit to the Department a permit application with supporting documents as outlined in Section D of this regulation.

6. Failure to begin construction of the treatment facility within twelve (12) months of the issuance of the Department permit shall render that permit invalid.

7. Upon reasonable cause to suspect that the treatment facility and/or treatment process poses a threat to human health or the environment, the Department, upon notification to the owner/operator, may require the owner/operator to investigate and, if appropriate, develop and implement a corrective action program approved by the Department.

8. Soil treatment facilities shall demonstrate consistency with the host Region/County Solid Waste Management Plan pursuant to Section D. of this regulation.

9. Open dumping of contaminated soil is prohibited.

10. Soil treatment facilities shall adhere to Federal and State rules and regulations and local zoning, land use and other applicable local ordinances and OSHA requirements.

11. Transfer of ownership.

a. The Department may, upon prior written request, transfer a permit to a new owner or operator of a soil treatment facility where no other change in the permit is necessary. The proposed new owner or operator of a

permitted soil treatment facility shall, at least forty-five (45) days prior to the scheduled change in ownership or operating responsibility, provide to the Department:

(1) Documentation of the new owner's name and address;

(2) Documentation of the name and address of the party responsible for the operation and maintenance of the facility, if different from the owner;

(3) A written agreement signed by the current owner/operator and the proposed new owner/operator indicating the intent to change ownership or operating responsibility of the facility. The agreement shall contain a specific date for the transfer of permit responsibility;

(4) Documentation indicating that the facility shall be operated in accordance with the existing permit in effect at the time of transfer;

(5) Documentation of financial assurance as required in Section E. of this regulation. The previous owner/operator shall maintain financial assurance responsibilities until the new owner/operator can demonstrate satisfactory compliance with the financial assurance requirements outlined in this regulation; and,

(6) A disclosure statement as required in Section D. of this regulation.

b. Upon approval of all documents required by Item 11.a. above, the Department shall transfer the permit from the current owner/operator of the facility to the new owner/operator.

c. A request for a permit modification shall be submitted with the permit transfer request, if the facility will not be operated in accordance with the approved plans. The permit modification shall be in accordance with all provisions of this regulation.

d. The new owner shall submit legal documentation to the Department of the transfer of ownership of the facility within fifteen (15) days of the actual transfer.

12. All chemical and biological analyses required by this regulation for submittal to the Department shall be analyzed by a laboratory certified by the Department for that particular parameter.

13. All analytical methods used shall be appropriate for the parameters being quantified given the sample matrix (gasoline and diesel range organics at a minimum.) Quantification of total petroleum hydrocarbons shall employ appropriate extraction methods and include both short and long chain hydrocarbons.

14. Approval from the State Toxicologist shall be required when intergeneric (i.e., bioengineered) microorganisms or pathogenic (i.e., disease-causing) microorganisms are used in the proposed technology.

15. A maintenance plan shall be submitted that describes how each major component of the soil treatment facility and all associated equipment shall be maintained at the facility, and how the facility shall be operated in accordance with its intended use.

16. It is incumbent on the soil treatment facility to ensure that any soil-like material is compatible with the approved treatment process. Any contaminants in the soil-like material shall be treated to acceptable standards.

D. Administrative Review. All off-site soil treatment facilities shall request and obtain a Department permit pursuant to this regulation.

1. The first phase of the Department's review is the administrative review. All permit requests submitted to the Department shall include three (3) copies of the following documents for administrative review:

a. A letter from the host region/county of the soil treatment facility stating that the facility is consistent with the host region/county's solid waste management plan;

b. A letter of proof of proper zoning and land use from the county or city;

c. A letter from the Office of Ocean and Coastal Resources Management (OCRM) stating that the project is consistent with the South Carolina Coastal Zone Management Plan if the proposed treatment facility is located in the coastal zone as defined by the OCRM or stating that the facility is exempt from this requirement because it is not located in that zone;

d. A letter from the Department's air program stating that the project is consistent with the goals of the South Carolina State Implementation Plan.

e. A disclosure statement, pursuant to S.C. Code Section 44-96-300, as amended. The Department may accept one disclosure statement for multiple facility permit applicants. Local governments and regions comprised of local governments are exempt from this requirement;

f. A cost estimate for complete closure of the facility. This estimate requires Department approval prior to the owner/operator establishing a financial assurance mechanism pursuant to Section E. of this regulation that shall ensure satisfactory closure of the facility;

g. A written request for any variances from the requirements of this regulation;

h. A completed permit application on a form provided by the Department, to include a brief description of the method of soil treatment;

i. Complete engineering plans and reports that are stamped by a South Carolina Licensed Professional Engineer in accordance with Section E. of this regulation; and,

j. A letter of approval from the State Toxicologist for the use of chemical and biological agents, if applicable.

2. When administratively complete, the Department will public notice the permit application and begin the technical review. Comments will be accepted throughout the technical review period.

E. Technical Review and Design Requirements. The Department's technical review of the permit application will involve the documents addressed in this section. All soil treatment facilities shall meet the criteria established in this section.

1. Siting Requirements.

a. Engineering Plans and Reports. The engineering plans and reports, pursuant to Section D.1.i. of this regulation, shall include the following documents:

(1) A site plan of the facility layout on a scale of not greater than two hundred (200) feet per inch clearly identifying conditions at the site. This plan shall at a minimum identify the following items:

(a) Identified on plan as "existing": property boundaries and all existing site conditions to be utilized in the operation of the soil treatment facility including, but not limited to, structures, access roads, on-site roads, parking areas, loading and unloading areas, soil storage areas, processing areas, fences, and gates; and

(b) Identified on plan as "proposed": all proposed site conditions that will be constructed including, but not limited to, structures, access roads, loading and unloading areas, soil storage areas, processing areas, fences,

and gates; and,

(2) A location map that shows the location of all residences, schools, churches, day-care centers, hospitals, publicly owned recreational park areas, drinking water wells, monitoring wells, injection wells, roads, surface water bodies, dry runs, wetlands, the 100-year flood plain boundaries, and other applicable details regarding the general topography of the site and adjacent properties within one-fourth (¼) mile of the proposed site's property line.

b. Depending on conditions defined in Items E.1.a.(1)(a) and (b), and E.1.a.(2) above, the Department may require additional hydrogeological investigation prior to permit approval.

c. Site Standards. The site for a new soil treatment facility or expansion of an existing facility shall meet the standards outlined below, unless otherwise approved by the Department. Compliance with these standards shall be demonstrated in the engineering plans and reports referenced in Section E.1.a. of this regulation.

(1) A soil treatment facility located in a 100-year floodplain shall not restrict the flow of the 100-year flood as demonstrated on a 100-year flood plain map.

(2) A soil treatment facility shall be in compliance with the U.S. Army Corps of Engineers and the U. S. Environmental Protection Agency requirements concerning wetlands, where applicable.

(3) The soil treatment and storage area boundaries, as identified in the location map, shall not be located within:

(a) One hundred (100) feet of any property line;

(b) Two hundred (200) feet of any residence, school, church, day-care center, hospital or publicly owned recreational park area;

(c) Two hundred (200) feet of any surface water body which holds visible water for greater than six (6) consecutive months, excluding drainage ditches, sedimentation ponds and other operational features on the site; and,

(d) One hundred (100) feet of any drinking water well.

2. Facility Layout Requirements/Design Criteria.

a. Engineering Plans and Reports. The engineering plans and reports, pursuant to Section D.1.i. of this regulation, shall, at a minimum, include the following:

(1) All pertinent engineering drawings, on a scale no greater than one (1) foot per quarter inch, that identify and distinguish all existing and proposed construction of items (a) & (b) listed immediately below. Representative cross sections shall be used to show compliance with these requirements.

(a) The treatment process; and,

(b) The entire soil treatment facility, including, but not limited to, loading/unloading area(s), in-coming contaminated soil storage area(s), out-going treated soil storage area(s), soil processing area(s), impermeable floor, containment system(s), alarm system, fire fighting system, and leachate control system, if applicable.

(2) Technical details and specifications necessary to support the engineering drawings and operation plans for the facility including, but not limited to:

(a) A general operating plan including, but not limited to, a description of the methods of keeping all incoming shipments of contaminated soil segregated, the types and maximum quantity of contaminated soil to be accepted on a yearly basis, the storage areas for in-coming contaminated and out-going treated soil, the method(s) of preventing releases to the environment, and the measures taken to prevent unauthorized dumping and access.

(b) A plan for handling process waste water generated by the facility, if appropriate.

(c) A description of the treatment process. This detailed description shall, at a minimum, specify the methodology of the process to address how each of the following criteria impacts the process:

(i) Temperature(s)

(ii) Concentrations of contaminants

(iii) Microorganism activity

(iv) Nutrients - including oxygen

(v) Physical adjustments (mixing, tilling, etc.)

(vi) Moisture

(vii) pH adjustments

(viii) Soil characteristics

(ix) Concentrations of chemicals added

(x) Process by-product(s), and

(xi) Any other criteria applicable to the process to be used.

(d) A soil screening plan to ensure that the facility accepts only properly characterized soil that it is permitted to treat, and removes only the soil from the soil treatment facility that has been tested and meets the standards set forth in this plan. This portion of the plan shall, at a minimum, specify the following:

(i) The criteria from which determinations are made on whether to accept or reject contaminated soil;

(ii) The procedure and time frame that will be used to verify that waste profile sheets provided by the generator match all shipments of soil;

(iii) The procedure and time frame that will be taken if an incoming shipment of contaminated soil does not match the waste profile sheet provided by the generator including, but not limited to, a description of how the shipment will be managed and stored or removed based on the type waste;

(iv) The criteria used to determine whether the shipment of treated soil meets the standards for removal from the soil treatment facility;

(v) The procedure for the proper handling, storage, and removal of all treated soil; and,

(vi) Analytical procedures and protocols.

(e) Upon receipt of a petition, the Department may consider sampling reduction based on consistent demonstration of treatment results. The petition shall include technical justification and a proposed alternate sampling plan. Upon approval by the Department in writing, the facility's permit will be amended to reflect the change in sampling frequency and the new sampling plan may be implemented.

(f) A contingency plan that describes a technically and financially feasible course of action to be taken in response to contingencies during the operation of the facility. This plan shall set forth procedures to be employed during periods of non-operation, e.g., equipment breakdown which may require standby equipment, extension of operation hours, or diversion of shipments to other facilities. The plan shall be designed to minimize hazards to human health and the environment from fires, explosions, or any unplanned sudden or non-sudden release of potentially harmful constituents to air, soil or surface water.

(g) A detailed closure plan which shall identify the steps necessary to close the facility. It shall identify the components at the facility that will remain in-place and those that will be removed. The plan shall be amended whenever changes in operating plans or facility design effect the closure plan. The plan shall address the satisfactory maintenance, closure and post-closure care, monitoring and/or corrective action, if appropriate.

(h) A plan for training personnel to perform their duties in a way that ensures the facility's compliance with this regulation and their health and safety.

b. Design Standards. Unless otherwise approved by the Department, all soil treatment facilities shall be designed in accordance with the following standards:

(1) Access to the facility shall be controlled through the use of fences, gates, berms, natural barriers, or other means to prevent unauthorized dumping and access;

(2) Contaminated soil awaiting processing shall be completely contained from the outside environment and shall be:

(a) Placed only on an impermeable surface, e.g., sealed concrete;

(b) Stored in such a manner as to prevent releases to the environment; and,

(c) Covered with either a structure or an impermeable cover.

(3) The Department may require the process area to be covered and containment barriers installed based on the technology approved. During processing, soil shall be:

(a) Placed only on an impermeable surface, e.g., sealed concrete; and,

(b) Maintained in such a manner as to prevent releases to the environment.

c. Operation Standards.

(1) The facility shall be operated and maintained in a manner which will protect the established water quality standards of the surface and ground waters, and the air quality standards.

(2) Dust, odors, fire hazards, litter and vectors shall be effectively controlled so they do not constitute nuisances or hazards.

(3) Personnel Training. The personnel training program shall at a minimum:

(a) Identify positions that will require training and a knowledge of the procedures, equipment, and

processes at the facility;

(b) Instruct facility personnel in how to perform their duties in a way that ensures the facility's compliance with this regulation, including the proper procedures for handling unauthorized solid waste;

(c) Instruct facility personnel in the proper responses to all emergencies and require employees to become familiar with the contingency plan, emergency and safety equipment, emergency procedures and emergency systems; and,

. (d) Document employee training. This documentation shall be maintained at the facility for all employees. Documentation of training shall include the following:

(i) The job title for each position related to solid waste management at the facility and the name of the employee filling each position;

(ii) A written job description for each position including the requisite skill, education or other qualifications, and duties of employees assigned to each position;

(iii) A written description of the type and amount of both introductory and continuing training that will be given to each employee; and,

(iv) Records that document the training and/or job experience completed by each employee. Training records for each employee shall be maintained at the facility for a minimum of three (3) years for all current personnel.

(4) Soil containing non-compatible contaminants shall not be mixed during processing.

(5) Any contaminated soil received that is not acceptable for treatment, based on the facility's permit, shall be removed from the facility within ten (10) days of receipt in accordance with an approved contingency plan. Should the facility receive known or suspected hazardous wastes, a representative of the facility shall call the appropriate Department EQC District Office within twenty-four (24) hours of receipt.

(6) A waste profile sheet shall be provided with each soil shipment received by the soil treatment facility.

(7) Leachate and washwater from a soil treatment facility, including soil storage areas, shall not be allowed to drain or discharge into waters of the State unless an effluent disposal permit, i.e., National Pollutant Discharge Elimination System (NPDES), No Discharge (ND), or Underground Injection Permit, has been granted by the Department.

(8) Treated soil stored outside shall be managed in such a manner as to comply with S.C. Regulation 61-9, Water Pollution Control Permits and the NPDES General Permit issued pursuant to Regulation 61-9, as amended.

(9) A construction permit from the Department's air program shall be required for the storage or processing of any soil that may cause the release of any regulated air pollutant unless an exemption is granted pursuant to S.C. Regulation 61-62.1.II.A, Air Pollution Control Regulations and Standards.

(10) Treated soils for restricted use shall be stored on a covered, nonporous surface.

(11) Emergency Preparedness. In addition to requirements set forth in the contingency plan, all soil treatment facilities shall, at a minimum:

(a) Provide access to fire equipment and make provisions for availability of local fire-fighting services;

(b) Be equipped with a device, e.g., telephone or hand held two-way radio, at the scene of operations

capable of summoning emergency assistance from local police departments, fire departments, and State or local emergency response teams;

(c) Be equipped with portable fire extinguishers and other fire control equipment; and,

(d) Ensure that facility personnel are trained to respond effectively to all emergencies, including different types of fires, by familiarizing them with the contingency plan, emergency and safety equipment, emergency procedures and emergency systems.

(12) Signs. Signs shall be posted and maintained in conspicuous places which:

(a) Identify the owner, operator, or a contact person and telephone number in case of emergencies and the hours during which the facility is open for business;

(b) Identify that the facility is a soil treatment facility; and,

(c) Identify the valid DHEC Solid Waste Permit Number for the soil treatment facility.

(13) Financial Assurance. Prior to accepting contaminated soil, soil treatment facilities shall fund a financial responsibility mechanism acceptable to the Department to ensure the satisfactory maintenance, closure and post-closure care. A final closure cost estimate, based on third party costs to complete closure by disposing of the maximum quantity of material at a facility, shall be calculated annually and adjusted annually, as necessary. Local governments are exempt from this requirement until such time as federal regulations require such local governments or regions to demonstrate financial responsibility for such facilities and the Department promulgates regulations addressing this issue.

F. Standards.

1. General Requirements. Soil shall be treated in accordance with the following criteria:

a. Soil shall be treated to levels that are protective of human health and the environment as approved by the Department. Treatment standards shall be based in part upon the intended use of the soil after the treatment process is complete. It is the responsibility of the permitted treatment facility to provide to the user of the treated soil written notice stating the treatment goals achieved and the end use of the soil as approved by the Department, including any restrictions on the use of the soil that are included in the facility's permit or in this regulation.

b. Contaminated soil treated under the purview of this regulation shall not be used to grow edible food crops nor to supplement soil used for the purpose of growing edible food crops. Other agricultural uses of soil treated under this regulation shall require approval from the Department prior to use.

c. Soil treated under the purview of this regulation shall not contain benzene in excess of 5 ppb after treatment unless it can be demonstrated that the end use of the treated soil will not impact groundwater such that it would exceed 5 ppb benzene or cause an adverse risk to human health as determined by the Department. Any soil treated to >5 ppb benzene shall be for restricted end use to be approved by the Department.

d. The type, composition, breakdown products and potential affect to human health and the environment shall be provided for all materials or microorganisms introduced into the soil for treatment purposes. In addition, the breakdown products for the microorganisms and contaminants being treated in the process shall be clearly defined.

e. The Department may require additional soil testing and/or alternate treatment activities, and/or soil removal for proper disposal, if the permittee is unable to demonstrate that the treatment process is effective, or the process has failed to perform to design standards. Additional testing and/or treatment may be required if constituents are

present in the soils for which the permitted treatment process will not be effective, e.g., metals.

f. Based on the nature of the treatment process and the types of soil proposed for treatment at the facility, the Department may require additional environmental monitoring to be performed at the facility. Likewise, additional engineering provisions may be required by the Department to ensure protection of human health and the environment.

g. Contaminated soil shall be categorized into three classes, i.e., Class I, Class II, or Class III, based on the contaminants present in the soil. Treatment levels to be achieved for each class of soil differ.

h. Soil treated under the purview of this regulation shall be used in a manner which minimizes contact with the seasonal high water table.

i. When facilities co-mingle compatible soils prior to treatment, the end use of the treated co-mingled soil shall be limited to the most conservative end use as determined from the approved end uses identified for each of the co-mingled soils by permit.

2. Class I. Class I soil is soil contaminated with one or more of the following contaminants: gasoline, jet fuels, diesel fuels, kerosene, and distillate fuel oils (number one and number two fuel oils.) Treatment levels for Class I contaminated soil shall depend on the planned end use of the soil after treatment processes are completed:

a. All Class I contaminated soil shall be analyzed for total petroleum hydrocarbons (TPH), and total benzene, toluene, ethyl benzene and xylene (BTEX).

b. Class I contaminated soil which is for restricted specific end uses as approved by the Department, e.g., as cover at municipal solid waste landfills, or in road base or similar types of construction, shall, unless otherwise approved by the Department, be treated to the following levels or below for TPH and BTEX:

TPH	BTEX (total)
200 ppm	20 ppm (with Benzene <5 ppb)

c. For all unrestricted end uses, Class I contaminated soil shall be treated to the following levels or below for TPH and BTEX:

TPH	BTEX (total)
10 ppm	1 ppm (with Benzene <5 ppb)

d. Alternate treatment levels may be specified by the Department based on the intended final use of the soil and the potential risk to human health and the environment.

e. The Department may require testing of incoming batches of contaminated soil and treated soil for additional parameters other than TPH and BTEX should there be reason to believe that other parameters of potential concern are present in the soil. Treatment levels for these additional parameters shall be determined by the Department on a case-by-case basis, taking end use into consideration and potential risk to human health and the environment.

3. Class II. Class II soil is soil contaminated with one or more of the following contaminants: combination fuel oils (number three and number four fuel oils), residual fuel oils (number five and number six fuel oils), virgin lubricating oils, weathered oils, and used oils that have not been mixed with other waste. Treatment levels for Class II contaminated soil shall depend on the planned end use of the soil after treatment processes are completed:

a. All Class II soil shall be analyzed for TPH, BTEX (total), and polynuclear aromatic hydrocarbons (PAH.)

b. Class II contaminated soil, including contaminated soil with polynuclear aromatic hydrocarbons (PAH) levels that exceed those levels listed in the current EPA approved Risk Based Concentrations (RBC) tables as determined by the Department, shall be restricted to specific end uses as approved by the Department, e.g., as cover at municipal solid waste landfills, or in road base or similar types of construction. Unless otherwise approved by the Department, this soil shall be treated to the following levels or below:

TPH	BTEX (total)	PAH
200 ppm	20 ppm (with Benzene <5 ppb)	≥ RBC values

c. For all unrestricted end uses, Class II contaminated soil shall be treated to the following levels or below:

TPH	BTEX (total)	PAH
10 ppm	1 ppm (with Benzene <5 ppb)	< RBC values

d. Soil contaminated with used oil and soil contaminated with weathered oil shall be considered as Class II.a. soil and shall be restricted to specific end use, as approved by the Department.

e. Alternate treatment levels may be specified by the Department based on the intended final use of the soil and the potential risk to human health and the environment.

f. The Department may require testing of incoming batches of contaminated soil and treated soil for additional parameters other than TPH, BTEX, and PAH should there be reason to believe that other parameters of potential concern are present in the soil. Treatment levels for these additional parameters shall be determined by the Department on a case-by-case basis, taking end use into consideration and potential risk to human health and the environment.

4. Class III. Class III soil is soil contaminated with any contaminant other than those listed under Classes I and II above.

a. Facilities applying for a Class III permit under this regulation shall submit for Department review, technical data that demonstrates that the proposed soil treatment technique can treat soil to concentration levels equal to or less than those levels listed in the current EPA approved Risk Based Concentrations (RBC) tables as determined by the Department. If the applicant fails to submit data, or the Department determines that the data submitted is insufficient, the facility shall obtain a Research, Development, and Demonstration (RD&D) permit as outlined in R.61-107.10. If the facility demonstrates to the Department under the RD&D permit that the soil treatment technique used is effective on each contaminant to be treated without the creation of harmful degradation products, the Department will issue the facility a Class III permit, pursuant to this regulation.

b. The permittee shall submit a list of contaminants to the Department for review and approval based on the chemical and physical nature of the Class III contaminated soil. Based on this information, the Department shall determine appropriate levels of treatment.

c. All Class III soil shall be analyzed for parameters approved by the Department.

d. The end use of Class III contaminated soil shall be approved by the Department prior to accepting the soil for treatment. Treatment levels for soil to be treated shall be determined by the Department on a case-by-case basis, and based on the intended end use. The Department will take potential risk to human health and the environment into consideration when determining appropriate treatment levels. These site specific determinations may be based on current EPA approved risk based concentrations (RBC) tables, toxicological review, scientifically defensible published data which are appropriate for use in developing permit limits and contaminant levels for which EPA has not developed national criteria or for which South Carolina has no standards. The Department will consider the site specific routes of potential exposure and the hydrogeological conditions for the potential to leach contaminants to the water table, and will use health and/or technical literature.

e. Those treatment processes which can be proved to the Department to effectively treat the contaminants in the Class III contaminated soil may be exempted from the requirements to obtain a RD&D permit under R.61-107.10 and may be permitted under this regulation. In all cases, the Department shall retain the authority to set treatment levels based on end use considerations to ensure treatment is protective of human health, surface water standards, and ground water standards.

5. Facilities may be permitted to treat only Class I soil, only Class II soil, only Class III soil, or a combination of any of these soil types. Any facility treating a combination of contaminated soil types that includes Class III soil type may be required to receive a permit under the authority of this regulation, and also a RD&D permit. Upon the two years expiration of the RD&D permit, if the process is proved to be a viable method for treating soil, the facility's existing permit issued under the authority of this regulation may be amended to include the treatment process proved viable under the RD&D permit.

G. Monitoring and Reporting Requirements.

1. Should the Department have evidence to suspect potential environmental and/or health problems associated with the treatment facility, monitoring (including groundwater, surface water, and air quality) may be required by the Department, as appropriate, and based on a case-by-case evaluation to ensure protection of the environment.

2. An annual report, on a form provided by, or acceptable to, the Department, shall be submitted to the Department by October 15 for the previous fiscal year (July 1 through June 30,) which includes, at a minimum, the following information:

a. The total quantity in tons of contaminated soil received at the facility for the previous fiscal year;

b. The total quantity in tons of treated soil transported off-site and the destination of this soil; and,

c. The county in South Carolina in which the contaminated soil originated, or the State if the soil originated outside South Carolina.

3. Analytical data showing that all treated soil met appropriate standards, pursuant to Section F. of this regulation, prior to removal from the facility, shall be maintained on-site for a minimum of five (5) years from the date the results are received from the laboratory. This data shall be generated by a laboratory certified by DHEC for the required parameters and in accordance with SW-846, Chapter 9. This data shall be made available to the Department upon request.

4. Documentation related to the acceptance, rejection, storage, operational data, and proper disposal of all contaminated soil received by the facility shall be maintained for a minimum of five (5) years, and made available to the Department upon request.

5. Upon implementation of the contingency plan, the owner or operator shall immediately notify the Department (using the 24-hour number 803-253-6488) and note, in the operating record and annual report, the following information:

a. The name, address and telephone number of the operator and the facility;

b. The date, time and type of incident (spill, fire, explosion, etc.); and,

c. The extent of physical damages to the operational part of the facility.

6. Upon request by the Department in response to a notification made in Item 5 of this Section, a written report shall be submitted to the Department that includes the following information:

a. An assessment of actual or potential hazards to human health or the environment, where this is applicable;

b. The procedures or equipment available to prevent a recurrence of the reported event; and,

c. Any long-term corrective action proposals. Upon Department review and approval, the corrective action proposal shall be implemented.

7. Records of all monitoring and reporting information, pursuant to these regulations, shall be maintained at the facility for a minimum of five (5) years from the sample or measurement date, unless otherwise specified by the Department. These reports shall be made available to Department personnel upon request.

H. Closure and Post-Closure Procedures. The following closure and post-closure procedures addressed in this section apply to all soil treatment facilities:

1. At least sixty (60) days prior to closure, the owner or operator shall submit to the Department written notice of intent to close and a proposed closure date;

2. Upon closing, the owner or operator shall immediately remove all treated soil, properly dispose of any waste associated with the treatment process, transport all contaminated soil to either another permitted soil treatment facility or permitted disposal facility, and post signs at the facility which state that the facility is no longer in operation;

3. Within thirty (30) days of final removal of all contaminated and treated soil, the owner or operator shall complete closure as outlined in the facility's approved closure plan and notify the Department;

4. After receiving notification that the facility closure is complete, the Department will conduct an inspection of the facility. If all procedures have been correctly completed, the Department will approve the closure in writing, at which time the Department permit shall be terminated; and,

5. If the Department's inspection reveals that closure, as outlined in the facility's approved closure plan, is incomplete, the owner or operator shall submit to the Department a post-closure care plan for Department approval to address the deficiencies noted by the Department. Post closure environmental monitoring and/or corrective action may be required. This post-closure care plan, if required, shall be submitted within thirty (30) days of the inspection, and shall include a time table.

I. Violations and Penalties. A violation of this regulation or any permit, order, or standard issued pursuant to or related to this regulation subjects the person to the issuance of a Department order or to civil enforcement action in accordance with S.C. Code Section 44-96-450, as amended, which may include civil penalties in accordance with the Solid Waste Policy and Management Act (SCPMA) and any amendments thereto. Willful violation of this regulation or any permit, order, or standard issued pursuant to or related to this regulation subjects the person to the issuance of a Department order which may also include civil penalties in accordance with the SCPMA, as amended, and may also result in a criminal enforcement action in accordance with S.C. Code Section 44-96-450, as amended. Any person to whom an administrative order is issued may appeal it as a contested case pursuant to R.61-72, Procedures for Contested Cases, and the S.C. Administrative Procedures Act, S.C. Code Section 1-23-310 et seq., as amended.

J. Severability. Should any section, paragraph, sentence, clause or phrase of this regulation be declared unconstitutional or invalid for any reason, the remainder of this regulation shall not be affected thereby.

Fiscal Impact Statement:

Staff anticipates no additional financial impacts upon local governments. Additional costs to the Department are

not anticipated beyond those resources allowed in the Act.

Statement of Need and Reasonableness:

The statement of need and reasonableness was determined based on staff analysis pursuant to S.C. Code Section 1-23-115(c)(1)-(3) and (9)-(11):

DESCRIPTION OF REGULATION: A new regulation that addresses the off-site treatment of contaminated soil.

Purpose: The purpose of this regulation is to establish minimum standards for the site selection, design, operation, and closure of facilities treating soil which is classified as non-hazardous waste that has been excavated and is being treated off-site. This regulation will encourage the recycling/treatment of contaminated soil in lieu of landfilling.

Legal Authority: This regulation is authorized by S.C. Code Sections 44-96-260, 44-96-290, 44-96-300, 44-96-310, 44-96-360, and 44-96-450 (1991)

Plan for Implementation: The regulation, as amended through public comment and Department response, would be incorporated within R.61-107, Solid Waste Management, upon approval of the General Assembly and publication in the State Register. The regulation will be implemented in the same manner in which other regulations are implemented.

DETERMINATION OF NEED AND REASONABLENESS OF THE REGULATION BASED ON ALL FACTORS HEREIN AND EXPECTED BENEFIT: This regulation is needed to allow the option of off-site treatment of contaminated soil and to ensure the activity is conducted in such a manner as to protect health and the environment. A traditional option for dealing with contaminated soil is landfilling. This regulation will establish criteria for treating contaminated soil that, in many cases, can return this soil to a usable form. Landfilling contaminated soil results in transferring contaminated material from one location to another, and does not permanently reduce pollution. This regulation will ensure that treatment of contaminated soil is conducted in an environmentally safe manner.

A workgroup, comprised of technical representatives from S.C. industries, Savannah River Site, a private consulting firm, and Department staff developed the criteria on which the regulation is based. Readily available data on treatment will be utilized as well as allowing for innovative approaches regarding treatment of contaminated soil. This regulation is reasonable because it requires the basics that are needed to ensure protection of health and the environment while allowing a cost effective mechanism for eliminating or diminishing contamination and restoring soil to a beneficial and usable state.

DETERMINATION OF COSTS AND BENEFITS: Costs of compliance with this regulation include engineering costs associated with preparation of a permit application containing detailed plans and specifications of a facility and preparation of an operating manual. Entities operating such facilities must also provide for financial assurance. For those entities which can self-insure, these costs will be minimal. For commercial operations, these are necessary operational costs.

For non-commercial operations, these costs will replace the cost of landfilling which is becoming more expensive because of rising transportation and landfill fees. The costs of landfilling can multiply further because of the potential liability and legal issues associated with landfilled soil. In most cases, treatment of contaminated soil is certainly advantageous environmentally.
UNCERTAINTIES OF ESTIMATES: The Department is unable to estimate these costs with precision, particularly since the size, design, and treatment method of such facilities may vary widely.

EFFECT ON ENVIRONMENT AND PUBLIC HEALTH: The treatment of contaminated soil is appropriate in many cases. Scientific evidence shows that contaminated soil can frequently be treated and returned to a usable

state with no harmful effects to health and the environment when regulations and guidelines are followed. Regulation requirements concerning treatment ensure public and environmental interests are well protected. The regulation requires that buffers be maintained between treatment facilities and residences, wells, surface waters, schools, churches, day-care centers, hospitals, publicly owned recreational parks, property lines, and the water table.

DETRIMENTAL EFFECT ON THE ENVIRONMENT AND PUBLIC HEALTH IF THE REGULATION IS NOT IMPLEMENTED: The detrimental effect of not implementing this regulation is that soil that could be treated and returned to a usable state will be landfilled. Landfilling this soil means moving the contamination from one area to another area and taking up valuable landfill space. Landfilled contaminated soil also carries with it liabilities if future problems/contamination occur in the landfill. Also, failure to establish minimum standards for treating contaminated soil would likely result in some facilities operating without regard to health and the environment.

Document No. 2531
DEPARTMENT OF HEALTH AND ENVIRONMENTAL CONTROL
CHAPTER 61
Statutory Authority**:** Statutory Authority: Section 44-7-110, *et. seq*., 1976 Code of Laws

R.61-93, Standards for Licensing Outpatient Facilities for Chemically Dependent or Addicted Persons

Synopsis:

This amendment will consolidate the standards for all of the alcohol and drug abuse treatment facilities which DHEC now licenses into one regulation adding standards for detoxification facilities and residential treatment program facilities, to include facilities for chemically dependent mothers with children; alcohol and drug abuse treatment programs within existing hospitals will continue to be licensed under the hospital regulation (R.61-16). This amendment will revise the regulation in its entirety to include: update and expand definitions; clarify licensing change requirements; update licensing fee amounts; describe inspection reporting requirements; add reference to DHEC consultations; update and clarify classification of standards and enforcement action procedures; enhance quality improvement standards; clarify admission requirements; reword sections related to treatment, services, and care; reword sections regarding client record content and maintenance; update tuberculin screening requirements; add reporting requirements; reword/clarify/enhance client rights requirements; reword sections regarding patient record content and maintenance; enhance existing outpatient standards, to include narcotic treatment programs; and add a severability clause. The amendment will include a title change to "Standards for Licensing Facilities that Treat Individuals for Psychoactive Substance Abuse or Dependence."

Discussion of Revisions:

The title is revised to read: “Standards for Licensing Facilities that Treat Individuals for Psychoactive Substance Abuse or Dependence.”

PART I is applicable to all facilities and services.

SECTION 100 includes definitions, references, and licensing requirements.

SECTION 200 addresses methods used in enforcing regulations, *i.e.*, investigations, inspections, and consultations.

SECTION 300 references the types of enforcement actions that may be taken by DHEC, the classifications of violations, range of penalty amounts, and the appeal process.

SECTION 400 includes requirements that the agency maintain policies and procedures that include

descriptions of how the standards in this regulation will be achieved.

SECTION 500 addresses general staff requirements including staff training, qualifications, and numbers to comply with applicable federal, state, and local laws and in accordance with professional organizational standards; requirements that direct care staff have no prior conviction of child/adult abuse, neglect, or mistreatment; staff practices which promote the prevention of the spread of infectious, contagious disease, and tuberculin testing, per CDC and DHEC TB Control requirements; and staff health status and specific requirements for counselors.

SECTION 600 provides reporting requirements to DHEC.

SECTION 700 addresses client record content and maintenance.

SECTION 800 provides requirements for care, treatment, and services to patients, the compliance with laws pertaining to patient care and treatment, treatment of minors, the referral process, use of restraints/seclusion.

SECTION 900 includes facility identification of client rights.

SECTION 1000 addresses client physical examination.

SECTION 1100 includes medication management requirements, i.e., administration, storage.

SECTION 1200 addresses meal service.

SECTION 1300 addresses facility maintenance.

SECTION 1400 describes the requirements for infection control and environment, i.e., staff practices, tuberculin screening, housekeeping, infectious waste, pets, and clean/soiled linen and clothing.

SECTION 1500 addresses emergency procedures/disaster preparedness.

SECTION 1600 includes fire prevention, i.e., arrangements for fire department response/protection, tests and inspections, fire drills.

SECTION 1700 provides a description of the essential elements of the quality improvement program**.**

SECTION 1800 addresses design and construction.

SECTION 1900 addresses general construction requirements.

SECTION 2000 includes hazardous elements of construction.

SECTION 2100 addresses fire protection equipment and systems.

SECTION 2200 includes standards for exits.

SECTION 2300 addresses water supply/hygiene.

SECTION 2400 includes electrical requirements.

SECTION 2500 includes heating, ventilation, and air conditioning requirements.

SECTION 2600 addresses specifics for the physical plant, i.e., client rooms and floor area,

bathrooms/restrooms, client care unit and station, doors, elevators, corridors, ramps, screens, telephone service, handrails/guardrails, landings, windows, janitor's closet, storage areas, location, and outdoor area.

SECTION 2700 adds a severability clause which indicates that if a court of competent jurisdiction determines that part of the regulation is invalid or otherwise unenforceable then the remainder of the regulation will not be affected and will still be in force.

SECTION 2800 includes "general" which refers to any conditions that have not been addressed in the regulation.

PART II contains standards applicable to outpatient facilities.

PART III is applicable to residential treatment program facilities.

PART IV is applicable to detoxification facilities including social and medical.

PART V is applicable to narcotic treatment program facilities.

Instructions:

Replace R.61-93 in its entirety by this amendment.

Text:

R.61-93 – Standards for Licensing Facilities that Treat Individuals for Psychoactive Substance Abuse or Dependence

TABLE OF CONTENTS

3207. Admission
3208. Physical Examination
3209. Urine Drug Testing
3210. Orientation
3211. Psycho-social Assessment
3212. Individualized Treatment Plan
3213. Emergency Medical Procedures
3214. Adverse Events
3215. Readmission
3216. Staffing
3217. NTP Medication Management
3218. Take-home Medication
3219. Guest-Dosing
3220. Security of Medications
3221. Outcome Effectiveness
3222. Detoxification from NTP Medication
3223. Community Liaison

PART I - ALL FACILITIES

SECTION 100 - DEFINITIONS, REFERENCES, AND LICENSE REQUIREMENTS

101. Definitions

For the purpose of this regulation, the following definitions shall apply:

A. Administering Medication. The direct application of a single dose of a medication to the body of a client by injection, ingestion, or any other means.

B. Administrator. The staff member designated by the licensee to have the authority and responsibility to manage the facility.

C. Adult. A person 18 years of age or older or person under the age of 18 who has been emancipated in accordance with state law.

D. Advanced Practice Registered Nurse. An individual who has Official Recognition as such by the SC Board of Nursing.

E. Aftercare/Continuing Care. Services provided to clients after discharge from a facility that facilitates the client's integration or reintegration into society. Activities may include self-help groups, supportive work programs, and staff follow-up contacts and interventions.

F. Annual. Once each 12-month period.

G. Architect. An individual currently registered as such by the SC State Board of Architectural Examiners.

H. Assessment. A procedure for determining the nature and extent of the problem for which the individual is seeking treatment/services/care/education to include risk assessment, diagnosis, evaluating the physical, emotional, behavioral, social, vocational, recreational, mental, and, when appropriate, the nutritional and legal status/needs of a client. Clinical consideration of each client's needs, strengths, and weaknesses shall be included in the assessment to assist in a level of care placement.

I. Authorized Healthcare Provider. An individual authorized by law in SC to provide specific treatments,

care, or services to clients. Examples of individuals who may be authorized by law to provide the aforementioned treatment/care/services may include, but are not limited to, advanced practice registered nurses, physician's assistants.

J. Client. A person who receives treatment, services, or care from a psychoactive substance abuse or dependence facility. This term is synonymous with the term "patient."

K. Client Room. An area enclosed by ceiling high walls that can house one or more clients of the facility.

L. Clinical Services Supervisor. The designated individual with responsibility for clinical supervision of treatment staff and interpretation of program policy and standards.

M. Consultation. A visit to a licensed facility by individuals authorized by the Department to provide information to facilities to enable/encourage facilities to better comply with the regulations.

N. Counselor. An appropriately licensed/certified individual who applies a specific body of knowledge and skills within a particular ethical context in order to facilitate behavior change or to facilitate greater comfort with an existing behavioral pattern. These services may be provided in individual, group and/or family modalities, and provided in a variety of settings (See Section 504).

O. DSS. The SC Department of Social Services

P. Department. The SC Department of Health and Environmental Control.

Q. Delivery of Medications. The actual, constructive, or attempted transfer of a medication or device from one person to another. In instances where the facility is storing medication, the act of presenting/making available the container of this medication to a client who has been authorized by physician or authorized healthcare provider orders to self-administer that medication.

R. Detoxification. A process of withdrawing a client from a specific psychoactive substance in a safe and effective manner.

S. Detoxification Facility. A 24-hour freestanding facility providing detoxification services of which there are two types:

1. Medical. A short-term residential facility, separated from an inpatient treatment facility, providing for medically-supervised withdrawal from psychoactive substance-induced intoxication, with the capacity to provide screening for medical complications of alcoholism and/or drug abuse, a structured program of counseling, if appropriate, and referral for further rehabilitation.

2. Social. A service providing supervised withdrawal from alcohol or other drugs in which neither the client's level of intoxication nor physical condition is severe enough to warrant direct medical supervision or the use of medications to assist in withdrawal, but which maintains medical backup and provides a structured program of counseling, if appropriate, educational services, and referral for further rehabilitation. A social detoxification facility provides 24-hour-a-day observation of the client until discharge.

T. Dietitian. A person who is registered by the Commission on Dietetic Registration.

U. Direct Care Staff/Volunteers. Those individuals who provide care/treatment to the client.

V. Discharge. The point at which the client's active involvement with a facility is terminated and the facility no longer maintains active responsibility for the care of the client, except for continuing care monitoring.

W. Dispensing Medication. The transfer of possession of one or more doses of a drug or device by a licensed pharmacist or person permitted by law, to the ultimate consumer or his/her agent pursuant to a lawful order of a practitioner in a suitable container appropriately labeled for subsequent administration to, or use by a client.

X. Existing Facility. A facility which was in operation and/or one which began the construction or renovation of a building, for the purpose of operating the facility, prior to the promulgation of this regulation. The licensing standards governing new facilities apply if and when an existing facility is not continuously operated and licensed under this regulation.

Y. Facility. An entity licensed by the Department that provides care/treatment/services for psychoactive substance abuse or dependence to two or more persons (not related to the licensee) and their families based on an individual treatment plan including diagnostic treatment, individual and group counseling, family therapy, vocational and educational development counseling, and referral services in any of the following modalities:

1. Outpatient;

2. Residential treatment program;

3. Medical detoxification;

4. Social detoxification;

5. Narcotic treatment program.

Z. Follow-up. Intermittent contact with a client following discharge from the program, for assessment of client status and needs.

AA. Health Assessment. An evaluation of the health status of a staff member/volunteer by a physician, other authorized healthcare provider, or a registered nurse, pursuant to standing orders approved by a physician as evidenced by the physician's signature. The standing orders shall be reviewed annually by the physician, with a copy maintained at the facility.

BB. Initial License. A license granted to a new facility.

CC. In-process Counselor. A counselor who has been accepted by SCAADAC as enrolled for certification.

DD. Inspection. A visit by authorized individuals to a facility or to a proposed facility for the purpose of determining compliance with this regulation.

EE. Intake. The administrative and assessment process for admission to a program.

FF. Individualized Treatment Plan (ITP). A written action plan based on assessment data that identifies the client’s needs, the strategy for providing services to meet those needs, treatment goals and objectives, and the criteria for terminating the specified interventions.

GG. Investigation. A visit by authorized individuals to a licensed or unlicensed entity for the purpose of determining the validity of allegations received by the Department relating to this regulation.

HH. Levo-alpha acetylmethadol (LAAM). A multi-day synthetic narcotic medication.

II. License. The authorization to operate a facility as defined in this regulation and as evidenced by a certificate issued by the Department to a facility.

JJ. Licensed Nurse. A person to whom the SC Board of Nursing has issued a license as a registered nurse or licensed practical nurse.

KK. Licensee. The individual, corporation, organization, or public entity who has received a license to provide psychoactive substance abuse or dependence treatment services and with whom rests the ultimate responsibility for compliance with this regulation.

LL. Methadone. A synthetic narcotic medication usually administered on a daily basis.

MM. Minor. Any person whose age does not meet the criteria indicated in Section 101.C.

NN. Mothers with Children Facilities. A residential treatment program facility for mothers undergoing psycho-substance abuse/dependence treatment where circumstances prohibit the child(ren) being housed/cared for in locations other than with the mother, and the child is under the mother's direct care or in a licensed child care facility approved by DSS. The terms "child" or "children" are considered synonymous with "infant," "baby," "adolescent," or "offspring."

OO. Narcotic Treatment Program (NTP). An outpatient psychoactive substance abuse/dependence program using methadone or other narcotic treatment medication such as LAAM, and offering a range of treatment procedures and services for the rehabilitation of persons dependent on opium, morphine, heroin, or any derivative or synthetic drug of that group. The NTP is designed to prevent the onset of abstinence symptoms for at least 24 hours; reduce or eliminate drug craving; and block the effects of other opiates without producing euphoria or other undesirable effects.

1. Clinic. A single location at which NTP medication and rehabilitative services to clients are provided.

2. Detoxification. A medically-supervised, gradual reduction or tapering of dose over time to achieve the elimination of tolerance and physical dependence to NTP medications, and not detoxification from other substances which shall be accomplished pursuant to R.61-4.

3. Maintenance. A treatment procedure using NTP medication or any of its derivatives administered over a period of time to relieve withdrawal symptoms, reduce craving and permit normal functioning.

4. Maintenance Continuing Care. A planned course of treatment for NTP maintenance clients directed toward reduction in dosage, achievement of abstinence and, with the aid of supportive counseling, the forging of a drug-free lifestyle.

PP. New Facility. All buildings or portions of buildings, new and existing building(s), that are:

1. Being licensed for the first time;

2. Providing a different modality/service when the licensee has changed the type of license;

3. Being licensed after the previous licensee's license has been revoked, suspended, or after the previous licensee has voluntarily surrendered his/her license.

QQ. Outpatient Facility. A facility providing specialized nonresidential services, which may include prevention services, for individuals dependent upon or abusing psychoactive substance(s) and for their families. (NTP is a separate type of facility)

RR. Outpatient Services. Services to individuals dependent upon or abusing psychoactive substance(s) and their families based on an individualized treatment plan (ITP) in a nonresidential setting including assessment, diagnosis, and treatment that may encompass individual, family, and group counseling, vocational and educational

counseling, and referral services.

SS. Peak Hours. Those hours in a 24-hour facility from the time when clients awake until going to bed, or other justifiable and reasonable time-period determined by the facility, and in consideration of clients' presence in the facility, and acuity of their needs.

TT. Pharmacist. An individual currently licensed as such by the SC Board of Pharmacy.

UU. Physical Examination. In facilities other than NTP (See Section 3208), an examination of a client by a physician or other authorized healthcare provider which addresses those issues identified in Section 1001.A.1 of this regulation.

VV. Physician. An individual currently licensed to practice medicine by the SC Board of Medical Examiners.

WW. Physician's Assistant. An individual currently licensed as such by the SC Board of Medical Examiners.

XX. Primary Counselor. An individual who is assigned by a facility to develop, implement, and periodically review the client's ITP and to monitor a client's progress in treatment.

YY. Psychoactive Substance Abuse or Dependence. A chronic disorder manifested by repeated use of alcohol or other drugs to an extent that interferes with a person's health, social, or economic functioning; some degree of habituation, dependence or addiction may be implied. Persons who are dependent or abusing psychoactive substance(s) are those whose compulsive use of alcohol or other drugs is such that they have lost the power of self-control with respect to the use of the chemical.

ZZ. Psychoactive Substance Abuse or Dependence Treatment Facility. A facility that provides specialized structured psychoactive substance abuse/dependence care/treatment for two or more persons unrelated to the licensee, including outpatient, NTP, residential treatment, or detoxification.

AAA. Quality Improvement Program. The process used by a facility to examine its methods and practices of providing care/services, identify the ways to improve its performance, and take actions that result in higher quality of care for the facility's clients.

BBB. Ramp. An inclined accessible route that facilitates entrance to or egress from or within a facility.

CCC. Related/Relative. A spouse, son, daughter, sister, brother, parent, aunt, uncle, grandchild, niece, nephew, grandparent, great-grandparent, grandchild, or great-grandchild. (This is also referred to as within the 3rd degree of consanguinity).

DDD. Repeat Violation. The recurrence of a violation cited under the same section of the regulation within a 36-month period. The time-period determinant of repeat violation status is also applicable in instances when there are ownership changes.

EEE. Residential Treatment Program Facility. A 24-hour facility offering an organized service in a residential setting which is designed to improve the client's ability to structure and organize the tasks of daily living and recovery through planned clinical activities, counseling, and clinical monitoring in order to promote successful involvement or re-involvement in regular, productive daily activity, and, as indicated, successful reintegration into family living.

FFF. Revocation of License. An action by the Department to cancel or annul a facility license by recalling, withdrawing, or rescinding its authority to operate.

GGG. Satellite Facility. An approved outpatient facility at a location other than the main outpatient facility that is owned or operated by the same licensee. Satellite locations are authorized only in the same county as the main facility or in contiguous counties to the county in which the main facility is located.

HHH. Staff. Those individuals who are employees (full and part-time) of the facility, to include those individuals contracted to provide treatment/care/services for the clients.

III. Suspend License. An action by the Department requiring a facility to cease operations for a period of time or to require a facility to cease admitting clients, until such time as the Department rescinds that restriction.

JJJ. Treatment. The process of providing for the physical, emotional, psychological, and social needs of clients which may include diagnostic evaluation, counseling, medical, psychiatric, psychological, nutritional, recreational, educational, or social service care, which may be extended to clients to influence the behavior of such individuals toward identified goals and objectives.

KKK. Twenty-Four Hour Facility. A facility which offers overnight accommodations to clients as well as psychoactive substance abuse or dependence treatment and other care/services appropriate to their condition.

LLL. Volunteer. An individual who performs tasks that are associated with the operation of the facility without pay and at the direction of the administrator or his/her designee.

102. References

A. The following Departmental publications are referenced in these regulations:

1. R. 61-4, SC Controlled Substances Regulation

2. R.61-20, Communicable Diseases;

3. R.61-25, Retail Food Establishments**;**

4. R.61-51, Public Swimming Pools;

5. R.61-58, State Primary Drinking Water Regulations;

6. R.61-67, Standards for Wastewater Facility Construction;

7. R.61-105, SC Infectious Waste Management Regulations;

8. SC Guidelines for Prevention and Control of Antibiotic Resistant Organisms.

B. The following non-Departmental publications are referenced within this regulation:

1. Standard Building Code;

2. National Fire Protection Association (NFPA) 101, Life Safety Code, 1985 edition and other NFPA standards, as applicable;

3. National Electrical Code;

4. Standard Plumbing Code;

5. Standard Mechanical Code;

6. Standard Gas Code;

7. State Fire Marshal Regulations;

8. American National Standards Institute (ANSI) 117.1, Specifications for Making Building and Facilities Accessible to and Useable by the Physically Handicapped;

9. Underwriters Laboratories - Fire Resistance Directory;

10. Underwriters Laboratories - Building Materials List;

11. Occupational Safety and Health Act of 1970 (OSHA);

12. Food and Nutrition Board of the National Research Council, National Academy of Sciences;

13. National Sanitation Federation;

14. Guidelines for Preventing the Transmission of Myco-bacterium Tuberculosis in Healthcare Facilities.

103. License Requirements

A. License. No person, private or public organization, political subdivision, or governmental agency shall establish, operate, maintain, or represent itself as a facility in SC without first obtaining a license from the Department. When it has been determined by the Department that care/treatment for psychoactive substance abuse or dependence to two or more individuals unrelated to the owner is being provided at a location, and the owner has not been issued a license from the Department to provide such care/treatment, the owner shall cease and desist operation immediately and ensure the safety, health, and well-being of the occupants within the scope of the law. Admission of clients prior to the effective date of licensure is a violation of Section 44-7-260(A)(1) of the SC Code of Laws, 1976, as amended. Current/previous violations of the SC Code and/or Department regulations may jeopardize the issuance of a license for the facility or the licensing of any other, facility or addition to an existing facility that is owned/operated by the licensee. The facility shall provide only the treatment, services, and care it is licensed to provide pursuant to the definition in Section 101 of this regulation. (I)

B. Compliance. An initial license shall not be issued to a proposed facility that has been not previously and continuously licensed under Department regulations until the licensee has demonstrated to the Department that the proposed facility is in substantial compliance with the licensing regulations. In the event a licensee of a currently licensed facility/activity makes application for another facility, the currently licensed facility/activity shall demonstrate substantial compliance with the applicable standards prior to the Department issuing a license to the proposed facility. A copy of this regulation shall be maintained at the facility. Facilities shall comply with applicable local, state, and federal laws, codes, and regulations.

C. Compliance to Structural Standards. Facilities licensed at the time of promulgation of this regulation (existing facility) as a detoxification facility, or residential treatment program facility under R.61-84, Standards for Licensing Community Residential Care Facilities, or as an outpatient facility under the previous version of R.61-93, Standards for Licensing Outpatient Facilities for Chemically Dependent or Addicted Persons, shall be licensed under this regulation as follows:

1. Existing facilities shall be allowed to continue utilizing the previously-licensed structure without modification. Existing facilities shall not be required to modify square footage of client rooms, sitting areas, and maximum number of beds in client rooms or provide a private client room.

2. The existing facility shall comply with the remainder of the standards within this regulation.

D. Compliance to Structural Standards (Ownership Change). When changes in ownership occur, the new licensee shall, through coordination with the Department's Division of Health Facilities Construction, formulate a plan for the facility to be in compliance with current building, fire and life safety codes within 18 months of the date of the ownership change, unless specific standards are exempted by the Department. Facilities are not required to modify square footage of client rooms and maximum number of beds in client rooms. (II)

E. Licensed Capacity. No facility that has been authorized to provide certain treatment/care/services shall provide other services outside the limits of the type facility identified on the face of the license and/or which it has been authorized to provide. (I)

F. Licensed Bed Capacity. No 24-hour facility that has been authorized to provide a set number of licensed beds, as identified on the face of the license, shall exceed the licensed bed capacity. No facility shall establish new treatment/care/services or occupy additional beds or renovated space without first obtaining authorization from the Department. (I)

G. Persons Received in Excess of Licensed Bed Capacity. No 24-hour facility shall receive for treatment/care/services persons in excess of the licensed bed capacity, except in cases of justified emergencies. (I)

EXCEPTION: Licensed Capacity Exception. In the event that the facility temporarily provides shelter for evacuees who have been displaced due to a disaster, then for the duration of that emergency, provided the health, safety, and well-being of all clients are not compromised, it is permissible to temporarily exceed the licensed capacity for the facility in order to accommodate these individuals (See Section 607).

H. Living Quarters for Staff in 24-hour Facilities. In addition to clients, only staff, volunteers, or owners of the facility and members of their immediate families may reside in facilities licensed under this regulation. Client rooms shall not be utilized by staff/family/volunteers nor shall staff/volunteers bedrooms be utilized by clients. However, children may occupy client rooms that have been licensed by the Department in programs specifically licensed to provide care/treatment for mothers who are chemically dependent. (II)

I. Issuance and Terms of License.

1. A license is issued by the Department and shall be posted in a conspicuous place in a public area within the facility.

2. The issuance of a license does not guarantee adequacy of individual care, treatment, personal safety, fire safety or the well-being of any client or occupant of a facility.

3. A license is not assignable nor transferable and is subject to revocation at any time by the Department for the licensee's failure to comply with the laws and regulations of this State.

4. A license shall be effective for a specified facility, at a specific location(s), for a specified period following the date of issue as determined by the Department. A license shall remain in effect until the facility is otherwise notified by the Department.

5. Except for outpatient satellite facilities, facilities owned by the same entity but which are not located on the same adjoining or contiguous property shall be separately licensed. Roads or local streets, except limited access, e.g., interstate highways, shall not be considered as dividing otherwise adjoining or contiguous property.

6. Separate licenses are not required, but may be issued, for separate buildings on the same or adjoining grounds where a single level or type of care is provided.

7. Multiple types of facilities on the same premises shall be licensed separately even though owned by the same entity.

J. Facility Name. No proposed facility shall be named nor may any existing facility have its name changed to the same or similar name as any other facility licensed in SC. If it is part of a "chain operation" it shall then have the geographic area in which it is located as part of its name. The Department shall determine if names are similar.

K. Application. Applicants for a license shall submit to the Department a completed application on a form prescribed, prepared and furnished by the Department prior to initial licensing and periodically thereafter at intervals determined by the Department. Applicants for a license shall file application with the Department, that includes both an oath assuring that the contents of the application are accurate/true and compliance with this regulation.

L. Licensing Fees. Fees shall be made payable by check or money order to the Department.

1. The initial and annual license fee shall be $75.00 for outpatient facilities and NTP's. The licensing fee for outpatient facility satellite locations shall be $50.00 initial and annual per satellite facility.

2. For all other facilities licensed under this regulation, the annual license fee shall be $10.00 per bed, with a minimum of $75.00.

3. Fees for additional beds shall be prorated based upon the remaining months of the licensure year.

4. All fees remaining unpaid 30 days after billing shall be issued a late notice with no penalty due; however, it shall contain advisement of penalty for non-payment after 60 days. Fees remaining unpaid after 60 days shall be assessed a 10% penalty. Fees remaining unpaid at the end of 90 days shall be assessed a 25% penalty in addition to the 60-day penalty.

5. If a license renewal is denied, a portion of the fee shall be refunded based upon the remaining months of the licensure year, or $75.00, whichever is greater.

6. Continual failure to submit completed and accurate renewal applications and/or fees by the time-periods specified by the Department may result in an enforcement action.

M. License Renewal. For a license to be renewed, applicants shall file an application with the Department, pay a license fee, and shall not be under consideration for, or undergoing enforcement actions by the Department. If the license renewal is delayed due to enforcement actions, the renewal license will be issued only when the matter has been resolved satisfactorily by the Department, or when the adjudicatory process is completed, whichever is applicable.

N. Change of License.

1. A facility shall request issuance of an amended license by application to the Department prior to any of the following circumstances:

a. Change of ownership;

b. Change in authorized capacity;

c. Reallocation of types of beds as shown on the license (if applicable).

d. Change of facility location from one geographic site to another.

2. Changes in a facility name or address initiated by the post office (no location change) may be accomplished by application or letter from the licensee.

O. Licensing is not required for any facility operated by the federal government.

P. Exceptions to the Standards of this Regulation. The Department has the authority to make exceptions to these standards when it is determined that the health, safety, and well-being of the clients will not be compromised and provided the standard is not specifically required by state or federal law.

SECTION 200 - ENFORCING REGULATIONS

201. General

The Department shall utilize inspections, investigations, consultations, and other pertinent documentation regarding a proposed or licensed facility in order to enforce this regulation.

202. Inspections/Investigations

A. Inspections shall be conducted prior to initial licensing of a facility and subsequent inspections conducted as deemed appropriate by the Department.

B. All facilities are subject to inspection/investigation at any time without prior notice by individuals authorized by the Department. When staff/clients are absent, the facility shall provide information to those seeking legitimate access to the facility, including visitors as to the expected return of staff/clients.

C. Individuals authorized by the Department shall be granted access to all properties and areas, objects, and records, and have the authority to require the facility to make photocopies of those documents required in the course of inspections or investigations. Photocopies shall be used only for purposes of enforcement of regulations and confidentiality shall be maintained except to verify individuals in enforcement action proceedings. (II)

D. When there is noncompliance with the standards of this regulation, the facility shall submit an acceptable written plan of correction to the Department that shall be signed by the administrator and returned by the date specified on the report of inspection/investigation. The written plan of correction shall describe: (II)

1. The actions taken to correct each cited deficiency;

2. The actions taken to prevent recurrences (actual and similar);

3. The actual or expected completion dates of those actions.

E. Reports of inspections conducted by the Department, including the facility response, shall be made available upon request with the redaction of the names of those individuals in the report as provided by Section 44-7-315 of the SC Code of Laws, 1976, as amended.

203. Consultations

Consultations shall be provided by the Department as requested by the facility or as deemed appropriate by the Department.

SECTION 300 - ENFORCEMENT ACTIONS

301. General

When the Department determines that a facility is in violation of any statutory provision or regulation relating to the operation or maintenance of such facility, the Department, upon proper notice, may initiate an enforcement action, i.e., deny, suspend, or revoke a license, or impose a monetary penalty.

302. Violation Classifications

Violations of standards in regulation are classified as follows:

A. Class I violations are those that the Department determines to present an imminent danger to the health, safety, or well-being of persons in the facility or a substantial probability that death or serious physical harm could result therefrom. A physical condition or one or more practices, means, methods or operations in use in a facility may constitute such a violation. The condition or practice constituting a Class I violation shall be abated or eliminated immediately unless a fixed period of time, as stipulated by the Department, is required for correction. Each day such violation exists after expiration of the time established by the Department shall be considered a subsequent violation.

B. Class II violations are those, other than Class I violations, that the Department determines to have a negative impact on the health, safety or well-being of persons in the facility. The citation of a Class II violation shall specify the time within which the violation is required to be corrected. Each day such violation exists after expiration of this time shall be considered a subsequent violation.

C. Class III violations are those that are not classified as Class I or II in these regulations or those that are

against the best practices as interpreted by the Department. The citation of a Class III violation shall specify the time within which the violation is required to be corrected. Each day such violation exists after expiration of this time shall be considered a subsequent violation.

D. The notations, "(I)" or "(II)," placed within sections of this regulation, indicate those standards are considered Class I or II violations if they are not met, respectively. Failure to meet standards not so annotated are considered Class III violations.

E. In arriving at a decision to take enforcement actions, the Department will consider the following factors: specific conditions and their impact or potential impact on health, safety or well-being; efforts by the facility to correct cited violations; behavior of the licensee that would reflect negatively on the licensees character such as illegal/illicit activities; overall conditions; history of compliance; and any other pertinent conditions that may be applicable to current statutes and regulations.

F. When a decision is made to impose monetary penalties, the following schedule will be used as a guide to determine the dollar amount:

Frequency of violation of standard within a 36-month period:

MONETARY PENALTY RANGES

FREQUENCY	CLASS I	CLASS II	CLASS III
1st	$ 500 - 1,500	$ 300 - 800	$100 - 300
2nd	1,000 - 3,000	500 - 1,500	300 - 800
3rd	2,000 - 5,000	1,000 - 3,000	500 - 1,500
4th	5,000	2,000 - 5,000	1,000 - 3,000
5th	7,500	5,000	2,000 - 5,000
6th	10,000	7,500	5,000

G. Any enforcement action taken by the Department may be appealed in a manner pursuant to the Administrative Procedures Act, Section 1-23-310, *et seq.* of the SC Code Laws, 1976, as amended.

SECTION 400 - POLICIES AND PROCEDURES

401. General (II)

A. Policies and procedures addressing each section of this regulation regarding client treatment, care, services, and rights, and the operation of the facility shall be developed and implemented, and revised as required in order to accurately reflect actual facility operation. Facilities shall establish a time-period for review of all policies and procedures. These policies and procedures shall be accessible at all times. A hard copy of the client care policies and procedures shall be available or be accessible electronically at each facility.

B. The policies and procedures shall describe the means by which the facility shall assure that the standards described in this regulation, which the licensee has agreed to meet as confirmed by his/her application, are met.

SECTION 500 - STAFF

501. General (II)

A. Appropriate staff/volunteers in numbers and training shall be provided to suit the needs and condition of the clients and meet the demands of effective emergency on-site action that might arise. Training requirements/qualifications for the tasks each performs shall be in compliance with all local, state, and federal laws, and current professional organizational standards. Direct care staff members/volunteers of the facility, shall

not have a prior conviction or pled no contest (nolo contendere) for child or adult abuse, neglect or mistreatment, or have an active dependency on psychoactive substances that would impair his/her ability to perform assigned duties. The facility shall coordinate with applicable organizations that maintain registries should licensed/certified individuals be considered as employees of the facility.

B. There shall be a qualified administrator available within a reasonable time and distance in order to appropriately manage the day-to-day operation of the facility. The administrator shall exercise judgement that reflects that s/he is mentally and emotionally capable of meeting the responsibilities involved in operating a facility to ensure that it is in compliance with these regulations, and shall demonstrate adequate knowledge of these regulations. A qualified staff member shall be designated, in writing, to act in the absence of the administrator.

C. Additional staff shall be provided if it is determined that the minimum staff requirements are inadequate to provide appropriate services and supervision to the clients of a facility.

D. Staff/volunteers shall be provided the necessary training to perform the duties for which they are responsible in an effective manner.

E. In 24-hour facilities, no care/treatment/services shall be provided to individuals who are not clients of the facility, except those services provided to family members as part of the client's recovery plan.

F. There shall be accurate information maintained regarding all staff/volunteers of the facility, to include at least current address, phone number, health and work/training background, as well as current information. All employees shall be assigned certain duties and responsibilities that shall be in writing and in accordance with the individual's capability. (II)

G. When care, treatment, or services are provided by another entity, there shall be a written agreement with the entity that describes how the services provided are in accordance with the individualized treatment plan (ITP) and states that the staff/volunteers providing these services are qualified and supervised properly. The entity with whom a facility has written agreement shall comply with this regulation in regard to client care, treatment, services and rights.

502. Inservice Training (II)

A. In all facilities, the following training shall be provided to all staff/volunteers, and those clients in residential treatment program facilities who may be utilized to supplement staffing, within one month of hiring and at least annually:

1. The nature of alcohol and other drug addiction, complications of addictions, and withdrawal symptoms.
2. Confidentiality of client information and records, and the protection of client rights.

B. In addition to the above, in 24-hour facilities, the following training shall be provided by appropriate resources, e.g., licensed persons, video tapes, books, etc., to all direct client care staff/volunteers prior to client contact and at a frequency as determined by the facility, but at least annually:

1. Cardio-pulmonary resuscitation to ensure that there is at least one certified individual present when clients are in the facility (detoxification facilities only);

2. Basic first-aid to include emergency procedures as well as procedures to manage/care for minor accidents or injuries;

3. Procedures for checking and recording vital signs (for those facilities to which applicable);

4. Management/care of persons with contagious and/or communicable disease, e.g., hepatitis, tuberculosis (TB), Human Immunodeficiency Virus (HIV) infection;

5. Medication management (for those facilities to which applicable);

6. Use of restraints and seclusion (detoxification facilities only, if applicable);

7. Seizure management (detoxification facilities only);

8. For those whose care for clients may involve contact with blood and may be at risk, those OSHA standards regarding blood-borne pathogens.

C. All new staff/volunteers shall be oriented to acquaint them with the organization and environment of the facility, specific duties and responsibilities of the staff/volunteers, and client needs.

503. Health Status (I)

A. All staff and volunteers who have contact with clients, including food service staff/volunteers, shall have a health assessment within 12 months prior to initial client contact. The health assessment shall include tuberculin skin testing as described in Section 1402.

B. If a staff member/volunteer is working at multiple facilities operated by the same licensee, copies of records for TB screening and the pre-employment health assessment shall be acceptable at each facility, provided that information is in compliance with this regulation. For any other staff member/volunteer, a copy of the TB screening record shall be acceptable provided the screening had been completed within three months prior to client contact.

504. Counselors (II)

A. Each facility shall have at least one staff counselor who is fully-certified or licensed. All non-certified/licensed counselors shall be under the direct supervision (on-site) of a fully-certified/licensed counselor. Staff/volunteers shall be considered qualified to provide clinical counseling services only by one of the following:

1. For direct client services:

a. Certification as a Clinical Supervisor or Addictions Counselor I or II under the system administered by the SC Association of Alcohol and Drug Abuse Counselors (SCAADAC) Certification Commission, or currently engaged (as verified and documented in the individual's personnel file) in the SCAADAC certification process that is to be completed within a three-year period from date of hire as a counselor;

b. Certification as an addictions counselor by:

(1) The National Association of Alcohol and Drug Abuse Counselors (NAADAC);

(2) An International Certification Reciprocity Consortium-approved certification board;

(3) Any other SC Department of Alcohol and Other Drug Abuse Services (DAODAS)-approved credentialing/certification association or commission.

c. Licensed as a:

(1) Psychiatrist by the SC Board of Medical Examiners;

(2) Psychologist by the SC Board of Examiners in Psychology;

(3) Social worker by the SC Board of Social Work Examiners;

(4) Counselor or therapist by the SC Board of Examiners for Professional Counselors and Marital and Family Therapists, pursuant to Section 40-75-30, of the SC Code of Laws, 1976, as amended.

2. For counselors in narcotic treatment programs (NTP):

a. Any of the certifications/licensures in 504.A.1 above; or

b. The American Academy of Health Care Providers in the Addictive Disorders;

c. The National Board for Certified Counselors; or

d. Any other equivalent, nationally-recognized, and DAODAS-approved association or accrediting body that includes similar competency-based testing, supervision, educational, and substantial experience.

3. For prevention services when provided:

a. Certification by the SC Association of Prevention Professionals and Advocates as a Prevention Professional or Senior Prevention Professional; or

b. In-process of becoming certified as a Prevention Professional. This certification shall be achieved within a 33-month period of time from the date of hire as a prevention counselor.

B. Any individual employed as a direct client, NTP, or prevention services counselor, to include contracted staff, who does not obtain his/her certification/licensing within the above time-periods, shall cease providing counseling services until that certification/licensing status is achieved.

SECTION 600 - REPORTING

601. Incidents/Accidents (II)

A. A record of each accident and/or incident, including usage of physical restraints, involving clients or staff/volunteers, occurring in the facility or on the facility grounds shall be retained.

1. Incidents/accidents and/or serious medical conditions as defined below and any illness resulting in death or inpatient hospitalization shall be reported via telephone to the next-of-kin or responsible person at the earliest practicable hour, but not to exceed 24 hours of the occurrence, and in writing to the Department's Division of Health Licensing (DHL) within 10 days of the occurrence.

2. Serious medical conditions shall be considered as, but not limited to: fractures of major limbs or joints, severe burns, severe lacerations, severe hematomas, and actual/suspected abuse/neglect/exploitation of clients.

B. Reports shall contain at a minimum: facility/program name, client age and sex, date of incident/ accident, location, witness names, extent/type of injury and how treated, e.g., hospitalization, identified cause of incident/accident, internal investigation results if cause unknown, identity of other agencies notified of incident, and the date of the report.

C. Medication errors and adverse medication reactions shall be reported immediately, as applicable, to the prescriber, supervising nurse, pharmacist, and administrator and recorded in the client record.

D. In medical detoxification facilities only, incidents where clients have left the premises without notice to staff/volunteers of intent to leave and have not returned to the facility within 24 hours, shall be reported to DHL, next-of-kin, responsible person, and, if there is evidence that the client may be a danger to himself or others, local law enforcement.

E. In 24-hour facilities, changes in the client's condition to the extent that serious health concerns, e.g., heart attack, are evident, shall be reported immediately to the attending physician, and no later than 12 hours to next-of-kin/responsible person and administrator. (I)

F. In NTP facilities, premature or stillborn births to clients shall be reported in writing to DHL within 10 working days.

602. Fire/Disasters (II)

A. DHL shall be notified immediately via telephone or fax regarding any fire in the facility, and followed by a complete written report to include fire reports, if any, to be submitted within a time-period determined by the facility, but not to exceed 72 hours from the occurrence of the fire.

B. Any natural disaster or fire, that requires displacement of the clients, or jeopardizes or potentially jeopardizes the safety of the clients, shall be reported to DHL via telephone/fax immediately, followed by a complete written report which includes the fire report from the local fire department, if appropriate, submitted within a time-period as determined by the facility, but not to exceed 72 hours.

603. Communicable Diseases and Animal Bites (I)

All cases of diseases and animal bites that are required to be reported to the appropriate county health department shall be accomplished in accordance with R.61-20.

604. Administrator Change

DHL shall be notified in writing by the licensee within 10 days of any change in administrator. The notice shall include at a minimum the name of the newly-appointed individual and effective date of the appointment.

605. Joint Annual Report

Facilities, e.g., medical detoxification, required by the Department's Planning and Certificate of Need Division to submit a "Joint Annual Report" shall complete and return this report within the time-period specified by that Division.

606. Accounting of Controlled Substances (I)

Any facility registered with the Department's Bureau of Drug Control and the United States Drug Enforcement Agency shall report any theft or loss of controlled substances to local law enforcement and to the Department's Bureau of Drug Control within five days of the discovery of the loss/theft. Any facility permitted by the SC Board of Pharmacy shall report the loss or theft of drugs or devices in accordance with Section 40-43-91 of the SC Code of Laws.

607. Emergency Placements

In instances where evacuees have been relocated to the facility, DHL shall be notified not later than the following

workday of the circumstances regarding the emergency placement and the aggregate number of individuals received.

608. Facility Closure

A. Prior to the permanent closure of a facility, DHL shall be notified in writing of the intent to close and the effective closure date. Within 10 days of the closure, the facility shall notify DHL of the provisions for the maintenance of the records, and the identification of the site where clients are relocated. On the date of closure, the license shall be returned to DHL.

B. In instances where a facility temporarily closes, DHL shall be given written notice within a reasonable time in advance of closure. At a minimum this notification shall include, but not be limited to: the reason for the temporary closure, the location where the clients have been/will be transferred (24-hour facility only), the manner in which the records are being stored, and the anticipated date for re-opening. DHL shall consider, upon appropriate review, the necessity of inspecting the facility prior to its re-opening. If the facility is closed for a period longer than one year, and there is a desire to re-open, the facility shall re-apply to the Department for licensure and shall be subject to all licensing requirements at the time of that application, including construction-related requirements for a new facility.

609. Zero Census

In instances when there have been no clients in a facility for a period of 90 days or more for any reason, the facility shall notify DHL in writing that there have been no admissions no later than the 100th calendar day following the date of departure of the last active client. At the time of that notification, DHL will consider, upon appropriate review of the situation, the necessity of inspecting the facility prior to any new and/or readmissions to the facility. If the facility has no clients for a period longer than one year, and there is a desire to admit a client, the facility shall re-apply to the DHL for licensure and shall be subject to all licensing requirements at the time of that application, including construction-related requirements for a new facility.

SECTION 700 - CLIENT RECORDS

701. Content (II)

A. The facility shall initiate and maintain a client record for every individual assessed and/or treated. The record shall contain sufficient information to identify the client and the agency and/or person responsible for each client, support the diagnosis, justify the treatment, and describe the response/reaction to treatment. The record contents shall also include the provisions for release of information, client rights, consent for treatment (approval by parent/guardian of client), medications prescribed and administered, and diet (24-hour facilities only), documentation of the course and results, and promote continuity of treatment among treatment providers, consistent with acceptable standards of practice. In facilities for mothers with children, the name and age of each child shall be maintained in the facility. All entries shall be written legibly in ink or typed and signed and dated.

B. Specific entries shall include at a minimum, if applicable:

1. Consultations by physicians or other authorized healthcare providers;

2. Orders and recommendations for all medication, care, treatment, services, procedures, and diet from physicians or other authorized healthcare providers, which shall be completed prior to, or at the time of admission, and subsequently, as warranted;

3. Care/treatment/services provided; medications administered and procedures followed if an error is made; special procedures and preventive measures performed; notes of counseling sessions; and notes of any other significant observation(s);

4. Provisions for routine and emergency medical care, to include the name and telephone number of the client's physician, plan for payment, and plan for securing drugs.

C. With the exception of those enrolled in primarily educational-related programs, each client, to include those being monitored or case-managed for services received elsewhere, shall have a written ITP.

D. The ITP shall contain specific goal-related objectives based on the needs of the client as identified during the assessment phase including adjunct support service needs and other special needs. The plan will also include the methods and strategies for achieving these objectives and meeting these needs in measurable terms with expected achievement dates. The type and frequency of counseling as well as counselor assignment shall be included. The criteria for terminating specified interventions will be included in the plan. ITP's shall be reviewed on a periodic basis as determined by the facility and/or revised as changes in client needs occur.

EXCEPTION: The ITP description in this section is not applicable to detoxification facilities. See Section 3106.

E. The client shall participate in the development of his/her ITP. The client and primary counselor shall sign and date this plan as documentation of their participation in its development.

F. There shall be a discharge summary, completed within a time-period as determined by the facility, and a copy provided to the client, which shall include at minimum:

1. Time and circumstances of discharge or transfer, including condition at discharge or transfer, or death;

2. The recommendations and arrangements for further treatment, including aftercare.

702. Authentication of Signatures (II)

A. Those entries in the client record that require authentication shall be defined by the facility. Any entry in the client record shall have the author identified.

B. Facilities employing electronic signatures or computer-generated signature codes shall ensure authentication and confidentiality.

703. Record Maintenance

A. The licensee shall provide accommodations, space, supplies, and equipment adequate for the protection, and storage of client records.

B. The client record is confidential and may be made available only to individuals authorized by the facility and/or in accordance with local, state, and federal laws, codes, and regulations. The written disclosure of information shall include: (II)

1. The name of the person/agency to which the information is to be disclosed;

2. The specific information to be disclosed;

3. The purpose of the disclosure;

4. A stipulation that the consent for disclosure is only for a specified period of time;

5. The signature of the client, date signed, and witness's signature.

C. Records generated by organizations/individuals contracted by the facility for services, treatment, or care shall be maintained by the facility that has admitted the client.

D. The facility shall determine the medium in which information is stored.

E. Upon discharge of a client, the record shall be completed and filed in an inactive/closed file within a time-period determined by the facility, but not to exceed 30 days, and shall be maintained by the licensee. Prior to the closing of a facility for any reason, the licensee shall arrange for preservation of records to ensure compliance with these regulations. The licensee shall notify DHL, in writing, describing these arrangements and the location of the records.

F. Records of adult clients may be destroyed after six years following discharge of the client. Records of minors shall be retained for six years or until majority, whichever period of time is greater. Other regulation-required documents, e.g., medication destruction, fire drills, etc., shall be retained for at least 12 months or since the last DHL general inspection, whichever is the longer period.

G. In the event of change of ownership, all active client records or copies of active client records shall be transferred to the new owner(s).

H. Records of clients are the property of the facility and may not be removed without court order.

EXCEPTION: When a client transfers from one licensed facility to another within the provider network (same licensee) the original record may follow the client; the sending facility shall maintain documentation of the client's transfer/discharge dates and identification information.

SECTION 800 - CLIENT CARE/TREATMENT/SERVICES

801. General (II)

A. Individuals seeking admission shall be identified as appropriate for the level of care or services, treatment, or procedures offered. The facility shall establish admission criteria that are consistently applied and comply with state and federal laws and regulations. The facility shall admit only those persons whose needs can be met within the accommodations and services provided. (I)

B. Care/treatment/services relative to the needs of the client, e.g., counseling, diet, medications, to include medical emergency situations, as identified in the client record and ordered by appropriate health care professionals, shall be provided, and coordinated among those responsible during the treatment process and modified as warranted based on any changing needs of the client. (I)

C. For 24-hour facilities:

1. Clients shall receive, as needed, appropriate assistance in activities of daily living;

2. Clients shall be neat, clean**,** and appropriately and comfortably clothed;

3. Clients shall be provided necessary items and assistance, if needed, to maintain their personal cleanliness;

4. An adequate supply of recreational supplies shall be available to clients to meet their recreational needs;

5. Opportunities shall be provided for participation in religious services. Reasonable assistance in obtaining pastoral counseling shall be provided upon request by the client.

D. Care/treatment/services shall be rendered effectively and safely in accordance with orders from physicians, other authorized healthcare providers, and certified/licensed counselors, and precautions taken for clients with special conditions, e.g., pacemakers, wheelchairs, etc. (I)

E. Clients shall be given the opportunity to participate in aftercare/continuing care programs offered by the facility or through referral.

F. Precautions shall be taken for the protection of the personal possessions of the clients including their personal funds. The facility may secure the personal funds of the client provided the client authorizes the facility to do so. The facility shall maintain an accurate accounting of the funds, including evidence of purchases by facility on behalf of the clients. No personal monies shall be given to anyone, including family members, without written consent of the client. If money is given to anyone by the facility, a receipt shall be obtained.

G. In the event of closure of a facility for any reason, the facility shall ensure continuity of treatment/care by promptly notifying the client's attending physician or other authorized healthcare provider or counselor and arranging for referral to other facilities at the direction of the physician or other authorized healthcare provider or counselor.

H. The provision of care/treatment/services to clients shall be guided by the recognition of and respect for cultural differences to assure reasonable accommodations will be made for clients with regard to differences, such as, but not limited to, religious practice and dietary preferences.

802. Transportation

Twenty-four hour facilities shall provide or assist in securing local transportation for clients for emergent or non-emergent health reasons to health care providers such as, but not limited to, physicians, dentists, physical therapists, or for treatment at renal dialysis clinics.

803. Safety Precautions/Restraints (I)

A. No restraint, neither mechanical nor physical, including seclusion, shall be used in the facility except in cases of extreme emergency when a client is a danger to him/herself or others, and then only as ordered by a physician or other authorized healthcare provider until appropriate medical care can be secured. Such orders shall include the reason for use of the restraint/seclusion, the type of restraint that may be used, the maximum time the restraint may be used or the client may be placed in seclusion, and instructions for observing the client while in physical restraint/seclusion if different from the facility's written procedures. Clients certified by a physician or other authorized healthcare provider as requiring restraint/seclusion for more than 24 hours shall be transferred to an appropriate facility.

B. During the course of routine treatment/care (non-emergent conditions), periodic or continuous restraint usage shall not be allowed.

C. Restraints/seclusion shall not be used for staff convenience or as a substitute for treatment.

D. Should it be necessary to temporarily restrain in emergency situations, the facility shall ensure that clients placed in physical restraints or seclusion are monitored at a frequency as determined by the facility, but at least every 15 minutes. Clients shall be provided bathroom privileges, offered fluids, given medications as prescribed, given the opportunity for nourishment, if desired, at regularly scheduled mealtimes, and if the client is in a restraint, given an opportunity for motion and exercise.

804. Treatment of Minors (II)

A. Minors shall not be admitted to residential treatment program facilities (with the exception of facilities for mothers with children) or detoxification facilities, except only by request to DHL on a case-by-case basis. These requests shall include:

1. A statement that the facility is able to provide services and accommodations for the minor;

2. A statement of agreement by parent(s) or legal guardian.

B. If the staff/volunteer considers consultation with the parents/guardians of minors regarding treatment issues to be appropriate without the consent of the minor, the reasons for such consultation shall be explained to the parents/guardians upon the minor's admission to the facility.

C. In 24-hour facilities, minors shall be housed separately from adults except in facilities for mothers with children.

D. In those instances where minors are served, the facility shall ensure that the special needs of these clients are addressed, including, but not limited to, education-related considerations.

EXCEPTION: A facility may admit a person 16 years or older to an outpatient or NTP facility, or to a facility for mothers with children; a child under 16 years of age may be admitted to these facilities with written consent of the parent or legal guardian.

805. Referral Services

A. Referrals shall not be made to unlicensed facilities if such facilities are required to be licensed. (II)

B. The facility shall offer current information regarding appropriate self-help groups to clients and encourage their participation in such activities.

C. Referral services shall be made available to individuals ineligible for admission to the facility's programs.

D. A community resource file shall be developed, maintained, and used for proper client referral and placement. The file shall contain listing of services, fees, hours of operation, and contact person as well as material to be provided to the client. Information regarding community resources such as transportation, hospital emergency services, ambulance services, and information and referral services shall be made available to clients.

E. An NTP shall establish linkages with the criminal justice system to encourage continuous treatment of individuals incarcerated or on probation and parole.

SECTION 900 - CLIENT RIGHTS AND ASSURANCES

901. Informed Consent (II)

All treatment, to include any new or innovative treatment or any research-oriented treatment or evaluation, shall be thoroughly explained to the client, to include the potential for any adverse effects/consequences of the specified treatment or research. In all instances of treatment, the client must voluntarily choose to participate in the program. The client shall be informed of any changes in treatment unless the client has waived, in writing, such consent.

902. Client Rights (II)

A. Client rights shall be guaranteed and prominently displayed in a public area. The facility shall inform the client in writing of these rights, to include, as a minimum:

1. The opportunity to participate in the ITP;

2. Informed consent for treatment;

3. Grievance/complaint procedures, including the address and phone number of DHL, and a provision prohibiting retaliation should the grievance right be exercised;

4. Confidentiality of client records;

5. Respect for the client's property;

6. Freedom from abuse, neglect, and exploitation; (I)

7. Privacy in visits unless contraindicated in the recovery and treatment process or as ordered by a physician or other authorized healthcare provider;

8. Privacy during treatment and while receiving personal care;

9. Respect and dignity in receiving care/treatment/services.

B. Clients shall be assured freedom of movement. Clients shall not be locked in or out of their rooms or any common usage areas, e.g., dining, sitting, activity rooms, in the facility, or in or out of the facility building. (I)

C. Care/treatment/services and items provided by the facility, the charge, and those services that are the responsibility of the client shall be delineated in writing and the client shall be made aware of such charges and services as verified by his/her signature.

D. The facility shall comply with all relevant federal, state, and local laws and regulations related to discrimination, e.g., Title VII, Section 601 of the Civil Rights Act of 1964, ADA, and ensure that there is no discrimination with regard to source of payment in the recruitment, location of client, acceptance or provision of goods and services to clients or potential clients, provided that payment offered is not less than the cost of providing services.

903. Discharge/Transfer

A. Unless a client is under court order or detained subject to a pending judicial process, a client may be transferred or discharged only for medical reasons, the welfare of the client, the welfare of other clients of the facility, lack of progress or participation in treatment, or successful completion of the program. S/he shall be given written notice of discharge except when the health, safety, or well-being of other clients of the facility would be endangered.

B. The conditions under which information regarding applicants or clients may be disclosed/released, including disclosure/release in client health emergency situations, shall be established by the facility.

C. When a client is transferred from one facility to another, e.g., from a detoxification facility to a hospital, appropriate information from his/her client record shall be forwarded to the receiving facility within a time-period as determined by the facility but not to exceed 72 hours from transfer. The facility shall ensure that medication, personal possessions/funds of the client, and other appropriate items are forwarded to the receiving facility/site in a manner that ensures continuity of care/treatment/services and maximum convenience to the client.

SECTION 1000 - CLIENT PHYSICAL EXAMINATION

1001. General (I)

A. A physical examination and history shall be completed within 30 days prior to admission or not later than 48 hours after admission for clients in 24-hour facilities. The procedure describing the need for a physical examination in outpatient facilities shall be determined by the facility with documented consultation with a physician or other authorized healthcare provider. For NTP's, see Section 3208.

EXCEPTION: If a client is admitted after 5:00 P.M. on Friday, a 24-hour facility has until close-of-business the next workday to obtain the admission physical examination.

1. As appropriate, the physical examination shall address the appropriateness of level of treatment placement, e.g., social detoxification, medical detoxification, residential treatment, etc., and identification of special conditions including the presence of communicable diseases.

2. In 24-hour facilities and NTP's, the physical examination shall include a tuberculin skin test, as described in Section 1402, unless there is a previously documented positive reaction.

3. The physical examination shall be performed only by a physician or other authorized healthcare provider.

4. If a client or potential client has a communicable disease, the administrator shall seek advice from a physician or other authorized healthcare provider in order to:

a. Ensure that the facility has the capability of providing adequate care and preventing the spread of that condition, and that the staff/volunteers are adequately trained;

b. Transfer the client to an appropriate facility, if necessary.

B. A discharge summary, which includes a physical examination from a health care facility, shall be acceptable as the physical examination provided the summary includes the requirements of Sections 1001.A. - 1001.A.3.

C. Isolation Provisions. Clients with contagious pulmonary tuberculosis shall be separated from non-infected clients until declared non-contagious by a physician or other authorized healthcare provider. Should it be determined that the facility cannot care for the client to the degree that assures his/her health and safety and that of the other clients in the facility, the client shall be relocated to a facility that can meet his/her needs.

D. In facilities for mothers with children, there shall be a report of a physical examination conducted not earlier than 30 days prior to the mother's admission or not later than 48 hours after admission for each child, attesting to health status and special care needs that may impact on the child, his/her mother, and/or others within the facility. The exception indicated in Section 1001.A shall be applicable for obtaining a physical examination for the child should the mother be admitted after 5pm on Friday.

E. In the event that a client transfers from one 24-hour facility to another (e.g., medical detoxification to a residential treatment program), an additional admission physical/tuberculin skin test shall not be necessary, provided the physical was conducted not earlier than 12 months prior to the admission of the client, and the physical meets all other requirements specified in Section 1001.A.1, unless the receiving facility has an indication that the health status of the client has changed significantly. Two-step tuberculin skin tests remain a requirement of residential treatment program facilities. In such instances of transfer, issues of appropriateness of level of treatment placement shall be addressed in the client record.

1101. General (I)

A. Medications, including controlled substances, medical supplies and those items necessary for the rendering of first aid shall be properly managed in accordance with local, state, and federal law and regulations, which includes the securing, storing, and administering/dispensing/delivering of medications, medical supplies, and biologicals, their disposal when discontinued or outdated, and their disposition at discharge, death, or transfer of a client. All facilities that manage medication of clients shall comply with this section.

B. Applicable reference materials, e.g., Physicians' Desk Reference, published within the previous three years, shall be available at the facility in order to provide staff/volunteers with adequate information concerning medications.

1102. Medication Orders (I)

A. Medication, including oxygen, shall be administered/delivered to clients only upon orders of/authorization by a physician or other authorized healthcare provider. Medications accompanying clients at admission, may be administered/delivered to clients provided the medication is in the original container and the order/authorization is subsequently obtained as a part of the admission physical. If there are concerns regarding whether or not such medications should be administered/delivered due to the condition or state of the medication, e.g., old, expired, makeshift labels, or the condition or state of health of the newly-admitted individual, staff/volunteers shall consult with or make arrangements to have the client examined by a physician or other authorized healthcare provider, or at the local hospital emergency room prior to administering/delivering any medications.

B. All orders (including verbal orders) shall be signed and dated by a physician or other authorized healthcare provider within a time-period as designated by the facility, but no later than 72 hours after the order is given.

C. Orders for controlled substances, as defined in R.61-4, shall be authenticated by the prescribing physician or designee.

D. Medications and medical supplies ordered for a specific client shall not be administered/delivered to any other client.

1103. Administering Medication (I)

A. Medications, including oxygen, shall be administered to clients only by those appropriately licensed to administer medications, pursuant to the SC Code of Laws.

B. Each medication dose administered/delivered or supervised shall be properly recorded by initialing on the client's medication record as the medication is administered. Doses of medication shall be administered by the same staff member/volunteer who prepared them for administration. Preparation of doses for more than one scheduled administration shall not be permitted, and such preparation shall occur no earlier than one hour prior to administering. The recording of medication administration shall include: the medication name, dosage, mode of administration, date, time, and the signature of the individual administering or supervising the taking of the medication. If the ordered dosage is to be given on a varying schedule, e.g., "take two tablets the first day and one tablet every other day by mouth with noon meal," the number of tablets shall also be recorded.

C. Self-administering of medications is permitted only when indicated by the physician or other authorized healthcare provider, verified by direct contact with the client by a staff member/volunteer, and recorded on the medication record by that same staff member/volunteer. Verification and documentation shall occur at the same frequency as the medication is given. Facilities may elect not to permit self-administration.

EXCEPTION: Documentation of medication taken by clients, as described in Sections 1103.B and C, is not required for nonlegend medication for those who are physically and mentally capable of self-administering medications provided:

1. The medication does not require a prescription and is not specifically prescribed;

2. The client's physician or other authorized healthcare provider documents in the client's record that the client may, at the client's discretion, use and self-administer all nonprescription medications;

3. A current (within two-year) statement, attesting to the conditions stated in Section 1103.C.2 above, is signed and dated by the physician or other authorized healthcare provider, and filed in the client's record;

4. The statement in Section 1103.C.3 above is specifically addressed during subsequent physical examinations and appropriately revised or restated in the report of that examination;

5. The condition is specifically addressed in the periodic review and update of the record.

D. When clients who cannot self-administer medications leave the facility for an extended time, the proper amount of medications, placed into a prescription vial or bottle, along with dosage, mode, date and time of administration, shall be given to a responsible person who will be in charge of the client during his/her absence from the facility and properly documented in the medication administration record. If there is no designated responsible party for the client, then the attending physician or other authorized healthcare provider shall be contacted for proper instructions.

1104. Pharmacy Services (I)

A. Any pharmacy within the facility shall be provided by or under the direction of a registered pharmacist in accordance with accepted professional principles and appropriate federal, state, and local laws and regulations.

B. Facilities which maintain stocks of legend drugs and biologicals for dispensing to clients shall obtain and maintain a valid, current pharmacy permit from the SC Board of Pharmacy.

C. Labeling of medications dispensed to clients shall be in compliance with local, state, and federal laws and regulations applicable to retail pharmacies.

1105. Medication Containers (I)

A. All medication containers shall be labeled. Medication containers having soiled, damaged, incomplete, illegible, or makeshift labels shall be returned to the pharmacy for re-labeling or disposal.

B. Medications for each client shall be kept in the original container(s) including unit dose or blister pack systems; there shall be no transferring between containers or opening blister packs to remove medications for destruction or adding new medications for administration. In addition, for those facilities that utilize the blister pack system, an on-site review of the medication program by a pharmacist shall be required to assure the program has been properly implemented and maintained.

C. Medications for clients shall be obtained from a permitted pharmacy or prescriber on an individual prescription basis. These medications shall bear a label affixed to the container which reflects at least the following: name of pharmacy, name of client, name of the prescribing physician or dentist, date and prescription number, directions for use, and the name and dosage unit of the medication. The label shall be brought into accord with the directions of the physician each time the prescription is refilled.

D. If a physician or other authorized healthcare provider changes the dosage of a medication, a label, which does not obscure the original label, shall be attached to the container which indicates the new dosage, date, and prescriber's name. In lieu of this procedure, it is acceptable to attach a label to the container that states, "see MAR and physician or other authorized healthcare provider orders for current administration instructions." The new directions shall be communicated to the pharmacist on reorder of the drug. The new directions shall be communicated to the pharmacist on reorder of the drug.

1106. Medication Storage (I)

A. Medications shall be properly stored and safeguarded to prevent access by unauthorized persons. Expired or discontinued medications shall not be stored with current medications. Storage areas shall be locked, and of sufficient size for clean and orderly storage. Storage areas shall not be located near sources of heat, humidity, or other hazards that may negatively impact medication effectiveness or shelf life. Refrigerators used for storage of medications shall maintain an appropriate temperature as identified on the manufacturer's label and as established by the US Pharmacopeia (36 – 46 degrees Fahrenheit), and as evidenced by a thermometer placed inside. Medications requiring refrigeration shall be stored in a refrigerator at the temperature recommended by the manufacturer of the medication. Medications may be stored in a separate locked box within a multi-use refrigerator at or near the medication storage area.

B. Controlled substances and ethyl alcohol, shall be stored in accordance with applicable state and federal laws. A record of the stock and distribution of all controlled substances shall be maintained in such a manner that the disposition of any particular item may be readily traced.

C. Medications shall be stored:

1. Separately from poisonous substances or body fluids;

2. In a manner which provides for separation between topical and oral medications, and which provides for separation of each individual client's medication.

D. Unless the facility has a permitted pharmacy, stocks of legend medications shall not be stored except those specifically prescribed for individual clients. Non-legend medications may be retained and labeled as stock in the facility for administration as ordered by a physician or other authorized healthcare provider.

E. No medication may be left in a client's room unless the facility provides an individual cabinet/ compartment that is kept locked in the room of each client who has been authorized to self-administer in writing by a physician, or other authorized healthcare provider. In lieu of a locked cabinet or compartment, a room that can be locked and is licensed for a capacity of one client is acceptable provided the medications are not accessible by unauthorized persons, the room is kept locked when the client is not in the room, the medications are not controlled substances, and all other requirements of this section are met.

F. The medications prescribed for a client shall be protected from use by other clients, visitors and staff/volunteers. For those clients who have been authorized by a physician or other authorized healthcare provider to self-administer medications, such medications may be kept on the client's person, i.e., a pocketbook, pocket, or any other method that would enable the client to control the items.

G. During nighttime hours in semi-private rooms, only medications that a physician or other authorized healthcare provider has ordered in writing for emergency/immediate use, e.g., nitroglycerin or inhalers, may be kept unlocked in or upon a cabinet or bedside table, and only when the client to whom that medication belongs is present in the client room.

1107. Disposition of Medications (I)

A. Medications shall be released to the client upon discharge, unless specifically prohibited by the ordering physician or authorized healthcare provider.

B. Clients' medications shall be destroyed by the facility administrator or his/her designee or returned to the dispensing pharmacy when:

1. Medication has deteriorated or exceeded its safe shelf-life and;

2. Unused portions remain due to death, discharge, or discontinuance of the medication. Medications that have been discontinued by order may be stored for a period not to exceed 30 days provided they are stored separately from current medications.

C. The destruction of medication shall occur within five days of the above-mentioned circumstances, be witnessed by the administrator or his/her designee, and the mode of destruction indicated.

D. The destruction of controlled medications shall be accomplished only by the administrator or his/her designee on-site and witnessed by a licensed nurse or pharmacist, or by returning them to the dispensing pharmacy and obtaining a receipt from the pharmacy.

SECTION 1200 - MEAL SERVICE

1201. General (II)

A. All facilities that prepare food on-site shall be approved by DHL, and shall be regulated, inspected, and graded pursuant to R.61-25. Facilities preparing food on-site, licensed for 16 beds or more subsequent to the promulgation of these regulations shall have commercial kitchens. Existing facilities with 16 licensed beds or more may continue to operate with equipment currently in use; however, only commercial kitchen equipment shall be used when replacements are necessary. Those facilities with 15 beds or less shall be regulated pursuant to R.61-25 with certain exceptions in regard to equipment (may utilize domestic kitchen equipment).

B. When meals are catered to a facility, such meals shall be obtained from a food service establishment permitted by the Department, pursuant to R.61-25 and there shall be a written executed contract with the food service establishment.

C. If food is prepared at a central kitchen and delivered to separate facilities or separate buildings and/or floors of the same facility, provisions shall be made and approved by the DHL for proper maintenance of food temperatures and a sanitary mode of transportation.

D. Food shall be prepared by methods that conserve the nutritive value, flavor and appearance. The food shall be palatable, properly prepared, and sufficient in quantity and quality to meet the daily nutritional needs of the clients in accordance with written dietary policies and procedures. Efforts shall be made to accommodate the religious, cultural, and ethnic preferences of each individual client and consider variations of eating habits, unless the orders of a physician or other authorized healthcare provider contraindicate.

1202. Food and Food Storage (II)

A. The storage, preparation, serving, transportation of food, and the sources from which food is obtained shall be in accordance with R.61-25. (I)

B. The use of home canned foods is prohibited. (I)

C. All food items shall be stored at a minimum of six inches above the floor on clean surfaces, and in such a manner as to be protected from splash and other contamination.

D. At least a one-week supply of staple foods and a two-day supply of perishable foods shall be maintained on the premises. Supplies shall be appropriate to meet the requirements of the menu and special or therapeutic diets.

E. Food stored in the refrigerator/freezer shall be covered, labeled, and dated. Prepared food shall not be stored in the refrigerator for more than 72 hours.

1203. Food Equipment and Utensils (II)

The equipment and utensils utilized, and the cleaning, sanitizing, and storage of such shall be in accordance with R.61-25.

EXCEPTION: In facilities with five licensed beds or less, in lieu of a three-compartment sink, a domestic dishwasher may be used to wash equipment/utensils provided the facility has at least a two-compartment sink that will be used to sanitize and adequately air dry equipment/utensils. In facilities with 10 beds or less and licensed prior to May 24, 1991, as a community residential care facility, in which a two-compartment sink serves to wash kitchen equipment/utensils, an additional container of adequate length, width, and depth may be provided to completely immerse all equipment/utensils for final sanitation. Domestic dishwashers may be utilized in facilities licensed with 10 beds or less prior to May 24, 1991, provided they are approved by DHL.

1204. Meals and Services

A. All facilities shall provide dietary services to meet the daily nutritional needs of the clients in accordance with the recommended dietary allowances of the Food and Nutrition Board of the National Research Council, National Academy of Sciences. (I)

B. The dining area shall provide a congenial and relaxed environment. Table service shall be planned in an attractive and colorful manner for each meal and shall include full place setting with napkins, tablecloths or place-mats, forks, spoons, knives, drink containers, plates, and other eating utensils/containers as needed.

C. A minimum of three nutritionally-adequate meals, in accordance with Section 1204.A above, in each 24-hour period, shall be provided for each client unless otherwise directed by the client's physician or other authorized healthcare provider. Not more than 14 hours shall elapse between the serving of the evening meal and breakfast the following day. (II)

D. Special attention shall be given to preparation and prompt serving in order to maintain correct food temperatures for serving at the table or client room (tray service). (II)

E. The same foods shall not be repetitively served during each seven-day period except to honor specific, individual client requests.

F. Specific times for serving meals shall be established and followed.

G. Suitable food and snacks shall be available and offered between meals at no additional cost to the clients. (II)

1205. Meal Service Workers (II)

A. The health, disease control and cleanliness of all those engaged in food preparation and serving shall be in accordance with R.61-25.

B. Dietary services shall be organized with established lines of accountability and clearly defined job

assignments for those engaged in food preparation and serving. There shall be trained staff/volunteers to supervise the preparation and serving of the proper diet to the clients including having sufficient knowledge of food values in order to make appropriate substitutions when necessary. Clients may engage in food preparation in accordance with facility guidelines; however, trained staff/volunteers shall supervise.

C. Sufficient staff/volunteers shall be available to serve food and to provide individual attention and assistance, as needed.

D. Approved hair restraints (covering all loose hair) shall be worn by all individuals engaged in the preparation and service of foods.

1206. Diets (II)

A. If the facility accepts or retains clients in need of medically-prescribed special diets, the menus for such diets shall be planned by a professionally-qualified dietitian or shall be reviewed and approved by a physician or other authorized healthcare provider. The facility shall provide supervision of the preparation and serving of any special diet, e.g., low-sodium, low-fat, 1200-calorie, diabetic diet. (I)

B. If special diets are required, the necessary equipment for those diets shall be available and utilized.

C. A diet manual published within the previous five years shall be available and shall address at minimum:

1. Food sources and food quality;

2. Food protection storage, preparation and service;

3. Food worker health and cleanliness;

4. Recommended dietary allowances of the Food and Nutrition Board of the National Research Council, National Academy of Sciences;

5. General menu planning;

6. Menu planning appropriate to special needs, e.g., diabetic, low-salt, low-cholesterol.

1207. Menus

A. Menus shall be planned and written at a minimum of one week in advance and dated as served. The current week's menu, including routine and special diets and any substitutions or changes made, shall be readily available or posted in one or more conspicuous places in a public area. All substitutions made on the master menu shall be recorded in writing.

B. Records of menus as served shall be maintained for at least 30 days.

1208. Ice and Drinking Water (II)

A. Ice from a water system that is in accordance with R.61-58, shall be available and precautions taken to prevent contamination. The ice scoop shall be stored in a sanitary manner outside of the ice container.

B. Potable drinking water shall be available and accessible in adequate amounts at all times.

C. The usage of common cups shall be prohibited.

D. Ice delivered to client areas in bulk shall be in nonporous, easily cleaned, covered containers.

1209. Equipment (II)

A. Liquid or powder soap dispensers and sanitary towels shall be available at each food service handwash lavatory.

B. In facilities of 16 or more licensed beds, separate handwash sinks shall be provided convenient to serving, food preparation, and dishwashing areas.

C. All walk-in refrigerators and freezers shall be equipped with opening devices which will permit opening of the door from the inside at all times. (I)

1210. Refuse Storage and Disposal (II)

Refuse storage and disposal shall be in accordance with R.61-25.

SECTION 1300 - MAINTENANCE

1301. General (II)

A. The structure, including its component parts and equipment, shall be properly maintained to perform the functions for which it is designed.

B. Noise, dust, and other related client intrusions shall be minimized when construction/renovation activities are underway.

C. If applicable, a procedure shall be developed for calibrating medication-dispensing instruments consistent with manufacturer's recommendations to ensure accurate dosing and tracking.

SECTION 1400 - INFECTION CONTROL AND ENVIRONMENT

1401. Staff Practices (I)

Staff practices shall promote conditions that prevent the spread of infectious, contagious, or communicable diseases and provide for the proper disposal of toxic and hazardous substances. These preventive measures/practices shall be in compliance with applicable guidelines of the Blood borne Pathogens Standard of the Occupational Safety and Health Act (OSHA) of 1970; the Centers for Disease Control and Prevention (CDC); the Department's Guidelines For Prevention and Control of Antibiotic Resistant Organisms in Health Care Settings, and R.61-105; and other applicable federal, state, and local laws and regulations.

1402. Tuberculin Skin Testing (I)

A. Tuberculin skin testing, utilizing a two-step intradermal (Mantoux) method of five tuberculin units of stabilized purified protein derivative (PPD), is a procedure recommended by the CDC Guidelines for Preventing Transmission of Myco-bacterium Tuberculosis in Healthcare Facilities to establish baseline status. The two-step procedure involves one initial tuberculin skin test with a negative result, followed 7-21 days later by a second test. It is permissible for a licensed nurse to perform the tuberculin screening.

B. Testing Procedures.

1. Staff/volunteers of all facilities and clients of 24-hour facilities shall be required to have evidence of a two-step tuberculin skin test. If there is a documented negative tuberculin skin test (at least single-step) within the previous 12 months, the person shall be required to have only one tuberculin skin test to establish a baseline

status.

2. Individuals with negative test results from the initial two-step procedure shall be required to have an annual one-step skin test.

3. Staff/volunteers of all facilities shall have the completed two-step tuberculin skin test prior to client contact.

4. Clients of 24-hour facilities shall have at least the first step within the period for completion of the physical examination as specified in Section 1001.

5. Narcotic treatment program clients shall have a single-step test as specified in Section 3208.

C. Positive Reactions/Exposure.

1. Individuals with tuberculin skin test reactions of 10mm or more of enduration and known human immunodeficiency virus (HIV)-positive individuals with tuberculin skin test reactions of 5mm or more of enduration shall be referred to a physician or other authorized healthcare provider for appropriate evaluation. In all facilities, staff/volunteers with the above reactions shall not be allowed to have direct contact with clients. Clients of 24-hour facilities with the above reactions shall be isolated and/or treated/referred as necessary until certified as non-contagious by a physician or other authorized healthcare provider. Clients of NTP facilities with the above reactions shall be referred to the local county health department or the DHEC TB Control Division for consultation.

2. All persons who are known or suspected to have tuberculosis (TB) shall be evaluated by a physician or other authorized healthcare provider.

3. Staff/volunteers will not be allowed to return to work until they have been declared non-contagious.

4. Individuals who have had a prior history of TB shall be required to have a chest radiograph and certification within one month prior to employment/admission by a physician or other authorized healthcare provider that they are not contagious.

5. If an individual who was previously documented as skin test negative has an exposure to a documented case of TB, the facility shall immediately contact the local county health department or the DHEC TB Control Division for consultation.

D. Treatment.

1. Preventive treatment of persons who are new positive reactors is recommended unless specifically contraindicated.

2. Individuals who complete treatment either for disease or infection, are exempt from further treatment unless they develop symptoms of TB. An individual who remains asymptomatic shall not be required to have a chest radiograph, but shall have an annual documented assessment by a physician or other authorized healthcare provider for symptoms suggestive of TB, e.g., cough, weight loss, night sweats, fever, etc.

1403. Housekeeping (II)

The facility and its grounds shall be neat, clean, and free of safety impediments, vermin, and offensive odors.

A. Interior housekeeping shall at a minimum include:

1. Cleaning each specific area of the facility;

2. Cleaning and disinfection, as needed, of equipment used and/or maintained in each area, appropriate to the area and the equipment's purpose or use.

3. Safe storage of harmful chemicals (as indicated on the product label), cleaning materials and supplies in well-lighted closets/rooms, inaccessible to clients. In 24-hour facilities only, when all clients have been authorized permission by a physician, authorized healthcare provider, or certified/licensed counselor to handle cleaning products, and housekeeping chores are part of the therapeutic program, cleaning agents may then be stored in an unsecured fashion.

B. Exterior housekeeping shall at a minimum include:

1. General cleaning of all exterior areas, e.g., porches and ramps, and removal of safety impediments such as water, snow, and ice;

2. Keeping facility grounds free of weeds, rubbish, overgrown landscaping, and other potential breeding sources for vermin;

1404. Infectious Waste (I)

Accumulated waste, including all contaminated sharps, dressings, pathological, and/or similar infectious waste, shall be disposed of in a manner compliant with the Department's SC Guidelines For Prevention and Control of Antibiotic Resistant Organisms in Health Care Settings, R.61-105, and OSHA Bloodborne Pathogens Standard.

1405. Pets (II)

A. Healthy animals that are free of fleas, ticks, and intestinal parasites, and have been examined by a veterinarian prior to entering the facility, have received required inoculations, if applicable, and that present no apparent threat to the health, safety, and well-being of the clients, shall be permitted in the facility, provided they are sufficiently fed, and cared for, and that the pets and their housing/food containers are kept clean.

B. Pets shall not be allowed near clients who have allergic sensitivities to pets, or for other reasons such as clients who do not wish to have pets near them.

C. Pets shall not be allowed in the kitchen area. Pets will be permitted in client dining/activities areas only during times when food is not being served. If the dining/activities area is adjacent to a food preparation or storage area, those areas shall be effectively separated by walls and closed doors while pets are present.

1406. Clean/Soiled Linen and Clothing (II)

A. Clean Linen/Clothing. A supply of clean, sanitary linen/clothing shall be available at all times. Clean linen/clothing shall be stored and transported in an enclosed/covered sanitary manner. Linen/Clothing storage rooms shall be used only for the storage of linen/clothing. Clean linen/clothing shall be separated from storage of other purposes. Enclosing/Covering may be accomplished by utilizing materials such as cloth, plastic, or canvas cover, in order to prevent the contamination of clean linen/clothing by dust or other airborne particles or organisms.

B. Soiled Linen/Clothing.

1. Soiled linen/clothing shall neither be sorted nor rinsed outside of the laundry service area.

2. Provisions shall be made for collecting, transporting, and storing soiled linen/clothing.

3. Soiled linen/clothing shall be kept in enclosed/covered containers.

4. Laundry operations shall not be conducted in client rooms, dining rooms, or in locations where food is prepared, served, or stored. Freezers/refrigerators may be stored in laundry areas, provided sanitary conditions are maintained.

SECTION 1500 - EMERGENCY PROCEDURES/DISASTER PREPAREDNESS

1501. General (II)

With the exception of outpatient facilities and NTP's, at the time of admission, a plan for routine and emergency medical care shall be written into the client record. This shall include the name of physician or other authorized healthcare provider, and provisions for emergency medical care, to include plan for obtaining medications. In social detoxification facilities, there shall be a transfer agreement with local providers for emergency medical and psychiatric services as needed.

1502. Disaster Preparedness (II)

A. All facilities shall develop a suitable written plan for actions to be taken in the event of a disaster. All 24-hour facilities shall develop this plan in coordination with their county emergency preparedness agency. Prior to initial licensing of a facility by the Department, the completed plan shall be submitted to DHL for review. Additionally, in instances when there are applications for increases in licensed bed capacity, the emergency/disaster plan shall be updated appropriately to reflect the proposed new total bed capacity. All staff/volunteers shall be made familiar with this plan and instructed as to any required actions.

B. The disaster plan for 24-hour facilities shall include, but not be limited to:

1. A sheltering plan to include:

a. The licensed bed capacity and average occupancy rate;

b. Name, address and phone number of the sheltering facility(ies) to which the clients will be relocated during a disaster;

c. A letter of agreement signed by an authorized representative of each sheltering facility which shall include: the number of relocated clients that can be accommodated; sleeping, feeding, and medication plans for the relocated clients; and provisions for accommodating relocated staff. The letter shall be updated annually with the sheltering facility and whenever significant changes occur. For those facilities located in Beaufort, Berkeley, Charleston, Colleton, Dorchester, Horry, Jasper, and Georgetown counties, at least one sheltering facility must be located in a county other than these counties.

2. A transportation plan to include agreements with entities for relocating clients which addresses:

a. The number and type of vehicles required;

b. How and when the vehicles are to be obtained;

c. Who (by name or organization) will provide drivers;

d. Procedures for providing appropriate medical support during relocation;

e. The estimated time to accomplish the relocation;

f. The primary and secondary routes to be taken to the sheltering facility.

3. A staffing plan for the relocated clients to include:

a. How care will be provided to the relocated clients including the number and type of staff;

b. Plans for relocating staff or assuring transportation to the sheltering facility;

c. Co-signed statement by an authorized representative of the sheltering facility if staffing will be provided by the sheltering facility.

C. A plan for the evacuation of clients, staff and visitors, in case of fire or other emergency, shall be posted in conspicuous public areas throughout the facility and a copy of the plan shall be provided to each client upon admission.

1503. Emergency Call Numbers (II)

Emergency call data shall be posted in a conspicuous place and shall include at least the telephone numbers of fire and police departments, an ambulance service, and the poison control center. Other emergency call information shall be available, to include the names, addresses, and telephone numbers of the staff to be notified in case of emergency, and the physician or other authorized healthcare provider on-call.

1504. Continuity of Essential Services (II)

There shall be a plan to be implemented to assure the continuation of essential client supportive services for such reasons as power outage, water shortage, or in the event of the absence from work of any portion of the work force resulting from inclement weather or other causes.

SECTION 1600 - FIRE PREVENTION

1601. Arrangements for Fire Department Response (I)

A. Each facility shall develop, in coordination with its supporting fire department and/or disaster preparedness agency, suitable written plans for actions to be taken in the event of fire.

B. Facilities located outside of a service area or range of a public fire department shall arrange for the nearest fire department to respond in case of fire by written agreement with that fire department. A copy of the agreement shall be kept on file in the facility and a copy shall be forwarded to DHL. If the agreement is changed, a copy shall be forwarded to DHL.

1602. Tests and Inspections (I)

A. Fire protection and suppression systems shall be maintained and tested in accordance with NFPA 10, 13, 14, 15, 25, 70, 72, and 96.

B. All electrical installations and equipment shall be maintained in a safe, operable condition in accordance with NFPA 70 and 99 and shall be inspected at least annually.

1603. Fire Response Training (I)

Each staff member/volunteer shall receive training within one week of hiring, and at a frequency determined by the facility, but at least annually thereafter, addressing at a minimum, the following:

A. Fire plan to include evacuation routes and procedures, and the training of staff;

B. Reporting a fire;

C. Use of the fire alarm system, if applicable;

D. Location and use of fire-fighting equipment;

E. Methods of fire containment;

F. Specific responsibilities, tasks, or duties of each individual.

1604. Fire Drills (I)

A. Clients shall be made familiar with the fire plan and evacuation plan.

B. An unannounced fire drill shall be conducted at least quarterly for all shifts. Each staff member/ volunteer shall participate in a fire drill at least once each year. Records of drills shall be maintained at the facility, indicating the date, time, shift, description, and evaluation of the drill, and the names of staff/volunteers and clients directly involved in responding to the drill.

C. All clients at the time of the fire drill shall participate in the drill. In instances when a client refuses to participate in a drill, efforts shall be made to encourage participation, e.g., counseling, implementation of incentives rewarding clients for participation, specific staff/volunteer to client assignments to promote client participation. Continued refusal may necessitate implementation of the discharge planning process to place the client in a setting more appropriate to their needs and abilities.

D. Drills shall be designed and conducted in consideration of and reflecting the content of the fire response training described in Section 1603 above.

E. Individuals participating in drills shall evacuate to the outside of the building.

SECTION 1700 - QUALITY IMPROVEMENT PROGRAM

1701. General (II)

A. There shall be a written, implemented quality improvement program that provides effective self-assessment and implementation of changes designed to improve the treatment/care/services provided by the facility.

B. The quality improvement program, as a minimum, shall:

1. Establish desired outcomes and the criteria by which policy and procedure effectiveness is regularly, systematically, and objectively accomplished;

2. Identify, evaluate, and determine the causes of any deviation from the desired outcomes;

3. Identify the action taken to correct deviations and prevent future deviation, and the person(s) responsible for implementation of these actions;

4. Establish ways to measure the quality of client care and staff performance as well as the degree to which the policies and procedures are followed;

5. Analyze the appropriateness of ITP's and the necessity of treatment/care/services rendered;

6. Analyze the effectiveness of the fire plan;

7. Analyze all incidents and accidents to include client deaths;

8. Analyze any infection, epidemic outbreaks, or other unusual occurrences which threaten the health, safety, or well-being of the clients;

9. Establish a systematic method of obtaining feedback from clients and other interested persons, e.g., family members and peer organizations, as expressed by the level of satisfaction with treatment/care/services received.

SECTION 1800 - DESIGN AND CONSTRUCTION

1801. General (II)

A. A facility shall be planned, designed and equipped to provide and promote the health, safety, and well-being of each client. Facility design shall be such that all clients have access to required services. There shall be 200 gross square feet per licensed bed in facilities 10 beds or less, and an additional 100 gross square feet per licensed bed for each licensed bed over 10.

B. Outpatient and NTP facilities shall meet the requirements of the SBC for Business Occupancy. Those sections of this regulation that specifically apply to a building for housing clients for more than 24 hours do not apply for outpatient and NTP facilities.

C. Twenty-four hour facilities licensed for five beds or less shall be classified as Residential Occupancy and shall follow the requirements of the SBC for Residential Occupancy.

D. Twenty-four hour facilities licensed for six beds or more shall follow the requirements of the SBC for Residential R-4 Occupancy and the requirements for dormitories.

E. Twenty-four hour facilities housing six or more clients who are incapable of self-preservation shall meet the requirements of the SBC for Institutional Occupancy.

1802. Local and State Codes and Standards (II)

A. Buildings shall comply with pertinent local and state laws, codes, ordinances and standards with reference to design and construction. No facility shall be licensed unless the Department has assurance that responsible local officials (zoning and building) have approved the facility for code compliance.

B. The Department utilizes as its basic codes, those indicated in Section 102.B.

C. Buildings designed in accordance with the above-mentioned codes will be acceptable to the Department provided the requirements set forth in this regulation are also met.

1803. Construction/Systems (II)

A. All buildings, new and existing, being licensed for the first time, or changing their license to provide a different service, shall meet the current codes and regulations.

B. Unless specifically required otherwise in writing by the Department's Division of Health Facilities

Construction (DHFC), all existing facilities licensed by the Department shall meet the construction codes and regulations for the building and its essential equipment and systems in effect at the time the license was issued. Except for proposed facilities that have received a current and valid written approval to begin construction, current construction codes, regulations, and requirements shall apply to those facilities licensed after the date of promulgation of these regulations.

C. Any additions or renovations to an existing licensed facility shall meet the codes, regulations, and requirements for the building and its essential equipment and systems in effect at the time of the addition or renovation. When the cost of additions or renovations to the building exceeds 50% of the then market value of the existing building and its essential equipment and systems, the building shall meet the then current codes, regulations, and requirements.

D. Buildings under construction at the time of the promulgation of these regulations shall meet the codes, regulations, and requirements in effect at the time of the plans approval.

E. Any facility that closes or has its license revoked and for which application for re-licensure is made at the same site shall be considered a new building and shall meet the current codes, regulations, and requirements for the building and its essential equipment and systems in effect at the time of application for re-licensing.

1804. Submission of Plans and Specifications (II)

A. New Buildings, Additions or Major Alterations to Existing Buildings.

1. In all new construction or existing structures proposed to be licensed by the Department, plans and specifications shall be submitted to DHFC for review and approval.

2. Where the SBC or other regulations require fire-rated walls or other fire-rated structural elements, these plans and specifications shall be prepared by an architect and shall bear his/her seal. Plans for a facility with five beds or less shall be drawn to scale, but preparation by an architect is not required.

3. Construction of, or within buildings of 5000 square feet or more, or three stories or more in height, and involving construction of fire-rated assemblies shall, in addition to Section 1804.A.2 above, provide the Minimum Construction Administration Services, as defined in Section (B)(5), Regulation 11-12, Code of Professional Ethics, published by The Board of Architectural Examiners, SC Department of Labor, Licensing, and Regulation.

4. When construction is contemplated for additions or alterations to existing licensed buildings, the facility shall contact DHFC regarding code and regulatory requirements that apply to that project. Plans and specifications shall be submitted to DHFC for review.

5. All plans shall be drawn to scale with the title, location, and date shown thereon.

6. Construction work shall not begin until approval of the final drawings or written permission has been received from DHFC. Any construction deviations from the approved documents shall be approved by that division.

B. Plans and specifications are reviewed as necessary to obtain a set of approvable drawings showing all necessary information. These reviews may be, but are not required to be, in three stages: Preliminary, Design Development, and Final.

1. Preliminary submission shall include the following:

a. Plot plan showing:

(1) Size and shape of entire site;

(2) Footprint showing orientation and location of proposed building;

(3) Location and description of any existing structures, adjacent streets, highways, sidewalks, railroads, etc., properly designated;

(4) Size, characteristics and location of all existing public utilities, including information concerning water supply available for fire protection, distance to nearest fire hydrant; parking; any hazardous areas, e.g., cliffs, roads, hills, pools, etc.

b. Floor plans showing blocked spaces (areas) of approximate size and shape and their relationship to other spaces.

2. Design Development drawings shall indicate the following in addition to the above:

a. Cover sheet:

(1) Title and location of the project;

(2) Index of drawings;

(3) Code analysis listing applicable codes (both local jurisdiction and state);

(4) Occupancy classification per SBC;

(5) Type of construction per SBC.

b. Floor plans:

(1) Overall dimensions of buildings;

(2) Locations, size and purpose of all rooms including furniture layout plan;

(3) Location and size of doors, windows and other openings with swing of doors properly indicated;

(4) Life Safety plan showing all fire walls, exits, exit calculations, locations of smoke barriers if required, fire rated walls, locations of stairs, elevators, dumbwaiters, vertical shafts and chimneys;

(5) Fixed equipment.

c. Outline specifications that include a general description of construction including interior finishes and mechanical systems.

3. Final submission shall include the above in addition to complete working drawings and contract specifications, including layouts for site preparation and landscaping, architectural, plumbing, electrical, mechanical, and complete fire protection.

4. Requirements for Facilities That Prepare Meals.

a. For facilities of six beds or more, food service operations shall be separated from living and sleeping quarters by complete ceiling high walls and solid, self-closing doors. (II)

b. Kitchen ventilation specifications shall be in compliance with Section 2501.

c. For commercial kitchens (meals prepared for 16 or more persons), construction shall be in compliance with Chapter VII (A - G) of R.61-25, and a separate floor plan shall be provided depicting:

(1) Location of all equipment;

(2) Make and model number of all equipment (including a thermometer schedule). All equipment used for the preparation and storage of food shall be approved by the NSF.

(3) Garbage can wash pad on exterior with hot and cold running water;

(4) Grease interceptor;

(5) Floor drains

(6) Separate hand washing sinks;

(7) Toilet and locker facilities for kitchen staff;

(8) Exhaust hood and duct system to the outside;

(9) Hood extinguishing system.

d. Plan submission for domestic kitchens (meals prepared for 15 or less persons) shall include:

(1) Location and identification of all equipment;

(2) An approved three-compartment sink in addition to a hand washing sink (facilities licensed for five beds or less may have a two-compartment sink and a dishwasher);

(3) An exhaust hood and fan of proper size installed over all cooking equipment and vented to the outside. Facilities with 13 or more clients shall have a hood extinguisher system.

5. If construction is delayed for a period exceeding 12 months from the time of approval of final submission, a new evaluation and/or approval is required.

6. One complete set of as-built drawings shall be filed with DHFC.

SECTION 1900 - GENERAL CONSTRUCTION REQUIREMENTS

1901. Height and Area Limitations (II)

Construction shall not exceed the allowable heights and areas provided by the SBC.

1902. Fire-Resistive Rating (I)

The fire-resistive ratings for the various structural components shall comply with the SBC. Fire-resistive ratings of various materials and assemblies not specifically listed in the SBC can be found in publications of recognized testing agencies such as Underwriters Laboratories - Building Materials List and Underwriters Laboratories - Fire Resistance Directory.

1903. Vertical Openings (I)

All vertical openings shall be protected in accordance with applicable sections of the SBC, State Fire Marshal Regulations, and NFPA 101.

1904. Wall and Partition Openings (I)

All wall and partition openings shall be protected in accordance with applicable sections of the SBC and NFPA 101.

1905. Ceiling Openings (I)

Openings into attic areas or other concealed spaces shall be protected by material consistent with the fire rating of the assembly penetrated.

1906. Fire Walls (I)

A. A building is defined by the outside walls and any interior four-hour fire walls and shall not exceed the height and area limitations set forth in the SBC for the type of construction.

B. An addition shall be separated from an existing building by a two-hour, fire-rated wall, unless the addition is of equal fire-resistive rating.

C. When an addition is to be constructed of a different type of construction from the existing building, the type of construction and resulting maximum area and height limitations allowed by the building code will be determined by the lesser of the types of construction of the building.

D. If the addition is separated by a four-hour fire wall, the addition is considered as a separate building, and the type of construction of the addition will determine the maximum area and height limitations.

1907. Floor Finishes (II)

A. Floor coverings and finishes shall meet the requirements of the SBC.

B. All floor coverings and finishes will be appropriate for use in each area of the facility and free of hazards, e.g., slippery surfaces. Floor finishes shall be of materials that permit frequent cleaning, and when appropriate, disinfection.

1908. Wall Finishes (I)

A. Wall finishes shall meet the requirements of the SBC.

B. Manufacturers' certifications or documentation of treatment for flame spread and other safety criteria shall be furnished and maintained.

1909. Curtains and Draperies

In bathrooms and client rooms, window treatments shall provide privacy.

SECTION 2000 - HAZARDOUS ELEMENTS OF CONSTRUCTION

2001. Furnaces and Boilers (I)

Furnaces and boilers shall be maintained in accordance with the applicable provisions of NFPA 31, 70, 85C, and 86.

2002. Dampers (I)

Smoke and fire dampers shall be installed on all heating, ventilating, and air conditioning systems as required by NFPA 90A and the SBC.

SECTION 2100 - FIRE PROTECTION EQUIPMENT AND SYSTEMS

2101. Firefighting Equipment (I)

A. Fire extinguishers shall be sized, located, installed and maintained in accordance with NFPA No. 10, except that portable fire extinguishers intended for use in client sleeping areas shall be of the 2-A: 2-1/2 gallon, stored pressure, water type.

B. At least one 4-A:20-BC type fire extinguisher shall be installed in the following hazardous areas:

1. Laundry;

2. Furnace room;

3. Any other area having a high-risk fire hazard.

C. At least one 2-A:10-BC type fire extinguisher shall be located within 25 feet of exits and no more than 75 feet travel distance.

D. The kitchen shall be equipped with a minimum of one K-type and one 20-BC extinguisher.

2102. Automatic Sprinkler System (I)

A. An automatic sprinkler system shall be required for all facilities with six or more licensed beds in accordance with the requirements of the SBC under Residential R-4 Occupancy.

B. The sprinkler system shall meet the requirements of NFPA 13, Standard for the Installation of Sprinkler Systems, or when permitted, NFPA 13R, Installation of Sprinkler Systems in Residential Occupancies Up to and Including Four Stories in Height.

C. All sprinkler systems, wet and dry, shall have remote inspection/test ports.

D. Facilities that house four or more clients who may require physical assistance to exit the building shall be fully sprinklered in accordance with NFPA 13.

E. Facilities with a soiled linen storage room over 100 square feet in size shall have an approved automatic sprinkler system unless contained in a separate building.

2103. Fire Alarms (I)

A. When a fire alarm system is required, it shall be provided in accordance with provisions of NFPA 72, National Fire Alarm Code, the SBC, and the State Fire Marshal Regulations.

B. The system shall be arranged to transmit an alarm automatically to the fire department by an approved method.

C. The alarm system shall notify by audible and visual alarm all areas and floors of the building.

D. The alarm system shall cause the central recirculating ventilation fans that serve the area(s) of alarm origination to cease operation and to shut the associated smoke dampers.

E. The fire alarm pull-station shall be placed in an area in accordance with NFPA 72.

F. All fire, smoke, heat, sprinkler-flow, fire-sensing detectors, manual pull-stations, hold-open devices on fire-rated doors, alarming devices, or other fire-related systems, shall be connected to and monitored by the main fire alarm system, and trigger the system when any of these devices are activated.

G. The fire alarm system shall have the main fire alarm panel located at a readily accessible location. An audible/visual trouble indicator shall be located where it can be observed by staff/volunteers.

H. The fire alarm system shall be tested initially by an individual licensed to install fire alarms, and at least annually thereafter.

I. When a fire alarm system is required and smoke detectors are placed in client sleeping rooms, there shall be an indicator light in the hall outside the door of the room to indicate when that smoke detector is in alarm.

EXCEPTION: When the fire alarm system is fully addressable and there are sufficient annunciator panel(s) such that travel distance in any hall to an annunciator panel does not exceed 50 feet, and the annunciator panel will indicate the activated smoke detector by location, the light over the door in the hall is not required.

2104. Smoke Detectors (I)

Smoke detectors shall be installed in accordance with NFPA 72, State Fire Marshal Regulations, and the SBC.

2105. Flammable Liquids (I)

The storage and handling of flammable liquids shall be in accordance with NFPA 30 and 99.

2106. Gases (I)

A. Gases, i.e., flammable and nonflammable shall be handled and stored in accordance with the provisions of NFPA 99 and 101.

B. Safety precautions shall be taken against fire and other hazards when oxygen is dispensed, administered, or stored. "No Smoking" signs shall be posted conspicuously, and cylinders shall be properly secured in place.

2107. Furnishings/Equipment (I)

A. The physical plant shall be maintained free of fire hazards or impediments to fire prevention.

B. No portable electric or unvented fuel heaters shall be permitted.

C. Fireplaces and fossil-fuel stoves, e.g., wood-burning, shall have partitions or screens or other means to prevent burns. Fireplaces shall be vented to the outside. “Unvented” type gas logs are not allowed. Gas fireplaces shall have a remote gas shutoff within the room and not inside the fireplace.

D. Wastebaskets, window dressings, portable partitions, cubicle curtains, mattresses, and pillows shall be noncombustible, inherently flame-resistant, or treated or maintained flame-resistant in accordance with NFPA 701,

Standard Methods of Fire Tests for Flame-Resistant Textiles and Films.

EXCEPTION: Window blinds require no flame treatments or documentation.

SECTION 2200 - EXITS

2201. Number and Locations (I)

A. Exits, corridors, doors, stairs, ramp, and smoke partitions shall be provided, installed, and maintained in accordance with the provisions of NFPA 101 and the SBC.

B. Rooms and/or suites greater than 1000 square feet shall have at least two exit access doors remote from each other.

C. If exit doors and cross-corridor doors are locked, the requirements in the SBC under Special Locking Arrangements shall be met.

D. Where it can be demonstrated that the provision of the required "irreversible opening upon a delay," as described in SBC, will create a security problem, an alternated method of locking cross corridor and exit doors may be used, provided the following requirements are met:

1. Unlocked exit doors will create a security problem as determined by the facility based upon the condition of clients in the facility;

2. The locking system complies with the requirements in the SBC for Special Locking Arrangements except the requirement for an irreversible opening upon delay;

3. The exit doors can be released electrically by the staff/volunteers by a switch(s) or button(s) located at a nearby control point that in not locked;

4. At each locked door, there shall be a key-operated switch that will unlock the door; a keypad may be used for unlocking the door, but this keypad shall not negate the requirement for a key-operated switch;

5. All staff/volunteers working in the area carry a readily identifiable (by sight and touch) key on their person;

6. Written approval has been granted by DHFC.

E. Fire alarm pull-stations may be locked if all staff/volunteers working in the area carry on their person a readily identifiable key (by sight and touch), and there is an unlocked pull-station centrally located in the facility.

F. Halls, corridors and all other means of egress from the building shall be maintained free of obstructions.

G. Those clients that may require physical or verbal assistance to exit the building shall not be located above or below the floor of exit discharge.

H. Each client room shall open directly to an approved exit access corridor without passage through another occupied space or shall have an approved exit directly to the outside at grade level and accessible to a public space free of encumbrances.

EXCEPTION: When two client rooms share a common "sitting" area that opens onto the exit access corridor**.**

SECTION 2300 - WATER SUPPLY/HYGIENE

2301. Design and Construction (II)

A. A water distribution system, provided by public or private source, shall be approved by the Department's Bureau of Water before the facility can be constructed and/or placed into operation. (I)

B. Before the construction, expansion, or modification of a water distribution system, application shall be made to the Department for a Permit for Construction. The application shall include such engineering, chemical, physical, or bacteriological data as may be required by the Department and shall be accompanied by engineering plans, drawings, and specifications prepared by an engineer registered in SC and shall carry his/her official signature and seal.

C. In general, the design and construction of such systems shall be in accordance with standard engineering practices for such installations. The Department shall establish such rules, regulations, and/or procedures as may be necessary to protect the health of the public and to ensure proper operation and functioning of the system. The facility's water system shall be in compliance with R.61-58 and other local, state, and federal laws and regulations.

D. Client and staff hand-washing lavatories and client showers/tubs shall be supplied with hot and cold water at all times.

E. Storage tanks shall be fabricated of corrosion-resistant metal or lined with noncorrosive material.

2302. Disinfection of Water Lines (I)

A. After construction, expansion, or modification, a water distribution system shall be disinfected in accordance with R.61-58.

B. Samples shall be taken from the water system and forwarded to an approved laboratory for bacteriological analysis in accordance with R.61-58. The water shall not be used as a potable supply until certified as satisfactory.

2303. Temperature Control (I)

A. Plumbing fixtures that require hot water and which are accessible to clients shall be supplied with water that is thermostatically controlled to a temperature of at least 100 degrees F. and not to exceed 120 degrees F. at the fixture.

B. The water heater or combination of heaters shall be sized to provide at least six gallons per hour per bed at the above temperature range. (II)

C. Hot water supplied to the kitchen equipment/utensil washing sink shall be supplied at 120 degrees F. provided all kitchen equipment/utensils are chemically sanitized. For those facilities sanitizing with hot water, the sanitizing compartment of the kitchen equipment/utensil washing sink shall be capable of maintaining the water at a temperature of at least 180 degrees F.

D. Hot water provided for washing linen/clothing shall not be less than 160 degrees F. Should chlorine additives or other chemicals which contribute to the margin of safety in disinfecting linen/clothing be a part of the washing cycle, the minimum hot water temperature shall not be less than 110 degrees F., provided hot air drying is used. (II)

2304. Stop Valves

Each plumbing fixture shall have stop valves to permit repairs without disrupting service to other fixtures. Each group of fixtures on a floor, each branch main, and each supply line shall be valved.

2305. Cross-connections (I)

There shall be no cross-connections in plumbing between safe and potentially unsafe water supplies, e.g., toilets, laundry fixtures, and fixtures of similar nature. Water shall be delivered at least two delivery pipe diameters above the rim or points of overflow to each fixture, equipment, or service unless protected against back-siphonage by approved vacuum breakers or other approved back-flow preventers. A faucet or fixture to which a hose may be attached shall have an approved vacuum breaker or other approved back-flow preventer.

2306. Design and Construction of Wastewater Systems (I)

A. A wastewater system, provided by a public or private source, shall be approved by the Department's Bureau of Water before the facility can be constructed and/or placed into operation.

B. Plans, specifications, reports and studies, for the construction, expansion or alteration of a wastewater system shall be prepared by an engineer registered in SC and shall carry his/her official signature and seal.

C. The design and construction of wastewater systems shall be in accordance with standard engineering practice and R.61-67.

D. The wastewater system for commercial kitchens shall be in accordance with R.61-25.

E. Liquid waste shall be disposed of in a wastewater system approved by the local authority, e.g., sewage treatment facility.

SECTION 2400 - ELECTRICAL

2401. General (I)

A. Electrical installations shall be in accordance with NFPA 70 and 99.

B. Wiring shall be inspected at least annually by a licensed electrician, registered engineer, or certified building inspector.

C. All materials shall be listed as complying with available standards of Underwriters Laboratories, Inc. or other similarly established standards.

D. New systems shall be tested to indicate that the equipment is installed and operates as planned or specified.

2402. Panelboards (II)

Panelboards shall be in accordance with NFPA 70. Panelboards serving lighting and appliance circuits shall be located on the same floor as the circuits served. This requirement does not apply to life safety system circuits. The directory shall be labeled to conform to the actual room designations. Clear access of stored materials, as per NFPA 70, shall be maintained to the panel. The panelboard directory shall be labeled to conform to the actual room numbers or designations.

2403. Lighting

A. Spaces occupied by persons, machinery, equipment within buildings, approaches to buildings, and parking lots shall be lighted. (II)

B. Adequate artificial light shall be provided to include sufficient illumination for reading, observation, and activities. There shall be a minimum of 35 foot-candles in areas used for reading, study, or close work. Lighting in work areas shall not be less than 30 foot-candles.

C. Client rooms shall have general lighting that provides a minimum of 20 foot-candles in all parts of the room, and shall have at least one light fixture for night lighting. A reading light shall be provided for each client. The switches to the general and night lighting shall be located at the strike side of the entrance door in each client room and shall be of the quiet operating type.

D. All food preparation areas, equipment and utensil washing areas, hand washing areas, toilet areas for kitchen staff/volunteers, walk-in refrigeration units, dry food storage areas, and dining areas during cleaning operation shall be lighted in accordance with R.61-25.

E. Hallways, stairs, and other means of egress shall be lighted at all times in accordance with NFPA 101, i.e., at a minimum, an average of one foot-candle at floor level. (I)

2404. Receptacles (II)

A. Client Room. Each client room shall have duplex grounding type receptacles located per NFPA 70, to include one at the head of each bed.

B. Corridors. Duplex receptacles for general use shall be installed approximately 50 feet apart in all corridors and within 25 feet of the ends of corridors.

2405. Ground Fault Protection (I)

A. Ground fault circuit-interrupter protection shall be provided for all outside receptacles and bathrooms in accordance with the provisions of NFPA 70.

B. Ground fault circuit-interrupter protection shall be provided for any receptacles within six feet of a sink or any other wet location. If the sink is an integral part of the metal splashboard grounded by the sink, the entire metal area is considered part of the wet location.

2406. Exit Signs (I)

A. In facilities licensed for six or more beds, required exits and ways to access thereto shall be identified by electrically-illuminated exit signs bearing the words “Exit” in red letters six inches in height on a white background.

B. Changes in egress direction shall be marked with exit signs with directional arrows.

C. Exit signs in corridors shall be provided to indicate two directions of exit.

2407. Emergency Electric Service (I)

Emergency electric services shall be provided as follows:

A. Exit lights, if required;

B. Exit access corridor lighting;

C. Illumination of means of egress;

D. Fire detection and alarm system, if required.

SECTION 2500 - HEATING, VENTILATION, AND AIR CONDITIONING

2501. General (II)

A. Heating, ventilation, and air conditioning (HVAC) systems shall comply with NFPA 90A and all other applicable codes.

B. The HVAC system shall be inspected at least once a year by a certified/licensed technician.

C. The facility shall maintain a temperature of between 72 and 78 degrees F. in client areas.

D. No HVAC supply or return grill shall be installed within three feet of a smoke detector. (I)

E. HVAC grills shall not be installed in floors.

F. Intake air ducts shall be filtered and maintained to prevent the entrance of dust, dirt, and other contaminating materials. The system shall not discharge in such a manner that would be an irritant to the clients/staff/volunteers.

G. All kitchen areas shall be adequately ventilated so that all areas are kept free from excessive heat, steam, condensation, vapors, smoke, and fumes.

H. Each bath/restroom shall have either operable windows or have approved mechanical ventilation.

SECTION 2600 - PHYSICAL PLANT

2601. Facility Accommodations/Floor Area (II)

A. For 24-hour facilities, there shall be sufficient living arrangements for everyone residing therein providing for clients' quiet reading, study, relaxation, entertainment or recreation. This shall include bedrooms, bathrooms, living, dining, and recreational areas available for clients' use. Consideration shall be given to the preferences of the clients in determining appropriate homelike touches in the facility client rooms and activity/dining areas.

B. Minimum square footage requirements shall be as follows: (II)

1. Twenty square feet per licensed bed of living and recreational areas combined, excluding bedrooms, halls, kitchens, dining rooms, bathrooms, and rooms not available to the clients. In facilities for mothers with children, there shall be at least 20 square feet per licensed bed and 10 square feet per child of living and recreational areas together.

2. Fifteen square feet of floor space in the dining area per licensed bed. In facilities for mothers with children, dining space shall accommodate 15 square feet per licensed bed and 7.5 square feet per child.

C. All required care/treatment/services furnished at the facility shall be provided in a manner which does not require clients to ambulate from one site to another outside the building, nor which impedes clients from ambulating from one site to another due to the presence of physical barriers.

D. There shall be accommodations available to meet group needs of clients and their visitors.

E. Methods for ensuring visual and auditory privacy between client and staff/volunteers shall be provided as

necessary.

2602. Client Rooms

A. Each client room shall be equipped with the following as a minimum for each client:

1. A comfortable single bed having a mattress with moisture-proof cover, sheets, blankets, bedspread, pillow and pillowcases; roll-away type beds, cots, bunkbeds, and folding beds shall not be used. It is permissible to remove a client bed and place the mattress on a platform or pallet, or utilize a recliner, provided the physician or other authorized healthcare provider has approved, and the decision is documented in the ITP. (II)

2. A closet or wardrobe, a bureau consisting of at least three drawers, and a compartmentalized bedside table/nightstand to adequately accommodate each client's personal clothing, belongings, and toilet articles. Built-in storage is permitted.

EXCEPTION: In existing facilities, if square footage is limited, clients may share these storage areas; however, specific spaces within these storage areas shall be provided particular to each client.

3. A comfortable chair for each client occupying the room. In existing facilities, if the available square footage of the client room will not accommodate a chair for each client or if the provision of multiple chairs impedes client ability to freely and safely move about within their room, at least one chair shall be provided and provisions made to have additional chairs available for temporary use in the client's room by visitors.

B. If hospital-type beds are used, there shall be at least two lockable casters on each bed, located either diagonally or on the same side of the bed.

C. Beds shall not be placed in corridors, solaria, or other locations not designated as client room areas. (I)

D. No client room shall contain more than three beds. In facilities with mothers with children, no client room shall contain more than one licensed bed and two cribs/beds. (II)

E. No client room shall be located in a basement.

F. Access to a client room shall not be by way of another client room, toilet, bathroom or kitchen .

EXCEPTION: Access through the kitchen is permissible in facilities with five beds or less.

G. Such equipment as bed pans, urinals and hot water bottles as necessary to meet client needs shall be provided. Portable commodes shall be permitted in client rooms only at night or in case of temporary illness. At all other times, they shall be suitably stored. Permanent positioning of a portable toilet at bedside shall only be permitted if the room is private, the commode is maintained in a sanitary condition, and the room is of sufficient size to accommodate the commode. (II)

H. Side rails may be utilized when required for safety and when ordered by a physician or other authorized healthcare provider. (II)

I. In semi-private rooms, when personal care is being given, arrangements shall be made to ensure privacy, e.g., portable partitions or cubicle curtains when needed or requested by a client.

J. Consideration shall be given to client compatibility in the assignment of rooms for which there is multiple occupancy.

K. At least one private room shall be available in the facility in order to provide assistance in addressing client

compatibility issues, client preferences, and accommodations for clients with communicable disease.

2603. Client Room Floor Area

A. Except for facilities of five beds or less, each client room is considered a tenant space and shall be enclosed by one hour fire-resistive construction with a 20-minute fire-rated door, opening onto an exit access corridor. (I)

B. Each client room shall be an outside room with an outside window or door for exit in case of emergency. This window or door may not open onto a common screened porch. (I)

C. The client room floor area is a usable or net area and does not include wardrobes (built-in or freestanding), closets, or the entry alcove to the room. The following allowance of floor space shall be as a minimum: (II)

1. Rooms for only one client: 100 square feet;

2. Rooms for more than one client: 80 square feet per client.

3. In facilities for mothers with children, rooms for client and child: 80 square feet per licensed bed and 40 square feet per child with a maximum of two children per client. When a bed is required in lieu of a crib for a child, the square footage shall be 50 square feet per child.

D. There shall be at least three feet between beds. (II)

2604. Bathrooms/Restrooms (II)

A. Privacy shall be provided at toilets, urinals, bathtubs, and showers.

B. An adequate supply of toilet tissue shall be maintained in each bathroom.

C. In bath/restrooms not designed for the disabled, the restroom floor area shall not be less than 15 square feet.

D. There shall be at least one lavatory in or adjacent to each bathroom/restroom. Liquid soap shall be provided and a sanitary individualized method of drying hands shall be available at each lavatory.

E. Easily cleanable receptacles shall be provided for waste materials. Such receptacles in toilet rooms for women shall be covered.

F. The number of bathrooms/restrooms for the disabled shall be provided as per the SBC whether any of the clients are classified as disabled or not.

G. All bathroom floors shall be entirely covered with an approved nonabsorbent covering. Walls shall be nonabsorbent, washable surfaces to the highest level of splash.

H. There shall be a mirror above each bathroom lavatory for clients' grooming.

I. In 24-Hour Facilities:

1. Toilets shall be provided in ample number to serve the needs of the clients and staff/volunteers. The minimum number shall be one toilet for each six licensed beds or fraction thereof.

2. All bathtubs, toilets, and showers used by clients shall have approved grab bars securely fastened in a

usable fashion.

3. There shall be one bathtub or shower for each eight licensed beds or fraction thereof.

4. Separate bathroom facilities shall be provided for live-in staff/volunteers and/or family. Where there is no live-in staff/volunteers, separate toilet facilities shall be provided for staff/volunteers in facilities with 11 or more beds.

5. Toilet facilities shall be conveniently located for kitchen employees. The doors of all toilet facilities located in the kitchen shall be self-closing.

6. Bath towels and washcloths shall be provided to the clients as needed. Bath linens assigned to specific clients may not be stored in centrally-located bathrooms. Provisions shall be made for each client to properly keep bath linens in his/her room, i.e., on a towel hook/bar designated for each client occupying that room, or bath linens to meet client needs shall be distributed as needed, and collected after use and stored properly, per Section 1406.

EXCEPTION: Bath linens assigned to specific clients for immediate use may be stored in the bathroom provided the bathroom serves a single occupancy (one client) room, or is shared by occupants of adjoining rooms, for a maximum of six clients. A method that distinguishes linen assignment and discourages common usage shall be implemented.

2605. Seclusion Room (II)

A. A room used for seclusion shall have at least 60 square feet of floor space and be free of safety hazards, and appropriately lighted. All areas of the room shall be clearly visible from the outside.

B. There shall not be items or articles in a seclusion room that a client might use to injure him/herself.

C. A mat and bedding shall be provided in the seclusion room unless an exception is authorized by order of a physician or other authorized healthcare provider.

2606. Client Care Unit and Station (Applicable to medical detoxification facilities only) (II)

A. Each client care unit shall have a client care station.

B. A client care unit shall contain not more than 60 licensed beds; and the client care station shall not be more than 150 feet from a client room, and shall be located and arranged to permit visual observation of the unit corridor(s).

C. Each client care station shall contain separate spaces for the storage of wheelchairs and general supplies/equipment for that station.

D. There shall be at, or near each client care station, a separate medicine preparation room with a cabinet with one or more locked sections for narcotics, work space for preparation of medicine, and a sink. As an alternative, a medicine preparation area with counter, cabinet space and a sink shall be required on those units where there is:

1. A unit dose system in which final medication preparation is not performed on the client care station; or

2. A 24-hour pharmacy on the premises; or

3. Procedures that preclude medication preparation at the client care station.

2607. Doors (II)

A. All client rooms and bath/restrooms shall have opaque doors for the purpose of privacy.

B. All glass doors, including sliding or patio type doors shall have a contrasting or other indicator that causes the glass to be observable, e.g., a decal located at eye level.

C. Exit doors required from each floor shall swing in the direction of exit travel. Doors, except those to spaces such as small closets that are not subject to occupancy, shall not swing into corridors in a manner that obstructs corridor traffic flow or reduces the corridor width to less than one-half the required width during the opening process.

EXCEPTION: Not applicable to facilities with five or less beds not built to institutional standards.

D. Doorways from exit-access passageways to the outside of the facility shall be at least 80 inches in height.

E. Door widths on exit doors be in accordance with the SBC.

F. Bath/restroom door widths shall be not less than 32 inches.

G. Doors to client occupied rooms shall be at least 32 inches wide.

H. Doors that have locks shall be unlockable and openable with one action.

I. If client room doors are lockable, there shall be provisions for emergency entry. There shall not be locks that cannot be unlocked and operated from inside the room. (See Section 2201.D)

J. All client room doors shall be solid-core**.**

K. Soiled linen storage room over 100 square feet shall be of one-hour fire-resistive construction with "C" labeled 3/4-hour door.

L. Seclusion room doors shall have a window through which all parts of the room are observable.

2608. Elevators (II)

A. Elevators, if utilized, shall be installed and maintained in accordance with the provisions of the SBC, ANSI17.1 Safety Code for Elevators and Escalators, and NFPA 101, if applicable.

B. Elevators shall be inspected and tested upon installation prior to first use, and annually thereafter by a certified elevator inspector.

2609. Corridors (II)

A. Corridor width requirements for 24-hour facilities shall be as follows:

1. Less than six licensed beds - not less than 36 inches;

2. Six to 10 licensed beds - not less than 40 inches;

3. Over 10 licensed beds - not less than 44 inches.

B. Corridors and passageways in all facilities shall be in accordance with the SBC.

2610. Ramps (II)

A. At least one exterior ramp, accessible by all clients, staff, and visitors shall be installed from the first floor to grade.

B. The ramp shall serve all portions of the facility where clients are located.

C. The surface of a ramp shall be of nonskid materials.

D. Ramps shall be constructed in a manner in compliance with ANSI 117.1, i.e., for every inch of height, the ramp shall be at least one foot long.

E. Ramps in facilities with 11 or more licensed beds shall be of noncombustible construction. (I)

F. Ramps shall discharge onto a surface that is firm and negotiable by disabled persons in all weather conditions and to a location accessible for loading into a vehicle.

2611. Landings (II)

Exit doorways shall not open immediately upon a flight of stairs. A landing shall be provided that is at least the width of the door and is the same elevation as the finished floor at the exit.

2612. Handrails/Guardrails (II)

A. Handrails shall be provided on all stairways, ramps, and porches with two or more steps, and in detoxification facilities only, at least one side of corridor/hallway. Ends of all installed handrails shall return to the wall.

B. All porches, walkways, and recreational areas (such as decks, etc.) that are elevated 30 inches or more above grade shall have guardrails 42 inches high to prevent falls. Open guardrails shall have intermediate rails through which a six-inch diameter sphere cannot pass.

2613. Screens (II)

Windows, doors and openings intended for ventilation shall be provided with insect screens.

2614. Windows

A. The window dimensions and maximum height from floor to sill shall be in accordance with the SBC and the Life Safety Code, as applicable.

B. Where clear glass is used in windows, with any portion of the glass being less than 18 inches from the floor, the glass shall be of "safety" grade, or there shall be a guard or barrier over that portion of the window. This guard or barrier shall be of sufficient strength and design so that it will prevent an individual from injuring him/herself by accidentally stepping into or kicking the glass. (II)

2615. Janitor's Closet (II)

There shall be a lockable janitor's closet in 24-hour facilities with 16 or more beds. Each closet shall be equipped with a mop sink or receptor and space for the storage of supplies and equipment.

2616. Storage Areas

A. Adequate general storage areas shall be provided for client and staff/volunteers belongings, equipment, and supplies.

B. Areas used for storage of combustible materials and storage areas exceeding 100 square feet in area shall be provided with an NFPA-approved automatic sprinkler system. (I)

C. In storage areas provided with a sprinkler system, a minimum vertical distance of 18 inches shall be maintained between the top of stored items and the sprinkler heads. The tops of storage cabinets and shelves attached to or built into the perimeter walls may be closer than 18 inches below the sprinkler heads. In nonsprinklered storage areas, there shall be at least 24 inches of space from the ceiling. (I)

D. All ceilings, floor assemblies, and walls enclosing storage areas of 100 square feet or greater shall be of not less than one-hour fire-resistive construction with 3/4-hour fire-rated door(s) and closer(s). (I)

E. Storage buildings on the premises shall meet the SBC requirement regarding distance from the licensed building. Storage in buildings other than on the facility premises shall be secure and accessible. An appropriate controlled environment shall be provided if necessary for storage of items requiring such an environment.

F. In mechanical rooms used for storage, the stored items shall be located away from mechanical equipment and shall not be a type of storage that might create a fire or other hazard. (I)

G. Supplies/equipment shall not be stored directly on the floor. Supplies/equipment susceptible to water damage/contamination shall not be stored under sinks or other areas with a propensity for water leakage.

H. In facilities licensed for 16 beds or more, there shall be a soiled linen storage room which shall be designed, enclosed, and used solely for that purpose, and provided with mechanical exhaust directly to the outside.

2617. Telephone Service

A. Appropriate telephone services shall be made available in the facility to clients and/or visitors.

B. At least one telephone shall be available on each floor of the facility for use by clients and/or visitors for their private, discretionary use; pay phones for this purpose are acceptable. Telephones capable of only local calls are acceptable for this purpose, provided other arrangements exist to provide client/visitor discretionary access to a telephone capable of long distance service.

C. At least one telephone shall be provided for staff/volunteers to conduct routine business of the facility and to summon assistance in the event of an emergency; pay station phones are not acceptable for this purpose.

2618. Location

A. Transportation. The facility shall be served by roads that are passable at all times and are adequate for the volume of expected traffic.

B. Parking. The facility shall have parking space to reasonably satisfy the needs of clients, staff/volunteers, and visitors.

C. Access to firefighting equipment. Facilities shall maintain adequate access to and around the building (s) for firefighting equipment. (I)

D. NTP facilities shall not operate within 500 feet of:

1. A church;

2. A public or private elementary or secondary school;

3. A boundary of any residential district;

4. A public park adjacent to any residential district;

5. The property line of a lot devoted to residential use.

2619. Outdoor Area

A. Outdoor areas deemed to be unsafe due to the existence of unprotected physical hazards such as steep grades, cliffs, open pits, high voltage electrical equipment, high speed or heavily traveled roads, and/or roads exceeding two lanes excluding turn lanes, lakes, ponds, or swimming pools, shall be enclosed by a fence or have natural barriers (shall be of size, shape, and density which effectively impedes travel to the hazardous area) to protect the clients. (I)

B. Where required, fenced areas that are part of a fire exit from the building, shall have a gate in the fence that unlocks in case of emergency per Special Locking Arrangements in the SBC. (I)

C. Mechanical or equipment rooms that open to the outside of the facility shall be kept protected from unauthorized individuals.

D. If a swimming pool is part of the facility, it shall be designed, constructed, and maintained pursuant to R.61-51. (II)

E. There shall be sufficient number of outside tables and comfortable chairs to meet the needs of the client.

SECTION 2700 - SEVERABILITY

2701. General

In the event that any portion of these regulations is construed by a court of competent jurisdiction to be invalid, or otherwise unenforceable, such determination shall in no manner affect the remaining portions of these regulations, and they shall remain in effect, as if such invalid portions were not originally a part of these regulations.

SECTION 2800 - GENERAL

2801. General

Conditions that have not been addressed in these regulations shall be managed in accordance with the best practices as interpreted by the Department.

PART II - OUTPATIENT FACILITIES

SECTION 2900 - PROGRAM DESCRIPTION

2901. General.

A. Outpatient facilities provide treatment/care/services to individuals who use, abuse, or are dependent upon or addicted to psychoactive substances, and their families, based upon an ITP in a nonresidential setting.

B. Outpatient treatment/care/services include assessment, diagnosis, individual and group counseling, family counseling, case management, crisis management services, and referral. Outpatient services are designed to treat the individual's level of problem severity and to achieve permanent changes in his/her behavior relative to alcohol/drug abuse. These services address major lifestyle, attitudinal and behavioral issues that have the potential to undermine the goals of treatment or the individual's ability to cope with major life tasks without the nonmedical use of alcohol or other drugs. The length and intensity of outpatient treatment varies according to the severity of the individual's illness and response to treatment.

2902. Assessment

A complete written assessment of the client shall be conducted within a time-period determined by the facility, but no later than the third visit. (II)

2903. Individualized Treatment Plan

An ITP in accordance with Section 701.C & D shall be completed within a time-period determined by the facility, but no later than the third visit. (II)

PART III - RESIDENTIAL TREATMENT PROGRAM FACILITIES

SECTION 3000 - PROGRAM DESCRIPTION

3001. General

A. Residential treatment programs utilize a multi-disciplinary staff for clients whose biomedical and emotional/behavioral problems are severe enough to require residential services and who are in need of a stable and supportive environment to aid in their recovery and transition back into the community. Twenty-four-hour observation, monitoring, and treatment shall be available.

B. Residential treatment programs shall provide or make available the following: (II)

1. Room and board including shared responsibility by clients for daily operation of the facility, e.g., cooking, cleaning, and maintenance of house rules as appropriate to the level of residential treatment provided.

2. Specialized professional consultation, supervision and direct affiliation with other levels of treatment;

3. Physician and nursing care and observation based on clinical judgement if appropriate to the level of treatment;

4. Arrangements for appropriate laboratory and toxicology tests as needed;

5. Availability of a physician 24 hours a day by telephone;

6. Counselors to assess and treat adult alcohol and/or other drug dependent clients and obtain and interpret information regarding the needs of these clients. Such counselors shall be knowledgeable of the biological and psychological dimensions of alcohol and/or other drug dependence;

7. Counselors to provide planned regimen of 24-hour professionally-directed evaluation, care and treatment services for addicted persons and their families to include individual, group, and/or family counseling directed toward specific client goals indicated in his/her ITP;

8. Health education services;

9. Educational guidance and educational program referral when indicated;

10. Vocational counseling for any client when indicated. For those not employed, staff/volunteers shall facilitate the client's pursuit of job placement, as appropriate;

11. Work activity participation by clients provided such activities are an integral part of the rehabilitative process, clients are made aware of the necessity of their participation in such activities, and such activities are not a substitute for staff;

12. Leisure time activities, including recreational activities;

13. Planned clinical program activities designed to enhance the client's understanding of addiction;

14. Multi-disciplinary individualized assessments and treatment are provided;

15. Family and significant other services;

16. Living skills training, as needed.

3002. Staffing

A. A staff member/volunteer/designated client shall be present and in charge at all times during daytime hours when clients are present in the facility. A staff member/volunteer/designated client-in-charge shall know how to respond to client needs and emergencies. (I)

B. Number of staff that shall be maintained in all facilities:

1. In each building, there shall be at least one staff member/volunteer/designated client on duty for each 10 clients or fraction there of present during peak activity hours. (II)

2. Required nighttime (after the evening meal) staffing shall be provided by a staff member, volunteer, or a designated client:

a. In each building, there shall be at least one staff member/volunteer/designated client on duty for each 20 clients or fraction thereof.

b. In buildings housing more than 10 clients, a staff member/volunteers/designated client shall be awake and dressed.

3. If a client serves as staff, the facility shall ensure that the following conditions are met: (II)

a. Client is approved by the administrator, in writing, to perform the duties required of a staff member during these particular hours, and s/he agrees in writing to perform them;

b. Client understands and enforces applicable regulatory requirements;

c. Client is trained and able to respond to emergencies;

d. Client is able to communicate with an on-call staff member;

e. Client is properly oriented to written applicable policies and/or procedures, to include the inservice training requirements in Section 502.

f. The condition of any other clients of the facility may preclude permitting a client to serve in a designated staff role.

3003. Admission (II)

Persons not eligible for admission are:

A. Any person who because of acute mental illness or intoxication presents an immediate threat of harm to him/herself and/or others;

B. Any minor as defined in Section 101.MM. See Section 804 for exceptions for minors;

C. Any person needing detoxification services, hospitalization, or nursing home care.

3004. Assessment (II)

A complete written assessment of the client in accordance with Section 101.H by a multi-disciplinary treatment team shall be conducted within a time-period determined by the facility, but no later than 72 hours after admission.

3005. Individualized Treatment Plan (II)

An ITP in accordance with Section 701.D shall be completed of the client by a multi-disciplinary treatment team within a time-period determined by the facility, but no later than seven days after admission.

3006. Facilities For Mothers With Children (II)

The health needs/care of the child shall be provided in the following manner:

A. Mothers shall provide or arrange for the health needs/care of their children.

B. Children shall be in the mother's care or in a child care program approved by DSS.

C. Arrangements for emergency care for the children shall be provided.

PART IV - DETOXIFICATION FACILITIES

SECTION 3100 - PROGRAM DESCRIPTION

3101. Freestanding Medical Detoxification Facility

Medical detoxification facilities shall provide at a minimum the following treatment and support services: (II)

A. Intake medical examination and screening by a physician or other authorized healthcare provider to determine need for medical services or referral for serious medical complications;

B. Continuing observation of each client's condition to recognize and evaluate significant signs and symptoms of medical distress and take appropriate action. Each client's general condition shall be monitored and his/her vital signs taken at a frequency as determined by the facility, but not less than three times during the first 72 hours of admission to the facility;

C. Medication as appropriate to assist in the withdrawal process;

D. A plan for supervised withdrawal, to be implemented upon admission;

E. Room, dietary service, and other care and supervision necessary for the health and safety of the client;

F. Counseling designed to motivate clients to continue in the treatment process and referral to the appropriate treatment modality.

3102. Social Detoxification Facility

Social detoxification facilities shall provide, at a minimum, the following services:

A. Screening and intake provided by staff/volunteers specially trained to monitor the client's physical condition;

B. Development of an ITP for supervised withdrawal;

C. Continuing observation of each client's condition to recognize and evaluate significant signs and symptoms of medical distress and take appropriate action;

D. Room, dietary service, and other care and supervision necessary for the maintenance of the client;

E. Counseling designed to motivate clients to continue in the treatment process.

3103. Staffing

A. A staff member/volunteer shall be present and in charge at all times. All staff members/volunteers shall be knowledgeable as to how to respond to emergencies. (I)

B. The staffing arrangement shall be, at a minimum, the following:

1. In each building, there shall be at least one direct care/counselor staff member for each 10 clients or fraction thereof on duty at all times. Staff members/volunteers shall be awake and dressed at all times, able to appropriately respond to client needs, and know how to respond to emergencies. (II)

2. In medical detoxification facilities only, staff/volunteers shall be under the general supervision of a physician or registered nurse; a physician, licensed nurse, or other authorized medical healthcare provider shall be present at all times. (I)

3. In social detoxification centers, there shall be consultation with medical authorities when warranted.

3104. Admission

A. Appropriate admission to a detoxification facility shall be determined by a licensed or certified counselor and subsequently shall be authorized by a physician or other authorized healthcare provider in accordance with Section 1001.A .

B. Persons not eligible for admission are:

1. Any person who, because of acute mental illness or intoxication, presents an immediate threat of harm to him/herself and others. (I)

2. Any person needing hospitalization, residential treatment program care, or nursing home care. (I)

3. Any person under 18 years of age. See Section 804 for exceptions for minors. (II)

4. Anyone not meeting facility requirements for admission.

C. Determination of the type of detoxification needed shall be guided by the definitions outlined in Sections 101.S.1 and 101.S.2.

3105. Assessment (II)

A clinical screening that includes a review of the client's drug abuse/usage and treatment history shall be conducted prior to the delivery of treatment.

3106. Individualized Treatment Plan (II)

An ITP shall be completed for supervised withdrawal within a time-period determined by the facility.

PART V - NARCOTIC TREATMENT PROGRAMS

SECTION 3200 - PROGRAM DESCRIPTION

3201. General

A. Narcotic treatment programs (NTP) provide medications for the rehabilitation of persons dependent on opium, morphine, heroin, or any derivative or synthetic drug of that group. Opioid maintenance therapy (OMT) is term that encompasses a variety of pharmacologic and non-pharmacologic treatment modalities, including the therapeutic use of specialized opioid compounds such as methadone and levo-alpha-acetylmethadol (LAAM) to psycho-pharmacologically occupy opiate receptors in the brain, extinguish drug craving, and thus establish a maintenance state. OMT is a separate service that can be provided in any level of care, as determined by the client's needs. Adjunctive non-pharmacologic interventions are essential and may be provided in OMT or through coordination with another addiction treatment provider.

B. An NTP has the following characteristics:

1. Support systems:

a. Linkage with or access to psychological, medical, and psychiatric consultation;

b. Linkage with or access to emergency medical and psychiatric affiliations with more intensive levels of care, as needed;

c. Linkage with or access to evaluation and ongoing primary medical care;

d. Ability to conduct or arrange for appropriate laboratory and toxicology tests;

e. Availability of physician to evaluate, prescribe, and monitor use of NTP medication, and of nurses and pharmacists to dispense and administer NTP medication.

2. Staff:

a. An interdisciplinary team of appropriately trained and certified or licensed addiction professionals, including a medical director, counselors, and the medical staff delineated below;

b. Licensed medical, nursing, or pharmacy staff who are available to administer medications in

accordance with the physician's prescription or orders. The intensity of nursing care is appropriate to the services provided by an outpatient treatment program that uses NTP medication;

c. A physician, available either in person or by telephone during NTP medication dispensing and clinic operating hours.

3. Therapies:

a. Interdisciplinary individualized assessment and treatment;

b. Assessing, prescribing, administering, reassessing and regulating dose levels appropriate to the individual; supervising detoxification from opiates, methadone or LAAM; overseeing and facilitating access to appropriate treatment, including medication for other physical and mental health disorders;

c. Monitored urine testing;

d. Counseling services;

e. Case management;

f. Psycho-education, including HIV/AIDS and other health education services.

3202. Services (II)

A. Services shall be directed toward reducing or eliminating the use of illicit drugs, criminal activity, or the spread of infectious disease while improving the quality of life and functioning of the client. NTP shall follow rehabilitation stages in sufficient duration to meet the needs of the client. These stages include initial treatment up to seven days in duration, early stabilization lasting up to eight weeks, long-term treatment, medical maintenance, and immediate emergency treatment when needed.

B. The NTP shall directly provide, contract or make referrals, for other services based upon the needs of the client.

C. As part of drug rehabilitative services provided by the NTP, each client shall be provided with individual, group and family counseling appropriate to his/her needs. The frequency and duration of counseling provided to clients shall be determined by the needs of the client and be consistent with the ITP. Counseling shall address, as a minimum:

1. Treatment and recovery objectives included in the ITP as well as education regarding HIV and other infectious diseases. HIV testing shall be made available as appropriate, while maintaining client confidentiality. Staff shall be knowledgeable of current procedures regarding the prevention and treatment of clients with HIV and sexually transmitted diseases (STD) to include testing and interpretation of test results;

2. Concurrent alcohol and drug abuse;

3. Involvement of family and significant others with the informed consent of the client;

4. Providing specialized treatment groups;

5. Guidance in seeking alternative therapies.

3203. Support Services

A. The NTP shall ensure that a comprehensive range of support services, including, but not limited to,

vocational, educational, employment, legal, mental health and family problems, medical, alcohol dependence or other addictions, HIV or other communicable diseases, pregnancy and prenatal care, and social services are made available to clients who demonstrate a need for such services. Support services may be provided either directly or by appropriate referral. Support services recommended and utilized shall be documented in the client record.

B. When appropriate, the NTP shall recommend that the client enroll in an education program, vocational activity (vocational evaluation, education or skill training) and/or to seek employment. Deviations from compliance with these recommendations shall be documented in the client's record.

C. The NTP shall establish and utilize linkages with community-based treatment facilities, i.e., an established set of procedures for referring clients to physician or other health care providers when the treatment of coexisting disorders become a major concern.

D. The NTP shall establish linkages with the criminal justice system to encourage continuous treatment of individuals incarcerated or on probation and parole.

3204. Services to Pregnant Clients (II)

A. The facility shall make reasonable effort to ensure that pregnant clients receive pre-natal care by a physician and that the physician is notified of the client's participation in the NTP when the facility becomes aware of the pregnancy.

B. The NTP shall provide, through in-house or referral and documented in the ITP, appropriate services/interventions for the pregnant client to include:

1. Physician consultation at least monthly;

2. Nutrition counseling;

3. Parenting training to include newborn care, health and safety, mother/infant interaction, and bonding.

C. Refusal of prenatal care shall be acknowledged through a signed statement from the client.

D. NTP medication dosage levels shall be maintained at an appropriate level for pregnant clients as determined by the NTP physician. (I)

E. When a pregnant client chooses to discontinue participation in the NTP, the program physician, in coordination with the attending obstetrician, shall supervise the termination process.

3205. Services to Adolescents (II)

A. Treatment and counseling shall be developmentally appropriate for the adolescent.

B. Adolescents who require special medical care shall be referred to a physician who has clinical experience with adolescents and addictions. Adolescents shall be monitored for treatment reactions that may be developmentally detrimental. A plan shall be in place in the event that special medical care is required.

3206. Operating Hours

The NTP shall be operational at least six days a week, except for holidays and days closed due to natural disaster. At least one designated staff member/volunteer shall be available "on-call" at all times for client emergencies and the verification of dosage levels.

3207. Admission (II)

A. The NTP shall only admit those clients whose narcotic dependency can be effectively treated by the NTP in accordance with applicable state and federal laws and regulations.

B. Applicants shall be screened in order to determine admission eligibility. The screening process shall include:

1. Evidence of tolerance to an opioid;

2. Current or past physiological dependence for at least one year prior to admission. The NTP physician may waive the one-year history of addiction when the client seeking admission meets one of the following criteria:

a. The client has been recently released from a penal or chronic care facility with a high risk of relapse;

b. The client has been previously treated and is at risk of relapse;

c. The client is pregnant and does not exhibit objective signs of opioid withdrawal or physiological dependence.

3. Evidence of multiple and daily self-administration of an opioid;

4. Reasonable attempts to confirm that the applicant is not enrolled in one or more other NTPs;

5. Drug history to determine dependence on opium, morphine, heroin or any derivative or synthetic drug of that group. The drug history shall include:

a. Drug(s) utilized;

b. Frequency of use;

c. Amount utilized;

d. Duration of use;

e. Age when first utilized;

f. Route of administration;

g. Previous treatment(s);

h. Criminal history related to drug abuse;

i. Family history of drug abuse and any medical problems.

6. A diagnosis of opioid addiction, referring to the initial screening criteria in Sections 3207.B.1-5 above, and the following behavioral signs:

a. Unsuccessful efforts to control use;

b. Large amounts of time obtaining drugs or recovering from the effects of abuse;

c. Continual use despite harmful consequences;

d. Obtaining opiates illegally;

e. Inappropriate use of prescribed opiates;

f. Harmful/negative effect on social, occupational or recreational activities.

C. Individuals shall not be admitted to the NTP to receive opioids for pain management only.

1. The NTP shall make the diagnostic distinctions between the disease of opioid addiction and the physical dependence associated with the chronic administration of opioids for the relief of pain, also known as pseudo-addiction. The drug seeking manifestations of persons who are opioid addicted for purpose of euphoria are very similar to the same behavioral manifestations of pseudo-addiction of those with chronic pain seeking only pain relief. Relevant criteria to distinguish pseudo-addiction from opioid addiction include:

a. Unsuccessful efforts to control use, including past failed detoxification efforts;

b. Large amounts of time spent in activities to obtain drugs, including past criminal involvements;

c. Written documentation from a pain management physician attesting to the clients need for NTP medication due to the client's physical dependence, resultant tolerance, and that physician's discontinuance of effective opioid pain relief measures with the client.

d. Continued use, despite having suffered lifestyle consequences of illicit use, e.g., arrests, hospitalizations, family problems, financial setbacks, and employment difficulties.

2. Appropriate referrals by the NTP physician shall be made as necessary, e.g., pain management specialist.

D. Minors may be treated pursuant to Section 804.

E. Prior to accepting an applicant for treatment, the NTP shall determine if the applicant requires special support services, e.g., psychiatric, prenatal, or alcohol/drug counseling.

F. The applicant's identity, including name, address, date of birth, and other identifying data shall be verified (See Section 701.A);

G. No client shall receive his/her initial dose of NTP medication until the program physician has determined that all admission criteria have been met, to include a completed physical examination by the program physician and confirmation of current medication regimen being taken by the applicant, i.e., contact attending physician.

3208. Physical Examination (II)

A. A physical examination conducted by the NTP physician shall be accomplished within 72 hours prior to the first dose of NTP medication and shall consist of the following as a minimum: (I)

1. Evidence of communicable/infectious disease, e.g., hepatitis, HIV, STD;

2. Pulmonary, liver, renal, and cardiac abnormalities;

3. Possible concurrent surgical problems;

4. Neurological assessment;

5. Vital signs;

6. Evidence of clinical signs of addiction, e.g., dermatologic sequella of addiction;

7. Examination of head, ears, eyes, nose, throat (thyroid), chest (including heart, lungs and breast), abdomen, extremities, and skin.

8. A single-step tuberculin skin test administered within one month prior to or not later than 10 days after admission as described in Section 1402.

B. The medical laboratory analysis shall be conducted within seven days of admission and shall include:

1. Complete blood count and differential to include multi-phasic blood chemistry profile;

2. Serological test for syphilis;

3. Initial urinalysis for drug profile;

4. Liver profile;

5. If indicated, an electrocardiogram, chest x-ray, Pap smear, biological pregnancy test, and/or screening for sickle cell disease.

3209. Urine Drug Testing (II)

A. Urine drug testing shall be used as a clinical tool for the purposes of diagnosis and in the development of ITP's.

B. Urine drug testing for the presence of NTP medication, benzodiazapines, cocaine, opiates, marijuana, amphetamines, and barbiturates, as well as other drugs, when clinically indicated by the NTP physician, shall be conducted at a frequency as determined by the NTP.

C. Once the results are available, they shall be addressed by the primary counselor with the client, in order to intervene in drug use behavior.

D. The NTP shall establish and implement collection procedures, including random collection of urine samples, to effectively minimize the possibility of falsification of the sample, to include security measures for prevention of tampering.

E. Following admission, the NTP shall ensure that significant treatment decisions are not based solely on the results of a single urine test.

F. Clients on a monthly schedule for whom urine drug testing reports indicate positive results for any illicit drugs, non-prescription drugs, or a negative result for NTP medication, shall be placed on a weekly urine drug test schedule for a period of time as clinically indicated by the NTP physician.

G. Clients granted take-home dosages shall undergo random urine drug testing on a monthly basis.

H. Only those laboratories certified in accordance with the federal Clinical Laboratories Improvement

Amendments of 1988 shall be utilized by the NTP for urinalysis.

3210. Orientation

Client orientation shall be accomplished within seven days of admission and documented in the client record. The orientation shall include:

A. NTP guidelines, rules, and regulations;

B. Confidentiality;

C. Urine drug testing procedure;

D. Administering NTP medication;

E. Signs and symptoms of overdose and when to seek emergency assistance;

F. Discharge procedures;

G. Treatment phases;

H. HIV/AIDS information/education;

I. Client rights (See Section 900);

J. Consent for autopsy;

K. The nature of addictive disorders and recovery including misunderstandings regarding methadone/LAAM treatment;

L. For pregnant clients, risk to the unborn child.

3211. Psycho-social Assessment (II)

A comprehensive psycho-social assessment shall be completed by the client's primary counselor once the client is stabilized but not later than 30 days following admission. The assessment shall include:

A. A description of the historical course of the addiction to include drugs of abuse such as alcohol and tobacco, amount, frequency of use, duration, potency, and method of administration, previous detoxification from NTP medication and/or treatment attempts, and any psychological or social complication.

B. A health history regarding chronic or acute medical conditions, such as HIV, STD's, hepatitis (B, C, Delta), TB, diabetes, anemia, sickle cell trait, pregnancy, chronic pulmonary diseases, and renal diseases.

C. Complete information related to the family of the client.

3212. Individualized Treatment Plan (II)

A. An ITP shall be developed within 30 days of admission with participation by the client and the primary counselor, as evidenced by their signatures. The ITP content shall be in accordance with Section 701.D.

B. Client progress in treatment and accomplishment of ITP goals shall be reviewed by the primary counselor not less than every 90 days during the first year of treatment and every six months thereafter. The counselor shall

sign and date these reviews.

3213. Emergency Medical Procedures (I)

Emergency medical procedures shall include, but not be limited to:

A. Client overdose or severe drug reaction;

B. Names and telephone numbers of individuals (e.g. physician, hospitals, EMT's) to be contacted in case of an emergency. These names and numbers shall be readily available within the facility;

C. Emergency dosing of NTP medications.

3214. Adverse Events

A. The NTP shall establish written procedures which address resolutions to adverse events such as:

1. Physical and verbal threats;

2. Violence;

3. Inappropriate behavior;

4. Medication errors;

5. Deaths;

6. Selling drugs on the premises;

7. Harassment and abuse.

B. Procedures to implement should adverse events occur shall include:

1. Documentation of the event and reporting as required to the Department (see Section 601);

2. Prompt review and investigation;

3. Timely and appropriate corrective action;

4. Monitoring to determine corrective action plan effectiveness.

3215. Readmission

If a client is readmitted to the same NTP, a physical examination will be required by the current NTP physician within 72 hours of admission.

3216. Staffing (II)

A. The NTP physician shall have authority over all medial aspects of care and make treatment decisions in consultation with treatment staff consistent with the needs of the client, clinical protocols, and research findings. At least one physician shall be available during dosing and facility operating hours either in person or by telephone for consultation and for emergencies.

B. A pharmacist or other person licensed to dispense NTP medications pursuant to the SC Code of Laws is

responsible for dispensing the amounts of NTP medications administered, and shall record and countersign all changes in dosing schedules.

C. The nursing staff shall include one licensed nurse. The total number of nurses on the staff shall be commensurate with NTP operating hours and the number of clients to be served in order to ensure that adequate nursing care will be provided at all times the facility is in operation. A licensed nurse shall be present at all times clients are in the facility.

D. There shall be an adequate number of qualified counselors on staff to ensure that necessary, appropriate and quality counseling and other rehabilitative services are provided in a timely manner. The NTP shall have a least one full-time counselor on staff for every 50 clients or fraction thereof. Counselors shall be qualified as specified in Section 504.

E. All direct care staff shall have training and experience in addictions and NTP medication treatment.

3217. NTP Medication Management (I)

A. A physician, licensed nurse, or registered pharmacist may administer NTP medication.

B. The NTP physician shall determine the initial and subsequent dosage and schedule, and prescribe such dose and schedule to include changes by verbal or written order to the pharmacist and licensed nurse. However, the verbal order shall be documented, signed, and dated by the NTP physician within 72 hours.

C. The procedure for administering NTP medication shall be as follows:

1. NTP medication, including guest and take-home doses, shall be administered to clients in oral liquid form and in single doses. Take-home bottles shall be labeled in accordance with federal and state law and regulations and shall contain necessary cautionary statements; caps shall be childproof.

2. No dose shall be administered until the client identity has been verified and the dosage compared with the currently ordered and documented dosage level.

3. The initial dose of methadone shall not exceed 30 mg. and the initial total daily dose for the first day shall not exceed 40 mg. unless the NTP physician justifies in the client record that 40 mg. did not suppress the abstinence symptoms after three hours of observation following the initial dose.

4. Ingestion shall be observed and verified by the person authorized to administer the medication.

5. A client's scheduled dose may be temporarily delayed if necessary, e.g., to obtain a urine sample or for counselor consultation. The dose shall not be withheld, however, for failure to comply with the NTP rules or procedures unless the decision is made to terminate the client's participation in the NTP. A dose may be withheld only when the NTP physician determines that such action is medically indicated.

6. There shall be written justification in the client record signed and dated by the NTP physician for doses in excess of 100 mg. of methadone per day after the first day.

D. A client transferring from another NTP facility shall have a physical examination and have his/her dose determined by a physician prior to receiving the first dosage.

E. When the NTP physician prescribes controlled substances other than NTP medications, such prescriptions shall not be administered to any client unless the NTP physician first examines the client and assesses his/her potential for abuse of such medications.

3218. Take-home Medication (II)

A. Take-home NTP medication may be given to clients who demonstrate a need for a more flexible schedule in order to enhance and continue the rehabilitative process. However, since NTP medication is a narcotic subject to abuse if not managed properly, precautions shall be taken to prevent its potential abuse. The NTP physician shall ensure that take-home medication is given to those clients who meet the following criteria for eligibility:

1. Adherence to NTP rules, regulations, and policies;

2. Length of time in the NTP and level of maintenance treatment;

3. Presence of NTP medication in urine samples;

4. Potential complications from concurrent health problems;

5. Lengthy travel distance to the facility;

6. Progress in maintaining a stable lifestyle as evidenced by:

a. Absence of abuse of narcotic and non-narcotic drugs;

b. Absence of alcohol abuse, or determination that the client is no longer abusing alcohol and is in treatment for the alcohol abuse problem;

c. Regularity of attendance at the NTP, to include required counseling sessions;

d. Absence of serious behavior problems, including loitering at the NTP;

e. Absence of known recent criminal activity;

f. Employment, school attendance, or other appropriate activity;

g. Assurance that take-home medication can be securely transported and stored by the client for his/her use only.

B. The decision to provide take-home medication to NTP clients and the amount provided shall be based upon and determined by the reasonable clinical judgement of the NTP physician and appropriately documented and recorded in the client's file prior to the initiation of the take-home dose. The NTP physician shall document compliance by the client with each and every one of the aforementioned requirements prior to providing the first take-home dose. (I)

C. The client's take-home status shall be reviewed and documented at least on a quarterly basis by the primary counselor.

D. If a client, due to special circumstances, such as illness, personal or family crisis, travel, or other hardship, is unable to conform to the applicable treatment schedule, s/he may be permitted to receive up to a two-week supply of NTP medication, based on the clinical judgment of the NTP physician. The justification for permitting the adjusted schedule shall be recorded in the client's record by the NTP physician.

E. One-time or temporary (usually not to exceed three days) take-home medication shall be approved by the facility for family or medical emergencies or other exceptional circumstances.

F. A client transferring from another NTP or readmitted after having left the NTP voluntarily and who has

complied with facility rules and program policies/procedures may be granted an initial take-home schedule that is no greater than that allowed at the time of transfer or voluntary discharge provided all criteria other than length of treatment are met.

G. A client discharged from another NTP shall only be initially granted take-home privileges from the new admitting NTP provided the requirements of Section 3218.A are met.

H. Take-home medication shall be labeled with the name of the NTP, address, telephone number, and packaged in conformance with state and federal regulations.

I. A diversion control plan shall be established to assure quality care while preventing the diversion of NTP medication from treatment to illicit use. The plan shall include:

1. Clinical and administrative continuous monitoring;

2. Problem identification, correction and prevention;

3. Accountability to the client and community;

4. NTP medication usage and amount accountability.

3219. Guest-Dosing (II)

A. When a client is separated from his/her NTP for an extended period, and the client is in the vicinity of a SC-licensed NTP, guest-dosing may occur provided there is: (I)

1. Authorization in writing from the sending NTP physician;

2. Information from the sending NTP to include at least the following: client name, identifying information, means of identity verification, dates of guest-dosing, amount of each day's dose, number of take-home doses (if any), urinalysis history, and any other information requested by the authorizing treatment NTP.

B. Records of guest-dosing shall be maintained at the NTP providing the guest-dosing.

C. Guest-dose status for a client shall not exceed 28 days unless there are special circumstances, and an extension of time is agreed upon by the two NTP's involved.

3220. Security of Medications (I)

A. The areas where NTP medication stocks are maintained or administered shall be secured. Access to controlled substances, which include NTP medication, shall be limited to persons licensed or registered to order, administer, or dispense those medications.

B. Immediately after administering, the remaining contents of the containers shall be purged (rinsed) to prevent the accumulation of residual NTP medication. The NTP shall ensure that take-home medication bottles are returned to the NTP. All used containers as well as take-home bottles given to clients shall be made inaccessible to unauthorized individuals. Used containers shall be disposed of by the NTP.

3221. Outcome Effectiveness

NTP outcome effectiveness measures shall include:

A. Improved client functioning, such as reducing or eliminating:

1. Abuse of licit and illicit drugs;

2. Criminal behavior;

3. Behaviors related to the spread of infectious diseases.

B. Improved quality of life.

3222. Detoxification from NTP Medication (II)

Detoxification from NTP medication shall be initiated only when strongly desired by the client, and shall include:

A. A schedule of dosage reduction from NTP medication that the client can tolerate;

B. Close documented monitoring of client clinical condition which may affect the detoxification process, i.e., symptoms of medial and emotional distress;

C. A review of the results of a recent pregnancy test;

D. A review of changes in counseling sessions and other support services during detoxification from NTP medication;

E. Providing continuing care after detoxification of NTP medication is completed.

3223. Community Liaison

The NTP shall assure that clients do not cause unnecessary disruption to the community, e.g., loitering in the vicinity of the NTP, or disorderly conduct.

Fiscal Impact Statement:

There will be no additional cost to the state and its political subdivisions.

Statement of Need and Reasonableness:

This statement was determined by staff analysis pursuant to SC Code Sections 1-23-115(C)(1)-(3) and (9)-(11).

DESCRIPTION OF REGULATION: R. 61-93, Standards for Licensing Outpatient Facilities for Chemically Dependent or Addicted Persons

Purpose of Regulation Amendment: R.61-93 is being revised in entirety and will replace the existing regulation. See the Synopsis above and the Determination of Need and Reasonableness below.

Legal Authority: The legal authority for R.61-93 is Section 44-7-110, *et. Seq.,* 1976 Code of Laws.

Plan for Implementation: The proposed amendment will take effect upon publication in the *State Register* following approval by the S.C. General Assembly. The amendment will be implemented by providing the regulated community with copies of the regulation.

DETERMINATION OF NEED AND REASONABLENESS OF THE REGULATION AMENDMENT BASED ON ALL FACTORS HEREIN AND EXPECTED BENEFITS:

R.61-93 was last amended in 1988. S.C. Code Ann. Section 1-23-120 of the S.C. Administrative Procedures Act requires state agencies to perform a review of its regulations every five years and update them if necessary.

In addition, the definition for "Facility for chemically dependent or addicted persons" in Section 44-7-130(14) of the SC Code already includes "residential services" as well as "outpatient." Also, Section 44-7-210 of the SC Code, enacted in 1998, requires that "The Department shall convene a study group to revise and propose licensure standards for methadone clinics." The amendment also requires that new methadone facilities obtain a Certificate of Need, and that DHEC may not issue a CON for new methadone facilities until revised methadone standards are promulgated

As a result of the review of this regulation, statutory mandates, and need to update and improve the overall quality of the regulation, the amendment is needed and reasonable. The amendment will clarify/add to the current regulation in a manner that will improve individual facility methods to provide quality care/treatment/service to clients.

DETERMINATION OF COSTS AND BENEFITS: No additional cost to the state and its political subdivisions is expected. Although there will be an increase in licensing fees, costs to the regulated community will still be minimum.

UNCERTAINTIES OF ESTIMATES: None

EFFECT ON ENVIRONMENT AND PUBLIC HEALTH: There will be no effect on the environment. The revision will promote public health by encouraging local solutions to local problems (more emphasis on facility policies and procedures/quality improvement) and contributing to the upgrading of services within 24-hour facilities, e.g., halfway houses and detoxification centers, by developing standards that are more alcohol and drug abuse treatment-related.

DETRIMENTAL EFFECT ON THE ENVIRONMENT IF THE REGULATION AMENDMENT IS NOT IMPLEMENTED: There will be no significant adverse effect on the public health if the revision is not implemented; however, 24-hour alcohol and drug abuse facilities will continue to be licensed under Regulation 61-84, Standards for Licensing Community Residential Care Facilities, which has limited alcohol and drug abuse treatment-related standards. In addition, new narcotic treatment programs cannot be established until revised standards are promulgated, pursuant to the requirements of Section 44-7-210 of the SC Code.

Document No. 2530
DEPARTMENT OF HEALTH AND ENVIRONMENT CONTROL
CHAPTER 61
Statutory Authority: S.C. Code Sections 44-1-140(11) and 48-1-10 et seq.

R.61-66, Industrial Waste Disposal Sites and Facilities
R.61-70, Sanitary Landfill Design, Construction and Operation

Synopsis:

In the interest of good government and efficiency, the Department is repealing Regulations 61-66 and 61-70. Regulations 61-66 and 61-70 were promulgated in 1972 and 1971 respectively and were never amended. Each of these regulations contains antiquated and obsolete requirements which were effectively superseded by standards promulgated pursuant to Solid Waste Management Regulations 61-107.11, Construction, Demolition, and Land-Clearing Debris Landfills, 61-107.13, Municipal Solid Waste Incinerator Ash Landfills, 61-107.16, Industrial Solid Waste Landfills, and 61-107.258, Municipal Solid Waste Landfills. Repeal of these regulations will eliminate any confusion as to which solid waste regulations apply and are being enforced. See Statement of Need and Reasonableness herein.

Instructions:

Regulation 61-66, Industrial Waste Disposal Sites and Facilities, is repealed. Delete this regulation from Chapter 61 regulations in the S.C. Code of Laws.

Regulation 61-70, Sanitary Landfill Design, Construction and Operation, is repealed. Delete this regulation from Chapter 61 regulations in the S.C. Code of Laws.

Fiscal Impact Statement: The Department estimates there will be no cost to the State or its political subdivisions regarding repeal of these regulations.

Statement of Need and Reasonableness:

The Statement of Need and Reasonableness of proposed repeal of Regulations 61-66 and 61-70 was determined by staff analysis pursuant to S.C. Code Section 1-23-115(c)(1)-(3) and (9)-(11):

DESCRIPTION OF REGULATION: Repeal of Regulation 61-66, Industrial Waste Disposal Site and Facilities, and Regulation 61-70, Sanitary Landfill Design, Construction and Operation.

Purpose: The purpose of this promulgation is to repeal Regulations 61-66 and 61-70. See Preamble above.

Authority: S.C. Code Sections 44-1-140(11) and 48-1-10 et seq.

Plan for Implementing: None.

DETERMINATION OF NEED AND REASONABLENESS OF THE REGULATION BASED ON ALL FACTORS HEREIN AND EXPECTED BENEFIT: The requirements and need of Regulations 61-66 and 61-70 have effectively been superseded by standards established pursuant to Regulations 61-107.11, 61-107.13, 61-107.16, and 61-107.258. See Preamble above.

DETERMINATION OF COSTS AND BENEFITS:

Cost: Not applicable. There will be no fiscal or economic impact on the State or its political subdivisions and the regulated community by the repeal of Regulations 61-66 and 61-70.

Benefit: Repeal of these antiquated and obsolete regulations will eliminate any confusion as to which solid waste regulations apply and are enforceable.

UNCERTAINTIES OF ESTIMATES:

The repeal of Regulations 61-66 and 61-70 will not create a burden for the public, the State and its political subdivisions.

EFFECT ON ENVIRONMENT AND PUBLIC HEALTH: There will be no environmental or public health effect.

DETRIMENTAL EFFECT ON THE ENVIRONMENT AND PUBLIC HEALTH IF THE REGULATION IS NOT IMPLEMENTED. There will be no detrimental effect on the environment and public health by repeal of Regulations 61-66 and 61-70.

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THE SOUTH CAROLINA STATE REGISTER

An official state publication, *The South Carolina State Register* is a temporary update to South Carolina's official compilation of agency regulations--the *South Carolina Code of Regulations*. Changes in regulations, whether by adoption, amendment, repeal or emergency action, must be published in the *State Register* pursuant to the provisions of the Administrative Procedures Act. The *State Register* also publishes the Governor's Executive Orders, notices or public hearings and meetings, and other documents issued by state agencies considered to be in the public interest. All documents published in the *State Register* are drafted by state agencies and are published as submitted. Publication of any material in the *State Register* is the official notice of such information.

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Documents are arranged within each issue of the *State Register* according to the type of document filed:

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Pending Regulations Submitted to General Assembly are regulations adopted by the agency pending approval by the General Assembly.
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Executive Orders are actions issued and taken by the Governor.

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Documents will be accepted for filing on any normal business day from 8:30 A.M. until 5:00 P.M. All documents must be submitted in the format prescribed in the Standards Manual for Drafting and Filing Regulations.

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	Jan.	Feb.	Mar.	Apr.	May	June	July	Aug.	Sept.	Oct.	Nov.	Dec.
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CERTIFICATE

PURSUANT TO SECTION 1-23-20, CODE OF LAWS OF SOUTH CAROLINA, 1976, THIS ISSUE CONTAINS ALL PREVIOUSLY UNPUBLISHED DOCUMENTS REQUIRED TO BE PUBLISHED AND FILED BEFORE THE CLOSING DATE OF THE ISSUE.

Lynn P. Bartlett
Editor

ADOPTION, AMENDMENT AND REPEAL OF REGULATIONS

To adopt, amend or repeal a regulation, an agency must publish in the *State Register* a Notice of Drafting; a Notice of the Proposed Regulation that contains an estimate of the proposed action's economic impact; and, a notice that gives the public an opportunity to comment on the proposal. If requested by twenty-five persons, a public hearing must be held at least thirty days after the date of publication of the notice in the *State Register*.

After the date of hearing, the regulation must be submitted to the General Assembly for approval. The General Assembly has one hundred twenty days to consider the regulation. If no legislation is introduced to disapprove or enacted to approve before the expiration of the one-hundred-twenty-day review period, the regulation is approved on the one hundred twentieth day and is effective upon publication in the *State Register*.

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AN EMERGENCY REGULATION MAY BE PROMULGATED BY AN AGENCY IF THE AGENCY FINDS IMMINENT PERIL TO PUBLIC HEALTH, SAFETY OR WELFARE. EMERGENCY REGULATIONS ARE EFFECTIVE UPON FILING FOR A NINETY-DAY PERIOD. IF THE ORIGINAL FILING BEGAN AND EXPIRED DURING THE LEGISLATIVE INTERIM, THE REGULATION CAN BE RENEWED ONCE.

REGULATIONS PROMULGATED TO COMPLY WITH FEDERAL LAW

Regulations promulgated to comply with Federal Law are exempt from General Assembly review. Following the notice of proposed regulation and hearing, regulations are submitted to the *State Register* and are effective upon publication.

EFFECTIVE DATE OF REGULATIONS

Final Regulations take effect on the date of publication in the *State Register* unless otherwise noted within the text of the regulation.
Emergency Regulations take effect upon filing with the Legislative Council and remain effective for ninety days. If the original ninety-day period begins and expires during legislative interim, the regulation may be renewable once.

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PART ONE

REGULATIONS SUBMITTED TO GENERAL ASSEMBLY

GOVERNOR'S EXECUTIVE ORDERS

NOTICES

NOTICES OF DRAFTING REGULATIONS

TABLE OF CONTENTS

PROPOSED REGULATIONS

EMERGENCY REGULATIONS

FINAL REGULATIONS

PART TWO

FINAL REGULATIONS

Document No. 2538

DEPARTMENT OF HEALTH AND ENVIRONMENTAL CONTROL

CHAPTER 61

Statutory Authority: S.C. Code Sections 13-7-10, 13-7-40 and 13-7-45 et seq. and Supplement

R.61-64, X-Rays (Title B)

Synopsis:

This amendment will substantially revise R.61-64, *X-Rays (Title B)* in its entirety. General areas of revision include: ensuring compatibility with Federal regulations; further clarifying and simplifying the regulations; adding new definitions as required; deleting regulations that are no longer applicable or necessary; and, increasing fees. Specific areas of revision include: changing State mammography regulations to be compatible with the Federal mammography requirements; adding regulations to allow South Carolina to become a certifying body for mammography facilities; simplifying the regulations relating to therapeutic equipment; clarifying and strengthening equipment performance standard testing; changing equipment standards to be compatible with Federal equipment standards; adding provisions for bone densitometry units; reorganizing the civil penalty schedule into a matrix system to be more consistent with the rest of the Department; increasing registration fees, which have not been increased since 1993; reorganizing the fee schedule to include requiring an application fee for new facilities and a shielding plan review fee (currently there are no fees); and, increasing instrument calibration fees, which have not been increased since 1993. The fee increases are needed due to the mandate, under the Atomic Energy and Radiation Control Act, to recover the cost of the program through the collection of fees. See Discussion of Revisions below and Statement of Need and Reasonableness herein.

Discussion of Revisions:

(1) Add new definitions to incorporate new requirements.

SECTION	REVISION
R.61-64, Part IX	Forty-seven definitions are added in alphabetical/numerical order. All of these definitions were added for compatibility purposes with the Federal Mammography requirements. Definitions are added for: "Accreditation body", "Action limits", "Adverse Event", "Air kerma", "Breast Implant", "Category I", "Certification", "Clinical Image", "Committed dose equivalent", "Consumer", "Continuing education unit or continuing education credit", "Contact hour", "Diagnostic mammography", "Direct instruction", "Direct supervision", "Established operating level", "Facility or mammography installation", "FDA", "First allowable time", "Interim regulations", "Interpreting physician", "Lead interpreting physician", "Mammogram", "Mammographic modality", "Mammography", "Mammography equipment evaluation," "Mammography medical outcomes audit", " Mammography unit or units", "Mean optical density", "Medical physicist", "MQSA", "Multi-reading", "Phantom" (Part V) , "Phantom image", "Physical science", "Positive mammogram", "Provisional certificate", "Qualified instructor", "Quality control technologist", "Radiological Technologist", "Screening mammography", "Serious adverse event", "Serious complaint", "Standard breast", "Survey", "Time cycle" and "Traceable to a national standard."

(3) Revise existing definitions to further clarify existing requirements.

R.61-64, Part IX	Three definitions are revised to include greater detail and descriptions. The revised definitions are: "Calendar quarter", "Misadministration" and "Phantom" (Part VI).

(4) Clarify and strengthen existing requirements.

R.61-64.1.5.2 Revised conditions for exemptions to change wording for further clarification and to reflect previously revised dose limits.

R.61-64.1.7 Revised to indicate notification with respect to action taken or planned to correct violations must be in writing and to specify a description must be provided of actions taken to correct the violations.

R.61-64.1.8 REVISED ENFORCEMENT PROVISIONS FOR FURTHER CLARIFICATION, TO SPECIFY CONDITIONS THAT WARRANT THE ISSUANCE OF AN ADMINISTRATIVE ORDER AND TO ADD PROVISIONS FOR IMPOUNDING OF RADIATION SOURCES.

R.61-64.1.10 REVISED RECORD KEEPING REQUIREMENTS TO ENSURE RECORDS ARE READILY AVAILABLE AND TO REQUIRE AN INVENTORY LISTING OF EQUIPMENT BE AVAILABLE TO THE DEPARTMENT. REVISED TO INCLUDE REFERENCES TO PART V, MAMMOGRAPHY.

R.61-64.1.11 REVISED TO ADD FURTHER CLARIFICATION AND STRENGTHENING TO EXISTING THERAPY AND DIAGNOSTIC MISADMINISTRATION NOTIFICATION AND REPORTING REQUIREMENTS.

R.61-64.1.12.2 REVISED TO CLARIFY AND STRENGTHEN EXISTING PROHIBITION OF MAKING A MATERIAL FALSE STATEMENT BY LISTING INFORMATION THAT CAN BE POTENTIALLY FALSIFIED.

R.61-64.1.13.2 Revised to substitute "Major", "Moderate" and "Minor" severity violations for "Severity Level I", "Severity Level IV" and "Severity Level VI" violations, respectively. Revised to include violations that represent deviation from the requirements. Revised to delete references to Severity Level II, III and V violations. The proposed civil penalty matrix will only have three severity levels, but this will adequately cover all previous severity levels.

R.61-64.1.13.3 Revised to make reference to the civil penalty matrix.

R.61-64.2.2.2 Revised to further clarify that other electronic products are exempt.

R.61-64.2.5 Revised to add that the Department will implement an identification system for registered x-ray equipment.

R.61-64.2.62 Revised to require vendors to submit samples of equipment performance test procedures and forms and a sample of a shielding plan for review.

R.61-64.2.6.6.9.3 REVISED TO INLCUDE DIAGNOSTIC RADIOLOGICAL PHYSICISTS BY THE AMERICAN BOARD OF RADIOLOGY.

R.61-64.2.7.3.3 REVISED TO CLARIFY TESTING REQUIREMENTS FOR LOANER UNITS. REVISED TO CLARIFY TESTS TO BE PERFORMED UPON INITIAL INSTALLATION AND WHO IS REQUIRED TO PERFORM THE TESTS.

R.61-64.2.6.6.7.1 REVISED TO INCLUDE CERTIFICATION IN THERAPEUTIC RADIOLOGICAL

PHYSICS BY THE AMERICAN BOARD OF MEDICAL PHYSICS.

R.61-64.2.6.6.9.3 REVISED TO INCLUDE CERTIFICATION IN DIAGNOSTIC RADIOLOGICAL PHYSICS BY THE AMERICAN COLLEGE OF RADIOLOGY.

R.61-64.2.7.3.4 Revised to require vendors to keep records pertaining to maintenance, repair, alterations, or reassemblies of x-ray equipment.

R.61-64.2.10.6 Revised schedule of fees to indicate the fee increases for each specific equipment type. The fee increase was needed to recover the cost of implementing the Department's Division of Electronic Products program.

R.61-64.3.1.3 Revised to add applicability to persons who install and service x-ray equipment.

R.61-64.3.4.4 Revised to limit the monitoring of doses from multiple locations to persons likely to receive less than fifty percent of their occupational exposure.

R.61-64.3.12.2 Revised to clarify consideration of monitoring results for the badge worn under the apron as a permanent record when two monitoring devices are worn. Revised to require detailed written procedures for use of monitoring devices worn in this manner.

R.61-64.3.19 REVISED TO CHANGE RETENTION OF RECORDS OF SURVEYS FROM 3 TO 5 YEARS.

R.61-64.3.20.6 REVISED TO CHANGE RETENTION OF RECORDS OF SURVEYS FROM 3 TO 5 YEARS.

R.61-64.4.2.3 Revised to delete the effective date of the regulations.

R.61-64.4.2.4 Revised to require registrants to adhere to their approved operating procedures and to maintain documentation that operators have read and agree to adhere to the operating procedures.

R.61-64.4.2.10 REVISED TO REQUIRE AN ANNUAL INTEGRITY CHECK OF LEAD APRONS AND GLOVES, AND TO DOCUMENT AND KEEP RECORDS OF THE TESTING.

R.61-64.4.2.13 Revised to add "electronically produced ionizing radiation" in order to be more precise.

R.61-64.4.2.13.1 Revised to require proper protection during demonstrations or training, and to require phantoms, not humans, to be used for demonstrations and training.

R.61-64.4.2.14.7 REVISED TO REQUIRE DOCUMENTATION AND RECORD RETENTION OF LEAD APRON AND GLOVE TESTING.

R.61-64.4.2.15.4 REVISED TO CHANGE "X-RAY TECHNOLOGIST" TO "RADIOLOGICAL TECHNOLOGIST."

R.61-64.4.2.16.1.2 Revised to add a reference to RHB 3.12.2 if more than one monitoring device is worn.

R.61-64.4.2.17 Revised to indicate dental and veterinary x-ray equipment are exempt from x-ray log requirements. Revised to indicate x-ray log records must be maintained for two years. Revised to exempt radiation therapy simulator systems.

R.61-64.4.2.18.1 Revised to clarify performance testing of x-ray equipment and to specify minimum performance criteria and testing frequency. Revised to indicate which facilities are exempt from testing. Revised to refer to Appendix F for specific testing parameters.

R.61-64.4.2.18.4 Revised to further clarify criteria for conducting a repeat analysis, and to indicate which facilities are exempt from this requirement.

R.61-64.4.2.19.2.5 Revised to require the specified developer temperature to be immediately available instead of posted.

R.61-64.4.2.19.3.4 REVISED TO REQUIRE FILM CASSETTES AND INTENSIFYING SCREENS TO BE INSPECTED IN ACCORDANCE WITH OPERATING PROCEDURES INSTEAD OF "PERIODICALLY." REVISED TO REQUIRE MAINTENANCE OF RECORDS OF INSPECTION AND CLEANING.

R.61-64.4.3.11 Revised to indicate use of mechanical timers is prohibited and delete previous reference to having 180 days to achieve compliance.

R.61-64.4.4.3 REVISED TO REQUIRE A FACILITY TO MAINTAIN A COPY OF SHIELDING PLANS AND AREA SURVEYS.

R.61-64.4.4.4 Revised to require the submission of "as-built" drawings within 30 days after construction and installation are complete, and to further specify what they must include.

R.61-64.4.5.4.2 REVISED TO INDICATE JANUARY 1, 1993, THE EFFECTIVE DATE OF THE LAST REVISION, FOR THE PURPOSE OF DETERMINING OPERATOR PROTECTION.

R.61-64.4.5.4.2.6 Revised to add provisions for an audible indication of x-ray production from the operator's position.

R.61-64.4.5.11.3 Revised to indicate all pass throughs for dental units shall be securely interlocked.

R.61-64.4.6.3 Revised to substitute "appropriate and/or proper" for "safe" for further clarity regarding additional requirements.

R.61-64.4.7 Revised to include the requirements as applicable for mammography.

R.61-64.4.7.5 Revised for further clarity to indicate exposure reproducibility testing is to be performed on "selectable" technique factors.

R.61-64.4.7.9.2 Revised to add the Department may grant exemptions upon determination that patient safety and image quality are not compromised.

R.61-64.4.7.13 Revised to further clarify requirements for systems with Positive Beam Limitation (PBL).

R.61-64.4.8.1	Revised to indicate an exception to the applicability of the regulations for mobile radiographic equipment.
R.61-64.4.8.8	Revised to specifically refer to the requirements of RHB 4.4.
R.61-64.4.9.4.1	Revised to indicate the requirements for fluoroscopic x-ray equipment are applicable to units manufactured prior to May 19, 1995.
R.61-64.4.9.4.3.6	Revised for further clarification to specify that entrance exposure rate measurements need to be performed in each mode used clinically.
R.61-64.4.9.4.3.7	Revised to delete "periodically" since testing frequencies are now specified for the measurement of maximum entrance exposure rate.
R.61-64.4.9.4.3.8	Revised to delete "periodically" since testing frequencies are now specified for the measurement of typical entrance exposure rate. Text was added for further clarity to specify that measurements need to be performed in each mode used clinically.
R.61-64.4.11.3.2.1	Revised to clarify type of radiological physicist performing CT spot checks.
R.6-64.4.12.1	Revised to include correct citation and delete regulations that are not applicable.
Appendix A	Revised for further clarification to indicate the information submitted to perform healing arts screening must be reviewed and approved by the Department.
Appendix C	Revised to specify the exposure switch location for an operator's barrier.
R.61-64.6.3.2.1	Revised to delete submission of operating procedures upon request for therapy units since this will become required.
R.61-64.6.3.2.2	Revised to require documentation that therapy equipment operators have read and agree to adhere to the operating procedures.
R.61-64.6.4.2.4	Revised to specify requirements for location and functioning parameters for interlocks in therapy treatment rooms.
R.61-64.6.4.4.1.1	Revised to delete unnecessary yearly area surveys for therapy equipment.
R.61-64.6.4.4.4	Revised to include prohibited use of therapy equipment until the Department's requirements have been met.
R.61-64.6.5.3	Revised for further clarification to reflect that the requirements are for "equipment installed after the effective date of these regulations" and not "new" equipment.
R.61-64.6.5.5.1	Revised to change "effective date of these regulations" to "January 1, 1994" which is the effective date of the last revision.
R.61-64.6.5.5.2	Revised to change "effective date of these regulations" to "January 1, 1994" which is the effective date of the last revision.
R.61-64.6.5.8.3	Revised to change "effective date of these regulations" to "January 1, 1994" which is the effective date of the last revision.

R.61-64.6.5.8.4	Revised to change "effective date of these regulations" to "January 1, 1994" which is the effective date of the last revision.
R.61-64.6.5.14	Revised to delete references that the regulations only apply to new equipment.
R.61-64.6.6.1.2	Revised to clarify that "dosimetry" refers to patient dosimetry.
R.61-64.6.6.5	Revised to prohibit use of the therapy equipment unless the Department's regulations have been met.
R.61-64.7.3.5.5	Revised to change "accidental" to "inadvertent" for further clarification.
R.61-64.7.3.1	Revised to include applicability to RHB 2.3.
R.61-64.7.3.6	Revised to change "one hour at any specified tube rating" to "any given hour at any specified tube rating" for further clarification.
R.61-64.7.3.7	Revised to change "one hour" to "any given hour" for further clarification. Revised to correct "2.5 mSv" to ".0025 mSv."
R.61-64.7.6.1	Revised to clarify radiation area requirements for local components of analytical x-ray equipment.
R.61-64.7.7.1	Revised to delete references to the maximum range of a survey instrument for analytical x-ray equipment since the minimum range of the equipment is more critical in performing surveys.
R.61-64.7.7.2.4	Revised to require survey instruments for analytical x-ray equipment to be calibrated at energy levels encountered.
R.61-64.7.8.1	Revised to operators of analytical x-ray equipment to demonstrate competence in use or repair of the equipment.
R.61-64.8.2	Revised to delete "suitable" from locking device requirements for further clarification.
R.61-64.8.4.1	Revised to specify radiation survey instruments for industrial x-ray equipment must meet the Department's requirements, to add a minimum operating range requirement for the instruments and to add specific calibration requirements.
R.61-64.8.5	Revised to use the more correct term of "kVp" instead of "voltage and kVA."
R.61-64.8.6	Revised to include applicability to RHB 2.3.
R.61-64.8.8.4	Revised for further clarification to specify that operating procedures must address locking and securing industrial x-ray equipment "when not in use or in storage."
R.61-64.8.11	Revised for further clarification to specify that training must be in "hazards of exposure to radiation," not "hazards of excessive exposure to radiation."
R.61-64.8.13.1	Revised to indicate cabinet radiography units must be surveyed annually instead of quarterly, which is more reasonable and still ensures adequate radiation safety.
R.61-64.8.13.1.2	Revised to require at least annual operational tests for high radiation area control devices.

R.61-64.8.13.2.4 Revised to require a Class IX vendor to review shielding plans and for the registrant to submit these to the Department.

R.61-64.8.13.2.6 Revised to delete a requirement for "as-built" drawings since areas surveys will be required to be submitted for shielded rooms.

R.61-64.11.3.1 Revised to indicate fee increases for the calibration of survey instruments.

(4) Add new requirements.

R.61-64.1.2.8 TEXT WAS ADDED TO PROHIBIT HAND-HELD IMAGING DEVICES, EXCEPT MINI C-ARMS THAT ARE DESIGNED TO BE HAND HELD.

R.61-64.1.2.9 Text was added to prohibit non-licensed practitioners from performing diagnostic positioning during radiation exposure.

R.61-64.1.2.10 Text was added to prohibit persons from using fluoroscopy when not in the presence of a licensed practitioner for uses other than therapy simulations, maintenance activities and training courses.

R.61-64.1.2.11 Text was added to prohibit use of direct exposure x-ray film for medical purposes.

R.61-64.1.2.12 Text was added to prohibit use of a mammographic imaging system not specifically designed by the manufacturer for imaging of the breast.

R.61-64.1.2.13 Text was added to prohibit intentional human exposure except for healing arts purposes, or unless specific research protocols are followed.

R.61-64.1.4.3 TEXT WAS ADDED TO REQUIRE THE SUBMISSION OF TESTS AND SURVEYS TO THE DEPARTMENT UPON REQUEST.

R.61-64.1.13 Text was added to define the civil penalty matrix and how to calculate the **PENALTIES.**

R.61-64.1.13.4.2 Text was added to define violations that constitute an imminent health and safety hazard and indicate the Department could impose civil penalties up to $25,000 for these violations.

R.61-64.1.13.4.3 Text was added to indicate Examples of Violations with Potential for Harm.

R.61-64.1.13.4.4 TEXT WAS ADDED TO INDICATE EXAMPLES OF VIOLATIONS CATEGORIZED BY DEVIATION FROM THE REQUIREMENT.

R.61-64.1.14 Text was added to require registrants to comply with other laws.

R.61-64.1.15 Text was added to include a provision for severability. This was added as required.

R.61-64.2.3.1 Text was added to require a non-refundable application fee of $50 upon submission of a "Facility Registration Approval Request" form. This provision was added to help recover the cost of the application review process.

R.61-64.2.3.2 TEXT WAS ADDED TO REQUIRE A NON-REFUNDABLE SHIELDING PLAN REVIEW FEE OF $50 PER X-RAY CONTROL UPON SUBMISSION OF A SHIELDING PLAN. THIS PROVISION WAS ADDED TO HELP RECOVER THE COST OF PLAN REVIEW AND TO DISCOURAGE THE DUPLICATION OF SUBMISSION OF SHIELDING PLANS.

R.61-64.2.4.1.2 TEXT WAS ADDED TO REFER TO THE APPLICATION AND SHIELDING PLAN REVIEW FEES.

R.61-64.2.4.2.2 TEXT WAS ADDED TO REFER TO THE APPLICATION AND SHIELDING PLAN REVIEW FEES.

R.61-64.2.4.3.2 Text was added to refer to the application and shielding plan review fees.

R.61-64.2.5.1 Text was added to require registration stickers, issued by the Department, on controls to indicate the control's status. This will allow vendors to determine a control's status.

R.61-64.2.7.3.6 TEXT WAS ADDED TO REQUIRE VENDORS TO KEEP RECORDS OF X-RAY EQUIPMENT TESTING AND TO SPECIFY THE DESIGN AND CONTENT OF THE EQUIPMENT PERFORMANCE TEST. THE TEXT WAS ADDED TO ENSURE ALL REQUIRED PARAMETERS ARE TESTED AND CAN BE REVIEWED IN AN UNDERSTANDABLE AND CONSISTENT MANNER.

R.61-64.2.7.5 TEXT WAS ADDED TO REQUIRE VENDORS TO MAINTAIN SUFFICIENT CALIBRATED AND OPERABLE SURVEY INSTRUMENTS, TO CALIBRATE THE INSTRUMENTS AT A SPECIFIED FREQUENCY AND TO MAINTAIN RECORDS OF CALIBRATIONS.

R.61-64.3.12.1.1.5 TEXT WAS ADDED TO REQUIRE INDIVIDUAL PERSONNEL MONITORING FOR ALL INDIVIDUALS WHO OPERATE MOBILE OR PORTABLE X-RAY EQUIPMENT, EXCEPT PERIPHERAL BONE DENSITOMETRY SYSTEMS.

R.61-64.4.2.19.1.5 Text was added to indicate that each darkroom must have a functional safelight.

R.61-64.4.2.19.2.3.1 Text was added to indicate that each darkroom must have a functional safelight.

R.61-64.4.2.19.2.7 Text was added to require and specify frequency of densitometric and sensitometric testing, and to retain documentation of such testing.

R.61-64.4.2.19.2.8 Text was added to require records of processor maintenance to be kept for at **LEAST TWO YEARS OR UNTIL THE NEXT DEPARTMENT INSPECTION.**

R.61-64.4.4.7 Text was added to require a radiation area survey to be performed by a Class IX vendor within thirty days of installation of x-ray equipment if the approved shielding plan indicates ordinary building materials are not sufficient for radiation protection purposes. The Department may determine that a survey is not needed. This will further ensure adequate radiation protection exists.

R.61-64.4.4.11 Text was added to indicate specific requirements for mobile and portable x-ray units used in conjunction with a permanently installed cassette holder.

R.61-64.4.5.4.2.3 Text was added to specify patient viewing requirements for systems installed before the effective date of this regulation.

R.61-64.4.5.4.2.4 Text was added to specify patient viewing requirements for systems installed after the effective date of this regulation.

R.61-64.4.7.15 TEXT WAS ADDED FOR MINIMUM FIELD SIZE REQUIREMENTS FOR COLLIMATORS.

R.61-64.4.8.12 Text was added to require minimum source-to-skin distances for mobile and portable x-ray units.

R.61-64.4.9.2.3.2 Text was added for spot film field size limits because it was inadvertently omitted from the last revision. The Department has always tested these parameters and made recommendations.

R.61-106.4.9.4.2 Text was added for fluoroscopic exposure rate limits for x-ray equipment manufactured after May 19, 1995.

R.61-64.4.10 TEXT WAS ADDED FOR REGISTRATION, SHIELDING, LOCATION AND ADMINISTRATIVE REQUIREMENTS FOR X-RAY BONE DENSITOMETRY SYSTEMS.

R.61-64.4.11.2.1 Text was added for computed tomography (CT) units regarding control panel and x-ray control location.

R.61-64.4.11.2.3 Text was added for CT units regarding radiation protection precautions to be taken for control rooms with open areas leading to the gantry.

R.61-64.4.11.2.4 Text was added for CT units requiring outside door(s) of the gantry room to be interlocked.

R.61-64.4.11.4 Text was added to require the operator's manual, radiation area surveys, x-ray operating procedures and current equipment performance testing to be available at the CT operator's console.

R.61-64.4.11.5 Text was added for CT units that prohibit unnecessary personnel from being present in the area of the CT unit during exposures.

R.61-64.4.11.6 Text was added to regulate CT units used in radiation therapy treatment planning. The units are proposed to be exempt from dose measurement requirements, but to comply with all other CT requirements.

R.61-64.4.12.10.1 Text was added for veterinary units that require means to accurately center the x-ray field. This has been tested in the past, but corrective action was recommended, not required.

R.61-64.4.12.10.2 Text was added for veterinary units that require collimation of the useful beam to the area of clinical interest. This will further ensure adequate operator protection.

R.61-64.4.12.10.3 Text was added for veterinary units that require the collimator to be able to be adjusted to a minimum field size.

R.61-64.4.12.20 Text was added to regulate veterinary CT x-ray systems.

Appendix F Text was added to specify minimum criteria for performance tests for medical radiographic, fluoroscopic, radiation therapy simulation, CT and dental units.

Part VI A section was added to specify quality standards and certification requirements for facilities performing mammography. This section was adopted from the Federal requirements and the Suggested State Regulations published by the Conference of Radiation Control Program Directors, Inc.

R.61-64.6.3.2.1.1 Text was added to require specific therapy equipment operating procedures to be approved by the Department.

R.61-64.6.3.2.1.2 Text was added to require specific emergency procedures for therapy equipment.

R.61-64.6.3.5 Text was added to require clearly identifiable technique indicators for therapy **EQUIPMENT.**

R.61-64.6.5.3.4 Text was added to require annual checks for the attenuation of blocks, wedge factors and compensator devices and monthly visual inspections of their mechanical integrity.

R.61-64.7.7.2.5 Text was added to require radiation survey instruments for analytical x-ray equipment to be checked prior to use.

R.61-64.8.13.2.7 Text was added to require an area survey to be performed within thirty days of installation of a shielded room radiographic unit.

(5) Delete requirements that are no longer applicable, feasible or necessary.

R.61-64.1.2.6 Text was deleted referring to "180 days after the effective date of these regulations" since this is no longer applicable.

R.61-64.1.13.1 ***Text was deleted to explain the purpose of civil penalties. This deletion was made because it is the Department's opinion that regulations should state what must and must not be done, not why something must or must not be done.***

R.61-64.1.14 Text was deleted that included the schedule of civil penalties. These deletions were made because of the proposed civil penalty matrix.

R.61-64.1.15 Text was deleted that referred to the schedule of severity schedules for civil penalties. These deletions were made because of the proposed civil penalty matrix.

R.61-64.1.16 Text of examples of administrative severity level violations was deleted due to the proposed civil penalty matrix.

R.61-64.1.17 Text of examples of x-ray equipment operational severity level violations was deleted due to the proposed civil penalty matrix.

R.61-64.1.18 Text of examples of industrial and analytical x-ray equipment severity level violations was deleted due to the proposed civil penalty matrix.

R.61-64.4.7.9.2 Text was deleted for testing contrast ratios of collimator lights. This would be very tedious to test and has not been enforced since the current collimator light illuminance requirements are adequate.

R.61-64.4.10 Text was deleted for "General Requirements for all Mammographic Systems" and replaced with Part V "Quality Standards and Certification Requirements for Facilities Performing Mammography."

R.61-64.8.13.2.5 Text was deleted requiring a registrant to use a qualified expert for a shielding plan since this has been revised and added to R.61-64.8.13.2.4.

R.61-64.8.13.2.7 Text was deleted requiring a registrant to submit "as-built" drawings since area surveys will be required.

(6) Make stylistic or grammatical changes, correct typographical errors, or change numbering.

It is noted that renumbering has taken place in each part of R.61-64, with extensive renumbering occurring in Parts I, II, IV, VI, VII, VIII, IX and X.

R.61-64.1.2.1 Revised to delete "any device or machine using" since it is not necessary for clarity. Revised to substitute "devices" for "x-ray or radiation principles" since it was stylistically awkward.

R.61-64.1.8.1.1.4 Revised to change "must to be submitted" to "to be submitted."

R.61-64.1.12 Revised to delete "its office located at" since the Department's office is no longer physically at this location.

R.61-64.3.23.1 Revised to change "See" to "in" for grammatical accuracy.

R.61-64.4.2.11.2 Revised to replace "personnel" with "persons" to be more grammatically correct.

R.61-64.4.4.1 Revised to change "and/or" to "and."

R.61-64.4.9.4.3.7.2 Revised to change "and/or" to "and."

R.61-64.6.4.2 Revised to delete "therapy" since this was redundant.

R.61-64.6.4.4 Revised to delete a reference to "Operating Procedures" since this is being covered separately.

R.61-64.6.5 Revised to delete "medical" since it is redundant.

R.61-64.7.2 Revised to change "However" to "except that" in order to be more grammatically correct.

R.61-64.7.3.3.1 Revised to change "a tube" to "an x-ray tube" in order to be more concise.

R.61-64.7.4.4.1 Revised to change "and/or" to "and."

R.61-64.7.8.1.9 Revised to correct "exposure" to "overexposure."

R.61-64.8.13.2.3 Revised to change "and/or" to "and."

R.61-64.9.41	Revised to correct formula.
R.61-64.9.87	Revised to change “and/or” to “and.”
R.61-64.9.150.3	Revised to change “and/or” to “and.”
R.61-64.9.156	Revised to change “and/or” to “and.”
R.61-64.9.208	Revised to change “and/or” to “and.”
R.61-64.9.239	Revised to change “and/or” to “and.”
R.61-64.9.259	Revised to change “and/or” to “and.”
R.61-64.266.1	Revised to change “and/or” to “and.”
R.61-64.10.7.2	Revised to correct “Environmental Quality Control” to “Health Services.”
R.61-64.10.8.1	Revised to correct “Environmental Quality Control” to “Health Services.”

Instructions: Replace existing R.61-64 in its entirety by this amendment.

Text:

R.61-64, X-Rays (Title B)

Contents:

PART I
GENERAL PROVISIONS

RHB 1.1 SCOPE. EXCEPT AS OTHERWISE SPECIFICALLY PROVIDED, THESE REGULATIONS APPLY TO ALL PERSONS WHO RECEIVE, POSSESS, USE, TRANSFER, OWN, OR ACQUIRE ANY X-RAY PRODUCING MACHINE. THE PROVISIONS OF THESE REGULATIONS SHALL NOT BE INTERPRETED AS LIMITING THE INTENTIONAL EXPOSURE OF PATIENTS TO RADIATION FOR THE PURPOSE OF DIAGNOSIS, ANALYSIS, OR THERAPY BY PERSONS LICENSED TO PRACTICE ONE OR MORE OF THE HEALTH PROFESSIONS WITHIN THE AUTHORITY GRANTED TO THEM BY STATUTE OR REGULATION.

RHB 1.2 PROHIBITED USE.

1.2.1 It shall be unlawful to operate or maintain fluoroscopic devices for fitting or selling footwear.

1.2.2 It shall be unlawful to intentionally apply radiation to human beings except by, or under the direct supervision of, persons licensed to practice the health professions and authorized to use such radiation.

1.2.3 IT SHALL BE UNLAWFUL FOR ANY PERSON TO USE, RECEIVE, OWN, OR POSSESS X-RAY EQUIPMENT UNLESS THE MACHINE IS REGISTERED WITH THE DEPARTMENT AND IS OPERATED IN COMPLIANCE WITH ALL APPLICABLE PROVISIONS.

1.2.4 No person, in any advertisement, shall refer to the fact that any x-ray facility, x-ray machine, or any activity under these regulations has been approved by the Department.

1.2.5 It shall be unlawful to use hand-held non-image intensified fluoroscopic screens.

1.2.6 It shall be unlawful to use plastic pointed position indicating devices on intraoral dental systems.

1.2.7 The use of any source of radiation may be prohibited when it is determined by the Department to be detrimental to public health and safety.

1.2.8 It shall be unlawful to use hand-held radiographic or fluoroscopic imaging devices, or hand-held therapy units, except for contact therapy units operated according to Part VI of these regulations. This prohibition does not apply to "mini" c-arms specifically designed to be hand held.

1.2.9 It shall be unlawful to use fluoroscopy for positioning a patient for radiographic imaging, except when done by a licensed practitioner of the healing arts, or except for radiation therapy simulators.

1.2.10 It shall be unlawful for a person other than a licensed practitioner of the healing arts to use fluoroscopy when the licensed practitioner of the healing arts is not physically present in the room, except during therapy simulations, maintenance activities, and training courses.

1.2.11 It shall be unlawful to use direct exposure x-ray film (without intensifying screens) for all radiological imaging other than intraoral dental radiography, therapeutic portal imaging, and industrial radiography.

1.2.12 It shall be unlawful to use a mammographic imaging system not specifically designed by the manufacturer for imaging of the breast.

1.2.13 It shall be unlawful to intentionally expose a human to electronically produced ionizing radiation except for healing arts purposes, or as part of a research protocol authorized by an institutional review board conforming to 21 CFR 50 and 21 CFR 56.

RHB 1.3 Inspections.

1.3.1 Each registrant shall afford, at all reasonable times, the Department or its duly authorized representative the opportunity to inspect sources of radiation and the premises and facilities wherein such sources of radiation are used or stored.

1.3.2 Each registrant shall make available to the Department or its authorized representative for inspection, upon reasonable notice, records maintained pursuant to these regulations.

1.3.3 The Department shall have the right to enter at all reasonable times upon any private or public property, except property under the jurisdiction of the federal government, for the purpose of determining whether there is compliance with the provisions of the Act and regulations issued by the Department pursuant thereto.

RHB 1.4 TEST AND SURVEYS.

1.4.1 Each registrant shall make or cause to be made such surveys as are necessary for him to comply with these regulations.

1.4.2 EACH REGISTRANT SHALL PERFORM, UPON INSTRUCTIONS FROM THE DEPARTMENT, OR SHALL PERMIT THE DEPARTMENT TO PERFORM, SUCH REASONABLE TESTS AS THE DEPARTMENT DEEMS APPROPRIATE OR NECESSARY INCLUDING, BUT NOT LIMITED TO, TESTS OF:

1.4.2.1 Sources of radiation;

1.4.2.2 Facilities wherein sources of radiation are used or stored;

1.4.2.3 Radiation detection and monitoring instruments; and

1.4.2.4 Other equipment and devices used in connection with utilization or storage of sources of radiation.

1.4.3 RESULTS OF SUCH TESTS AND SURVEYS SHALL BE SUBMITTED TO THE DEPARTMENT UPON REQUEST.

RHB 1.5 Exemptions.

1.5.1 The Department may, upon application by any user, or upon its own initiative grant such exemptions from the requirements of these regulations as it determines are authorized by law, and will not result in undue hazard to health, life, or property. Applications for exemptions shall specify why such exemption is necessary.

1.5.2 Before granting an exemption, the Department shall determine that there is reasonable and adequate assurance that:

1.5.2.1 The occupational dose to any individual adult will not exceed those specified in RHB 3.4.

1.5.2.2 The dose to an individual member of the public will not exceed those specified in RHB 3.9.

1.5.2.3 There is no significant hazard to life or property.

RHB 1.6 ADDITIONAL REQUIREMENTS.

1.6.1 The Department may, by rule, regulation, or order, impose upon any registrant such requirements in addition to those established in these regulations as it deems appropriate or necessary to minimize danger to public health and safety or property.

1.6.2 The Department is authorized to inspect and investigate the premises and operations and personnel of any radiation installation, whether or not such installation is required to be registered by the Department, for the purpose of studying and evaluating the health hazard(s) caused by the use and operation of such machines and material.

1.6.3 Equipment Not Covered In Regulations. Prior to operation of x-ray producing equipment not specifically covered in these regulations, the facility shall submit for review and approval to the Department a listing of manufacturer's specifications for the equipment, an analysis of exposure rates around the equipment, and written operating procedures describing how the equipment is to be used.

1.6.4 Radiation Safety Officer. The registrant shall designate an individual who will be responsible for radiation protection at the facility. Such individual shall:

1.6.4.1 Be qualified by training and experience concerning all hazards and precautions involved in operating the equipment for which he is responsible;

1.6.4.2 Recommend a program of radiation safety for effective compliance with the applicable requirements of these regulations;

1.6.4.3 Give instructions concerning hazards and safety practices to individuals who may be exposed to radiation from the equipment;

1.6.4.4 Ensure that surveys are made, procedures are carried out, and radiation safety instructions are given as required by these regulations.

RHB 1.7 VIOLATIONS.

1.7.1 The Department may obtain an injunction or other court order prohibiting any violation or any provision of the Act or any regulation or order issued thereunder. Any person who willfully violates any provision of the Act or any regulation or order issued thereunder shall be guilty of a misdemeanor and, upon conviction, shall be punished by fine or imprisonment or both, as provided by the Act.

1.7.2 Any person found in violation of any regulation shall notify the Department, in writing, within twenty calendar days, from the date of citation with respect to action that has been taken or planned to correct the violation.

1.7.3 All violations shall be corrected within sixty (60) calendar days from the date of citation. The Department shall be notified in writing of all action taken to correct the violations.

1.7.4 THE DEPARTMENT IS AUTHORIZED TO HOLD PUBLIC HEARINGS, COMPEL ATTENDANCE OF WITNESSES, MAKE FINDINGS OF FACT AND DETERMINATIONS AND TO ASSESS FINES AND CIVIL PENALTIES RELATING TO VIOLATIONS OF THE PROVISIONS OF THE ACT OR ANY REGULATION, TEMPORARY OR PERMANENT ORDER, OR FINAL DETERMINATION OF THE DEPARTMENT.

1.7.5 The Department may impose a civil penalty not to exceed Twenty-five Thousand Dollars ($25,000) on a person who violates a provision of the Act, rules, regulations, or orders issued. Each day of continued violation shall constitute a separate offense in computing the civil penalty. Civil penalties shall be assessed as specified in RHB 1.13.

RHB 1.8 Enforcement.

1.8.1 Upon determination by the Department that the Act or these regulations have been violated or that a public health risk exists, the Department will:

1.8.1.1 Provide written notification to the non-compliant facility as soon as possible after violations are noted which:

1.8.1.1.1 CITES EACH SECTION OF THE ACT OR REGULATIONS VIOLATED.

1.8.1.1.2 SPECIFIES THE MANNER IN WHICH THE REGISTRANT FAILED TO COMPLY.

1.8.1.1.3 Requires submission of a timely and comprehensive corrective action plan, including a time schedule for completion of the plan.

1.8.1.1.4 Establishes a firm time schedule within which a corrective action plan must be submitted. The Department will approve the plan and proposed time schedule for its completion if the plan is adequate.

1.8.1.2 In cases where the registrant fails to comply with the conditions of the written notification sent, a certified letter will be sent ordering compliance and advising appropriate persons that unless corrective action is initiated within ten days, the Department will seek further enforcement action, appropriate penalties and direct remedial relief.

1.8.1.3 IF THE REGISTRANT FAILS TO COMPLY WITH THE REQUIREMENTS OF THE CERTIFIED LETTER WITHIN TEN DAYS, OR IN CASES WHERE THERE IS AN IMMINENT HAZARD TO HUMAN HEALTH AND SAFETY, THE DEPARTMENT WILL TAKE ONE OR A COMBINATION OF THE FOLLOWING STEPS:

1.8.1.3.1. Issue an administrative order which:

1.8.1.3.1.1 Imposes an appropriate civil penalty; or

1.8.1.3.1.2 Requires corrective action; or

1.8.1.3.1.3 Impounds or orders the impounding of sources of radiation in accordance with the Act;

1.8.1.3.1.4 Revokes the facility's registration in accordance with Part II; or

1.8.1.3.2 Requests the Department attorney or the attorney general to seek court action to enjoin violations and seek conviction for a simple misdemeanor; or

1.8.1.3.3 Take enforcement action that the Department feels appropriate and necessary and is authorized by law.

1.8.2 Under an actual or potential condition posing a risk to any individual comparable to a Major severity level violation, the Department may immediately impound or order the impounding of sources of radiation in accordance with the Act.

RHB 1.9 Impounding.

1.9.1 The Department may immediately impound or order the impounding of sources of radiation in the possession of any person who fails to observe these regulations or provisions of the Act, or when the Department deems a situation to constitute an emergency.

RHB 1.10 RECORDS.

1.10.1 Each registrant shall keep records showing the receipt, transfer, use, storage, and disposal of all sources of radiation and major components, including, but not limited to controls, tubes, tables, cassette holders, and transformers. These records shall be maintained by the registrant until disposal is authorized by the Department. Such authorization shall be made in writing. All records shall be readily available at the facility for Department review. Additional record requirements are specified elsewhere in these regulations.

1.10.2 THE REGISTRANT SHALL MAINTAIN THE FOLLOWING INFORMATION FOR EACH X-RAY SYSTEM FOR INSPECTION BY THE DEPARTMENT:

1.10.2.1 Model and serial numbers of all tubes, controls, beam limiting devices, vertical cassette holders and tables;

1.10.2.2 Tube rating charts and cooling curves, for units certified by the Food and Drug Administration, and for units regulated under Part IV and Part V;

1.10.2.3 Aluminum equivalent filtration of the useful beam, including any routine variation for units regulated under Part IV and Part V;

1.10.2.4 Records of surveys, calibrations, maintenance, and modifications performed on the x-ray system(s), with the names of persons who performed such services. Records shall be maintained for five years.

1.10.2.5 A copy of all correspondence with the Department regarding that x-ray system.

1.10.3 Each registrant possessing more than 10 radiation machine controls shall maintain a current inventory listing that indicates the location and status of each control. The inventory listing shall be made available to the Department upon request.

1.10.4 ALL RECORDS REQUIRED BY THESE REGULATIONS SHALL BE ACCURATE AND TRUE.

RHB 1.11 RECORDS AND REPORTS OF MISADMINISTRATION.

1.11.1 Therapy Misadministrations.
When a misadministration involves any therapy procedure, the registrant shall notify the Department by telephone no later than 24 hours after discovery of the misadministration. The registrant shall also notify the referring physician and the patient of the misadministration no later than 24 hours after its discovery, unless the referring physician personally informs the registrant that he or she will inform the patient or that, based on medical judgement, telling the patient would be harmful. The registrant is not required to notify the patient without first consulting the referring physician. If the referring physician or patient cannot be reached within 24 hours, the registrant shall notify the patient as soon as possible thereafter. The registrant may not delay any appropriate medical care for the patient, including any necessary remedial care as a result of the misadministration, because of any delay in notification.

1.11.1.1 The registrant shall submit a written report to the Department within 15 days after the discovery of the misadministration. The report must not include the patient's name or other information that could lead to identification of the patient. The written report must include the registrant's name; the prescribing physician's name; a brief description of the event; why the event occurred; the effect on the patient; what improvements are needed to prevent recurrence; the action taken to prevent recurrence; whether the registrant notified the patient or the patient's responsible relative or guardian; and if not, why the individual involved was not informed; and if the patient was notified, what information was provided to the patient.

1.11.1.2 The registrant shall furnish the following to the patient within 15 days after discovery of the misadministration if the patient was notified:

1.11.1.2.1 A copy of the report that was submitted to the Department; or

1.11.1.2.2 A brief description of both the event and the consequences, as they may affect the patient, provided a statement is included that the report submitted to the Department can be obtained from the registrant.

1.11.2 Diagnostic Misadministrations. When a misadministration involves a diagnostic procedure, the registrant shall promptly investigate its cause, make a record for the Department review, and maintain the record as directed in RHB 1.11.3.

1.11.3 Each registrant shall retain a record of each therapy misadministration for ten years and three years for each diagnostic misadministration. The record must contain the names of all individuals involved in the event (including the prescribing physician, allied health personnel, the patient, and the patient's referring physician), the patient's social security number or identification number if one has been assigned, a brief description of the event misadministration, the effect on the patient, what improvements are needed to prevent recurrence; and the actions taken to prevent recurrence.

1.11.4 Aside from the notification requirement, nothing in RHB 1.11.1 through 1.11.3 shall affect any rights or duties of registrants and physicians in relation to each other, registrants, patients or responsible relatives or guardians.

RHB 1.12 Communications.

1.12.1 All communications and reports concerning these regulations, and registrations filed thereunder, shall be addressed to the Department at:

SC Department of Health and Environmental Control
Bureau of Radiological Health
2600 Bull Street
Columbia, South Carolina 29201

1.12.2 Material False Statements. It shall be unlawful to make a material false statement to the Department regarding information contained in the application for registration, information pertaining to an inspection or any other information required by any provision of these regulations.

RHB 1.13 Administration of Civil Penalties.

1.13.1 Assessment - Assessment of civil penalties shall be based on the following criteria:

1.13.1.1 the seriousness of the violation(s);

1.13.1.2 previous compliance history;

1.13.1.3 the amount necessary to deter future violations;

1.13.1.4 efforts to correct the violation; and

1.13.1.5 any other mitigating or enhancing factors.

1.13.2 Severity Levels - The seriousness of violations shall be categorized by one of the following severity levels.

1.13.2.1 Major- Violations that are most significant and have a direct negative impact on occupationalor public health and safety, or which represent a significant deviation from the requirements of this regulation.

1.13.2.2 Moderate- Violations that are of more than minor significance, but if left uncorrected, could lead to more serious circumstances, or which represent a moderate deviation from the requirements of this regulation.

1.13.2.3 Minor- Violations that are of minor safety significance, or which represent a minor deviation from the requirements of this regulations.

1.13.2.4 In each case, the severity of a violation will be characterized at the level best suited to the significance of the particular violation. In some cases, violations may be evaluated in the aggregate and a single severity level assigned for a group of violations.

1.13.3 Application - Examples of violations in each severity level are given in RHB 1.13.4. While examples are given for determining the appropriate severity level for violations, the examples are neither exhaustive nor controlling. These examples do not create new requirements. Each is designed to illustrate the significance which the Department of Health and Environmental Control places on a particular type of violation of state requirements. Adjustments to the values listed in RHB 1.13.4 under each severity level may be made for the presence or absence of the following factors:

1.13.3.1 Prompt Identification and Reporting. Reduction of a civil penalty may be given when a Registrant identifies the violation and promptly reports the violation to the Department. In weighing this factor, consideration will be given to, among other things, the length of time the violation existed prior to discovery, the opportunity available to discover the violation, the ease of discovery and the promptness and completeness of any required report. No consideration will be given to this factor if the Registrant does not take immediate action to correct the problem upon discovery.

1.13.3.2 Corrective Action to Prevent Recurrence. Recognizing that corrective action is always required to meet regulatory requirements, the promptness and extent to which the Registrant takes corrective action, including actions to prevent recurrence, may be considered in modifying the civil penalty to be assessed. Unusually prompt and extensive corrective action may result in reducing the proposed civil penalty. On the other hand, the civil penalty may be increased if initiation of corrective action is not prompt or if the corrective action is only minimally acceptable. In weighing this factor, consideration will be given to, among other things, the timeliness of the corrective action, degree of Registrant initiative, and comprehensiveness of the corrective action - such as whether the action is focused narrowly to the specific violation or broadly to the general area of concern.

1.13.3.3 Compliance History. Reduction of the civil penalty may be given for prior good performance in the general area of concern. In weighing this factor, consideration will be given to, among other things, the effectiveness of previous corrective action for similar problems, overall performance such as previous compliance history in the area of concern. For example, failure to implement previous corrective action for prior similar problems may result in an increase in the civil penalty.

1.13.3.4 Prior Notice of Similar Events. The civil penalty may be increased for cases where the Registrant had prior knowledge of a problem as a result of a Registrant audit, or specific industry notification, and had failed to take effective preventive steps.

1.13.3.5 Multiple Occurrences. The civil penalty may be increased where multiple examples of a particular violation are identified during the inspection period.

1.13.3.6 The above factors are additive. However, the civil penalty will not exceed twenty five thousand dollars ($25,000) for any one violation. Each day of noncompliance shall constitute a separate violation.

1.13.4 The Department shall issue civil penalties according to the following schedule:

1.13.4.1 Penalty Matrix

Deviation from Requirement: Potential for Harm:	Major (11-30)	Moderate (4-10)	Minor (1-3)
Major	$25,000-5,000	$15,000-5,000	$10,000-2,500

(11-70)			
Moderate (6-10)	$10,000-2,500	$7,500-1,000	$5,000-500
Minor (0-5)	$5,000-1,000	$3,000-500	$2,500-250

Calculation of Base Penalty:
Each violation is assigned a relative point value as follows: Potential for Harm- 0-70, with 70 being maximum harm; Deviation from Requirement- 1-30, with 30 being the maximum deviation. Add the two values together, convert to a decimal value (15 to .15, for example), and multiply by the maximum per day per violation per civil penalty ($25,000). This is the base civil penalty per violation. The base penalty may be increased for repeat violations, multi-day penalties, or degree of recalcitrance, willfulness, negligence, or indifference.

Minimum Increase for Repeat Violations Found on Follow-up Inspections or Reinspections

Second Offense (First Follow-up Inspection or First Reinspection)	15%
Third Offense (Second Follow-up Inspection or Second Reinspection)	30%
Fourth Offense (Third Follow-up Inspection or Third Reinspection)	45%
Fifth and Subsequent Offenses	60%

Multi-Day Penalties

Increase penalty 1% to 7% for each day of noncompliance.

Degree of Recalcitrance, Willfullness, Negligence, or Indifference

Increase Penalty 10% to 50%

1.13.4.2 The Department reserves the right to impose a civil penalty up to Twenty-five Thousand Dollars on a person who violates the regulations in such a manner so as to present an imminent hazard to human health and safety. The Twenty-five Thousand Dollar civil penalty may be levied for the following:

1.13.4.2.1 Two or more incidents of workers receiving excess radiation exposures, when such exposures are contrary to the provisions of RHB 3.4.

1.13.4.2.2 Two or more incidents of members of the general public, or non-radiation workers, receiving excess radiation exposures. (3.9)

1.13.4.2.3 Two or more incidents in a one year period of deliberate exposure of an individual except by or under the direct supervision of an individual licensed to engage in the healing arts. (1.2.2)

1.13.4.2.4 Two or more incidents on two consecutive inspections of failing to perform required equipment performance testing, surveys, tests, or evaluations. (1.4)

1.13.4.2.5 Four or more incidents in a one year period of making, selling, leasing, transferring, lending, assembling, or installing equipment without the equipment meeting all applicable regulations when properly placed in operation. (2.7.2)

1.13.4.2.6 Two or more incidents in a five year period of initiating a healing arts screening program without prior approval from the Department. (4.2.13.2)

1.13.4.2.7 Two or more incidents on two consecutive inspections of failing to provide a safety device on open-beam configuration analytical x-ray equipment. (7.4.1)

1.13.4.2.8 Two or more incidents on two consecutive inspections of ESEs that vary from the average ESE by more than a factor of 2, as determined by Appendix D of Part IV. (4.2.15.2)

1.13.4.2.9 Operation of a mammography facility without possessing a current, valid certificate issued by the Department, as required by RHB 5.2.

1.13.4.2.10 Two or more incidents of a registrant failing to ensure that operators of x-ray equipment possess a valid, current certificate from the South Carolina Radiation Quality Standards Association. (4.2.3, 6.3.3.1)

1.13.4.3 Example of Violations with Potential for Harm

Major

Workers receiving excess radiation exposures, when such exposures are contrary to the provisions of RHB 3.4.

Members of the general public, or non-radiation workers, receiving excess radiation exposures. (3.9)

Deliberate exposure of an individual except by or under the direct supervision of an individual licensed to engage in the healing arts. (4.2.13)

Two or more incidents on three consecutive inspections of failing to perform required calibrations, surveys, tests, or evaluations. (1.4)

Two or more incidents in a one year period of making, selling, leasing, transferring, lending, assembling, or installing equipment without it meeting all applicable regulations when properly placed in operation. (2.7.2)

Exposure to an individual for training, demonstration, or other purposes when there are not healing arts requirements or proper prescription provided. (4.2.13.1)

Two or more incidents on two consecutive inspections of a fluoroscopic system with a source to skin distance less than those specified in RHB 4.9.1.

Two or more incidents on two consecutive inspections of a fluoroscopic system with an x-ray field exceeding the length or width of the visible area of the image receptor by greater than 5%, or the sum of the excess length and width of greater than 6%. (4.9.2.2)

Initiating a healing arts screening program without prior approval from the Department. (4.2.13.2)

Failing to provide a safety device on open-beam configuration analytical x-ray equipment. (7.4.1)

ESEs that vary from the average ESE by more than a factor of 2, as determined by Appendix D of Part IV. (4.2.15.2)

A fluoroscopic x-ray system with a tabletop entrance exposure rate that exceeds the limits specified in 4.9.4 by more than a factor of 2.

Two or more incidents on two consecutive inspections of a fluoroscopic system such that the entire x-ray beam is not intercepted by the primary protective barrier. (4.9.2.1)

Two or more incidents on two consecutive inspections if a required system or equipment designed to prevent or mitigate a serious safety event or unnecessary exposure is absent or inoperable.

An x-ray system having a malfunction such that inadvertent exposures could occur, e.g., a system such that when the exposure switch is activated, not one but repeated exposures occur, or the timer fails to terminate exposure, or exposure initiated without utilizing the exposure switch.

Two or more incidents on two consecutive inspections that have a potential for serious overexposure of patients, radiation worker, non-radiation workers, or a member of the public.

Moderate

Making, selling, leasing, transferring, lending, assembling, or installing equipment without it meeting all applicable regulations when properly placed in operation. (2.7.2)

Routine holding of patients or films at a registrant's facility. (4.2.14.4)

Two or more incidents on two consecutive inspections of a registrant failing to ensure that an x-ray operator receives the training required by RHB 4.2.3.7 or RHB 6.3.3.9.

Two or more incidents on two consecutive inspections of lack of adequate filtration present in an x-ray machine. (4.3.5)

Two or more incidents on two consecutive inspections of failure to use exposure reduction devices properly (e.g., collimators, filtration). (4.3.5, 4.7.4.1, 4.7.14)

Two or more incidents on two consecutive inspections of having a fluoroscopic system with a tabletop entrance exposure rate that exceeds the limits specified in 4.9.4.

Two or more incidents on two consecutive inspections of ESEs that vary from the average ESE as determined by Appendix D of Part IV. (4.2.15.2)

Two or more incidents on two consecutive inspections of having a capacitor storage radiographic system such that the standby radiation exceeds the limits specified in RHB 4.3.4 by a factor of 2.

Two or more incidents on two consecutive inspections of failure to provide appropriate warning devices as required by RHB 7.4.4.

Two or more incidents on two consecutive inspections of failure to secure unused ports on radiation source housings. (7.3.5.5)

Two or more incidents on two consecutive inspections of inadequate mechanical support of tube head. (4.3.8)

Use of mechanical timer. (4.3.11)

Use of x-ray equipment before submission and approval of a shielding plan. (4.4.5)

Two or more incidents in two consecutive inspections of failing to meet the x-ray control requirements of RHB 4.5.4.

Two or more incidents on two consecutive inspections of failure to provide shutters on open-beam configuration x-ray units. (7.4.6.2)

Two or more incidents on two consecutive inspections of failure to control access to equipment, or failure to control access to restricted areas. (7.4.3)

Two or more incidents on two consecutive inspections of an intraoral dental x-ray unit capable of operation in the above 50 kVp range for which the field size at the cone tip is greater than or equal to 9 centimeters or which exhibit a minimum SSD less than 18 centimeters. (4.5.1, 4.5.2)

Two or more incidents on two consecutive inspections of a mobile radiographic system for which the minimum source to skin distance is less than 30 centimeters. (4.8.12)

Minor

Two or more incidents on two consecutive inspections of having a capacitor storage radiographic system such that the standby radiation exceeds the limits specified in RHB 4.3.4.

Repeated violations (Two or more incidents on two consecutive inspections) not covered in a more severe category that have minor safety significance.

1.13.4.4. Examples of Violations Categorized by Deviation from the Requirement

Major

Failure to allow authorized Department personnel access to x-ray facilities or equipment to conduct inspections or investigations. (1.3.1)

Two or more failures on two consecutive inspections to correct violations within sixty days. (1.7.3)

Two or more incidents of a person who is not certified by the South Carolina Radiation Quality Standards Association using or exhibiting a title, sign, display or declaration that misleads the public to believe the person is authorized to apply ionizing radiation on humans for diagnostic or therapeutic purposes. (4.2.3.4, 6.3.3.6)

Continuation of registrant activities after revocation of registration.

Two or more incidents of making material false statements to the Department. (1.12.2)

Two or more failures of a person to apply for registration approval prior to beginning operation of an x-ray facility. (2.4)

Two or more failures of a registrant to register x-ray equipment. (2.1.1)

Two or more incidents of providing x-ray vendor services without being registered with the Department. (2.6.1)

Two or more failures on two consecutive inspections of a person to notify the Department in writing within thirty days when he has sold, leased, transferred, lent, assembled, or installed x-ray equipment. (2.5.3)

Two or more failures of a vendor to notify the Department of installation of equipment. (2.7.1)

Intentional exposure of a radiation monitoring device to deceptively indicate a dose. (3.11.4)

Two or more incidents on two consecutive inspections of failure to provide personnel monitoring if required. (3.12)

Two or more incidents on two consecutive inspections of failing to adhere to the operating procedures. (4.2.4)

Two or more incidents on two consecutive inspections of management action to discriminate against an employee for attempting to communicate or for actually communicating with the Department. (10.7.3)

Two or more incidents of operation of an out of state x-ray machine for more than 365 days. (2.8)

Two or more incidents of a registrant failing to report or record misadministrations. (1.11)

Moderate

Two or more incidents on two consecutive inspections of failing to perform a repeat analysis. (4.2.18.4)

Two or more incidents on two consecutive inspections of failing to perform densitometric and sensitometric testing if required by RHB 4.2.19.2.6.

Two or more incidents on two consecutive inspections of failing to perform periodic measurements of entrance exposure rates on fluoroscopes. (4.9.4.3.6)

Failure of a person to register prior to providing or offering to provide x-ray services. (2.6.1)

Making, selling, leasing, transferring, lending, assembling, or installing equipment without it meeting all applicable regulations when properly placed in operation. (2.7.2)

Failure of a registrant to display each operator's current certificate from the South Carolina Radiation Quality Standards Association, as required by RHB 4.2.3.6 or RHB 5.3.3.8.

Failure of a registrant to register x-ray equipment with the Department. (2.1.1)

Failure of a registrant to notify the Department when he has sold, leased, transferred, lent, assembled, or installed x-ray equipment. (2.5.3)

Failure to notify the Department prior to operating an out-of-state x-ray machine in South Carolina. (2.8)

Failure to make notifications as required by RHB 3.25.1.

Failure of a vendor to notify the Department of installation of equipment. (2.7.1)

Failure by a registrant to correct violations within sixty days. (1.7.3)

Failure to report misadministrations to the Department as required. (1.11)

Two or more incidents in two consecutive inspections of a registrant failing to verify that a person providing x-ray machine services or servicing is registered with the Department. (2.5.4)

Two or more incidents on two consecutive inspections of a registrant not notifying the Department within 20 days of a violation citation with regards to corrective action taken or planned to correct the violation. (1.7.2)

Minor

Failure to maintain required records including, but not limited to, patient logs, utilization logs, and technique charts.

Failure to post Department notices as required in RHB 10.2.

Failure to correctly label x-ray equipment.

1.14 Compliance with other Laws. The registrant shall comply with all other applicable federal, state and local regulations.

1.15 Severability. If any provision of this regulation or its application to any person or circumstance is held invalid, the invalidity does not affect other provisions or applications of the regulation which can be given effect without the invalid provision or application, and to this end the provisions of the regulation are severable.

PART II
REGISTRATION OF X-RAY MACHINES AND SERVICES

RHB 2.1 Scope. This part provides for the registration of x-ray machines, (controls and tubes), and facilities, and for the registration of persons providing x-ray machine installation, servicing, and/or services.

2.1.1 EXCEPT AS SPECIFICALLY EXEMPTED IN RHB 2.2, EACH PERSON WHO RECEIVES, POSSESSES, USES, OR ACQUIRES AN X-RAY MACHINE SHALL REGISTER THE CONTROL AND TUBES OF SUCH MACHINE WITH THE DEPARTMENT IN ACCORDANCE WITH THE REQUIREMENTS OF THIS PART.

2.1.2 In addition to the requirements of this Part, all registrants are subject to the applicable provisions of other Parts of these regulations.

RHB 2.2 EXEMPTIONS.

2.2.1 Electronic equipment that produces radiation incidental to its operation for other purposes is exempt from the registration requirements of this part, providing dose equivalent rate averaged over an area of 10 square centimeters does not exceed 0.5 mrem per hour at 5 cm from any accessible surface of such equipment. The production, testing, or factory servicing of such equipment shall not be exempt.

2.2.2 Television receivers, video display terminals, and computer monitors, when used without modification to their internal or external construction, are exempt from the requirements of this Part.

2.2.3 Any facility where a federal agency has exclusive jurisdiction is exempt from the requirements of this Part.

2.2.4 X-ray machines while in transit or storage incident thereto are exempt from the requirements of this Part.

RHB 2.3 APPLICATION AND REVIEW FEES.

2.3.1 Application Fee. Each registrant shall pay a non-refundable application fee of fifty dollars upon submission of the initial Facility Registration Approval Request form. A facility registration approval shall not be issued until payment of the application fee.

2.3.2 Shielding Plan Review Fee. Each registrant shall pay a non-refundable shielding plan review fee of fifty dollars per x-ray control upon submission of any shielding plan. A shielding plan approval shall not be issued until payment of the review fee.

RHB 2.4 Facility Registration Approval.

2.4.1 Fixed Installation-Fixed Facility. Any facility planning to install an x-ray producing machine in a fixed location shall meet the provisions of this Subpart.

2.4.1.1 Prior to installation of any x-ray producing equipment, the facility where the installation will be shall submit to the Department the following information:

2.4.1.1.1 Facility Name, Location Address, and Mailing Address;

2.4.1.1.2 The name of the radiation safety officer, who is responsible for radiation protection, and the individual's qualifications to serve in such a capacity;

2.4.1.1.3 Type and make of x-ray equipment to be installed;

2.4.1.1.4 Operating procedures as required by RHB 4.2.4, 6.3.2.1,7.8.3, or 8.8;

2.4.1.1.5 A training plan as required by RHB 4.2.3,7.8.1, or 8.11;

2.4.1.1.6 A shielding plan, if required by RHB 4.4 or 8.13.2;

2.4.1.1.7 The name, address, and contact person of the company selling and installing the equipment. If more than one company is involved in the sale and/or installation, then the above information shall be provided for all companies involved.

2.4.1.2 Prior to installation of any x-ray producing equipment, the facility where the installation will be shall submit any application and shielding review fees as required by RHB 2.3.

2.4.1.3 Upon review of the above information, the Department shall issue a facility registration approval.

2.4.1.4 A facility shall not install or cause to be installed any x-ray producing equipment until the Department has issued a facility registration approval.

2.4.2 Fixed Installation-Mobile Facility. Any facility planning to install an x-ray producing machine in a fixed location of a mobile facility shall meet the provisions of this Subpart.

2.4.2.1 Prior to installation of any x-ray producing equipment, the facility where the equipment will be installed shall submit to the Department the following information:

2.4.2.1.1 Facility Name and Mailing Address where correspondence may be sent;

2.4.2.1.2 The name of the radiation safety officer, who is responsible for radiation protection, and the individual's qualifications to serve in such a capacity;

2.4.2.1.3 Type and make of x-ray equipment to be installed;

2.4.2.1.4 Operating procedures as required by RHB 4.2.4, 6.3.2.1, 7.8.3, or 7.8;

2.4.2.1.5 A training plan as required by RHB 4.2.3, 7.8.1, or 8.11;

2.4.2.1.6 An operating schedule, indicating when and where the equipment will be used;

2.4.2.1.7 A shielding plan, as required by RHB 4.4 or 8.13.2;

2.4.2.1.8 The name, address, and contact person of the company selling and installing the equipment. If more than one company is involved in the sale or installation, then the above information shall be provided for all companies involved.

2.4.2.2 Prior to installation of any x-ray producing equipment, the facility where the equipment will be installed shall submit any application and shielding review fees as required by RHB 2.3.

2.4.2.3 Upon review of the above information, the Department shall issue a facility registration approval.

2.4.2.4 A facility shall not install or cause to be installed any x-ray producing equipment until the Department has issued a facility registration approval.

2.4.3 Mobile or Portable Equipment. Any facility acquiring or using mobile or portable x-ray producing equipment shall meet the provisions of this Subpart.

2.4.3.1 Prior to acquisition of any mobile x-ray producing equipment, the facility where the equipment will be used shall submit to the Department the following information:

2.4.3.1.1 Facility Name, Location Address and Mailing Address;

2.4.3.1.2 The name of the radiation safety officer, who is responsible for radiation protection, and the individual's qualifications to serve in such a capacity;

2.4.3.1.3 Type and make of x-ray equipment to be used;

2.4.3.1.4 Operating procedures as required by RHB 4.2.4, 6.3.2.1, 7.8.3, or 7.8;

2.4.3.1.5 A training plan as required by RHB 4.2.3,7.8.1, or 8.11.

2.4.3.1.6 The name, address, and contact person of the company selling the equipment. If more than one company is involved in the sale, then the above information shall be provided for all companies involved.

2.4.3.2 Prior to acquisition of any mobile x-ray producing equipment, the facility where the equipment will be used shall submit any application and shielding review fees as required by RHB 2.3.

2.4.3.3 Upon review of the above information, the Department shall issue a facility registration approval.

2.4.3.4 A FACILITY SHALL NOT USE ANY X-RAY PRODUCING EQUIPMENT UNTIL THE DEPARTMENT HAS ISSUED A FACILITY REGISTRATION APPROVAL.

2.4.4 It shall be unlawful for any person to install x-ray producing equipment until the facility acquiring that equipment has received a facility registration approval from the Department.

RHB 2.5 EQUIPMENT REGISTRATION REQUIREMENTS, USERS OF X-RAY MACHINES.

2.5.1 Initial Equipment Registration. Every person who possesses an x-ray machine shall register the machine's control and tubes with the Department, within thirty days of the date of acquisition. Registration shall be made on Form DHEC 819, "Registration of X-Ray Producing Machines", furnished by the Department.

2.5.1.1 Upon registration of a control, the Department shall issue the facility a registration sticker to be placed on each control. The registration sticker shall be placed on the control panel in a clearly visible location.

2.5.1.2 When a control is removed from a facility, the facility shall remove the registration sticker.

2.5.1.3 A registration sticker on a control, displaying the facility's proper name, shall be considered indicative of a facility's and a control's registration status, as required to be confimed by RHB 2.7.2.

2.5.2 Renewal of Equipment Registration. The Department shall provide an annual re-registration statement to all registrants. The re-registration statements shall be reviewed, corrected, signed, and returned to the Department within 30 days.

2.5.3 Report of Change. The registrant shall report to the Department, within thirty days, any changes of status affecting any x-ray machine or facility. Report of a change of status shall be made in writing, and forwarded to the Department.

2.5.4 Verification of Service Representative. Each registrant shall require any person furnishing x-ray machine servicing or services as described in this Part to provide evidence that he has been registered with the Department as a vendor in accordance with these regulations.

2.5.5 Leasing of Equipment. When a facility leases x-ray equipment, it shall be the facility's responsibility to register the equipment and to ensure that the equipment is maintained to meet these regulations.

RHB 2.6 REGISTRATION REQUIREMENTS-SERVICING AND SERVICES (VENDOR)

2.6.1 Each person who is engaged in the business of selling, leasing or installing or offering to sell, lease or install x-ray machines or machine components or is engaged in the business of furnishing or offering to furnish any equipment services in this State shall apply for registration as a vendor with the Department within thirty days following the effective dates of these regulations or thereafter prior to furnishing or offering to furnish any such services.

2.6.2 Application for vendor registration shall be completed on forms DHEC 824 and DHEC 825, furnished by the Department and shall contain all information required by the Department as indicated on the forms, and accompanying instructions. This information shall include:

2.6.2.1 The name, address, and telephone number of the individual or company to be registered, along with the owner(s) of the company;

2.6.2.2 The description of the services to be provided;

2.6.2.3 The name, training, and experience of each person who provides services;

2.6.2.4 The date of the application and the signature of the individual responsible for the company;

2.6.2.5 A sample of equipment performance test procedures and forms;

2.6.2.6 A sample of a shielding plan, if registering as a Class III or Class IV vendor;

2.6.2.7 Any additional information the Department determines to be necessary for evaluation of the application for registration;

2.6.3 Each person applying for registration under this Part shall specify that he has read and understands the applicable requirements of these regulations.

2.6.4 For the purpose of this section, equipment services are:

2.6.4.1 Direct sale and transfer of radiation machines and machine components to end users.

2.6.4.2 Installation or servicing of radiation machines and associated radiation machine components;

2.6.4.3 Diagnostic radiographic facility and shielding design;

2.6.4.4 Diagnostic fluoroscopic facility and shielding design;

2.6.4.5 Diagnostic area radiation survey, e.g., shielding evaluation;

2.6.4.6 Radiation instrument calibration;

2.6.4.7 Therapeutic facility and shielding design, area radiation surveys, or calibration;

2.6.4.8 Personnel dosimetry services;

2.6.4.9 General health physics consulting, e.g., independent diagnostic radiation output measurements, dose analysis, design of safety programs and radiation safety training programs, non-healing arts facility and shielding design, and area radiation surveys; and

2.6.4.10 Such other equipment services which can affect compliance with these Regulations by a registrant, as determined by the Department.

2.6.5 Report of Change. The vendor shall notify the Department in writing, within thirty days of any changes which would render the information contained in the Application for Registration no longer accurate. Report of changes shall be made for changes in employee's status.

2.6.6 Training and Educational Requirements for Equipment Services. Each person registered pursuant to RHB 2.6 shall be qualified by reason of education, training and experience to provide the service for which registration is requested. The following are minimum qualifications for specific types of services:

2.6.6.1 Class I - Sales of radiation machines and machine components to end users: The applicant must certify knowledge of familiarity with the rules and regulations which govern the possession, installation and use of radiation machines in South Carolina.

2.6.6.2 Class II - Installation and service of radiation machines and machine components including the making of diagnostic radiation output measurements to verify performance associated with the installation or service:

2.6.6.2.1 Manufacturer's equipment school for service, or equivalent training,

2.6.6.2.2 Maintenance and installation for the type of machine use (e.g., dental intraoral, medical diagnostic or medical fluoroscopic) or equivalent training;

2.6.6.2.3 Training in principles of radiation protection; and three to six months of experience in installation and service of radiation machines and machine components.

2.6.6.3 Class III - Diagnostic radiographic facility and shielding design:

2.6.6.3.1 Formalized training in principles of radiation protection;

2.6.6.3.2 Formalized training in shielding design; and

2.6.6.3.3 One year of experience in diagnostic radiographic facility and shielding design for the specific type of machine application.

2.6.6.4 Class IV - Diagnostic fluoroscopic facility and shielding design:

2.6.6.4.1 Formalized training in principles of radiation protection;

2.6.6.4.2 Formalized training in shielding design; and

2.6.6.4.3 One year of experience in diagnostic fluoroscopic facility and shielding design for the specific type of machine application.

2.6.6.5 Class V - Diagnostic area radiation survey, e.g., shielding evaluation:

2.6.6.5.1 Formalized training in basic radiological health;

2.6.6.5.2 Formalized training in shielding evaluation; and one year of experience performing area radiation surveys.

2.6.6.6 Class VI - Radiation instrument calibration:

2.6.6.6.1 The applicant must possess a current radioactive materials license or registration authorizing radiation instrument calibration;

2.6.6.6.2 Training in principles of radiation protection;

2.6.6.6.3 Training in operation and calibration of radiation detection and measurement instrumentation;

2.6.6.6.4 One year experience in an instrument calibration laboratory;

2.6.6.6.5 Shall submit a description of the procedures that will be utilized in performing instrument calibrations.

2.6.6.7 Class VII - Therapeutic facility and shielding design, area radiation survey, or calibration:

2.6.6.7.1 Certification by the American Board of Radiology in therapeutic radiological physics, radiological physics, or x-ray and gamma ray physics, or certification by the American Board of Medical Physics in therapeutic radiological physics; or

2.6.6.7.2 Having the following minimum training and experience:

2.6.6.7.2.1 A Master's or a Doctoral degree in Physics, Biophysics, Radiological Physics, or Health Physics or Medical Physics; one year full-time training in therapeutic radiological physics;

2.6.6.7.2.2 One year full-time experience in a therapeutic facility where the individual's duties involve calibration and spot checks of a medical accelerator, and includes personal calibration and spot check of at least one machine;

2.6.6.7.3 Shall submit a description of the procedures that will be utilized in performing therapeutic calibrations including a list of all guides and references to be employed.

2.6.6.7.4 Shall submit a copy of all forms, reports and documents that will be supplied to registrants; and shall submit one sample of each specific type, e.g., therapy, accelerator.

2.6.6.8 Class VIII - Personnel dosimetry service: The applicant must hold current personnel dosimetry service accreditation from the National Voluntary Laboratory Accreditation Program (NVLAP) of the National Institute of Standards and Technology or use NVLAP accredited dosimetry.

2.6.6.9 Class IX - General health physics consulting, e.g., independent diagnostic radiation output measurements, dose analysis, design of safety programs, and radiation safety training programs, non-healing arts facility and shielding design, and area radiation surveys:

2.6.6.9.1 Baccalaureate degree in a physical science (e.g., physics, chemistry or radiologic science), engineering or related field and two years of progressive experience in medical or health physics;

2.6.6.9.2 Graduate training in medical or health physics may be substituted on a year for year basis; or

2.6.6.9.3 Certification by the American Board of Radiology in diagnostic radiological physics, therapeutic radiological physics, radiological physics, roentgen-ray and gamma ray physics, or x-ray and radium physics; certification by the American Board of Health Physics in comprehensive practice, or certification by the American Board of Medical Physics.

2.6.6.10 For the purpose of RHB 2.6, the required work experience may be gained while working for a manufacturer or while working under the direct supervision of a vendor registered in the particular class.

2.6.6.11 Any person not meeting the requirements of this Part may apply to the Department for vendor registration, provided such person demonstrates education, training, and experience which is equivalent to that required for a particular class.

2.6.6.12 Any person registered prior to the effective date of this regulation as a vendor shall meet the education, training, and experience requirements of this Part no later than 24 months after the effective date of these regulations.

2.6.6.13 The Department shall initiate action to terminate the registration of any person who fails to comply with RHB 2.6.6.12.

2.6.7 Any branch office of a vendor shall be considered a separate entity and shall be registered separately pursuant to RHB 2.6.

2.6.8 Approval not Implied. No person, in any advertisement, shall refer to the fact that he or his facility is registered with the Department or that any activity under such registration has been approved by the Department.

RHB 2.7 Vendor Obligation.

2.7.1 Any person who sells, leases, transfers, lends, moves, assembles or installs x-ray machines in this State shall notify the Department within thirty days of:

2.7.1.1 The name and address of persons who have received these machines;

2.7.1.2 The manufacturer, the control and tube(s) model number, the control and tube(s) serial number of each radiation machine transferred; and

2.7.1.3 The date of transfer of each x-ray machine.

2.7.1.4 Notification to the Department shall be made on DHEC Form 823. A DHEC 823 form shall be submitted to the Department each month by Class I and Class II vendors regardless of whether x-ray equipment was sold that month. A vendor may be exempted from monthly reporting upon written request by the Department.

2.7.2 No person shall make, sell, lease, transfer, lend, maintain, repair, assemble, reassemble, reinstall or install radiation machines or the supplies used in connection with such machines unless such supplies and equipment when properly placed in operation and used meet the requirements of these regulations. Each vendor shall ensure that the facility it is providing with services or supplies is registered with the Department prior to providing services or supplies.

2.7.3 Each vendor shall maintain records for review by the Department. These records shall include, at a minimum:

2.7.3.1 ALL INFORMATION REQUIRED BY RHB 2.7.

2.7.3.2 A copy of the shielding plan, if one was required, and if provided by that vendor;

2.7.3.3 Tests performed at the time of installation to ensure that the equipment complies with these regulations. A copy of these results shall be provided to the registrant at the time of installation;

2.7.3.4 Records of any routine maintenance, repair, alterations, or reassembly of x-ray equipment. Records of maintenance, repair, alterations, or reassemblies shall include the date that the service was performed. A copy of these records shall be provided to the registrant at the time the service is provided;

2.7.3.5 NAMES OF ALL EMPLOYEES AND THEIR DATES OF EMPLOYMENT WITH THE VENDOR. RECORDS SHALL ALSO BE MAINTAINED OF TRAINING PROVIDED TO THE EMPLOYEES DURING THEIR TERM OF EMPLOYMENT.

2.7.3.6 Records of equipment performance testing, including data collected during the testing. A copy of the equipment performance test must be provided to the facility either at the time of testing, or within thirty days of the testing date. The report of equipment performance testing shall include the testing of all items listed in Part IV, Appendix F, except as noted in the Appendix. The equipment performance test record provided to the facility must clearly indicate all equipment parameters tested, and must include a designation, such as “Pass/Fail” or “Compliant/Non-compliant”, that is easily understandable by the facility. Use of any designation other than “Pass/Fail” or “Compliant/Non-compliant” shall be approved by the Department prior to use on equipment performance reports of testing. If the equipment performance test record includes any recommendations for improvement, such recommendations shall be clearly indicated as a recommendation. The record of equipment performance shall include the date that the testing was performed.

2.7.4 All records required by this Part shall be maintained by the vendor until their disposal is authorized by the Department. All records shall be accurate and factual.

2.7.5 Each vendor shall maintain sufficient calibrated and operable instruments to perform the testing appropriate to the class in which the vendor is registered. Instruments must be calibrated with sources consistent with the conditions under which they are used. Records shall be maintained of the calibrations performed on instrumentation used for testing. Instruments used shall be calibrated at the following frequencies:

2.7.5.1 Ion chambers and survey meters used for equipment performance testing and radiation area surveys shall be calibrated at intervals not to exceed twelve months and after each instrument servicing.

2.7.5.2 Ion chambers used for calibration of therapy units to meet the requirements of Part VI shall be calibrated at intervals not to exceed twenty four months and after each instrument servicing.

2.7.5.3 Other instruments used in performance testing of equipment, such as light meters, mAs meters, and kVp meters, shall be calibrated at intervals not to exceed twenty four months and after each instrument servicing.

RHB 2.8 OUT OF STATE X-RAY MACHINES.

2.8.1 Whenever an x-ray machine is to be brought into the State, for any temporary use, the person proposing to bring such machine into the State shall give written notice to the Department at least two working days before such machine is to be used in the State. The notice shall include:

2.8.1.1 The type of x-ray machine.

2.8.1.2 The exact location where the machine is to be used;

2.8.1.3 The date(s) the machine is to be used; and

2.8.1.4. The state the machine is registered in and the registration number. If the machine is not registered in another state, the machine shall be registered with the Department.

2.8.2 If for a specific case the two working day period would impose an undue hardship on the person, he may, upon application to the Department, obtain permission to proceed sooner.

2.8.3 IN ADDITION THE OUT-OF-STATE REGISTRANT SHALL:

2.8.3.1 Comply with all applicable regulations of the Department;

2.8.3.2 Supply the Department with such other information as the Department may request; and

2.8.3.3 Not operate within the state on a temporary basis in excess of 180 calendar days per year.

RHB 2.9 MODIFICATION, REVOCATION, TERMINATION OF REGISTRANTS.

2.9.1 The terms and conditions of all registrations are subject to amendment, revision, or modification and all registrations are subject to suspension or revocation by reason of:

2.9.1.1 Amendments to the Act;

2.9.1.2 Rules and regulations adopted pursuant to provisions of the Act; or

2.9.1.3 Orders issued by the Department.

2.9.2 Any registration may be revoked, suspended, or modified in whole or part:

2.9.2.1 For any material false statement in the application or in any statement of fact required by provisions of this part;

2.9.2.2 Because of any statement of fact, any report, record, inspection, or other means which would warrant the Department to refuse to grant a registration on original application; or

2.9.2.3 For violations of, or failure to observe any of the terms and conditions of the Act, the registration, these regulations, or any order of the Department.

2.9.3 An order of revocation may be appealed as a contested case pursuant to Regulation 61-72. Emergency orders requiring immediate cessation of operations may be appealed for an expedited hearing which shall be provided within 72 hours of the request.

2.9.4 Except in cases of willfulness or those in which the public health, interest, or safety requires otherwise, prior to the institution of proceedings for modification, revocation, or suspension of a registrant, the Department shall:

2.9.4.1 Call to the attention of the registrant in writing the facts or conduct which may warrant these actions, and

2.9.4.2 Provide an opportunity for the registrant to demonstrate or achieve compliance with all regulations.

2.9.5 The Department may terminate a registration upon written request submitted by the registrant to the Department.

2.9.6 The provisions of this part shall apply to both registration of x-ray equipment and registration of x-ray services (vendors).

RHB 2.10 ANNUAL FEES.

2.10.1 Any person issued or granted a registration for the possession and use of x-ray machine(s) shall pay an annual registration fee per machine tube. Vendors shall pay an annual flat fee. The annual registration fee shall be due on January 15 of each year.

2.10.2 Persons failing to pay the fees required by RHB 2.10.1 by March 15 of that year shall also pay a penalty of Fifty Dollars. If the required fees are not paid by April 15 of that year, the registrant shall be notified by certified mail to be sent to his last known address that his registration is revoked, and that any activities permitted under the authority of the registration must cease immediately.

2.10.3 A registrant suspended for failure to pay the required fee under RHB 2.10.2 may be reinstated by the Department upon payment of the required fee, the penalty of Fifty Dollars and an additional penalty of One Hundred Dollars, if the registrant is otherwise in good standing and presents to the Department a satisfactory explanation for his failure to pay the required fee.

2.10.4 Payment of fees shall be made in accordance with the instructions of a "Statement of Fees Due" issued annually by the Department.

2.10.5 Fees required by RHB 2.10.1 for an x-ray machine or vendor registration which is issued during a calendar year shall be prorated for the remainder of that year based on the date of issuance of the registration.

2.10.6 Schedule of Fees. The following fee schedule shall be used by the Department to determine the annual fee due:

Type of Equipment	Fee
Radiographic	$80
Fluoroscopic	80
Combination Rad/Fluoro	160
Dental	50

Therapy	100
Diffraction	55
X-ray Fluorescence	55
Accelerator	100
Electron Microscope	30
Spectrograph	55
Cephalometer	80
Panoramic	40
Cabinet X-ray	75
CT Scanner	80
C-Arm Fluoroscopic	80
Mammography	(See RHB 5.6)
Stereotactic Mammography	80
Baggage Checker	55
Bone Densitometer	80
Lithotripter	80
Simulator	80
Other	80
Vendors and Installers	125

PART III
STANDARDS FOR PROTECTION AGAINST RADIATION

RHB 3.1 Purpose and Scope

3.1.1 This Part establishes standards for protection against ionizing radiation resulting from activities conducted pursuant to registrations issued by the Department pursuant to these regulations.

3.1.2 The requirements of this Part are designed to control the receipt, possession, use, transfer, and disposal of sources of radiation by any registrant so the total dose to an individual, including doses resulting from all sources of radiation other than background radiation, does not exceed the standards for protection against radiation prescribed in this Part. However, nothing in this Part shall be construed as limiting actions that may be necessary to protect health and safety.

3.1.3 Except as specifically provided in other Parts of these regulations, this Part applies to persons registered by the Department to receive, possess, use, install, service, transfer, or dispose of sources of radiation. The limits in this Part do not apply to doses due to background radiation, to exposure of patients to radiation for the purpose of medical diagnosis or therapy, or to voluntary participation in medical research programs.

RHB 3.2 Implementation

3.2.1 Any existing registration condition that is more restrictive than this Part remains in force until there is an amendment of the registration.

3.2.2 If a registration condition exempts a registrant from a provision of a previous Part III in effect on or before the effective date of these regulations, it also exempts the registrant from the corresponding provision of this Part III.

3.2.3 If a registration condition cites provisions of a previous Part III in effect prior to the effective date of these regulations, which do not correspond to any provisions of this Part, the registration condition remains in force until there is an amendment or renewal of the registration that modifies or removes this condition.

3.2.4 For determining the doses specified in this Part, a dose from x-rays up to 3 MeV may be assumed to be equivalent to the exposure measured by a properly calibrated appropriate instrument in air at or near the body surface in the region of the highest dose rate.

RHB 3.3 Radiation Protection Programs

3.3.1 Each registrant shall develop, document, and implement a radiation protection program sufficient to ensure compliance with the provisions of this Part. See RHB 3.18 for record keeping requirements relating to these programs.

3.3.2 The registrant shall use, to the extent practicable, procedures and engineering controls based upon sound radiation protection principles to achieve occupational doses and public doses that are as low as is reasonably achievable (ALARA).

3.3.3 The registrant shall, at intervals not to exceed 12 months, review the radiation protection program content and implementation.

RHB 3.4 Occupational Dose Limits for Adults.

3.4.1 THE REGISTRANT SHALL CONTROL THE OCCUPATIONAL DOSE TO INDIVIDUAL ADULTS, EXCEPT FOR PLANNED SPECIAL EXPOSURES PURSUANT TO RHB 3.6, TO THE FOLLOWING DOSE LIMITS:

3.4.1.1 AN ANNUAL LIMIT, WHICH IS THE MORE LIMITING OF:

3.4.1.2 The total effective dose equivalent being equal to 5 rem (0.05 Sv); or

3.4.1.3 The sum of the deep dose equivalent and the committed dose equivalent to any individual organ or tissue other than the lens of the eye being equal to 50 rem (0.5 Sv).

3.4.1.4 The annual limits to the lens of the eye, to the skin, and to the extremities which are:

3.4.1.4.1 An eye dose equivalent of 15 rem (0.15 Sv), and

3.4.1.4.2 A shallow dose equivalent of 50 rem (0.5 Sv) to the skin or to any extremity.

3.4.2 Doses received in excess of the annual limits, including doses received during accidents, emergencies, and planned special exposures, shall be subtracted from the limits for planned special exposures that the individual may receive during the current year and during the individual's lifetime. Dose limits for planned special exposures are provided in RHB 3.6.

3.4.3 The assigned deep dose equivalent and shallow dose equivalent shall be for the portion of the body receiving the highest exposure. The deep dose equivalent, eye dose equivalent and shallow dose equivalent may be assessed from surveys or other radiation measurements for the purpose of demonstrating compliance

with the occupational dose limits, if the individual monitoring device was not in the region of highest potential exposure, or the results of individual monitoring are unavailable.

3.4.4 If an occupationally exposed adult is likely to receive in one year, from sources external to the body, a dose in excess of fifty percent (50%) of the limits in RHB 3.4.1, the registrant shall monitor all of the individual's occupationally received doses, and shall reduce the dose that an individual may be allowed to receive in the current year by the amount of occupational dose received while employed by any other person.

RHB 3.5 COMPLIANCE WITH REQUIREMENTS FOR SUMMATION OF EXTERNAL AND INTERNAL DOSES. IF A REGISTRANT IS ALSO A RADIOACTIVE MATERIAL LICENSEE OF THE DEPARTMENT, ALL REGULATIONS OF TITLE A PERTAINING TO DOSE LIMITS ARE APPLICABLE. NOTHING IN THIS PART RELIEVES A REGISTRANT FROM COMPLYING WITH TITLE A.

RHB 3.6 Planned Special Exposures. A registrant may authorize an adult worker to receive doses in addition to and accounted for separately from the dose received under the limits specified in RHB 3.4 provided that each of the following conditions is satisfied:

3.6.1 The registrant authorizes a planned special exposure only in an exceptional situation when alternatives that might avoid the higher exposure are unavailable or impractical.

3.6.2 The registrant, and employer if the employer is not the registrant, specifically authorizes the planned special exposure, in writing, before the exposure occurs.

3.6.3 Before a planned special exposure, the registrant ensures that each individual involved is:

3.6.3.1 Informed of the purpose of the planned operation; and

3.6.3.2 Informed of the estimated doses and associated potential risks and specific radiation levels or other conditions that might be involved in performing the task; and

3.6.3.3 Instructed in the measures to be taken to keep the dose ALARA considering other risks that may be present.

3.6.4 Prior to permitting an individual to participate in a planned special exposure, the registrant ascertains prior doses as required by RHB 3.20 during the lifetime of the individual for each individual involved.

3.6.5 Subject to RHB 3.4.2, the registrant shall not authorize a planned special exposure that would cause an individual to receive a dose from all planned special exposures and all doses in excess of the limits to exceed:

3.6.5.1 The numerical values of any of the dose limits in RHB 3.4.1 in any year; and

3.6.5.2 Five times the annual dose limits in RHB 3.4.1 during the individual's lifetime.

3.6.6 The registrant maintains records of the conduct of a planned special exposure in accordance with RHB 3.21 and submits a written report in accordance with RHB 3.27.

3.6.7 The registrant records the best estimate of the dose resulting from the planned special exposure in the individual's record and informs the individual, in writing, of the dose within 30 days from the date of the planned special exposure. The dose from planned special exposures shall not be considered in controlling future occupational dose of the individual pursuant to RHB 3.4.2.

RHB 3.7 Occupational Dose Limits for Minors. The annual occupational dose limits for minors are ten (10) percent of the annual occupational dose limits specified for adult workers in RHB 3.4.

RHB 3.8 Dose to an Embryo/Fetus.

3.8.1 The registrant shall ensure that the dose to an embryo/fetus during the entire pregnancy, due to occupational exposure of a declared pregnant woman, does not exceed 0.5 rem (5 mSv). See RHB 3.22 for record keeping requirements.

3.8.2 The registrant shall make efforts to avoid substantial variation above a uniform monthly exposure rate to a declared pregnant woman so as to satisfy the limit in RHB 3.8.1.

3.8.3 The dose to an embryo/fetus shall be taken as the sum of:

3.8.3.1 The deep dose equivalent to the declared pregnant woman; and

3.8.3.2 The dose to the embryo/fetus from radionuclides in the embryo/fetus and radionuclides in the declared pregnant woman.

3.8.4 If by the time the woman declares pregnancy to the registrant, the dose to the embryo/fetus has exceeded 0.45 rem (4.5 mSv), the registrant shall be deemed to be in compliance with RHB 3.8.1 if the additional dose to the embryo/fetus does not exceed 0.05 rem (0.5 mSv) during the remainder of the pregnancy.

RHB 3.9 DOSE LIMITS FOR INDIVIDUAL MEMBERS OF THE PUBLIC.

3.9.1 Each registrant shall conduct operations so that:

3.9.1.1 The total effective dose equivalent to individual members of the public from the registered operation does not exceed 0.1 rem (1 mSv) in a year, and

3.9.1.2 The dose in any unrestricted area from external sources does not exceed 0.002 rem (0.02 mSv) in any one hour.

3.9.2 If the registrant permits members of the public to have access to controlled areas, the limits for members of the public continue to apply to those individuals.

3.9.3 A registrant, or an applicant for a registration may apply for prior Department authorization to operate up to an annual dose limit for an individual member of the public of 0.5 rem (5 mSv). This application shall include the following information:

3.9.3.1 Demonstration of the need for and the expected duration of operations in excess of the limit in RHB 3.9.1; and

3.9.3.2 THE REGISTRANT'S PROGRAM TO ASSESS AND CONTROL DOSE WITHIN THE 0.5 REM (5 MSV) ANNUAL LIMIT; AND

3.9.3.3 The procedures to be followed to maintain the dose ALARA.

3.9.4 RETROFIT SHALL NOT BE REQUIRED FOR LOCATIONS WITHIN FACILITIES WHERE ONLY RADIATION MACHINES EXISTED PRIOR TO THE EFFECTIVE DATE OF THESE REGULATIONS, AND MET THE PREVIOUS REQUIREMENTS OF 0.5 REM (5 MSV) IN A YEAR.

RHB 3.10 Compliance with Dose Limits for Individual Members of the Public.

3.10.1 The registrant shall make or cause to be made surveys of radiation levels in unrestricted and controlled areas to demonstrate compliance with the dose limits for individual members of the public in RHB 3.9.

3.10.2 A registrant shall show compliance with the annual dose limit in RHB 3.9 by:

3.10.2.1 Demonstrating by measurement or calculation that the total effective dose equivalent to the individual likely to receive the highest dose from the registered operation does not exceed the annual dose limit; or

3.10.2.2 Demonstrating that if an individual were continually present in an unrestricted area, the dose from external sources would not exceed 0.002 rem (0.02 mSv) in an hour and 0.05 rem (0.5 mSv) in a year.

RHB 3.11 Surveys and Monitoring

3.11.1 Each registrant shall make, or cause to be made, surveys that:

3.11.1.1 Are necessary for the registrant to comply with this Part; and

3.11.1.2 Are necessary under the circumstances to evaluate:

3.11.1.2.1 Radiation levels; and

3.11.1.2.2 The potential radiological hazards that could be present.

3.11.2 The registrant shall ensure that instruments and equipment used for quantitative radiation measurements, for example, dose rate and effluent monitoring, are calibrated at intervals not to exceed 12 months for the radiation measured.

3.11.3 All personnel dosimeters, except for direct and indirect reading pocket ionization chambers and those dosimeters used to measure the dose to any extremity, that require processing to determine the radiation dose and that are used by registrants to comply with RHB 3.4, with other applicable provisions of these regulations, or with conditions specified in a registration shall be processed and evaluated by a dosimetry processor:

3.11.3.1 Holding current personnel dosimetry accreditation from the National Voluntary Laboratory Accreditation Program (NVLAP) of the National Institute of Standards and Technology; and

3.11.3.2 Approved in this accreditation process for the type of radiation or radiations included in the NVLAP program that most closely approximates the type of radiation or radiations for which the individual wearing the dosimeter is monitored.

3.11.4 Exposure of a personnel monitoring device to deceptively indicate a dose delivered to an individual is prohibited.

RHB 3.12 Conditions requiring Individual Monitoring of Occupational Dose.

3.12.1 Each registrant shall monitor exposures from sources of radiation at levels sufficient to demonstrate compliance with the occupational dose limits of this part. As a minimum:

3.12.1.1 EACH REGISTRANT SHALL MONITOR OCCUPATIONAL EXPOSURE TO RADIATION AND SHALL SUPPLY AND REQUIRE THE USE OF INDIVIDUAL MONITORING

DEVICES BY:

3.12.1.1.1 Adults likely to receive, in 1 year from sources external to the body, a dose in excess of 10 percent of the limits in RHB 3.4; and

3.12.1.1.2 Minors and declared pregnant women likely to receive, in 1 year from sources external to the body, a dose in excess of 10 percent of any of the applicable limits in RHB 3.7 or 3.8; and

3.12.1.1.3 Individuals entering a high or very high radiation area.

3.12.1.1.4 All employees who may be required to hold patients or films during x-ray examinations more than three times a quarter; or

3.12.1.1.5 All individuals who operate mobile or portable x-ray equipment. Operators of peripheral bone densitometers are exempt from this requirement.

3.12.1.1.6 Such other individuals as the Department deems necessary.

3.12.2 When a lead apron is worn, the monitoring device shall be worn at the collar, outside the apron. When two monitoring devices are worn (one outside and one under the apron) the one outside will be considered the permanent record for the individual. The Department may give consideration that the badge under the apron be used as the permanent record provided that the registrant submits written procedures detailing the protective apparel used and means to ensure that this apparel is worn at all times. Written procedures shall be submitted to and approved by the Department prior to the badge under the apron being used as the permanent record.

3.12.3 When an individual who has been given responsibility that involves occupational exposure to x-rays declares that she is pregnant, the employer must, at her request, provide her with an additional personnel monitoring device to be worn on the trunk underneath the leaded apron, when such apron is worn.

RHB 3.13 Control of Access to High Radiation Areas.

3.13.1 The registrant shall ensure that each entrance or access point to a high radiation area has one or more of the following features:

3.13.1.1 A control device that, upon entry into the area, causes the level of radiation to be reduced below that level at which an individual might receive a deep dose equivalent of 0.1 rem (1 mSv) in 1 hour at 30 centimeters from the source of radiation from any surface that the radiation penetrates; or

3.13.1.2 A control device that energizes a conspicuous visible or audible alarm signal so that the individual entering the high radiation area and the supervisor of the activity are made aware of the entry; or

3.13.1.3 Entryways that are locked, except during periods when access to the areas is required, with positive control over each individual entry.

3.13.2 In place of the controls required by RHB 3.13.1 for a high radiation area, the registrant may substitute continuous direct or electronic surveillance that is capable of preventing unauthorized entry.

3.13.3 The registrant may apply to the Department for approval of alternative methods for controlling access to high radiation areas.

3.13.4 The registrant shall establish the controls required by RHB 3.13.1 and 3.13.3 in a way that does not prevent individuals from leaving a high radiation area.

RHB 3.14 Control of Access to Very High Radiation Areas. In addition to the requirements in RHB 3.13, the registrant shall institute measures to ensure that an individual is not able to gain unauthorized or inadvertent access to areas in which radiation levels could be encountered at 500 rad (5 Gy) or more in 1 hour at 1 meter from a source of radiation or any surface through which the radiation penetrates. This requirement does not apply to rooms or areas in which diagnostic x-ray systems are the only source of radiation.

RHB 3.15 CAUTION SIGNS.

3.15.1 The radiation symbols prescribed by this regulation shall be the conventional three-bladed design as shown. The cross-hatched area shall be magenta, purple, or black, and the background shall be yellow.

3.15.2 Additional Information on Signs and Labels. In addition to the contents of signs and labels prescribed in this Part, the registrant shall provide, on or near the required signs and labels, additional information, as appropriate, to make individuals aware of potential radiation exposures and to minimize the exposures.

RHB 3.16 Posting Requirements.

3.16.1 Posting of Radiation Areas. The registrant shall post each radiation area with a conspicuous sign or signs bearing the radiation symbol and the words "CAUTION, RADIATION AREA."

3.16.2 Posting of High Radiation Areas. The registrant shall post each high radiation area with a conspicuous sign or signs bearing the radiation symbol and the words "CAUTION, HIGH RADIATION AREA" or "DANGER, HIGH RADIATION AREA."

3.16.3 Posting of Very High Radiation Areas. The registrant shall post each very high radiation area with a conspicuous sign or signs bearing the radiation symbol and words "GRAVE DANGER, VERY HIGH RADIATION AREA."

3.16.4 Exceptions to Posting Requirements. A registrant is not required to post caution signs in areas or rooms containing sources of radiation for periods of less than 8 hours, if each of the following conditions is met:

3.16.4.1 The sources of radiation are constantly attended during these periods by an individual who takes the precautions necessary to prevent the exposure of individuals to sources of radiation in excess of the limits established in this Part; and

3.16.4.2 The area or room is subject to the registrant's control.

RHB 3.17 General Provisions for Records.

3.17.1 Each registrant shall use the SI units becquerel, gray, sievert and coulomb per kilogram, or the special units curie, rad, rem and roentgen, including multiples and subdivisions, and shall clearly indicate the units of all quantities on records required by this Part.

3.17.2 The registrant shall make a clear distinction among the quantities entered on the records required by this Part, such as, total effective dose equivalent, total organ dose equivalent, shallow dose equivalent, eye dose equivalent, deep dose equivalent, or committed effective dose equivalent.

RHB 3.18 Records of Radiation Protection Programs.

3.18.1 Each registrant shall maintain records of the radiation protection program, including:

3.18.1.1 The provisions of the program; and

3.18.1.2 Audits and other reviews of program content and implementation.

3.18.2 The registrant shall retain the records required by (RHB 3.18.1.1) until the Department terminates each pertinent registration requiring the record. The registrant shall retain the records required by RHB 3.18.1.2 for 5 years after the record is made.

RHB 3.19 Records of Surveys.

3.19.1 Each registrant shall maintain records showing the results of surveys and calibrations required by RHB 3.11. The registrant shall retain these records for 5 years after the record is made.

3.19.2 The registrant shall retain records of the results of surveys to determine the dose from external sources of radiation used, in the absence of or in combination with individual monitoring data, in the assessment of individual dose equivalents for 5 years after the record is made.

RHB 3.20 Determination and Records of Prior Occupational Dose.

3.20.1 For each individual who may enter the registrant's restricted or controlled area and is likely to receive, in a year, an occupational dose requiring monitoring pursuant to RHB 3.12, the registrant shall:

3.20.1.1 Determine the occupational radiation dose received during the current year; and

3.20.1.2 Attempt to obtain the records of lifetime cumulative occupational radiation dose.

3.20.2 Prior to permitting an individual to participate in a planned special exposure, the registrant shall determine:

3.20.2.1 The internal and external doses from all previous planned special exposures; and

3.20.2.2 All doses in excess of the limits, including doses received during accidents and emergencies, received during the lifetime of the individual; and

3.20.2.3 All lifetime cumulative occupational radiation dose.

3.20.3 In complying with the requirements of RHB 3.20.1, a registrant may:

3.20.3.1 Accept, as a record of the occupational dose that the individual received during the current year, a written signed statement from the individual, or from the individual's most recent employer for work involving radiation exposure, that discloses the nature and the amount of any occupational dose that the individual received during the current year; and

3.20.3.2 Accept, as the record of lifetime cumulative radiation dose, an up-to-date Department form SC-RHA-40 or equivalent, signed by the individual and countersigned by an appropriate official of the most recent employer for work involving radiation exposure, or the individual's current employer, if the individual is not employed by the registrant; and

3.20.3.3 Obtain reports of the individual's dose equivalent from the most recent employer for work involving radiation exposure, or the individual's current employer, if the individual is not employed by the registrant, by telephone, telegram, facsimile, or letter. The registrant shall request a written verification of the dose data if the authenticity of the transmitted report cannot be established.

3.20.4 The registrant shall record the exposure history, as required by RHB 3.20.1, on Department form SC-RHA-40, or other clear and legible record, of all the information required on that form. The form or record

shall show each period in which the individual received occupational exposure to radiation or radioactive material and shall be signed by the individual who received the exposure. For each period for which the registrant obtains reports, the registrant shall use the dose shown in the report in preparing Department form SC-RHA-40 or equivalent. For any period in which the registrant does not obtain a report, the registrant shall place a notation on Department form SC-RHA-40 or equivalent indicating the periods of time for which data are not available.

3.20.5 If the registrant is unable to obtain a complete record of an individual's current and previously accumulated occupational dose, the registrant shall assume:

3.20.5.1 In establishing administrative controls pursuant to RHB 3.4.4 for the current year, that the allowable dose limit for the individual is reduced by 1.25 rem (12.5 mSv) for each quarter for which records were unavailable and the individual was engaged in activities that could have resulted in occupational radiation exposure; and

3.20.5.2 That the individual is not available for planned special exposures.

3.20.6 The registrant shall retain the records of prior occupational dose and exposure history on Department form SC-RHA-40 or equivalent until the Department terminates each pertinent registration requiring this record. The registrant shall retain records used in preparing Department form SC-RHA-40 or equivalent for 5 years after the record is made.

RHB 3.21 Records of Planned Special Exposures.

3.21.1 For each use of the provisions of RHB 3.6 for planned special exposures, the registrant shall maintain records that describe:

3.21.1.1 The exceptional circumstances requiring the use of a planned special exposure; and

3.21.1.2 The name of the management official who authorized the planned special exposure and a copy of the signed authorization; and

3.21.1.3 What actions were necessary; and

3.21.1.4 Why the actions were necessary; and

3.21.1.5 What precautions were taken to assure that doses were maintained ALARA; and

3.21.1.6 What individual and collective doses were expected to result; and

3.21.1.7 The doses actually received in the planned special exposure.

3.21.2 The registrant shall retain the records until the Department terminates each pertinent registration requiring these records.

RHB 3.22 RECORDS OF INDIVIDUAL MONITORING RESULTS.

3.22.1 Record keeping Requirement. Each registrant shall maintain records of doses received by all individuals for whom monitoring was required pursuant to RHB 3.12, and records of doses received during planned special exposures, accidents, and emergency conditions. Assessments of dose equivalent and records made using units in effect before the effective date of this Part need not be changed. These records shall include the deep dose equivalent to the whole body, eye dose equivalent, shallow dose equivalent to the skin, and shallow dose equivalent to the extremities.

3.22.2 Record keeping Frequency. The registrant shall make entries of the records specified in RHB 3.22.1 at intervals not to exceed 1 year.

3.22.3 Record keeping Format. The registrant shall maintain the records specified in RHB 3.22.1 on Department form SC-RHA-40, in accordance with the instructions for Department form SC-RHA-40, or in clear and legible records containing all the information required by Department form SC-RHA-40.

3.22.4 The registrant shall maintain the records of dose to an embryo/fetus with the records of dose to the declared pregnant woman. The declaration of pregnancy, including the estimated date of conception, shall also be kept on file, but may be maintained separately from the dose records.

3.22.5 The registrant shall retain each required form or record until the Department terminates each pertinent registration requiring the record.

RHB 3.23 Records of Dose to Individual Members of the Public.

3.23.1 EACH REGISTRANT SHALL MAINTAIN RECORDS SUFFICIENT TO DEMONSTRATE COMPLIANCE WITH THE DOSE LIMIT FOR INDIVIDUAL MEMBERS OF THE PUBLIC IN RHB 3.10.

3.23.2 The registrant shall retain the records required by RHB 3.23.1 until the Department terminates each pertinent registration requiring the record.

RHB 3.24 FORM OF RECORDS. EACH RECORD REQUIRED BY THIS PART SHALL BE LEGIBLE THROUGHOUT THE SPECIFIED RETENTION PERIOD. THE RECORD SHALL BE THE ORIGINAL OR A REPRODUCED COPY OR A MICROFORM, PROVIDED THAT THE COPY OR MICROFORM IS AUTHENTICATED BY AUTHORIZED PERSONNEL AND THAT THE MICROFORM IS CAPABLE OF PRODUCING A CLEAR COPY THROUGHOUT THE REQUIRED RETENTION PERIOD. THE RECORD MAY ALSO BE STORED IN ELECTRONIC MEDIA WITH THE CAPABILITY FOR PRODUCING LEGIBLE, ACCURATE, AND COMPLETE RECORDS DURING THE REQUIRED RETENTION PERIOD. RECORDS, SUCH AS LETTERS, DRAWINGS, AND SPECIFICATIONS, SHALL INCLUDE ALL PERTINENT INFORMATION, SUCH AS STAMPS, INITIALS, AND SIGNATURES. THE REGISTRANT SHALL MAINTAIN ADEQUATE SAFEGUARDS AGAINST TAMPERING WITH AND LOSS OF RECORDS.

RHB 3.25 NOTIFICATION OF INCIDENTS.

3.25.1 Immediate Notification. Notwithstanding other requirements for notification, each registrant shall immediately report each event involving a source of radiation possessed by the registrant that may have caused or threatens to cause an individual to receive:

3.25.1.1 A total effective dose equivalent of 25 rem (0.25 Sv) or more; or

3.25.1.2 An eye dose equivalent of 75 rem (0.75 Sv) or more; or

3.25.1.3 A shallow dose equivalent to the skin or extremities or a total organ dose equivalent of 250 rad (2.5 Gy) or more; or

3.25.2 Twenty-Four Hour Notification. Each registrant shall, within 24 hours of discovery of the event, report to the Department each event that may have caused, or threatens to cause, an individual to receive, in a period of 24 hours:

3.25.2.1 A total effective dose equivalent exceeding 5 rem (0.05 Sv); or

3.25.2.2 An eye dose equivalent exceeding 15 rem (0.15 Sv); or

3.25.2.3 A shallow dose equivalent to the skin or extremities or a total organ dose equivalent exceeding 50 rem (0.5 Sv); or

3.25.3 The registrant shall prepare each report filed with the Department pursuant to this Part so that names of individuals who have received exposure to sources of radiation are stated in a separate and detachable portion of the report.

3.25.4 Registrants shall make the reports required by this Part to the Department by telephone, telegram, mailgram, or facsimile to the Department.

3.25.5 The provisions of this Part do not apply to doses that result from planned special exposures, provided such doses are within the limits for planned special exposures and are reported pursuant to RHB 3.27.

RHB 3.26 Reports of Exposures and Radiation Levels Exceeding the Limits.

3.26.1 In addition to the notification required by RHB 3.25, each registrant shall submit a written report within 30 days after learning of any of the following occurrences:

3.26.1.1 Any incident for which notification is required by RHB 3.25;

3.26.1.2 Doses in excess of any of the following:

3.26.1.2.1 The occupational dose limits for adults in RHB 3.4;

3.26.1.2.2 The occupational dose limits for a minor in RHB 3.7;

3.26.1.2.3 The limits for an embryo/fetus of a declared pregnant woman in RHB 3.8; or

3.26.1.2.4 The limits for an individual member of the public in RHB 3.9.

3.26.2 Each report required by RHB 3.26.1 shall describe the extent of exposure of individuals to radiation, including, as appropriate:

3.26.2.1 Estimates of each individual's dose; and

3.26.2.2 The levels of radiation involved; and

3.26.2.3 The cause of the elevated exposures or dose rates; and

3.26.2.4 Corrective steps taken or planned to ensure against a recurrence, including the schedule for achieving conformance with applicable limits.

3.26.3 Each report files pursuant to RHB 3.26.1 shall include for each individual exposed: the name, Social Security account number, and date of birth. With respect to the limit for the embryo/fetus in RHB 3.8, the identifying information shall be that of the declared pregnant woman. The report shall be prepared so that this information is stated in a separate and detachable portion of the report.

3.26.4 Reports made by registrants in response to the requirements of this Part shall be addressed to the department as specified in RHB 1.12.

RHB 3.27 Reports of Planned Special Exposures. The registrant shall submit a written report to the Department within 30 days following any planned special exposure conducted in accordance with RHB 3.6, informing the Department that a planned special exposure was conducted and indicating the date the planned special exposure occurred and the information required by RHB 3.21.

RHB 3.28 REPORTS OF INDIVIDUAL MONITORING. THE DEPARTMENT MAY REQUIRE BY REGISTRATION CONDITION, OR ORDER PURSUANT TO RHB 1.6.1, ANNUAL REPORTS OF THE RESULTS OF INDIVIDUAL MONITORING CARRIED OUT BY THE REGISTRANT FOR EACH INDIVIDUAL FOR WHOM MONITORING WAS REQUIRED BY RHB 3.12.

RHB 3.29 Notifications and Reports to Individuals.

3.29.1 Requirements for notification and reports to individuals of exposure to radiation are specified in RHB10.4.

3.29.2 When a registrant is required pursuant to RHB 3.26 to report to the Department any exposure of an individual to radiation, the registrant shall also notify the individual. Such notice shall be transmitted at a time not later than the transmittal to the Department, and shall comply with the provisions of RHB10.4.

RHB 3.30 Storage and Control of Radiation Sources

3.30.1 Security of Stored Sources of Radiation. The registrant shall secure from unauthorized removal or access sources of radiation that are stored in controlled or unrestricted areas.

3.30.2 Control of Sources of Radiation not in Storage. The registrant shall maintain control of radiation machines that are in a controlled or unrestricted area and that are not in storage.

RHB 3.31 Reports of Stolen, Lost, or Missing Radiation Sources

3.31.1 Telephone Reports. Each registrant shall report to the Department by telephone, immediately after its occurrence becomes known to the registrant, a stolen, lost, or missing radiation machine.

3.31.2 Written Reports. Each registrant required to make a report pursuant to RHB 3.31.1 shall, within 30 days after making the telephone report, make a written report to the Department setting forth the following information:

3.31.2.1 A description of the registered source of radiation involved, including the manufacturer, model and serial number, type and maximum energy of radiation emitted;

3.31.2.2 A description of the circumstances under which the loss or theft occurred; and

3.31.2.3 A statement of disposition, or probable disposition, of the registered source of radiation involved; and

3.31.2.4 Actions that have been taken, or will be taken, to recover the source of radiation; and

3.31.2.5 Procedures or measures that have been, or will be, adopted to ensure against a recurrence of the loss or theft of registered sources of radiation.

3.31.3 Subsequent to filing the written report, the registrant shall also report additional substantive information on the loss or theft within 30 days after the registrant learns of such information.

PART IV
USE OF X-RAY IN THE HEALTH PROFESSIONS

RHB 4.1 Scope. This part establishes requirements for which a registrant is responsible, for use of x-ray equipment by or under the supervision of an individual authorized by and licensed in accordance with State statutes to engage in the healing arts or veterinary medicine.

RHB 4.2 General Safety Provisions.

4.2.1 No person shall make, sell, lease, transfer, lend, repair, or install x-ray equipment or the supplies used in connection with such equipment unless such supplies or equipment, when properly placed in operation and properly used will meet the requirements of these regulations. This includes but is not limited to such items as cones, filters, adequate timers, and fluoroscopic shutters (where applicable). Also, such person shall be registered with the Department in accordance with RHB 2.5.

4.2.2 An x-ray system which does not meet the provisions of these regulations shall not be operated for diagnostic or therapeutic purposes if so directed by the Department.

4.2.3 THE REGISTRANT SHALL ASSURE THAT ALL X-RAY MACHINES UNDER HIS CONTROL ARE OPERATED ONLY BY A RADIOLOGIC TECHNOLOGIST POSSESSING A CURRENT, VALID CERTIFICATE FROM THE SOUTH CAROLINA RADIATION QUALITY STANDARDS ASSOCIATION, OR A LICENSED PRACTITIONER. FOR THE PURPOSE OF THIS PART, A RADIOLOGIC TECHNOLOGIST IS DEFINED AS A PERSON WHO IS A LIMITED PRACTICE RADIOGRAPHER, RADIOGRAPHER, PODIATRIC LIMITED PRACTICE RADIOGRAPHER OR LIMITED CHEST RADIOGRAPHER CERTIFIED BY THE AMERICAN REGISTRY OF RADIOLOGIC TECHNOLOGISTS OR WHO IS CERTIFIED BY THE SOUTH CAROLINA RADIATION QUALITY STANDARDS ASSOCIATION OR WHO HAS OBTAINED A CERTIFICATE ACCEPTABLE TO THE SOUTH CAROLINA RADIATION QUALITY STANDARDS ASSOCIATION. A PERSON WHO APPLIES IONIZING RADIATION TO HUMANS OR PERFORMS X-RAY EXAM SETUPS, INCLUDING, BUT NOT LIMITED TO, PATIENT POSITIONING AND TECHNIQUE SELECTION SHALL BE CONSIDERED A RADIOLOGIC TECHNOLOGIST.

4.2.3.1 NO PERSON OTHER THAN A LICENSED PRACTITIONER OR A RADIOLOGIC TECHNOLOGIST POSSESSING A CURRENT, VALID CERTIFICATE FROM THE SOUTH CAROLINA RADIATION QUALITY STANDARDS ASSOCIATION SHALL USE EQUIPMENT EMITTING IONIZING RADIATION ON HUMANS FOR DIAGNOSTIC PURPOSES.

4.2.3.2 No person shall employ or designate as a radiologic technologist a person who does not hold a current, valid certificate issued by the South Carolina Radiation Quality Standards Association.

4.2.3.3 No person holding a certificate issued by the South Carolina Radiation Quality Standards Association shall use equipment emitting ionizing radiation on humans for diagnostic purposes unless under the direction and supervision of a licensed practitioner and unless so directed by prescription of a licensed practitioner.

4.2.3.4 No person who is not certified by the South Carolina Radiation Quality Standards Association shall take, use, or exhibit the title of "limited practice radiographer", "podiatric limited practice radiographer", "limited chest radiographer", or "radiographer" or any other title, sign, display, or declaration that tends to lead the public to believe that the person is authorized to apply ionizing radiation on humans for diagnostic purposes.

4.2.3.5 A student enrolled in and attending a school or college of medicine, osteopathy, chiropractic, podiatry, radiologic technology, or a curriculum approved by the South Carolina Radiation Quality Standards Association, or a resident in an approved graduate education program of medicine, osteopathy, chiropractic, or podiatry may apply ionizing radiation to humans without a certificate from the South Carolina Radiation

Quality Standards Association, as long as the student or resident is under the supervision of a licensed practitioner or direct supervision of a certified radiologic technologist appropriately trained to supervise the specific procedure.

4.2.3.6 THE REGISTRANT SHALL DISPLAY EACH OPERATOR'S CURRENT CERTIFICATE IN PUBLIC VIEW, NOT OBSTRUCTED BY ANY BARRIER, EQUIPMENT, OR OTHER OBJECT.

4.2.3.7 The registrant shall ensure that each operator has received training specific to the equipment and procedures in use at his facility, including machine specific training, use of personnel monitoring devices, quality assurance procedures, and the operating procedures required by RHB 4.2.4. The registrant shall maintain a record of this training for each operator. Such records shall be made available for Departmental review.

4.2.3.8 Dentists and their auxiliaries who meet the requirements of the South Carolina Dental Practice Act are exempt from the requirements of 4.2.3.1 through 4.2.3.6.

4.2.4 THE REGISTRANT SHALL CREATE AND MAKE AVAILABLE TO X-RAY OPERATORS WRITTEN OPERATING PROCEDURES, INCLUDING ANY RESTRICTIONS OF THE OPERATING TECHNIQUES REQUIRED FOR THE PROPER OPERATION OF THE PARTICULAR X-RAY SYSTEM. THE REGISTRANT SHALL ADHERE TO THE OPERATING PROCEDURES IN ALL RESPECTS. AFTER INITIAL REVIEW AND APPROVAL OF THE PROCEDURES BY THE DEPARTMENT, ANY SUBSTANTIVE CHANGES MUST BE SUBMITTED IN WRITING TO THE DEPARTMENT FOR REVIEW AND APPROVAL PRIOR TO IMPLEMENTATION OF THE CHANGE. THE OPERATOR SHALL BE ABLE TO DEMONSTRATE FAMILIARITY AND COMPETENCE WITH THESE PROCEDURES. DOCUMENTATION MUST BE MAINTAINED, INDICATING THAT THE OPERATOR HAS READ AND AGREES TO ADHERE TO THE OPERATING PROCEDURES. THE PROCEDURES SHALL INCLUDE, BUT NOT BE LIMITED TO:

4.2.4.1 Policies and procedures for Patient Holding;

4.2.4.2 Policies and procedures for Pregnant Workers; NRC Regulatory Guide 8.13, "Instruction Concerning Prenatal Radiation Exposure", should be used for guidance concerning pregnant workers.

4.2.4.3 Policies and procedures regarding the use of Gonadal shielding; (Registrants using x-ray equipment for veterinary purposes are exempt from this requirement.)

4.2.4.4 Policies and procedures for Pregnant patients; (Registrants using x-ray equipment for veterinary purposes are exempt from this requirement.)

4.2.4.5 Policies and procedures for Personnel Monitoring;

4.2.4.6 Procedures for training New Employees;

4.2.4.7 Methods for Quality Assurance.

4.2.5 X-ray producing machines and associated equipment shall be maintained in such a condition to ensure that the patient and staff are not exposed to radiation unnecessarily.

4.2.6 The Department may waive compliance with the specific requirements of any regulation for existing x-ray equipment or installation if:

4.2.6.1 Such compliance would require the replacement or substantial modification of the x-ray equipment or installation; and

4.2.6.2 The registrant demonstrates, to the Department's satisfaction, achievement through other means, radiation protection equivalent to that required by these regulations.

4.2.7 If an x-ray system is identified as not being in compliance with the provisions of these regulations and cannot meet the regulations, or if the registrant is unwilling to make corrections, and if that system is accessible for use, it shall be rendered inoperable (i.e. dismantle the x-ray source from the source support assembly) if so ordered by the Department.

4.2.8 In the vicinity of each diagnostic x-ray system's control panel, a chart shall be provided which specifies for all examinations performed with that system, the following information:

4.2.8.1 Patient's body part and anatomical size, or body part thickness or age (for pediatrics), versus technique factors to be used;

4.2.8.2 Type and size of the film or film-screen combination to be used;

4.2.8.3 Source to image receptor distance (SID) to be used (except for dental intra-oral radiography) and

4.2.8.4 Type and location of placement of patient shielding (e.g., gonad, thyroid, etc.) to be used.

4.2.8.5 For automatic exposure control (AEC) systems with selectable exposure detectors and density settings, the technique chart shall also specify the appropriate exposure detector(s) and density setting to be utilized for each radiographic examination listed.

4.2.8.6 For AEC systems, the technique chart shall specify the requirements of RHB 4.2.8.1 through RHB 4.2.8.4 to be followed when operated in a non-automatic mode.

4.2.8.7 The technique chart shall accurately reflect techniques currently in use at the facility.

4.2.9 A sign shall be posted in a conspicuous area so as to be easily seen by the patient to the effect that if there is a pregnancy or the possibility of a pregnancy, the physician shall be notified. Prescription of x-ray examinations of pregnant or possibly pregnant patients shall assure that medical consideration has been given to possible fetal exposure and appropriate protective measures are taken.

4.2.10 The effectiveness of protective equipment shall not be impaired. Lead aprons and gloves shall be checked at least annually for cracks and holes that could compromise the radiation protection it provides. This testing shall be documented. Records of this testing shall be kept two years, or until the next Department inspection, whichever is later.

4.2.11 Except for patients who cannot be moved out of the room, only the staff and ancillary personnel required for the medical procedure or training shall be in the room during the radiographic exposure other than the patient being examined.

4.2.11.1 All individuals shall be positioned such that no part of the body will be struck by the useful beam, unless protected by not less than 0.5 mm lead equivalent material.

4.2.11.2 The x-ray operator, other staff, and ancillary persons shall be protected from the direct scatter radiation by protective aprons or whole body protective barriers of not less than 0.5 mm lead equivalent material.

4.2.11.3 When feasible, patients who cannot be removed from the room shall be protected from the direct scatter radiation by whole body protective barriers of 0.25 mm lead equivalent or shall be so positioned that the nearest portion of the body is a least 2 meters from both the tube head and the nearest edge of the image receptor.

4.2.11.4 When a portion of the body of any staff or ancillary personnel is potentially subjected to stray radiation which could result in that individual receiving one quarter of the maximum permissible dose as defined in RHB 3.2 of these regulations, additional protective devices may be required by the Department.

4.2.12 Gonadal shielding of not less than 0.5 mm lead equivalent material shall be used for human patients who have not passed the reproductive age during radiographic procedures in which the gonads are in the direct beam, except in cases where the gonadal shielding would interfere with the diagnostic image desired.

4.2.13 Individuals shall not be exposed to the useful beam of electronically produced ionizing radiation except for healing arts purposes, and unless such exposure has been authorized by a licensed practitioner of the healing arts. This provision specifically prohibits deliberate exposure for the following purposes:

4.2.13.1 Exposure of an individual for training, demonstration or other purposes unless there are also healing arts requirements and proper prescription has been provided. Demonstrations or training on new x-ray equipment must be performed with proper protection of the observers and operator(s). Phantoms, not humans, must be used for demonstrations and training.

4.2.13.2 Healing arts screening. Any person proposing to conduct a healing arts screening program shall not initiate such a program without prior approval of the Department. When requesting such approval, that person shall submit the information outlined in Appendix A of this part. If any information submitted to the Department becomes invalid or outdated, the Department shall be notified within 15 days. Approval to conduct a healing arts screening program shall be renewed on an annual basis if deemed necessary by the Department.

4.2.14 When a patient or film must be provided with auxiliary support during a radiation exposure:

4.2.14.1 Mechanical holding devices shall be used when the technique permits. The written safety procedures required by RHB 4.2.4 shall list individual projections where holding devices cannot be used.

4.2.14.2 Written safety procedures, as required in RHB 4.2.4, shall indicate the requirements for selecting a holder, and the procedure the holder shall follow.

4.2.14.3 The human holder shall be instructed in personal radiation safety and shall be protected as required by 4.2.11.

4.2.14.4 No person shall be used routinely to hold patients or film.

4.2.14.5 In those cases where the patient must hold the film, except during intraoral examinations, any portion of the body other than the area of clinical interest struck by the useful beam shall be protected by not less than 0.5 mm lead equivalent material.

4.2.14.6 When practical a pregnant female should not be used to hold film or patients.

4.2.14.7 Each facility shall have leaded aprons and gloves available in sufficient numbers to provide protection to all personnel who are involved in x-ray operations who are not otherwise shielded. Lead aprons and gloves shall be checked at least annually for cracks and holes that could compromise the radiation protection they provide. This testing shall be documented. Records of this testing shall be kept two years, or until the next Department inspection, whichever is later.

4.2.15 Procedures and auxiliary equipment designed to minimize patient and personnel exposure commensurate with the needed diagnostic information shall be used.

4.2.15.1 The speed of the screen and film combinations used shall be the fastest speed consistent with the diagnostic objective of the examinations. Film cassettes without intensifying screens shall not be used for any routine diagnostic radiological imaging. The film cassettes shall provide good contact between the intensifying screens and the film.

4.2.15.2 THE RADIATION EXPOSURE TO THE PATIENT SHALL BE THE MINIMUM EXPOSURE REQUIRED TO PRODUCE IMAGES OF GOOD DIAGNOSTIC QUALITY. APPENDIX D PROVIDES PATIENT EXPOSURES THAT ARE TYPICAL OF GOOD PRACTICES. THESE SHOULD BE USED BY THE REGISTRANT IN EVALUATING PATIENT EXPOSURE.

4.2.15.3 Portable or mobile x-ray equipment shall be used only for examinations where it is impractical to transfer the patient(s) to a stationary x-ray installation.

4.2.15.4 Radiologic technologists performing fluoroscopy as a localizing procedure shall be monitored by the supervising radiologist who is personally and immediately available.

4.2.16 Personnel Monitoring

4.2.16.1 All persons who are associated with the operation of an X-ray system are subject to the occupational exposure limits and the requirements for the determination of the doses which are stated in RHB 3.4. In addition, the following requirements are made:

4.2.16.1.1 When protective clothing or devices are worn on portions of the body and a personnel monitoring device(s) is required, at least one such device shall be utilized as follows:

4.2.16.1.2 When an apron is worn, and one monitoring device is worn, the monitoring device shall be worn at the collar outside of the apron. If more than one monitoring device is worn, the devices shall be worn in accordance with RHB 3.12.2.

4.2.16.1.3 The dose to the whole body based on the maximum dose attributed to any one critical organ shall be recorded in the reports required by RHB 3.22. If more than one device is used and a record is made of the data, each dose shall be identified with the area where the device was worn on the body.

4.2.16.2 Exposure of a personnel monitoring device to falsely indicate a dose delivered to an individual is prohibited.

4.2.16.3 WHEN AN INDIVIDUAL WHO HAS BEEN GIVEN RESPONSIBILITY THAT INVOLVES OCCUPATIONAL EXPOSURE TO X-RAYS DECLARES THAT SHE IS PREGNANT, THE EMPLOYER MUST, AT HER REQUEST, PROVIDE HER WITH AN ADDITIONAL PERSONNEL MONITORING DEVICE TO BE WORN ON THE TRUNK UNDERNEATH THE LEADED APRON, WHEN SUCH APRON IS WORN.

4.2.16.4 All employees who may be required to hold patients or films during x-ray examinations more than three times a quarter shall wear a personnel monitoring device.

4.2.17 X-RAY LOG. EACH FACILITY SHALL KEEP AN X-RAY LOG CONTAINING THE PATIENT'S NAME, THE TYPE OF EXAMINATION, GIVEN BY TITLE AS DENOTED ON THE TECHNIQUE CHART, AND THE DATES THE EXAMINATIONS WERE PERFORMED. WHEN THE PATIENT OR FILM MUST BE PROVIDED WITH HUMAN AUXILIARY SUPPORT, THE NAME OF THE HUMAN HOLDER SHALL BE RECORDED. WHEN THE EXAMINATION IS PERFORMED USING ANY TYPE OF FLUOROSCOPY, THE LOGBOOK SHALL INCLUDE AN

ESTIMATE OF THE AMOUNT OF TIME THAT FLUOROSCOPY WAS PERFORMED OR THE NUMBER OF TIMES THAT THE CUMULATIVE TIMER WAS RESET. THE FLUOROSCOPY TIME IS NOT REQUIRED TO BE RECORDED FOR RADIATION THERAPY SIMULATION UNITS. LOGS ARE NOT REQUIRED FOR DENTAL OR VETERINARY X-RAY EQUIPMENT. X-RAY LOG RECORDS SHALL BE MAINTAINED FOR TWO YEARS OR UNTIL THE NEXT DEPARTMENT INSPECTION, WHICHEVER IS LATER.

4.2.18 Quality Assurance

4.2.18.1 Each registrant covered under RHB 4.5 through 4.12 must have "Equipment Performance Tests" performed on each x-ray unit. The registrant is required to meet the minimum performance criteria and test frequency. Facilities utilizing x-ray equipment for teaching or demonstration purposes only are exempt from this Part. Appendix F provides the required minimum performance criteria that must be tested. Equipment performance tests results must include numerical data. Items found to be non-compliant during such testing shall be corrected within sixty (60) days of receipt of the report. Records showing the test results and the correction of any non-compliant items found must be retained for five years. Equipment performance tests are to be performed:

4.2.18.1.1 At the time installation at all facilities, including veterinary facilities, or

4.2.18.1.2 Within thirty (30) days of installation, provided that the manufacturer's specified testing is performed at the time of installation and before patient use.

4.2.18.1.3 At the following specified intervals thereafter:

4.2.18.1.3.1 Dental x-ray equipment, including cephalometric units, shall be tested every four years alternating with Department inspections.

4.2.18.1.3.2 All medical x-ray equipment, including fluoroscopic, computerized tomography, and radiation therapy simulators, shall be tested annually. Self calibrating bone densitometry systems are exempt from this requirement. Mammography units shall meet the requirements of Part V.

4.2.18.1.3.3 Veterinary facilities are required to have equipment performance tests performed at the time of installation and at any time the Department deems necessary.

4.2.18.1.4 ON ANY UNIT EXPECTED TO REMAIN AT A FACILITY FOR MORE THAN THIRTY (30) CALENDAR DAYS. IF A UNIT IS EXPECTED TO REMAIN AT A FACILITY FOR LESS THAN THIRTY (30) CALENDAR DAYS, THE MANUFACTURER'S SPECIFIED TESTING MUST BE PERFORMED, AT A MINIMUM, PRIOR TO PATIENT USE. MAMMOGRAPHY UNITS SHALL MEET THE REQUIREMENTS OF PART V.

4.2.18.2 THE DARKROOM SHALL BE LIGHT TIGHT TO THE DARK ADAPTED EYE AND USE PROPER SAFELIGHTING SUCH THAT A FILM EXPOSED TO X-RADIATION SUFFICIENT TO PRODUCE AN OPTICAL DENSITY FROM 1 TO 2 WHEN PROCESSED SHALL NOT SUFFER AN INCREASE IN DENSITY GREATER THAN 0.1 WHEN EXPOSED IN THE DARKROOM FOR 2 MINUTES WITH ALL SAFELIGHTS ON. IF USED, DAYLIGHT FILM HANDLING BOXES SHALL PRECLUDE FOGGING OF THE FILM.

4.2.18.3 If grids are used between the patient and the image receptor to decrease scatter to the film and improve contrast the grid shall:

4.2.18.3.1 BE POSITIONED PROPERLY, I.E., TUBE SIDE FACING THE RIGHT DIRECTION, AND GRID CENTERED TO THE CENTRAL RAY,

4.2.18.3.2 If of the focused type, be of the proper focal distance for the SID's being used.

4.2.18.4 Each registrant shall establish a repeat analysis program. An analysis of repeats shall include, at a minimum, the overall repeat rate and the causes for the repeats. The repeat analysis shall be done monthly at facilities that produce less than 250 radiographs per month. Facilities that produce 250 or more radiographs per month shall do a repeat analysis weekly or after 1000 radiographs, whichever comes first. A different repeat analysis frequency may be granted upon application to the Department, provided that the requested frequency allows adequate monitoring, as determined by the Department. Registrants possessing dental or veterinary x-ray equipment are exempt from this requirement.

4.2.19 X-ray Film Processing. Each installation using a radiographic x-ray system and using analog imaging systems (radiographic film) shall have available suitable equipment for handling and processing radiographic film in accordance with the following provisions:

4.2.19.1 Manual Film Processing Systems

4.2.19.1.1 Processing tanks shall be constructed of mechanically rigid, corrosion resistant material.

4.2.19.1.2 A dedicated darkroom thermometer shall be used. The thermometer shall be used to adjust the film processing time according to solution temperature.

4.2.19.1.3 A dedicated darkroom timer with an adjustable preset function shall be used. The timer shall be used to adjust film processing time according to solution temperature.

4.2.19.1.4 Documentation shall be kept of the frequency at which film processing chemicals are changed. At a minimum, the interval as recommended by the chemical manufacturer shall be used.

4.2.19.1.5 Safelight.

4.2.19.1.5.1 The darkroom shall have a functional safelight.

4.2.19.1.5.2 The darkroom safelight shall be adequate for the film speed(s) and the darkroom operating procedures used to prevent fogging of unprocessed film.

4.2.19.1.6 THE TEMPERATURE OF SOLUTIONS IN THE TANKS SHALL BE MAINTAINED WITHIN THE RANGE OF 60° F TO 80° F (16° C TO 27° C). FILM SHALL BE DEVELOPED IN ACCORDANCE WITH THE TIME-TEMPERATURE RELATIONSHIPS RECOMMENDED BY THE FILM MANUFACTURER, OR, IN THE ABSENCE OF SUCH RECOMMENDATIONS, WITH THE FOLLOWING TIME-TEMPERATURE CHART:

TIME TEMPERATURE CHART

Thermometer Reading (Degrees)		Minimum Developing Time (Minutes)
°C	°F	
26.7	80	2
26.1	79	2
25.6	78	2 2
25.0	77	2 2
24.4	76	3
23.9	75	3
23.3	74	3 2
22.8	73	3 2

22.2	72	4
21.7	71	4
21.1	70	4 2
20.6	69	4 2
20.0	68	5
19.4	67	5
18.9	66	5 2
18.3	65	6
17.8	64	6 2
17.2	63	7
16.7	62	8
16.1	61	8 2
15.6	60	9 2

4.2.19.1.7 Radiographs shall not be "sight developed."

4.2.19.2 Automated Processors and Other Closed Processing Systems.

4.2.19.2.1 The temperature of film processing chemicals shall be appropriate for the type of film(s) being processed at the film transport speed selected.

4.2.19.2.2 The film processing chemicals used and their replenishing rate (if applicable) shall be appropriate for the film transport speed selected.

4.2.19.2.3 Safelight.

4.2.19.2.3.1 The darkroom shall have a functional safelight.

4.2.19.2.3.2 The darkroom safelight shall be adequate for the film speed(s) and the darkroom operating procedures used to prevent fogging of unprocessed film.

4.2.19.2.4 FILMS SHALL BE DEVELOPED IN ACCORDANCE WITH THE TIME-TEMPERATURE RELATIONSHIPS RECOMMENDED BY THE FILM MANUFACTURER, OR, IN THE ABSENCE OF SUCH RECOMMENDATIONS, THE FILM SHALL BE DEVELOPED USING THE FOLLOWING CHART:

Developer Temperature		Minimum Immersion Time *
°C	°F	Seconds
35	95	20
34	94	21
34	93	22
33	92	23
33	91	24
32	90	25

*Immersion time only, no crossover time included.

4.2.19.2.5 The specified developer temperature shall be immediately available.

4.2.19.2.6 THE SENSITOMETRIC PERFORMANCE OF AN AUTOMATIC PROCESSOR

SHALL BE EQUIVALENT TO OTHER OPERATING PROCESSOR MODELS SET UP TO MEET THE ABOVE DEVELOPER TEMPERATURE AND IMMERSION TIME SPECIFICATIONS. THIS IS DETERMINED BY PROCESSING IDENTICALLY EXPOSED FILM THROUGH EACH MODEL AND COMPARING THE RESULTS.

4.2.19.2.7 Densitometric and sensitometric performance testing of the processor is required of facilities who process more than 250 films per week. Control limits shall be established for each parameter monitored. Provisions for correctable action shall be undertaken whenever the pre-established control limits are exceeded. Documentation of testing must be maintained for at least two years or until the next Department inspection, whichever is later. Registrants possessing dental or veterinary x-ray equipment are exempt from this requirement. Facilities processing more than 250 films per day are required to perform this testing on each day that examinations are performed before any clinical films are processed that day. Facilities processing less than 250 films per day, but more than 250 films per week, are required to perform this testing on a weekly basis, at a minimum. Facilities that operate 24 hours per day must perform the required testing once each day.

4.2.19.2.8 Records of processor maintenance shall be kept for at least two years or until the next Department inspection, whichever is later.

4.2.19.3 Other Requirements

4.2.19.3.1 Film pass boxes, if provided, shall be so constructed as to exclude light when film is placed in or removed from the boxes, and shall incorporate adequate shielding to prevent exposure of undeveloped film to stray radiation.

4.2.19.3.2 Darkrooms typically used by more than one individual shall be provided a positive method to prevent accidental entry while undeveloped films are being handled or processed.

4.2.19.3.3 Film shall be stored in a cool, dry place and shall be protected from exposure to stray radiation. Film in open packages shall be stored in a light tight container.

4.2.19.3.4 Film cassettes and intensifying screens shall be inspected in accordance with the facility's approved procedures and shall be cleaned and replaced as necessary to best assure radiographs of good diagnostic quality. Documentation of this periodic inspection and cleaning must be maintained for at least two years or until the next Department inspection, whichever is later.

4.2.19.3.5 Outdated x-ray film shall not be used for human diagnostic radiographs, unless the film has been stored in accordance with the manufacturer's recommendations and a sample of the film passes a sensitometric test for normal ranges of base fog and speed.

4.2.19.3.6 Film developing solutions shall be prepared in accordance with the directions given by the manufacturer, and shall be maintained in strength by replenishment or renewal so that full development is accomplished within the time specified by the manufacturer.

RHB 4.3 General Requirements for all Diagnostic X-ray Systems. All diagnostic x-ray systems shall meet the following requirements.

4.3.1 Warning Label. The control panel containing the main power switch shall bear the warning statement, legible and accessible to view: "WARNING: This x-ray unit may be dangerous to patient and operator unless safe exposure factors and operating instructions are observed."

4.3.2 Battery Charge Indicator. On battery powered generators, visual means shall be provided on the control panel to indicate whether the battery is in a state of charge adequate for proper operation.

4.3.3 Leakage Radiation from the Diagnostic Source Assembly. The leakage radiation from the diagnostic source assembly measured at a distance of 1 meter in any direction from the source shall not exceed 100 milliRoentgen in 1 hour when the X-ray tube is operated at its maximum technique factors.

4.3.4 Radiation from Components Other than the Diagnostic Source Assembly. The radiation emitted by a component other than the diagnostic source assembly shall not exceed 2 milliRoentgen in 1 hour at 5 centimeters from any accessible surface of the component when it is operated in an assembled X-ray system under any conditions for which it was designed.

4.3.5 Beam Quality. The half-value layer (HVL) of the useful beam for a given x-ray tube potential shall not be less than the values shown in Table I. If it is necessary to determine such half-value layer at an X-ray tube potential which is not listed in Table I, linear interpolation or extrapolation may be made. For the purpose of this chart, specified dental systems shall be any dental intraoral unit manufactured before August 1, 1974 and on or after December 1, 1980.

TABLE I

Design Operating Range	Measured Potential	Specified Dental Systems	All other diagnostic
Below 51----------	30	N/A	0.3
	40	N/A	0.4
	50	1.5	0.5
51 to 70	51	1.5	1.2
	60	1.5	1.3
	70	1.5	1.5
Above 70	71	2.1	2.1
	80	2.3	2.3
	90	2.5	2.5
	100	2.7	2.7
	110	3.0	3.0
	120	3.2	3.2
	130	3.5	3.5
	140	3.8	3.8
	150	4.1	4.1

4.3.5.1 Beryllium window tubes shall have a minimum of 0.5 mm aluminum equivalent filtration permanently mounted in the useful beam.

4.3.5.2 For capacitor energy storage equipment, compliance with RHB 4.3.5 shall be determined with the maximum quantity of charge per exposure.

4.3.5.3 The required minimal half-value layer of the useful beam shall include the filtration contributed by all materials which are permanently between the source and the patient.

4.3.5.4 All intraoral dental units manufactured after December 1, 1980 shall have at least 1.5 millimeters aluminum equivalent filtration permanently installed in the useful beam.

4.3.6 Filtration Controls. For x-ray systems which have variable kVp and variable filtration for the useful beam, a device shall link the kVp selector with the filter(s) and shall prevent an exposure unless the minimum amount of filtration required by RHB 4.3.5 is in the useful beam for the given kVp which has been selected.

4.3.7 Multiple Tubes. Where two or more radiographic tubes are controlled by one exposure switch, the tube or tubes which have been selected shall be clearly indicated prior to initiation of the exposure. This indication shall be on both the X-ray control and at or near tube housing assembly which has been selected.

4.3.8 Mechanical Support of Tube Head. The tube housing assembly supports shall be adjusted such that the tube housing assembly will remain stable during an exposure unless the tube housing movement is a designed function of the X-ray system.

4.3.9 Technique Indicators

4.3.9.1 The technique factors to be used during an exposure shall be indicated before the exposure begins. If automatic exposure controls are used, the technique factors which are set prior to the exposure shall be indicated.

4.3.9.2 THE REQUIREMENT OF RHB 4.3.9.1 MAY BE MET BY PERMANENTLY MARKING ON EQUIPMENT HAVING FIXED TECHNIQUE FACTORS. INDICATION OF TECHNIQUE FACTORS SHALL BE VISIBLE FROM THE OPERATOR'S POSITION EXCEPT IN THE CASE OF SPOT FILMS MADE BY THE FLUOROSCOPIST.

4.3.9.3 The x-ray control shall provide visual indication of the production of x-rays.

4.3.9.4 X-ray systems utilizing arbitrary number or letter designators for kVp, time and milliAmperage shall be accompanied by a chart giving the value of physical factors for each arbitrary designator.

4.3.10 Focal Spot Indication. The focal spot shall be denoted in such a manner and area as to be easily seen on the tube housing.

4.3.11 Mechanical Timers. Use of mechanical timers is prohibited.

RHB 4.4 Shielding. Prior to construction, the floor plans and equipment arrangement of all new installations, or modifications of existing installations utilizing ionizing radiation for diagnostic or therapeutic purposes shall be reviewed by a Class III or Class IV vendor and submitted to the Department for review and approval. The registrant shall submit plans and a report, including any recommendations and all basic assumptions used, from the vendor to the Department. In order for the Department to provide evaluation and approval, the information listed in Appendix B shall be submitted. The design considerations listed in Appendix C shall be followed. If design criteria in Appendix C cannot be followed, the registrant may offer alternative design criteria to the Department for approval as long as the same degree of safety is being met.

4.4.1 Each installation shall be provided with such primary barriers andsecondary barriers as are necessary to assure compliance with RHB 3.3, RHB 3.4 and RHB 3.5. The requirement shall be deemed to be met if the thickness of such barriers is equivalent to the thickness as computed in accordance with Appendix D of the National Council of Radiation Protection and Measurements, Handbook 49 "Medical X-ray and Gamma-ray Protection for Energies up to 10 MEV", Handbook 35 "Dental X-ray Protection," or an equivalent reference.

4.4.2 The approval of such plans shall not preclude the requirement of additional modifications should a subsequent analysis of operating conditions indicate the possibility of an individual receiving a dose in excess of the limits prescribed in Part III of these regulations.

4.4.3 After installation of a radiation machine, the facility shall maintain for inspection by the Department:

4.4.3.1 The maximum rating of technique factors;

4.4.3.2 A scale drawing of the room in which a stationary radiation machine system is located with such drawing indicating the use of areas adjacent to the room and an estimation of the extent of occupancy by

an individual in such areas. The drawing shall include the type and thickness of materials, or lead equivalency of each protective barrier.

4.4.3.3 A copy of the shielding plan, required by RHB 4.4 and approved by the Department.

4.4.3.4 A copy of the area survey, if required by RHB 4.4.7.

4.4.4 Within 30 days after construction and installation are complete, the facility shall ensure that "as-built" drawings are submitted to the Department. The drawings must indicate the composition of the walls, floor, ceiling, windows and doors. The drawings must also indicate the placement of the x-ray equipment, including the table, control, and vertical cassette holder, if provided, as well as the location and composition of the film bin, if present.

4.4.5 X-ray equipment shall not be used before a shielding plan for the unit has been approved by the Department.

4.4.6 A shielding plan shall also be required when a facility replaces an existing x-ray machine control or generator or when operating procedures at the facility change to an extent so as to render the original shielding plan inaccurate. A shielding plan may not be required upon replacement of a x-ray machine control or generator if the facility can document to the Department's satisfaction, that the original shielding plan remains adequate for that installation.

4.4.7 The registrant shall have a radiation area survey performed by a Class IX vendor, registered with the Department, within thirty days after installation of the x-ray equipment. A survey shall be required for all installations of x-ray equipment where the approved shielding plan indicates that ordinary building materials, such as sheetrock, concrete and brick are not sufficient for radiation protection purposes. The Department may determine that a survey is not required for some installations. The Department shall make a determination as to whether or not a survey is required, and shall notify the facility, in writing, of its determination. The survey shall be submitted to the Department for review, and shall include a scale drawing of the room, indicating the composition of the walls, floor, ceiling, windows, and doors, and the placement of the x-ray equipment, including the table, control, and vertical cassette holder, if provided. The location and composition of the film bin shall also be included. The survey shall include an evaluation of the adequacy of each protective barrier, the operator's location, and the film storage area, if appropriate.

4.4.8 All wall, floor, and ceiling areas exposed to the useful beam shall have primary barriers. Primary barriers in walls shall extend to a minimum height of 2.13 meters above the floor.

4.4.9 Secondary barriers shall be provided in all wall, floor and ceiling areas not having primary barriers.

4.4.10 The operator's station at the control shall be behind a protective barrier either in a separate room, in a protected booth, or behind a shield which will intercept the useful beam and any radiation which has been scattered only once.

4.4.11 Mobile and portable x-ray systems used in conjunction with a permanently installed cassette holder shall be considered a stationary radiographic system and shall meet the requirements for such an installation.

RHB 4.5 Dental Radiographic Installations. In addition to the provisions of RHB 4.3 and 4.4, the requirements of RHB 4.5 apply to x-ray equipment and associated facilities used for dental radiography.

4.5.1 Source to Skin Distance (SSD). X-ray systems designed for use with an intraoral image receptor shall be provided with means to limit the source-to-skin distance, to not less than eighteen (18) centimeters.

4.5.2 Field Limitation. Radiographic systems designed for use with an intraoral image receptor shall be provided with means to limit the x-ray field such that:

4.5.2.1 The x-ray field at the minimum SSD shall be containable in a circle having a diameter of no more than 7 centimeters.

4.5.2.2 An open ended PID shall be used, and shall provide the same degree of protection as the housing. Pointed PIDs shall not be used.

4.5.2.3 The operator shall position the end of the PID as close as practicable to the skin of the patient.

4.5.3 Timers. Means shall be provided to terminate the exposure at a preset time interval, preset product of current and time, a preset number of pulses, or a preset radiation exposure to the image receptor. In addition:

4.5.3.1 It shall not be possible to make an exposure when the timer is set to a "zero" or "off" position if either position is provided.

4.5.3.2 Termination of an exposure shall cause automatic resetting of the timer to its initial setting or to "Zero".

4.5.3.3 Timer reproducibility. The average exposure period ($\overline{T}$) shall be greater than or equal to 5 times the maximum exposure period (Tmax) minus the minimum exposure period (Tmin) when 4 timer tests are performed: $\overline{T} \geq 5 (Tmax - Tmin)$.

4.5.4 X-ray Control.

4.5.4.1 An x-ray control shall be incorporated into each x-ray system such that an exposure can be terminated by the operator at any time, except for exposures of one-half (1/2) second or less.

4.5.4.2 Each x-ray control shall be located in such a way as to meet the following requirements:

4.5.4.2.1 Stationary x-ray systems installed after July 1, 1993, shall have the x-ray control permanently mounted in a protected area, so that the operator is required to remain in that protected area during the entire exposure; and

4.5.4.2.2 FOR STATIONARY X-RAY SYSTEMS WITHOUT A PROTECTED AREA AND INSTALLED BEFORE JULY 1, 1993, THE EXPOSURE SWITCH SHALL BE SUCH THAT THE OPERATOR SHALL STAND AT LEAST SIX FEET AWAY FROM THE TUBE HOUSING AND OUT OF THE DIRECT BEAM.

4.5.4.2.3 The operator shall be able to view the patient during all exams in which x-rays are produced. For systems installed before July 1, 1993, the exposure switch and viewing position shall be no less than six feet away from the x-ray tube head.

4.5.4.2.4 For mobile and portable x-ray systems, the exposure switch shall meet the requirements of 4.5.4.2.2.

4.5.4.2.5 The x-ray control shall provide visual and/or audible indication observable at or from the operator's protected position whenever x-rays are produced. The visual and/or audible signal shall indicate that the exposure has terminated.

4.5.5 Exposure Reproducibility. The coefficient of variation shall not exceed 0.05 when all selectable technique factors are held constant. This requirement shall be deemed to have been met if, when 4 exposures are made at identical technique factors, the value of the average exposure ($\overline{E}$) is greater than or equal to 5 times the maximum exposure (Emax) minus the minimum exposure (Emin): $\overline{E} \geq 5 (Emax - Emin)$.

4.5.6 Linearity. When the equipment allows a choice of x-ray tube current settings and is operated on a power supply as specified by the manufacturer for any fixed x-ray tube potential within the maximum rating, the average ratios of exposure to the indicated milliAmpere-seconds product obtained at any two tube current settings shall not differ by more than 0.10 times their sum: $[X1 - X2] < 0.10 [X1 + X2]$ where X1 and X2 are the average mR/mAs values obtained at each of the two tube current settings.

4.5.7 Accuracy. Deviation of technique factors from indicated values shall not exceed the limits specified for that system by the manufacturer. In the absence of manufacturer's specifications the deviation shall not exceed 10% of the indicated value.

4.5.8 kVp limitations. Dental x-ray machines with a nominal fixed kVp of less than 50 kVp shall not be used to make diagnostic dental radiographs of humans.

4.5.9 Multiple Tubes. Where two or more radiographic tubes are controlled by one exposure switch, the tube or tubes which have been selected shall be clearly indicated prior to initiation of the exposure. This indication shall be both on the X-ray control and at or near the tube housing which has been selected.

4.5.10 Mechanical Support of Tube Head. The tube housing assembly supports shall be adjusted so that the tube housing assembly will remain stable during an exposure unless the tube housing movement is a designed function of the X-ray system.

4.5.11 Structural Shielding.

4.5.11.1 Dental rooms containing x-ray machines shall be provided with primary barriers for all areas struck by the useful beam.

4.5.11.2 When dental x-ray units are installed in adjacent rooms or areas, protective barriers shall be provided between the rooms or areas.

4.5.11.3 Pass throughs. Pass throughs between adjacent areas shall be securely interlocked.

4.5.12 Operating Procedures.

4.5.12.1 Neither the dentist nor his assistant shall hold patients or films during exposure, nor shall any individual be regularly used for this service.

4.5.12.2 The tube housing and the PID shall not be hand-held during an exposure.

4.5.12.3 Dental fluoroscopy without image intensification shall not be used.

4.5.12.4 Each patient undergoing dental radiography shall be draped with a protective apron of not less than 0.25 millimeter lead equivalent to cover the gonadal area unless the patient refuses.

4.5.12.5 Only persons required for the radiographic procedure shall be in the radiographic room during exposures.

RHB 4.6 EXTRAORAL DENTAL RADIOGRAPHIC INSTALLATIONS.

4.6.1 Cephalometric Installations

4.6.1.1 All provisions of RHB 4.7 apply.

4.6.1.2 The radiographic field shall be restricted to the area of the image receptor.

4.6.2 Panoramic Installations

4.6.2.1 All provisions of RHB 4.5 apply, except 4.5.1 and 4.5.2.1.

4.6.3 Other Installations. The Department may impose by rule, regulation, or order any requirements deemed appropriate or necessary to ensure appropriate and proper operation of any extraoral dental radiographic installation that is not a cephalometric or panoramic unit.

RHB 4.7 Medical Radiographic Systems. The requirements of this Part apply to x-ray equipment and associated facilities used for radiography with stationary radiographic systems other than intraoral dental, fluoroscopic, computed tomography (CT), mammography or veterinary medical systems.

4.7.1 Stationary General Purpose Units. In addition to the other provisions of this part, all stationary general purpose units must also meet the following requirements:

4.7.1.1 Means shall be provided for independent stepless adjustment of at least two dimensions of the x-ray field.

4.7.1.2 Means shall be provided to indicate when the axis of the x-ray beam is perpendicular to the plane of the image receptor.

4.7.1.3 Means shall be provided for visually defining the perimeter of the X-ray field. The total misalignment of the edges of the visually defined field with the respective edges of the X-ray field along either the length or width of the visually defined field shall not exceed two percent (2%) of the distance from the source to the center of the visually defined field when the surface upon which it appears is perpendicular to the axis of the X-ray beam.

4.7.1.4 The beam limiting device shall indicate numerically the field size in the plane of the image receptor to which it is adjusted.

4.7.1.5 Indication of field size dimensions and SID's used shall be specified in inches and/or centimeters on the collimator. The indications on the collimator shall be such that aperture adjustments result in X-ray field dimensions in the plane of the image receptor which correspond to those of the image receptor to within two percent (2%) of the SID when the beam axis is perpendicular to the plane of the image receptor.

4.7.1.6 The beam limiting device shall be provided with SID scales that reflect the actual SID(s) used for radiographic procedures.

4.7.1.7 Means shall be provided to align the center of the x-ray field with the center of the image receptor to within 2 percent of the SID.

4.7.2 X-ray Systems Designed for One Image Receptor Size. Radiographic equipment designed for only one image receptor size at a fixed SID shall be provided with means to limit the field at the plane of the image receptor, and to align the center of the x-ray field with the center of the image receptor to within two percent (2%) of the SID, or shall be provided with means to both size and align the x-ray field such that the x-ray field at the plane of the image receptor does not extend beyond any edge of the image receptor.

4.7.3 Special Purpose X-ray Systems. In addition to the other provisions of this Part, all special purpose x-ray systems shall also meet the following requirements:

4.7.3.1 Means shall be provided to limit the x-ray field in the plane of the image receptor such that the x-ray field does not exceed each dimension of the image receptor by more than 2% of the SID when the axis of the x-ray beam is perpendicular to the plane of the image receptor.

4.7.3.2 Means shall be provided to align the center of the X-ray field with the center of the image receptor to within two percent (2%) of the SID, or means shall be provided to both size and align the x-ray field such that the x-ray field at the plane of the image receptor doe snot extend beyond any edge of the image receptor. Compliance shall be determined with the axis of the x-ray beam perpendicular to the plane of the image receptor.

4.7.3.3 The above RHB 4.7.3.1 and 4.7.3.2 may be met with a system that meets the requirements for a general purpose X-ray system as specified in Part RHB 4.7.3, above or, when alignment means are also provided, may be met with either:

4.7.3.3.1 An assortment of removable, fixed aperture, beam limiting devices sufficient to meet the requirement for each combination of image receptor size and SID for which the unit is designed. Each such device shall have clear and permanent markings to indicate the image receptor size and SID for which it is designed; or

4.7.3.3.2 A beam limiting device having multiple fixed apertures sufficient to meet the requirement for each combination of image receptor size and SID for which the unit is designed. Permanent, clearly legible markings shall indicate the image receptor size and SID for which each aperture is designed and shall indicate which aperture is in position for use.

4.7.4 Radiation Exposure Control Devices.

4.7.4.1 Timers. Means shall be provided to terminate the exposure at a preset time interval, preset product of current and time, a preset number of pulses, or a preset radiation exposure to the image receptor. In addition, it shall not be possible to make an exposure when the timer is set to a zero or off position if either position is provided.

4.7.4.2 X-ray Control.

4.7.4.2.1 An x-ray control shall be incorporated into each x-ray system such that an exposure can be terminated by the operator at any time ("deadman" switch) except for exposures of one-half (1/2) second or less, or during serial radiography when means shall be provided to permit completion of any single exposure of the series in process.

4.7.4.2.2 Stationary x-ray systems shall have the x-ray control permanently mounted in a protected area so that the operator is required to remain in that protected area during the entire exposure.

4.7.4.2.3 Mobile and portable x-ray systems which are:

4.7.4.2.3.1 Used for greater than 1 week in same location, i.e., a room or suite, shall meet the requirements of 4.7.4.2.2;

4.7.4.2.3.2 Used for greater than 1 hour and less than 1 week at the same location, i.e., a room or suite, shall meet the requirement of 4.7.4.2.3.1 or be provided with a 6.5 feet high protective barrier which is placed at least 6 feet from the tube housing assembly and at least 6 feet from the patient; or

4.7.4.2.3.3 Used to make an exposure(s) of a patient at the use location shall meet the requirement of 4.7.4.2.3.1 or be provided with a method of x-ray control which will permit the operator to be at least 6 feet from the tube housing assembly during an exposure.

4.7.4.2.4 The X-ray control shall provide visual indication observable at or from the operator protected position whenever X-rays are produced. In addition, a signal audible to the operator shall indicate that the exposure has terminated.

4.7.4.2.5 The X-ray control shall be so placed that the operator can view the patient during any exposure and still stand in a protected area.

4.7.4.2.6 Automatic Exposure Controls. When an automatic exposure control is provided:

4.7.4.2.6.1 Indication shall be made on the control panel when this mode of operation is selected;

4.7.4.2.6.2 If the x-ray tube potential is equal to or greater than 50 kVp, the minimum exposure time for field emission equipment rated for pulsed operation shall be equal to or less than a time interval equivalent to 2 pulses;

4.7.4.2.6.3 The minimum exposure time for all equipment other than that specified in 4.7.4.2.6.2 shall be equal to or less than one-sixtieth (1/60) second or a time interval required to deliver 5 mAs, whichever is greater;

4.7.4.2.6.4 Either the product of peak x-ray tube potential, current, and exposure time shall be limited to not more than 60 kWs per exposure, or the product of x-ray tube current and exposure time shall be limited to not more than 600 mAs per exposure except that, when the x-ray tube potential is less than 50 kVp, the product of x-ray tube current and exposure time shall be limited to not more than 2000 mAs per exposure; and

4.7.4.2.6.5 A visible signal shall indicate when an exposure has been terminated at the limits required by 4.7.4.2.6.4, and manual resetting shall be required before further automatically timed exposures can be made.

4.7.4.2.7 Timer Reproducibility. With a timer setting of 0.5 second or less, the average exposure period ($\overline{T}$) shall be greater than or equal to 5 times the maximum exposure period (Tmax) minus the minimum exposure period (Tmin) when 4 timer tests are performed: $\overline{T} \geq 5 (T_{max} - T_{min})$.

4.7.5 Exposure Reproducibility. The coefficient of variation of exposure shall not exceed 0.05 when all selectable technique factors are held constant. This requirement shall be deemed to have been met if, when four exposures are made at identical technique factors, the value of the average exposure ($\overline{E}$) is greater than or equal to 5 times the maximum exposure (Emax) minus the minimum exposure (Emin): $\overline{E} \geq 5 (E_{max} - E_{min})$.

4.7.6 Radiation from Capacitor Energy Storage Equipment in Standby Status. Radiation emitted from the X-ray tube when the exposure switch or timer is not activated shall not exceed a rate of 2 milliRoentgen per hour at five (5) centimeters from any accessible surface of the diagnostic source assembly, with the beam limiting device fully open.

4.7.7 Accuracy. Deviation of technique factors from indicated values shall not exceed the limits specified for that system by its manufacturer. In the absence of manufacturer's specifications, the deviation shall not exceed 10% of the indicted value.

4.7.8 Linearity. The following requirements apply when the equipment is operated on a power supply as specified by the manufacturer for any fixed x-ray tube potential within the range of 40 percent to 100 percent of the maximum rated.

4.7.8.1 Equipment having independent selection of x-ray tube current (mA). The average ratios of exposure to the indicated milliAmpere-seconds product (C/kg/mAs (or mR/mAs)) obtained at any tube current settings shall not differ by more than 0.10 times their sum. This is: $[X1-X2] < 0.10 (X1+X2)$; where X1 and X2 are the average C/kg/mAs (or mR/mAs) values obtained at any two tube current settings.

4.7.8.2 Equipment having a combined x-ray tube current-exposure time product (mAs) selector, but not a separate tube current (mA) selector. The average ratios of exposure to the indicated milliAmpere-seconds product (C/kg/mAs (or mR/mAs)) obtained at any two mAs selector settings shall not differ by more than 0.10 times their sum. This is : $[X1-X2] < 0.10 (X1+X2)$; where X1 and X2 are the average C/kg/mAs (or mR/mAs) values obtained at any two mAs selector settings.

4.7.8.3 Measuring Compliance. Determination of compliance shall be based on 4 exposures, at each of the two settings. The two settings may include any two focal spot sizes provided that neither focal spot size is equal to or less than 0.45 millimeter, in which case the two settings shall be restricted to the same focal spot size. For purposes of this requirement, focal spot size is the nominal focal spot size specified by the x-ray tube manufacturer.

4.7.9 Light Localization.

4.7.9.1 When a light localizer is used to define the x-ray field, it shall provide an average illumination of not less than 15 footcandles at 100 centimeters or at the maximum SID, whichever is less. The average illumination shall be based upon measurements made in the approximate center of each quadrant of the light field. Radiation therapy simulation systems manufactured on and after May 27, 1980, are exempt from this requirement.

4.7.9.2 Exemptions to RHB 4.7.9.1 shall be granted if the registrant demonstrates to the Department that their equipment is unable to meet these regulations, and the Department determines that patient safety or image quality is not compromised.

4.7.10 Certified Systems. In addition to the requirements of these rules, the registrant shall not make, nor cause to be made, any modification of components or installations of components certified pursuant to US Food and Drug Administration Regulation 21 CFR 1020 "Performance Standards for Ionizing Radiation Emitting Products" in any manner that could cause the installations or the components to fail to meet the requirements of the applicable parts of the standards specified in 21 CFR 1020, except where a variance has been granted by the Director, Center for Devices and Radiological Health, Food and Drug Administration.

4.7.11 Maintenance Schedule. On all equipment containing components certified pursuant to US Food and Drug Administration Regulation CFR 1020 "Performance Standards for Ionizing Radiation Emitting Products" the registrant shall perform, or cause to be performed, the schedule of maintenance provided by the manufacturer pursuant to 21 CFR 1020.30(h)(l)(ii). A log book of such maintenance shall be maintained for inspection by the Department.

4.7.12 SID Indication. Means shall be provided to indicate the SID. SIDs shall be indicated in inches and/or centimeters, and shall be indicated to within 2 percent.

4.7.13 Positive Beam Limitation. For units having an operable positive beam limitation (PBL) system, the following requirements must be met:

4.7.13.1 Neither the length nor width of the x-ray field shall differ from the corresponding image receptor dimensions by more than 3 percent of the SID; and

4.7.13.2 The sum of the length and width differences, without regard to sign, shall not exceed 4 percent of the SID.

4.7.13.3 The positive beam limitation system shall be capable of operation, at the discretion of the operator, such that the size of the field may be made smaller than the size of the image receptor through stepless adjustment of the field size. The minimum field size at an SID of 100 centimeters shall be equal to or less than 5 centimeters by 5 centimeters.

4.7.13.4 The positive beam limitation system shall be designed such that if a change in image receptor does not cause automatic return to positive beam limitation function as described in 4.7.10.1 and 4.7.10.2, then any change of image receptor size or SID must cause the automatic return.

4.7.13.5 PBL compliance shall be determined with the beam axis perpendicular to the plane of the image receptor. Compliance shall be determined no sooner than 5 seconds after insertion of the image receptor.

4.7.14 The useful beam shall be limited to the area of clinical interest. This shall be deemed to have been met if a positive beam limiting device has been properly used or if evidence of collimation has been shown on at least three sides or three corners of the film, (for example, projections from the shutters of the collimator, cone cutting at the corners, or borders at the film's edge).

4.7.15 MINIMUM FIELD SIZE. THE MINIMUM FIELD SIZE AT AN SID OF 100 CM SHALL BE EQUAL TO OR LESS THAN 5 CENTIMETERS BY 5 CENTIMETERS.

RHB 4.8 MOBILE RADIOGRAPHIC EQUIPMENT.

4.8.1 All provisions of RHB 4.7.4 through 4.7.15 apply, except 4.7.13.

4.8.2 Means shall be provided for independent stepless adjustment of at least two dimensions of the x-ray field.

4.8.3 Means shall be provided to indicate when the axis of the x-ray beam is perpendicular to the plane of the image receptor.

4.8.4 Means shall be provided for visually defining the perimeter of the X-ray field. The total misalignment of the edges of the visually defined field with the respective edges of the X-ray field along either the length or width of the visually defined field shall not exceed two percent (2%) of the distance from the source to the center of the visually defined field when the surface upon which it appears is perpendicular to the axis of the X-ray beam.

4.8.5 If provided, the beam-limiting device shall indicate numerically the field size in the plane of the image receptor to which it is adjusted.

4.8.6 If collimator indications are provided, the indications shall be such that aperture adjustments result in X-ray field dimensions in the plane of the image receptor which correspond to those of the image receptor to within two percent (2%) of the SID when the beam axis is perpendicular to the plane of the image receptor.

4.8.7 Means shall be provided to measure SIDs, and shall be accurate to within 2%.

4.8.8 Mobile and portable x-ray systems which are used continually in a single location for a period of greater than one week shall be considered a stationary radiographic system and shall meet the requirements of RHB 4.4.

4.8.9 Mobile and portable x-ray systems which are used at multiple locations shall be provided with an adequate protective barrier or protective apron for the operator and with a method of control which will permit the operator to be at least 12 feet from the tube head and the nearest edge of the useful beam during exposures.

4.8.10 Personnel monitoring shall be required for all operators of mobile and portable x-ray systems.

4.8.11 Tube stands. A tube stand or other mechanical support shall be used for portable x-ray systems so that the x-ray tube housing assembly need not be hand-held during exposures.

4.8.12 ALL MOBILE OR PORTABLE RADIOGRAPHIC SYSTEMS SHALL BE PROVIDED WITH MEANS TO LIMIT THE SOURCE-TO-SKIN DISTANCE TO EQUAL TO OR GREATER THAN 30 CENTIMETERS.

RHB 4.9 Fluoroscopic X-ray Systems. All fluoroscopic x-ray systems shall be image intensified, and meet the following requirements. The requirements of this part apply to all stationary, portable, mobile, and C-arm type fluoroscopes.

4.9.1 Source-to-Skin Distance (SSD). The SSD shall not be less than:

4.9.1.1 38 centimeters on stationary fluoroscopic systems manufactured on or after August 1, 1974.

4.9.1.2 35.5 centimeters on stationary fluoroscopic systems manufactured prior to August 1, 1974.

4.9.1.3 30 centimeters on all mobile and portable fluoroscopes, and

4.9.1.4 20 centimeters for mobile fluoroscopes used for specific surgical procedures. The written safety procedures as required by RHB 4.2.4 must provide precautionary measures to be taken during the use of this type of fluoroscope. If removable, the appropriate spacer shall be replaced after the specific surgical procedure application is complete.

4.9.2 Limitation of Useful Beam.

4.9.2.1 Primary Barrier

4.9.2.1.1 The fluoroscopic imaging assembly shall be provided with a primary protective barrier which intercepts the entire cross section of the useful beam at any SID.

4.9.2.1.2 The x-ray tube used for fluoroscopy shall not produce x-rays unless the barrier is in position to intercept the entire useful beam.

4.9.2.2 X-ray field. Neither the length nor the width of the x-ray field in the plane of the image receptor shall exceed that of the visible area of the image receptor by more than 3 percent of the SID. The sum of the excess length and the excess width shall be no greater than 4 percent of the SID. In addition:

4.9.2.2.1 Means shall be provided to permit further limitation of the x-ray field. Beam-limiting devices manufactured after May 22, 1979, and incorporated in equipment with a variable SID and/or a visible area of greater than 300 square centimeters shall be provided with means for stepless adjustment of the x-ray field;

4.9.2.2.2 All equipment with a fixed SID and a visible area of 300 square centimeters or less shall be provided with either stepless adjustment of the x-ray field or with means to further limit the x-ray field size at the plane of the image receptor to 125 square centimeters or less. Stepless adjustment shall, at the greatest SID, provide continuous field sizes from the maximum obtainable to a field size of 5 centimeters by 5 centimeters or less.

4.9.2.2.3 For equipment manufactured after February 25, 1978, when the angle between the image receptor and beam axis is variable, means shall be provided to indicate when the axis of the x-ray beam is perpendicular to the plane of the image receptor.

4.9.2.2.4 Compliance shall be determined with the beam axis indicated to be perpendicular to the plane of the image receptor. For rectangular x-ray fields used with circular image reception, the error in alignment shall be determined along the length and width dimensions of the x-ray field which pass through the center of the visible area of the image receptor.

4.9.2.2.5 For uncertified image-intensified fluoroscopic equipment with a spot film device, the x-ray beam with the shutters fully opened (during fluoroscopy or spot filming) shall be no larger than the largest spot film size for which the device is designed. Measurements shall be made at the minimum SID available but at no less than 20 centimeters table top to the film plane distance.

4.9.2.3 Spot film devices which are certified components shall meet the following additional requirements.

4.9.2.3.1 Means shall be provided between the source and the patient for adjustment of the x-ray field size in the plane of the film to the size of that portion of the film which has been selected on the spot film selector. Such adjustment shall be automatically accomplished except when the x-ray field size in the plane of the film is smaller than that of the selected portion of the film. For spot film devices manufactured after June 21, 1979, if the x-ray field size is less than the size of the selected portion of the film, the means for adjustment of the field size shall be only at the operator's option.

4.9.2.3.2 Spot film field size. Neither the length nor the width of the x-ray field in the spot film plane shall exceed the image receptor by more than 3 percent of the SID. The sum of the excess length and the excess width shall be no greater than 4 percent of the SID.

4.9.2.3.3 It shall be possible to adjust the x-ray field size in the plane of the film to a size smaller than the selected portion of the film. The minimum field size at the greatest SID shall be equal to, or less than, 5 centimeters by 5 centimeters.

4.9.2.3.4 The center of the x-ray field in the plane of the film shall be aligned with the center of the selected portion of the film to within 2 percent of the SID.

4.9.2.3.5 On spot-film devices manufactured after February 25, 1978, if the angle between the plane of the image receptor and beam axis is variable, means shall be provided to indicate when the axis of the x-ray beam is perpendicular to the plane of the image receptor, and compliance shall be determined with the beam axis indicated to be perpendicular to the plane of the image receptor.

4.9.3 ACTIVATION OF THE FLUOROSCOPIC TUBE. X-RAY PRODUCTION IN THE FLUOROSCOPIC MODE SHALL BE CONTROLLED BY A DEVICE WHICH REQUIRES CONTINUOUS PRESSURE BY THE FLUOROSCOPIST FOR THE ENTIRE TIME OF ANY EXPOSURE. WHEN RECORDING SERIAL FLUOROSCOPIC IMAGES, THE FLUOROSCOPIST SHALL BE ABLE TO TERMINATE THE X-RAY EXPOSURE(S) AT ANY TIME, BUT MEANS MAY BE PROVIDED TO PERMIT COMPLETION OF ANY SINGLE EXPOSURE OF THE SERIES IN PROCESS.

4.9.4 Exposure Rate Limits. Entrance Exposure Rate Allowable Limits.

4.9.4.1 For equipment manufactured prior to May 19, 1995:

4.9.4.1.1 Equipment with automatic exposure rate control. Fluoroscopic equipment which is provided with automatic exposure rate control shall not be operable at any combination of tube potential and current which will result in an exposure rate in excess of 10 Roentgens (2.58 mC/kg) per minute at the point where the center of the useful beam enters the patient, except:

4.9.4.1.1.1 During recording of fluoroscopic images, or

4.9.4.1.1.2 When an optional high level control is provided. When so provided, the equipment shall not be operable at any combination of tube potential and current which will result in an exposure rate in excess of 5 Roentgens (1.29 mC/kg) per minute at the point where the center of the useful

beam enters the patient unless the high level control is activated. Specials means of activation of high level control shall be required. The high level control shall only be operable when continuous manual activation is provided by the operator. A continuous signal audible to the fluoroscopist shall indicate that the high level control is being employed.

4.9.4.1.2 Equipment without automatic exposure rate control. Fluoroscopic equipment which is not provided with automatic exposure rate control shall not be operable at any combination of tube potential and current which will result in an exposure rate in excess of 5 Roentgens (1.29 mC/kg) per minute at the point where the center of the useful beam enters the patient, except:

4.9.4.1.2.1 During recording of fluoroscopic images, or

4.9.4.1.2.2 When an optional high level control is activated. Special means of activation of high level controls shall be required. The high level control shall only be operable when continuous manual activation is provided by the operator. A continuous signal audible to the fluoroscopist shall indicate that the high level control is being employed.

4.9.4.2 For equipment manufactured after May 19, 1995:

4.9.4.2.1 Equipment with automatic exposure rate control. Fluoroscopic equipment which is provided with automatic exposure rate control shall not be operable at any combination of tube potential and current which will result in an exposure rate in excess of 10 Roentgens (2.58 mC/kg) per minute at the point where the center of the useful beam enters the patient, except:

4.9.4.2.1.1 During recording of fluoroscopic images, or

4.9.4.2.1.2 When an optional high level control is provided. When so provided, the equipment shall not be operable at any combination of tube potential and current which will result in an exposure rate in excess of 20 Roentgens (5.16 mC/kg) per minute at the point where the center of the useful beam enters the patient when the high level control is activated. Special means of activation of high level control shall be required. The high level control shall only be operable when continuous manual activation is provided by the operator. A continuous signal audible to the fluoroscopist shall indicate that the high level control is being employed.

4.9.4.2.2 Equipment without automatic exposure control. Fluoroscopic equipment which is not provided with automatic exposure rate control shall not be operable at any combination of tube potential and current which will result in an exposure rate in excess of 5 Roentgens (1.29 mC/kg) per minute at the point where the center of the useful beam enters the patient, except:

4.9.4.2.2.1 During recording of fluoroscopic images, or

4.9.4.2.2.2 When an optional high level control is provided. When so provided, the equipment shall not be operable at any combination of tube potential and current which will result in an exposure rate in excess of 20 Roentgens (5.16 mC/kg) per minute at the point where the center of the useful beam enters the patient when the high level control is activated. Special means of activation of high level control shall be required. The high level control shall only be operable when continuous manual activation is provided by the operator. A continuous signal audible to the fluoroscopist shall indicate that the high level control is being employed.

4.9.4.3 Compliance with 4.9.4.1 and 4.9.4.2 shall be determined as follows:

4.9.4.3.1 If the source is below the x-ray table, the exposure rate shall be measured 1 centimeter above the tabletop or cradle.

4.9.4.3.2 If the source is above the x-ray table, the exposure rate shall be measured at 30 centimeters above the tabletop with the end of the beam-limiting device or spacer positioned as closely as possible to the point of measurement.

4.9.4.3.3 In a C-arm type of fluoroscope, the exposure rate shall be measured 30 centimeters from the input surface of the fluoroscopic imaging assembly.

4.9.4.3.4 For a variable SID C-arm type of fluoroscope the exposure rate shall be measured 30 centimeters from the input surface of the fluoroscopic imaging assembly, with the end of the beam-limiting device or spacer positioned as close as possible to the point of measurement.

4.9.4.3.5 In a lateral type fluoroscope, the exposure rate shall be measured at a point 15 centimeters from the centerline of the x-ray table and in the direction of the x-ray source with the end of the beam-limiting device or spacer positioned as closely as possible to the point of measurement. If the tabletop is movable, it shall be positioned as closely as possible to the lateral x-ray source, with the end of the beam-limiting device or spacer no closer than 15 centimeters to the centerline of the x-ray table.

4.9.4.3.6 Periodic measurement of entrance exposure rate shall be performed for both maximum and typical values in each mode used clinically annually, and after any maintenance of the system which might affect the exposure rate. Results of the most recent measurements in each mode used clinically shall be posted where any fluoroscopist may have ready access to such results while using the fluoroscope and be included in the records required in RHB 4.2.18.1. The measurement results shall be stated in Roentgens per minute and include the technique factors used in determining such results. The name of the person performing the measurements and the date the measurements were performed shall be included in the results.

4.9.4.3.7 Conditions of measurement of maximum entrance exposure rate are as follows:

4.9.4.3.7.1 The measurement shall be made under the conditions that satisfy the requirements of RHB 4.9.4.3.

4.9.4.3.7.2 The kVp, mA, andother selectable parameters shall be adjusted to those settings which give the maximum entrance exposure rate.

4.9.4.3.7.3 The x-ray system that incorporates automatic exposure rate control shall have sufficient attenuative material placed in the useful beam to produce the maximum output of that system.

4.9.4.3.7.4 Testing shall be performed in each mode used clinically.

4.9.4.3.8 Conditions of measurement of typical entrance exposure rate are as follows:

4.9.4.3.8.1 The measurement shall be made under the conditions that satisfy the requirements of RHB 4.9.4.3.

4.9.4.3.8.2 The kVp and mA shall be typical of clinical use of the x-ray system.

4.9.4.3.8.3 The x-ray system(s) that incorporates automatic exposure rate control shall have sufficient attenuative material placed in the useful beam to produce a milliAmpere and/or kiloVoltage typical of the use of the x-ray system.

4.9.4.3.8.4 Testing shall be performed in each mode used clinically.

4.9.5 BARRIER TRANSMITTED RADIATION RATE LIMITS. THE EXPOSURE RATE DUE TO TRANSMISSION THROUGH THE PRIMARY PROTECTIVE BARRIER WITH THE ATTENUATION BLOCK IN THE USEFUL BEAM, COMBINED WITH RADIATION FROM THE

IMAGE INTENSIFIER, SHALL NOT EXCEED 2 MILLIROENTGEN (0.516 UC/KG) PER HOUR AT 10 CENTIMETERS FROM ANY ACCESSIBLE SURFACE OF THE FLUOROSCOPIC IMAGING ASSEMBLY BEYOND THE PLANE OF THE IMAGE RECEPTOR FOR EACH ROENTGEN PER MINUTE OF ENTRANCE EXPOSURE RATE.

4.9.5.1 Measuring Compliance of Barrier Transmission.

4.9.5.1.1 The exposure rate due to transmission through the primary protective barrier combined with radiation from the image intensifier shall be determined by measurements averaged over an area of 100 square centimeters with no linear dimension greater than 20 centimeters.

4.9.5.1.2 If the source is below the tabletop, the measurement shall be made with the input surface of the fluoroscopic imaging assembly positioned 30 centimeters above the tabletop.

4.9.5.1.3 If the source is above the tabletop and the SID is variable, the measurement shall be made with the end of the beam-limiting device or spacer as close to the tabletop as it can be placed, provided that it shall not be closer than 30 centimeters.

4.9.5.1.4 Compression devices shall be removed from the useful beam during the measurement.

4.9.6 Indication of Potential and Current. During fluoroscopy and cinefluoroscopy the kV and mA shall be continuously indicated.

4.9.7 Fluoroscopic Timer.

4.9.7.1 Means shall be provided to preset the cumulative on-time of the fluoroscopic x-ray tube. The maximum cumulative time of the timing device shall not exceed 5 minutes without resetting.

4.9.7.2 A signal audible to the fluoroscopist shall indicate the completion of any preset cumulative on-time. Such signal shall continue to sound while x-rays are produced until the timing device is reset.

4.9.8 Control of Scattered Radiation.

4.9.8.1 Fluoroscopic table designs when combined with procedures utilized shall be such that no unprotected part of any staff or ancillary individual's body shall be exposed to unattenuated scattered radiation which originates from under the table. The attenuation required shall be not less than 0.25 millimeter lead equivalent.

4.9.8.2 Equipment configuration when combined with procedures shall be such that no portion of any staff or ancillary individual's body, except the extremities, shall be exposed to the unattenuated scattered radiation emanating from above the tabletop unless that individual:

4.9.8.2.1 Is at least 120 centimeters from the center of the useful beam, or

4.9.8.2.2 The radiation has passed through not less than 0.25 millimeter lead equivalent material including, but not limited to, drapes, Bucky-slot cover panel, or self-supporting curtains, in addition to any lead equivalency provided by the protective apron referred to in RHB 4.2.11.2.

4.9.8.3 The Department may grant exemptions to RHB 4.9.8.2.2 where a sterile field will not permit the use of the normal protective barriers. Automatic exemptions will be granted for fluoroscopic procedures listed in Appendix E.

4.9.9 Spot-Filming Procedures. Fluoroscopic x-ray systems equipped with a spot-film device must meet the following requirements for spot-film procedures:

4.9.9.1 Timers. Means shall be provided to terminate the exposure at a preset time interval, preset product of current and time, a preset number of pulses, or a preset radiation exposure to the image receptor. In addition, it shall not be possible to make an exposure when the timer is set to a zero or off position if either position is provided.

4.9.9.2 Timer Reproducibility. With a timer setting of 0.5 second or less, the average exposure period ($\overline{T}$) shall be greater than or equal to 5 times the maximum exposure period (Tmax) minus the minimum exposure period (Tmin) when 4 timer tests are performed: $\overline{T} \geq 5 (Tmax - Tmin)$.

4.9.9.3 Exposure Reproducibility. The coefficient of variation of exposure shall not exceed 0.05 when all technique factors are held constant. This requirement shall be deemed to have been met if, when four exposures are made at identical technique factors, the value of the average exposure (E) is greater than or equal to 5 times the maximum exposure (Emax) minus the minimum exposure (Emin): $E \geq 5 (Emax - Emin)$.

4.9.10 Mobile and Portable fluoroscopic x-ray systems which are used for greater than one week in the same location, i.e., a room or suite, shall be considered as a fixed installation, and shall meet all the requirements of RHB 4.4.

4.9.11 Radiation Therapy Simulation Systems. Radiation therapy simulation systems shall be exempt from all the requirements of 4.9.2, 4.9.4, 4.9.5, and 4.9.7 provided that:

4.9.11.1 Such systems are designed and used in such a manner that no individual other than the patient is in the x-ray room during periods of time when the system is producing x-rays, unless the procedure requires the presence of other individuals.

4.9.11.2 Systems which do not meet the requirements of RHB 4.9.7 are provided with a means of indicating the cumulative time that an individual patient has been exposed to x-rays. Procedures shall require in such cases that the timer be reset between examinations.

4.9.12 Fluoroscopic Quality Assurance. In addition to the requirements of RHB 4.2.18, the fluoroscopic image resolution shall be tested as part of the quality assurance program. This shall be performed at least annually.

4.9.13 Vertical Fluoroscopic Imaging Systems.

4.9.13.1 SSD. The SSD shall not be less than 38 centimeters.

4.9.13.2 Limitation of Useful Beam. All provisions of 4.9.2 apply.

4.9.13.3 Entrance Exposure Rates. All provisions of 4.9.4 apply.

4.9.13.4 Activation of the Fluoroscopic Tube. X-ray production in the fluoroscopic mode shall be controlled by a device which requires continuous pressure by the fluoroscopist for the entire time of any exposure. When recording serial fluoroscopic images, the fluoroscopist shall be able to terminate the x-ray exposure(s) at any time, but means may be provided to permit completion of any single exposure of the series in process.

4.9.13.5 Indication of Potential and Current. During fluoroscopy and cinefluorography the kV and mA shall be continuously indicated.

4.9.13.6 Fluoroscopic Timer.

4.9.13.6.1 Means shall be provided to preset the cumulative on-time of the fluoroscopic x-ray tube. The maximum cumulative time of the timing device shall not exceed 5 minutes without resetting.

4.9.13.6.2 A signal audible to the fluoroscopist shall indicate the completion of any preset cumulative on-time. Such signal shall continue to sound while x-rays are produced until the timing device is reset.

4.9.13.7 Operators shall remain in a protected area during exposures, or shall be protected by aprons of not less than 0.25 mm lead equivalent material.

4.9.13.8 Spot-Filming Procedures. Fluoroscopic x-ray systems equipped with a spot-film device must meet the following requirements for spot-film procedures:

4.9.13.8.1 Timers. Means shall be provided to terminate the exposure at a preset time interval, preset product of current and time, a preset number of pulses, or a preset radiation exposure to the image receptor. In addition, it shall not be possible to make an exposure when the timer is set to a zero or off position if either position is provided.

4.9.13.8.2 Timer Reproducibility. With a timer setting of 0.5 second or less, the average exposure period ($\overline{T}$) shall be greater than or equal to 5 times the maximum exposure period (Tmax) minus the minimum exposure period (Tmin) when 4 timer tests are performed: $\overline{T} \geq 5 (Tmax - Tmin)$.

4.9.13.8.3 EXPOSURE REPRODUCIBILITY. THE COEFFICIENT OF VARIATION OF EXPOSURE SHALL NOT EXCEED 0.05 WHEN ALL TECHNIQUE FACTORS ARE HELD CONSTANT. THIS REQUIREMENT SHALL BE DEEMED TO HAVE BEEN MET IF, WHEN FOUR EXPOSURES ARE MADE AT IDENTICAL TECHNIQUE FACTORS, THE VALUE OF THE AVERAGE EXPOSURE ($\overline{E}$) IS GREATER THAN OR EQUAL TO 5 TIMES THE MAXIMUM EXPOSURE (EMAX) MINUS THE MINIMUM EXPOSURE (EMIN): $\overline{E} \geq 5 (EMAX - EMIN)$.

RHB 4.10 Bone Densitometry Systems. The requirements of this part apply to all stationary, portable, and mobile x-ray bone densitometry systems.

4.10.1 Registration. All provisions of RHB 2.3 and 2.4 apply.

4.10.2 Shielding.

4.10.2.1 Stationary units. The registrant shall submit to the Department for review and approval a shielding plan, as required by RHB 4.4. The shielding plan may be, but is not required to be, prepared by a vendor registered with the Department to perform such service. In lieu of a shielding plan, the Department may accept a radiation area survey, performed by a vendor registered with the Department to perform such service. The shielding plan shall be submitted for review and approval prior to use of the bone densitometry unit. The radiation area survey shall be performed and submitted to the Department within thirty days of initial use of the unit.

4.10.2.2 Mobile and portable units are exempt from 4.10.2.1.

4.10.2.3 The Department may require the registrant to submit a shielding plan prepared by a vendor registered with the Department to perform such service.

4.10.3 Location. The bone densitometry system shall be placed in a controlled area. The operator, ancillary personnel, and members of the general public shall be positioned at least one meter from the patient and bone densitometry system during examination.

4.10.4 Administrative Requirements.

4.10.4.1 Personnel Monitoring. All provisions of RHB 3.12 and 3.22 apply.

4.10.4.2 Posting Requirements. All provisions of RHB 3.16.1, 4.2.9, and 9.2.1 apply.

4.10.4.3 Operating Procedures. All provisions of RHB 4.2.4 apply.

4.10.4.4 Operators. All provisions of RHB 4.2.3 apply.

4.10.4.5 The operator shall advise the patient, prior to the exam, that the bone densitometry examination is a type of x-ray.

RHB 4.11 Computed Tomography (CT) X-ray Systems.

4.11.1 Equipment Requirements.

4.11.1.1 Tomographic Plane Indication and Alignment.

4.11.1.1.1 For any single tomogram system, means shall be provided to permit visual determination of the tomographic plane or a reference plane offset from the tomographic plane.

4.11.1.1.2 For any multiple tomogram system, means shall be provided to permit visual determination of the location of a reference plane. The reference plane can be offset from the location of the tomographic planes.

4.11.1.1.3 If a device using a light source is used to satisfy 4.11.1.1.1 or 4.11.1.1.2, the light source shall provide illumination levels sufficient to permit visual determination of the location of the tomographic plane or reference plane under ambient light conditions of up to 500 lux.

4.11.1.2 Indication of CT Conditions of Operation. The CT x-ray system shall be designed to be used during a scan or a scan sequence are indicated prior to the initiation of a scan or a scan sequence. On equipment having all or some of these conditions of operation at fixed values, this requirement may be met by permanent markings. Indication of CT conditions of operation shall be visible from any position from which scan initiation is possible.

4.11.1.3 Initiation of Operation.

4.11.1.3.1 The x-ray control and gantry shall provide visual indication whenever x-rays are produced and, if applicable, whether the shutter is open or closed.

4.11.1.3.2 Means shall be provided to require operator initiation of each individual scan or series of scans.

4.11.1.3.3 All emergency buttons/switches shall be clearly labeled as to their functions.

4.11.1.4 Termination of Exposure.

4.11.1.4.1 Means shall be provided to terminate the x-ray exposure automatically by either de-energizing the x-ray source or shuttering the x-ray beam in the event of equipment failure affecting data

collection. Such termination shall occur within an interval that limits the total scan time to no more than 110 percent of its preset value through the use of either a backup timer or devices which monitor equipment function.

4.11.1.4.2 A visible signal shall indicate when the x-ray exposure has been terminated through the means required by 4.11.1.4.1.

4.11.1.4.3 The operator shall be able to terminate the x-ray exposure at any time during a scan, or series of scans under x-ray system control, of greater than 0.5 second duration. Termination of the x-ray exposure shall necessitate resetting of the CT conditions of operation prior to initiation of another scan.

4.11.1.5 Extraneous Radiation. The system shall perform such that the radiation produced adjacent to the tube housing assembly, including the tube port, during periods of time that scans are not being performed does not exceed the levels permitted by RHB 4.3.3.

4.11.1.6 Additional Requirements Applicable to CT X-ray Systems Containing a Gantry Manufactured After September 3, 1985.

4.11.1.6.1 The total error in the indicated location of the tomographic plane or reference plane shall not exceed 5 millimeters.

4.11.1.6.2 If the x-ray production period is less than 0.5 second, the indication of x-ray production shall be actuated for at least 0.5 second. Indicators at or near the gantry shall be discernable from any point external to the patient opening where insertion of any part of the human body into the primary beam is possible.

4.11.1.6.3 The deviation of indicated scan increment versus actual increment shall not exceed to within 1 millimeter with any mass from 0 to 100 kilograms resting on the support device. The patient support device shall be incremented from a typical starting position to the maximum incremented distance or 30 centimeters, whichever is less, and then returned to the starting position. Measurement of actual versus indicated scan increment can be taken anywhere along this travel.

4.11.2 Facility Design Requirements.

4.11.2.1 The control panel and x-ray control must be mounted in a permanently protected area outside the computed tomography room. The operator is required to remain in that protected area during the entire exposure.

4.11.2.2 Aural Communication. Provision shall be made for two-way aural communication between the patient and the operator at the control panel.

4.11.2.3 After the effective date of these regulations, facilities designed with an open area in the control room that leads to the gantry shall mark this open area conspicuously indicating not to stand or sit in this area during x-ray exposures.

4.11.2.4 Units installed after the effective date of these regulations shall have the outside door(s) of the gantry room interlocked so that a scan cannot be initiated if the door is not completely closed.

4.11.2.5 Viewing Systems.

4.11.2.5.1 Windows, mirrors, closed-circuit television, or an equivalent shall be provided to permit continuous observation of the patient during irradiation and shall be so located that the operator can observe the patient from the control panel.

4.11.2.5.2 When the primary viewing system is by electronic means, an alternate viewing system (which may be electronic) shall be available for use in the event of failure of the primary viewing system.

4.11.3 Dose Measurements and Spot Checks.

4.11.3.1 Dose Measurement.

4.11.3.1.1 DOSE MEASUREMENTS OF THE RADIATION OUTPUT OF THE CT X-RAY SYSTEM SHALL BE PERFORMED BY, OR UNDER THE DIRECTION OF, A CLASS IX VENDOR.

4.11.3.1.2 Dose measurements of a CT x-ray system shall be performed at intervals specified by a Class IX Vendor and after any change or replacement of components which, in the opinion of the vendor could cause a significant change in the radiation output.

4.11.3.1.3 Measurements of the radiation output of the CT x-ray system shall be performed with a calibrated dosimetry system. The dosimetry system shall have been calibrated or intercompared with a calibrated chamber within the preceding 2 years. The calibration of such system shall be traceable to a national standard.

4.11.3.1.4 Calibration procedures shall be in writing. Records of calibration performed shall be maintained for inspection by the Department.

4.11.3.2 Spot Checks.

4.11.3.2.1 Spot check procedures shall be developed by a Class IX vendor who specializes in diagnostic radiological physics.

4.11.3.2.2 All spot checks shall be included in the calibration required by RHB 4.11.3.1, and otherwise at time intervals and system conditions specified by a Class IX Vendor.

4.11.3.2.3 Spot checks shall include acquisition of images obtained with the phantoms using the same processing mode and CT conditions of operation as are used to perform dose measurements required by RHB 4.11.3.1. The images shall be retained, until a new dose measurement is performed, in two forms as follows:

4.11.3.2.3.1 Photographic copies of the images obtained from the image display view; and

4.11.3.2.3.2 Images stored in digital form of the most recent spot check on a storage medium compatible with the CT x-ray system.

4.11.4 Operating Procedures.
The operator's manual, radiation area surveys, and current equipment performance testing of the system shall be available at the control console.

4.11.5 Ancillary personnel who are not necessary for the safety of the patient shall not be present in the area of the CT unit while exposures are being made.

4.11.6 CT units used in radiation therapy treatment planning are exempt from the requirements of RHB 4.11.3.1. All other provisions of RHB 4.11 apply.

RHB 4.12 Veterinary Radiographic Systems.

4.12.1 Administrative Requirements. All provisions of RHB 4.2 apply, except 4.2.3, 4.2.9, 4.2.12, and 4.2.13.

4.12.2 Radiation Protection. All provisions of RHB 4.2.11 apply, except 4.2.11.3.

4.12.3 Holding of Patients and Films. All provisions of RHB 4.2.14 apply. In addition:

4.12.3.1 Each veterinary facility shall have lead gloves and aprons available in the area of the x-ray unit.

4.12.3.2 Each veterinary facility that holds patients shall provide personnel monitoring devices. If the human holder's hands are in or near the primary beam, then ring badges shall also be provided.

4.12.4 General Requirements. All provisions of RHB 4.3 and 4.4 apply.

4.12.5 Means shall be provided for independent stepless adjustment of at least two dimensions of the x-ray field.

4.12.6 Means shall be provided to indicate when the axis of the x-ray beam is perpendicular to the plane of the image receptor.

4.12.7 Means shall be provided for visually defining the perimeter of the X-ray field. The total misalignment of the edges of the visually defined field shall not exceed two percent (2%) of the distance from the source to the center of the visually defined field when the surface upon which it appears is perpendicular to the axis of the x-ray beam.

4.12.8 The beam-limiting device shall indicate numerically the field size in the plane of the image receptor to which it is adjusted.

4.12.9 Indication of field size dimensions and SID's used shall be specified in inches and/or centimeters on the collimator. The indications on the collimator shall be such that aperture adjustments result in X-ray field dimensions in the plane of the image receptor which correspond to those of the image receptor to within two percent (2%) of the SID when the beam axis is perpendicular to the plane of the image receptor.

4.12.10 The beam-limiting device shall be provided with SID scales that reflect the actual SID(s) used for radiographic procedures.

4.12.10.1 MEANS SHALL BE PROVIDED TO ALIGN THE CENTER OF THE X-RAY FIELD WITH THE CENTER OF THE IMAGE RECEPTOR TO WITHIN 2% OF THE SID.

4.12.10.2 Diaphragms or cones when provided for collimating the useful beam to the area of clinical interest shall meet the requirements of RHB 4.7.2.

4.12.10.3 Minimum Field Size. The minimum field size at an SID of 100 cm shall be equal to or less than 5 cm X 5 cm.

4.12.11 Radiation Exposure Control Devices.

4.12.11.1 Timers. Means shall be provided to terminate the exposure at a preset time interval, preset product of current and time, a preset number of pulses, or a preset radiation exposure to the image receptor. In addition, it shall not be possible to make an exposure when the timer has been set to a zero or off position if either position is provided.

4.12.11.2 X-ray Control.

4.12.11.2.1 An x-ray control shall be incorporated into each x-ray system such that an exposure can be terminated by the operator at any time ("deadman" switch) except for exposures of one-half (1/2) second or less, or during serial radiography when means shall be provided to permit completion of any single exposure of the series in process.

4.12.11.2.2 THE X-RAY CONTROL SHALL PROVIDE VISUAL INDICATION OBSERVABLE AT OR FROM THE OPERATOR PROTECTED POSITION WHENEVER X-RAYS ARE PRODUCED. IN ADDITION, A SIGNAL AUDIBLE TO THE OPERATOR SHALL INDICATE THAT THE EXPOSURE HAS TERMINATED.

4.12.11.2.3 Timer Reproducibility. With a timer setting of 0.5 second or less, the average exposure period ($\overline{T}$) shall be greater than or equal to 5 times the maximum exposure period (Tmax) minus the minimum exposure period (Tmin) when 4 timer test are performed: $\overline{T} \geq 5 (T_{max} - T_{min})$.

4.12.12 Exposure Reproducibility. The coefficient of variation of exposure shall not exceed 0.05 when all technique factors are held constant. This requirement shall be deemed to have been met if, when four exposures are made at identical technique factors, the value of the average exposure ($\overline{E}$) is greater than or equal to 5 times the maximum exposure (Emax) minus the minimum exposure (Emin): $\overline{E} \geq 5 (E_{max} - E_{min})$.

4.12.13 Radiation from Capacitor Energy Storage Equipment in Standby Status. Radiation emitted from the X-ray tube when the exposure switch or timer is not activated shall not exceed a rate of 2 milliRoentgen per hour at five (5) centimeters from any accessible surface of the diagnostic source assembly, with the beam-limiting device fully open.

4.12.14 Accuracy. Deviation of technique factors from indicated values shall not exceed the limits specified for that system by its manufacturer. In the absence of manufacturer's specifications, the deviation shall not exceed 10% of the indicated value.

4.12.15 Linearity. The following requirements apply when the equipment is operated on a power supply as specified by the manufacturer for any fixed x-ray tube potential within the range of 40 percent to 100 percent of the maximum rated.

4.12.15.1 Equipment having independent selection of x-ray tube current (mA). The average ratios of exposure to the indicated milliAmpere-seconds product (C/kg/mAs (or mR/mAs)) obtained at any tube current settings shall not differ by more than 0.10 times their sum. This is: $[X1-X2] < 0.10 [X1+X2]$; where X1 and X2 are the average C/kg/mAs (or mR/mAs) values obtained at any two tube current settings.

4.12.15.2 Equipment having a combined x-ray tube current-exposure time product (mAs) selector, but not a separate tube current (mA) selector. The average ratios of exposure to the indicated milliAmpere-seconds product (C/kg/mAs (or mR/mAs)) obtained at any two mAs selector settings shall not differ by more than 0.10 times their sum. This is: $[X1-X2] < 0.10 [X1+X2]$; where X1 and X2 are the average C/kg/mAs (or mR/mAs) values obtained at any two mAs selector settings.

4.12.15.3 Measuring compliance. Determination of compliance shall be based on 4 exposures, at each of the two settings. These two settings may include any two focal spot sizes provided that neither focal spot size is equal to or less than 0.45 millimeter, in which case the two settings shall be restricted to the same focal spot size. For purposes of this requirement, focal spot size is the nominal focal spot size specified by the x-ray tube manufacturer.

4.12.16 Light Localization.

4.12.16.1 When a light field is used to define the x-ray field, it shall provide an average illumination of not less than 15 footcandles at 100 centimeters or at the maximum SID, whichever is less. The average

illumination shall be based upon measurements made in the approximate center of each quadrant of the light field.

4.12.16.2 The edge of the light field at 100 centimeters or at the maximum SID, whichever is less, shall have a contrast ratio, corrected for ambient lighting devices designed for use on stationary equipment, and a contrast ratio of not less than 3 in the case of beam-limiting devices designed for use on mobile equipment. the contrast ratio is defined as I1/I2 where I1 is the illumination 3 millimeters from the edge of the light field toward the center of the field; and I2 is the illumination 3 millimeters from the edge of the light field away from the center of the field. Compliance shall be determined with a measuring instrument aperture of 1 millimeter in diameter.

4.12.16.3 Exemptions to RHB 4.12.16.1 and 4.12.16.2 shall be granted if the registrant demonstrates to the Department that their equipment is unable to meet these regulations.

4.12.17 SID Indication. Means shall be provided to indicate the SID. SIDs shall be indicated in inches and/or centimeters, and shall be indicated to within 2 percent.

4.12.18 Fluoroscopic X-ray Systems. Veterinary fluoroscopic x-ray systems shall meet the following requirements:

4.12.18.1 Limitation of Useful Beam.

4.12.18.1.1 Primary Barrier.

4.12.18.1.1.1 The fluoroscopic imaging assembly shall be provided with a primary protective barrier which intercepts the entire cross section of the useful beam at any SID.

4.12.18.1.1.2 The x-ray tube used for fluoroscopy shall not produce x-rays unless the barrier is in position to intercept the entire useful beam.

4.12.18.1.2 X-ray Field. The x-ray field produced by non-image intensified fluoroscopic equipment shall not extend beyond the entire visible area of the image receptor. This requirement applies to field size for both fluoroscopic procedures and spot filming procedures. In addition:

4.12.18.1.2.1 Means shall be provided for stepless adjustment of the field size;

4.12.18.1.2.2 The minimum field size at the greatest SID shall be equal to or less than 5 centimeters by 5 centimeters.

4.12.18.1.2.3 For image-intensified fluoroscopic equipment, neither the length nor the width of the x-ray field in the plane of the image receptor shall exceed that of the visible area of the image receptor by more than 3 percent of the SID. The sum of the excess length and the excess width shall be no greater than 4 percent of the SID. In addition, means shall be provided to permit further limitation of the field.

4.12.18.2 Activation of the Fluoroscopic Tube. X-ray production in the fluoroscopic mode shall be controlled by a device which requires continuous pressure by the fluoroscopist for the entire time of any exposure. When recording serial fluoroscopic images, the fluoroscopist shall be able to terminate the x-ray exposure(s) at any time, but means shall be provided to permit completion of any single exposure of the series in process.

4.12.18.3 Barrier Transmitted Radiation Rate Limits.

4.12.18.3.1 The exposure rate due to transmission through the primary protective barrier with the attenuation block in the useful beam, combined with radiation from the image intensifier, if provided, shall not

exceed 2 milliRoentgen (0.516 uC/kg) per hour at 10 centimeters from any accessible surface of the fluoroscopic imaging assembly beyond the plane of the image receptor for each Roentgen per minute of entrance exposure rate.

4.12.18.3.2 Measuring Compliance of Barrier Transmission.

4.12.18.3.2.1 The exposure rate due to transmission through the protective barrier with the attenuation block in the useful beam, combined with radiation from the image intensifier shall be determined by measurements averaged over an area of 100 square centimeters with no linear dimension greater than 20 centimeters.

4.12.18.3.2.2 If the source is below the tabletop, the measurement shall be made with the input surface of the fluoroscopic imaging assembly positioned 30 centimeters above the tabletop.

4.12.18.3.2.3 If the source is above the tabletop and the SID is variable, the measurement shall be made with the end of the beam-limiting device or spacer as close to the tabletop as it can be placed, provided that it shall not be closer than 30 centimeters.

4.12.18.4 Indication of Potential and Current. During fluoroscopy the kV and mA shall be continuously indicated.

4.12.18.5 Mobile Fluoroscopes. In addition to the other requirements of this Part, mobile fluoroscopes shall provide intensified imaging.

4.12.18.6 Control of Scattered Radiation.

4.12.18.6.1 Fluoroscopic table designs when combined with procedures utilized shall be such that no unprotected part of any staff or ancillary individual's body shall be exposed to unattenuated scattered radiation which originates from under the table. The attenuation required shall be not less than 0.25 millimeter lead equivalent.

4.12.18.6.2 Equipment configuration when combined with procedures shall be such that no portion of any staff or ancillary individual's body, except the extremities, shall be exposed to unattenuated scattered radiation emanating from above the tabletop unless that individual:

4.12.18.6.2.1 Is at least 120 centimeters from the center of the useful beam, or

4.12.18.6.2.2 The radiation has passed through not less than 0.25 millimeter lead equivalent material including, but not limited to, drapes, Bucky-slot cover panel, or self-supporting curtains, in addition to any lead equivalency provided by the protective apron referred to in RHB 4.12.3.1.

4.12.19 X-ray Systems Designed for One Image Receptor Size. Radiographic equipment designed for only one image receptor size at a fixed SID shall be provided with means to limit the field at the plane of the image receptor, and to align the center of the x-ray field with the center of the image receptor to within two percent (2%) of the SID, or shall be provided with means to both size and align the x-ray field such that the x-ray field at the plane of the image receptor does not extend beyond any edge of the image receptor.

4.12.20 Veterinary Computed Tomography X-ray Systems - All provisions of RHB 4.11.1 through 4.11.1.5 apply.

4.12.20.1 Facility Design Requirements - All provisions of RHB 4.11.2 apply except 4.11.2.2.

4.12.20.2 Operating Procedures. All provisions of RHB 4.11.5 apply.

4.12.21 Operator Requirements. The registrant shall assure that all x-ray machines under his control are operated only by individuals adequately instructed in safe operating procedures and competent in the safe use of the equipment.

4.12.21.1 The registrant shall require persons operating registered equipment and associate equipment to receive, at a minimum, instruction in the following areas:

4.12.21.1.1 Radiation Protection. Training in radiation protection shall include protective clothing; patient holding; time, distance, and shielding; and radiation protection standards.

4.12.21.1.2 Darkroom Techniques. Training in darkroom techniques shall include developing chemicals; film protection; cassettes; and screens.

4.12.21.1.3 Machine Safety. Training in machine safety shall include machine functions; safety procedures; and recognizing problems.

4.12.21.1.4 General Operating Procedures. Training in general operating procedures shall include patient positioning for x-ray exams; radiographic techniques; use of personnel monitoring devices; and quality assurance procedures.

4.12.21.2 Instruction required by 4.12.21.1 shall begin within 30 days after employment. Training shall be provided for each type of exam that the operator will be required to perform at that facility. The registrant shall maintain a record of all training for each operator. Such records shall be made available for Departmental inspection.

Appendix A

Information To Be Submitted By Persons Proposing To Conduct Healing Arts Screening. Persons requesting that the Department approve a healing arts screening program shall submit the following information for review and approval:

1. Name and address of the applicant, and where applicable, the names and addresses of agents within the State.

2. Diseases or conditions for which the X-ray examinations are to be used.

3. Description in detail of the X-ray examinations proposed in the screening program.

4. Description of the population to be examined in the screening program, i.e., age, sex, physical condition, and other appropriate information.

5. An evaluation of any known alternate methods not involving ionizing radiation which could achieve the goals of the screening program and why these methods are not used in preference to the X-ray examinations.

6. An evaluation by a qualified expert of the X-ray system(s) to be used in the screening program. The evaluation by the qualified expert shall show that such system(s) do satisfy all requirements of these regulations.

7. A description of the diagnostic film quality control program.

8. A copy of the technique chart for the X-ray examinations procedures to be used.

9. The qualifications of each individual who will be operating the X-ray system(s).

10. The qualifications of the individual who will be supervising the operators of the X-ray system(s).

11. The name and address of the individual who will interpret the radiograph(s).

12. A description of the procedures to be used in advising the individuals screened and their private practitioners of the healing arts of the results of the screening procedure and any further medical needs indicated.

13. A description of the procedures for the retention or disposition of the radiographs and other records pertaining to the X-ray examinations.

Appendix B

Information on Radiation Shielding Required for Plan Review. The following information must be provided to the Department for review and approval of a shielding plan:

1. Plans shall show, as a minimum, the following:

a) The normal location of the x-ray system's radiation port; the port's travel and traverse limits; general direction(s) of the useful beam; locations of any windows and doors; the location of the operator's booth; the location of the x-ray control panel, and the location of the wall bucky or chest board, if applicable.

b) The structural composition and thickness or lead equivalent of all walls, doors, partitions, floor, and ceiling of the room(s) concerned.

c) The dimensions of the room(s) concerned.

d) The type of occupancy of all adjacent areas inclusive of space above and below the room(s) concerned. If there is an exterior wall, show distance to the closest area(s) where it is likely that individuals may be present.

e) The make and model of the x-ray equipment and the maximum technique factors.

f) The type of examination(s) or treatment(s) which will be performed with the equipment.

g) Location of the darkroom and the area where the film will be stored. Any shielding which will be used to protect the film must be noted. Include the type of film bin and the type and thickness of the material from which it is constructed. If no film bin will be used this must also be noted.

2. Information on the anticipated workload of the x-ray system(s). Give the number of individual exposures per week. This is the total number of exposures (not patients) taken each week. This figure should include allowances for future growth so that shielding will continue to remain adequate.

3. The most common exam and the average technique factors for this exam must be included. The mA, kVp, exposure time, and number of exposures per week will allow the workload of the facility to be calculated. If exposures are phototimed, include manual backup techniques.

4. Include all source-to-image distance (SIDs) used and the percent of time each will be used. Include the percent of time the beam will be directed toward the table and the chest board, upright bucky, or head unit, if applicable.

Appendix C

Design Requirements for an Operator's Booth

1. Space Requirements:

a) The operator shall be allotted not less than 7.5 square feet (0.697 m2) of unobstructed floor space in the booth.

b) The operator's booth may be any geometric configuration with no dimension less than 2 feet (0.61m).

c) The space shall be allotted excluding any encumbrance by the x-ray control panel, such as overhang, cables, or other similar encroachments.

d) The booth shall be located or constructed such that unattenuated direct scatter radiation originating on the examination table or at the wall cassette cannot reach the operator's station in the booth.

2. Structural Requirements:

a) The booth walls shall be permanently fixed barriers of at least 7 feet (2.13m) high.

b) When a door or movable panel is used as an integral part of the booth structure, it must have an interlock which will prevent an exposure when the door or panel is not closed.

c) Shielding shall be provided to meet the requirements of RHB 4.4.

3. X-ray Control Placement:

The x-ray control for the system shall be fixed within the booth and:

a) Shall be at least 40 inches (1.02m) from any open edge of the booth wall which is nearest to the source of radiation. If the exposure switch is separate from the control panel, the exposure switch shall be at least 40 inches (1.02m) from any open edge of the booth wall which is nearest to the source of radiation.

b) Shall allow the operator to use the majority of the available viewing windows.

4. Viewing System Requirements:

a) Each booth shall have at least one viewing device which will:

aa) Be so placed that the operator can view the patient during any exposure, and

ab) The device shall be so placed that the operator can have full view of any occupant of the room and should be so placed that the operator can view any entry into the room. If any door which allows access to the room cannot be seen from the booth, then that door must have an interlock controlling the exposure which will prevent the exposure if the door is not closed.

b) When the viewing system is a window, the following requirements also apply:

ba) It shall have a viewing area of at least 1 square foot (0.0929 m2)

bb) The design of the booth shall be such that the operator's expected position when viewing the patient and operating the x-ray system is at least 18 inches (0.457mm) from the edge of the booth.

bc) The material constituting the window shall have the same lead equivalence as that required in the booth's wall in which it is mounted.

c) When the viewing system is by mirrors, the mirror(s) shall be so located as to accomplish the general requirements of Appendix B.

d) When the viewing system is by electronic means:

da) The camera shall be so located as to accomplish the general requirements of Appendix B, and

db) There shall be an alternate viewing system as a backup for the primary system.

Appendix D

Average Patient Exposure Guide

Medical ESE's

Compliance with RHB 4.2.15.2 may be determined if the patient's exposure at skin entrance (ESE) does not vary from the national averages listed below by more than 50%. Facilities should strive for an ESE that does not vary from the national average by more than 20%.

	National Average ESE (mR)		ESE Limits	
Projection	200 speed	400 speed	200 speed	400 speed
Abdomen (A/P)	490	300	245-735	150-450
Lumbar Spine (A/P)	450	350	225-675	175-525
Full Spine (A/P)	260	145	130-390	72-218
Cervical Spine (A/P)	135	95	67-203	47-142
Skull (Lat)	145	70	72-218	35-105
Chest (P/A) w/grid	25	15	12-38	7-23
Without grid	15	5	7-23	2-8

	Film/Screen All Types	Film/Screen All Types
Retrograde Pyelogram (A/P)	595	297-893
Thoracic Spine (A/P)	408	204-612
Foot (D/P)	74	37-111
Cephalometric	30	15-45

Notes:

a) Patient thicknesses are expressed in centimeters (cm).
b) All measurements are made in air (no phantom).
c) If the film/screen speed cannot be determined, it will be assumed to be 200 speed.
d) Patient thickness (cm):

Abdomen (A/P)	23	Lumbar Spine (A/P)	23
Full Spine (A/P)	23	Cervical Spine (A/P)	13
Skull (Lat)	15	Chest (P/A)	23
Ret Pyelogram (A/P)	23	Thoracic Spine (A/P)	23
Foot (D/P)	8	Cephalometric	15

Mammography ESE's: Refer to RHB 5.11.5.10

Dental Intraoral ESE's:

This chart represents the range of exposures that will produce acceptable quality radiographs. Compliance with RHB 4.2.15.2 shall be considered met if the patient's exposure at skin entrance (ESE) is within the limits shown.

kVp	"D" Speed Film		"E" Speed Film	
	ESE	ESE Limits	ESE	ESE Limits
50	425-575	340-690	220-320	176-384
55	350-500	280-600	190-270	152-324
60	310-440	248-528	165-230	132-276
65	270-400	216-480	140-200	112-240
70	240-350	192-420	120-170	96-204
75	170-260	136-312	100-140	80-168
80	150-230	120-276	90-120	72-144
85	130-200	104-240	80-105	64-126
90	120-180	96-216	70-90	56-108
95	110-160	88-192	60-80	48-64
100	100-140	80-168	50-70	40-56

Appendix E

Automatic exemptions to RHB 4.9.8.2.2 will be granted for the following procedures:

1. Myelograms
2. Arthrograms
3. Angiograms
4. Percutaneous nephrostomies
5. Biliary drainage procedures
6. Percutaneous cholangiograms
7. T-tube cholangiograms

8. Sinograms or fistulograms
9. Fluoroscopic biopsy procedures

Appendix F

Minimum Criteria for Performance Tests

The following items must be tested. Items marked with an asterick (*) indicate that this item is not necessarily required to be tested by the vendor, but must be tested in order for the facility to meet the requirements of RHB 4.2.18.1.

MEDICAL RADIOGRAPHIC (INCLUDING VETERINARY FACILITIES)

1. Half-value layer (HVL) (4.3.5)
2. X-ray field/light field alignment (4.7.1.3, 4.8.4)
3. Exposure reproducibility (4.7.5)
4. mA/mAs linearity (4.7.8)
5. kVp accuracy (4.7.7)
6. Timer reproducibility and accuracy (4.7.4.2.7, 4.7.7)
7. X-ray beam/image receptor centering (4.7.1.7)
8. Collimator light illuminance (4.7.9)
9. Actual vs. indicated collimator field sizes (4.7.1.5, 4.8.6)
10. Positive beam limitation function, if operable (4.7.13)
11. Visual and audible indication of exposure (4.7.4.2.5)
12. Capacitor discharge radiation levels, if provided (4.7.6)
13. Minimum field size (4.7.15)
14. Patient exposure at skin entrance, for most common exams performed at the facility (except veterinary facilities)
    (4.2.15.2)
15. Proper function of automatic exposure control devices, including AEC reproducibility, kV compensation, and
    minimum response time (4.7.4.2.6)
16. Grid uniformity and alignment (4.2.18.3)
17. Integrity of lead aprons, gloves, and other protective clothing (4.2.10)*
18. Screen-film contact *
19. Actual vs. Indicated Source to Image Distance (SID), for all clinically used SIDs (4.7.12, 4.8.7)
20. Beam size(s) for fixed collimation, if applicable (4.7.3)

These items must be checked upon initial installation and after any maintenance or repair that could affect its status:

1. Adherence to the approved shielding plan (4.4) (Visual inspection of layout of equipment, location of exposure
    button, location of film, etc.)
2. Minimum source to skin distance on mobile radiographic units (4.8.12)
3. Proper indication of multiple tubes on units so equipped (4.7.4.2.4)

FLUOROSCOPIC

1. X-ray beam/Viewed image size comparison (4.9.2.2)
2. Exposure rate output measurement, using average techniques, using maximum techniques, and in high level
    exposure mode, if so equipped, in each mode routinely used (4.9.4)
3. Image intensifier interlock with unit in park position (4.9.2.1.2)
4. Primary barrier transmission (4.9.5)

5. Cumulative timer function (4.9.7.1)
6. Measurement of scattered radiation (4.9.8)
7. High contrast resolution and low contrast performance
8. Minimum source to skin distance, upon initial installation (4.9.1)
9. Spot film beam size (4.9.2.3.2)
10. Spot film beam centering (4.9.2.3.4)
11. Spot film exposure reproducibility (4.9.9.3)
12. Spot film mA/mAs linearity (4.7.8)
13. Spot film timer reproducibility and accuracy (4.9.9.2, 4.7.7)
14. Proper function of spot film automatic exposure control devices, including AEC reproducibility, kV compensation, and minimum response time (4.7.4.2.6)
15. kVp accuracy (4.7.7)
16. Half-value layer (HVL) (4.3.5)
17. Cinefluorographic exposure rates (4.9.4)
18. Integrity of lead aprons, gloves, and other protective clothing (4.2.10)*
19. Integrity of bucky slot cover shielding and lead drapes (4.2.10)*
20. Continuous indication of kV and mA during fluoroscopy (4.9.6)

RADIATION THERAPY SIMULATION SYSTEMS

1. Half-value layer (HVL) (4.3.5)
2. X-ray field/light field alignment (4.7.1.3)
3. Exposure reproducibility (4.7.5)
4. mA/mAs linearity (4.7.8)
5. kVp accuracy (4.7.7)
6. Timer reproducibility and accuracy (4.7.4.2.7, 4.7.7)
7. X-ray beam/image receptor centering (4.7.1.7)
8. Actual vs. indicated collimator field sizes (4.7.1.5)
9. Positive beam limitation function, if operable (4.7.13)
10. Visual and audible indication of exposure (4.5.4.2.5)
11. Proper function of automatic exposure control devices, including AEC reproducibility, kV compensation, and minimum response time (4.7.4.2.6)
12. Grid uniformity and alignment (4.2.18.3)
13. Integrity of lead aprons, gloves, and other protective clothing (4.2.10)*
14. Screen-film contact *
15. Actual vs. Indicated Source to Image Distance (SID), for all clinically used SIDs (4.7.12)
16. Exposure rate output measurement, using average techniques, using maximum techniques, and in high level exposure mode, if so equipped, in each mode routinely used (4.9.4)
17. Cumulative timer function (4.9.7.1)
18. Measurement of scattered radiation (4.9.8)
19. High contrast resolution and low contrast performance
20. Minimum source to skin distance, upon initial installation (4.9.1)

THESE ITEMS MUST BE CHECKED UPON INITIAL INSTALLATION AND AFTER ANY MAINTENANCE OR REPAIR THAT COULD AFFECT ITS STATUS: ADHERENCE TO THE APPROVED SHIELDING PLAN (4.4) (VISUAL INSPECTION OF LAYOUT OF EQUIPMENT, LOCATION OF EXPOSURE BUTTON, LOCATION OF FILM, ETC.)

COMPUTED TOMOGRAPHY (CT) (INCLUDING CT TREATMENT PLANNING SYSTEMS USED IN RADIATION THERAPY)

1. Actual vs. indicated scan increment (4.11.1.6.3)

2. Measurement of radiation output(patient dose) (CT treatment planning systems are exempt) (4.11.3.1)
3. CT number calibration and constancy (4.11.3)
4. High and low contrast resolution
5. Precision (noise)
6. Contrast scale
7. Spot checks as specified by a Class IX Vendor (4.11.3.2)
8. An area survey, upon initial installation
9. Integrity of lead aprons, gloves, and other protective clothing (4.2.10)*

THESE ITEMS MUST BE CHECKED UPON INITIAL INSTALLATION AND AFTER ANY MAINTENANCE OR REPAIR THAT COULD AFFECT ITS STATUS: ADHERENCE TO THE APPROVED SHIELDING PLAN (4.4) (VISUAL INSPECTION OF LAYOUT OF EQUIPMENT, LOCATION OF EXPOSURE BUTTON, LOCATION OF FILM, ETC.)

DENTAL

1. Half-value layer (HVL) (4.3.5)
2. Exposure reproducibility (4.5.5)
3. mA/mAs linearity (4.5.6)
4. kVp accuracy (4.5.7)
5. Timer reproducibility and accuracy (4.5.3.3, 4.5.7)
6. Visual and audible indication of exposure (4.5.4.2.5)
7. Patient exposure at skin entrance, bitewing and/or periapicals (4.2.15.2)
8. Mechanical support of tubehead (4.5.10)
9. Integrity of pass through interlocks (4.5.11.3)
10. Integrity of lead aprons, gloves, and other protective clothing (4.2.10)*

These items must be checked upon initial installation and after any maintenance or repair that could affect its status:

1. Adherence to the approved shielding plan, if applicable (4.4) (Visual inspection of layout of equipment, location
   of exposure button, location of film, etc.)
2. Minimum source to skin distance (4.5.1)
3. X-ray beam size (4.5.2)
4. Proper indication of multiple tubes on units so equipped (4.5.9)
5. NOTE: Cephalometric units are considered medical units by the Department, and are subject to the requirements
   for medical radiographic units.

PART V

QUALITY STANDARDS AND CERTIFICATION REQUIREMENTS FOR FACILITIES PERFORMING MAMMOGRAPHY

RHB 5.1 Scope. This Part establishes quality standards and certification requirements for facilities performing mammography to ensure that all mammography facilities are adequately and consistently evaluated for compliance with the standards provided.

5.1.1 Any person proposing to conduct a healing arts screening program shall not initiate such a program without prior approval of the Department. When requesting such approval, that person shall submit the information outlined in Appendix A of Part IV. If any information submitted to the Department becomes invalid or outdated, the Department shall be notified within 15 days. Approval to conduct a healing arts screening program shall be renewed on an annual basis if deemed necessary by the Department.

5.1.2 Exemptions.

5.1.2.1 Mammography units used only during invasive interventions for localization or biopsy procedures are exempt from the requirements of this Part, except that such systems shall satisfy the criteria specified in RHB 5.25, and all parts to which RHB 5.25 refers.

5.1.2.2 Each mobile mammography facility based outside of South Carolina that operates in South Carolina and which has not been certified by the Department is exempt from the requirements of RHB 5.3 and RHB 5.6, provided that:

5.1.2.2.1 The mobile mammography facility is certified to perform mammography by FDA or other FDA-approved certifying agency at all times while conducting operations in South Carolina; and

5.1.2.2.2 The mobile mammography facility meets the requirements of RHB 5.28.

5.1.2.2.3 The mobile mammography facility shall comply with all other requirements in Part V.

RHB 5.2 Requirements for Certification. A certificate issued by the Department is required for lawful operation of all mammography facilities subject to the provisions of this Part. After the effective date of these regulations, the Department will issue a certificate to each facility holding a currently valid certificate issued by FDA under the Mammography Quality Standards Act of 1992, Public Law 102-539, and 21 C.F.R. Part 900. The term of such certificate shall be for the same period of time as the remainder of the term of the certificate issued by FDA. Certificate holding facilities shall meet the requirements of RHB 5.6 and be accredited by an FDA-approved accreditation body.

RHB 5.3 CERTIFICATES.

5.3.1 In order to qualify for a certificate, a facility must apply to an FDA-approved accreditation body.

5.3.2 Following the Department's receipt of the accreditation body's decision to accredit a facility, the Department may issue a certificate to the facility, or renew an existing certificate, if the Department determines that the facility has satisfied the requirements for certification or recertification.

5.3.3 Provisional Certificates.

5.3.3.1 A new facility is eligible to apply for a provisional certificate. The provisional certificate will enable the facility to perform mammography and to obtain the clinical images needed to complete the accreditation process.

5.3.3.2 Following the Department's receipt of the accreditation body's decision that a facility has submitted the required information, the Department may issue a provisional certificate to a facility upon determination that the facility has satisfied the requirements for provisional certification. A provisional certificate shall be effective for up to 6 months from the date of issuance. A provisional certificate cannot be renewed, but a facility may apply for a 90 day extension of the provisional certificate.

5.3.4 EXTENSION OF PROVISIONAL CERTIFICATE.

5.3.4.1 To apply for a 90 day extension to a provisional certificate, a facility shall submit to its accreditation body a statement of what the facility is doing to obtain certification and evidence that there would be a significant adverse impact on access to mammography in the geographic area served if such facility did not obtain an extension.

5.3.4.2 Following the Department's receipt of the accreditation body's decision that a facility has submitted the required information, the Department may issue a 90 day extension of the provisional certificate to the facility upon determination that the facility has satisfied the requirements for the 90 day extension.

5.3.4.3 There can be no renewal of a provisional certificate beyond the 90 day extension.

5.3.5 Interim Notices. The Department may issue an interim notice of mammography certification by facsimile to a facility if a delay is anticipated in providing a certificate to the facility under one or more of the following circumstances:

5.3.5.1 The Department has been notified by an accrediation body that the facility meets the requirements for a provisional or provisional reinstatement certificate and delivery of the certificate may be delayed;

5.3.5.2 The Department has been notified by an accreditation body that the facility has completed accreditation or reaccreditation and delivery of the certificate to the facility may be delayed; or

5.3.5.3 The Department has been notified by an accreditation body that the facility has timely submitted an application for accreditation or reaccreditation but the completion of the accreditation process may extend beyond the expiration date of a facility's existing certificate through no fault of the facility.

5.3.5.4 An interim notice shall authorize the facility to perform mammography until the facility receives its certificate but in no case for more than 45 days. No more than one interim notice may be issued to a facility per application for certification.

RHB 5.4 Reinstatement Policy. A previously certified facility that has allowed its certificate to expire, that has been refused a renewal of its certificate by FDA or the Department, or that has had its certificate suspended or revoked by FDA or the Department, may apply for reinstatement. If reinstated, the facility will be eligible for a provisional certificate.

5.4.1 Unless prohibited from reinstatement under 5.4.4, a facility applying for reinstatement shall:

5.4.1.1 Contact an FDA-approved accreditation body to determine the requirements for reapplication or accreditation;

5.4.1.2 Fully document its history as a previously provisionally certified or certified mammography facility, including the following information:

5.4.1.2.1 Name and address of the facility under which it was previously provisionally certified or certified;

5.4.1.2.2 Name of previous owner/lessor;

5.4.1.2.3 FDA FACILITY IDENTIFICATION NUMBER ASSIGNED TO THE FACILITY UNDER ITS PREVIOUS CERTIFICATION; AND

5.4.1.2.4 Expiration date of the most recent FDA provisional certificate or certificate.

5.4.1.3 Justify application for reinstatement of accreditation by submitting to the accreditation body, a corrective action plan that details how the facility has corrected deficiencies that contributed to the lapse of, denial of renewal, or revocation of its certificate.

5.4.2 The Department may issue a provisional certificate to the facility if:

5.4.2.1 Following the Department's receipt of the accreditation body's decision that a facility has adequately corrected, or is in the process of correcting, pertinent deficiencies; and

5.4.2.2 The Department determines that the facility has taken sufficient corrective action since the lapse of, denial or revocation of its previous certificate.

5.4.3 After receiving the provisional certificate, the facility may lawfully resume performing mammography services while completing the requirements for certification.

5.4.4 If a facility's certificate was revoked on the basis of an act described in 5.24, no person who owned or operated that facility at the time the act occurred may own or operate a mammography facility within two years of the date of revocation.

RHB 5.5 Appeals of adverse accreditation or reaccreditation decisions. The appeals procedures described in this Part are available only for adverse accreditation or reaccreditation decisions that preclude certification by the Department. Department decisions to suspend or revoke certificates that are already in effect shall be conducted in accordance with RHB 5.24.

5.5.1 Upon learning that a facility has failed to become accredited or reaccredited, the Department will notify the facility that the Department is unable to certify that facility without proof of accreditation.

5.5.2 A facility that has been denied accreditation or reaccreditation is entitled to an appeals process from the accreditation body. A facility shall avail itself of the accreditation body's appeal process before requesting a review from the Department.

5.5.3 In the event that a facility, after availing itself of the accreditation body's appeal process, receives an adverse accreditation or reaccreditation decision, the facility may within 30 days after such adverse decision submit a request for review of the adverse accreditation decision to the Department.

5.5.4 Within 30 days following receipt of such written request, the Deputy Commissioner for Health Services shall review the facility's appeal.

5.5.5 A facility cannot perform mammography services while an adverse accreditation decision is being appealed.

RHB 5.6 Fees

5.6.1 The Department shall assess each certified mammography facility an annual certification fee of $1000 in accordance with RHB 2.10. This certification fee includes one mammographic tube. The Department shall assess each certified mammography facility an additional fee of $200 per mammographic tube for each additional tube.

5.6.2 For mammography facilities holding valid FDA mammography certificates on the effective date of this Part, the initial annual fee shall be billed as soon as practicable after the effective date of this regulation. The annual fee described in 5.6.1 applies to both fully and provisionally certified mammography facilities.

5.6.3 A new mammography facility issued an initial provisional certificate during the calendar year shall be issued a prorated fee for the remainder of the year, in accordance with RHB 2.10.

5.6.4 All fees shall be due and payable in accordance with RHB 2.10.

RHB 5.7 Personnel Requirements. The following requirements apply to all personnel involved in any aspect of mammography, including the production, processing, and interpretation of mammograms and related quality assurance activities:

5.7.1 Interpreting physicians. All physicians interpreting mammograms shall meet the following qualifications:

5.7.1.1 Initial qualifications. Unless the exemption in 5.7.1.3.1 applies, before beginning to interpret mammograms independently, the interpreting physician shall:

5.7.1.1.1 Be a licensed physician to practice medicine in this State;

5.7.1.1.2 Be certified in diagnostic radiology by either the American Board of Radiology, the American Osteopathic Board of Radiology, or Royal College of Physicians and Surgeons of Canada or have had at least 3 months of documented formal training in the interpretation of mammograms and in topics related to mammography. The training shall include instruction in radiation physics, including radiation physics specific to mammography, radiation effects and radiation protection. The mammographic interpretation component shall be under the direct supervision of a physician who meets the requirements of 5.7.1 of this Part.

5.7.1.1.3 Have a minimum of sixty hours of documented medical education in mammography, which shall include instruction in the interpretation of mammograms and education in basic breast anatomy, pathology, physiology, technical aspects of mammography and quality assurance and quality control in mammography. All sixty of these hours shall be Category I and have at least fifteen hours of the Category I hours shall have been acquired within three years immediately prior to the date that the physician qualifies as an interpreting physician. Hours spent in residency specifically devoted to mammography will be considered as equivalent to Category I continuing medical education credits and will be accepted if documented in writing by the appropriate representative of the training institution; and

5.7.1.1.4 Unless the exemption in RHB 5.7.1.3.2 applies, have interpreted or multi-read at least 240 mammograms examinations within the 6 month period immediately prior to the date that the physician qualifies as an interpreting physician. The interpretation or multi-reading shall be under direct supervision of an qualified interpreting physician.

5.7.1.2 Continuing experience and education. All interpreting physicians shall maintain their qualifications by meeting the following requirements:

5.7.1.2.1 Following the second anniversary date of the end of the calendar quarter in which the requirements of 5.7.1.1 of this Part, were completed, the interpreting physician shall have interpreted or multi-read at least 960 mammographic examinations during the twenty-four months immediately preceding the date of the facility's annual MQSA inspection, or the last day of the calendar quarter preceding the inspection or any date in between the two. The facility will choose one of these dates to determine the 24-month period.

5.7.1.2.2 Following the third anniversary of the end of the calendar quarter in which the requirements of 5.7.1.1 of this Part were completed, the interpreting physician shall have taught or completed at least 15 Category I continuing medical education units in mammography during the thirty six months immediately preceding the date of the facility's annual MQSA inspection, or the last day of the calendar quarter preceding the inspection or any date in between the two. The facility shall choose one of these dates to determine the 36-month period. This training shall include at least six Category I continuing medical education credits in each mammographic modality used by the interpreting physician in his or her practice.

5.7.1.2.3 Before an interpreting physician may begin independently interpreting mammograms produced by a new mammographic modality, that is, a mammographic modality in which the physician has not previously been trained, the interpreting physician shall have at least eight hours of training in the new mammographic modality.

5.7.1.2.4 Units earned through teaching a specific course can be counted only once towards the fifteen units required by RHB 5.7.1.2.2, even if the course is taught multiple times during the previous 36 months.

5.7.1.3 Exemptions

5.7.1.3.1 Those physicians who qualified as interpreting physicians under FDA's interim regulations prior to April 28, 1999, are considered to have met the initial requirements of 5.7.1.1 of this Part. These physicians may continue to interpret mammograms provided they continue to meet the requirement of 5.7.1 and the continuing experience and education requirements of 5.7.1.2.

5.7.1.3.2 Physicians who have interpreted or multi-read at least 240 mammographic examinations under the direct supervision of an interpreting physician in any six month period during the last two years of a diagnostic radiology residency and who become appropriately board certified at the first allowable time, as defined by an eligible certifying body, are exempt from 5.7.1.1.4.

5.7.1.4 Reestablishing qualifications. Interpreting physicians who fail to maintain the required continuing experience or continuing education requirements, shall reestablish their qualifications before resuming the independent interpretation of mammograms as follows:

5.7.1.4.1 Interpreting physicians who fail to meet the continuing experience requirements of 5.7.1.2.1 shall interpret or multi-read at least 240 mammographic examinations within six months or less under the direct supervision of an interpreting physician; or interpret or multi-read a sufficient number of mammographic examinations, under the direct supervision of an interpreting physician, to bring the physician's total up to 960 examinations from the prior twenty-four months, whichever is less. The interpretations required shall be done within the six months immediately prior to resuming independent interpretation.

5.7.1.4.2 Interpreting physicians who fail to meet the continuing education requirements of 5.7.1.2.2 shall obtain a sufficient number of additional Category I continuing medical education credits in mammography to bring their total up to the required fifteen credits in the previous thirty-six months before resuming independent interpretation.

5.7.2 Radiologic technologists. All mammographic examinations shall be performed by radiologic technologists who meet the following general requirements, mammography requirements, and continuing education requirements:

5.7.2.1 General Requirements

5.7.2.1.1 BE REGISTERED IN ACTIVE STATUS WITH THE AMERICAN REGISTRY OF RADIOLOGIC TECHNOLOGISTS IN THE FIELD OF RADIOGRAPHY; AND

5.7.2.1.2 ALL PROVISIONS OF RHB 4.2.3 APPLY TO THE OPERATORS OF MAMMOGRAPHY EQUIPMENT.

5.7.2.2 Mammography requirements. Have, prior to April 28, 1999, qualified as a radiologic technologist under FDA's interim regulations or completed at least forty contact hours of documented training specific to mammography under the supervision of a qualified instructor. The hours of documented training shall include, but not necessarily be limited to:

5.7.2.2.1 Training in breast anatomy and physiology, positioning and compression, quality assurance/quality control techniques, imaging of patients with breast implants;

5.7.2.2.2 The performance of a minimum of twenty- five examinations under the direct supervision of an individual qualified under 5.7.2; and

5.7.2.2.3 At least eight hours of training in each mammography modality to be used by the technologist in performing mammography exams.

5.7.2.3 Continuing education requirements

5.7.2.3.1 Following the third anniversary date of the end of the calendar quarter in which the requirements of 5.7.2.1 and 5.7.2.2 were completed, the radiologic technologist who performs mammography shall have taught or completed at least fifteen continuing education units in mammography during the thirty-six months immediately preceding the date of the facility's annual mammography inspection, or the last day of the calendar quarter preceding the inspection or any day in between the two. The facility will choose one of these dates to determine the 36 month period.

5.7.2.3.2 Units earned through teaching a specific course can be counted only once towards the fifteen hours of continuing education requirements required in 5.7.2.3.1, even if the course is taught multiple times during the previous 36 months.

5.7.2.3.3 At least six of the continuing education units required in 5.7.2.3.1 shall be related to each mammographic modality used by the technologist.

5.7.2.3.4 Requalification. Radiologic technologists who fail to meet the continuing education requirements of 5.7.2.3.1, shall obtain a sufficient number of continuing education units in mammography to bring their total up to at least 15 in the previous three years, at least six of which shall be related to each modality used by the technologist in mammography. The technologist shall not resume performing unsupervised mammography examinations until the continuing education requirements are completed.

5.7.2.3.5 Before a radiologic technologist may begin independently performing mammography examinations using a mammographic modality other than one of those for which the technologist received training under 5.7.2.3.3, the technologist shall have at least eight hours of continuing education units in the new modality.

5.7.2.3.6 Programs, courses or other activities intended to meet the requirement for initial, or requalification, mammography training or continuing education in mammography shall be approved by the Department.

5.7.2.3.7 Completion of initial or requalification mammography training and continuing education in mammography shall be verified to the Department.

5.7.2.4 Continuing experience requirements.

5.7.2.4.1 Following the second anniversary date of the end of the calendar quarter in which the requirements of 5.7.2.1 and 5.7.2.2 were completed or of April 28, 1999, whichever is later, the radiologic technologist shall have performed a minimum of 200 mammography examinations during the twenty-four months immediately preceding the date of the facility's annual mammography inspection, or the last day of the calendar quarter preceding the inspection or any date in between the two. The facility will choose one of these dates to determine the 24-month period.

5.7.2.4.2 Requalification. Radiologic technologists who fail to meet the continuing experience requirements of 5.7.2.4.1 shall perform a minimum of twenty five mammography examinations under the direct supervision of a qualified radiologic technologist before resuming the performance of unsupervised mammography.

5.7.3 Medical Physicists. All medical physicists conducting surveys of mammography facilities and providing oversight of the facility quality assurance program shall meet the following:

5.7.3.1 Initial Qualifications. The medical physicist must be approved by the Department as a Class IX vendor, prior to providing or offering to provide services, as required in 2.5.6.9. Unless the alternative initial qualifications in RHB 5.7.3.2 apply, the medical physicist must be certified in diagnostic radiological physics

or radiological physics by either the American Board of Radiology (ABR), the American Board of Medical Physics (ABMP) or another FDA approved certifying board.

5.7.3.1.1 Have a masters degree or higher in a physical science from an accredited institution, with no less than twenty semester hours or equivalent (e.g., thirty quarter hours) of college undergraduate or graduate level physics;

5.7.3.1.2 Have twenty contact hours of documented specialized training in conducting surveys of mammography facilities; and

5.7.3.1.3 Have the experience of conducting surveys of at least one mammography facility and a total of at least ten mammography units. No more than one survey of a specific unit within a period of sixty days can be counted towards the total mammography unit survey requirement. After April 28, 1999, experience conducting surveys shall be acquired under the direct supervision of a medical physicist who meets all the requirements of 5.7.3.1 and 5.7.3.3.

5.7.3.2 Alternative initial qualifications.

5.7.3.2.1 Have qualified as a medical physicist under FDA's interim-regulations and retained that qualification by maintenance of the active status of any licensure, approval or certification required;

5.7.3.2.2 Prior to April 28, 1999, obtained a bachelor's degree or higher in a physical science from an accredited institution with no less than ten semester hours or equivalent of college undergraduate or graduate level physics;

5.7.3.2.3 Prior to April 28, 1999, have forty contact hours of documented specialized training in conducting surveys of mammography facilities; and

5.7.3.2.4 Prior to April 28, 1999, have the experience of conducting surveys of at least one mammography facility and a total of at least twenty mammography units. No more than one survey of a specific unit within a period of sixty days can be counted towards the total mammography survey requirement. The training and experience requirements shall be met after fulfilling the degree requirement.

5.7.3.3 Continuing education and experience.

5.7.3.3.1 Continuing education. Following the third anniversary date of the end of the calendar quarter in which the requirements of 5.7.3.1 and 5.7.3.2 were completed, the medical physicist shall have taught, or completed, at least fifteen continuing education units in mammography during the thirty six-months immediately preceding the date of the facility annual inspection, or the last day of the calendar quarter preceding the inspection or any date in between the two. The facility shall choose one of these dates to determine the 36-month period. This continuing education shall include hours of training appropriate to each mammography modality evaluated by the medical physicist during his or her surveys or oversight of quality assurance programs. Units earned through teaching a specific course can be counted only once towards the required fifteen continuing education units in a 36-month period, even if the course is taught multiple times during the thirty-six months.

5.7.3.3.2 Continuing experience. Following the second anniversary date of the end of the calendar quarter in which the requirements of 5.7.3.1 and 5.7.3.2 were completed or of April 28, 1999, whichever is later, the medical physicist shall have surveyed at least two mammography facilities and a total of at least six mammography units during the twenty-four months immediately preceding the date of the facility's annual mammography inspection, or the last day of the calendar quarter preceding the inspection or any date in between the two. The facility shall choose one of these dates to determine the 24-month period. No more than one survey of a specific facility within a 10-month period or a specific unit within a period of sixty days can be counted towards the total mammography unit survey requirement.

5.7.3.3.3 Before a medical physicist may begin independently performing mammographic surveys of a new mammographic modality, that is, a mammographic modality other than one for which the physicist received training to qualify under 5.7.3.1 and 5.7.3.2, the physicist shall receive at least eight hours of training in surveying units of the new mammographic modality.

5.7.3.4 Reestablishing qualifications. Medical physicists who fail to maintain the required continuing qualifications of 5.7.3.3 may not perform the MQSA surveys without the supervision of a qualified medical physicist. Before independently surveying another facility, medical physicists shall reestablish their qualifications, as follows:

5.7.3.4.1 Medical physicists who fail to meet the continuing educational requirements of 5.7.3.3.1 shall obtain a sufficient number of continuing education units to bring their total units up to the required fifteen in the previous three years.

5.7.3.4.2 Medical physicists who fail to meet the continuing experience requirement of 5.7.3.3.2 shall complete a sufficient number of surveys under the direct supervision of a medical physicist who meets the qualification of 5.7.3.1 and 5.7.3.3 to bring their total surveys up to the required two facilities and six units in the previous twenty-four months. No more than one survey of a specific unit within a period of sixty days can be counted towards the total mammography unit survey requirement.

5.7.4 Retention of personnel records. Facilities shall maintain records to document the qualifications of all personnel who worked at the facility as interpreting physicians, radiologic technologists, or medical physicists. These records must be available for review by the Department. Records of personnel no longer employed by the facility should not be discarded until the next annual inspection has been completed and the Department has determined that the facility is in compliance with the MQSA/State personnel requirements of this Part.

RHB 5.8 Equipment Requirements. The equipment requirements of this Part are intended to ensure that mammography equipment is capable of producing quality mammograms over the full range of clinical conditions.

5.8.1 Prohibited equipment. Xeromammography equipment shall not be used for mammography procedures. Radiographic equipment designed for general purpose or special non-mammography procedures shall not be used for mammography. This prohibition includes systems that have been modified or equipped with special attachments for mammography. This requirement supersedes the implied acceptance of such systems in 21 CFR, Section 1020.31(f)(3).

5.8.2 General. Only special purpose equipment designed for mammography shall be specifically used for mammography and shall be certified pursuant to 21 CFR, Section 1010.2 as meeting the applicable requirements of 21 CFR, 1020.30, effective as of April 1, 1997.

5.8.3 Motion of tube-image receptor assembly.

5.8.3.1 The assembly shall be capable of being fixed in any position where it is designed to operate. Once fixed in any such position, it shall not undergo unintended motion.

5.8.3.2 The mechanism ensuring compliance with RHB 5.8.3.1 shall not fail in the event of power interruption.

5.8.4 Image receptor sizes.

5.8.4.1 Systems using screen-film image receptors shall provide, at a minimum, for operation with image receptors of 18 x 24 centimeters (cm) and 24 x 30 cm.

5.8.4.2 Systems using screen-film image receptors shall be equipped with moving grids matched to all image receptor sizes provided.

5.8.4.3 Systems used for magnification procedures shall be capable of operation with the grid removed from between the source and image receptor.

5.8.5 Beam limitation and light fields.

5.8.5.1 All systems shall have beam-limiting devices that allow the useful beam to extend to or beyond the chest wall edge of the image receptor.

5.8.5.2 For any mammography system with a light beam that passes through the x-ray beam limiting device, the light shall provide an average illumination of not less than 160 lux (15 footcandles) at 100 cm or the maximum source-image receptor distance (SID), whichever is less.

5.8.6 Magnification

5.8.6.1 Systems used to perform noninterventional problem solving procedures shall have radiographic magnification capability available for use by the operator.

5.8.6.2 Systems used for magnification procedures shall provide, at a minimum, at least one magnification value within the range of 1.4 to 2.0.

5.8.7 Focal Spot Selection

5.8.7.1 When more than one focal spot is provided, the system shall indicate, prior to exposure, which focal spot is selected.

5.8.7.2 When more than one target material is provided, the system shall indicate, prior to exposure, the preselected target material.

5.8.7.3 When the target material and/or focal spot is selected by a system algorithm that is based on the exposure or on a test exposure, the system shall display, after the exposure, the target material and /or focal spot actually used during the exposure

5.8.8 Compression. All mammography systems shall incorporate a compression device that shall be used for all routine projections and for all projections except when necessity requires imaging without compression.

5.8.8.1 Application of compression. Effective October 28, 2002, each system shall provide:

5.8.8.1.1 An initial power-driven compression activated by hands-free controls operable from both sides of the patient; and

5.8.8.1.2 Fine adjustment compression controls operable from both sides of the patient.

5.8.8.2 Compression paddle:

5.8.8.2.1 Systems shall be equipped with different sized compression paddles that match the sizes of all full-field image receptors provided for the system. Compression paddles for special purposes, including those smaller than the full size of the image receptor (for "spot compression") may be provided. Such compression paddles for special purposes are not subject to the requirements of subsections 5.8.8.2.4 and 5.8.8.2.5 of this Section.

5.8.8.2.2 Except as provided in subsection 5.8.8.2.3 of this Part, the compression paddle shall be flat and parallel to the breast support table and shall not deflect from parallel by more than 1.0 cm at any point on the surface of the compression paddle when compression is applied.

5.8.8.2.3 Equipment intended by the manufacturer's design to not be flat and parallel to the breast support table during compression shall meet the manufacturer's design specifications and maintenance requirements.

5.8.8.2.4 The chest wall edge of the compression paddle shall be straight and parallel to the edge of the image receptor.

5.8.8.2.5 The chest wall edge may be bent upward to allow for patient comfort but shall not appear on the image.

5.8.9 Technique factor selection and display.

5.8.9.1 Manual selection of milliAmpere seconds (mAs) or at least one of its component parts (milliAmpere (mA) and /or time) shall be available.

5.8.9.2 The technique factors (peak tube potential in kilovolt (kV) and either tube current in mA and exposure time in seconds or the product of tube current and exposure time in mAs) to be used during an exposure shall be indicated before the exposure begins, except when automatic exposure controls (AEC) are used, in which case the technique factors that are set prior to the exposure shall be indicated.

5.8.9.3 Following AEC mode use, the system shall indicate the actual kiloVoltage peak (kVp) and mAs used during the exposure. The mAs may be displayed as mA and time.

5.8.10 Automatic exposure control.

5.8.10.1 EACH SCREEN-FILM SYSTEM SHALL PROVIDE AN AEC MODE THAT IS OPERABLE IN ALL COMBINATIONS OF EQUIPMENT CONFIGURATION PROVIDED, E.G., GRID, NONGRID, MAGNIFICATION, NONMAGNIFICATION AND VARIOUS TARGET- FILTER COMBINATIONS.

5.8.10.2 The positioning or selection of the detector shall permit flexibility in the placement of the detector under the target tissue.

5.8.10.2.1 The size and available positions of the detector shall be clearly indicated at the x-ray input surface of the breast compression paddle.

5.8.10.2.2 The selected position of the detector shall be clearly indicated.

5.8.10.3 The system shall provide means for the operator to vary the selected optical density from the normal (zero) setting.

5.8.11 X-ray film. The facility shall use x-ray film for mammography that has been designated by the film manufacturer as appropriate for mammography.

5.8.12 Intensifying screens. The facility shall use intensifying screens for mammography that have been designated by the screen manufacturer as appropriate for mammography and shall use film that is matched to the screen's spectral output as specified by the manufacturer.

5.8.13 Film processing solutions. When processing mammography films, the facility shall use chemical solutions that are capable of developing the film used by the facility in a manner equivalent to the minimum requirements specified by the film manufacturer.

5.8.14 Film Processor. The film processor shall be compatible with single emulsion film

5.8.15 Lighting. The facility shall make special lights for film illumination, i.e., hot-lights, capable of producing light levels greater than that provided by the view box, available to the interpreting physicians.

5.8.16 Film masking devices. Facilities shall ensure that filmmasking devices that can limit the illumination area to a region equal to or smaller than the exposed portion of the film are available to all interpreting physicians.

RHB 5.9 Medical Records and Mammography Reports

5.9.1 Contents and terminology. Each facility shall prepare a written report of the results of each mammography examination performed under its certificate. The mammography report shall include the following information:

5.9.1.1 The name of the patient and an additional patient identifier;

5.9.1.2 Date of examination;

5.9.1.3 The name of the interpreting physician who interpreted the mammogram;

5.9.1.4 Overall final assessment of findings, classified in one of the following categories:

5.9.1.4.1 "Negative." Nothing to comment upon (if the interpreting physician is aware of clinical findings or symptoms, despite the negative assessment, these shall be explained);

5.9.1.4.2 "Benign." Also a negative assessment;

5.9.1.4.3 "Probably Benign." Finding(s) has a high probability of being benign;

5.9.1.4.4 "Suspicious." Finding(s) without all the characteristic morphology of breast cancer but indicating a definite probability of being malignant;

5.9.1.4.5 "Highly suggestive of malignancy." Finding(s) has a high probability of being malignant,

5.9.1.5 In cases where no final assessment category can be assigned due to incomplete work-up, "Incomplete: Need additional imaging evaluation" shall be assigned as an assessment and reasons why no assessment can be made shall be stated by the interpreting physician; and

5.9.1.6 Recommendations made to the health care provider about what additional actions, if any, should be taken. All clinical questions raised by the referring health care provider shall be addressed in the report to the extent possible, even if the assessment is negative or benign.

5.9.2 Communication of mammography results to the patient. Each facility shall send each patient a summary of the mammography report written in lay terms within 30 days of the mammographic examination. If assessments are "Suspicious" or "Highly suggestive of malignancy", the facility shall make reasonable attempts to ensure that the results are communicated to the patient as soon as possible.

5.9.2.1 Patients who do not name a health care provider to receive the mammography report shall be sent the report described in RHB 5.9.1 within 30 days, in addition to the written notification of results in lay terms.

5.9.2.2 Each facility that accepts patients who do not have a health care provider shall maintain a system for referring such patients to a health care provider when clinically indicated.

5.9.3 Communication of mammography results to health care providers. When the patient has a referring health care provider or the patient has named a health care provider, the facility shall:

5.9.3.1 Provide a written report of the mammography examination,including the items listed in subsection 5.9.1 of this Section, to that health care provider as soon as possible, but no later than 30 days after the date of the mammography examinations; and

5.9.3.2 If the assessment is "Suspicious" or "Highly suggestive of malignancy," make reasonable attempts to communicate with the health care provider as soon as possible, or if the health care provider is unavailable, to a responsible designee of the health care provider.

5.9.4 Record keeping. Each facility that performs mammograms:

5.9.4.1 Shall,except as provided in RHB 5.9.3.2, maintain mammography films and reports in a permanent medical record of the patient for a period of not less than 5 years, or not less than 10 years if no additional mammograms of the patient are performed at the facility;

5.9.4.2 Shall upon request by, or on behalf of, the patient permanently or temporarily transfer the original mammograms and copies of the patient's reports to a medical institution, or to a physician or health care provider of the patient, or to the patient directly.

5.9.4.3 Any fee charged to the patient for providing the services in RHB 5.9.4 shall not exceed the documented costs associated with this service.

5.9.5 Mammographic image identification. Each mammographic image shall have the following information indicated on it in a permanent, legible, and unambiguous manner and placed so as not to obscure anatomic structures:

5.9.5.1 Name of patient and an additional patient identifier.

5.9.5.2 Date of examination.

5.9.5.3 View and laterality. This information shall be placed on the image in a position near the axilla. Standardized codes specified by the accreditation body shall be used to identify view and laterality.

5.9.5.4 Facility name and location. At a minimum, the location shall include the city, state, and zip code of the facility.

5.9.5.5 Technologist identification.

5.9.5.6 Cassette/screen identification.

5.9.5.7 Mammography unit identification, if there is more than one unit in the facility.

RHB 5.10 Quality Assurance Requirements. Each facility shall establish and maintain a quality assurance program to ensure the safety, reliability, clarity, and accuracy of mammography services performed at the facility.

5.10.1 Responsible individuals. Responsibility for the quality assurance program and for each of its elements shall be assigned to individuals who are qualified for their assignments and who shall be allowed adequate time to perform these duties.

5.10.1.1 Lead interpreting physician. The facility shall identify a lead interpreting physician who shall have the general responsibility of ensuring that the quality assurance program meets all requirements of this Part. No other individual shall be assigned or shall retain responsibility for quality assurance tasks unless the lead interpreting physician has determined that the individual's qualifications for, and performance of, the assignment are adequate.

5.10.1.2 Interpreting physicians. All physicians interpreting mammograms for the facility shall:

5.10.1.2.1 Follow the facility procedures for corrective action when the images that they are asked to interpret are of poor quality; and

5.10.1.2.2 Participate in the facility's medical outcomes audit program.

5.10.1.3 Medical physicist. Each facility shall have the services of a medical physicist available to survey mammography equipment and oversee the equipment-related quality assurance practices of the facility. At a minimum, the medical physicist(s) shall be responsible for performing the surveys and mammography equipment evaluations and providing the facility with the reports described in RHB 5.12 and RHB 5.13.

5.10.1.4 Quality control technologist. Responsibility for all individual tasks within the quality assurance program not assigned to the lead interpreting physician or the medical physicist shall be assigned to a quality control technologist(s). The tasks are to be performed by the quality control technologist or by other personnel qualified to perform the tasks. When other personnel are utilized for these tasks, the quality control technologist shall ensure that the tasks are completed in such a way as to meet the requirements of RHB 5.11.

5.10.2 Quality assurance records.

5.10.2.1 The lead interpreting physician, quality control technologist and medical physicist shall ensure that records concerning employee qualifications to meet assigned quality assurance tasks, mammography technique and procedures, quality control(including monitoring data, problems detected by analysis of that data, corrective actions and the effectiveness of the corrective actions), safety, and protection are properly maintained and updated.

5.10.2.2 These quality control records shall be kept for each test specified in RHB 5.11 until the next annual inspection has been completed and the Department has determined that the facility is in compliance with the quality assurance requirements or until the test has been performed two additional times at the required frequency, whichever is longer.

5.10.2.3 A report of the medical physicist's test results with numerical values shall be submitted to the Department annually as required by RHB 5.12.

RHB 5.11 Equipment Quality Assurance Tests

5.11.1 Daily quality control tests. Film processors used to develop mammograms shall be adjusted and maintained to meet the technical development specifications for the mammography film in use. A processor performance test shall be performed on each day that examinations are performed before any clinical films are processed that day. The test shall include an assessment of base plus fog density, mid- density, and density difference, using the mammography film used clinically at the facility.

5.11.1.1 The base plus fog density shall be within plus or minus 0.03 of the established operating level.

5.11.1.2 The mid-density shall be within plus or minus 0.15 of the established operating level.

5.11.1.3 The density difference shall be within plus or minus 0.15 of the established operating level.

5.11.1.4 The solution temperature control limits shall be plus or minus 1.0 degree F.

5.11.2 Weekly quality control tests. Facilities with screen-film systems shall perform a phantom image quality evaluation test, using an FDA-approved phantom, at least weekly.

5.11.2.1 The optical density of the film at the center of an image of the phantom shall be at least 1.20 when exposed under a typical clinical condition.

5.11.2.2 The optical density of the film at the center of the phantom image shall not change by more than plus or minus 0.20 from the established operating level.

5.11.2.3 The phantom image shall achieve at least the minimum score established by the accreditation body.

5.11.2.4 The density difference between the background of the phantom and an added test object, used to assess image contrast, shall be measured and shall not vary by more than plus or minus 0.05 from the established operating level.

5.11.3 Quarterly quality control tests. Facilities with screen-film systems shall perform the following quality control tests at least quarterly:

5.11.3.1 Fixer retention in film. The residual fixer shall be no more than 5 micrograms per square cm.

5.11.3.2 Repeat analysis. If the total repeat or reject rate changes from the previously determined rate by more than 2.0 percent of the total films included in the analysis, the reason(s) for the change shall be determined. Any corrective actions shall be recorded and the results of these corrective actions shall be assessed.

5.11.4 Semiannual quality control tests. Facilities with screen-film systems shall perform the following quality control tests at least semiannually:

5.11.4.1 Darkroom fog. The optical density attributable to darkroom fog shall not exceed 0.05 when a mammography film of the type used in the facility, which has a mid-density of no less than 1.20, is exposed to typical darkroom conditions for 2 minutes while such film is placed on the counter top emulsion side up. If the darkroom has a safelight used for mammography film, it shall be on during this test.

5.11.4.2 Screen-film contact. Testing for screen-film contact shall be conducted using 40 mesh copper screen. All cassettes used in the facility for mammography shall be tested.

5.11.4.3 Compression device performance. The compression device performance shall:

5.11.4.3.1 Be capable of maintaining a compression force of at least 111 newtons (25 pounds) for at least 15 seconds;

5.11.4.3.2 Effective October 28, 2002, the maximum compression force for the initial power drive shall be between 111 newtons (25 pounds) and two hundred nine newtons (forty-five pounds).

5.11.5 Annual quality control tests. Facilities with screen-film systems shall perform the following quality control tests at least annually:

5.11.5.1 Automatic exposure control performance.

5.11.5.1.1 The AEC shall be capable of maintaining film optical density within plus or minus 0.30 of the mean optical density when the thickness of a homogeneous material is varied over a range of 2 to 6 cm and the kVp is varied appropriately for such thicknesses over the kVp range used clinically in the facility. If this requirement cannot be met, a technique chart shall be developed showing appropriate techniques(kVp and density control settings) for different breast thicknesses and compositions that shall be used so that optical densities within plus or minus 0.30 of the average under phototimed conditions can be produced.

5.11.5.1.2 After October 28, 2002, the AEC shall be capable of maintaining film optical density within plus or minus 0.15 of the mean optical density when thickness of a homogeneous material is varied over a range of 2 to 6 cm and the kVp is varied appropriately for such thicknesses over the kVp range used clinically in the facility.

5.11.5.1.3 The optical density of the film in the center of the phantom image shall not be less than 1.20.

5.11.5.2 Kilovoltage peak accuracy and reproducibility. The kVp shall be accurate within plus or minus 5 percent of the indicated or selected kVp at:

5.11.5.2.1 The lowest clinical kVp that can be measured by a kVp test device;

5.11.5.2.2 The most commonly used clinical kVp;

5.11.5.2.3 The highest available clinical kVp; and

5.11.5.2.4 At the most commonly used clinical setting of kVp, the coefficient of variation of reproducibility of the kVp shall be equal to or less than 0.02. The kVp shall be checked annually or upon new x-ray tube installation.

5.11.5.3 Focal spot condition. Until October 28, 2002, focal spot condition shall be evaluated by measuring focal spot dimensions or by determining system resolution. After October 28, 2002, facilities shall evaluate focal spot condition only by determining the system resolution. For focal spot dimensions, the measured values of the focal spot length (dimension parallel to the anode cathode axis) and width (dimension perpendicular to the anode cathode axis) shall be within the following tolerance limits:

Focal Spot Tolerance Limit

Nomical Focal Spot Size (mm)	Maximum Measured Dimensions	
	Width(mm)	Length(mm)
0.10	0.15	0.15
0.15	0.23	0.23
0.20	0.30	0.30
0.30	0.45	0.65
0.40	0.60	0.85
0.60	0.90	1.30

5.11.5.3.1 System Resolution.

5.11.5.3.1.1 Each x-ray system used for mammography, in combination with the mammography screen-film combination used in the facility, shall provide a minimum resolution of 11 cycles per millimeter (mm)(line-pairs/mm) when a high contrast resolution bar test pattern is oriented with the bars

perpendicular to the anode cathode axis, and a minimum resolution of 13 line-pairs/mm when the bars are parallel to that axis.

5.11.5.3.1.2 The bar pattern shall be placed 4.5 cm above the breast support surface, centered with respect to the chest wall edge of the image receptor, and with the edge of the pattern within 1 cm of the chest wall edge of the image receptor.

5.11.5.3.1.3 When more than one target material is provided, the measurement shall be made using the appropriate focal spot for each target material.

5.11.5.3.1.4 When more than one source-image receptor distance is provided, the test shall be performed at the SID most commonly used clinically

5.11.5.3.1.5 Test kVp shall be set at the value used clinically by the facility for a standard breast and shall be performed in the AEC mode, if available. If necessary, a suitable absorber may be placed in the beam to increase exposure times. The screen-film cassette combination used by the facility shall be used to test for this requirement and shall be placed in the normal location used for clinical procedures.

5.11.5.3.2 Focal spot dimensions. Measured values of the focal spot length (dimension parallel to the anode cathode axis) and width (dimension perpendicular to the anode cathode axis) shall be within the tolerance limits specified in this Part. The focal spot shall be checked annually or upon new x-ray tube installation.

5.11.5.4 Exposure Reproducibility. The coefficient of variation of exposure shall not exceed 0.05 for any specific combination of selected technique factors. This requirement shall be deemed to have been met if, when four exposures are made at identical technique factors, the value of the average exposure ($\overline{E}$) is greater than or equal to 5 times the maximum exposure (Emax) minus the minimum exposure (Emin): $\overline{E} > 5$ (Emax - Emin). This requirement shall be checked annually or upon a new mammography x-ray unit or a new tube installation.

5.11.5.5 Timer Reproducibility. The coefficient of variation of the timer shall not exceed 0.05. This requirement shall be deemed to have been met if, with a selected timer setting, the average exposure period ($\overline{T}$) shall be greater than or equal to 5 times the maximum exposure period (Tmax) minus the minimum exposure period (Tmin) when 4 timer tests are performed: $\overline{T} > 5$ (Tmax- Tmin). This requirement shall be checked annually or upon a new mammography x-ray unit or a new tube installation.

5.11.5.6 Timer Accuracy. Deviation of the selected time setting from indicated time values shall not exceed the limits specified for that system by its manufacturer. In the absence of manufacturer's specifications, the deviation shall not exceed 10% of the indicated time value. This requirement shall be checked annually or upon a new mammography x-ray unit or a new tube installation.

5.11.5.7 Linearity. The following requirements apply when the equipment is operated on a power supply as specified by the manufacturer for any fixed x-ray tube potential within the range of 40 percent to 100 percent of the maximum rated:

5.11.5.7.1 Equipment having independent selection of x-ray tube current (mA). The average ratios of exposure to the indicated milliAmpere-seconds product (C/kg/mAs (or mR/mAs)) obtained at any tube current settings shall not differ by more than 0.10 times their sum. This is: $[X1-X2] < 0.10 (X1+X2)$; where X1 and X2 are the average C/kg/mAs (or mR/mAs) values obtained at any two tube current settings.

5.11.5.7.2 Equipment having a combined x-ray tube current-exposure time product (mAs) selector, but not a separate tube current (mA) selector. The average ratios of exposure to the indicated milliAmpere-seconds product (C/kg/mAs (or mR/mAs)) obtained at any two mAs selector settings shall not differ by more

than 0.10 times their sum. This is [X1-X2] <0.10 (X1+X2); where X1 and X2 are the average C/kg/mAs (or mR/mAs) values obtained at any two mAs selector settings.

5.11.5.7.3 Measuring Compliance. Determination of compliance shall be based on 4 exposures, at each of the two settings. The two settings may include any two focal spot sizes provided that neither focal spot size is equal to or less than .45 millimeter, in which case the two settings shall be restricted to the same focal spot size. For purposes of this requirement, focal spot size is the nominal focal spot size specified by the tube manufacturer. Linearity shall also be checked annually or upon new x-ray tube installation.

5.11.5.8 Beam quality and half-value layer (HVL). For mammography systems operating at x-ray tube potentials of less than 50 kVp, the HVL in millimeters of aluminum of the useful beam shall be equal to or greater than the product of the measured tube potential in kilovolts multiplied by 0.01. The half-value layer shall be measured with the compression device in the beam and shall be measured at the same tube potential used in Appendix A of this Part, Mammography Dose Measurement Protocol and Appendix B of this Part, Mammography Phantom Image Evaluation. The HVL shall be checked annually and after repairs to the system have been made that could affect the filtration or upon new x-ray tube installation.

5.11.5.9 Breast entrance air kerma and AEC reproducibility. The coefficient of variation for both air kerma and mAs shall not exceed 0.05.

5.11.5.10 Dosimetry. The average glandular dose delivered during a single craniocaudal view of a phantom simulating a standard breast shall not exceed 3.0 milligray (Gy) (0.3 rad) per exposure. The dose shall be determined with technique factors and conditions used clinically for a standard breast. The average glandular dose shall be checked annually or upon new tube installation.

5.11.5.11 X-ray field/light field/image receptor/compression paddle alignment.

5.11.5.11.1 All systems shall have beam-limiting devices that allow the entire chest wall edge of the x-ray field to extend to the chest wall edge of the image receptor and provide means to assure that the x-ray field does not extend beyond any edge of the image receptor by more than 2 percent of the SID. This requirement is for both large and small cassettes sizes.

5.11.5.11.2 If a light field that passes through the x-ray beam limitation device is provided, it shall be aligned with the x-ray field so that the total of any misalignment of the edges of the light field and the x-ray field along either the length or the width of the visually defined field at the plane of the breast support surface shall not exceed 2 percent of the SID.

5.11.5.11.3 The chest wall edge of the compression paddle shall not extend beyond the chest wall edge of the image receptor by more than one percent of the SID when tested with the compression paddle placed above the breast support surface at a distance equivalent to standard breast thickness. The shadow of the vertical edge of the compression paddle shall not be visible on the image.

5.11.5.12 Uniformity of screen speed. Uniformity of screen speed of all the cassettes in the facility shall be tested and the difference between the maximum and minimum optical densities shall not exceed 0.30. Screen artifacts shall also be evaluated during this test.

5.11.5.13 System artifacts. System artifacts shall be evaluated with a high-grade, defect-free sheet of homogeneous material large enough to cover the mammography cassette and shall be performed for all cassette sizes used in the facility using a grid appropriate for the cassette size being tested. System artifacts shall also be evaluated for all available focal spot sizes and target filter combinations used clinically.

5.11.5.14 Radiation output.

5.11.5.14.1 The system shall be capable of producing a minimum output of 4.5 Gy air kerma per second (513 mR per second) when operating at 28 kVp in the standard mammography (moly/moly) mode at any SID where the system is designed to operate and when measured by a detector with its center located 4.5 cm above the breast support surface with the compression paddle in place between the source and the detector. After October 28, 2002, the system, under the same measuring conditions, shall be capable of producing a minimum output of 7.0 Gy air kerma per second (800 mR per second) when operating at 28 kVp in the standard (moly/moly) mammography mode at any SID where the system is designed to operate .

5.11.5.14.2 The system shall be capable of maintaining the required minimum radiation output averaged over a 3.0 second period.

5.11.5.15 Decompression. If the system is equipped with a provision for automatic decompression after completion of an exposure or interruption of power to the system, the system shall be tested to confirm that it provides:

5.11.5.15.1 An override capability to allow maintenance of compression;

5.11.5.15.2 A continuous display of the override status; and

5.11.5.15.3 A manual emergency compression release that can be activated in the event of power or automatic release failure.

5.11.6 The quality assurance requirements of 4.2.18 and film processing requirements of 4.2.19.2 shall be met except where otherwise mentioned.

5.11.7 Quality control tests-other modalities. For systems with image receptor modalities other than screen-film, the quality assurance program shall be substantially the same as the quality assurance program recommended by the image receptor manufacturer.

5.11.8 Mobile Units. The facility shall verify that mammography units used to produce mammograms at more than one location meet the requirements in RHB 5.11.1 through 5.11.7. In addition, at each examination location, before any examinations are conducted, the mobile mammography system shall be tested using the mammography phantom image evaluation to establish the adequacy of the image quality produced by the unit.

5.11.9 Use of test results.

5.11.9.1 After completion of the tests specified in RHB 5.11.1 through 5.11.8, the facility shall compare the test results to the corresponding specified action limits; or, for non-screen film modalities, to the manufacturer's recommended action limits; or for post-move, preexamination testing of mobile units, to the limits established in the test method used by the facility.

5.11.9.2 If the test results fall outside the action limits, the source of the problem shall be identified and corrective actions shall be taken and documented:

5.11.9.2.1 Before any further examinations are performed or any films are processed using the component of the mammography system that failed any of the tests described in RHB 5.11.1, 5.11.2, 5.11.4.1, 5.11.4.2, 5.11.4.3, 5.11.5.10, 5.11.6, 5.11.7, or 5.11.8.

5.11.9.2.2 Within thirty days of the test date for all other tests described in RHB 5.11.

RHB 5.12 SURVEYS.

5.12.1 At least once a year, each facility shall undergo a survey by a medical physicist or by an individual under the direct supervision of a medical physicist. At a minimum, this survey shall include the performance

of tests and numerical values to ensure that the facility meets the quality assurance requirements of the annual tests described in RHB 5.11.5 and RHB 5.11.6 and the weekly phantom image quality test described in 5.11.2.

5.12.2 The results of all these tests conducted by the facility in accordance with RHB 5.11.1 through RHB 5.11.8, as well as written documentation of any corrective actions taken and their results, shall be evaluated for adequacy by the medical physicist performing the survey.

5.12.3 The medical physicist shall prepare a survey report that includes a summary of this review and recommendations for necessary improvements.

5.12.4 The survey report shall be sent to the facility within thirty days of the date of the survey.

5.12.5 The facility shall send a copy of the survey report to the Department within ten days of completion of corrective action required by the report. Documentation of corrective action, required as a result of the survey, must to be sent to the Department.

5.12.6 The survey report shall be dated and signed by the medical physicist performing and/or supervising the survey. If the survey was performed entirely or in part by another individual under the direct supervision of the medical physicist, that individual and the part of the survey that individual performed shall also be identified in the survey report.

RHB 5.13 Mammography equipment evaluations. Additional evaluations of mammography units or image processors shall be conducted whenever a new unit or processor isinstalled, a unit or processor is disassembled and reassembled at the same or a new location, or major components of a mammography unit or processor equipment are changed or repaired. These evaluations shall be used to determine whether the new or changed equipment meets the applicable standards in RHB 5.8 and RHB 5.11. All problems shall be corrected before the new or changed equipment is put into service for examinations or film processing. The mammography equipment evaluation shall be performed by a medical physicist or an individual under the direct supervision of a medical physicist.

RHB 5.14 Calibration of air kerma measuring instruments. Instruments used by medical physicists in their annual survey to measure the air kerma or air kerma rate from a mammography unit shall be calibrated at least once every two years and each time the instrument is repaired. The instrument calibration must be traceable to a national standard and calibrated with an accuracy of plus or minus six percent (ninety-five percent confidence level) in the mammography energy range.

RHB 5.15 Additional Administrative Requirements. Each facility where mammography services are provided shall ensure the availability for each mammography patient:

5.15.1 Instructions on how to perform breast self-examination, and

5.15.2 Information that early detection of breast cancer is maximized through a combined approach, using monthly breast self-examination, a thorough physical examination performed by a physician, and mammography performed at recommended intervals; and

5.15.3 Information that mammography is the most accurate method for making an early detection of breast cancer, however, no diagnostic tool is 100% effective.

RHB 5.16 Facility Cleanliness

5.16.1 The facility shall establish and implement written procedures for maintaining darkroom, screen, and view box cleanliness.

5.16.2 The facility shall document that all cleaning procedures are performed at the frequencies specified in the written procedures.

RHB 5.17 Infection Control. Facilities shall establish and comply with a system specifying procedures to be followed by the facility for cleaning and disinfecting mammography equipment after contact with blood or other potentially infectious materials. This system shall specify the methods for documenting facility compliance with the infection control procedures established and shall:

5.17.1 Comply with the manufacture recommended procedures for the cleaning and disinfection of the mammography equipment used in the facility; or

5.17.2 If adequate manufacturer's recommendations are not available, comply with generally accepted guidance on infection control, until such recommendations become available.

RHB 5.18 MAMMOGRAPHY PROCEDURES, TECHNIQUES, FOR MAMMOGRAPHY PATIENTS WITH BREAST IMPLANTS.

5.18.1 Each facility shall have a procedure to inquire whether or not the patient has breast implants prior to the actual mammographic exam.

5.18.2 Except where contraindicated, or unless modified by a physician's directions, patients with breast implants undergoing mammography shall have mammographic views to maximize the visualization of breast tissue.

RHB 5.19 Consumer Complaint Mechanism. Each facility shall:

5.19.1 Establish a written and documented system for collecting and resolving consumer complaints.

5.19.2 Maintain a record of each serious complaint received by the facility for at least three years after the date the complaint was received;

5.19.3 Provide the consumer with adequate directions for filing serious complaints with the facility's accreditation body if the facility is unable to resolve a serious complaint to the consumer's satisfaction;

5.19.4 Report unresolved serious complaints to the accreditation body in a manner and time frame specified by the accreditation body.

RHB 5.20 Clinical image quality. Clinical images produced by any certified facility shall continue to comply with the standards for clinical image quality established by that facility's accreditation body.

RHB 5.21 Mammography Medical Outcomes Audit. Each facility shall establish and maintain a mammography medical outcomes audit program to follow up positive mammographic assessments and to correlate pathology results with the interpreting physician's findings. This program shall be designed to ensure the reliability, clarity and accuracy of the interpretation of mammograms.

5.21.1 General Requirements. Each facility shall establish a system to collect and review outcome data for all mammograms performed, including follow-up on the disposition of all positive mammograms and correlation of pathology results with the interpreting physician's mammography report. Analysis of these outcome data shall be made individually and collectively for all interpreting physicians at the facility. In addition, any cases of breast cancer among patients imaged at the facility that subsequently become known to the facility shall prompt the facility to initiate follow-up on surgical and/or pathology results and review of the mammograms taken prior to the diagnosis of a malignancy.

5.21.2 Frequency of audit analysis. The facility's first audit analysis shall be initiated no later than twelve months after the date the facility becomes certified, or 12 months after April 28, 1999, whichever is later. This audit analysis shall be completed within an additional twelve months to permit completion of diagnostic procedures and data collection. Subsequent audit analyses shall be conducted at least once every twelve months.

5.21.3 Reviewing interpreting physician. Each facility shall designate at least one interpreting physician to review the medical outcomes audit data at least once every twelve months. This individual shall record the dates of the audit period(s) and shall be responsible for analyzing results based on this audit. This individual shall also be responsible for documenting the results, notifying other interpreting physicians of their results and the facility aggregate results. If follow-up actions are taken, the reviewing interpreting physician shall also be responsible for documenting the nature of the follow-up.

RHB 5.22 ADDITIONAL MAMMOGRAPHY REVIEW AND PATIENT NOTIFICATION.

5.22.1 If the Department believes that mammography quality at a facility has been compromised and may present a serious risk to human health, the facility shall provide clinical images and otherrelevant information, as specified by the Department, for review by the accreditation body. The Department will determine whether the facility is in compliance with this Part and if not, whether there is a need to notify affected patients, their physicians, or the public that the liability, clarity, and accuracy of interpretation of mammograms has been compromised.

5.22.2 If the Department determines that the quality of mammography performed by a facility, whether or not certified under RHB 5.3, was so inconsistent with the quality standards established in this Part as to present a significant risk to individual or public health, the Department may require such facility to notify patients who received mammograms at such facility, and their referring physicians, of the deficiencies presenting such risk, the potential harm resulting, appropriate remedial measures and such other relevant information as the Department may require.

RHB 5.23 Revocation of Accreditation. If a facility's accreditation is revoked by an accreditation body, the Department may conduct an investigation into the reasons for the revocation. Following such investigation, the Department may suspend or revoke the facility's certificate and take whatever other action or combination of actions to protect public health, including requiring the establishment and implementation of a corrective plan of action that shall permit the certificate to continue in effect while the facility seeks reaccreditation. A facility whose certificate is suspended or revoked because it has lost its accreditation may not practice mammography.

RHB 5.24 Suspension or Revocation of Certificates

5.24.1 Except as provided in 5.24.2, the Department may suspend or revoke a certificate if the Department finds that the owner, operator, or any employee of the facility:

5.24.1.1 Has been guilty of misrepresentation in obtaining the certificate;

5.24.1.2 Has failed to comply with the standards of RHB 5.2 through 5.22.

5.24.1.3 Has failed to comply with reasonable requests of the Department or the accreditation body for records, information, reports, or materials that the Department believes are necessary to determine the continued eligibility of the facility for a certificate or continued compliance with the standards of RHB 5.2 through RHB 5.22.

5.24.1.4 Has refused a reasonable request of a duly designated FDA inspector, Department inspector or accreditation body representative for permission to inspect the facility or the operations and pertinent records of the facility;

5.24.1.5 Has violated or aided and abetted in the violation of any provision of this regulation;

5.24.1.6 Has failed to comply with prior sanctions imposed by the Department; or

5.24.1.7 Has failed to pay any required fees.

5.24.2 The Department may suspend the certificate of a facility if the Department makes a finding described in RHB 5.24.1 and also determines that:

5.24.2.1 The failure to comply with required standards present a serious risk to human health;

5.24.2.2 The refusal to permit inspection makes immediate suspension necessary; or

5.24.2.3 There is a reason to believe that the violation or aiding and abetting of the violation was intentional or associated with fraud.

5.24.3 If the Department suspends a certificate in accordance with 5.24.2.

5.24.3.1 The facility may request a review from the Deputy Commissioner of Health Services no later than thirty days from the effective date of this suspension;

5.24.3.2 The suspension shall remain in effect until the Department determines that:

5.24.3.2.1 Allegations of violations or misconduct were not substantiated;

5.24.3.2.2 Violations of required standards have been corrected to the Department's satisfaction; or

5.24.3.2.3 The facility's certificate is revoked in accordance with 5.24.4;

5.24.4 The Department may revoke the facility's certificate if the Department determines that the facility:

5.24.4.1 Is unwilling or unable to correct violations that were the basis for suspension; or

5.24.4.2 Has engaged in fraudulent activity to obtain or continue certification.

RHB 5.25 Mammography Units Used for Localization or Stereotactic Breast Biopsy Procedures

5.25.1 Personnel. The following requirements apply to all personnel involved in localization or biopsy procedures performed with mammography units:

5.25.1.1 Interpreting Physicians. The interpreting physician shall:

5.25.1.1.1 Be responsible for quality assurance activities including medical audit (tracking of number of biopsies done, cancers found, benign lesions, biopsies needing repeat, and complications).

5.25.1.1.2 Be responsible for oversight of all quality control.

5.25.1.1.3 Be responsible for the supervision of the radiologic technologist and the medical physicist.

5.25.1.1.4 Be responsible for post-biopsy management of the patient.

5.25.1.1.5 Documentation of compliance with this Part shall be provided to the Department upon request.

5.25.1.2 Radiologic Technologists.

5.25.1.2.1 The radiologic technologist shall be currently registered in good standing with the American Registry of Radiologic Technologists.

5.25.1.2.2 The technologist shall have previously received documented training specifically in stereotactic breast biopsy procedures and techniques along with positioning for stereotactic units. This training shall consist of 15 hours of continuing education in mammography every three years and three hours of Category A continuing education in stereotactic breast biopsy every three years.

5.25.1.2.3 Documentation of registration and training shall be provided to the Department upon request.

5.25.1.3 Medical Physicists. The medical physicist shall:

5.25.1.3.1 Be approved by the Department as a Class IX vendor as required in 2.6.6.9 and be certified in diagnostic radiological physics or radiological physics by either the American Board of Radiology (ABR) or The American Board Medical Physics (ABMP);

5.25.1.3.2 Meet the requirements of RHB 5.7.3.1.1, 5.7.3.1.2, and 5.7.3.1.3.

5.25.1.3.3 Have fifteen hours of continuing education in mammography physics every three years.

5.25.1.3.4 Have performed at least two stereotactic breast biopsy surveys per year and;

5.25.1.3.5 Have three hours of continuing education in stereotactic breast biopsy physics every three years.

5.25.2 Equipment. Mammography units used for stereotactic breast biopsy or localization procedures shall meet the requirements of RHB 5.8, 5.11.5.2, 5.11.5.3, and 5.11.5.8 with the exception of RHB 5.11.5.10. Digital output mammography systems that do not use screen-film image receptors are exempt from the requirements of RHB 5.8 of these regulations as they relate to screen-film image receptors.

5.25.3 Quality Assurance.

5.25.3.1 Each facility shall establish and maintain a quality assurance program to ensure the safety, reliability, clarity and accuracy of mammography localization or biopsy procedures performed at the facility.

5.25.3.2 Each facility shall have the services of a medical physicist available to survey mammography equipment and to oversee the equipment-related quality assurance practices of the facility.

5.25.3.3 The quality assurance program shall be in writing and shall have been developed by a medical physicist. The program shall include, but need not be limited to the following:

5.25.3.3.1 Specifications of the tests that are to be performed, including instructions to be employed in the performance of those tests; and

5.25.3.3.2 Specifications of the frequency at which tests are to be performed, the acceptable tolerance for each parameter measured and actions to be taken if tolerances are exceeded.

5.25.3.4 The medical physicist shall conduct a review of the quality assurance program each year. Such review shall include evaluation of the results of quality assurance testing and quality control tests as specified in the American College of Radiology's Stereotactic Breast Biopsy Accreditation Program Overview.

5.25.3.5 Each facility shall maintain written records of the radiation dose measurements and quality assurance testing performed, as required in this Part, for inspection by the Department for a period of at least one year, or until the next Department inspection, whichever is later. Such records shall include, but not be limited to, the following:

5.25.3.5.1 The date of the test and identification of the person performing the test;

5.25.3.5.2 Identification of the type of testing that was performed; and

5.25.3.5.3 Notification of whether the results of the testing were within the parameters established by the medical physicist.

5.25.3.6 The facility shall send a copy of the medical physicist's survey report to the Department within ten days of completions of corrective action required by the report. Documentation of corrective action, required as a result of the survey, must to be sent to the Department.

5.25.3.7 The survey report shall be dated and signed by the medical physicist performing and/or supervising the survey. If the survey was performed entirely or in part by another individual under the direct supervision of the medical physicist, that individual and the part of the survey that individual performed shall also be identified in the survey report.

RHB 5.26 Shielding. All mammography facilities shall meet the shielding requirements specified in RHB 4.4.

RHB 5.27 Operating procedures. All mammography facilities shall meet the requirements of RHB 4.2.4.

RHB 5.28 Notification Requirements for Mobile Mammography Facilities Certified by Another Certifying Agency. Mobile mammography facilities that operate in South Carolina and are certified under MQSA by the FDA, or another State authorized by FDA to certify mammography facilities under MQSA, shall:

5.28.1 Notify the Department by telephone, facsimile, or letter of each date and location of operation of the mobile mammography facility in South Carolina prior to conducting such operation.

5.28.2 At all times while operating in South Carolina, have the following documentation available for review and inspection by the Department:

5.28.2.1 A copy of the mammography facility certificate issued by the FDA or another State, showing that the facility is currently certified.

5.28.2.2 A summary of the most recent physics survey of the mammography machine(s) and documentation of any corrective actions recommended by the medical physicist who performed the physics survey.

5.28.2.3 Documentation that personnel meet the qualifications of RHB 5.7.

RHB 5.29 Failure of Mobile Mammography Facilities Certified by Another Certifying Entity to Meet Requirements. The Department shall notify the certifying entity of the facts and circumstances and may take other actions as may be appropriate under the Atomic Energy and Radiation Control Act and regulations thereunder if the Department has reason to believe that the owner, operator, or any employee of a mobile facility certified by another certifying entity:

5.29.1 Has been guilty of misrepresentation in obtaining the certificate;

5.29.2 Has failed to comply with the standards of this Part;

5.29.3 Has failed to comply with reasonable requests of the Department for records, information, reports, or materials that the Department believes are necessary to determine the continued eligibility of the facility for a certificate or continued compliance with the standards of this Part;

5.29.4 Has refused a reasonable request of a Department representative for permission to inspect the facility or the operations and pertinent records of the facility.

Appendix A
Mammography Dose Measurement Protocol

The technique factors used for performing a mammography examination shall not permit the mean glandular absorbed dose to exceed the limits specified in RHB 5.11.5.10. Radiation measurements shall be performed with an integrating radiation measuring device that is appropriate to the high beam intensity and mammographic kilovoltage peak (kVp) used, and sufficiently sensitive to determine compliance with the criteria specified in RHB 5.14. The instrument shall have been calibrated as specified in RHB 5.14.

The mammography exam dose limits are based on an average compressed breast value of 4.2 centimeters having an average density (i.e., 50 percent adipose and 50 percent glandular).

Perform the following steps to determine the mean glandular dose to a nominal 4.2 centimeter compressed breast:

a) Measure and record the x-ray system's useful beam half value layer (HVL). (See RHB 5.11.5.8.) Any compression device normally in the useful beam during mammography procedures shall be required to be placed between the x-ray tube target and measuring device when determining the HVL. The useful beam shall be collimated to a size encompassing the detector.

   NOTE: Filters used for the HVL evaluation should be placed as close to the target as practical. The HVL for screen-film mammography should not exceed the minimum acceptable HVL by more than 0.1 millimeter of aluminum equivalent.

b) Determine the glandular dose to entrance exposure factor from the Mammography Dose Evaluation Table (see Appendix C of this Part) using the appropriate HVL, kVp and x-ray tube target-filter material.

   NOTE: The kVp of screen-film mammography systems with molybdenum target-filter combinations should be accurately measured to determine the appropriate glandular dose to entrance exposure factor from Appendix C of this Part.

c) If the equipment has the capability for variable source to image receptor distance, set the craniocaudal source to image receptor distance (SID) for the image receptor system used.

d) Position in the useful beam any compression apparatus normally used.

   NOTE: Some mammography systems have the capability of providing automatic adjustment of technique factors through feedback from the position of the compression device. On such systems, the compression device should be lowered to a position 4.2 centimeters above the breast support assembly (BSA). The device should then be removed, inverted and replaced to allow placement of the phantom and measuring device on the BSA below the compression device. If the compression device cannot be replaced in an inverted position, the device should be placed in the beam using auxiliary support.

e) Placement of the Radiation Measuring Device

1) For systems equipped with automatic exposure control (AEC):

   A) Place a properly loaded film cassette in the cassette holder.

      NOTE: The loaded cassette is placed in the cassette holder to simulate, as much as is possible, the conditions under which actual patient exposures are made. Following radiation measurements, the film should be discarded and the cassette reloaded with unexposed film.

   B) Place a mammography phantom (see the definition for "Phantom" in RHB 9.168) on the breast support assembly (BSA). Align the phantom so that the edge of the phantom is aligned with the chest wall side of the BSA and the phantom is over the automatic exposure control device(s).

   C) Place a radiation measuring device in the useful beam so the center axis of the device is parallel to the breast support assembly (13SA). The geometric center of the measuring device shall be positioned 4.5 centimeters above the BSA, 2.5 centimeters from the chest wall edge of the BSA and immediately adjacent to either side of the mammography phantom.

2) For systems not equipped with AEC, place a radiation measuring device in the useful beam so that the center axis of the device is parallel to the breast support assembly (BSA). The geometric center of the measuring device shall be positioned so that it is centered 4.5 centimeters above the BSA, 2.5 centimeters from the chest wall edge of the BSA and at the center line of the BSA. No part of the devices detector area shall be outside of the useful beam.

f) Collimate the x-ray field to the size normally used and assure that the area covered by the useful beam includes the detector area of the radiation measuring device and the mammography phantom if the equipment is equipped with automatic exposure.

g) Set the appropriate technique factors or automatic exposure controls normally used for a nominal 4.2 centimeter compressed breast.

h) Measure and record the exposure in air with the radiation measuring device.

i) Calculate the mean glandular dose for a 4.2 centimeter compressed breast by multiplying the measured exposure in millicoulombs per kilogram or in roentgens by the glandular dose to entrance exposure factor, which was determined using the procedure described in subsection (b) of this Appendix.

   EXAMPLE: A mammography system is provided with a molybdenum target-filter combination, and the HVL and kVp are determined to be 0.3 and 30, respectively. Therefore, for a 4.2 centimeter compressed breast, the glandular dose to entrance exposure factor from the Mammography Dose Evaluation Table (Appendix C of this Part) would be 159 mrad. The measured roentgen output determined in subsection (h) of this Appendix is determined to be 1.8 R. Therefore, the mean glandular dose would be 1.8 R multiplied by 159 mrad/R- This results in a mean glandular dose measurement of 286 mrad. As such, the system would be in compliance with RHB 5.11.5.10.

Appendix B
Mammography Phantom Image Evaluation

Mammography Phantom image evaluation shall be performed using the procedure below. The evaluation shall be performed weekly as a part of the quality assurance program. The evaluation shall be performed with the mammography phantom specified in RHB 9.168.

a) Equipment necessary for mammography phantom image evaluation includes a densitometer, the mammography phantom and mammographic cassette and film.

b) Load film in the mammographic cassette according to the manufacturer's instructions.

c) Place the properly loaded cassette in the cassette holder.

d) Place the mammography phantom on the breast support assembly (BSA) so that the edge of the phantom is aligned with the chest wall side of the BSA. Align the phantom so that the ma ses in the phantom are nearest the chest wall edge of the BSA and the fibers in the phantom are away from the chest wall edge of the BSA. If the mammography machine has the capability of automatic exposure control, place the phantom so that the phantom covers the phototimer sensor.

e) Position the compression device so that it is in contact with the phantom.

f) Select the technique factors used most frequently in the clinical setting for a 4.2 centimeter compressed breast and make an exposure of the phantom.

g) Process the filin in the processor used for clinical mammography films.

h) Examine the processed image for areas of nonuniformity of optical density and for the presence of artifacts due to dirt, dust, grid lines or processing.

NOTE: If any of the problems noted above are evident on the processed image, the mammography machine film processor and film cassette(s) should be evaluated and the problem corrected. The phantom image evaluation should be repeated after the problem is corrected.

i) Measure and record the optical density of the film near the center of the phantom image. The optical density of the film at the center of the image of the phantom shall be at least 1.20 when exposed under a typical clinical condition.

j) Examine the phantom image and count and record the number of masses visualized. Repeat this procedure for the speck groups and the f1brils and record the number of objects visualized. There are a total of 16 imaging objects (5 masses, 5 speck groups and 6 fibrils) in the phantom. Evaluation criteria for objects visualized in the phantom image are in RHB 5.11.2.3. and RHB 5.11.2.4. As a minimum, the objects that must be visualized in the phantom image are:

1) The masses that are 0.75 millimeter or larger (a total of 3 masses);

2) The speck groups that are 0.32 millimeter or larger (a total of 3 speck groups);

3) The fibrils that are 0.75 millimeter or larger (a total of 4 fibrils).

NOTE: The phantom image should be compared with previous films, including the original phantom image, to determine if subtle changes are occurring from week to week.

Appendix C
Mammography Dose Evaluation Tables

These tables are used to determine the mean glandular dose in milligrays delivered by 25.9 mC/kg (or millirad) delivered by 1 R in air incident on a 4.2 centimeter thickness compressed breast of average density (50 percent adipose and 50 percent glandular tissue. Linear extrapolation or interpolation shall be made for any HVL not listed. To convert from entrance exposure in air in roentgens to mean glandular breast dose in millirads, multiply the entrance exposure by the factor shown in the table for the appropriate kVp and beam quality (HVL) combination.

GLANDULAR DOSE (IN MRAD) FOR 1 ROENTGEN ENTRANCE EXPOSURE TO A 4.2-CM BREAST THICKNESS---50% ADIPOSE-50%GLANDULAR BREAST TISSUE---USING A MO/MO TARGET-FILTER COMBINATION*

X-ray Tube Voltage (kVp)												W/Al
HVL	23	24	25	26	27	28	29	30	31	32	33	Target-Filter Combination
0.23	116											
0.24	121	124										
0.25	126	129	131									
0.26	130	133	135	138								
0.27	135	138	140	142	143							
0.28	140	142	144	146	147	149						
0.29	144	146	148	150	151	153	154					
0.30	149	151	153	155	156	157	158	159				170
0.31	154	156	157	159	160	161	162	163	164			175
0.32	158	160	162	163	164	166	167	168	168	170	171	180
0.33	163	165	166	168	169	170	171	173	173	174	175	185
0.34	168	170	171	172	173	174	175	176	177	178	179	190
0.35		174	175	176	177	178	179	180	181	182	183	194
0.36			179	181	182	183	184	185	185	186	187	199
0.37				185	186	187	188	189	190	191	191	204
0.38					190	191	192	193	194	195	195	208
0.39						196	197	198	198	199	200	213
0.40							201	202	203	204	204	217
0.41								206	207	208	208	221
0.42									211	212	212	225
0.43										215	216	230
0.44											220	234
0.45												238

GLANDULAR DOSE (IN MRAD) FOR 1 ROENTGEN ENTRANCE EXPOSURE TO A 4.2-CM BREAST THICKNESS ---50% ADIPOSE 50% GLANDULAR BREAST TISSUE ---USING A MO/RH TARGET-FILTER COMBINATION*

	X-ray Tube Voltage (kVp)										
HVL	25	26	27	28	29	30	31	32	33	34	35
0.28	149	151	154								
0.29	154	156	158	159							
0.30	158	160	162	162	163						
0.31	163	164	166	166	166	167	167				
0.32	167	169	171	171	171	171	172	172			
0.33	171	173	175	176	176	176	176	177			
0.34	176	178	179	179	180	180	180	181	181		
0.35	180	181	183	183	184	185	185	186	187		
0.36	185	186	187	187	188	188	189	190	191	191	
0.37	189	190	191	191	192	193	193	194	195	195	
0.38	193	194	196	196	197	197	197	198	199	199	200
0.39	198	199	200	200	201	201	202	202	203	203	204
0.40	202	203	204	204	205	205	206	207	208	208	208
0.41	206	207	208	208	209	209	210	211	212	212	212
0.42	211	211	212	212	213	213	214	215	216	216	217
0.43	215	216	217	217	218	218	219	219	220	220	221
0.44	220	220	221	221	222	222	223	223	224	224	225
0.45	224	224	225	225	226	226	227	227	228	228	229
0.46		228	229	229	230	231	231	232	233	233	234
0.47			233	233	234	235	235	236	237	237	238
0.48			238	238	239	240	240	241	241	242	242
0.49				242	243	243	244	244	245	245	246
0.50					247	247	248	248	249	250	251
0.51						251	252	253	254	254	255
0.52							257	257	258	258	259
0.53							261	261	262	263	264
0.54								265	266	267	268
0.55								269	270	271	272
0.56									275	276	276
0.57									279	280	281
0.58										284	285
0.59										288	289
0.60											293

GLANDULAR DOSE (IN MRAD) FOR 1 ROENTGEN ENTRANCE EXPOSURE TO A 4.2-CM BREAST THICKNESS ---50% ADIPOSE 50% GLANDULAR BREAST TISSUE ---USING A RH/RH TARGET-FILTER COMBINATION*

	X-RAY TUBE VOLTAGE (KVP)										
HVL	25	26	27	28	29	30	31	32	33	34	35
0.28	150	155	159								
0.29	155	160	164	168							
0.30	160	164	168	172	176						
0.31	165	168	172	174	180	182					
0.32	169	173	177	181	184	186	188				
0.33	174	178	181	185	188	190	192				
0.34	179	183	186	190	193	195	196	199			
0.35	184	187	190	194	197	199	201	203			
0.36	189	192	195	198	201	204	205	207	209		
0.37	193	196	199	202	205	207	209	211	213		
0.38	198	201	204	207	209	211	213	215	217	219	221
0.39	203	206	208	211	214	216	217	219	221	223	224
0.40	208	211	213	216	218	220	221	223	224	226	228
0.41	213	215	217	220	222	224	225	227	228	230	232
0.42	218	220	222	224	226	228	229	231	232	234	236
0.43	222	224	226	228	230	232	233	235	236	238	240
0.44	227	229	231	233	235	237	238	239	240	242	243
0.45	232	234	235	237	239	241	242	243	244	246	247
0.46			239	241	243	245	246	247	248	250	251
0.47					247	249	250	251	252	254	255
0.48					251	253	254	255	256	258	259
0.49						257	258	259	260	261	262
0.50						261	262	263	264	265	266
0.51							266	267	268	269	270
0.52							270	271	272	273	274
0.53							275	276	276	277	278
0.54								279	280	280	281
0.55								283	284	284	285
0.56									288	288	289
0.57										292	293
0.58										296	297
0.59											300
0.60											304

PART VI
USE OF THERAPEUTIC EQUIPMENT

RHB 6.1 Scope. This part establishes requirements for use of therapeutic equipment by persons licensed to practice one or more of the health professions within the authority granted to them by statute or regulation. Therapeutic equipment in this part will be defined as any therapeutic machine capable of producing a useful beam of x-rays, or x-rays and charged particles with energies greater than 500 keV. Particle accelerators meeting this definition will be regulated under this part while all other particle accelerators will be regulated

under Title C. The provisions of this part are in addition to, and not in substitution for, other applicable provisions of these regulations. All provisions of this Part apply to therapeutic veterinary installations.

RHB 6.2 Shielding Requirements for all Therapeutic X-ray Equipment.

6.2.1 Each installation shall be provided with protective barriers as are necessary to assure compliance with RHB 3.3, RHB 3.4 and RHB 3.6. The requirement shall be deemed met if the thickness of such barriers is equivalent to the thickness as computed in accordance with calculations in the National Council on Radiation Protection and Measurements (NCRP) Report #51, "Radiation Protection Design Guidelines for .1-100 MeV Particle Accelerator Facilities", NCRP Report #49 "Structural Shielding Design and Evaluation for Medical Use of X-rays and Gamma Rays of Energies up to 10 MeV", or an equivalent reference.

6.2.2 Shielding. Prior to construction, the floor plans and equipment arrangement of all new installations, or modifications of existing installations, utilizing ionizing radiation for therapeutic purposes shall be reviewed by a Class VII vendor and submitted to the Department for review and approval. The registrant shall submit plans and a report, including any recommendations and all basic assumptions used, from the vendor to the Department. The approval of such plans shall not preclude the requirement of additional modifications should a subsequent analysis of operating conditions indicate the possibility of an individual receiving a dose in excess of the limits prescribed in Part III of these regulations.

6.2.3 After installation of a radiation machine, the facility shall maintain for inspection by the Department:

6.2.3.1 The maximum rating of technique factors;

6.2.3.2 A scale drawing of the room in which a stationary radiation machine system is located with such drawing indicating the use of areas adjacent to the room and an estimation of the extent of occupancy by an individual in such areas. In addition, the drawing shall include:

6.2.3.2.1 The results of a survey for radiation levels present at the operator's position and at pertinent points outside the room at specified test conditions, or

6.2.3.2.2 The type and thickness of materials, or lead equivalency, of each protective barrier.

6.2.4 After construction and installation are complete, the registrant shall submit "as built" drawings to the Department for review. These drawings shall indicate the composition of all walls and the placement of the x-ray equipment and control. "As built" drawings may be submitted after shielding installation is complete while cosmetic finishing continues.

6.2.5 The therapeutic x-ray equipment shall not be used before a shielding plan for the unit has been approved by the Department, and "as built" drawings have been submitted.

RHB 6.3 GENERAL PROVISIONS FOR ALL THERAPEUTIC EQUIPMENT.

6.3.1 Radiation Safety Officer.

6.3.1.1 The registrant shall designate an individual who will be responsible for radiation protection for the therapeutic equipment. Such individual may be a radiological physicist, and shall:

6.3.1.1.1 Be qualified by training and experience concerning all hazards and precautions involved in operating the therapeutic equipment for which he is responsible.

6.3.1.1.2 Recommend a detailed program of radiation safety for effective compliance with the applicable requirements of these regulations.

6.3.1.1.3 Give instructions concerning hazards and safety practices to individuals who may be exposed to radiation from the therapeutic equipment.

6.3.1.1.4 Make surveys and carry out other procedures as required by these regulations.

6.3.1.2 Each therapeutic machine shall be under the administrative control of a radiological physicist who will be responsible for the safe operation of the equipment.

6.3.2 Procedures.

6.3.2.1 Written operating procedures as well as specified safety rules shall be established for each therapeutic unit facility and approved by the radiation safety officer.

6.3.2.1.1 Operating procedures. The written operating procedures to be implemented shall include the following:

6.3.2.1.1.1 The accelerator is used in such a manner that patients, workers, and the general public are protected from radiation hazards and the provisions of Part III of these regulations are met;

6.3.2.1.1.2 No therapeutic machine shall be left unattended unless it is secured against unauthorized use;

6.3.2.1.1.3 The safety interlock system shall not be used to terminate the exposure except in an emergency;

6.3.2.1.1.4 If a patient needs support or restraint during therapy, mechanical supporting or restraining devices shall be used;

6.3.2.1.1.5 No individual other than the patient shall be in the therapy room during irradiation;

6.3.2.1.1.6 Startup procedures for the accelerator, specified by the therapeutic radiological physicist, shall be performed daily prior to treatment of patients;

6.3.2.1.1.7 The accelerator shall not be used for treatment of patients unless the operator can maintain visual observation of the patient and audible communication with the patient; and

6.3.2.1.1.8 Policies and procedures for pregnant workers; NRC Regulatory Guide 8.13, "Instruction Concerning Prenatal Radiation Exposure" should be used for guidance concerning pregnant workers;

6.3.2.1.1.9 Policies and procedures for personnel monitoring;

6.3.2.1.1.10 Policies and procedures for training new employees; and

6.3.2.1.1.11 Policies and procedures for identifying and reporting misadministrations, as defined by RHB 9.150.

6.3.2.1.1.12 Policies and procedures for quality assurance. In addition to other quality assurance and quality control procedures required at a therapy facility, the facility must have a policy and procedure which specifically addresses annual equipment performance testing on radiation therapy simulators and CT scanners used for treatment planning. This policy and procedure must address standards for film processing, which includes processor quality assurance, evaluation of darkroom conditions and film, periodic inspection and cleaning of film cassettes and screens, view box lighting conditions, and periodic testing of safety interlocks and warning systems.

6.3.2.1.2 Emergency Procedures. The emergency procedures shall include:

6.3.2.1.2.1 Instructions for alternate methods for termination of irradiation and machine movements.

6.3.2.1.2.2 Instructions for contacting the therapeutic radiological physicist when operational problems or emergencies occur and the actions that are to be taken until the physicist can be contacted.

6.3.2.2 Operators and maintenance personnel shall be familiar with and have available a copy of the written operating and emergency procedures. Documentation must be maintained indicating that the operator or maintenance person has read and agrees to adhere to the operating procedures.

6.3.3 Operator Requirements and Training.

6.3.3.1 THE REGISTRANT SHALL ASSURE THAT ALL THERAPEUTIC EQUIPMENT UNDER HIS CONTROL IS OPERATED ONLY BY A RADIATION THERAPIST POSSESSING A CURRENT, VALID CERTIFICATE FROM THE SOUTH CAROLINA QUALITY STANDARDS ASSOCIATION, OR A LICENSED PRACTITIONER. FOR THE PURPOSE OF THIS PART, A RADIATION THERAPIST IS DEFINED AS A PERSON WHO APPLIES RADIATION TO HUMANS FOR THERAPEUTIC PURPOSES; PERFORMS TREATMENT SETUPS, INCLUDING, BUT NOT LIMITED TO, PATIENT POSITIONING, SETTING OF TREATMENT PARAMETERS ON THE CONTROL PANEL, AND VERIFICATION OF TREATMENT ACCESSORIES; OR DOCUMENTS DAILY TREATMENTS FOR A PATIENT'S CHART.

6.3.3.2 In-house modification, repairs, or preventative maintenance on therapeutic equipment components or safety interlocks may be performed only by or under the direct supervision of persons who have received at least the minimum training specified in RHB 6.3.3.12 and demonstrated competence specified in RHB 6.3.3.13.

6.3.3.3 No person other than a licensed practitioner or a radiation therapist possessing a current, valid certificate from the South Carolina Radiation Quality Standards Association shall use equipment emitting ionizing radiation on humans for therapeutic purposes.

6.3.3.4 No person shall employ or designate as a radiation therapist a person who does not hold a certificate issued by the South Carolina Radiation Quality Standards Association.

6.3.3.5 NO PERSON HOLDING A CERTIFICATE ISSUED BY THE SOUTH CAROLINA RADIATION QUALITY STANDARDS ASSOCIATION SHALL USE EQUIPMENT EMITTING IONIZING RADIATION ON HUMANS FOR THERAPEUTIC PURPOSES UNLESS UNDER THE DIRECTION AND SUPERVISION OF A LICENSED PRACTITIONER AND UNLESS SO DIRECTED BY PRESCRIPTION OF A LICENSED PRACTITIONER.

6.3.3.6 No person who is not certified by the South Carolina Radiation Quality Standards Association shall take, use, or exhibit the title of "limited practice radiographer," "radiographer," or "radiation therapist" or any other title, sign, display, or declaration that tends to lead the public to believe that the person is authorized to apply ionizing radiation on humans for therapeutic purposes.

6.3.3.7 A student enrolled in and attending a school or college of medicine, radiologic technology, radiation therapy, or a curriculum approved by the South Carolina Radiation Quality Standards Association, or a resident in an approved graduate education program of medicine may apply ionizing radiation to humans without a certificate from the South Carolina Radiation Quality Standards Association as long as the student or resident is under the supervision of a licensed practitioner or direct supervision of a certified radiation therapist appropriately trained to supervise the specific procedure.

6.3.3.8 The registrant shall display each operator's current certificate in public view, not obstructed by any barrier, equipment, or other object.

6.3.3.9 The registrant shall ensure that each operator has received training specific to the equipment and procedures in use at his facility, including machine specific training, use of personnel monitoring devices, quality assurance procedures, and the operating procedures required by RHB 6.3.2.

6.3.3.10 All operators shall receive at least one month of on the job training before assuming operational responsibility.

6.3.3.11 The registrant shall maintain a record of all training for each operator. Such records shall be made available for Departmental inspection.

6.3.3.12 Training of in-house and test maintenance personnel shall include:

6.3.3.12.1 Fundamentals of Radiation Safety;

6.3.3.12.1.1 Characteristics of radiation.

6.3.3.12.1.2 Units of radiation dose.

6.3.3.12.1.3 Hazards of excessive exposure to radiation.

6.3.3.12.1.4 Levels of radiation from therapeutic equipment.

6.3.3.12.1.5 Methods used to prevent radiation exposure including shielding, interlocks, safety rules, and radiation monitoring equipment.

6.3.3.12.2 Use and care of personnel monitoring equipment employed at the facility.

6.3.3.12.3 Location and use of all operating controls.

6.3.3.12.4 Requirements of pertinent State Regulations.

6.3.3.12.5 Registrant's written operating and emergency procedures.

6.3.3.13 In-house personnel who are to perform or directly supervise modifications, tests or maintenance work shall demonstrate the following capabilities to the radiation safety officer:

6.3.3.13.1 Ability to read and understand electrical diagrams.

6.3.3.13.2 A thorough knowledge of the principles and operation of the therapeutic equipment.

6.3.3.13.3 A thorough knowledge of the safety interlock system.

6.3.3.13.4 Ability to understand, use, and check the operation of radiation survey instruments.

6.3.3.14 The registrant shall maintain a record of all training for in-house testing and maintenance personnel. Such records shall be made available for Departmental inspection.

6.3.4 Control.

6.3.4.1 The radiation safety officer shall maintain a current list of all personnel who are qualified to service the therapeutic equipment.

6.3.4.2 No registrant shall permit a therapeutic unit to operate at any time with a safety interlock bypassed, except for necessary testing.

6.3.5 Technique indicators. Instrumentation readouts and controls on the therapy control console must be clearly identified and easily discernable.

RHB6.4 THERAPEUTIC X-RAY SYSTEMS OF LESS THAN 1 MEV.

6.4.1 Equipment requirements.

6.4.2 LEAKAGE RADIATION. WHEN THE TUBE IS OPERATED AT ITS LEAKAGE TECHNIQUE FACTORS, THE LEAKAGE RADIATION SHALL NOT EXCEED THE VALUES SPECIFIED AT THE DISTANCE STATED FOR THE CLASSIFICATION OF THAT X-RAY SYSTEM SHOWN IN TABLE 1.

TABLE 1. LEAKAGE LIMITS FOR THERAPEUTIC X-RAY SYSTEMS OF LESS THAN 1 MeV.

System	Leakage Limit	Measurement Location
Contact Therapy	100 mR/hr	5 cm from surface of tube housing
0-150 kVp (manufactured or installed prior to the effective date of these regulations)	1 R in 1 hr.	1 m from source
0-150 kVp (manufactured on or after the effective date of these regulations)	100 mR in 1 hr	1 m from source
151-500 kVp	1 R in 1 hr	1 m from source
500-999 kVp	.1 percent of useful beam or R in 1 hr.	1 m from source

6.4.1.2 Permanent Beam-Limiting Devices. Permanent fixed diaphragms or cones used for limiting the useful beam shall provide the same or a higher degree of protection as required for the tube housing assembly.

6.4.1.3 Removable and Adjustable Beam-Limiting Device.

6.4.1.3.1 Removable beam-limiting devices shall, for the portion of the useful beam to be blocked by these devices, transmit not more than 1 percent of the useful beam at the maximum kV and maximum treatment filter. This requirement does not apply to auxiliary blocks or materials placed in the useful beam to shape the useful beam to the individual patient.

6.4.1.3.2 Adjustable beam-limiting devices shall, for the portion of the x-ray beam to be blocked by these devices, transmit not more than 5 percent of the useful beam at the maximum kV and maximum treatment filter.

6.4.1.3.3 Adjustable beam-limiting devices installed after the effective date of these regulations shall meet the requirements of 6.4.1.3.

6.4.1.4 The filter system shall be so designed that:

6.4.1.4.1 The filters cannot be accidentally displaced at any possible tube orientation;

6.4.1.4.2 For equipment installed after the effective date of these regulations, an interlock system prevents irradiation if the proper filter is not in place;

6.4.1.4.3 The radiation at 5 centimeters from the filter insertion slot opening does not exceed 30 Roentgens (7.74 mC/kg) per hour under any operating conditions; and

6.4.1.4.4 Each filter is marked as to its material of construction and its thickness. For wedge filters, the wedge angle shall appear on the wedge or wedge tray.

6.4.1.5. Tube Immobilization. The tube housing assembly shall be capable of being immobilized for stationary treatments.

6.4.1.6 Focal Spot Marking. The tube housing assembly shall be so marked that it is possible to determine the location of the focal spot to within 5 millimeters, and such markings shall be readily accessible for use during calibration procedures.

6.4.1.7 Beam Block. Contact therapy tube housing assemblies shall have a removable shield of at least 0.5 millimeter lead equivalency at 100 kVp that can be positioned over the entire useful beam exit port during periods when the beam is not in use.

6.4.1.8 Beam Monitor System. Systems of greater than 150 kVp manufactured after the effective date of these regulations shall be provided with a beam monitor system which:

6.4.1.8.1 Shall have the detector of the monitor system interlocked to prevent incorrect positioning;

6.4.1.8.2 Shall not allow irradiation until a preselected value of exposure has been made at the treatment control panel;

6.4.1.8.3 Shall independently terminate irradiation when the preselected exposure has been reached;

6.4.1.8.4 Shall be so designed that, in the event of a system malfunction or electrical power failure, the dose administered to a patient prior to the system malfunction or power failure can be accurately determined;

6.4.1.8.5 Shall have a display at the control panel from which the dose at a reference point in soft tissue can be calculated;

6.4.1.8.6 Shall have a control panel display which maintains the administered dose reading until intentionally reset to zero; and

6.4.1.8.7 Shall have a control panel display which does not have scale multiplying factors and utilizes a design such that increasing dose is displayed by increasing numbers.

6.4.1.9 TIMER.

6.4.1.9.1 A timer which has a display shall be provided at the treatment control panel. The timer shall have a preset time selector.

6.4.1.9.2 The timer shall activate with the production of radiation and retain its reading after irradiation is interrupted. After irradiation is terminated and before irradiation can be reinitiated, it shall be necessary to reset the elapsed time indicator to zero.

6.4.1.9.3 The timer shall terminate irradiation when a preselected time has elapsed, if any dose monitoring system present has not previously terminated irradiation.

6.4.1.9.4 THE TIMER SHALL PERMIT ACCURATE PRESETTING AND DETERMINATION OF EXPOSURE TIMES AS SHORT AS 1 SECOND.

6.4.1.9.5 The timer shall not permit an exposure if set at zero.

6.4.1.9.6 The timer shall not activate until the shutter is opened when irradiation is controlled by a shutter mechanism unless calibration includes a timer factor to compensate for mechanical lag.

6.4.1.9.7 Timers shall be accurate to within 1 percent of the selected value or 1 second, whichever is greater.

6.4.1.10. Control Panel Functions. Within one year of the effective date of these regulations, the control panel, in addition to the displays required in other provisions of this Part shall have:

6.4.1.10.1 An indication of whether electrical power is available at the control panel and if activation of the x-ray tube is possible;

6.4.1.10.2 An indication of whether x-rays are being produced;

6.4.1.10.3 Means for indicating x-ray tube potential and current;

6.4.1.10.4 Means for terminating an exposure at any time

6.4.1.10.5 A locking device which will prevent unauthorized use of the x-ray system; and

6.4.1.10.6 For x-ray systems manufactured after the effective date of these regulations, a positive display of specific filters in the beam.

6.4.1.11 Multiple Tubes. When a control panel may energize more than one x-ray tube:

6.4.1.11.1 It shall be possible to activate only one x-ray tube at any time;

6.4.1.11.2 There shall be an indication at the control panel identifying which x-ray tube is activated; and

6.4.1.11.3 There shall be an indication at the tube housing assembly when that tube is energized.

6.4.1.12 Source to Skin Distance (SSD). There shall be means of determining initially the SSD to within 1 centimeter and of producing this measurement to within 2 millimeters thereafter.

6.4.1.13 Shutters. Unless it is possible to bring the x-ray output to the prescribed exposure parameters within 5 seconds, the beam shall be attenuated by a shutter having a lead equivalency not less than that of the tube housing assembly.

6.4.1.13.1 After the unit is at operating parameters, the shutter shall be controlled electrically by the operator from the control panel.

6.4.1.13.2 An indication of shutter position shall appear on the control panel.

6.4.2 Facility Design Requirements for Therapy X-ray Systems Capable of Operating Above 50 kVp.

6.4.2.1 Aural Communication. Provision shall be made for two-way aural communication between the patient and the operator at the control panel. However, where excessive noise levels or treatment requirements make aural communication impractical, other methods of communication shall be used.

6.4.2.2 Viewing Systems.

6.4.2.2.1 Windows, mirrors, closed circuit television, or an equivalent system shall be provided to permit continuous observation of the patient during irradiation and shall be so located that the operator can observe the patient from the control panel.

6.4.2.2.2 When the primary viewing system is by electronic means, an alternate viewing system, which may be electronic, shall be available for use in the event of failure of the primary viewing system.

6.4.2.2.3 Should both systems described in 6.4.2.2.2 above fail or be inoperative, treatment shall not be performed with the unit until one of the systems is restored.

6.4.2.3 Barriers. With equipment operating at voltages above fifty (50) kVp, the required barriers shall be an integral part of the building.

6.4.2.4 Multiple Access. Treatment rooms to which access is possible through more than one entrance shall be provided with flashing warning lights in a readily observable position near the outside of all access doors, which will indicate when the useful beam is "on". Interlocks shall be provided such that all entrance doors must be closed, including doors to any interior booths, before treatment can be initiated or continued. If the radiation beam is interrupted by any door opening, it shall not be possible to restore the machine to operation without closing the door and reinitiating irradiation by manual action at the control panel.

6.4.3 Additional Requirements for X-ray Systems Capable of Operating Above 150 kVp.

6.4.3.1 All protective barriers shall be fixed except for entrance doors or beam interceptors.

6.4.3.2 The control panel shall be within a protective booth equipped with an interlocked door or located outside the treatment room or in a totally enclosed booth, which has a ceiling, inside the room.

6.4.3.3 Interlocks shall be provided such that all entrance doors must be closed, including doors to any interior booths, before treatment can be initiated or continued. If the radiation beam is interrupted by any door opening, it shall not be possible to restore the machine to operation without closing the door and reinitiating irradiation by manual action at the control panel.

6.4.3.4 When any door referred to in 6.4.3.3 is opened while the x-ray tube is activated, the exposure at a distance of 1 meter from the source shall be reduced to less than 100 milliroentgen per hour.

6.4.3.5 A scram button or other emergency power cut-off switch shall be located and easily identifiable in all accessible high radiation areas.

6.4.3.6 All safety and warning devices, including interlocks, shall be tested and appropriately serviced after each 500 hours of operation or at intervals not to exceed six months, whichever comes first. Documentation shall be kept and available for review of all testing and servicing.

6.4.4 Surveys, Calibrations, and Spot Checks.

6.4.4.1 Surveys.

6.4.4.1.1 All new facilities, and existing facilities not previously surveyed shall have a survey made by or under the direction of a qualified expert who is authorized by the Department to perform such surveys. Such surveys shall be done after any change in the facility or equipment which might cause a significant increase in radiation hazard. A record shall be made of the therapeutic operating conditions and radiation levels measured at specific control points. One of these control points must be at the normal work station of the operator.

6.4.4.1.2 The registrant shall obtain a written report of the survey from the qualified expert. A copy of the initial report shall be transmitted by the registrant to the Department within 30 days of the first patient treatment following the survey. The registrant shall maintain all subsequent reports for inspection by the Department.

6.4.4.1.3 The survey and report shall indicate all instances where the installation, in the opinion of the qualified expert, is in violation of applicable rules or regulations.

6.4.4.1.4 The registrant shall maintain sufficient calibrated and operable radiation survey instruments to make physical radiation surveys as required by this part of these regulations. Each radiation survey instrument shall be response checked every three months and calibrated once a year. After each instrument servicing, a record shall be maintained of the latest response check or calibration date.

6.4.4.2 Calibrations. Calibrations of x-ray systems subject to the requirements of this Part shall meet the following requirements:

6.4.4.2.1 The calibration of an x-ray system shall be performed at intervals not to exceed 1 year and after any change or replacement of components which could cause a change in the radiation output. on output.

6.4.4.2.2 The calibration of the radiation output of the x-ray system shall be performed by or under the direction of a radiological physicist who is physically present at the facility during such calibration.

6.4.4.2.3 Calibration of the radiation output of an x-ray system shall be performed with a calibrated dosimetry system. The calibration of such system shall be traceable to a national standard. The system shall have been calibrated within the preceding two years.

6.4.4.2.4 The calibration shall be such that the dose at a reference point in a water or tissue equivalent phantom can be calculated to within an uncertainty of 5 percent. For superficial units, free-in-air calibrations are acceptable.

6.4.4.2.5 The calibration of the x-ray system shall include, but not be limited to, the following determinations:

6.4.4.2.5.1 Verification that the x-ray system is operating in compliance with the design specifications;

6.4.4.2.5.2 Half-value layer for each kV setting and filter combination used;

6.4.4.2.5.3 The exposure rates as a function of field size, technique factors, filter, and treatment distance used; and

6.4.4.2.5.4 The degree of congruence between the radiation field and the field indicated by the localizing device if such device is present which shall be within 5 millimeters for any field edge.

6.4.4.2.6 Records of calibrations shall be maintained by the registrant for 5 years after completion of the calibration. The records shall be available for review.

6.4.4.2.7 A copy of the most recent x-ray system calibration shall be available at or in the general area of the control panel.

6.4.4.2.8 A copy of the most recent x-ray system calibration shall be submitted to the Department upon request.

6.4.4.3 Spot Checks. Spot checks shall be performed on x-ray systems capable of operation at greater than 150 kVp. Such spot checks shall meet the following requirements:

6.4.4.3.1 The spot check procedures shall be in writing and shall have been developed by a radiological physicist. A copy of the procedures shall be submitted to the Department upon request.

6.4.4.3.2 If the radiological physicist does not perform the spot check measurement, the results of the spot check measurements shall be reviewed by the radiological physicist within 7 treatment days and a record made of the review.

6.4.4.3.3 The spot check procedures shall specify the frequency at which tests or measurements are to be performed. The spot check procedures shall specify that the spot check shall be performed during the calibration specified in 6.4.4.2. The acceptable tolerance for each parameter measured in the spot check when compared to the value for that parameter determined in the calibration specified in 6.4.4.2 shall be stated.

6.4.4.3.4 THE WRITTEN SPOT CHECK PROCEDURES SHALL INCLUDE SPECIAL OPERATING INSTRUCTIONS WHICH SHALL BE CARRIED OUT WHENEVER A PARAMETER IN 6.4.4.2 EXCEEDS AN ACCEPTABLE TOLERANCE.

6.4.4.3.5 Whenever a spot check indicates a significant change in the operating characteristics of a system, as specified in the spot check procedures, the system shall be recalibrated, as required in 6.4.4.2.

6.4.4.3.6 Records of spot check measurements and any necessary corrective actions shall be maintained by the registrant for 2 years after completion of the spot check measurements. A copy of the most recent spot check shall be available at or in the area of the control panel.

6.4.4.3.7 Where a spot check involves a radiation measurement, such measurement shall be obtained using a system satisfying the requirements of 6.4.4.2.3 or which has been intercompared with a system meeting those requirements within the previous year.

6.4.4.4 Prohibited use. The x-ray system shall not be used in the administration of radiation therapy unless the requirements of 6.4.4.2 and 6.4.4.3 have been met.

RHB6.5 X-ray and Electron Therapy Systems with Energies of 1 MeV and Above. These rules shall apply to facilities using therapy systems with energies 1 MeV and above. The records shall be maintained and available for review.

6.5.1 Leakage Radiation to the Patient Area. Equipment shall meet the following requirements:

6.5.1.1 For operating conditions producing maximum leakage radiation, the absorbed dose in rads (Grays) due to leakage radiation, including x-rays and electrons, at any point in a circular plane of 2 meters radius centered on and perpendicular to the central axis of the beam at the isocenter or normal treatment distance and outside the maximum useful beam size shall not exceed 0.1 percent of the maximum absorbed dose in rads (Grays) of the unattenuated useful beam measured at the point of intersection of the central axis of the beam and plane surface. Measurements excluding those for neutrons shall be averaged over an area up to,

but not exceeding, 100 square centimeters at the positions specified. Measurements of the portion of the leakage radiation dose contributed by neutrons shall be averaged over an area up to, but not exceeding, 200 square centimeters.

6.5.1.2 For each system, the registrant shall determine or obtain from the manufacturer the leakage radiation existing at the positions specified in 6.5.1.1 for the specified operating conditions. Records on leakage radiation measurements shall be maintained for inspection by the Department.

6.5.2 Beam-Limiting Devices. Adjustable or interchangeable beam limiting devices shall be provided and such devices shall transmit no more than 2 percent of the useful photon beam at the normal treatment distance for the portion of the useful beam which is to be attenuated by the beam-limiting device. The neutron component of the useful beam shall not be included in this requirement.

6.5.3 Filters.

6.5.3.1 Each filter which is removable from the system shall be clearly marked with an identification number. Documentation available at the control panel shall contain a description of the filter. For wedge filters, the wedge angle shall appear on the wedge or wedge tray (if permanently mounted to the tray). If the wedge tray is damaged, the wedge transmission factor shall be redetermined.

6.5.3.2 IF THE ABSORBED DOSE RATE DATA REQUIRED BY 6.5.15 RELATES EXCLUSIVELY TO OPERATION WITH A FIELD-FLATTENING FILTER OR BEAM SCATTERING FOIL IN PLACE, SUCH FILTER SHALL BE REMOVABLE ONLY BY THE USE OF TOOLS.

6.5.3.3 For equipment installed after the effective date of these regulations, which utilizes a system of wedge filters, interchangeable field-flattening filters, or interchangeable beam scattering foils:

6.5.3.3.1 Irradiation shall not be possible until a selection of a filter or a positive selection to use "no filter" has been made at the treatment control panel, either manually or automatically.

6.5.3.3.2 An interlock system shall be provided to prevent irradiation if the filter selected is not in the correct position.

6.5.3.3.3 A display shall be provided at the treatment control panel showing filters in use.

6.5.3.3.4 An interlock shall be provided to prevent irradiation if any filter selection operation carried out in the treatment room does not agree with the filter selection operation carried out at the treatment control panel.

6.5.3.4 Attenuation of wedges and compensator devices must be checked before the device is placed into service. A visual inspection of the mechanical integrity of these accessories must be done monthly.

6.5.4 Beam Quality. The registrant shall determine data sufficient to assure that the following beam quality requirements in tissue equivalent material are met:

6.5.4.1 The absorbed dose resulting from x-rays in a useful electron beam at a point on the central axis of the beam 10 centimeters greater than the practical range of the electrons shall not exceed the values stated in Table 2. Linear interpolation shall be used for values not stated.

Table 2

Maximum Energy of	X-ray Absorbed Dose As a Fraction of

Electron Beam in MeV	Maximum Absorbed Dose
1	0.03
1	0.05
35	0.10
50	0.20

6.5.4.2 Compliance with 6.5.4 shall be determined using:

6.5.4.2.1 A measurement within a tissue equivalent phantom with the incident surface of the phantom at the normal treatment distance and normal to the central axis of the beam;

6.5.4.2.2 The largest field size available which does not exceed 15 centimeters by 15 centimeters; and

6.5.4.2.3 A phantom whose cross-sectional dimensions exceed the measurement radiation field by at least 5 centimeters and whose depth is sufficient to perform the required measurement.

6.5.4.3 The measured ionization at the surface relative to maximum ionization along the central axis shall not exceed the limits stated in Table 3. Linear interpolation shall be used for values not stated.

Table 3

Maximum Photon Energy in MeV	Measured Ionization at surface relative to Maximum Ionization along central axis
1	0.80
2	0.70
5	0.60
15	0.50
35	0.40
50	0.20

6.5.4.4 Compliance with 6.5.4.3 shall be determined by measurements made:

6.5.4.4.1 Within a tissue equivalent phantom using an instrument which will allow extrapolation to the surface absorbed dose;

6.5.4.4.2 Using a phantom whose size and placement meet the requirements of 6.5.4.2;

6.5.4.4.3 After removal of all beam modifying devices which can be removed without the use of tools, except for beam scattering or beam-flattening filters; and

6.5.4.4.4 Using the largest field size available which does not exceed 15 centimeters by 15 centimeters.

6.5.5 Beam Monitors. All therapy systems shall be provided with radiation detectors in the radiation head.

6.5.5.1 Equipment manufactured after January 1, 1994, shall be provided with at least two independent radiation detectors. The detectors shall be incorporated into two independent dose monitoring systems.

6.5.5.2 Equipment manufactured before January 1, 1994, shall be provided with at least one radiation detector. This detector shall be incorporated into a primary dose monitoring system.

6.5.5.3 The detector and the system into which that detector is incorporated shall meet the following requirements:

6.5.5.3.1 Each detector shall be removable only with tools and shall be interlocked to prevent incorrect positioning.

6.5.5.3.2 Each detector shall form part of a dose monitoring system from whose readings in dose monitor units the absorbed dose at a reference point in the treatment volume can be calculated.

6.5.5.3.3 Each dose monitoring system shall be capable of independently monitoring, interrupting, and terminating irradiation.

6.5.5.3.4 For new equipment, the design of the dose monitoring systems shall assure that: a) Malfunctioning of one system shall not affect the correct functioning of the secondary system; and b) Failure of any element common to both systems which could affect the correct function of both systems shall terminate irradiation.

6.5.5.3.5 Each dose monitoring system shall have a legible display at the treatment control panel. For new equipment, each display shall:

6.5.5.3.5.1 Maintain a reading until intentionally reset to zero;

6.5.5.3.5.2 Have only one scale and no scale multiplying factors for each mode of operation; and

6.5.5.3.5.3 Utilize a design such that increasing dose is displayed by increasing numbers and shall be so designed that, in the event of an overdosage of radiation, the absorbed dose may be accurately determined; and

6.5.5.3.6 In the event of power failure, the dose monitoring information required by 6.5.5.3.5 displayed at the control panel at the time of failure shall be retrievable in at least one system for a 20 minute period of time.

6.5.6 Beam Symmetry. In new equipment inherently capable of producing useful beams with unattenuated asymmetry exceeding 5 percent, the asymmetry of the radiation beam in two orthogonal directions shall be monitored before the beam passes through the beam-limiting device. Facilities shall be provided so that, if the difference in dose rate between one region and another region symmetrically displaced from the central axis of the beam exceeds 5 percent of the central axis dose rate, indication of this condition is made at the control panel; and if this difference exceeds 10 percent, the irradiation is terminated.

6.5.7 Selection and Display of Dose Monitor Units.

6.5.7.1 Irradiation shall not be possible until a selection of a number of dose monitor units has been made at the treatment control panel.

6.5.7.2 The preselected number of dose monitor units shall be displayed at the treatment control panel until reset manually for the next irradiation.

6.5.7.3 After termination of irradiation, it shall be necessary to manually reset the dosimeter display to zero before subsequent treatment can be initiated.

6.5.7.4 For new equipment, after termination of irradiation, it shall be necessary to manually reset the preselected dose monitor units before irradiation can be initiated.

6.5.8 Termination of Irradiation by the Dose Monitoring System or Systems during Stationary Beam Therapy.

6.5.8.1 Each primary system shall terminate irradiation when the preselected number of dose monitor units has been detected by the system.

6.5.8.2 If original design of the equipment included a secondary dose monitoring system, that system shall be capable of terminating irradiation when not more than 15 percent or 40 dose monitor units, whichever is smaller, above the preselected number of dose monitor units set at the control panel has been detected by the secondary dose monitoring system.

6.5.8.3 For equipment manufactured after January 1, 1994, a secondary dose monitoring system shall be present. That system shall be capable of terminating irradiation when not more than 10 percent or 25 dose monitoring units, whichever is smaller, above the preselected number of dose monitor units set at the control panel has been detected by the secondary dose monitoring system.

6.5.8.4 For equipment manufactured after January 1, 1994, an indicator on the control panel shall show which dose monitoring system has terminated irradiation.

6.5.9 Interruption Switches. It shall be possible to interrupt irradiation and equipment movements at any time from the operator's position at the treatment control panel. Following an interruption, it shall be possible to restart irradiation without any reselection of operating conditions. If any change is made of a preselected value during an interruption, irradiation and equipment movements shall be automatically terminated.

6.5.10 Termination Switches. It shall be possible to terminate irradiation and equipment movements or go from any interruption condition to termination conditions at any time from the operator's position at the treatment control panel.

6.5.11 Timer.

6.5.11.1 A timer which has a display shall be provided at the treatment control panel. The timer shall have a preset time selector and an elapsed time indicator.

6.5.11.2 The timer shall be a cumulative timer which activates with the production of radiation and retains its reading after irradiation is interrupted or terminated. After irradiation is terminated and before irradiation can be reinitiated, it shall be necessary to reset the elapsed time indicator to zero.

6.5.11.3 For equipment manufactured after the effective date of these regulations, after termination of irradiation and before irradiation can be reinitiated, it shall be necessary to manually reset the preset time selector.

6.5.11.4 The timer shall terminate irradiation when a preselected time has elapsed if the dose monitoring systems have not previously terminated irradiation.

6.5.12 Selection of Radiation Type. Equipment capable of both x-ray therapy and electron therapy shall meet the following additional requirements:

6.5.12.1 Irradiation shall not be possible until a selection of radiation type has been made at the treatment control panel.

6.5.12.2 An interlock system shall be provided to ensure that the equipment can emit only the radiation type which has been selected.

6.5.12.3 An interlock system shall be provided to prevent irradiation if any selected operations carried out in the treatment room do not agree with the selected operations at the treatment control panel.

6.5.12.4 An interlock system shall be provided to prevent irradiation with x-ray except to obtain a port film when electron applicators are fitted.

6.5.12.5 An interlock system shall be provided to prevent irradiation with electrons when accessories specific for x-ray therapy are fitted.

6.5.12.6 The radiation type selected shall be displayed at the treatment control panel before and during irradiation.

6.5.13 Selection of Energy. Equipment capable of generating radiation beams of different energies shall meet the following requirements:

6.5.13.1 Irradiation shall not be possible until a selection of energy has been made at the treatment control panel.

6.5.13.2 An interlock system shall be provided to prevent irradiation if any selected operations carried out in the treatment room do not agree with the selected operations carried out at the treatment control panel.

6.5.13.3 The nominal energy value selected shall be displayed at the treatment control panel before and during irradiation.

6.5.13.4 For new equipment, an interlock system utilizing monitoring of the bending magnet current shall be provided to terminate irradiation if the energy of the electrons striking the target or electron window deviates by more than 20 percent or 3 MeV, whichever is smaller, from the selected nominal energy.

6.5.14 Selection of Stationary Beam Therapy or Moving Beam Therapy. Equipment capable of both stationary beam therapy and moving beam therapy shall meet the following requirements:

6.5.14.1 Irradiation shall not be possible until a selection of stationary beam therapy or moving beam therapy has been made at the treatment control panel.

6.5.14.2 An interlock system shall be provided to ensure that the equipment can operate only in the mode which has been selected.

6.5.14.3 An interlock system shall be provided to prevent irradiation if any selected operations carried out in the treatment room do not agree with the selected operations carried out at the treatment control panel.

6.5.14.4 The mode of operation shall be displayed at the treatment control panel.

6.5.14.5 An interlock system shall be provided to terminate irradiation if movement of the gantry:

6.5.14.5.1 Occurs during stationary beam therapy; or

6.5.14.5.2 Stops during moving beam therapy unless such stoppage is a preplanned function.

6.5.14.6 Moving beam therapy shall be controlled to obtain the selected relationships between incremental dose monitor units and incremental angle of movement:

6.5.14.6.1 An interlock system shall be provided to terminate irradiation if the number of dose monitor units delivered in any 10 degrees of arc differs by more than 20 percent from the selected value.

6.5.14.6.2 Where gantry angle terminates the irradiation in arc therapy, the dose monitor units shall differ by less than 5 percent from the value calculated from the absorbed dose per unit angle relationship.

6.5.14.7 WHERE THE DOSE MONITOR SYSTEM TERMINATES THE IRRADIATION IN MOVING BEAM THERAPY, THE TERMINATION OF IRRADIATION SHALL BE AS REQUIRED IN 6.5.8.

6.5.15 Absorbed Dose Rate. A system shall be provided from whose readings the absorbed dose rate at a reference point in the treatment volume can be calculated. The radiation detectors specified in 6.5.5 may form part of this system. In addition:

6.5.15.1 The dose monitor rate shall be displayed at the treatment control panel.

6.5.15.2 If the equipment can deliver under any conditions an absorbed dose rate at the normal treatment distance more than twice the maximum value specified by the manufacturer for any machine parameter utilized, a device shall be provided which terminates irradiation when the absorbed dose rate exceeds a value twice the specified maximum. The dose rate at which the irradiation will be terminated shall be in a record maintained by the registrant.

6.5.16 Location of Virtual Source and Beam Orientation. The registrant shall determine, or obtain from the manufacturer, the location with reference to an accessible point on the radiation head of:

6.5.16.1 The x-ray target or the virtual source of x-rays; and

6.5.16.2 The electron window or the virtual source of electrons if the system has electron beam capabilities.

6.5.17 System Checking. Capabilities shall be provided so that all radiation safety interlocks can be checked for operation.

6.5.18 Facility and Shielding Requirements. In addition to RHB6.2 of these rules, the following design requirements shall apply:

6.5.18.1 Protective Barriers. All protective barriers shall be fixed except for entrance doors or beam interceptors.

6.5.18.2 Control Panel. The control panel shall be located outside the treatment room.

6.5.18.3 Viewing Systems.

6.5.18.3.1 Windows, mirrors, closed-circuit television, or an equivalent system shall be provided to permit continuous observation of the patient following positioning and during irradiation and shall be so located that the operator may observe the patient from the control panel.

6.5.18.3.2 When the primary viewing system is by electronic means, an alternate viewing system, which may be electronic, shall be available for use in the event of failure of the primary viewing system.

6.5.19 Aural Communications. Provision shall be made for continuous two-way aural communication between the patient and the operator at the control panel independent of the particle accelerator. However, where excessive noise levels or treatment requirements make aural communication impractical, other methods of communication shall be used. When this is the case, a description of the alternate method shall be submitted to, and approved by the Department.

6.5.20 Room Entrances. Treatment room entrances shall be provided with warning lights in readily observable positions near the outside of all accessible doors to indicate when the useful beam is "on" and "off".

6.5.21 Entrance Interlocks. Interlocks shall be provided such that all entrance doors must be closed before treatment can be initiated or continued. If the radiation beam is interrupted by any door opening, it shall not be possible to restore the machine to operation without closing the door and reinitiating irradiation by manual action at the control panel.

RHB 6.6 OPERATIONAL REQUIREMENTS FOR X-RAY AND ELECTRON THERAPY SYSTEMS WITH ENERGIES OF 1 MEV AND ABOVE.

6.6.1 Radiological Physics Support. The services of a radiological physicist shall be utilized in facilities having therapy systems with energies of 1 MeV and above. The radiological physicist shall be responsible for:

6.6.1.1 Calibration;

6.6.1.2 Supervision and review of patient dosimetry;

6.6.1.3 Beam data acquisition and storage for computer dosimetry, and supervision of its use;

6.6.1.4 Quality assurance, including spot check review; and

6.6.1.5 Consultation with the radiation therapist in treatment planning, as needed.

6.6.1.6 The radiological physicist described in 6.6.1 shall also be available and responsive to immediate problems or emergencies.

6.6.2 Surveys.

6.6.2.1 All new facilities, and existing facilities not previously surveyed, shall have a survey made by, or under the direction of, the radiological physicist. In addition, such surveys shall be done after any change in the facility or equipment which might cause a significant increase in radiation hazard.

6.6.2.2 The registrant shall obtain a written report of the survey and a copy of the report shall be transmitted by the registrant to the Department within 30 days of the first patient treatment following the survey.

6.6.2.3 The survey and report shall indicate all instances where the installation, in the opinion of the radiological physicist, is in violation of applicable rules or regulations.

6.6.3 Calibrations.

6.6.3.1 The calibration of systems subject to 6.5 shall be performed in accordance with an established calibration protocol acceptable to the Department before the system is first used for irradiation of a patient and thereafter at time intervals which do not exceed 12 months and after any change which might significantly alter the calibration, spatial distribution, or other characteristics of the therapy beam. The protocol used shall be a nationally accepted standard, such as one established by the American Association of Physicists in Medicine.

6.6.3.2 The calibration shall be performed by or under the direct supervision of the radiological physicist who is physically present at the facility during the calibration.

6.6.3.3 Calibration radiation measurements required by 6.6.3 shall be performed using a dosimetry system:

6.6.3.3.1 Having a calibration factor traceable to a national standard;

6.6.3.3.2 Which has been calibrated within the previous 2 years and after any servicing that may have affected its calibration;

6.6.3.3.3 Which has been calibrated in such a fashion that an uncertainty can be stated for the radiation quantities monitored by the system; and

6.6.3.3.4 Which has had constancy checks performed on the system as specified by the radiological physicist.

6.6.3.4 Calibrations shall be in sufficient detail that the dose at a reference point in tissue equivalent phantom may be calculated to within an uncertainty of 5 percent.

6.6.3.5 The calibration of the therapy unit shall include, but not be limited to, the following determinations:

6.6.3.5.1 Verification that the equipment is operating in compliance with the design specifications concerning the light localizer, all patient positioning lights, and back-pointer alignment with the isocenter when applicable, variation in the axis of rotation for the table, gantry, and collimator system, and beam flatness and symmetry at the specified depth.

6.6.3.5.2 The absorbed dose rate at various depths in a tissue equivalent phantom for the range of field sizes used, for each effective energy, that will verify the accuracy of the dosimetry of all therapy procedures utilized with that therapy beam.

6.6.3.5.3 The uniformity of the radiation field to include symmetry, flatness, and dependence on gantry angle.

6.6.3.5.4 Verification that existing isodose charts applicable to the specific machine continue to be valid or are updated to existing machine conditions.

6.6.3.5.5 Verification of transmission factors for all accessories such as wedges, shadow trays, and/or universal beam modifying devices.

6.6.3.6 Records of calibration measurements under 6.6.3.1 and dosimetry system calibrations under6.6.3.3 shall be maintained for 5 years after completion of the full calibration.

6.6.3.7 A copy of the latest calibrated absorbed dose rate measured pursuant to 6.6.3.1 shall be available.

6.6.4 Spot Checks. Spot checks shall be performed on systems subject to RHB 6.5 during calibrations and at intervals established by the radiological physicist, not to exceed monthly, using a nationally accepted standard such as one established by the American College of Radiology, American Association of Physicists in Medicine, American College of Medical Physics, etc.

6.6.4.1 The spot check procedures shall be in writing and shall have been developed by the radiological physicist. A copy of the procedure shall be submitted to the Department upon request.

6.6.4.2 If a radiological physicist does not perform the spot check measurements, the results of the spot check measurements shall be reviewed by the radiological physicist within 7 treatment days.

6.6.4.3 The spot check procedures shall specify the frequency at which tests or measurements are to be performed and the acceptable tolerance for each parameter measured in the spot check when compared to the value for that parameter determined in the calibration.

6.6.4.4 Spot checks shall be made at a depth beyond the calibration depth but no deeper than the 80% ionization depth.

6.6.4.5 Where a system has built-in devices which provide a measurement of any parameter during irradiation, such measurement shall not be utilized as a spot check measurement.

6.6.4.6 A parameter exceeding a tolerance set by the radiological physicist shall be corrected before the system is used for patient irradiation.

6.6.4.7 Whenever a spot check indicates a significant change in the operating characteristics of a system, as specified in the radiological physicist's spot check procedures, the system shall be recalibrated, as required in6.6.3.

6.6.4.8 Records of spot check measurements and any necessary corrective actions shall be maintained by the registrant for a period of 3 years after completion of the spot check measurements.

6.6.4.9 Whenever a spot check requires a radiation measurement, such measurement shall be obtained using a system satisfying the requirements of 6.6.3.3 or which has been intercompared with a system meeting those requirements within the previous year.

6.6.5 Prohibited Use. The system shall not be used in the administration of radiation therapy unless the requirements of RHB 6.6.1 through 6.6.4 have been met.

RHB 6.7 Misadministration Report Requirements of All Therapeutic X-ray Systems. All facilities utilizing therapeutic x-ray systems are subject to the misadministration reporting requirements in RHB 1.11.

PART VII
RADIATION SAFETY REQUIREMENTS FOR ANALYTICAL X-RAY EQUIPMENT

RHB 7.1 Scope. This part establishes special requirements for analytical X-ray equipment. The provisions of this Part are in addition to, and not in substitution for, other applicable provisions of these regulations.

RHB 7.2 Electron Microscopes. Electron microscopes shall be exempt from the other requirements of this Part except that they:

7.2.1 Shall be registered with the Department, and

7.2.2 Shall be installed, shielded, and operated in such a manner that no one shall be exposed beyond the limits defined in Section 3.4.1 of these regulations.

RHB 7.3 General Requirements for All Analytical X-ray Equipment.

7.3.1 Registration. All requirements of RHB 2.3 and 2.4 apply.

7.3.2 Posting. Each area or room containing analytical x-ray equipment shall be conspicuously posted with a sign or signs bearing the radiation symbol and the words "CAUTION- X-RAY EQUIPMENT", or words having similar intent.

7.3.3 Labeling. All analytical x-ray equipment shall be labeled with a readily discernible sign or signs bearing the radiation symbol, and

7.3.3.1 A label bearing the words "Caution - Radiation - This Equipment Produces Radiation When Energized" or words having a similar intent shall be placed near any switch which energizes an x-ray tube.

7.3.3.2 A sign bearing the words "Caution- High Intensity X-ray Beam", or words having a similar intent on the x-ray source housing, shall be placed in the area immediately adjacent to each tube head. The sign shall be so located that it is clearly visible to any person operating, aligning, or adjusting the unit, or handling or changing a sample.

7.3.4 Warning Lights.

7.3.4.1 An easily visible warning light labeled with the words "X-RAY ON," or words having a similar intent, shall be located near any switch that energizes an X-ray tube and shall be illuminated only when the tube is energized.

7.3.4.2 Warning lights shall have fail-safe characteristics.

7.3.5 Safety Devices.

7.3.5.1 Any temporary alteration to safety devices, such as by-passing interlocks or removing shielding shall be:

7.3.5.1.1 Approved in advance by the radiation safety officer.

7.3.5.1.2 Specified in writing and posted near the x-ray tube housing so that other individuals will know the existing status of the x-ray apparatus.

7.3.5.1.3 Terminated as soon as possible.

7.3.5.1.4 Recorded and the record maintained for inspection by the Department. This record should contain such information as date alteration was made, type of alteration, length of time unit remained in the altered condition, and signed by the individual who made the alteration and the individual who restored the unit to original condition.

7.3.5.2 Tests of safety devices such as interlocks, shutters, and warning lights shall be conducted at intervals not to exceed 3 months for all operable analytical x-ray equipment. Records of such tests shall be maintained for inspection by the Department.

7.3.5.3 THE INSPECTION AND TESTING OF SAFETY DEVICES SHALL NOT BE A SUBSTITUTE FOR A RADIATION PROTECTION SURVEY.

7.3.5.4 Interlocks shall not be used to de-activate the x-ray tube, except in an emergency or during testing of the interlock system. After such shut-off, it shall be possible to restore the machine to full operation only from the control panel.

7.3.5.5 Unused ports on radiation source housings shall be secured in the closed position in a manner to prevent inadvertent opening.

7.3.6 Each x-ray tube housing shall be so constructed that with all shutters closed the leakage radiation measured at a distance of 5 cm from its surface does not exceed 2.5 milliRoentgen in any given hour at any specified tube rating.

7.3.7 Generator Cabinet. Each X-ray generator shall be supplied with a protective cabinet which limits leakage radiation measured at a distance from its surface to 0.25 milliRoentgen in any given hour.

7.3.8 Repair or Modification of X-ray Tube System. Except as specified in7.3.5.1, no operation involving removal of covers, shielding materials or tube housings or modifications to shutters, collimators, or beam stops shall be performed without ascertaining that the tube is off and will remain off until safe conditions have been restored. The main switch, rather than interlocks, shall be used for routine shutdown in preparation for repairs.

RHB 7.4 Additional Requirements for Open Beam Configuration X-ray Equipment.

7.4.1 Safety Device. A device which prevents the entry of any portion of an individual's body into the primary beam path or which causes the beam to be shut off upon entry into its path shall be provided on all open-beam configuration x-ray equipment. A registrant may apply to the Department for an exemption from the requirement of a safety device. Such application shall include:

7.4.1.1 A description of the various safety devices that have been evaluated.

7.4.1.2 The reason each of these devices cannot be used, and

7.4.1.3 A description of the alternative methods that will be employed to minimize the possibility of an accidental exposure, including procedures to assure that operators and others in the area will be informed of the absence of the safety devices.

7.4.2 The operator shall be in immediate attendance at all times when the equipment is in operation except when the area is locked to protect against unauthorized or accidental entry.

7.4.3 When not in use, equipment shall be secured in such a manner as to be inoperable by unauthorized persons.

7.4.4 Warning Devices. Open-beam configuration x-ray equipment shall be provided with a readily discernible indication of:

7.4.4.1 X-ray tube status (ON-OFF) located near the radiation source housing, if the primary beam is controlled in this manner, or

7.4.4.2 Shutter status (OPEN-CLOSED) located near each port on the radiation source housing, if the primary beam is controlled in this manner.

7.4.5 Warning devices shall be labeled so that their purpose is easily identified.

7.4.6 Warning devices shall have fail-safe characteristics.

7.4.6.1 Where couplings exist, e.g., between the x-ray tube and the collimator of the diffractometer, etc., they shall prevent radiation from escaping the coupling.

7.4.6.2 Each port of the radiation source housing shall be provided with a beam shutter interlocked with the x-ray apparatus coupling, or collimator, in such a way that the port will be open only when the collimator or coupling is in place.

RHB 7.5 Additional Requirements for Enclosed Beam X-ray Equipment.

7.5.1 The radiation source, sample, detector and analyzing crystal (if used) shall be enclosed in a chamber or coupled chambers that cannot be entered by any part of the body during normal operation.

7.5.2 The sample chamber closure shall be interlocked with the x-ray tube high voltage supply or a shutter in the primary beam so that no x-ray beam can enter the sample chamber while it is open unless the interlock

has been conspicuously and deliberately defeated. The interlock required by this section shall be of fail-safe design or adequate administrative controls shall be exercised to ensure operations will not continue without a proper functioning interlock.

RHB 7.6 Area Requirements for All Analytical X-ray Equipment.

7.6.1 Radiation levels. The local components of an analytical x-ray system shall be located and arranged and shall include sufficient shielding or have access control such that no radiation in any area surrounding the local component group which could result in a dose to an individual present therein in excess of the dose limits given in RHB 3.2.2. These levels shall be met at any specified tube rating.

7.6.2 Surveys, Tests and Inspections. Radiation surveys, as required by 1.4.1 of all analytical x-ray systems to show compliance with 7.6.1 shall be performed and records kept and available for review:

7.6.2.1 Upon installation of the equipment and at least once every twelve (12) months thereafter.

7.6.2.2 Following any change in the initial arrangement, number, or type of local components in the system.

7.6.2.3 Following any change in operating parameters.

7.6.2.4 Following any maintenance requiring the disassembly or removal of a local component of the system.

7.6.2.5 During the performance of maintenance and alignment procedures if the procedures require the presence of a primary x-ray beam when any local component in the system is disassembled or removed.

7.6.2.6 Any time a visual inspection of the local components in the system reveals an abnormal condition.

7.6.2.7 Whenever personnel monitoring devices show a significant increase over the previous monitoring period or the readings are approaching the Radiation Protection Guides (radiation dose limits).

7.6.3 Radiation survey measurements shall not be required if a registrant can demonstrate compliance to the satisfaction of the Department with7.6.1 in some other manner.

7.6.4 Tests and inspections of all safety devices shall be performed at least yearly to insure their proper operation. The results shall be documented and available for review.

7.6.5 Radiation in excess of the limits specified in RHB7.3.6 and RHB7.3.7 shall be eliminated prior to using the analytical x-ray equipment.

RHB 7.7 RADIATION SURVEY INSTRUMENTS.

7.7.1 The radiation survey instrument used to meet the requirements of RHB 8.13 shall have a minimum operation range not to exceed 5 milliRoentgens (2.58×10^{-4} C/kg) per hour.

7.7.2 Each radiation survey instrument shall be calibrated:

7.7.2.1 At intervals not to exceed 12 months and after each instrument servicing;

7.7.2.2 Such that accuracy within 20 percent traceable to a national standard can be demonstrated; and

7.7.2.3 At two or more widely separated points, other than zero, on each scale, and

7.7.2.4 At energy levels encountered.

7.7.3 Records of these calibrations shall be maintained for inspection by this Department.

RHB 7.8 Personnel Requirements.

7.8.1 Instruction. No person shall be permitted to operate, repair, modify, or maintain analytical x-ray equipment unless such person has received instruction and demonstrated competence in:

7.8.1.1 Identification of radiation hazards associated with the use of the equipment;

7.8.1.2 Significance of the various radiation warning and safety devices incorporated into the equipment, or the reasons they have not been installed on certain pieces of equipment and the extra precautions required in such cases;

7.8.1.3 Proper operating procedures for the equipment;

7.8.1.4 Radiation survey instruments: operation, calibration, limitations, and survey techniques;

7.8.1.5 Characteristics of x-radiation;

7.8.1.6 Units of radiation dose;

7.8.1.7 Personnel monitoring and the use of personnel monitoring equipment;

7.8.1.8 Symptoms of an acute localized exposure; and

7.8.1.9 Proper procedures for reporting an actual or suspected overexposure.

7.8.1.10 The regulations contained in this Part, Part IX, and the applicable sections of Part III.

7.8.2 Instruction and demonstration of competence shall be documented in writing and these records shall be available for review.

7.8.3 Procedures. Normal operating procedures shall be written and available to all analytical and research and development workers. No person shall be permitted to operate analytical x-ray equipment in any manner other than that specified in the procedures unless such person has obtained written approval of the radiation safety officer.

7.8.4 A copy of instructions provided as required by RHB 7.8.1 and a copy of normal operating procedures as required by RHB 7.8.3 shall be provided to the Department upon request.

RHB 7.9 PERSONNEL MONITORING.

7.9.1 Personnel monitoring shall be required as outlined in RHB 3.12.

7.9.2 Personnel monitoring devices shall be assigned to and only worn by one individual.

7.9.3 Finger or wrist dosimetric devices shall be provided to and shall be used by:

7.9.3.1 Analytical x-ray equipment workers using systems having an open-beam configuration and not equipped with a safety device; and

7.9.3.2 Personnel maintaining analytical or research and development x-ray equipment if the maintenance procedures required the presence of a primary x-ray beam when any local component in the analytical or research and development x-ray system is disassembled or removed.

7.9.4 Reported dose values shall not be used for the purpose of determining compliance with Section 3.3 of these regulations unless evaluated by a qualified expert.

PART VIII
RADIATION SAFETY REQUIREMENTS FOR INDUSTRIAL USES OF RADIOGRAPHIC SOURCES

RHB 8.1 Scope. The regulations in this part establish radiation safety requirements for industrial uses of X-ray machines. The requirements of this part are in addition to and not in substitution for the other requirements of these regulations.

RHB 8.2 Locking of X-ray Machines. Each x-ray machine shall be provided with a locking device designed to prevent unauthorized or accidental production of radiation, and shall be kept locked at all times except when under the direct surveillance of a radiographer, radiographer's assistant, a radiation safety officer, or an operator, as applicable.

RHB 8.3 Permanent Storage Precautions. Radiation machines shall be secured while in storage to prevent tampering or removal by unauthorized individuals.

RHB 8.4 Radiation Survey Instruments.

8.4.1 The radiation survey instrument used to meet the requirements of 8.13.1, 8.13.2, 8.13.3 and 8.13.4 shall have a minimum operation range not to exceed 5 milliRoentgens (2.58 x 10-4 C/kg) per hour.

8.4.1.1 Each radiation survey instrument shall be calibrated:

8.4.1.1.1 At intervals not to exceed 12 months and after each instrument servicing;

8.4.1.1.2 Such that the accuracy within 20 percent traceable to a national standard can be demonstrated; and

8.4.1.2.3 At two or more widely separated points, other than zero, on each scale; and

8.4.1.1.4 At energy levels encountered.

8.4.1.2 Records of these calibrations shall be maintained for inspection by this Department.

8.4.1.3 Each radiation survey instrument shall be checked with a radiation source at the beginning of each day of use and at the beginning of each work shift to ensure it is operating properly.

RHB 8.5 LABELING. THERE SHALL BE A DURABLE PERMANENT LABEL INDICATING THE MAXIMUM OPERATING CURRENT, KVP, THE STANDARD RADIATION SYMBOL, AND A CAUTION NOTICE WHICH SHALL READ AS FOLLOWS OR SIMILARLY: "CAUTION-RADIATION; THIS EQUIPMENT PRODUCES RADIATION WHEN ENERGIZED" IN ADDITION, A LABEL WHICH READS, "CAUTION-RADIATION; THIS EQUIPMENT PRODUCES RADIATION WHEN ENERGIZED" SHALL BE LOCATED NEAR OR ADJACENT TO EACH SWITCH THAT CONTROLS THE PRODUCTION OF X-RAYS.

RHB 8.6 Registration. Each facility shall meet the requirements of RHB 2.3 and 2.4 of these regulations.

RHB 8.7 Minimum Personal Radiation Safety Requirements For Radiation Safety Officers and Operators.

8.7.1 No registrant shall permit any individual to act as a radiation safety officer until such person:

8.7.1.1 Has been instructed in the subjects outlined in RHB 8.11 of this Part;

8.7.1.2 Has received copies of and instruction in: the regulations contained in this Part, Part IX, the applicable sections of Part III, and the registrant's operating and emergency procedures, and shall have demonstrated understanding thereof; and

8.7.1.3 Has demonstrated competence to use the X-ray machine, related handling tools, and survey instruments which will be employed in his assignment.

8.7.2 No registrant shall permit any individual to act as an operator or radiographer until such person:

8.7.2.1 Has been instructed in the subjects outlined in RHB 8.11 of this Part;

8.7.2.2 HAS RECEIVED COPIES OF AND INSTRUCTION IN: PART IX, OF THESE REGULATIONS, AND THE REGISTRANT'S OPERATING AND EMERGENCY PROCEDURES, AND SHALL HAVE DEMONSTRATED UNDERSTANDING THEREOF; AND

8.7.2.3 Has demonstrated competence to use, under the personal supervision of the Radiation Safety Officer, the X-ray machine, related handling tools, and survey instruments which will be employed in his assignment.

8.7.2.4 The registrant shall have all training procedures and testing documented in writing, and available for the Department's review.

RHB 8.8 OPERATING AND EMERGENCY PROCEDURES. THE REGISTRANT SHALL HAVE WRITTEN OPERATING AND EMERGENCY PROCEDURES. THESE PROCEDURES SHALL INCLUDE INSTRUCTION IN:

8.8.1 THE HANDLING AND USE OF X-RAY MACHINES TO BE EMPLOYED SUCH THAT NO PERSON IS LIKELY TO BE EXPOSED TO RADIATION DOSES IN EXCESS OF THE LIMITS ESTABLISHED IN THESE REGULATIONS;

8.8.2 Methods and occasions for conducting radiation surveys;

8.8.3 Methods for controlling access to radiographic areas;

8.8.4 Methods for locking and securing X-ray machines, when not in use or in storage;

8.8.5 Personnel monitoring and the use of personnel monitoring equipment; including steps that must be taken by radiography personnel in the event a pocket dosimeter is found to be off-scale;

8.8.6 The proper handling of exposed personnel;

8.8.7 Minimizing exposure of individuals in the event of an accident;

8.8.8 The procedure for notifying proper persons in the event of an accident. This shall include the listing of names, addresses, and telephone numbers; and

8.8.9 MAINTENANCE OF RECORDS.

RHB 8.9 Inspection and Maintenance. Each registrant shall ensure that checks for obvious defects in radiation machines are made at the beginning of each day of equipment use.

8.9.1 At least quarterly, each registrant shall inspect and repair components associated with radiation safety of the machines. Records of inspection and maintenance shall be maintained for the Department's inspection.

8.9.2 If any inspection conducted by the registrant reveals damage to the components affecting radiation safety, the radiation machine shall not be used and shall be labeled as defective until repaired.

RHB 8.10 Personnel Monitoring. No registrant shall permit any individual to act as a Radiation Safety Officer or as an operator unless, at all times during radiographic operations, each such person wears a film badge, thermoluminescent dosimeter (TLD), or other dosimeter approved by the Department. Film badges (or other dosimeter approved by the Department) shall be:

8.10.1 Assigned to and worn only by one individual; and

8.10.2 If a film badge or TLD is lost or damaged, the worker shall cease work immediately until a replacement film badge or TLD is provided and the exposure is calculated for the time period from issuance to loss or damage of the film badge or TLD.

RHB 8.11 Minimum Subjects To Be Covered In Training Radiation Safety Officers and Radiographers.

8.11.1 Fundamentals of Radiation Safety:

8.11.1.1 Characteristics of ionizing radiation;

8.11.1.2 Units of radiation dose (rem or Sievert);

8.11.1.3 Hazards of exposure to radiation;

8.11.1.4 Levels of radiation from sources of radiation;

8.11.1.5 Methods of controlling radiation dose;

8.11.1.5.1 Working time;

8.11.1.5.2 Working distances; and

8.11.1.5.3 Shielding.

8.11.2 Radiation Detection Instrumentation to be Used:

8.11.2.1 Use of radiation survey instruments;

8.11.2.1.1 Operation;

8.11.2.1.2 Calibration; and

8.11.2.1.3 Limitations.

8.11.2.2 Survey techniques; and

8.11.2.3 Use of personnel monitoring equipment:

8.11.2.3.1 Film badges or other approved dosimeters; and

8.11.2.3.2 Pocket dosimeters or pocket chambers, if applicable.

8.11.3 Operation and control of X-ray machines.

8.11.4 THE REQUIREMENTS OF PERTINENT STATE REGULATIONS.

8.11.5 The registrant's written operating and emergency procedures.

RHB 8.12 Posting. Areas in which radiography is being performed shall be conspicuously posted as required by RHB 3.15.

RHB 8.13 Special Requirements for Certain Industrial Radiographic Techniques.

8.13.1 Cabinet Radiography.

8.13.1.1 Upon installation, a cabinet radiography unit shall not be operated until a physical radiation survey of the unit and areas adjacent to the unit has been performed. A radiation survey of the unit and area adjacent to the unit shall also be performed at least annually, and after any repair modification, or maintenance on the system.

8.13.1.2 Tests for proper operation of high radiation area control devices, alarm systems or interlocks must be conducted, at least annually, recorded, and maintained in accordance with RHB 8.9.

8.13.1.3 Radiation emitted from the cabinet x-ray unit shall not exceed 0.5 milliRoentgen per hour at any point five centimeters from the external surface.

8.13.1.4 A CABINET X-RAY SYSTEM SHALL HAVE A PERMANENT FLOOR. ANY SUPPORT SURFACE TO WHICH A CABINET X-RAY SYSTEM IS PERMANENTLY AFFIXED MAY BE DEEMED THE FLOOR OF THE SYSTEM.

8.13.1.5 The insertion of any part of the human body through any port into the primary beam or through any aperture shall not be possible.

8.13.1.6 Interlocks.

8.13.1.6.1 Each door of a cabinet x-ray system shall have a minimum of two safety interlocks. One, but not both of the required interlocks shall be such that door opening results in physical disconnection of the energy supply circuit to the high-voltage generator, and such disconnection shall not be dependent upon any moving part other than the door.

8.13.1.6.2 Each access panel shall have at least one safety interlock.

8.13.1.6.3 FOLLOWING INTERRUPTION OF X-RAY GENERATION BY THE FUNCTIONING OF ANY SAFETY INTERLOCK, USE OF A CONTROL PROVIDED IN ACCORDANCE WITH RHB 8.13.1.8.2 SHALL BE NECESSARY FOR RESUMPTION OF X-RAY GENERATION.

8.13.1.6.4 Failure of any single component of the cabinet x-ray system shall not cause failure of more than one required safety interlock.

8.13.1.7 A ground fault, or an accidental electrical grounding of an electrical conductor, shall not result in the generation of x-rays.

8.13.1.8 Controls and indicators for all cabinet x-ray systems. For all systems to which this section is applicable, there shall be provided:

8.13.1.8.1 A key actuated control to insure that x-ray generation is not possible with the key removed.

8.13.1.8.2 A control or controls to initiate and terminate the generation of x-rays other than by functioning of a safety interlock or the main power control.

8.13.1.8.3 Two independent means which indicate when and only when x-rays are being generated, unless the x-ray generation period is less than one-half second in which case the indicators shall be activated for one-half second, and which are discernible from any point at which initiation of x-ray generation is possible. Failure of a single component of the cabinet x-ray system shall not cause failure of both indicators to perform their intended function. One, but not both, of the indicators required by this regulation may be a milliammeter labeled to indicate x-ray tube current. All other indicators shall be legibly labeled "X-RAY ON."

8.13.1.8.4 Additional means other than milliammeters which indicate when and only when x-rays are being generated, unless the x-ray generation period is less than one-half second in which case the indicators shall be activated for one-half second, as needed to insure that at least one indicator is visible from each door, access panel, and port, and is legibly labeled "X-RAY ON."

8.13.1.9 Additional controls and indicators for cabinet x-ray systems designed to admit humans. For cabinet x-ray systems designed to admit humans, there shall also be provided:

8.13.1.9.1 A control within the cabinet for preventing and terminating x-ray generation, which cannot be reset, overridden or bypassed from the outside of the cabinet.

8.13.1.9.2 No means by which x-ray generation can be initiated from within the cabinet.

8.13.1.9.3 Audible and visible warning signals within the cabinet which are actuated for at least 10 seconds immediately prior to the first initiation of x-ray generation after closing any door designed to admit humans. Failure of any single component of the cabinet x-ray system shall not cause the failure of both the audible and visible warning signals.

8.13.1.9.4 A VISIBLE WARNING SIGNAL WITHIN THE CABINET WHICH REMAINS ACTUATED WHEN AND ONLY WHEN X-RAYS ARE BEING GENERATED, UNLESS THE X-RAY GENERATION PERIOD IS LESS THAN ONE-HALF SECOND IN WHICH CASE THE INDICATOR SHALL BE ACTIVATED FOR ONE-HALF SECOND.

8.13.1.9.5 SIGNS INDICATING THE MEANING OF THE WARNING SIGNALS REQUIRED BY RHB.8.13.1.12.3 AND.8.13.1.12.4 AND CONTAINING INSTRUCTIONS FOR THE USE OF THE CONTROL REQUIRED BY RHB.8.13.1.12.1. THESE SIGNS SHALL BE LEGIBLE, ACCESSIBLE TO VIEW, AND ILLUMINATED WHEN THE MAIN POWER CONTROL IS IN THE "ON" POSITION.

8.13.1.10 Warning labels. There shall be permanently affixed or inscribed on the cabinet x-ray system at the location of any controls which can be used to initiate x-ray generation, a clearly legible and visible label bearing the statement: "CAUTION: X-RAYS PRODUCED WHEN ENERGIZED." There shall also be a permanently affixed or inscribed on the cabinet x-ray system adjacent to each port a clearly legible and visible label bearing the statement:"CAUTION: DO NOT INSERT ANY PART OF THE BODY WHEN SYSTEM IS ENERGIZED--X-RAY HAZARD."

8.13.1.11 Additional requirements for x-ray baggage inspection systems. X-ray systems designed primarily for the inspection of carry-on baggage at airline, railroad, and bus terminals, and at similar facilities, shall be provided with means to ensure operator presence at the control area in a position which permits surveillance of the ports and doors during generation of x-rays.

8.13.1.11.1 During an exposure or preset succession of exposures of one-half second or greater duration, the means provided shall enable the operator to terminate the exposure or preset succession of exposures at any time.

8.13.1.11.2 During an exposure or preset succession of exposures of less than one-half second duration, the means provided may allow completion of the exposure in progress but shall enable the operator to prevent additional exposures.

8.13.2 Shielded Room Radiography.

8.13.2.1 Each registrant shall supply appropriate personnel monitoring equipment to, and shall require the use of such equipment by, every individual who operates, makes "set-ups," or performs maintenance on a radiation machine for shielded room radiography.

8.13.2.2 A physical radiation survey shall be conducted to determine that the X-ray machine is "off" prior to each entry into the shielded room. Such surveys shall be made with a radiation measuring instrument capable of measuring radiation of the energies and at the dose rates to be encountered, which is in good working order, and which has been properly calibrated within the preceding twelve months or following the last instrument servicing, whichever is later.

8.13.2.3 Each installation shall be provided with such primary barriers andsecondary barriers are as necessary to assure compliance with RHB 3.4, and RHB 3.9.

8.13.2.4 PRIOR TO CONSTRUCTION, THE FLOOR PLANS AND EQUIPMENT ARRANGEMENT OF ALL INSTALLATIONS (NEW OR MODIFICATIONS OF EXISTING INSTALLATIONS) UTILIZING X-RAYS SHALL BE REVIEWED BY CLASS IX VENDOR AND SUBMITTED TO THE DEPARTMENT FOR REVIEW AND APPROVAL. THE REGISTRANT SHALL SUBMIT PLANS AND A REPORT, INCLUDING ANY RECOMMENDATIONS AND ALL BASIC ASSUMPTIONS USED, FROM THE VENDOR TO THE DEPARTMENT. A SCALE DRAWING OF THE ROOM IN WHICH A STATIONARY X-RAY SYSTEM IS LOCATED SHALL BE SUBMITTED. THE DRAWING SHALL DENOTE THE TYPE OF MATERIALS AND THEIR THICKNESS (OR LEAD EQUIVALENCE) PROVIDED BY EACH BARRIER OF THE ROOM (WALLS, CEILINGS, FLOORS, DOORS, WINDOWS). THE DRAWING SHALL ALSO DENOTE THE TYPE OF OCCUPANCY OF ADJACENT AREAS TO INCLUDE ABOVE AND BELOW THE X-RAY ROOMS OF CONCERN (E.G., HALLWAYS, OFFICES, PARKING LOTS, AND TOILETS). ESTIMATES OF THE FREQUENCY OF SUCH OCCUPANCY SHALL ALSO BE NOTED ON THE DRAWING.

8.13.2.5 The approval of such plans shall not preclude the requirement of additional modifications should a subsequent analysis of operating conditions indicate the possibility of an individual receiving a dose in excess of the limits prescribed in Part III of these regulations.

8.13.2.6 X-ray equipment shall not be used before a shielding plan for the unit has been approved by the Department.

8.13.2.7 The registrant shall have a radiation area survey performed by a Class IX vendor, registered with the Department, within thirty days after installation of the x-ray equipment. The survey shall be submitted to the Department for review, and shall include a scale drawing of the room, indicating the composition of the

walls, floor, ceiling, windows, and doors, and the placement of the x-ray equipment, including control and operator's position. The survey shall include an evaluation of the adequacy of each protective barrier and the operator's location.

RHB.8.13.3 FIELD RADIOGRAPHY.

8.13.3.1 Utilization Logs. Each registrant shall maintain current logs, which shall be kept available for inspection by the Department, showing for each X-ray machine the following information:

8.13.3.2 A description (or make and model number) of each X-ray machine;

8.13.3.3 The identity of the radiographer to whom assigned;

8.13.3.4 The plant or site where used and dates used; and

8.13.3.5 The dates each radiation machine is energized or used and number of exposures made.

8.13.3.6 Security. During each radiographic operation, the radiographer or radiographer's assistant shall maintain a direct surveillance of the operation to protect against unauthorized entry into a high radiation area, except a) where the high radiation area is equipped with a control device which turns the X-ray machine off upon unauthorized entry into the high radiation area or an alarm system which visibly or audibly signals the presence of a high radiation area, or b) where the high radiation area is locked to protect against unauthorized or accidental entry.

8.13.3.7 Radiation Surveys and Survey Records. No radiographic operation shall be conducted unless calibrated, operable radiation survey instrumentation is available and used at each site where radiographic exposures are made, as described in RHB 8.4.

8.13.3.7.1 A physical radiation survey shall be conducted to determine that the radiation machine is "off" prior to each entry into the radiographic exposure area.

8.13.3.7.2 Survey results and records of boundary locations shall be maintained and kept available for inspection by the Department.

8.13.3.8 Personnel Monitoring. In addition to the requirements of 8.10, each radiographer or radiographer's assistant shall wear a pocket dosimeter or pocket chamber along with a film badge during all radiographic operations. Pocket chambers or dosimeters shall be:

8.13.3.8.1 Capable of measuring doses from zero to at least 200 milliRoentgen;

8.13.3.8.2 Read and doses recorded daily; and

8.13.3.8.3 Recharged daily or at the start of each shift;

8.13.3.8.4 Reports received from the dosimeter processor and records of the pocket dosimeter and pocket chamber readings shall be maintained for inspection by the Department;

8.13.3.8.5 Pocket dosimeters shall be checked for correct response to radiation at periods not to exceed 1 year. Acceptable dosimeters shall read within plus or minus 30% of the true exposure calibration shall be maintained by the registrant for the Department's inspection.

8.13.4 Gauging Devices Radiography and Other Industrial Applications. The source shall be such that no radiation is emitted except by application of an electric current through an x-ray tube. Provisions shall be

made to limit both the current through the tube and the voltage across the tube, so that radiation levels do not exceed the device classification under use conditions or through circuit component failures. In the event of fire or abnormal elevated temperatures, provisions shall be made to insure the high voltage is automatically disabled before loss of any integral shielding. This provision exempts x-ray tube sources from accident classification conditions.

8.13.4.1 A USEFUL BEAM CONTROL SYSTEM SHALL BE PROVIDED IN GAUGES WHENEVER THE USEFUL BEAM IS ACCESSIBLE AND THE RADIATION LEVELS EXCEED 100 MREM/H (1 MSV/H) AT 5 CM FROM ANY ACCESSIBLE SURFACE OR 5 MREM/H (.05 MSV/H) AT 30 CM. THE USEFUL BEAM CONTROLS MAY INCLUDE (BUT NOT BE LIMITED TO) A MOVING SHUTTER, A MOVING SOURCE, OR A HIGH VOLTAGE POWER SUPPLY.

8.13.4.2 A yellow or amber warning light with the radiation "High Voltage On" shall be located on the control panel and on or adjacent to the source housing and shall light only when power is applied to the x-ray tube high voltage circuit.

PART IX
DEFINITIONS

As used in these regulations, the following definitions apply:

9.1 "Absorbed Dose" is the energy imparted to matter by ionizing radiation per unit mass of irradiated material at the place of interest. The special units of absorbed dose are the rad or the gray.

9.2 "Accessible Surface" means the external surface of the enclosure or housing provided by the manufacturer.

9.3 "Accreditation body" or "body" means an entity that has been approved by FDA to accredit mammography facilities.

9.4 "Act" means Act No. 223, Atomic Energy and Radiation Control Act enacted by the 1967 Session South Carolina Legislature. (Section 13-7-40 et seq., 1976 SC Code of Law [as amended]).

9.5 "Action limits" or "action levels" means the minimum and maximum values of a quality assurance measurement that can be interpreted as representing acceptable performance with respect to the parameter being tested. Values less than the minimum or greater than the maximum action limit or level indicate that corrective action shall be taken by the facility. Action limits or levels are also sometimes called control limits or levels.

9.6 "Added filtration" means any filtration which is in addition to the inherent filtration.

9.7 "Adverse event" means an undesirable experience associated with mammography activities that include but are not limited to: poor image quality; failure to send mammography reports within 30 days to the referring physician or in a timely manner to the self-referred patient; and use of personnel that do not meet the requirements

9.8 "Adult" means an individual 18 or more years of age.

9.9 "Air kerma" means kerma in a given mass of air. The unit used to measure the quantity of air kerma is the Gray (Gy). For x-rays with energies less than 300 kiloelectronvolts 9keV), 1Gy=100rad.

9.10 "ALARA" (acronym for "as low as is reasonably achievable") means making every reasonable effort to maintain exposures to radiation as far below the dose limits in the Rules in this Chapter as is practical consistent with the purpose for which the licensed or registered activity is undertaken, taking into account the

state of technology, the economics of improvements in relation to state of technology, the economics of improvements in relation to benefits to the public health and safety, and other societal and socioeconomic considerations, and in relation to utilization of sources of radiation in the public interest.

9.11 "Aluminum equivalent" means the thickness of type 1100 aluminum alloy affording the same attenuation, under specified conditions, as the material in question.

9.12 "Analytical x-ray equipment" means any machine utilizing x-rays for examination of the microscopic structure, or elemental or chemical composition of materials. This includes x-ray equipment used for x-ray diffraction, fluorescence analysis, or spectroscopy.

9.13 "Analytical X-ray System" means a group of local and remote components utilizing x-rays to determine the elemental composition or to examine the microstructure of materials. Local components include those that are struck by x-rays such as radiation source housings, port and shutter assemblies, collimators, sample holders, cameras, goniometers, detectors, and shielding. Remote components include power supplies, transformers, amplifiers, readout devices, and control panels.

9.14 "Annually" means at intervals not to exceed 12 consecutive months.

9.15 "Applicator" means a structure which determines the extent of the treatment field at a given distance from the virtual source.

9.16 "Assembler" means any person engaged in the business of assembling, reassembling, replacing, installing, or reinstalling one or more components into an x-ray system or subsystem. The term includes the owner of an x-ray system, his employee, or agent who assembles components into an x-ray system that is subsequently used to provide professional or commercial services.

9.17 "Attenuation block" means a block or stack, having dimensions 20 centimeters by 20 centimeters by 3.8 centimeters, of type 1100 aluminum alloy or other materials having equivalent attenuation.

9.18 "AUTHORIZED REPRESENTATIVE" MEANS AN EMPLOYEE OF THE DEPARTMENT, OR AN INDIVIDUAL OUTSIDE THE DEPARTMENT WHEN THE INDIVIDUAL IS SPECIFICALLY SO DESIGNATED BY THE DEPARTMENT.

9.19 "Automatic exposure control" means a device which automatically controls one or more technique factors in order to obtain at a preselected location(s) a required quantity of radiation (See also "Phototimer").

9.20 "Average Glandular dose" means, in mammography, the value in millirad for a given breast or phantom thickness which estimates the average absorbed dose to the glandular tissue extrapolated from free air exposures and based on fixed filter thickness and target material.

9.21 "Background radiation" means radiation from cosmic sources, naturally occurring radioactive materials, including radon (except as a decay product of source or special nuclear material) and global fallout as it exists in the environment from the testing of nuclear explosive devices. "Background radiation" does not include sources of radiation regulated by the agency.

9.22 "Barrier" (See "Protective Barrier").

9.23 "Beam Axis" means a line from the source through the centers of the x-ray fields.

9.24 "Beam-limiting device" means a device which provides a means to restrict the dimensions of the x-ray field.

9.25 "Beam monitoring system" means a system designed to detect and measure the radiation present in the useful beam.

9.26 "Beam scattering foil" means a foil used in order to scatter a beam of electrons.

9.27 "Breast implant" means a prosthetic device implanted in the breast.

9.28 "Cabinet x-ray system" means an x-ray system with the x-ray tube installed in an enclosure which is intended to contain at least that portion of a material being irradiated, provide radiation attenuation, and exclude personnel from its interior during x-ray production. An x-ray tube used within a shielded part of a building, or x-ray equipment which may temporarily or occasionally incorporate portable shielding is not considered a cabinet x-ray system.

9.29 "Calendar Quarter" means not less than 12 consecutive weeks nor more than 14 consecutive weeks. The first calendar quarter of each year shall begin in January; and subsequent calendar quarters shall be such that no day is included in more than one calendar quarter or omitted from inclusion within a calendar quarter. No registrant shall change the method observed by him of determining calendar quarters for purposes of these regulations, except at the beginning of a calendar year. For the purpose of Part V, "Calendar quarter" means any one of the following time periods during a given year: January 1 through March 31, April 1 through June 30, July 1 through September 30 or October 1 through December 31.

9.30 "Calibration" means:

a) the response or reading of an instrument relative to a series of known radiation values over the range of the instrument; or

b) the strength of a source of radiation relative to a standard.

9.31 "Category I" means medical educational activities that have been designated as Category I by the Accreditation Council for Continuing Medical Education (ACCME), the American Osteopathic Association (AOA), a state medical society or an equivalent organization.

9.32 "C-Arm" means an x-ray system in which the image receptor and x-ray tube housing assembly are connected by a common mechanical support system in order to maintain a desired spatial relationship.

9.33 "Central axis of the Beam" means a line passing through the virtual source and the center of the plane figure formed by the edge of the first beam-limiting device.

9.34 "Cephalometric" means a device intended for the radiographic visualization and measurement of the dimensions of the human head.

9.35 "Certification" means the process of approval of a facility by the Department to provide mammography services.

9.36 "Certified components" means components of x-ray systems which are subject to the Regulations for the Administration and Enforcement of the Radiation Control for Health and Safety Act of 1968, promulgated under Public Law 90-602.

9.37 "Certified system" means any x-ray system which has one or more certified component(s).

9.38 "Changeable filters" means any filter, exclusive of inherent filtration, which can be removed from the useful beam through any electronic, mechanical, or physical process.

9.39 "Change of Status" means transfer of ownership, change of address, or disposal of any X-ray system.

9.40 "Clinical image" means a mammogram.

9.41 "Coefficient of Variation" or "C" means the ratio of the standard deviation to the mean value of a population of observations. It is estimated using the following equation:

where:
s = Estimated standard deviation of the population.
X = Mean value of observations in sample.
Xx = ith observation in sample.
N = NUMBER OF OBSERVATIONS IN SAMPLE.

$$C = \frac{s}{X} = \frac{1}{X} \sum \frac{(X_i - X)^2}{n - 1}$$

9.42 "Collimator" means a device or mechanism by which the x-ray beam is restricted in size.

9.43 "Committed dose equivalent" means the dose equivalent to organs or tissues of reference (T) that will be received from an intake of radioactive material by an individual during the 50-year period following the intake.

9.44 "Consumer" means an individual who chooses to comment or complain in reference to a mammography examination, including the patient or representative of the patient (e.g., family member or referring physician).

9.45 "Continuing education unit or continuing education credit" means one contact hour of training.

9.46 "Contact hour" means an hour of training received through direct instruction.

9.47 "Controlled area" means an area outside of a restricted area but inside the site boundary, access to which can be limited by the registrant for any reason.

9.48 "Coulomb per Kilogram" (C/kg) is the unit of exposure. One Roentgen is equal to 2.58 x 10-4 Coulomb per kilogram. Submultiples of this unit are the milliCoulomb per kilogram (mC/kg) and the microCoulomb per kilogram (uC/kg).

9.49 "CT" (See "Computed Tomography")

9.50 "CT conditions of operation" means all selectable parameters governing the operation of a CT x-ray system including, but not limited to, nominal tomographic section thickness, filtration, and the technique factors as defined in 8.173.

9.51 "CT GANTRY" MEANS THE TUBE HOUSING ASSEMBLIES, BEAM-LIMITING DEVICES, DETECTORS, AND THE SUPPORTING STRUCTURES AND FRAMES WHICH HOLD THESE COMPONENTS.

9.52 "Computed Tomography" means the production of a tomogram by the acquisition and computer processing of x-ray transmission data.

9.53 "Contact Therapy System" means an x-ray system used for therapy with the x-ray tube port placed in contact with or within 5 centimeters of the surface being treated.

9.54 "CONTROL PANEL" MEANS THAT PART OF THE X-RAY CONTROL UPON WHICH ARE MOUNTED THE SWITCHES, KNOBS, PUSHBUTTONS, AND OTHER HARDWARE NECESSARY FOR MANUALLY SETTING THE TECHNIQUE FACTORS.

9.55 "Cooling Curve" means the graphical relationship between heat units stored and cooling time.

9.56 "Dead-man Switch" means a switch so constructed that a circuit closing contact can be maintained only by continuous pressure on the switch by the operator.

9.57 "Declared pregnant woman" means a woman who has voluntarily informed her employer, in writing, of her pregnancy and the estimated date of conception.

9.58 "Deep-dose equivalent" (H_d), which applies to external whole-body exposure, is the equivalent at a tissue depth of 1 cm (1000 mg/cm^2).

9.59 "Department" means the South Carolina Department of Health and Environmental Control.

9.60 "Detector" (See "Radiation detector")

9.61 "Diagnostic mammography" means mammography performed on a patient with:
Clinical signs, symptoms or physical findings suggestive of breast cancer;
An abnormal or questionable screening mammogram;
A history of breast cancer with breast conservation surgery regardless of absence of clinical breast signs, symptoms or physical findings; or
Augmented breast regardless of absence of clinical breast signs, symptoms or physical findings.

9.62 "Diagnostic source assembly" means the tube housing assembly with a beam-limiting device attached.

9.63 "Diagnostic x-ray imaging system" means an assemblage of components for the generation, emission and reception of x-rays and the transformation, storage and visual display of the resultant x-ray image.

9.64 "Diagnostic x-ray system" means an x-ray system designed for irradiation of any part of the human or animal body for the purpose of diagnosis or visualization.

9.65 "Diaphragm" means a device or mechanism by which the x-ray beam is restricted in size.

9.66 "Direct instruction" means face-to-face interaction between instructor(s) and student(s), as when the instructor provides a lecture, conducts demonstrations or reviews student performance; or the administration and correction of student examinations by an instructor(s) with subsequent feedback to the student(s).

9.67 "Direct scattered radiation" means that scattered radiation which has been deviated in direction only by materials irradiated by the useful beam (See "Scattered Radiation").

9.68 "Direct supervision", in Part V, means that:
During joint interpretation of mammograms, the supervising interpreting physician reviews, discusses, and confirms the diagnosis of the physician being supervised and signs the resulting report before it is entered into the patient's records; or
During the performance of a mammography examination or survey of the facility's equipment and quality assurance program, the supervisor is present to observe and correct, as needed, the performance of the individual being supervised who is performing the examination or conducting the survey.

9.69 "Dose" is a generic term which means absorbed dose, dose equivalent, effective dose equivalent, or total effective dose equivalent as defined in these regulations.

9.70 "Dose Equivalent" (H_T) means the product of the absorbed dose in tissue, quality factor, and all other necessary modifying factors at the location of interest. The units of dose equivalent at the rem and sievert (Sv).

9.71 "Dose limits" (See Limits)

9.72 "Dose monitoring system" means a system of devices for the detection, measurement, and display of quantities of radiation.

9.73 "Dose monitor unit" means a unit response from the dose monitoring system from which the absorbed dose can be calculated.

9.74 "DOSIMETRY PROCESSOR" MEANS AN INDIVIDUAL OR AN ORGANIZATION THAT PROCESSES AND EVALUATES INDIVIDUAL MONITORING DEVICES IN ORDER TO DETERMINE THE RADIATION DOSE DELIVERED TO THE MONITORING DEVICES.

9.75 "Effective dose equivalent" (H_E) is the sum of the products of the dose equivalent to the organ or tissue (H_T) and the weighting factors (W_T) applicable to each of the body organs or tissues that are irradiate ($H_E = w_T H_T$).

9.76 "Embryo/fetus" means the developing human organism from conception until the time of birth.

9.77 "Entrance or access point" means any location through which an individual could gain access to radiation areas or to a source of radiation. This includes entry or exit portals of sufficient size to permit human entry, irrespective of their intended use.

9.78 "Entrance exposure rate" means the exposure free in air per unit time at the point where the center of the useful beam enters the patient.

9.79 "ESE" means the exposure at skin entrance where the center of the useful beam enters the patient.

9.80 "Equipment" (See "X-ray system").

9.81 "Established operating level" means the value of a particular quality assurance parameter that has been established as an acceptable normal level by the facility's quality assurance program.

9.82 "Exposure" is the amount of ionization per unit mass of air due to x-rays. It is the quotient of dQ by dm where "dQ" is the absolute value of the total charge of the ions of one sign produced in air when all the electrons (negatrons and positrons) liberated by photons in a volume element of air having mass "dm" are completely stopped in air. The special units of exposure are the Roentgen (R), or the coulomb per kilogram.

9.83 "EXPOSURE RATE" MEANS THE EXPOSURE PER UNIT OF TIME, SUCH AS R/MIN AND MR/H.

9.84 "External dose" means that portion of the dose equivalent received from radiation sources outside the body.

9.85 "Extremities" means hand, elbow, arm below the elbow, foot, knee, and leg below the knee.

9.86 "Eye dose equivalent" applies to the external exposure of the lens of the eye and is taken as the dose equivalent at a tissue depth of 0.3 centimeter (300 mg/cm^2).

9.87 "Facility" means the location at which one or more x-ray machines are installedor located within one building, vehicle, or under one roof and are under the same administrative control.

9.88 "Facility" or "mammography installation" means a hospital, outpatient department, clinic, radiology practice, mobile unit, office of a physician or other facility that conducts mammography activities, including

operation of equipment to produce a mammogram, processing of the mammogram, initial interpretation of the mammogram and maintaining viewing conditions for that interpretation.

9.89 "Fail-safe characteristics" means a design feature which causes beam port shutters to close, or otherwise prevents emergence of the primary beam, upon the failure of a safety or warning device.

9.90 "FDA" means the Food and Drug Administration.

9.91 "Field emission equipment" means equipment which uses an x-ray tube in which an electron emission from the cathode is due solely to the action of an electric field.

9.92 "Field-flattening filter" means a filter used to provide dose uniformity over the area of a useful beam of x-rays at a specified depth.

9.93 "Field Radiography" means the examination of the macroscopic structure of materials by nondestructive methods of utilizing sources of radiation in a non-fixed or non-permanent location.

9.94 "Field size" means the dimensions along the major axes of an area in a plane perpendicular to the central axis of the useful beam of incident radiation at the normal treatment distance and defined by the intersection of the major axes and the 50 percent isodose line. Material shall be placed in the beam such that dose maximum is produced at the normal treatment distance when field size is being determined.

9.95 "FILTER" MEANS MATERIAL PLACED IN THE USEFUL BEAM TO PREFERENTIALLY ABSORB SELECTED RADIATION.

9.96 "First allowable time" means the earliest time a resident physician is eligible to take the diagnostic radiology boards from an FDA-designated certifying body.

9.97 "Fluoroscopic imaging assembly" means a subsystem in which x-ray photons produce a fluoroscopic image. It includes the image receptor(s) such as the image intensifier and spot-film device, electrical interlocks, if any, and structural material providing linkage between the image receptor and diagnostic source assembly.

9.98 "Focal spot (actual)" means the area projected on the anode of the x-ray tube bombarded by the electrons accelerated from the cathode and from which the useful beam originates.

9.99 "FOG TEST" MEANS AN EVALUATION OF INCREASED DENSITY AND REDUCED CONTRAST ON FILM WHICH HAS NOT BEEN EXPOSED TO THE RADIATION FIELD. THIS IS USUALLY DONE BY PROCESSING UNEXPOSED FILM AND MEASURING THE DENSITY.

9.100 "Gantry" means that part of the system supporting and allowing possible movements of the radiation head.

9.101 "Gauge" means a mechanism designed and manufactured for the purpose of determining or controlling thickness, density, level, interface location, or qualitative or quantative chemical composition. It may include components such as radiation shields and useful beam controls incorporated into the gauge in order to meet the requirements or specifications of this regulation.

9.102 "General purpose radiographic x-ray system" means any radiographic x-ray which, by design, is not limited to radiographic examination of specific anatomical regions.

9.103 "Gonadal shield" means a protective barrier for the testes or ovaries.

9.104 "The "Gray" is the unit of absorbed dose. It is equal to 1 joule per kilogram. One rad is equal to 1 x 10-2 Gray. Submultiples included in this document are the milliGray (Gy) and the microGray (uGy).

9.105 "HALF-VALUE LAYER (HVL)" MEANS THE THICKNESS OF SPECIFIED MATERIAL WHICH ATTENUATES THE BEAM OF RADIATION TO AN EXTENT SUCH THAT THE EXPOSURE RATE IS REDUCED TO ONE-HALF OF ITS ORIGINAL VALUE. IN THIS DEFINITION, THE CONTRIBUTION OF ALL SCATTERED RADIATION, OTHER THAN ANY WHICH MIGHT BE PRESENT INITIALLY IN THE BEAM CONCERNED, IS DEEMED TO BE EXCLUDED.

9.106 "Healing arts" means any system, treatment, operation, diagnosis, prescription, or practice for the ascertainment, cure, relief, palliation, adjustment, or correction of any human disease, ailment, deformity, injury, or unhealthy or abnormal physical or mental condition.

9.107 "Healing arts screening" means the testing of human beings using x-ray machines for the detection or evaluation of health indications when such tests are not specifically and individually ordered by a licensed practitioner of the healing arts legally authorized to prescribe such x-ray tests for the purpose of diagnosis or treatment.

9.108 "Health Professions" means the professional persons authorized by the laws of the State to use x-rays in the diagnosis or treatment of human or animal disease.

9.109 "Heat unit" means a unit of energy equal to the product of the peak kilovoltage, milliamperes, and seconds, i.e., kVp x mA x second.

9.110 "High radiation area" means any area, accessible to individuals, in which there exists radiation at such levels that the whole body could receive in any one hour, a dose in excess of 0.1 rem (mSv) in 1 hour at 30 centimeters from the radiation source or from any surface that the radiation penetrates.

9.111 "HVL" (SEE "HALF-VALUE LAYER").

9.112 "Image intensifier" means a device, installed in its housing, which instantaneously converts an x-ray pattern into a corresponding light image of higher energy density.

9.113 "IMAGE RECEPTOR" MEANS ANY DEVICE, SUCH AS RADIOGRAPHIC FILM, WHICH TRANSFORMS INCIDENT PHOTONS EITHER INTO A VISIBLE IMAGE OR INTO ANOTHER FORM WHICH CAN BE MADE INTO A VISIBLE IMAGE BY FURTHER TRANSFORMATIONS.

9.114 "Image receptor support" means, for mammographic systems, that part of the system designed to support the image receptor during mammography.

9.115 "Individual" means any human being.

9.116 "Individual monitoring" means:

(a) the assessment of dose equivalent by the use of devices designed to be worn by an individual; or
(B) THE ASSESSMENT OF DOSE EQUIVALENT BY THE USE OF SURVEY DATA.

9.117 "Individual Monitoring Devices" or "individual monitoring equipment" means devices designed to be worn by a single individual for the assessment of dose equivalent such as film badges, thermoluminescent dosimeters (TLDs), and pocket ionization chambers.

9.118 "Inherent filtration" means the filtration of the useful beam provided by the permanently installed components of the tube housing assembly.

9.119 "Inoperative" means any x-ray machine or device that is temporarily or permanently rendered incapable of producing x-rays.

9.120 "Inspection" means an official examination or observation including, but not limited to, tests, surveys, and monitoring to determine compliance with rules, regulations, orders, requirements, and conditions of the Department.

9.121 "Interim regulations" means the regulations entitled "Requirements for Accrediting Bodies of Mammography facilities" (58 FR 67558-67565) and "Quality Standards and Certification Requirements for Mammography Facilities"(58 FR 67565-67572), published by FDA on December 21, 1993, and amended on September 30, 1994 (59 FR 49808-49813). These regulations established the standards that had to be met by mammography facilities in order to lawfully operate between October 1, 1994 and April 28, 1999.

9.122 "Interlock" means a device for precluding access to a high radiation area by automatically reducing the exposure rate upon entry by personnel.

9.123 "Interpreting physician" means a licensed physician who interprets mammograms and who meets the requirements of Section 5.4.2 and 5.4.4.

9.124 "Irradiation" means the exposure of matter to ionizing radiation.

9.125 "Isocenter" means the intersection of the collimator axis of rotation and the gantry axis of rotation.

9.126 "Kilovolts peak" (See "Peak tube potential").

9.127 "kV" means kilovolts.

9.128 "KVP" (SEE "PEAK TUBE POTENTIAL").

9.129 "Lead interpreting physician" means the interpreting physician assigned the general responsibility for ensuring that a facility's quality assurance program meets all of the requirements of Sections 5.9, 5.10.1, 5.10.2, 5.10.4, 5.10.5, 5.10.6 and 5.10.7 of this Part. The administrative title and other supervisory responsibilities of the individual, if any, are left to the discretion of the facility.

9.130 "Leakage radiation (non-diagnostic)" means all radiation coming from within the tube housing complex except the useful beam(s).

9.131 "Leakage radiation (diagnostic)" means radiation emanating from the diagnostic source assembly except for:

1) the useful beam, and

2) radiation produced when the exposure switch or timer is not activated.

9.132 "Leakage technique factors" means the technique factors associated with the diagnostic or therapeutic source assembly which are used in measuring leakage radiation. They are defined as follows:

1) For diagnostic source assemblies intended for capacitor energy storage equipment, the maximum-rated peak tube potential and the maximum-rated number of exposures in an hour for operation at the maximum-rated peak tube potential with the quantity of charge per exposure being 10 millicoulombs, i.e., 10 milliampere seconds, or the minimum obtainable from the unit, whichever is larger.

2) For diagnostic source assemblies intended for field emission equipment rated for pulsed operation, the maximum-rated peak tube potential and the maximum-rated number of x-ray pulses in an hour for operation at the maximum-rated peak tube potential.

3) For all other diagnostic or therapeutic source assemblies, the maximum-rated peak tube potential and the maximum-rated continuous tube current for the maximum-rated peak tube potential.

9.133 "Light field" means that area of the intersection of the light beam from the beam-limiting device and one of the set of planes parallel to and including the plane of the image receptor, whose perimeter is the locus of points at which the illumination is one-fourth of the maximum in the intersection.

9.134 "Limits" or "Dose Limits" means the permissible upper bounds of radiation doses.

9.135 "Linear attenuation coefficient" or " " means the quotient of dN/N divided by dl when dN/N is the fraction of uncharged ionizing radiation that experience interactions in traversing a distance dl in a specified material.

9.136 "Line voltage regulation" means the difference between the no-load and the load line potentials expressed as a percent of the load line potential. It is calculated using the following equation.

Percent line-voltage regulation = 100 (Vn-Vl)/Vl where
Vn = No load line potential and
Vl = Load line potential.

9.137 "mA" means milliAmpere.

9.138 "Mammogram" means a radiographic image produced through mammography.

9.139 "Mammographic modality" means a technology for radiography of the breast. Examples are screen-film mammography and digital mammography.

9.140 "Mammography" means radiography of the breast.

9.141 "Mammography equipment evaluation" means an onsite assessment of mammography unit or image processor performance by a medical physicist for the purpose of making a preliminary determination as to whether the equipment meets all of the applicable standards in this Part.

9.142 "Mammography medical outcomes audit" means a systematic collection of mammography results and the comparison of those results with outcomes data.

9.143 "Mammography unit" or "units" means an assemblage of components for the production of x-rays for use during mammography, including, at a minimum, an x-ray generator, an x-ray control, a tube housing assembly, a beam limiting device and the supporting structures for these components.

9.144 "mAs" means milliAmpere second.

9.145 "Maximum line current" means the root-mean-square current in the supply line of an x-ray machine operating at its maximum rating.

9.146 "Mean optical density" means the average of the optical densities (OD) measured using phantom thicknesses of 2, 4, and 6 centimeters with values of kilovolt peak (kVp) clinically appropriate for those thicknesses.

9.147 "Medical physicist", for the purpose of Part V, means a person trained in evaluating the performance of mammography equipment and facility quality assurance programs and who meets the qualifications set forth in RHB 5.7.3.

9.148 "Member of the public" means an individual in a controlled or unrestricted area; however, an individual is not a member of the public during any period in which the individual receives an occupational dose.

9.149 "Minor" means an individual less than 18 years of age.

9.150 "Misadministration" means the administration of:

9.150.1 Radiation to the wrong patient, wrong treatment site, or wrong mode of treatment;

9.150.2 Performance of a diagnostic or therapeutic procedure other than that ordered by the prescribing physician.

9.150.3 A therapeutic radiation dose from a source such that errors in the source calibration, time of exposure,or treatment geometry result in a calculated total treatment dose differing from the total prescribed treatment dose by more than20 percent.

9.150.4 When the treatment consists of three or fewer fractions, a therapeutic radiation dose from a source such that errors in the source calibration, time of exposure, or treatment geometry result in a calculated total treatment dose differing from the total prescribed treatment dose by more than 10 percent.

9.150.5 When the calculated weekly treatment dose exceeds the weekly prescribed dose by 30 percent or more of the weekly prescribed dose.

9.151 "Mobile x-ray equipment" (See "X-ray equipment").

9.152 "Monitoring", "radiation monitoring" or "radiation protection monitoring" means the measurement of radiation levels, concentrations, surface area concentrations or quantities of radioactive material and the use of the results of these measurements to evaluate potential exposures and doses.

9.153 "MQSA" means the federal Mammography Quality Standards Act of 1992.

9.154 "Multi-reading" means two or more physicians, at lest one of whom is an interpreting physician, interpreting the same mammogram.

9.155 "Nonstochastic effect" means health effects, the severity of which varies with the dose and for which a threshold is believed to exist. Radiation-induced cataract formation is an example of nonstochastic effect (also called a deterministic effect).

9.156 "Moving beam therapy" means radiation therapy with relative displacement of the useful beamor the patient during irradiation. It includes arc therapy, skip therapy, conformational therapy, and rotational therapy.

9.157 "NORMAL TREATMENT DISTANCE" MEANS :

1) For electron irradiation, the distance from the scattering foil or exit window of the electron beam to the surface along the central axis of the useful beam, or from the virtual source to the surface along the central axis of the useful beam as specified by the manufacturer.

2) For x-ray irradiation, the virtual source or target to isocenter distance along the central axis of the useful beam. For non-isocentric equipment, this distance shall be specified by the manufacturer.

9.158 "OCCUPATIONAL DOSE" MEANS THE DOSE RECEIVED BY AN INDIVIDUAL IN A RESTRICTED AREA OR IN THE COURSE OF EMPLOYMENT IN WHICH THE INDIVIDUAL'S ASSIGNED DUTIES INVOLVE EXPOSURE TO RADIATION, WHETHER IN THE POSSESSION OF THE REGISTRANT OR OTHER PERSON. OCCUPATIONAL DOSE DOES NOT INCLUDE DOSE RECEIVED FROM BACKGROUND RADIATION, AS A PATIENT FROM MEDICAL PRACTICES, FROM VOLUNTARY PARTICIPATION IN MEDICAL RESEARCH PROGRAMS, OR AS A MEMBER OF THE GENERAL PUBLIC.

9.159 "Open beam configuration" means an analytical x-ray system in which an individual could accidentally place some part of his body in the primary beam path during normal operation.

9.160 "Operating procedures" means detailed written instructions including, but not limited to, use of the x-ray equipment, use of shielding and barriers, quality assurance methods, occasions and methods for conducting area surveys, use of personnel monitoring devices, and alignment, calibration, or preventative maintenance of x-ray equipment. Routine and emergency radiation safety considerations are part of these procedures. Emergency procedures shall include methods of notifying proper persons in the event of an emergency, to include the listing of names, addresses and phone numbers.

9.161 "Operative" means any x-ray machine or device that is capable of producing x-rays.

9.162 "PATIENT" MEANS AN INDIVIDUAL OR ANIMAL SUBJECTED TO HEALING ARTS EXAMINATION, DIAGNOSIS, OR TREATMENT, INCLUDING A MAMMOGRAPHY EVALUATION.

9.163 "PBL" (See "Positive Beam Limitation").

9.164 "Peak tube potential" means the maximum value of the potential difference across the x-ray tube during an exposure.

9.165 "Person" means any individual, corporation, partnership, firm, association, trust, estate, public or private institution, group, agency, political subdivision of this State, any other state or political subdivision or agency thereof, and any legal successor, representative, agent or agency of the foregoing, other than entities over which a federal government agency has exclusive jurisdiction.

9.166 "PERSONNEL MONITORING EQUIPMENT" MEANS DEVICES DESIGNED TO BE CARRIED OR WORN BY AN INDIVIDUAL FOR THE PURPOSE OF MEASURING THE DOSE WHICH AN INDIVIDUAL RECEIVES (E.G., FILM BADGES, POCKET CHAMBERS, POCKET DOSIMETERS).

9.167 "Phantom" in Part VI, means a volume of material behaving in a manner similar to tissue with respect to the attenuation and scattering of radiation. This requires that both the atomic number (Z) and the density of the material be similar to that of the tissue.

9.168 "Phantom" in Part V, means a test object used to simulate radiographic characteristics of compressed breast tissue and containing components that radiographically model aspects of breast disease and cancer. This definition does not apply to phantoms used for Quality Assurance testing of stereotactic biopsy units. It is equivalent to a nominal 4.2 centimeter compressed breast of average density (i.e., 50 percent adipose and 50 percent glandular tissue) and shall contain the following objects:

1) Spherical masses, composed of phenolic plastic with thicknesses of: 2.00, 1.00, 0.75, 0.50 and 0.25 millimeter;

2) Specks, composed of aluminum oxide, with diameters of : 0.54, 0.40, 0.32, 0.24 and 0.16 millimeter

3) Fibers composed of nylon, with thicknesses of: 1.56, 1.12, 0.89, 0.75, 0.54, and 0.40 millimeter.

9.169 "Phantom image" means a radiographic image of a phantom.

9.170 "Phototimer" means a method for controlling radiation exposure to image receptors by measuring the amount of radiation which reaches a radiation monitoring device(s). The radiation monitoring device(s) is part of an electronic circuit which controls the duration of time the tube is activated (See "Automatic exposure control).

9.171 "Physical science" means physics, chemistry, radiation science (including medical physics and health physics) and engineering.

9.172 "PID" (See "Position indicating device").

9.173 "Planned special exposure" means an infrequent exposure to radiation, separate from and in addition to the annual occupational dose limits.

9.174 "Portable x-ray equipment" (See "X-ray equipment").

9.175 "Position indicating device" means a device on dental x-ray equipment used to indicate the beam position and to establish a definite source-surface (skin) distance. It may or may not incorporate or serve as a beam-limiting device.

9.176 "Positive Beam Limitation" means the automatic or semiautomatic adjustment of an x-ray beam to the selected image receptor size, whereby exposures cannot be made without such adjustments.

9.177 "Positive mammogram" means a mammogram that has an overall assessment of findings that are either "suspicious" or "highly suggestive of malignancy."

9.178 "Primary beam" means ionizing radiation which passes through an aperture of the source housing by a direct path from the x-ray tube located in the radiation source housing.

9.179 "Primary dose monitoring system" means a system which will monitor the useful beam during irradiation and which will terminate irradiation when a preselected number of dose monitor units have been acquired.

9.180 "Primary protective barrier" (See "Protective barrier").

9.181 "Protective apron" means an apron made of radiation absorbing material used to reduce radiation exposure.

9.182 "Protective barrier" means a barrier of radiation absorbing material(s) used to reduce radiation exposure. The types of protective barriers are as follows:

1) "Primary protective barrier" means the material, excluding filters, placed in the useful beam, to protect anyone other than the patient from radiation exposure.

2) "Secondary protective barrier" means a barrier sufficient to attenuate the stray radiation to the required degree.

9.183 "Protective glove" means a glove made of radiation absorbing materials used to reduce radiation exposure.

9.184 "Provisional certificate" means the provisional certificate described in RHB 5.3.3.

9.185 "Public dose" means the dose received by a member of the public from exposure to radiation by a registrant, or to another source of radiation either within a registrant's controlled area or in unrestricted areas. It does not include occupational dose or doses received from background radiation, as a patient from medical practices, or from voluntary participation in medical research programs.

9.186 "Qualified expert" means an individual who has demonstrated to the satisfaction of the Department that such individual possesses the knowledge, training and experience to measure ionizing radiation, to evaluate safety techniques, and to advise regarding radiation protection needs.

9.187 "Qualified instructor" means an individual whose training and experience adequately prepares him or her to carry out specified training assignments. Interpreting physicians, radiologic technologists or medical physicists who meet the requirements of Section 5.4 and 5.5 of this Part would be considered qualified instructors in their respective areas of mammography. Other examples of individuals who may be qualified instructors for the purpose of providing training to meet the requirements of this Part include, but are not limited to, instructors in a post-high school training institution and manufacturer's representatives.

9.188 "Quality Assurance" is a program designed to produce high quality radiographs at minimal cost and minimal patient exposure.

9.189 "Quality Control" is the routine measurement of image quality and the performance of the diagnostic x-ray imaging system, from x-ray beam output to the viewing of radiographs, and the continual adjustment of that performance to an optimal and consistent level.

9.190 "Quality control technologist" means an individual meeting the requirements of RHB 5.7.2 who is responsible for those quality assurance responsibilities not assigned to the lead interpreting physician or to the medical physicist.

9.191 "Quality Factor" (Q) means the modifying factor that is used to derive dose equivalent from absorbed dose. Quality factors are provided in the definition of rem.

9.192 THE "RAD" IS A MEASURE OF THE ABSORBED DOSE OF ANY RADIATION TO BODY TISSUE IN TERMS OF THE ENERGY ABSORBED PER UNIT MASS OF THE TISSUE. ONE RAD IS THE ABSORBED DOSE CORRESPONDING TO 100 ERGS PER GRAM OF TISSUE. (ONE MILLIRAD {MRAD} = 0.001 RAD.)

9.193 "Radiation" means ionizing radiation, including gamma rays, x-rays, alpha particles, beta particles, high speed electrons, neutrons, high speed protons, and other atomic particles, but not sound or radio waves, or visible, infrared, or ultraviolet light.

9.194 "Radiation area" means any area accessible to individuals in which there exists radiation at such levels that the whole body could receive in any one hour, a dose in excess of 5 millirem (.05 mSv) at 30 centimeters from the radiation source or from any surface that the radiation penetrates.

9.195 "Radiation detector" means a device which in the presence of radiation provides a signal or other indication suitable for use in measuring one or more quantities of incident radiation.

9.196 "Radiation dose" means dose.

9.197 "Radiation Installation" is any location or facility where radiation machines are used.

9.198 "Radiation Safety Officer" means one who has the knowledge and responsibility to apply appropriate radiation protection regulations, and is approved in writing by the registrant.

9.199 "Radiation therapy simulation system" means a radiographic or fluoroscopic x-ray system intended for localizing the volume to be exposed during radiation therapy and confirming the position and size of the therapeutic irradiation field.

9.200 "RADIOGRAPH" MEANS AN IMAGE RECEPTOR ON WHICH THE IMAGE IS CREATED DIRECTLY OR INDIRECTLY BY AN X-RAY PATTERN AND RESULTS IN A PERMANENT RECORD.

9.201 "Radiographer" means any individual who performs or who, in attendance at the site where sources of radiation are being used, personally supervises field radiography operations, and who is responsible to the registrant for assuring compliance with the requirements of these regulations.

9.202 "Radiographer's Assistant" means any individual who, under the personal supervision of a radiographer, uses sources of radiation, related handling tools, or survey instruments in field radiography.

9.203 "Radiographic imaging system" means any system whereby a permanent or temporary image is recorded on an image receptor by the action of ionizing radiation.

9.204 "Radiological physicist" means an individual who is certified by the American Board of Radiology in therapeutic radiological physics, radiological physics, or x- and gamma ray physics; or certified by the American Board of Medical Physicists in radiation oncology physics, or have the equivalent training experience as approved, or have the following minimum training and experience:

9.204.1 A Master's or a Doctoral degree in Physics, Biophysics, Radiological Physics, or Health Physics or Medical Physics; one year full-time training in therapeutic radiological physics;

9.204.2 One year full-time experience in a therapeutic facility where the individual's duties involve calibration and spot checks of a medical accelerator, and includes personal calibration and spot check of at least one machine.

9.205 "Radiologic technologist", in Part V, means an individual specifically trained in the use of radiographic equipment and the positioning of patients for radiographic examinations and when performing mammography without direct supervision, also meets the requirements set forth in RHB 5.7.2.

9.206 "Rating" means the operating limits as specified by the component manufacturer.

9.207 "Recording" means producing a permanent form of an image resulting from x-ray photons.

9.208 "Registrant" means any person who is registered with the Departmentor is legally obligated to register with the Department pursuant to the Act and these regulations.

9.209 "Registration" means registering with the Department in accordance with these regulations and the Act.

9.210 "Rem" is the special unit of any of the quantities expressed as dose equivalent. The dose equivalent in rems is equal to the absorbed dose in rads multiplied by the quality factor (1 rem = 0.01 sievert). The quality factors for converting absorbed dose to dose equivalent are as follows:

QUALITY FACTORS AND ABSORBED DOSE EQUIVALENCIES

TYPE OF RADIATION	Quality Factor (Q)	Absorbed Dose Equal to a Unit Dose Equivalent*

X-, gamma, or beta radiation	1	1
Alpha particles, multiple-charged particles, fission fragments and heavy particles of unknown charge	20	0.05
Neutrons of unknown energy	10	0.1
High-energy protons	10	0.1

*Absorbed dose in rad equal to 1 rem or the absorbed dose in gray equal to 1 sievert.

9.211 "RESPONSE TIME" MEANS THE TIME REQUIRED FOR AN INSTRUMENT SYSTEM TO REACH 90 PERCENT OF ITS FINAL READING WHEN THE RADIATION SENSITIVE VOLUME OF THE INSTRUMENT SYSTEM IS EXPOSED TO A STEP CHANGE IN RADIATION FLUX FROM ZERO SUFFICIENT TO PROVIDE A STEADY STEP MIDSCALE READING.

9.212 "Restricted area" (controlled area) means any area, access to which is controlled by the registrant for purposes of protection of individuals from exposure to radiation. A "restricted area" shall not include any areas used for residential quarters, although a separate room or rooms in a residential building may be set apart as a restricted area.

9.213 "Roentgen" (R) is the special unit of exposure. One Roentgen equals 2.58 x 10-4 Coulombs/kilogram of air. (See exposure.)

9.214 "Safety device" means a device which prevents the entry of any portion of an individual's body into the primary x-ray beam path or which causes the beam to be shut off upon entry into its path.

9.215 "Scan" means the complete process of collecting x-ray transmission data for the production of a tomogram. Data can be collected simultaneously during a single scan for the production of one or more tomograms.

9.216 "Scan increment" means the amount of relative displacement of the patient with respect to the CT x-ray system or between successive scans measured along the direction of such displacement.

9.217 "Scan sequence" means a preselected set of two or more scans performed consecutively under preselected CT conditions of operation.

9.218 "SCAN TIME" MEANS THE PERIOD OF TIME BETWEEN THE BEGINNING AND END OF X-RAY TRANSMISSION DATA ACCUMULATION FOR A SINGLE SCAN.

9.219 "Scattered radiation" means radiation that, during passage through matter, has been deviated in direction (See "Direct scattered radiation).

9.220 "Screening mammography" means mammography performed on an asymptomatic patient to detect the presence of breast cancer at an early stage.

9.221 "SECONDARY DOSE MONITORING SYSTEM" MEANS A SYSTEM WHICH WILL TERMINATE IRRADIATION IN THE EVENT OF FAILURE OF THE PRIMARY SYSTEM.

9.222 "Secondary protective barrier" (See "Protective barrier").

9.223 "Serious adverse event" mens an adverse advent that may significantly compromise clinical outcomes, or an adverse event for which a facility fails to take appropriate corrective action in a timely manner.

9.224 "Serious complaint" means a report of a serious adverse event.

9.225 "Shadow tray" means a device attached to the radiation head to support auxiliary beam blocking material.

9.226 "Shallow-dose equivalent" (H_S), which applies to the external exposure of the skin or an extremity, is taken as the dose equivalent at a tissue depth of 0.007 centimeter (7 mg/cm^2) averaged over an area of 1 square centimeter.

9.227 "Shielded room radiography" means industrial radiography using radiation machines, which is conducted in an enclosed room, the interior of which is not occupied during radiographic operations, which is so shielded that every location on the exterior meets conditions for an unrestricted area and the only access to which is through openings which are interlocked so that the radiation machine will not operate unless all openings are securely closed.

9.228 "Shutter" means a device attached to the tube housing assembly which can totally intercept the entire cross sectional area of the useful beam and which has a lead equivalency not less than that of the tube housing assembly.

9.229 "SID" (SEE SOURCE TO IMAGE RECEPTOR DISTANCE).

9.230 "Sievert (Sv)" is the unit of dose equivalent. The dose equivalent is Sieverts is equal to the absorbed dose in grays multiplied by the quality factor. (1 Sv = 100 rems). Submultiples included in this document are the milliSievert (mSv) and the microSievert (uSv).

9.231 "Site boundary" means that line beyond which the land or property is not owned, leased, or otherwise controlled by the registrant.

9.232 "Source" means the focal spot of the x-ray tube.

9.233 "Source to image receptor distance (SID)" means the distance from the source to the center of the input surface of the image receptor.

9.234 "Source of radiation" means any device or equipment emitting or capable of producing x-ray radiation.

9.235 "Special procedures" means the application of special x-ray equipment and specialized techniques to obtain required diagnostic information. This usually provides enhanced detail of a given anatomical structure but with reduced visualization of others. Special procedures include, but are not limited to, angiography, cardiac catheterization, myelogram, and surgery.

9.236 "SPECIAL PURPOSE X-RAY SYSTEM" MEANS ANY RADIOGRAPHIC X-RAY SYSTEM WHICH IS LIMITED, BY DESIGN, TO RADIOGRAPHIC EXAMINATIONS OF SPECIFIED ANATOMICAL REGIONS. SPECIAL PURPOSE X-RAY SYSTEMS INCLUDE, BUT ARE NOT LIMITED TO, MAMMOGRAPHY UNITS, DEDICATED CHEST UNITS, CYSTOGRAPHY UNITS, AND HEAD AND SKULL UNITS.

9.237 "Spot check" means a procedure which is performed to assure that a previous calibration continues to be valid.

9.238 "Spot film" means a radiograph which is made during a fluoroscopic examination to permanently record conditions which exist during that fluoroscopic procedure.

9.239 "Spot film device" means a device intended to transportor position a radiographic image receptor between the x-ray source and fluoroscopic image receptor. It includes a device intended to hold a cassette over the input end of an image intensifier for the purpose of making a radiograph.

9.240 "SSD" means the distance between the source and the skin entrance plane of the patient.

9.241 "Standard breast" means a 4.2 centimeter (cm) thick compressed breast consisting of 50 percent glandular and 50 percent adipose tissue.

9.242 "Stationary x-ray equipment" (See "X-ray equipment").

9.243 "Stochastic effects" means health effects that occur randomly and for which the probability of the effect occurring, rather than its severity, is assumed to be a linear function of dose without threshold. Hereditary effects and cancer incidence are examples of stochastic effects (also called a probabilistic effect).

9.244 "STRAY RADIATION" MEANS THE SUM OF LEAKAGE AND SCATTERED RADIATION.

9.245 "Supervision" means the delegating of the task of applying radiation pursuant to this part by persons, not licensed in the healing arts or veterinary medicine, who provide services under the practitioner's control. The licensed practitioner assumes full responsibility for these tasks and must assure that the tasks will be administered correctly.

9.246 "Survey" means an evaluation of the use, of sources of radiation under a specific set of conditions to determine actual or potential radiation hazards. When appropriate, such evaluation includes, but is not limited to tests, physical examination, and measurements of levels of radiation.

9.247 "Survey" in Part V, means an onsite physics consultation and evaluation of a facility's quality assurance program performed by a medical physicist.

9.248 "Target" means that part of a radiation head which by design intercepts a beam of accelerated particles with subsequent emission of other radiation.

9.249 "Technique factors" means the following conditions of operations:

1) For capacitor energy storage equipment, peak tube potential in kV and quantity of charge in mAs;

2) For field emission equipment rated for pulsed operation, peak tube potential in kV and number of x-ray pulses;

3) For CT x-ray systems designed for pulsed operation, peak tube potential in kV, scan time in seconds, and either tube current in mA, x-ray pulse width in seconds, and the number of x-ray pulses per scan, or the product of tube current, x-ray pulse width, and the number of x-ray pulses in mAs;

4) For CT x-ray systems not designed for pulsed operation, peak tube potential in kV, scan time in seconds, and either tube current in mA and scan time in seconds, or the product of tube current and exposure time in mAs and the scan time when the scan time and exposure time are equivalent; and

5) For all other equipment, peak tube potential in kV, and either tube current in mA and exposure time in seconds, or the product of tube current and exposure time in mAs.

9.250 "TERMINATION OF IRRADIATION" MEANS THE STOPPING OF IRRADIATION IN A FASHION WHICH WILL NOT PERMIT CONTINUANCE OF IRRADIATION WITHOUT THE RESETTING OF OPERATING CONDITIONS AT THE CONTROL PANEL.

9.251 "Test" means a method for determining the characteristics or condition of sources of radiation or components thereof.

9.252 "Therapeutic-type-protective tube housing" (1) For x-ray therapy equipment not capable of operating at 500 kVp or above, the following definition applies: An x-ray tube housing so constructed that the leakage radiation at a distance of one meter from the source does not exceed one Roentgen in an hour when the tube is operated at its maximum rated continuous current for the maximum rated tube potential. (2) For x-ray therapy equipment capable of operation at 500 kVp or above, the following definition applies: An x-ray tube housing so constructed that leakage radiation at a distance of one meter from the source does not exceed an exposure of one Roentgen in an hour or 0.1 percent of the useful beam dose rate at one meter at its maximum rated continuous current for the maximum rated accelerating potential.

9.253 "Time cycle" means the film development time.

9.254 "Tomogram" means the depiction of the x-ray attenuation properties of a section through the body.

9.255 "Total Effective Dose Equivalent" (TEDE) means the sum of the deep-dose equivalent (for external exposures) and the committed effective dose equivalent (for internal exposures).

9.256 "Traceable to a national standard" means an instrument is calibrated at either the National Institute of Standards and Technology (NIST) or at a calibration laboratory that participates in a proficiency program with NIST at least once every 2 years and the results of the proficiency test conducted within 24 months of calibration show agreement within plus or minus 3 percent of the national standard in the mammography energy range.

9.257 "TUBE" MEANS AN X-RAY TUBE, UNLESS OTHERWISE SPECIFIED.

9.258 "Tube housing-apparatus complex" means those parts of an analytical x-ray device in which x-rays are produced and utilized for a useful purpose. This includes the x-ray tube housing, shutter or port assemblies, collimators, cameras, goniometers, and electronic radiation detectors.

9.259 "TUBE HOUSING ASSEMBLY" MEANS THE TUBE HOUSING WITH TUBE INSTALLED. IT INCLUDES HIGH VOLTAGEOR FILAMENT TRANSFORMERS AND OTHER APPROPRIATE ELEMENTS WHEN SUCH ARE CONTAINED WITHIN THE TUBE HOUSING.

9.260 "Unrestricted area" (uncontrolled area) means any area to which access is not controlled by the registrant for purposes of protection of individuals from exposure to radiation, and any area used for residential quarters.

9.261 "Vendor" means a person who is engaged in the business of selling, leasing, installing, or offering to sell, lease, or install x-ray machines or machine components or is engaged in the business of furnishing or offering to furnish x-ray machine services, which includes, but is not limited to, reinstalling, reassembling, leasing, servicing, maintenance, calibration, and repair of x-ray equipment, facility and shielding design, radiation surveys, instrument calibration, personnel dosimetry, processor cleaning and maintenance, and health physics consultations.

8.262 "Very high radiation area" means an area, accessible to individuals, in which radiation levels could result in an individual receiving an absorbed dose in excess of 500 rads (5 grays) in 1 hour at 1 meter from a radiation source or from any surface that the radiation penetrates. At very high doses received at high dose rates, units of absorbed dose (e.g., rads and grays) are appropriate, rather than units of dose equivalent (e.g., rems and sieverts).

9.263 "Virtual source" means a point from which radiation appears to originate.

9.264 "Whole body" means, for purposes of external exposure, head, trunk (including male gonads), arms above the elbow, or legs above the knee.

9.265 "WORKER" MEANS AN INDIVIDUAL ENGAGED IN WORK UNDER A LICENSE OR REGISTRATION ISSUED BY THE AGENCY AND CONTROLLED BY A LICENSEE OR REGISTRANT, BUT DOES NOT INCLUDE THE LICENSEE OR REGISTRANT.

9.266 "X-ray equipment" means an x-ray system, subsystem, or component thereof.

9.266.1 Mobile means X-ray equipment mounted on a permanent base with wheelsor casters for moving while completely assembled.

9.266.2 Portable means X-ray equipment designed to be hand carried.

9.266.3 Stationary means X-ray equipment designed which is installed in a fixed location.

9.266.4 Transportable means X-ray equipment installed in a vehicle or trailer.

9.267 "X-ray system" means an assemblage of components for the controlled production of x-rays. It includes minimally an x-ray high voltage generator, an x-ray control, a tube housing assembly, a beam limiting device, and the necessary supporting structures. Additional components which function with the system are considered integral parts of the system.

9.268 "X-ray subsystem" means any combination of two or more components of an x-ray system.

9.269 "X-ray tube" means any electron tube which is designed to be used primarily for the production of x-rays.

9.270 "Year" means the period of time beginning in January used to determine compliance with the provisions of this part. The registrant may change the starting date of the year used to determine compliance by the registrant provided that the change is made at the beginning of the year and that no day is omitted or duplicated in consecutive years.

PART X
NOTICES, INSTRUCTIONS, AND REPORTS TO WORKERS: INSPECTIONS

RHB 10.1 Purpose and Scope. This Part establishes requirements for notices, instructions, and reports by registrants to individuals employed by them, and options available to such individuals in connection with Department inspections of registrants to ascertain compliance with the provisions of the Act and regulations issued thereunder regarding radiological working conditions. The regulations in this Part apply to all persons who receive, possess, use, own, or transfer radiation producing equipment registered by the Department pursuant to the regulation in Part II.

RHB 10.2 Posting of Notices to Workers.

10.2.1 Each registrant shall post current copies of the following documents: 1) the regulations in this Part and in Part III; 2) "Notice to Employees" Form SC-RHA-20; 3) any notice of violation involving radiological working conditions; or order issued pursuant to Part I and any response from the registrant.

10.2.2 If posting of a document is not practicable, the registrant may post a notice which describes the document and states where it may be examined.

10.2.3 Documents, notices of forms posted pursuant to this section shall appear in a sufficient number of places to permit individuals engaged in work associated with the X-ray equipment to observe them on the way

to or from any equipment location to which the document applies, shall be conspicuous, and shall be replaced if defaced or altered.

10.2.4 Department documents posted pursuant to RHB10.2.3, of this section shall be posted within five (5) working days after receipt of the documents from the Department; the registrant's response, if any, shall be posted within five (5) working days after dispatch from the registrant. Such document shall remain posted for a minimum of five (5) working days or until action correcting the violation has been completed, whichever is later.

RHB 10.3 Instructions to Workers. All individuals working in or frequenting any portion of a restricted area shall be kept informed of the use of x-ray equipment or of radiation in portions of the unrestricted area; shall be instructed in the health protection problems associated with exposure to such x-ray equipment or radiation, in precautions or procedures to minimize exposure, and in the purposes and functions of protective devices employed; shall be instructed in, and instructed to observe, to the extent within the worker's control, the applicable provisions of Department regulations for the protection of personnel from radiation occurring in such areas; shall be instructed of their responsibility to report promptly to the registrant any conditions which may lead to or cause a violation of Department regulations or unnecessary exposure to radiation; shall be instructed in the appropriate response to warnings made in the event of an unusual occurrence or malfunction that may involve exposure to radiation; and shall be advised as to the radiation exposure requests which workers may request pursuant to RHB 10.4. The extent of these instructions shall be commensurate with potential radiological health protection problems in the restricted area.

RHB 10.4 NOTIFICATION AND REPORTS TO INDIVIDUALS.

10.4.1 Radiation exposure data for an individual and the results of any measurements, analyses, and calculations of radiation exposure to the body of an individual shall be reported to the individual as specified in this section. The information reported shall include data and results obtained pursuant to Department regulations, orders, or inspections. Each notification and report shall: be in writing; include appropriate identifying data such as the name of the registrant, the name of the individual, the individual's social security number; include the individual's exposure information; and contain the following statement: "This report is furnished to you under the provisions of the South Carolina Department of Health and Environmental Control's Radiation Control Regulations. You should preserve this report for future reference."

10.4.2 At the request of any worker, each registrant shall advise such worker annually of the worker's exposure to radiation as shown in records maintained by the registrant pursuant to RHB 3.22.

10.4.3 At the request of the worker formerly engaged in work controlled by the registrant, each registrant shall furnish to the worker a report of the workers' exposure to radiation. Such report shall be furnished within 30 days from the time the request is made, or within 30 days after the exposure of the individual has been determined by the registrant, whichever is later; shall cover, within the period of time specified in the request, each calendar quarter in which the workers' activities involved exposure to radiation from x-ray producing equipment registered by the Department; and shall include the dates and locations of work under the registrant in which the worker participated during this period.

10.4.4 When a registrant is required pursuant to RHB 3.25 or 3.26 to report to the Department any exposure of an individual to radiation, the registrant shall also provide the individual a report on his exposure data included therein. Such reports shall be transmitted at a time not later than the transmittal to the Department.

RHB 10.5 PRESENCE OF REGISTRANTS AND WORKERS DURING INSPECTIONS.

10.5.1 Each registrant shall afford to the Department, at all reasonable times, opportunity to inspect machines, activities, facilities, premises, and records pursuant to these regulations.

10.5.2 During an inspection, Department inspectors may consult privately with workers as specified in RHB 10.6. The registrant may accompany Department inspectors during other phases of an inspection.

10.5.3 If, at any time of inspection, an individual has been authorized by the workers to represent them during Department inspections, the registrant shall notify the inspectors of such authorization and shall give the workers' representative an opportunity to accompany the inspectors during the inspection of the physical working conditions.

10.5.4 Each workers' representative shall be routinely engaged in work under control of the registrant and shall have received instructions as specified in RHB 10.3. With approval of the registrant, the workers' representative may be an individual who is not routinely engaged in work under control of the registrant, for example, a consultant to the registrant or to the workers' representative shall be afforded the opportunity to accompany Department inspectors during the inspection of physical working conditions.

10.5.5 Different representatives of registrants and workers may accompany the inspectors during different phases of an inspection if there is no resulting interference with the conduct of the inspection. However, only one workers' representative at a time may accompany the inspector.

10.5.6 Notwithstanding the other provisions of this section, Department inspectors are authorized to refuse to permit accompaniment by any individual who deliberately interferes with a fair and orderly inspection. With regard to any area containing proprietary information, the workers' representative for the area shall be an individual previously authorized by the registrant to enter that area.

RHB 10.6 Consultation with Workers During Inspection.

10.6.1 Department inspectors may consult privately with workers concerning matters of occupational radiation protection and other matters related to the extent of an effective and thorough inspection.

10.6.2 During the course of an inspection any worker may bring privately to the attention of the inspectors, either orally or in writing, any past or present condition which the worker has reason to believe may have contributed to or caused any violation of the Act, or these regulations, or any unnecessary exposure of an individual to radiation from x-ray producing equipment under the registrant's control. Any such notice in writing shall comply with the requirements of RHB 10.7.1.

10.6.3 The provisions of RHB 10.6.2 of this section shall not be interpreted as authorization to disregard instructions pursuant to RHB 10.3.

RHB 10.7 REQUEST BY WORKERS FOR INSPECTIONS.

10.7.1 Any worker or representative of workers who believes that a violation of the Act, or these regulations exists or has occurred in work under a registrant with regard to radiological working conditions in which the worker is engaged, may request an inspection by giving notice of the alleged violation to the Department. Any such notice shall be in writing and shall set forth the specific grounds for the notice. A copy shall be provided to the registrant by the Department no later than at the time of inspection.

10.7.2 If, upon receipt of such notice, the Deputy Commissioner for Health Regulations or the Chief of the Bureau of Radiological Health determines that the complaint meets the requirements set forth in RHB 10.7.1 of this section, and that there are reasonable grounds to believe that the alleged violation exists or has occurred, he shall cause an inspection to be made as soon as practicable, to determine if such alleged violation exists or has occurred. Inspections pursuant to this section need not be limited to matters referred to in this complaint.

10.7.3 No registrant shall discharge or in any manner discriminate against any worker because such worker has filed any compliant or instituted or caused to be instituted any proceeding under these regulations or has

testified or is about to testify in any such proceeding or because of the exercise by such worker on behalf of the worker or others of any option afforded by this Part.

RHB 10.8 Inspections not Warranted. Informal Review.

10.8.1 If the Chief of the Bureau of Radiological Health determines, with respect to a complaint under RHB10.7 that an inspection is not warranted because there are no reasonable grounds to believe that a violation exists or has occurred, the Bureau Chief shall notify the complainant, if identified, in writing of such determination. The complainant, if identified, may obtain a review of such determination by submitting a written statement of position with the Deputy Commissioner for Health Regulations, who will provide the registrant with a copy of such statement by certified mail, excluding, at the request of the complainant, the name of the complainant. The registrant may submit an opposing written statement of position with the Bureau of Radiological Health who will provide the complainant with a copy of such statements by certified mail. Upon the request of the complainant, the Bureau of Radiological Health may hold an informal conference in which the complainant and the registrant may orally present their views. An informal conference may also be held at the request of the registrant, but disclosure of the identity of the complainant will be made only following receipt written authorization from the complainant. After considering all written or oral views present, the Deputy Commissioner for Health Regulations shall affirm, modify, or reverse the determination of the Chief of the Bureau of Radiological Health and furnish the complainant and the registrant a written notification of the decision and the reason therefore.

10.8.2 If the Chief of the Bureau of Radiological Health determines that an inspection is not warranted because the requirements of RHB 10.7.1 have not been met, he shall notify the complainant in writing of such determination. Such determination shall be without prejudice to the filing of a new complaint meeting the requirements of RHB 10.7.1.

PART XI
REGIONAL CALIBRATION LABORATORY

RHB 11.1 Scope. This part establishes operating requirements and fees for the South Carolina Regional Calibration Laboratory (SCRCL).

RHB 11.2 Operations.

11.2.1 The SCRCL shall maintain a current accreditation from the Conference of Radiation Control Program Directors. In accordance with this accreditation, a yearly proficiency test, provided by the National Institute of Standards and Technology, shall be performed.

11.2.2 The SCRCL shall maintain current operating procedures that will be followed for all calibrations performed.

11.2.3 Upon initial receipt of instruments to be calibrated, each instrument shall be surveyed for contamination. No contaminated instrument will be calibrated at the South Carolina Regional Calibration Laboratory.

RHB 11.3 Fees.

11.3.1 A calibration fee shall be charged for each instrument and probe calibrated at the SCRCL. The following fee schedule shall be used by the Department to determine calibration fees:

Type of Instrument	Fee
Geiger-Mueller (GM) instrument Calibrated at 2 points on each scale	$60

Ion Chamber	
First mode-2 points on each scale	$60
Second mode-2 points on each scale	$15
PIC-6 Calibrated at 2 points on each scale	$60
R Meter Calibrated at 2 points on each scale	$40
MDH 1015 or 1515	
One probe-five calibration points	$200
Additional probe-five calibration points	$85
300 V battery replacement	Market price plus tax
MDH 2025	
One probe- five calibration points	$85
Additional probe-five calibration points	$60
Dosimeter response check	$15
Minimum handling fee, any instrument-no calibration	$25
Other services	$50 per hour

11.3.2 Shipping and insurance fees will be charged to the person requesting the calibration. Charges will be the same as the cost to the Department.

11.3.3 After calibration, an invoice for services will be issued to the person requesting the calibration. The calibration fees are due upon receipt of the invoice.

Fiscal Impact Statement:

There will be no cost to the state and its political subdivisions with the implementation of these proposed amendments. This program is funded by the collection of fees from the regulated community as mandated by the Atomic Energy and Radiation Control Act. The Act requires the cost of running the program to be recovered through the collection of fees. See Determination of Costs and Benefits herein.

Statement of Need and Reasonableness:

The statement of need and reasonableness was determined by staff analysis pursuant to S.C. Code Section 1-23-115(C)(1)-(3) and (9)-(11):

DESCRIPTION OF REGULATION: Amendment of Regulation 61-64, *X-Rays (Title B),* Rules and Regulations for Radiation Control.

Purpose: The Department is substantially revising R.61-64, *X-Rays (Title B)* in its entirety. See Synopsis above and Determination of Need and Reasonableness below.

Legal Authority: The Rules and Regulations for Radiation Control (Title B) are authorized by the S.C. Code Section 13-7-45 *et seq.* (1976, as amended). Regulations assessing fees are authorized by Section 13-7-45 (Supp. 1999).

Plan for Implementation: These amendments will make changes to and be incorporated into R.61-64 upon approval of the General Assembly and publication in the State Register. These amendments will be implemented by providing the regulated community with copies of the regulation.

DETERMINATION OF NEED AND REASONABLENESS OF THE REGULATIONS BASED ON ALL FACTORS HEREIN AND EXPECTED BENEFITS:

The changes are needed in order to update existing regulations due to technological advances, incorporate mammography regulations to be compatible with Federal regulations, recover the cost of implementing our program, clarify and strengthen existing requirements, add new requirements that will promote greater health and safety to the public, delete requirements that are no longer applicable, and make stylistic and grammatical changes.

The changes are reasonable because they will be implemented with existing staff.

DETERMINATION OF COSTS AND BENEFITS: This program is funded by the collection of fees from the regulated community as mandated by the Atomic Energy and Radiation Control Act. This Act requires the cost of running the program to be recovered through the collection of fees. The fees have not been increased since 1993. The 1993 increase in fees was based on costs to the program in 1991. Since 1991, the inflation rate has increased 22.7%. Examples of the increase are from $40 to $50 per year for a dental unit and from $60 to $80 per year for a medical radiographic unit. However, there will be some relief from fees for the state's 135 mammography facilities. The Food and Drug Administration currently charges each facility $1549 per year to inspect mammography units, and the Department is proposing to reduce that fee to $1000 per year upon approval to become a certifying body. The total fee to a mammography facility would be reduced from $1549 to $1509.

The Department also proposes to implement a $50 application fee for new facilities. This type of system is currently in place for the tanning facility regulations and will ensure consistency between the programs. The application review process is time consuming and tedious, and this new fee will help recover the cost of this program. In addition, the Department proposes to implement a $50 shielding plan review fee for each shielding plan submitted. This fee will be required of the vendors who submit the plans and should reduce the duplication of plans among vendors competing to sell the same registrant x-ray equipment. The shielding review process is also time consuming and tedious, and the new fee will help recover the cost of this program.

The fees for calibration of x-ray equipment, which have not been increased since 1993, will be increased to account for the increased inflation rate.

UNCERTAINTIES OF ESTIMATES: None.

EFFECT ON ENVIRONMENT AND PUBLIC HEALTH: There will be no effect upon the environment. The amendments will have a positive effect upon the public health of the citizens of the state.

DETRIMENTAL EFFECTS ON THE ENVIRONMENT AND PUBLIC HEALTH IF THE REGULATIONS ARE NOT IMPLEMENTED: There will be no detrimental effects on the environment if these changes are not implemented. The public health of the citizens would not be reduced over that which is present with the current regulations, but it would be increased with more stringent requirements.

Document No. 2585
COMMISSION ON HIGHER EDUCATION
CHAPTER 62
Statutory Authority: 1976 Code Section 59-103-45 (4)(c) and (5)

62-700 through 62-750: Performance Standards and Funding and the Reduction, Expansion, Consolidation or Closure of an Institution

Synopsis:

This regulation amends, replaces, or deletes sections in the current regulation in order to change language to conform to Commission approved changes in the performance funding process, eliminates outdated sections of the regulations, and adds language on institutional reduction, expansion, consolidation or closure as required by 1976 Code, Section 59-103-45 (5).

Sections 700 through 740 provide structure and definition for the implementation of the performance funding process as required by 1976 Code Section 59-103-45 (4).

Section 750 provides for the reduction, expansion, consolidation or closure of an institution as required by 1976 Code Section 59-103-45 (5).

Section-by-Section Discussion of Changes and Additions to Existing Regulations:

Section	Changes
Title	Change the word “Benchmarks” to “Standards” and add the words “and the Reduction, Expansion, Consolidation or Closure of an Institution” to the title.
Section 62-700. Authority	Change the word ”benchmarks” to “standards” and added the phrase on institutional reduction, expansion, consolidation or closure.
Section 62-710. Definitions	Revise definitions to reflect language approved by the Commission, add definitions to include new terms in the regulations, and eliminate definitions for terms no longer used.
Section 62-720. Implementation	Replaced by Section 62-720. Measures and Standards.
Section 62-730. Performance Indicators	Replaced by Section 62-740. Performance Evaluation.
Section 62-740. Development of Measures and Benchmarks	Replaced by Section 62-720. Measures and Standards.
Section 62-750. Development of Performance Funding Allocation Plan	Replaced by Section 62-730. Performance Funding Allocation Plan.
Section 62-760. Review and Reporting to the	Deleted. Elements of this section are contained in

General Assembly	Section 62-720.
New section added	Section 62-750. Process for Review for Reduction, Expansion, Consolidation or Closure is added to comply with requirements in 59-103-45 (5).

Instructions: Replace current 62-700 through 62-760.

Text:

Section 62-700 through 750: Performance Standards and Funding and the Reduction, Expansion, Consolidation or Closure of an Institution

Table of Contents:

Section 62-700.
~~CURRENT LANGUAGE IN REGULAR TYPE~~
~~REVISED OR NEW LANGUAGE IS BOLDED~~
~~MOST RECENT ADDITIONS UNDERLINED~~

~~MOST RECENT DELETIONS STRIKETHROUGH~~

Authority

Pursuant to the authority granted to the Commission on Higher Education by Section 59-103-45 (4)(c) and (5), regulations for the development of standards for performance in higher education; a funding mechanism based on an institution's achievement towards those standards; and the reduction, expansion, consolidation or closure of an institution are hereby established.

Section 62-710. Definitions

As used in this section:

(1) "Critical Success Factors" are the nine performance areas identified in Section 59-103-30(A) of the South Carolina Code of Laws.

(2) "Education and General Costs" are the expenditures associated with the following activities: Instruction, Research, Public Service, Academic Support, Student Services, Institutional Support, Operation and Maintenance of Plant, and Scholarships and Fellowships. Expenditures not included are those associated with Auxiliary Enterprises, Hospitals and Independent Operations.

(3) "Indicators" are the elements found in Section 59-103-30 (B) as approved by the General Assembly to assess the success of a public postsecondary institution in meeting the nine critical success factors identified by the General Assembly.

(4) "Measure" is the specific representation or measurement mechanism of an indicator using quantitative or qualitative characteristics.

(5) "Mission Resource Requirement (MRR) Model" is the mechanism to determine funding needs.

(6) "Performance Category" is the level of overall performance of an institution.

(7) "Performance Improvement Plan" refers to strategies for addressing performance weaknesses and the improvement of specific indicators.

(8) "Performance Rating" is a score based on the analysis of performance in comparison to standards.

(9) "Performance Score" is the overall evaluation of an institution's performance based on Performance Ratings on indicators.

(10) "Sector" refers to groupings of South Carolina's public postsecondary institutions as defined by Section 59-103-15(B), based on their primary missions.

(11) "Standard" is a goal approved by the Commission on Higher Education that an institution strives to meet or exceed.

Section 62-720. Measures and Standards

The Commission on Higher Education will define measures, standards and applicability of performance indicators that will guide the institutions in the State toward nationally and globally competitive performance. These measures and standards will be reviewed for possible revision on a periodic basis as determined by the Commission on Higher Education.

Section 62-730. Performance Funding Allocation Plan

As required by Section 59-103-45(4)(d), the Commission on Higher Education will utilize a mechanism to determine the funding needs of the State's postsecondary education institutions. This methodology, referred to as the Mission Resource Requirement (MRR) model, is based on national and regional data sources. The Commission on Higher Education will determine annually the allocation of available state funds to meet institutional need based on performance in achieving standards.

Section 62-740. Performance Evaluation

A. The Commission on Higher Education will approve a methodology for scoring and assessing overall performance, subject to its periodic review.

B. The Commission on Higher Education will assess annually each institution's performance in relation to standards and the approved scoring methodology.

C. The Commission on Higher Education will approve annually the performance score for each institution in order to ensure that the allocation to each institution can be made known within 10 days of adoption of the Appropriations Bill by the General Assembly.

D. An institution's performance category, based on the institution's performance score, will determine the level of funding for the institution.

E. The data used to evaluate the institutional performance ~~on measures used to assess indicators~~will come from the Commission on Higher Education Management Information System (CHEMIS) and other data received by the Commission on Higher Education. All data utilized, regardless of source, will be subject to approval and audit by the Commission on Higher Education.

F. The Commission on Higher Education will ensure that funds are set aside ~~F~~for which eligible institutions may apply to improve their performance. Criteria for eligibility will be determined by the Commission on Higher Education.

Section 62-750. Process for Review for Reduction, Expansion, Consolidation or Closure

A. The Commission on Higher Education will identify institutions for possible~~annually~~ reduction, expansion, consolidation or closure by reviewing institutions that are unable to achieve standards, as defined by the performance score. Institutions scoring in a performance category indicating standards have not been achieved for two consecutive years will be identified for possible reduction, expansion, consolidation or closure.

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B.~~. Notification of eligibility will be forwarded to the institution's respective~~ Once an institution is identified for possible reduction, expansion, consolidation or closure, the Commission on Higher Education will notify the institution's Board of Trustees, local boards and/or the State Board for Comprehensive and Technical Education, ~~if~~ as applicable.

C. The notified institution will have an opportunity at a meeting of the Commission on Higher Education to appeal its~~it'~~ inclusion in the review process.

D. Following the opportunity for appeal, the Commission on Higher Education will either withdraw the recommendation or proceed with a formal review from which a decision may be made leading to reduction, expansion, consolidation or closure of the institution.

E. The formal review will include a meeting between the Commission on Higher Education and representatives of the institution at which the Commission on Higher Education will identify its expectations for performance improvement.

F. Within ~~thirty~~ ninety days of this meeting, the institution will submit for approval a Performance Improvement Plan to the Commission on Higher Education that addresses the expectations outlined.

(1) The Performance Improvement Plan will include, at a minimum: a strategy for meeting the Commission on Higher Education's expectations, a detailed time table for implementation not to exceed three years, identification of resource requirements, and identification of the assessment strategies to be utilized for assessment and reporting.

(2) The Performance Improvement Plan must be approved by the institution's Board of Trustees, local boards and/or the State Board for Comprehensive and Technical Education, ~~if~~ as applicable.

G. Implementation of the approved Performance Improvement Plan will be monitored by the Commission on Higher Education.

(1) The ~~C~~chief ~~E~~executive ~~O~~officer, or his or her designee, will serve as the contact person for the institution's implementation of the Performance Improvement Plan.

(2) The Commission on Higher Education will review annually the institution's progress in meeting expectations.

(3) Changes to the Performance Improvement Plan must be submitted to and approved by the Commission on Higher Education.

H. The Commission on Higher Education will review the progress of the institution during and/or at the conclusion of its Performance Improvement Plan and make a preliminary decision on the action to be taken. ~~with regard to the institution's performance.~~ In accordance with its adopted policies and procedures, the Commission on Higher Education will decide either to:

(1) Remove the institution from the review process;

(2) Continue monitoring the institution's progress with regard to their performance for a specified amount of time;

(3) Reduce the whole or any part of the institution or the functions thereof;

(4) Expand the whole or any part of the institution or the functions thereof;

(5) Consolidate the whole or any part of the institution or the functions thereof; or

(6) Close the whole or any part of the institution or the functions thereof.

I. A decision to reduce, expand, consolidate or close the whole or any part of the institution may include fiscal allocations, departments, programs, and/or infrastructure. In accordance with its adopted policies and procedures and in the event of a reduction, expansion, consolidation or closure of the whole or any part of the institution, the Commission on Higher Education will proceed with action based on the recommendations of appropriate ~~agency~~ committees of the Commission on Higher Education.

J. The Commission on Higher Education will present its decision as a preliminary report, following which the institution will ~~be provided~~have the opportunity to ~~be heard~~respond at a public hearing called by the Commission on Higher Education. The public hearing will be held no earlier than thirty days after presentation of the report. ~~, held at least thirty days after notification by the Commission on Higher Education, to address the Commission on Higher Education's preliminary decision before a final report is issued.~~

K. Upon receipt of testimony at such hearing, and pursuant to any other research or inquiries it deems appropriate, the Commission on Higher Education will report its findings and final decision to the institution's respective boards, as applicable, the President Pro Tempore of the Senate, the Speaker of the House of Representatives, and the Governor.

(1) In the event that the Commission on Higher Education should determine to reduce, expand or consolidate an institution, the Commission on Higher Education will provide for the redistribution of allocated funds from institutions reduced to those which are required to take on additional duties. Any residual dollars will be reallocated in a manner prescribed by the Commission on Higher Education. Such action shall occur no later than the last day (June 30) of the next complete fiscal year for the purpose of providing institutions time to make the determined changes in institutional configuration.

(2) In the event that the Commission on Higher Education should determine to reduce, expand or consolidate an institution, that institution shall develop a comprehensive plan for that process to be presented to the Commission on Higher Education for approval within 90 days of the announcement of reduction, expansion or consolidation.

(3) In the event that the Commission on Higher Education finds it necessary to close an institution, that institution may be continued in existence no later than the last day (June 30) of the next complete fiscal year for the purpose of winding up its affairs, at which time it shall cease all activities. Any remaining funds will not revert to the general fund but instead will be reallocated to higher education funding through use of the funding formula in the manner the Commission on Higher Education shall determine as provided by SC Code of Laws, Section 59-103-65.

(4) In the event that the Commission on Higher Education finds it necessary to close an institution, that institution shall develop a comprehensive plan for the closure process, including specific procedures to ensure the preservation of student records and the transfer of students to other institutions as necessary. The plan shall be presented to the Commission on Higher Education for approval within 90 days of the announcement of closure.

(5) Termination of an institution shall not cause the dismissal of any claim or right of a citizen against any such institution or any claim or right of an institution terminated pursuant to these regulations which is subject to litigation.

Fiscal Impact Statement: The staff estimates that there will be no additional costs incurred by the State or any political subdivision.

Document No. 2551
DEPARTMENT OF INSURANCE
Chapter 69
Statutory Authority: 1976 Code Sections 38-3-110, et seq., 1-23-110, et seq., 38-9-180, et seq.

69-57. Valuation of Life Insurance Policies

Synopsis:

THIS REGULATION WILL PROVIDE CLARIFICATION OF THE APPROPRIATE RESERVE METHODOLOGY FOR LIFE INSURANCE POLICIES. FURTHERMORE, THIS REGULATION MAY AFFECT CURRENT RESERVING PRACTICES WITH RESPECT TO TERM AND TERM-LIKE POLICIES.

Instructions: Add new R. 69-57, Valuation of Life Insurance Policies, to Chapter 69 regulations.

Text:

R. 69-57. Valuation of Life Insurance Policies

Table of Contents

Section 1. Purpose

A. The purpose of this regulation is to provide:

(1) Tables of select mortality factors and rules for their use;

(2) Rules concerning a minimum standard for the valuation of plans with nonlevel premiums or benefits; and

(3) Rules concerning a minimum standard for the valuation of plans with secondary guarantees.

B. The method for calculating basic reserves defined in this regulation will constitute the Commissioners' Reserve Valuation Method for policies to which this regulation is applicable.

Section 2. Authority

This regulation is issued under the authority of Section 38-9-180 of the Insurance Laws of South Carolina.

Section 3. Applicability

This regulation shall apply to all life insurance policies, with or without nonforfeiture values, issued on or after the effective date of this regulation, subject to the following exceptions and conditions.

A. EXCEPTIONS

(1) This regulation shall not apply to any individual life insurance policy issued on or after the effective date of this regulation if the policy is issued in accordance with and as a result of the exercise of a reentry provision contained in the original life insurance policy of the same or greater face amount, issued before the effective date of this regulation, that guarantees the premium rates of the new policy. This regulation also shall not apply to subsequent policies issued as a result of the exercise of such a provision, or a derivation of the provision, in the new policy.

(2) This regulation shall not apply to any universal life policy that meets all the following requirements:

(a) Secondary guarantee period, if any, is five (5) years or less;

(b) Specified premium for the secondary guarantee period is not less than the net level reserve premium for the secondary guarantee period based on the CSO valuation tables as defined in Section 4F and the applicable valuation interest rate; and

(c) The initial surrender charge is not less than 100 percent of the first year annualized specified premium for the secondary guarantee period.

(3) This regulation shall not apply to any variable life insurance policy that provides for life insurance, the amount or duration of which varies according to the investment experience of any separate account or accounts.

(4) This regulation shall not apply to any variable universal life insurance policy that provides for life insurance, the amount or duration of which varies according to the investment experience of any separate account or accounts.

(5) This regulation shall not apply to a group life insurance certificate unless the certificate provides for a stated or implied schedule of maximum gross premiums required in order to continue coverage in force for a period in excess of one year.

B. CONDITIONS

(1) Calculation of the minimum valuation standard for policies with guaranteed nonlevel gross premiums or guaranteed nonlevel benefits (other than universal life policies), or both, shall be in accordance with the provisions of Section 6.

(2) Calculation of the minimum valuation standard for flexible premium and fixed premium universal life insurance policies, that contain provisions resulting in the ability of a policyholder to keep a policy in force over a secondary guarantee period shall be in accordance with the provisions of Section 7.

Section 4. Definitions

For purposes of this regulation:

A. "Basic reserves" means reserves calculated in accordance with South Carolina Code § 38-9-180 (Standard Valuation Law).

B. "Contract segmentation method" means the method of dividing the period from issue to mandatory expiration of a policy into successive segments, with the length of each segment being defined as the period from the end of the prior segment (from policy inception, for the first segment) to the end of the latest policy year as determined below. All calculations are made using the 1980 CSO valuation tables, as defined in Subsection F of this section, (or any other valuation mortality table adopted by the National Association of Insurance Commissioners (NAIC) after the effective date of this regulation and promulgated by regulation by the director for this purpose), and, if elected, the optional minimum mortality standard for deficiency reserves stipulated in Section 5B of this regulation.

The length of a particular contract segment shall be set equal to the minimum of the value *t* for which G_t is greater than R_t (if G_t never exceeds R_t the segment length is deemed to be the number of years from the beginning of the segment to the mandatory expiration date of the policy), where G_t and R_t are defined as follows:

$$G_t = \frac{GP_{x+k+t}}{\quad}$$

$GP_{x+k+t-1}$

where:

x = original issue age;

k = the number of years from the date of issue to the beginning of the segment;

t = 1, 2, ...; *t* is reset to 1 at the beginning of each segment;

$GP_{x+k+t-1}$ = Guaranteed gross premium per thousand of face amount for year *t* of the segment, ignoring policy fees only if level for the premium paying period of the policy.

$R_t = \frac{q_{x+k+t}}{q_{x+k+t-1}}$, However, R_t may be increased or decreased by one percent in any policy year, at the company's option, but R_t shall not be less than one;

where:

x, k and t are as defined above, and

$q_{x+k+t-1}$ =valuation mortality rate for deficiency reserves in policy year k+t but using the mortality of Section 5B(2) if Section 5B(3) is elected for deficiency reserves.

However, if GP_{x+k+t} is greater than 0 and $GP_{x+k+t-1}$ is equal to 0, G_t shall be deemed to be 1000. If GP_{x+k+t} and $GP_{x+k+t-1}$ are both equal to 0, G_t shall be deemed to be 0.

C. "DEFICIENCY RESERVES" MEANS THE EXCESS, IF GREATER THAN ZERO, OF

(1) Minimum reserves calculated in accordance with South Carolina Code §38-9-180/Standard Valuation Law over

(2) Basic reserves.

D. "Guaranteed gross premiums" means the premiums under a policy of life insurance that are guaranteed and determined at issue.

E. "Maximum valuation interest rates" means the interest rates defined in South Carolina Code §38-9-180 (Computation of Minimum Standard by Calendar Year of Issue) that are to be used in determining the minimum standard for the valuation of life insurance policies.

F. "1980 CSO valuation tables" means the Commissioners' 1980 Standard Ordinary Mortality Table (1980 CSO Table) without ten-year selection factors, incorporated into the 1980 amendments to the NAIC Standard Valuation Law, and variations of the 1980 CSO Table approved by the NAIC, such as the smoker and nonsmoker versions approved in December 1983.

G. "Scheduled gross premium" means the smallest illustrated gross premium at issue for other than universal life insurance policies. For universal life insurance policies, scheduled gross

premium means the smallest specified premium described in Section 7A(3), if any, or else the minimum premium described in Section 7A(4).

H. (1) "Segmented reserves" means reserves, calculated using segments produced by the contract segmentation method, equal to the present value of all future guaranteed benefits less the present value of all future net premiums to the mandatory expiration of a policy, where the net premiums within each segment are a uniform percentage of the respective guaranteed gross premiums within the segment. The uniform percentage for each segment is such that, at the beginning of the segment, the present value of the net premiums within the segment equals:

(a) The present value of the death benefits within the segment, plus

(b) The present value of any unusual guaranteed cash value (see Section 6D) occurring at the end of the segment, less

(c) Any unusual guaranteed cash value occurring at the start of the segment, plus

(d) For the first segment only, the excess of the Item (i) over Item (ii), as follows:

(i) A net level annual premium equal to the present value, at the date of issue, of the benefits provided for in the first segment after the first policy year, divided by the present value, at the date of issue, of an annuity of one per year payable on the first and each subsequent anniversary within the first segment on which a premium falls due. However, the net level annual premium shall not exceed the net level annual premium on the nineteen-year premium whole life plan of insurance of the same renewal year equivalent level amount at an age one year higher than the age at issue of the policy.

(ii) A net one year term premium for the benefits provided for in the first policy year.

(2) The length of each segment is determined by the "contract segmentation method," as defined in this section.

(3) The interest rates used in the present value calculations for any policy may not exceed the maximum valuation interest rate, determined with a guarantee duration equal to the sum of the lengths of all segments of the policy.

(4) For both basic reserves and deficiency reserves computed by the segmented method, present values shall include future benefits and net premiums in the current segment and in all subsequent segments.

I. "Tabular cost of insurance" means the net single premium at the beginning of a policy year for one-year term insurance in the amount of the guaranteed death benefit in that policy year.

J. "Ten-year select factors" means the select factors adopted with the 1980 amendments to the NAIC Standard Valuation Law.

K. (1) "Unitary reserves" means the present value of all future guaranteed benefits less the present value of all future modified net premiums, where:

(a) Guaranteed benefits and modified net premiums are considered to the mandatory expiration of the policy; and

(b) Modified net premiums are a uniform percentage of the respective guaranteed gross premiums, where the uniform percentage is such that, at issue, the present value of the net premiums

equals the present value of all death benefits and pure endowments, plus the excess of Item (i) over Item (ii), as follows:

(i) A net level annual premium equal to the present value, at the date of issue, of the benefits provided for after the first policy year, divided by the present value, at the date of issue, of an annuity of one per year payable on the first and each subsequent anniversary of the policy on which a premium falls due. However, the net level annual premium shall not exceed the net level annual premium on the nineteen-year premium whole life plan of insurance of the same renewal year equivalent level amount at an age one year higher than the age at issue of the policy.

(ii) A net one year term premium for the benefits provided for in the first policy year.

(2) The interest rates used in the present value calculations for any policy may not exceed the maximum valuation interest rate, determined with a guarantee duration equal to the length from issue to the mandatory expiration of the policy.

L. "Universal life insurance policy" means any individual life insurance policy under the provisions of which separately identified interest credits (other than in connection with dividend accumulations, premium deposit funds, or other supplementary accounts) and mortality or expense charges are made to the policy.

Section 5. General Calculation Requirements for Basic Reserves and Premium Deficiency Reserves

A. At the election of the company for any one or more specified plans of life insurance, the minimum mortality standard for basic reserves may be calculated using the 1980 CSO valuation tables with select mortality factors (or any other valuation mortality table adopted by the NAIC after the effective date of this regulation and promulgated by regulation by the director for this purpose). If select mortality factors are elected, they may be:

(1) The ten-year select mortality factors incorporated into the 1980 amendments to the NAIC Standard Valuation Law;

(2) The select mortality factors in the Appendix; or

(3) Any other table of select mortality factors adopted by the NAIC after the effective date of this regulation and promulgated by regulation by the director for the purpose of calculating basic reserves.

B. Deficiency reserves, if any, are calculated for each policy as the excess, if greater than zero, of the quantity A over the basic reserve. The quantity A is obtained by recalculating the basic reserve for the policy using guaranteed gross premiums instead of net premiums when the guaranteed gross premiums are less than the corresponding net premiums. At the election of the company for any one or more specified plans of insurance, the quantity A and the corresponding net premiums used in the determination of quantity A may be based upon the 1980 CSO valuation tables with select mortality factors (or any other valuation mortality table adopted by the NAIC after the effective date of this regulation and promulgated by regulation by the director). If select mortality factors are elected, they may be:

(1) The ten-year select mortality factors incorporated into the 1980 amendments to the NAIC Standard Valuation Law;

(2) The select mortality factors in the Appendix of this regulation;

(3) For durations in the first segment, X percent of the select mortality factors in the Appendix, subject to the following:

(a) X may vary by policy year, policy form, underwriting classification, issue age, or any other policy factor expected to affect mortality experience;

(b) X shall not be less than twenty percent (20%);

(c) X shall not decrease in any successive policy years;

(d) X is such that, when using the valuation interest rate used for basic reserves, Item (i) is greater than or equal to Item (ii);

(i) The actuarial present value of future death benefits, calculated using the mortality rates resulting from the application of X;

(ii) The actuarial present value of future death benefits calculated using anticipated mortality experience without recognition of mortality improvement beyond the valuation date;

(e) X is such that the mortality rates resulting from the application of X are at least as great as the anticipated mortality experience, without recognition of mortality improvement beyond the valuation date, in each of the first five (5) years after the valuation date;

(f) The appointed actuary shall increase X at any valuation date where it is necessary to continue to meet all the requirements of Subsection B(3);

(g) The appointed actuary may decrease X at any valuation date as long as X does not decrease in any successive policy years and as long as it continues to meet all the requirements of Subsection B(3); and

(h) The appointed actuary shall specifically take into account the adverse effect on expected mortality and lapsation of any anticipated or actual increase in gross premiums.

(i) If X is less than 100 percent at any duration for any policy, the following requirements shall be met:

(i) The appointed actuary shall annually prepare an actuarial opinion and memorandum for the company in conformance with the requirements of Regulation 69-52; and

(ii) The appointed actuary shall annually opine for all policies subject to this regulation as to whether the mortality rates resulting from the application of X meet the requirements of Subsection B(3). This opinion shall be supported by an actuarial report, subject to appropriate Actuarial Standards of Practice promulgated by the Actuarial Standards Board of the American Academy of Actuaries. The X factors shall reflect anticipated future mortality, without recognition of mortality improvement beyond the valuation date, taking into account relevant emerging experience.

(4) Any other table of select mortality factors adopted by the NAIC after the effective date of this regulation and promulgated by regulation by the director for the purpose of calculating deficiency reserves.

C. This subsection applies to both basic reserves and deficiency reserves. Any set of select mortality factors may be used only for the first segment. However, if the first segment is less than ten (10) years, the appropriate ten-year select mortality factors incorporated into the 1980 amendments to the NAIC Standard Valuation Law may be used thereafter through the tenth policy year from the date of issue.

D. In determining basic reserves or deficiency reserves, guaranteed gross premiums without policy fees may be used where the calculation involves the guaranteed gross premium but only if the policy fee is a level dollar amount after the first policy year. In determining deficiency reserves, policy fees may be included in guaranteed gross premiums, even if not included in the actual calculation of basic reserves.

E. Reserves for policies that have changes to guaranteed gross premiums, guaranteed benefits, guaranteed charges, or guaranteed credits that are unilaterally made by the insurer after issue and that are effective for more than one year after the date of the change shall be the greatest of the following: (1) reserves calculated ignoring the guarantee, (2) reserves assuming the guarantee was made at issue, and (3) reserves assuming that the policy was issued on the date of the guarantee.

F. The director may require that the company document the extent of the adequacy of reserves for specified blocks, including but not limited to policies issued prior to the effective date of this regulation. This documentation may include a demonstration of the extent to which aggregation with other non-specified blocks of business is relied upon in the formation of the appointed actuary opinion pursuant to and consistent with the requirements of Regulation 69-52.

Section 6. Calculation of Minimum Valuation Standard for Policies with Guaranteed Nonlevel Gross Premiums or Guaranteed Nonlevel Benefits (Other than Universal Life Policies)

A. BASIC RESERVES

Basic reserves shall be calculated as the greater of the segmented reserves and the unitary reserves. Both the segmented reserves and the unitary reserves for any policy shall use the same valuation mortality table and selection factors. At the option of the insurer, in calculating segmented reserves and net premiums, either of the adjustments described in Paragraph (1) or (2) below may be made:

(1) Treat the unitary reserve, if greater than zero, applicable at the end of each segment as a pure endowment and subtract the unitary reserve, if greater than zero, applicable at the beginning of each segment from the present value of guaranteed life insurance and endowment benefits for each segment.

(2) Treat the guaranteed cash surrender value, if greater than zero, applicable at the end of each segment as a pure endowment; and subtract the guaranteed cash surrender value, if greater than zero, applicable at the beginning of each segment from the present value of guaranteed life insurance and endowment benefits for each segment.

B. Deficiency Reserves

(1) The deficiency reserve at any duration shall be calculated:

(a) On a unitary basis if the corresponding basic reserve determined by Subsection A is unitary;

(b) On a segmented basis if the corresponding basic reserve determined by Subsection A is segmented; or

(c) On the segmented basis if the corresponding basic reserve determined by Subsection A is equal to both the segmented reserve and the unitary reserve.

(2) This subsection shall apply to any policy for which the guaranteed gross premium at any duration is less than the corresponding modified net premium calculated by the method used in determining the basic reserves, but using the minimum valuation standards of mortality (specified in Section 5B) and rate of interest.

(3) Deficiency reserves, if any, shall be calculated for each policy as the excess if greater than zero, for the current and all remaining periods, of the quantity A over the basic reserve, where A is obtained as indicated in Section 5B.

(4) For deficiency reserves determined on a segmented basis, the quantity A is determined using segment lengths equal to those determined for segmented basic reserves.

C. Minimum Value

Basic reserves may not be less than the tabular cost of insurance for the balance of the policy year, if mean reserves are used. Basic reserves may not be less than the tabular cost of insurance for the balance of the current modal period or to the paid-to-date, if later, but not beyond the next policy anniversary, if mid-terminal reserves are used. The tabular cost of insurance shall use the same valuation mortality table and interest rates as that used for the calculation of the segmented reserves. However, if select mortality factors are used, they shall be the ten-year select factors incorporated into the 1980 amendments of the NAIC Standard Valuation Law. In no case may total reserves (including basic reserves, deficiency reserves and any reserves held for supplemental benefits that would expire upon contract termination) be less than the amount that the policyowner would receive (including the cash surrender value of the supplemental benefits, if any, referred to above), exclusive of any deduction for policy loans, upon termination of the policy.

D. Unusual Pattern of Guaranteed Cash Surrender Values

(1) For any policy with an unusual pattern of guaranteed cash surrender values, the reserves actually held prior to the first unusual guaranteed cash surrender value shall not be less than the reserves calculated by treating the first unusual guaranteed cash surrender value as a pure endowment and treating the policy as an *n* year policy providing term insurance plus a pure endowment equal to the unusual cash surrender value, where *n* is the number of years from the date of issue to the date the unusual cash surrender value is scheduled.

(2) The reserves actually held subsequent to any unusual guaranteed cash surrender value shall not be less than the reserves calculated by treating the policy as an *n* year policy providing term insurance plus a pure endowment equal to the next unusual guaranteed cash surrender value, and treating any unusual guaranteed cash surrender value at the end of the prior segment as a net single premium, where

(a) *n* is the number of years from the date of the last unusual guaranteed cash surrender value prior to the valuation date to the earlier of:

(i) The date of the next unusual guaranteed cash surrender value, if any, that is scheduled after the valuation date; or

(ii) The mandatory expiration date of the policy; and

(b) The net premium for a given year during the *n* year period is equal to the product of the net to gross ratio and the respective gross premium; and

(c) The net to gross ratio is equal to Item (i) divided by Item (ii) as follows:

(i) The present value, at the beginning of the *n* year period, of death benefits payable during the *n* year period plus the present value, at the beginning of the n year period, of the next unusual guaranteed cash surrender value, if any, minus the amount of the last unusual guaranteed cash surrender value, if any, scheduled at the beginning of the *n* year period.

(ii) The present value, at the beginning of the *n* year period, of the scheduled gross premiums payable during the *n* year period.

(3) For purposes of this subsection, a policy is considered to have an unusual pattern of guaranteed cash surrender values if any future guaranteed cash surrender value exceeds the prior year's guaranteed cash surrender value by more than the sum of:

(a) One hundred ten percent (110%) of the scheduled gross premium for that year;

(b) One hundred ten percent (110%) of one year's accrued interest on the sum of the prior year's guaranteed cash surrender value and the scheduled gross premium using the nonforfeiture interest rate used for calculating policy guaranteed cash surrender values; and

(c) Five percent (5%) of the first policy year surrender charge, if any.

E. Optional Exemption for Yearly Renewable Term Reinsurance. At the option of the company, the following approach for reserves on YRT reinsurance may be used:

(1) Calculate the valuation net premium for each future policy year as the tabular cost of insurance for that future year.

(2) Basic reserves shall never be less than the tabular cost of insurance for the appropriate period, as defined in Subsection C.

(3) Deficiency reserves.

(a) For each policy year, calculate the excess, if greater than zero, of the valuation net premium over the respective maximum guaranteed gross premium.

(b) Deficiency reserves shall never be less than the sum of the present values, at the date of valuation, of the excesses determined in accordance with Subparagraph (a) above.

(4) For purposes of this subsection, the calculations use the maximum valuation interest rate and the 1980 CSO mortality tables with or without ten-year select mortality factors, or any other table adopted after the effective date of this regulation by the NAIC and promulgated by regulation by the director for this purpose.

(5) A reinsurance agreement shall be considered YRT reinsurance for purposes of this subsection if only the mortality risk is reinsured.

(6) If the assuming company chooses this optional exemption, the ceding company's reinsurance reserve credit shall be limited to the amount of reserve held by the assuming company for the affected policies.

F. Optional Exemption for Attained-Age-Based Yearly Renewable Term Life Insurance Policies. At the option of the company, the following approach for reserves for attained-age-based YRT life insurance policies may be used:

(1) Calculate the valuation net premium for each future policy year as the tabular cost of insurance for that future year.

(2) Basic reserves shall never be less than the tabular cost of insurance for the appropriate period, as defined in Subsection 6C.

(3) Deficiency reserves.

(a) For each policy year, calculate the excess, if greater than zero, of the valuation net premium over the respective maximum guaranteed gross premium.

(b) Deficiency reserves shall never be less than the sum of the present values, at the date of valuation, of the excesses determined in accordance with Subparagraph (a) above.

(4) For purposes of this subsection, the calculations use the maximum valuation interest rate and the 1980 CSO valuation tables with or without ten-year select mortality factors, or any other table adopted after the effective date of this regulation by the NAIC and promulgated by regulation by the director for this purpose.

(5) A policy shall be considered an attained-age-based YRT life insurance policy for purposes of this subsection if:

(a) The premium rates (on both the initial current premium scale and the guaranteed maximum premium scale) are based upon the attained age of the insured such that the rate for any given policy at a given attained age of the insured is independent of the year the policy was issued; and

(b) The premium rates (on both the initial current premium scale and the guaranteed maximum premium scale) are the same as the premium rates for policies covering all insureds of the same sex, risk class, plan of insurance and attained age.

(6) For policies that become attained-age-based YRT policies after an initial period of coverage, the approach of this subsection may be used after the initial period if:

(a) The initial period is constant for all insureds of the same sex, risk class and plan of insurance; or

(b) The initial period runs to a common attained age for all insureds of the same sex, risk class and plan of insurance; and

(c) After the initial period of coverage, the policy meets the conditions of Paragraph (5) above.

(7) If this election is made, this approach shall be applied in determining reserves for all attained-age-based YRT life insurance policies issued on or after the effective date of this regulation.

G. Exemption from Unitary Reserves for Certain *n*-Year Renewable Term Life Insurance Polices. Unitary basic reserves and unitary deficiency reserves need not be calculated for a policy if the following conditions are met:

(1) The policy consists of a series of *n*-year periods, including the first period and all renewal periods, where *n* is the same for each period, except that for the final renewal period, n may be truncated or extended to reach the expiry age, provided that this final renewal period is less than 10 years and less than twice the size of the earlier n-year periods, and for each period, the premium rates on both the initial current premium scale and the guaranteed maximum premium scale are level;

(2) The guaranteed gross premiums in all *n*-year periods are not less than the corresponding net premiums based upon the 1980 CSO Table with or without the ten-year select mortality factors; and

(3) There are no cash surrender values in any policy year.

H. Exemption from Unitary Reserves for Certain Juvenile Policies

Unitary basic reserves and unitary deficiency reserves need not be calculated for a policy if the following conditions are met, based upon the initial current premium scale at issue:

(1) At issue, the insured is age twenty-four (24) or younger;

(2) Until the insured reaches the end of the juvenile period, which shall occur at or before age twenty-five (25), the gross premiums and death benefits are level, and there are no cash surrender values; and

(3) After the end of the juvenile period, gross premiums are level for the remainder of the premium paying period, and death benefits are level for the remainder of the life of the policy.

Section 7. Calculation of Minimum Valuation Standard for Flexible Premium and Fixed Premium Universal Life Insurance Policies That Contain Provisions Resulting in the Ability of a Policyowner to Keep a Policy in Force Over a Secondary Guarantee Period

A. General

(1) Policies with a secondary guarantee include:

(a) A policy with a guarantee that the policy will remain in force at the original schedule of benefits, subject only to the payment of specified premiums;

(b) A policy in which the minimum premium at any duration is less than the corresponding one year valuation premium, calculated using the maximum valuation interest rate and the 1980 CSO valuation tables with or without ten-year select mortality factors, or any other table adopted after the effective date of this regulation by the NAIC and promulgated by regulation by the director for this purpose; or

(c) A policy with any combination of Subparagraph (a) and (b).

(2) A secondary guarantee period is the period for which the policy is guaranteed to remain in force subject only to a secondary guarantee. When a policy contains more than one secondary guarantee, the minimum reserve shall be the greatest of the respective minimum reserves at that valuation date of each unexpired secondary guarantee, ignoring all other secondary guarantees. Secondary guarantees that are unilaterally changed by the insurer after issue shall be considered to have been made at issue. Reserves described in Subsections B and C below shall be recalculated from issue to reflect these changes.

(3) Specified premiums mean the premiums specified in the policy, the payment of which guarantees that the policy will remain in force at the original schedule of benefits, but which otherwise would be insufficient to keep the policy in force in the absence of the guarantee if maximum mortality and expense charges and minimum interest credits were made and any applicable surrender charges were assessed.

(4) For purposes of this section, the minimum premium for any policy year is the premium that, when paid into a policy with a zero account value at the beginning of the policy year, produces a zero account value at the end of the policy year. The minimum premium calculation shall use the policy cost factors (including mortality charges, loads and expense charges) and the interest crediting rate, which are all guaranteed at issue.

(5) The one-year valuation premium means the net one-year premium based upon the original schedule of benefits for a given policy year. The one-year valuation premiums for all policy years are calculated at issue. The select mortality factors defined in Section 5B(2), (3), and (4) may not be used to calculate the one-year valuation premiums.

(6) The one-year valuation premium should reflect the frequency of fund processing, as well as the distribution of deaths assumption employed in the calculation of the monthly mortality charges to the fund.

B. Basic Reserves for the Secondary Guarantees

Basic reserves for the secondary guarantees shall be the segmented reserves for the secondary guarantee period. In calculating the segments and the segmented reserves, the gross premiums shall be set equal to the specified premiums, if any, or otherwise to the minimum premiums, that keep the policy in force and the segments will be determined according to the contract segmentation method as defined in Section 4B.

C. Deficiency Reserves for the Secondary Guarantees

Deficiency reserves, if any, for the secondary guarantees shall be calculated for the secondary guarantee period in the same manner as described in Section 6B with gross premiums set equal to the specified premiums, if any, or otherwise to the minimum premiums that keep the policy in force.

D. Minimum Reserves

The minimum reserves during the secondary guarantee period are the greater of:

(1) The basic reserves for the secondary guarantee plus the deficiency reserve, if any, for the secondary guarantees; or

(2) The minimum reserves required by other rules or regulations governing universal life plans.

Section 8. This regulation will take effect January 1, 2002.

APPENDIX

SELECT MORTALITY FACTORS

This appendix contains tables of select mortality factors that are the bases to which the respective percentage of Section 5A(2), 5B(2) and 5B(3) are applied.

The six tables of select mortality factors contained herein include: (1) male aggregate, (2) male nonsmoker, (3) male smoker, (4) female aggregate, (5) female nonsmoker, and (6) female smoker.

These tables apply to both age last birthday and age nearest birthday mortality tables.

For sex-blended mortality tables, compute select mortality factors in the same proportion as the underlying mortality. For example, for the 1980 CSO-B Table, the calculated select mortality factors are eighty percent (80%) of the appropriate male table in this Appendix, plus twenty percent (20%) of the appropriate female table in this Appendix.

APPENDIX

SELECT MORTALITY FACTORS

Male, Aggregate

Issue	Duration																			
Age	**1**	**2**	**3**	**4**	**5**	**6**	**7**	**8**	**9**	**10**	**11**	**12**	**13**	**14**	**15**	**16**	**17**	**18**	**19**	**20+**
0-15	100	100	100	100	100	100	100	100	100	100	100	100	100	100	100	100	100	100	100	100
16	100	100	100	100	100	100	100	100	100	100	100	100	100	100	100	100	100	100	100	100
17	100	100	100	100	100	100	100	100	100	100	100	100	100	100	100	100	100	100	100	100
18	96	98	98	99	99	100	100	90	92	92	92	92	93	93	96	97	98	98	99	100
19	83	84	84	87	87	87	79	79	79	81	81	82	82	82	85	88	91	94	97	100
20	69	71	71	74	74	69	69	67	69	70	71	71	71	71	74	79	84	90	95	100
21	66	68	69	71	66	66	67	66	67	70	70	70	70	71	71	77	83	88	94	100
22	65	66	66	63	63	64	64	64	65	68	68	68	68	69	71	77	83	88	94	100
23	62	63	59	60	62	62	63	63	64	65	65	67	67	69	70	76	82	88	94	100
24	60	56	56	59	59	60	61	61	61	64	64	64	66	67	70	76	82	88	94	100
25	52	53	55	56	58	58	60	60	60	63	62	63	64	67	69	75	81	88	94	100
26	51	52	55	56	58	58	57	61	61	62	63	64	66	69	66	73	80	86	93	100
27	51	52	55	57	58	60	61	61	60	63	63	64	67	66	67	74	80	87	93	100
28	49	51	56	58	60	60	61	62	62	63	64	66	65	66	68	74	81	87	94	100
29	49	51	56	58	60	61	62	62	62	64	64	62	66	67	70	76	82	88	94	100
30	49	50	56	58	60	60	62	63	63	64	62	63	67	68	71	77	83	88	94	100
31	47	50	56	58	60	62	63	64	64	62	63	66	68	70	72	78	83	89	94	100
32	46	49	56	59	60	62	63	66	62	63	66	67	70	72	73	78	84	89	95	100
33	43	49	56	59	62	63	64	62	65	66	67	70	72	73	75	80	85	90	95	100
34	42	47	56	60	62	63	61	63	66	67	70	71	73	75	76	81	86	90	95	100
35	40	47	56	60	63	61	62	65	67	68	71	73	74	76	76	81	86	90	95	100
36	38	42	56	60	59	61	63	65	67	68	70	72	74	76	77	82	86	91	95	100
37	38	45	56	57	61	62	63	65	67	68	70	72	74	76	76	81	86	90	95	100
38	37	44	53	58	61	62	65	66	67	69	69	73	75	76	77	82	86	91	95	100
39	37	41	53	58	62	63	65	65	66	68	69	72	74	76	76	81	86	90	95	100
40	34	40	53	58	62	63	65	65	66	68	68	71	75	76	77	82	86	91	95	100

Male, Aggregate

Issue	Duration																			
Age	**1**	**2**	**3**	**4**	**5**	**6**	**7**	**8**	**9**	**10**	**11**	**12**	**13**	**14**	**15**	**16**	**17**	**18**	**19**	**20+**
41	34	41	53	58	62	63	65	64	64	66	68	70	74	76	77	82	86	91	95	100
42	34	43	53	58	61	62	63	63	63	64	66	69	72	75	77	82	86	91	95	100
43	34	43	54	59	60	61	63	62	62	64	66	67	72	74	77	82	86	91	95	100
44	34	44	54	58	59	60	61	60	61	62	64	67	71	74	77	82	86	91	95	100
45	34	45	53	58	59	60	60	60	59	60	63	66	71	74	77	82	86	91	95	100
46	31	43	52	56	57	58	59	59	59	60	63	67	71	74	75	80	85	90	95	100
47	32	42	50	53	55	56	57	58	59	60	65	68	71	74	75	80	85	90	95	100
48	32	41	47	52	54	56	57	57	57	61	65	68	72	73	74	79	84	90	95	100
49	30	40	46	49	52	54	55	56	57	61	66	69	72	73	74	79	84	90	95	100
50	30	38	44	47	51	53	54	56	57	61	66	71	72	73	75	80	85	90	95	100
51	28	37	42	46	49	53	54	56	57	61	66	71	72	73	75	80	85	90	95	100
52	28	35	41	45	49	51	54	56	57	61	66	71	72	74	75	80	85	90	100	100
53	27	35	39	44	48	51	53	55	57	61	67	71	74	75	76	81	86	100	100	100
54	27	33	38	44	48	50	53	55	57	61	67	72	74	75	76	81	100	100	100	100
55	25	32	37	43	47	50	53	55	57	61	68	72	74	75	78	100	100	100	100	100
56	25	32	37	43	47	49	51	54	56	61	67	70	73	74	100	100	100	100	100	100
57	24	31	38	43	47	49	51	54	56	59	66	69	72	100	100	100	100	100	100	100
58	24	31	38	43	48	48	50	53	56	59	64	67	100	100	100	100	100	100	100	100
59	23	30	39	43	48	48	51	53	55	58	63	100	100	100	100	100	100	100	100	100
60	23	30	39	43	48	47	50	52	53	57	100	100	100	100	100	100	100	100	100	100
61	23	30	39	43	49	49	50	52	53	75	100	100	100	100	100	100	100	100	100	100
62	23	30	39	44	49	49	51	52	75	75	100	100	100	100	100	100	100	100	100	100
63	22	30	39	45	50	50	52	75	75	75	100	100	100	100	100	100	100	100	100	100
64	22	30	39	45	50	51	75	75	75	75	100	100	100	100	100	100	100	100	100	100
65	22	30	39	45	50	65	70	70	70	70	100	100	100	100	100	100	100	100	100	100
66	22	30	39	45	60	65	70	70	70	70	100	100	100	100	100	100	100	100	100	100
67	22	30	39	60	60	65	70	70	70	70	100	100	100	100	100	100	100	100	100	100
68	23	32	55	60	60	65	70	70	70	70	100	100	100	100	100	100	100	100	100	100
69	23	52	55	60	60	65	70	70	70	70	100	100	100	100	100	100	100	100	100	100
70	48	52	55	60	60	65	70	70	70	70	100	100	100	100	100	100	100	100	100	100

Male, Aggregate

Issue	Duration																			
Age	**1**	**2**	**3**	**4**	**5**	**6**	**7**	**8**	**9**	**10**	**11**	**12**	**13**	**14**	**15**	**16**	**17**	**18**	**19**	**20+**
71	48	52	55	60	60	65	70	70	70	70	100	100	100	100	100	100	100	100	100	100
72	48	52	55	60	60	65	70	70	70	70	100	100	100	100	100	100	100	100	100	100
73	48	52	55	60	60	65	70	70	70	70	100	100	100	100	100	100	100	100	100	100
74	48	52	55	60	60	65	70	70	70	70	100	100	100	100	100	100	100	100	100	100
75	48	52	55	60	60	65	70	70	70	70	100	100	100	100	100	100	100	100	100	100
76	48	52	55	60	60	65	70	70	70	100	100	100	100	100	100	100	100	100	100	100
77	48	52	55	60	60	65	70	70	100	100	100	100	100	100	100	100	100	100	100	100
78	48	52	55	60	60	65	70	100	100	100	100	100	100	100	100	100	100	100	100	100
79	48	52	55	60	60	65	100	100	100	100	100	100	100	100	100	100	100	100	100	100
80	48	52	55	60	60	100	100	100	100	100	100	100	100	100	100	100	100	100	100	100
81	48	52	55	60	100	100	100	100	100	100	100	100	100	100	100	100	100	100	100	100
82	48	52	55	100	100	100	100	100	100	100	100	100	100	100	100	100	100	100	100	100
83	48	52	100	100	100	100	100	100	100	100	100	100	100	100	100	100	100	100	100	100
84	48	100	100	100	100	100	100	100	100	100	100	100	100	100	100	100	100	100	100	100
85+	100	100	100	100	100	100	100	100	100	100	100	100	100	100	100	100	100	100	100	100

Male, Non-Smoker

Issue	Duration																			
Age	**1**	**2**	**3**	**4**	**5**	**6**	**7**	**8**	**9**	**10**	**11**	**12**	**13**	**14**	**15**	**16**	**17**	**18**	**19**	**20+**
0-15	100	100	100	100	100	100	100	100	100	100	100	100	100	100	100	100	100	100	100	100
16	100	100	100	100	100	100	100	100	100	100	100	100	100	100	100	100	100	100	100	100
17	100	100	100	100	100	100	100	100	100	100	100	100	100	100	100	100	100	100	100	100
18	93	95	96	98	99	100	100	90	92	92	92	92	95	95	96	97	98	98	99	100
19	80	81	83	86	87	87	79	79	79	81	81	82	83	83	86	89	92	94	97	100
20	65	68	69	72	74	69	69	67	69	70	71	71	72	72	75	80	85	90	95	100
21	63	66	68	71	66	66	67	66	67	70	70	70	71	71	73	78	84	89	95	100
22	62	65	66	62	63	64	64	64	67	68	68	68	70	70	73	78	84	89	95	100
23	60	62	58	60	62	62	63	63	64	67	68	68	67	69	71	77	83	88	94	100
24	59	55	56	58	59	60	61	61	63	65	67	66	66	69	71	77	83	88	94	100
25	52	53	55	56	58	58	60	60	61	64	64	64	64	67	70	76	82	88	94	100
26	51	53	55	56	58	60	61	61	61	63	64	64	66	69	67	74	80	87	93	100
27	51	52	55	58	60	60	61	61	62	63	64	66	67	66	67	74	80	87	93	100
28	49	52	57	58	60	61	63	62	62	64	66	66	63	66	68	74	81	87	94	100
29	49	51	57	60	61	61	62	62	63	64	66	63	65	67	68	74	81	87	94	100
30	49	51	57	60	61	62	63	63	63	64	62	63	66	68	70	76	82	88	94	100
31	47	50	57	60	60	62	63	64	64	62	63	65	67	70	71	77	83	88	94	100
32	46	50	57	60	62	63	64	64	62	63	65	66	68	71	72	78	83	89	94	100
33	45	49	56	60	62	63	64	62	63	65	66	68	71	73	74	79	84	90	95	100
34	43	48	56	62	63	64	62	62	65	66	67	70	72	74	74	79	84	90	95	100
35	41	47	56	62	63	61	62	63	66	67	68	70	72	74	75	80	85	90	95	100
36	40	47	56	62	59	61	62	63	66	67	68	70	72	74	75	80	85	90	95	100
37	38	45	56	58	59	61	62	63	66	67	67	69	71	73	74	79	84	90	95	100
38	38	45	53	58	61	62	63	65	65	67	68	70	72	74	73	78	84	89	95	100
39	37	41	53	58	61	62	63	64	65	67	68	70	71	73	73	78	84	89	95	100
40	34	41	53	58	61	62	63	64	64	66	67	69	71	73	72	78	83	89	94	100

Male, Non-Smoker

Issue	Duration																			
Age	**1**	**2**	**3**	**4**	**5**	**6**	**7**	**8**	**9**	**10**	**11**	**12**	**13**	**14**	**15**	**16**	**17**	**18**	**19**	**20+**
41	34	41	53	58	61	61	62	62	63	65	65	67	69	71	71	77	83	88	94	100
42	34	43	53	58	60	61	62	61	61	63	64	66	67	69	71	77	83	88	94	100
43	32	43	53	58	60	61	60	60	60	60	62	64	66	68	69	75	81	88	94	100
44	32	44	52	57	59	60	60	59	59	58	60	62	65	67	69	75	81	88	94	100
45	32	44	52	57	59	60	59	57	57	57	59	61	63	66	68	74	81	87	94	100
46	32	42	50	54	56	57	57	56	55	56	59	61	63	65	67	74	80	87	93	100
47	30	40	48	52	54	55	55	54	54	55	59	61	62	63	66	73	80	86	93	100
48	30	40	46	49	51	52	53	53	54	55	57	61	62	63	63	70	78	85	93	100
49	29	39	43	48	50	51	50	51	53	54	57	61	61	62	62	70	77	85	92	100
50	29	37	42	45	47	48	49	50	51	54	57	61	61	61	61	69	77	84	92	100
51	27	35	40	43	45	47	48	50	51	53	57	60	61	61	62	70	77	85	92	100
52	27	34	39	42	44	45	48	49	50	53	56	60	60	62	62	70	77	85	100	100
53	25	31	37	41	44	45	47	49	50	51	56	59	61	61	62	70	77	100	100	100
54	25	30	36	39	43	44	47	48	49	51	55	59	59	61	62	70	100	100	100	100
55	24	29	35	38	42	43	45	48	49	50	56	58	59	61	62	100	100	100	100	100
56	23	29	35	38	42	42	44	47	48	50	55	57	58	59	100	100	100	100	100	100
57	23	28	35	38	42	42	43	45	47	49	53	55	56	100	100	100	100	100	100	100
58	22	28	33	37	41	41	43	45	45	47	51	53	100	100	100	100	100	100	100	100
59	22	26	33	37	41	41	42	44	44	46	50	100	100	100	100	100	100	100	100	100
60	20	26	33	37	41	40	41	42	42	45	100	100	100	100	100	100	100	100	100	100
61	20	26	33	37	41	40	41	42	42	75	100	100	100	100	100	100	100	100	100	100
62	19	25	32	38	40	40	41	42	75	75	100	100	100	100	100	100	100	100	100	100
63	19	25	33	36	40	40	41	75	75	75	100	100	100	100	100	100	100	100	100	100
64	18	24	32	36	39	40	75	75	75	75	100	100	100	100	100	100	100	100	100	100
65	18	24	32	36	39	65	70	70	70	70	100	100	100	100	100	100	100	100	100	100
66	18	24	32	36	60	65	70	70	70	70	100	100	100	100	100	100	100	100	100	100
67	18	24	32	60	60	65	70	70	70	70	100	100	100	100	100	100	100	100	100	100
68	18	24	55	60	60	65	70	70	70	70	100	100	100	100	100	100	100	100	100	100
69	18	52	55	60	60	65	70	70	70	70	100	100	100	100	100	100	100	100	100	100
70	48	52	55	60	60	65	70	70	70	70	100	100	100	100	100	100	100	100	100	100

Male, Non-Smoker

Issue	Duration																			
Age	**1**	**2**	**3**	**4**	**5**	**6**	**7**	**8**	**9**	**10**	**11**	**12**	**13**	**14**	**15**	**16**	**17**	**18**	**19**	**20+**
71	48	52	55	60	60	65	70	70	70	70	100	100	100	100	100	100	100	100	100	100
72	48	52	55	60	60	65	70	70	70	70	100	100	100	100	100	100	100	100	100	100
73	48	52	55	60	60	65	70	70	70	70	100	100	100	100	100	100	100	100	100	100
74	48	52	55	60	60	65	70	70	70	70	100	100	100	100	100	100	100	100	100	100
75	48	52	55	60	60	65	70	70	70	70	100	100	100	100	100	100	100	100	100	100
76	48	52	55	60	60	65	70	70	70	100	100	100	100	100	100	100	100	100	100	100
77	48	52	55	60	60	65	70	70	100	100	100	100	100	100	100	100	100	100	100	100
78	48	52	55	60	60	65	70	100	100	100	100	100	100	100	100	100	100	100	100	100
79	48	52	55	60	60	65	100	100	100	100	100	100	100	100	100	100	100	100	100	100
80	48	52	55	60	60	100	100	100	100	100	100	100	100	100	100	100	100	100	100	100
81	48	52	55	60	100	100	100	100	100	100	100	100	100	100	100	100	100	100	100	100
82	48	52	55	100	100	100	100	100	100	100	100	100	100	100	100	100	100	100	100	100
83	48	52	100	100	100	100	100	100	100	100	100	100	100	100	100	100	100	100	100	100
84	48	100	100	100	100	100	100	100	100	100	100	100	100	100	100	100	100	100	100	100
85+	100	100	100	100	100	100	100	100	100	100	100	100	100	100	100	100	100	100	100	100

Male, Smoker

Issue	Duration																			
Age	**1**	**2**	**3**	**4**	**5**	**6**	**7**	**8**	**9**	**10**	**11**	**12**	**13**	**14**	**15**	**16**	**17**	**18**	**19**	**20+**
0-15	100	100	100	100	100	100	100	100	100	100	100	100	100	100	100	100	100	100	100	100
16	100	100	100	100	100	100	100	100	100	100	100	100	100	100	100	100	100	100	100	100
17	100	100	100	100	100	100	100	100	100	100	100	100	100	100	100	100	100	100	100	100
18	100	100	100	100	100	100	100	100	100	100	100	100	100	100	100	100	100	100	100	100
19	100	100	100	100	100	100	100	100	100	100	100	100	100	100	100	100	100	100	100	100
20	98	100	100	100	100	100	100	99	99	99	100	99	99	99	100	100	100	100	100	100
21	95	98	99	100	95	96	96	95	96	97	97	96	96	96	96	97	98	98	99	100
22	92	95	96	90	90	93	93	92	93	95	95	93	93	92	93	94	96	97	99	100
23	90	92	85	88	88	89	89	89	90	90	90	90	89	90	92	94	95	97	98	100
24	87	81	82	85	84	86	88	86	86	88	88	86	86	88	89	91	93	96	98	100
25	77	78	79	82	81	83	83	82	83	85	84	84	84	85	86	89	92	94	97	100
26	75	77	79	82	82	83	83	82	83	84	84	84	84	85	81	85	89	92	96	100
27	73	75	78	82	82	83	83	82	82	82	82	84	84	80	81	85	89	92	96	100
28	71	73	79	82	81	82	83	81	81	82	82	82	80	80	81	85	89	92	96	100
29	69	72	78	81	81	82	82	81	81	81	81	77	80	80	81	85	89	92	96	100
30	68	71	78	81	81	81	82	81	81	81	76	77	80	80	81	85	89	92	96	100
31	65	70	77	81	79	81	82	81	81	76	77	79	81	81	83	86	90	93	97	100
32	63	67	77	78	79	81	81	81	76	77	77	80	83	83	85	88	91	94	97	100
33	60	65	74	78	79	79	81	76	77	77	79	80	83	85	85	88	91	94	97	100
34	57	62	74	77	79	79	75	76	77	79	79	81	83	85	87	90	92	95	97	100
35	53	60	73	77	79	75	75	76	77	79	80	82	84	86	88	90	93	95	98	100
36	52	59	71	75	74	75	75	76	77	79	79	81	83	85	87	90	92	95	97	100
37	49	58	70	71	74	74	75	76	77	78	79	81	84	86	86	89	92	94	97	100
38	48	55	66	70	72	74	74	75	76	78	79	81	83	85	87	90	92	95	97	100
39	45	50	65	70	72	72	74	74	75	77	79	81	84	86	86	89	92	94	97	100
40	41	49	63	68	71	72	73	74	74	76	78	80	83	85	86	89	92	94	97	100

Male, Smoker

Issue	Duration																			
Age	**1**	**2**	**3**	**4**	**5**	**6**	**7**	**8**	**9**	**10**	**11**	**12**	**13**	**14**	**15**	**16**	**17**	**18**	**19**	**20+**
41	40	49	63	68	71	72	72	72	73	75	76	78	81	84	85	88	91	94	97	100
42	40	49	62	68	70	71	71	71	71	73	75	76	81	83	85	88	91	94	97	100
43	39	50	62	67	69	69	70	70	70	71	73	76	79	83	85	88	91	94	97	100
44	39	50	60	66	68	69	68	69	69	69	71	74	79	81	85	88	91	94	97	100
45	37	50	60	66	68	68	68	67	67	67	69	73	78	81	85	88	91	94	97	100
46	37	48	58	63	65	67	66	66	66	67	71	74	78	81	84	87	90	94	97	100
47	36	47	55	61	63	64	64	64	65	67	71	75	79	81	84	87	90	94	97	100
48	35	46	53	58	60	62	63	63	65	67	72	75	79	81	83	86	90	93	97	100
49	34	45	51	56	58	59	61	62	63	67	72	77	80	81	83	86	90	93	97	100
50	34	43	49	53	55	57	60	61	63	67	73	78	80	81	81	85	89	92	96	100
51	32	42	47	52	55	57	60	61	63	67	73	78	80	83	84	87	90	94	97	100
52	32	40	46	50	54	56	60	61	63	67	73	78	81	84	85	88	91	94	100	100
53	30	37	44	49	54	56	59	61	65	67	74	79	83	85	87	90	92	100	100	100
54	30	36	43	48	53	55	59	61	65	67	74	80	84	85	89	91	100	100	100	100
55	29	35	42	47	53	55	59	61	65	67	75	80	84	86	90	100	100	100	100	100
56	28	35	42	47	53	55	57	60	63	68	74	79	83	85	100	100	100	100	100	100
57	28	35	42	47	53	54	57	60	64	67	74	78	81	100	100	100	100	100	100	100
58	26	33	43	48	54	54	56	59	63	67	73	78	100	100	100	100	100	100	100	100
59	26	33	43	48	54	53	57	59	63	66	73	100	100	100	100	100	100	100	100	100
60	25	33	43	48	54	53	56	58	62	66	100	100	100	100	100	100	100	100	100	100
61	25	33	43	49	55	55	57	59	63	75	100	100	100	100	100	100	100	100	100	100
62	25	33	43	50	56	56	58	61	75	75	100	100	100	100	100	100	100	100	100	100
63	24	33	45	51	56	56	59	75	75	75	100	100	100	100	100	100	100	100	100	100
64	24	34	45	51	57	57	75	75	75	75	100	100	100	100	100	100	100	100	100	100
65	24	34	45	52	57	65	70	70	70	70	100	100	100	100	100	100	100	100	100	100
66	24	35	45	53	60	65	70	70	70	70	100	100	100	100	100	100	100	100	100	100
67	25	35	45	60	60	65	70	70	70	70	100	100	100	100	100	100	100	100	100	100
68	25	36	55	60	60	65	70	70	70	70	100	100	100	100	100	100	100	100	100	100
69	27	52	55	60	60	65	70	70	70	70	100	100	100	100	100	100	100	100	100	100
70	48	52	55	60	60	65	70	70	70	70	100	100	100	100	100	100	100	100	100	100

Male, Smoker

Issue	Duration																			
Age	**1**	**2**	**3**	**4**	**5**	**6**	**7**	**8**	**9**	**10**	**11**	**12**	**13**	**14**	**15**	**16**	**17**	**18**	**19**	**20+**
71	48	52	55	60	60	65	70	70	70	70	100	100	100	100	100	100	100	100	100	100
72	48	52	55	60	60	65	70	70	70	70	100	100	100	100	100	100	100	100	100	100
73	48	52	55	60	60	65	70	70	70	70	100	100	100	100	100	100	100	100	100	100
74	48	52	55	60	60	65	70	70	70	70	100	100	100	100	100	100	100	100	100	100
75	48	52	55	60	60	65	70	70	70	70	100	100	100	100	100	100	100	100	100	100
76	48	52	55	60	60	65	70	70	70	100	100	100	100	100	100	100	100	100	100	100
77	48	52	55	60	60	65	70	70	100	100	100	100	100	100	100	100	100	100	100	100
78	48	52	55	60	60	65	70	100	100	100	100	100	100	100	100	100	100	100	100	100
79	48	52	55	60	60	65	100	100	100	100	100	100	100	100	100	100	100	100	100	100
80	48	52	55	60	60	100	100	100	100	100	100	100	100	100	100	100	100	100	100	100
81	48	52	55	60	100	100	100	100	100	100	100	100	100	100	100	100	100	100	100	100
82	48	52	55	100	100	100	100	100	100	100	100	100	100	100	100	100	100	100	100	100
83	48	52	100	100	100	100	100	100	100	100	100	100	100	100	100	100	100	100	100	100
84	48	100	100	100	100	100	100	100	100	100	100	100	100	100	100	100	100	100	100	100
85+	100	100	100	100	100	100	100	100	100	100	100	100	100	100	100	100	100	100	100	100

Female, Aggregate

Issue	Duration																			
Age	**1**	**2**	**3**	**4**	**5**	**6**	**7**	**8**	**9**	**10**	**11**	**12**	**13**	**14**	**15**	**16**	**17**	**18**	**19**	**20+**
0-15	100	100	100	100	100	100	100	100	100	100	100	100	100	100	100	100	100	100	100	100
16	100	100	100	100	100	100	100	100	100	100	100	100	100	100	100	100	100	100	100	100
17	99	100	100	100	100	100	100	100	93	95	96	97	97	100	100	100	100	100	100	100
18	83	83	84	84	84	84	86	78	78	79	82	84	85	88	88	90	93	95	98	100
19	65	66	68	68	68	68	63	63	64	66	69	71	72	74	75	80	85	90	95	100
20	48	50	51	51	51	47	48	48	49	51	56	57	58	61	63	70	78	85	93	100
21	47	48	50	51	47	47	48	49	51	53	57	60	61	64	64	71	78	86	93	100
22	44	47	48	45	47	47	48	49	53	54	60	61	63	64	66	73	80	86	93	100
23	42	45	44	45	47	47	49	51	53	54	61	64	64	67	69	75	81	88	94	100
24	39	40	42	44	47	47	50	51	54	56	64	64	66	69	70	76	82	88	94	100
25	34	38	41	44	47	47	50	53	56	57	64	67	69	71	73	78	84	89	95	100
26	34	38	41	45	49	49	51	56	58	59	66	69	70	73	70	76	82	88	94	100
27	34	38	41	47	50	51	54	57	59	60	69	70	73	70	71	77	83	88	94	100
28	34	37	43	47	53	53	56	59	62	63	70	73	70	72	74	79	84	90	95	100
29	34	38	43	49	54	56	58	60	63	64	73	70	72	74	75	80	85	90	95	100
30	35	38	43	50	56	56	59	63	66	67	70	71	74	75	76	81	86	90	95	100
31	35	38	43	51	56	58	60	64	67	65	71	72	74	75	76	81	86	90	95	100
32	35	39	45	51	56	59	63	66	65	66	72	72	75	76	76	81	86	90	95	100
33	36	39	44	52	58	62	64	65	66	67	72	74	75	76	76	81	86	90	95	100
34	36	40	45	52	58	63	63	66	67	68	74	74	76	76	76	81	86	90	95	100
35	36	40	45	53	59	61	65	67	68	70	75	74	75	76	75	80	85	90	95	100
36	36	40	45	53	55	62	65	67	68	70	74	74	74	75	75	80	85	90	95	100
37	36	41	47	52	57	62	65	67	68	69	72	72	73	75	74	79	84	90	95	100
38	34	41	44	52	57	63	66	68	69	70	72	71	72	74	75	80	85	90	95	100
39	34	40	45	53	58	63	66	68	69	69	70	70	70	73	74	79	84	90	95	100
40	32	40	45	53	58	65	65	67	68	69	70	69	70	73	73	78	84	89	95	100

Female, Aggregate

Issue Age	Duration 1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17	18	19	20+
41	32	40	45	53	57	63	64	67	68	68	69	69	69	73	74	79	84	90	95	100
42	32	40	45	52	56	61	63	65	66	68	69	68	70	74	75	80	85	90	95	100
43	31	39	45	51	55	59	61	65	65	66	68	69	69	74	77	82	86	91	95	100
44	31	39	45	50	54	58	61	63	64	66	67	68	71	75	78	82	87	91	96	100
45	31	38	44	49	53	56	59	62	63	65	67	68	71	77	79	83	87	92	96	100
46	29	37	43	48	51	54	59	62	63	65	67	69	71	77	78	82	87	91	96	100
47	28	35	41	46	49	54	57	61	62	66	68	69	71	77	77	82	86	91	95	100
48	28	35	41	44	49	52	57	61	63	66	68	71	72	75	77	82	86	91	95	100
49	26	34	39	43	47	52	55	61	63	67	69	71	72	75	75	80	85	90	95	100
50	25	32	38	41	46	50	55	61	63	67	69	72	72	75	74	79	84	90	95	100
51	25	32	38	41	45	50	55	61	63	66	68	69	71	74	74	79	84	90	95	100
52	23	30	36	41	45	51	56	61	62	65	66	68	68	73	73	78	84	89	100	100
53	23	30	36	41	47	51	56	61	62	63	65	66	68	72	72	78	83	100	100	100
54	22	29	35	41	47	53	57	61	61	62	62	66	66	69	70	76	100	100	100	100
55	22	29	35	41	47	53	57	61	61	61	62	63	64	68	69	100	100	100	100	100
56	22	29	35	41	45	51	56	59	60	61	62	63	64	67	100	100	100	100	100	100
57	22	29	35	41	45	50	54	56	58	59	61	62	63	100	100	100	100	100	100	100
58	22	30	36	41	44	49	53	56	57	57	61	62	100	100	100	100	100	100	100	100
59	22	30	36	41	44	48	51	53	55	56	59	100	100	100	100	100	100	100	100	100
60	22	30	36	41	43	47	50	51	53	55	100	100	100	100	100	100	100	100	100	100
61	22	29	35	39	42	46	49	50	52	80	100	100	100	100	100	100	100	100	100	100
62	20	28	33	39	41	45	47	49	80	80	100	100	100	100	100	100	100	100	100	100
63	20	28	33	38	41	44	46	80	80	80	100	100	100	100	100	100	100	100	100	100
64	19	27	32	36	40	42	80	80	80	80	100	100	100	100	100	100	100	100	100	100
65	19	25	30	35	39	72	75	75	80	80	100	100	100	100	100	100	100	100	100	100
66	19	25	30	35	72	72	75	75	80	80	100	100	100	100	100	100	100	100	100	100
67	19	25	30	72	72	72	75	75	80	80	100	100	100	100	100	100	100	100	100	100
68	19	25	68	72	72	72	75	75	80	80	100	100	100	100	100	100	100	100	100	100
69	19	64	68	72	72	72	75	75	80	80	100	100	100	100	100	100	100	100	100	100
70	60	60	64	68	68	72	75	75	80	80	100	100	100	100	100	100	100	100	100	100

Female, Aggregate

Issue	Duration																			
Age	**1**	**2**	**3**	**4**	**5**	**6**	**7**	**8**	**9**	**10**	**11**	**12**	**13**	**14**	**15**	**16**	**17**	**18**	**19**	**20+**
71	60	60	64	68	68	72	75	75	80	80	100	100	100	100	100	100	100	100	100	100
72	60	60	64	68	68	72	75	75	80	80	100	100	100	100	100	100	100	100	100	100
73	60	60	64	68	68	72	75	75	80	80	100	100	100	100	100	100	100	100	100	100
74	60	60	64	68	68	72	75	75	80	80	100	100	100	100	100	100	100	100	100	100
75	60	60	64	68	68	72	75	75	80	80	100	100	100	100	100	100	100	100	100	100
76	60	60	64	68	68	72	75	75	80	100	100	100	100	100	100	100	100	100	100	100
77	60	60	64	68	68	72	75	75	100	100	100	100	100	100	100	100	100	100	100	100
78	60	60	64	68	68	72	75	100	100	100	100	100	100	100	100	100	100	100	100	100
79	60	60	64	68	68	72	100	100	100	100	100	100	100	100	100	100	100	100	100	100
80	60	60	64	68	68	100	100	100	100	100	100	100	100	100	100	100	100	100	100	100
81	60	60	64	68	100	100	100	100	100	100	100	100	100	100	100	100	100	100	100	100
82	60	60	64	100	100	100	100	100	100	100	100	100	100	100	100	100	100	100	100	100
83	60	60	100	100	100	100	100	100	100	100	100	100	100	100	100	100	100	100	100	100
84	60	100	100	100	100	100	100	100	100	100	100	100	100	100	100	100	100	100	100	100
85+	100	100	100	100	100	100	100	100	100	100	100	100	100	100	100	100	100	100	100	100

Female, Non-Smoker

Issue	Duration																			
Age	**1**	**2**	**3**	**4**	**5**	**6**	**7**	**8**	**9**	**10**	**11**	**12**	**13**	**14**	**15**	**16**	**17**	**18**	**19**	**20+**
0-15	100	100	100	100	100	100	100	100	100	100	100	100	100	100	100	100	100	100	100	100
16	100	100	100	100	100	100	100	100	100	100	100	100	100	100	100	100	100	100	100	100
17	96	98	98	98	98	99	99	99	92	92	93	95	95	97	99	99	99	100	100	100
18	78	80	80	80	80	81	81	74	75	75	78	79	82	83	85	88	91	94	97	100
19	60	62	63	63	63	65	59	59	60	60	64	67	67	70	72	78	83	89	94	100
20	42	44	45	45	45	42	42	42	45	45	50	51	53	56	58	66	75	83	92	100
21	41	42	44	45	41	42	42	44	47	47	51	53	54	57	59	67	75	84	92	100
22	39	41	44	41	41	42	44	45	49	49	54	56	57	58	60	68	76	84	92	100
23	38	41	38	40	41	42	44	46	49	50	56	57	58	60	62	70	77	85	92	100
24	36	36	38	40	41	42	46	47	50	51	58	59	60	62	63	70	78	85	93	100
25	32	34	37	40	41	43	46	49	51	53	59	60	62	63	64	71	78	86	93	100
26	32	34	37	41	43	45	47	50	53	53	60	62	63	64	62	70	77	85	92	100
27	32	34	38	43	46	47	49	51	53	55	62	63	64	62	62	70	77	85	92	100
28	30	34	39	43	47	49	51	53	56	58	63	63	61	62	63	70	78	85	93	100
29	30	35	40	45	50	51	52	55	58	59	64	61	62	63	63	70	78	85	93	100
30	31	35	40	46	51	52	53	56	59	60	62	62	63	65	65	72	79	86	93	100
31	31	35	40	46	51	53	55	58	60	58	62	62	63	65	65	72	79	86	93	100
32	32	35	40	45	51	53	56	59	57	58	62	63	63	65	64	71	78	86	93	100
33	32	36	41	47	52	55	58	55	58	59	63	63	65	65	65	72	79	86	93	100
34	33	36	41	47	52	55	55	57	58	59	63	65	64	65	64	71	78	86	93	100
35	33	36	41	47	52	53	57	58	59	61	63	64	64	64	64	71	78	86	93	100
36	33	36	41	47	49	53	57	58	59	61	63	64	63	64	63	70	78	85	93	100
37	32	36	41	44	49	53	57	58	59	60	62	62	61	62	63	70	78	85	93	100
38	32	37	39	45	50	54	57	58	60	60	61	61	61	62	61	69	77	84	92	100
39	30	35	39	45	50	54	57	58	60	59	60	60	59	60	61	69	77	84	92	100
40	28	35	39	45	50	54	56	57	59	59	60	59	59	59	60	68	76	84	92	100

Female, Non-Smoker

Issue	Duration																			
Age	**1**	**2**	**3**	**4**	**5**	**6**	**7**	**8**	**9**	**10**	**11**	**12**	**13**	**14**	**15**	**16**	**17**	**18**	**19**	**20+**
41	28	35	39	45	49	52	55	55	58	57	58	59	58	59	60	68	76	84	92	100
42	27	35	39	44	49	52	54	55	56	57	57	57	58	60	61	69	77	84	92	100
43	27	34	39	44	47	50	53	53	55	55	56	57	56	60	61	69	77	84	92	100
44	26	34	38	42	47	50	52	53	54	55	55	55	56	61	62	70	77	85	92	100
45	26	33	38	42	45	48	51	51	52	53	54	55	56	61	62	70	77	85	92	100
46	24	32	37	40	43	47	49	51	52	53	54	55	56	60	61	69	77	84	92	100
47	24	30	35	39	42	45	47	49	51	53	54	55	56	59	60	68	76	84	92	100
48	23	30	35	37	40	44	47	49	50	53	54	55	55	59	57	66	74	83	91	100
49	23	29	33	35	39	42	45	48	50	53	54	55	55	57	56	65	74	82	91	100
50	21	27	32	34	37	41	44	48	50	53	54	55	55	56	55	64	73	82	91	100
51	21	26	30	34	37	41	44	48	49	51	53	53	54	55	55	64	73	82	91	100
52	20	25	30	33	37	41	44	47	48	50	50	51	51	55	53	62	72	81	100	100
53	19	24	29	32	37	41	43	47	48	48	49	49	51	52	52	62	71	100	100	100
54	18	24	29	32	37	41	43	45	47	47	47	49	49	51	51	61	100	100	100	100
55	18	23	28	32	37	41	43	45	45	45	46	46	47	50	50	100	100	100	100	100
56	18	23	28	32	36	39	42	44	44	45	46	46	46	49	100	100	100	100	100	100
57	18	23	28	31	35	38	41	42	44	44	45	45	46	100	100	100	100	100	100	100
58	17	23	26	31	35	36	38	41	41	42	45	45	100	100	100	100	100	100	100	100
59	17	23	26	30	33	35	38	39	40	41	44	100	100	100	100	100	100	100	100	100
60	17	23	26	30	32	34	36	38	39	40	100	100	100	100	100	100	100	100	100	100
61	17	22	25	29	32	33	35	36	38	80	100	100	100	100	100	100	100	100	100	100
62	16	22	25	28	30	32	34	35	80	80	100	100	100	100	100	100	100	100	100	100
63	16	20	24	28	30	32	34	80	80	80	100	100	100	100	100	100	100	100	100	100
64	14	21	24	27	29	30	80	80	80	80	100	100	100	100	100	100	100	100	100	100
65	15	19	23	25	28	72	75	75	80	80	100	100	100	100	100	100	100	100	100	100
66	15	19	23	25	72	72	75	75	80	80	100	100	100	100	100	100	100	100	100	100
67	15	19	22	72	72	72	75	75	80	80	100	100	100	100	100	100	100	100	100	100
68	13	18	68	72	72	72	75	75	80	80	100	100	100	100	100	100	100	100	100	100
69	13	64	68	72	72	72	75	75	80	80	100	100	100	100	100	100	100	100	100	100
70	60	60	64	68	68	72	75	75	80	80	100	100	100	100	100	100	100	100	100	100

Female, Non-Smoker

Issue	Duration																			
Age	**1**	**2**	**3**	**4**	**5**	**6**	**7**	**8**	**9**	**10**	**11**	**12**	**13**	**14**	**15**	**16**	**17**	**18**	**19**	**20+**
71	60	60	64	68	68	72	75	75	80	80	100	100	100	100	100	100	100	100	100	100
72	60	60	64	68	68	72	75	75	80	80	100	100	100	100	100	100	100	100	100	100
73	60	60	64	68	68	72	75	75	80	80	100	100	100	100	100	100	100	100	100	100
74	60	60	64	68	68	72	75	75	80	80	100	100	100	100	100	100	100	100	100	100
75	60	60	64	68	68	72	75	75	80	80	100	100	100	100	100	100	100	100	100	100
76	60	60	64	68	68	72	75	75	80	100	100	100	100	100	100	100	100	100	100	100
77	60	60	64	68	68	72	75	75	100	100	100	100	100	100	100	100	100	100	100	100
78	60	60	64	68	68	72	75	100	100	100	100	100	100	100	100	100	100	100	100	100
79	60	60	64	68	68	72	100	100	100	100	100	100	100	100	100	100	100	100	100	100
80	60	60	64	68	68	100	100	100	100	100	100	100	100	100	100	100	100	100	100	100
81	60	60	64	68	100	100	100	100	100	100	100	100	100	100	100	100	100	100	100	100
82	60	60	64	100	100	100	100	100	100	100	100	100	100	100	100	100	100	100	100	100
83	60	60	100	100	100	100	100	100	100	100	100	100	100	100	100	100	100	100	100	100
84	60	100	100	100	100	100	100	100	100	100	100	100	100	100	100	100	100	100	100	100
85+	100	100	100	100	100	100	100	100	100	100	100	100	100	100	100	100	100	100	100	100

Female, Smoker

Issue	Duration																			
Age	**1**	**2**	**3**	**4**	**5**	**6**	**7**	**8**	**9**	**10**	**11**	**12**	**13**	**14**	**15**	**16**	**17**	**18**	**19**	**20+**
0-15	100	100	100	100	100	100	100	100	100	100	100	100	100	100	100	100	100	100	100	100
16	100	100	100	100	100	100	100	100	100	100	100	100	100	100	100	100	100	100	100	100
17	100	100	100	100	100	100	100	100	100	100	100	100	100	100	100	100	100	100	100	100
18	99	100	100	100	100	100	100	95	96	97	100	100	100	100	100	100	100	100	100	100
19	87	89	92	92	92	92	84	84	86	86	92	93	95	96	99	99	99	100	100	100
20	74	77	80	80	80	73	73	73	75	77	83	83	86	88	90	92	94	96	98	100
21	71	74	78	78	71	71	73	74	77	79	85	86	88	89	90	92	94	96	98	100
22	68	71	75	70	71	71	73	74	78	79	88	90	89	89	92	94	95	97	98	100
23	65	69	67	70	70	70	73	77	79	81	89	90	90	92	92	94	95	97	98	100
24	62	60	64	69	70	70	74	77	79	81	92	90	92	93	93	94	96	97	99	100
25	53	58	63	67	69	70	74	78	81	82	92	93	93	95	95	96	97	98	99	100
26	53	58	63	69	71	72	75	79	82	82	93	93	95	96	90	92	94	96	98	100
27	52	56	63	70	74	74	78	81	82	84	93	95	95	90	90	92	94	96	98	100
28	52	56	64	71	75	77	79	82	85	86	95	95	90	92	92	94	95	97	98	100
29	51	56	64	71	78	78	81	84	86	88	95	90	90	92	92	94	95	97	98	100
30	51	56	64	72	79	79	82	85	88	89	90	90	92	93	93	94	96	97	99	100
31	51	56	64	72	78	81	84	84	88	84	90	90	92	93	93	94	96	97	99	100
32	51	56	64	71	78	81	85	86	84	85	90	90	92	94	93	94	96	97	99	100
33	51	57	62	71	78	82	85	83	84	85	90	92	93	93	93	94	96	97	99	100
34	51	56	62	71	78	82	81	83	85	86	90	92	92	94	93	94	96	97	99	100
35	51	56	62	71	78	79	83	84	85	86	90	91	91	93	93	94	96	97	99	100
36	49	56	62	71	74	79	83	84	85	86	90	90	91	93	92	94	95	97	98	100
37	48	55	62	67	74	79	83	84	85	86	89	90	89	92	91	93	95	96	98	100
38	47	55	57	66	72	77	81	84	86	86	87	88	88	90	91	93	95	96	98	100
39	45	50	57	66	72	77	81	83	85	86	86	87	86	89	90	92	94	96	98	100
40	41	50	57	66	72	77	81	83	84	85	86	86	86	89	89	91	93	96	98	100

Female, Smoker

Issue	Duration																			
Age	**1**	**2**	**3**	**4**	**5**	**6**	**7**	**8**	**9**	**10**	**11**	**12**	**13**	**14**	**15**	**16**	**17**	**18**	**19**	**20+**
41	40	50	57	65	71	76	79	81	83	84	85	86	85	89	90	92	94	96	98	100
42	40	49	57	65	69	74	77	80	82	83	84	85	86	90	92	94	95	97	98	100
43	39	49	55	63	69	73	76	78	80	82	83	84	85	92	93	94	96	97	99	100
44	39	48	55	62	67	71	75	78	80	80	82	84	86	93	96	97	98	98	99	100
45	37	47	55	61	65	70	73	76	78	80	81	84	86	94	97	98	98	99	99	100
46	36	46	53	59	63	68	71	75	77	79	83	85	86	93	96	97	98	98	99	100
47	34	44	51	57	62	66	70	75	77	80	83	85	86	93	94	95	96	98	99	100
48	34	44	50	54	60	64	69	74	77	80	84	86	87	92	92	94	95	97	98	100
49	33	42	48	53	58	63	68	74	77	81	84	86	87	92	91	93	95	96	98	100
50	31	41	46	51	57	61	67	74	77	81	85	87	87	91	90	92	94	96	98	100
51	30	39	45	51	56	61	67	74	75	80	83	85	85	90	90	92	94	96	98	100
52	29	38	45	50	56	62	68	74	75	79	81	83	84	90	90	92	94	96	100	100
53	28	37	43	49	57	62	68	73	74	77	79	81	83	89	89	91	93	100	100	100
54	28	36	43	49	57	63	69	73	74	75	78	80	81	87	89	91	100	100	100	100
55	26	35	42	49	57	63	69	73	73	74	76	78	79	86	87	100	100	100	100	100
56	26	35	42	49	56	62	67	71	72	74	76	78	79	85	100	100	100	100	100	100
57	26	35	42	49	55	61	66	69	72	73	76	78	79	100	100	100	100	100	100	100
58	28	36	43	49	55	59	63	68	69	72	76	78	100	100	100	100	100	100	100	100
59	28	36	43	49	54	57	63	67	68	70	76	100	100	100	100	100	100	100	100	100
60	28	36	43	49	53	57	61	64	67	69	100	100	100	100	100	100	100	100	100	100
61	26	35	42	48	52	56	59	63	66	80	100	100	100	100	100	100	100	100	100	100
62	26	33	41	47	51	55	58	62	80	80	100	100	100	100	100	100	100	100	100	100
63	25	33	41	46	51	55	57	80	80	80	100	100	100	100	100	100	100	100	100	100
64	25	33	40	45	50	53	80	80	80	80	100	100	100	100	100	100	100	100	100	100
65	24	32	39	44	49	72	75	75	80	80	100	100	100	100	100	100	100	100	100	100
66	24	32	39	44	72	72	75	75	80	80	100	100	100	100	100	100	100	100	100	100
67	24	32	39	72	72	72	75	75	80	80	100	100	100	100	100	100	100	100	100	100
68	24	32	68	72	72	72	75	75	80	80	100	100	100	100	100	100	100	100	100	100
69	24	64	68	72	72	72	75	75	80	80	100	100	100	100	100	100	100	100	100	100
70	60	60	64	68	68	72	75	75	80	80	100	100	100	100	100	100	100	100	100	100

Female. Smoker

Issue **Duration**

Age	1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17	18	19	20+
71	60	60	64	68	68	72	75	75	80	80	100	100	100	100	100	100	100	100	100	100
72	60	60	64	68	68	72	75	75	80	80	100	100	100	100	100	100	100	100	100	100
73	60	60	64	68	68	72	75	75	80	80	100	100	100	100	100	100	100	100	100	100
74	60	60	64	68	68	72	75	75	80	80	100	100	100	100	100	100	100	100	100	100
75	60	60	64	68	68	72	75	75	80	80	100	100	100	100	100	100	100	100	100	100
76	60	60	64	68	68	72	75	75	80	100	100	100	100	100	100	100	100	100	100	100
77	60	60	64	68	68	72	75	75	100	100	100	100	100	100	100	100	100	100	100	100
78	60	60	64	68	68	72	75	100	100	100	100	100	100	100	100	100	100	100	100	100
79	60	60	64	68	68	72	100	100	100	100	100	100	100	100	100	100	100	100	100	100
80	60	60	64	68	68	100	100	100	100	100	100	100	100	100	100	100	100	100	100	100
81	60	60	64	68	100	100	100	100	100	100	100	100	100	100	100	100	100	100	100	100
82	60	60	64	100	100	100	100	100	100	100	100	100	100	100	100	100	100	100	100	100
83	60	60	100	100	100	100	100	100	100	100	100	100	100	100	100	100	100	100	100	100
84	60	100	100	100	100	100	100	100	100	100	100	100	100	100	100	100	100	100	100	100
85+	100	100	100	100	100	100	100	100	100	100	100	100	100	100	100	100	100	100	100	100

Document No. 2575
DEPARTMENT OF LABOR, LICENSING AND REGULATION
SOUTH CAROLINA STATE BOARD OF ACCOUNTANCY
CHAPTER 1
STATUTORY AUTHORITY: 1976 CODE SECTIONS 40-2-140 AND 380

Synopsis:

The Board of Accountancy is drafting regulations to be consistent with the provisions of 2000 Act 274, including provisions for use of the abbreviation "EA", acceptance of experience under a public accountant, and provisions concerning forms of practice of public accountants and accounting practitioners. The regulations will clarify the provisions for forms of practice, contingent fees and commissions by providing a definition of the term licensee.

Instructions: Amend current regulations, by repealing current regulations and replacing them with new regulations as it appears in the text below.

Text:

1-01. Definition of Firm and Licensee, Definition of Holding Out; Firms Jointly Owned by Certified Public Accountants and Public Accountants.

A. Definition of "Firm" and "Licensee." When used in these regulations, "firm" shall refer to a person or persons practicing public accounting in the form of a proprietorship, partnership, limited liability partnership, limited liability company, or professional corporation or association. A "Licensee" shall refer to a person who holds a license from this board as a (Certified Public Accountant (CPA), Public Accountant (PA) or Accounting Practitioner.

B. Definition of "Holding Out." The existence of any of the following conditions with reference to a person or firm will mean that person or firm "holds himself or itself out" to the public within the meaning of this act:

(1) use of the title or designation "Certified Public Accountant" or the abbreviation "CPA" or the title "Public Accountant" or the abbreviation "PA" or the title "Accounting Practitioner" or any other title, designation, words, abbreviations, signs, cards, or other devices tending or intended to indicate the offering of accounting services to the public; or

(2) maintenance of an office or other quarters in connection with which there is an inference or implication through the use of any listings, titles, names, abbreviations, or devices that accounting services are offered to the public therefrom; or

(3) offering to render or rendering the following services to the public; or

(a) offering to prospective clients in South Carolina to perform for compensation one (1) or more of these services:

(i) the development, recording, analysis, or presentation of financial information including, but not limited to, the preparation of financial statements; or

(ii) advice or assistance in regard to accounting controls, systems, and procedures; or

(b) in any manner holding himself or itself out to the public in South Carolina as skilled in one(1) or more of the type of services described in item (a).

C. Public Accounting Firms Owned Jointly by Certified Public Accountants and Public Accountants. Except as permitted by Regulation 1-21(D), public accounting firms owned jointly by Certified Public Accountants and Public Accountants in their holding out to the general public and in the signing of reports and related documents (either in the firm name or as individual owners) must employ a style which indicates that the firm is a firm of Public Accountants and not a firm of Certified Public Accountants. However, a Certified Public Accountant may style himself as such on the letterhead of his firm and in directories and listings which do not disclose his firm

affiliation. A Certified Public Accountant signing a document on behalf of the firm must not use the CPA designation.

D. Public Accounting Firms Owned Jointly by Public Accountants and Accounting Practitioners. Except as permitted by Regulation 1-21 (D), Public accounting firms owned jointly by Public Accountants and Accounting Practitioners must in their holding out to the general public employ a style which indicates that the firm is a firm of Accounting Practitioners.

1-07. Experience Required in Addition to Examination.

A. Required experience shall include:

(1) at least two (2) years of accounting experience satisfactory to the Board in public, governmental, or private employment under the direct supervision and review of a Certified Public Accountant or Public Accountant licensed to practice accounting in some state or territory of the United States or the District of Columbia; or

(2) at least five (5) years experience teaching accounting in a college or university recognized by the Board; or

(3) any combination of experience determined by the Board to be substantially equivalent to the foregoing.

B. Experience other than public accounting experience shall count only in proportion to duties which, in the opinion of the Board, contribute to competence in public accounting.

C. Experience may be gained in either full-time or part-time employment. Two thousand (2000) hours of part-time accounting experience is deemed to be equivalent to one (1) year. Experience may not accrue more rapidly than forty (40) hours per week.

D. The five (5) years of teaching experience provided for under A(2) shall consist of five (5) years of full-time teaching of accounting courses at a college or university accredited by the Southern Association of Colleges and Schools or any other regional accrediting associations having equivalent standards, or any independent senior college in South Carolina certified by the State Department of Education for teacher training.

(1) In order for teaching experience to qualify as full-time teaching, the applicant must have been employed on a full-time basis as defined by the educational institution where the experience was obtained; provided, however, that teaching less than twelve (12) semester hours per year, or the equivalent in quarter hours, shall not be considered as full-time teaching experience.

(2) Experience credit for teaching on a part-time basis shall qualify on a pro rata basis based upon the number of semester hours required for full-time teaching at the educational institution where the teaching experience was obtained.

(a) Teaching experience may not accrue more rapidly than elapsed chronological time.

(i) An applicant shall not be granted credit for full-time teaching completed in less than one (1) academic year.

(ii) An applicant shall be granted no more than one (1) full-time teaching year credit for teaching completed within one (1) calendar year.

(3) Teaching experience shall not be granted for teaching subjects outside the field of accounting.

(a) Subjects considered to be outside the field of accounting include, but are not limited to, business law, finance, computer applications, personnel management, economics, and statistics.

(4) Of the five (5) years of full-time teaching experience, credit for teaching accounting principles courses or fundamental accounting (below intermediate accounting) may not exceed two (2) full-time teaching years and the remaining three (3) full-time teaching years experience must be obtained in teaching courses above accounting principles.

(a) Accounting courses considered to be above accounting principles include, but are not limited to intermediate accounting, advanced accounting, auditing, income tax, financial accounting, management accounting, and cost accounting.

E. A record of experience must be detailed on Certificate of Experience forms provided by the Board.

(1) A separate Certificate of Experience form shall be required from each employer.

(2) The Certificate of Experience form shall be signed by:

(a) the supervisory licensed Certified Public Accountant; or

(b) the dean or department head of the institution where qualifying teaching experience was gained.

(3) The Board may require such other information as it deems necessary to determine the acceptability of experience, including, but not limited to:

(a) review of work papers and other work products; and

(b) review of time record; and

(c) interviews with applicants and supervisors.

1-21. Other Responsibilities and Practices.

A. Acts Discreditable. A licensee shall not commit an act discreditable to the profession.

B. Solicitation and Advertising. A licensee shall not seek to obtain clients by advertising or other forms of solicitation in a manner that is false, misleading, deceptive, or tends to promote unsupported claims. Such activities include those that:

(1) create false or unjustified expectations of favorable results; or

(2) imply the ability to influence any court, tribunal, regulatory agency, or similar body or official; or

(3) consist of statements that are self-laudatory and that are not based on verifiable facts; or

(4) make incomplete comparisons with other licensees; or

(5) contain any other representations that would be likely to cause a reasonable person to misunderstand or be deceived; or

(6) consist of the use of coercion, duress, compulsion, intimidation, or vexatious or harassing conduct.

C. Commissions and Referral Fees.

(1) Prohibited Commissions. A licensee shall not for a commission recommend or refer to a client any product or service, or for a commission recommend or refer any product or service to be supplied by a client, or receive a commission, when the license or the licensee's firm also performs for that client:

(a) an audit or review of a financial statement; or

(b) a compilation of a financial statement when the licensee expects, or reasonably might expect, that a third party will use the financial statement and the licensee's compilation report does not disclose a lack of independence; or

(c) an examination of prospective financial information.

This prohibition applies during the period in which the licensee is engaged to perform any of the services listed above and the period covered by any historical financial statements involved in such listed services.

(2) Disclosure of Permitted Commissions. A licensee who is not prohibited by this regulation from performing services for or receiving a commission may charge a commission for performing services if the client and the licensee enter into a separate written contract, executed by both parties, specifying the terms of the commission for each transaction to be conducted. No commission is payable or enforceable in the absence of a clearly executed written contract.

(3) Referral Fees. Any licensee who accepts a referral fee for recommending or referring any service of a Certified Public Accountant, Public Accountant, or Accounting Practitioner to any person or entity or who pays a referral fee to obtain a client shall disclose such acceptance or payment to the client in writing.

(4) This regulation shall not prohibit payments for the purchase of an accounting practice or retirement payments to individuals formerly engaged in the practice of public accounting or payments to their heirs or estates.

D. Form of Practice and Ownership and Practice Limitations.

(1) A licensee shall practice public accounting, whether as an owner or employee, only in an entity organized in accordance with applicable South Carolina law as a proprietorship, partnership, limited liability partnership, limited liability company or professional corporation or association.

(2) Ownership and Practice Limitations of Certified Public Accounting Firms. The characteristics of ownership of Certified Public Accountant entities (firms) and practice limitations shall be:

(a) A super majority sixty six and two thirds (66 2/3%) percent of the ownership of the firm in

terms of financial interests and voting rights must belong to Certified Public Accountants. The non-Certified Public Accountant owner shall be actively engaged as a firm member in providing services to the firm's clients as his or her principal occupation. Ownership by investors or commercial enterprises is prohibited.

(b) There must be a Certified Public Accountant or group of Certified Public Accountants who has ultimate responsibility for all the services provided by the firm and by each business unit (geographic or functional) performing financial statement attest, review, or compilation services and other engagements governed by the American Institute of Certified Public Accountants (AICPA) Statements on Auditing Standards or Statements on Standards for Accounting and Review Services. At least one (1) managing owner and every resident manager in charge of an office in South Carolina must be a Certified Public Accountant in this State.

(c) Non-Certified Public Accountant owners shall not assume ultimate responsibility for any financial statement attest or compilation engagement.

(d) Non-Certified Public Accountant owners shall possess a baccalaureate degree and, beginning in the year 2010, have obtained one hundred fifty (150) semester hours of education at an accredited college or university.

(e) Non-Certified Public Accountant owners will be permitted to use the title "principal," "partner," "owner," "officer," "member" or "shareholder," but not hold themselves out to be Certified Public Accountants.

(f) Non-Certified Public Accountant owners shall abide by this Code of Professional Ethics.

(g) Non-Certified Public Accountant owners shall complete the same work-related continuing professional education requirements as set forth in Section 40-2-380 and Regulation 1-17.

(h) Owners shall at all times maintain ownership equity in their own right and shall be the beneficial owners of the equity capital ascribed to them. Provision shall be made for the ownership to be

transferred to the firm or to other qualified owners if the non-Certified Public Accountant ceases to be actively engaged in the firm.

3. Ownership and Practice Limitations of Firms of Public Accountants. The characteristics of ownership of Public Accountant entities (firms) and practice limitations shall be:

(a) A super majority sixty six and two thirds (66 2/3%) percent of the ownership of the firm in terms of financial interests and voting rights must belong to Public Accountants (PAs) or Certified Public Accountants (CPAs). Owners who are not PAs or CPAs shall be actively engaged as a firm member in providing services to the firm's clients as his or her principal occupation. Ownership by investors or commercial enterprises is prohibited.

(b) There must be a Public Accountant, CPA, or group of Public Accountants or CPAs who has ultimate responsibility for all the services provide by the firm and by each business unit (geographic or functional) performing financial statement attest, review, or compilation services and other engagements governed by the American Institute of Certified Public Accountants (AICPA) Statements on Auditing Standards or Statements on Standards for Accounting and Review Services. At least one (1) managing owner and every resident manager in charge of an office in South Carolina must be a Public Accountant or CPA in this State.

(c) Owners who are not PAs or CPAs shall not assume ultimate responsibility for any financial statement attest or compilation engagement.

(d) Owners who are not PAs or CPAs shall possess a baccalaureate degree and, beginning in the year 2010, have obtained one hundred fifty (150) semester hours of education at an accredited college or university.

(e) Owners who are not PAs or CPAs will be permitted to use the title "principal," "partner," "owner," "officer," "member" or "shareholder," but not hold themselves out to be Public Accountants (or PAs).

(f) Owners who are not PAs or CPAs shall abide by this Code of Professional Ethics.

(g) Owners who are not PAs or CPAs shall complete the same work-related continual professional education requirements as set forth in Section 40-2-380 and Regulation 1-17.

4. Ownership and Practice Limitations of Accounting Practitioner Firms. The characteristics of ownership of Accounting Practitioner entities (firms) and practice limitations shall be:

(a) A super majority sixty six and two thirds (66 2/3%) percent of the ownership of the firm in terms of financial interests and voting rights must belong to Accounting Practitioners, Certified Public Accountants (CPAs) or Public Accountants (PAs). Owners who are not Accounting Practitioners, CPAs or PAs shall be actively engaged as a firm member in providing services to the firm's clients as his or her principal occupation. Ownership by investors or commercial enterprises is prohibited.

(b) There must be an Accounting Practitioner, CPA or PA or group of Accounting Practitioners, CPAs or PAs who has ultimate responsibility for all the services provide by the firm and by each business unit (geographic or functional) performing compilation services. At least one (1) managing owner and every resident manager in charge of an office in South Carolina must be an Accounting Practitioner, CPA or PA in this State.

(c) Owners who are not Accounting Practitioners, CPAs or PAs shall not assume ultimate responsibility for any financial statement compilation engagement.

(d) Owners who are not Accounting Practitioners, CPAs or PAs shall be permitted to use the title "principal," "partner," "owner," "officer," "member" or "shareholder," but not hold themselves out of be Accounting Practitioners, CPAs or PAs.

(e) Owners who are not Accounting Practitioners, CPAs or PAs shall abide by this Code of Professional Ethics.

(f) Owners who are not Accounting Practitioners, CPAs or PAs shall complete the same work-related continuing professional education requirements as set forth in Section 40-2-380 and Regulation 1-17.

(g) Owners shall at all times maintain ownership equity in their own right and shall be the beneficial owners of the equity capital ascribed to them. Provision shall be made for the ownership to be transferred to the firm or to other qualified owners if the owner who is not an Accounting Practitioner, CPA or PA ceases to be actively engaged in the firm.

E. Firm Name. No licensee shall engage in a practice of public accountancy using a professional or firm name or designation that is fictitious, or that is misleading about the form of the firm, or that is misleading about any other matter, provided, however, that names of one (1) or more former partners, members, or shareholders may be included in the name of a firm or its successor.

(1) A Certified Public Accountant firm shall not include the name or names of non-Certified Public Accountant owners.

(2) A Certified Public Accountant firm shall not include the name of a Public Accountant or Accounting Practitioner who may be an owner.

(3) The name of a firm of Public Accountants shall not contain the name of an Accounting Practitioner who may be an owner.

(4) The terms, "and associates" and "and company" shall be used in firm names only to refer to owners whose names are not otherwise identified or included in the firm name.

(5) The Board of Accountancy shall determine whether a name is misleading.

Fiscal Impact Statement: No additional funds will be incurred by the State or any political subdivision.

Document No. 2576

DEPARTMENT OF LABOR, LICENSING AND REGULATION

BOARD OF ARCHITECTURAL EXAMINERS

CHAPTER 11

Statutory Authority: 1976 Code Section 40-3-250

Synopsis:

The Board of Architectural Examiners is proposing to amend existing regulations to establish continuing education requirements for license renewal.

Instructions: Amend current regulations, by amending Regulations 11-1, 11-8 and 11-8.1 as they appear in the text below.

Text:

Regulation 11-1. Definitions.

(5) "Continuing Education Hour" means one (1) contact hour of participation in a continuing education activity.

(6) "Contact hour" means a minimum of fifty (50) minutes of instruction.

Regulation 11-8. Renewals.

A. Certificates of Registration issued to individuals expire annually on June 30. They must be renewed annually for the following fiscal year by payment of the renewal fee and by reporting completion of the required continuing education hours on or before July l. Certificates shall become invalid after that date unless renewed.

B. Certificates of Authorization issued to firms expire annually on December 31. They must be renewed annually for the following calendar year by payment of the renewal fee on or before January 1 and shall become invalid after that date unless renewed.

C. Lapsed Certificates may be reinstated by the Board at any time during the remainder of the following year on demonstration of qualification and payment of the annual renewal fee plus late penalties. In case of failure to reinstate within a year from the date of expiration, the Certificate cannot be reissued except by a new application accompanied by the application fee and approval by the Board.

Regulation 11-8.1. Continuing Education.

A. These requirements shall apply to every South Carolina registered architect as a condition for renewal of registration on an annual basis.

B. Exemptions: A registrant may be exempt from the continuing education requirements for one of the following reasons:

(1) A first-time new registrant by examination or reciprocity will be exempt for the first renewal.

(2) Registrant is a civilian who serves on active duty in the Armed Forces of the United States for a period of time exceeding ninety consecutive days during the annual report period.

(3) Registrants are non-residents of South Carolina and are required to obtain continuing education hours for license renewal by the licensing authority of any state in which he or she is registered. If the Board determines the continuing education requirements are substantially equivalent to those of South Carolina, the Board may accept a statement of compliance from the registrant.

(4) Hardship cases may be considered on an individual basis.

C. Requirements.

(1) Each South Carolina Registered architect shall complete a minimum of twelve continuing education hours of structured course study each fiscal year.

(2) Structured course study shall consist of participation in education activities presented by individuals or groups qualified by professional, practical, or academic experience to conduct courses of study.

(3) Topics for the twelve continuing education hours shall meet the following requirements:

(a) A minimum of eight continuing education hours shall include the study of relevant technical and professional architectural subjects related to safeguarding life, health, property, and promoting the public welfare.

(b) A maximum of four continuing education hours may consist of elective topics related to any other area in the practice of architecture.

(4) Each registrant shall submit, on a form provided by the board, a signed affidavit attesting to the fulfillment of continuing education requirements during the preceding period of one fiscal year ending June 30. The first report will be due before June 30, 2003. Reports will be due with each renewal thereafter. Carry-over of a maximum of twelve continuing education hours for one year is permitted.

(5) Each affidavit may be subject to audit for verification of compliance with requirements. Registrants shall retain proof of fulfillment of requirements for a period of one year after submission in the event the affidavit is selected for audit.

(6) The Board may disallow claimed credit for continuing education hours. The registrant shall have one hundred eighty calendar days after notification of disallowance of credit to substantiate the original claim or earn other continuing education credit which fulfills minimum requirements.

D. Noncompliance and Sanctions. Failure to fulfill the continuing education requirements or to file the required annual report, properly completed and signed, shall be considered a violation of the Architectural Registration Law.

Fiscal Impact Statement: No additional funds will be incurred by the State or any political subdivision.

Resubmitted March 14, 2001

Document No. 2574
DEPARTMENT OF LABOR, LICENSING AND REGULATION
SOUTH CAROLINA AUCTIONEERS' COMMISSION
CHAPTER 14
STATUTORY AUTHORITY: 1976 CODE SECTION 40-6-60

Synopsis:

The South Carolina Auctioneers' Commission is drafting regulations to be consistent with the recently enacted practice act. The proposed regulations will include, but are not limited to, provisions for examination, renewal of licenses, apprenticeships, advertising, and professional standards as well as provisions for declaratory rulings, changes of address and other procedures before the Commission. The proposed regulations will not include language from the current regulations, which repeat the language of the enabling statute.

Instructions: Amend current regulations by repealing current regulations and replacing them with new regulations as it appears in the text below.

Text:

14-1.EXAMINATIONS.

A. Examinations for auctioneers and apprentice auctioneers are to be held in the months of March, June, September and December, unless there are no applications received for a particular examination period. Special examinations shall be administered upon majority vote of the Commission in exceptional circumstances to be determined in the discretion of the Commission.

B. Applications for an examination must be received in proper form in the Commission office at least two weeks prior to the date of a scheduled examination.

C. The examination fee is non-refundable.

D. The examination shall test the applicant's knowledge of:

1. Fundamentals of auctioneering, auctioneer contracts, bid calling, advertisement, ethical practices and mathematics relating to the auction business;
2. The South Carolina Auctioneer law;
3. The South Carolina Uniform Commercial Code as it relates to auction and bulk sales.
4. Regulations of the South Carolina Auctioneers' Commission.

E. Any applicant who shall fail to pass the examination may be re-examined, but no applicant shall be allowed to take the examination within six months after having failed it a second time. Such applicants must submit an application form and pay the required fee.

F. An applicant who takes and fails to pass the examination, may, within fifteen days after he receives the results thereof, request permission to inspect his examination book, together with his examination questions. All requests for permission to inspect examination books shall be in writing and addressed to the Administrator of the Auctioneers' Commission. Within five days of receipt of such request the applicant shall be notified of the date and time when inspection will be permitted. No applicant shall be permitted to copy or remove the examination questions, the sample answers or the examination. Examinations are not contestable. All examination papers shall remain the property of the South Carolina Auctioneers' Commission.

No applicant who passes the examination shall be permitted to inspect his examination, examination questions or the sample answers.

G. The applicants who have passed the examination shall be considered for licensing. The Commission will consider any information before it, including references, with respect to the good moral character of the applicant. In the event the information is not adequate for determination, the Commission may request additional

references or information from an applicant, conduct an independent investigation, or request the applicant to appear before the Commission. Action of the Commission will be deferred until it affirmatively appears that the applicant is possessed of the required good moral character. Evidence of less than good moral character would include but is not limited to conviction of any felony or revocation of any professional license.

14-2. REPORTING OF CONTINUING EDUCATION.

A. Four hours of continuing education credit must be reported on each renewal application on a form to be provided by the Commission. All credits must be earned during the previous licensing year and at pre-approved classes. Individuals who have completed auctioneer's school within one year of the renewal application will be deemed to have four hours of continuing education hours.

B. Licensees may apply to the Commission for continuing education credit for activities of service to the industry including, but not limited to, writing articles for professional publications, teaching courses on professional subjects and serving as a hearing officer for professional matters. The burden of demonstrating that the activity is the equivalent of classroom education is placed upon the licensee.

14-3. CHANGE OF ADDRESS.

Licensees shall notify the Commission in writing of each change of address or change of business trade name within ten days of such change. The change of address notification must include a change of address fee.

14-4. DISPLAY OF LICENSE.

All licensees shall prominently display their licenses at their business address and the pocket card shall be carried by the licensee whenever he is conducting auction business.

14-5. ADVERTISING.

Misleading and untruthful advertising by licensees is prohibited. All advertisements for an auction shall contain the name and license number of the auctioneer or firm conducting the auction. Every advertisement shall clearly indicate that it is the advertisement of an auctioneer or auction firm. An apprentice auctioneer shall not advertise without the approval of the auctioneer-supervisor. Such advertisements must include not only the name and license number of the apprentice auctioneer but also the name and license number of the auctioneer-supervisor.

14-6. ALLOWING UNLICENSED BID CALLERS.

Licensees are prohibited from allowing an unlicensed bid caller (auctioneer) to cry bids at an auction.

14-7. PROFESSIONAL STANDARDS.

Any licensee who evidences incompetence or unprofessional conduct is subject to disciplinary action, suspension, or revocation by the Commission as directed by 40-6-110 and 120, Code of Laws of South Carolina, 1976, (as amended).

14-8. FALSIFICATION OF DOCUMENTS.

An applicant who falsifies an application will be denied a license. A licensee who falsifies any document required by the Commission or assists in the falsification of an application or document of another will be subject to disciplinary action, suspension, or revocation by the Commission as directed by 40-6-110 and 120, Code of Laws of South Carolina, 1976 (as amended).

14-9. DECLARATORY RULINGS.

The Commission will promptly dispose of any requests in letter form for declaratory rulings concerning the applicability of any statutory provision or of any rule or order of the Commission.

14-10. PROMULGATION, AMENDMENT, REPEAL OF RULES.

Any person who is adversely affected by a Commission rule or the absence of a rule may petition the Commission requesting the promulgation, amendment or repeal of a rule. Such petition shall be in letter form.

The Commission shall within thirty days either deny the petition in writing, stating the reasons for denial or initiate rule making proceedings.

14-11. WRITTEN AGREEMENTS RELATING TO AUCTIONS.

A. The Commission shall have the authority to demand a copy of any written agreement or records of an auction which the licensee is required to maintain by 40-6-290, Code of Laws of South Carolina, 1976, (as amended). If the documents relate to an auction being conducted or to be conducted within ten days of demand, the licensee must produce such documents before the auction can proceed. If the documents relate to any other auction, the licensee must produce such documents within ten days of the demand. Failure to produce such documents in accordance with this regulation shall be grounds for disciplinary action, suspension or revocation of the license.

B. The Commission shall have the authority to demand copies of escrow account records as required to be maintained by 40-6-300. The licensee must produce such records within 10 days of the demand. Failure to produce such escrow records in accordance with this regulation shall be grounds for disciplinary action, suspension or revocation of the license.

14-12. LATE FEES.

A. All applications for renewal of licenses pursuant to 40-6-240, Code of Laws of South Carolina, 1976 (as amended) shall be filed with the Commission on or before June 30 of each year. A late fee of twenty-five dollars shall be paid thereafter for a license renewal application received on or before July 31 of that year.

B. A late fee of one hundred dollars shall be paid after July 31 of that year and on or before September 30 of that year.

C. After September 30 of that year any license of an auctioneer, apprentice auctioneer, or auction firm that has not been renewed shall be lapsed. Any licensee in lapse status must make application for a new auctioneer, apprentice auctioneer or auction firm license and must be in accordance with 40-6-220, 40-6-230, or 40-6-235, as applicable, Code of Laws of South Carolina, 1976, (as amended).

14-13. CONDITIONS FOR APPRENTICE; EXCEPTIONS.

No applicant, pursuant to 40-6-230, Code of Laws of South Carolina,1976 (as amended), shall be deemed to have satisfactorily completed an apprenticeship until the applicant has participated in eighty hours of supervised training including forty hours of auctioneering, ten hours of auction ringing, twenty hours of clerking, and ten hours of cashiering. Such training must be completed in not less than one year nor more than two years. This section does not apply to apprentice auctioneers under supervising tobacco auctioneers.

14-14. DUPLICATE WALL OR POCKET CARD LICENSE; FEES.

A licensee may obtain a duplicate wall or pocket card license upon payment of a duplicate licensee fee for each such license.

14-15. SUPERVISION OF APPRENTICE AUCTIONEER.

A. An apprentice license is valid only while the licensee has a licensed auctioneer who serves as the licensee's duly appointed supervisor. No apprentice auctioneer may enter into an agreement to conduct an auction without the express approval of the supervisor.

B. No licensed auctioneer shall serve as the supervisor of an apprentice auctioneer pursuant to 40-6-220, Code of Laws of South Carolina, 1976 (as amended), unless that person shall have held a valid South Carolina auctioneering license for three consecutive years preceding the date on which that licensed auctioneer is appointed as supervisor of the apprentice.

C. The supervising auctioneer assumes responsibility for the compliance of the apprentice with all laws and regulations governing the practice of auctioneering. The auctioneer-supervisor shall review the records of the apprentice auctioneer before each monthly report to the Commission. Upon termination of such association, the auctioneer-supervisor shall immediately endorse the back of the apprentice's license, showing date of termination and return same to the Commission for cancellation or transfer.

14-16. AUCTIONEER, APPRENTICE PROHIBITED FROM WORKING FOR UNLICENSED FIRM;

EXCEPTION; PENALTY.

No licensed auctioneer or apprentice auctioneer shall be employed as an auctioneer or apprentice auctioneer by an auction firm unless that firm holds a valid auction firm license issued by the Commission or unless the firm is otherwise not required to hold an auction firm license pursuant to Section 40-6-235, Code of Laws of South Carolina, 1976 (as amended). A violation of this regulation shall be grounds for disciplinary action, suspension or revocation of an auctioneer or apprentice auctioneer license pursuant to Section 40-6-110 and 120, Code of Laws of South Carolina, 1976 (as amended.)

14-17. LICENSE CERTIFICATION.

The South Carolina Auctioneers' Commission shall, upon the payment of a fee, provide a letter certifying that a licensee holds a currently valid license issued by the Commission.

Fiscal Impact Statement: No additional funds will be incurred by the State or any political subdivision.

Document No. 2549
DEPARTMENT OF LABOR, LICENSING AND REGULATION
BOARD OF LONG TERM HEALTH CARE ADMINISTRATORS
CHAPTER 93
Statutory Authority: 1976 Code Section 40-35-240

Synopsis:

The Board of Long Term Health Care Administrators is considering drafting regulations to amend the regulations to require licensees to notify the Board of changes of address and employment in nursing homes or community residential care facilities.

Instructions: Amend current regulations, by amending section 93-160 (D)as it appears in the text below.

Text:

93-160. Registration of Licenses.
D. All licensees must notify the Board in writing within fifteen (15) days of any change of address and employment in a nursing home or community residential care facility.

Fiscal Impact Statement: No additional funds will be incurred by the State or any other political subdivision.

Document No. 2548
DEPARTMENT OF LABOR, LICENSING AND REGULATION
BOARD OF MEDICAL EXAMINERS
CHAPTER 81
Statutory Authority: 1976 Code Sections 40-47-20; 40-1-70

Synopsis:

The Board of Medical Examiners is proposing a regulation that would define and regulate the requirements for the initial prescribing of medications by South Carolina licensed physicians including prescribing via the Internet and toll-free telephone prescribing, and define unprofessional conduct related to initial prescribing.

Instructions: Amend current regulations, by amending regulation 81-28 as it appears in the text below.

Text:
81-28. Contact with Patients before Prescribing.

A. It is unprofessional conduct for a physician to initially prescribe drugs to an individual without first establishing a proper physician-patient relationship. A proper relationship, at a minimum, requires that the physician make an informed medical judgment based on the circumstances of the situation and on his/her training and experience. This will require that the physician:

(1) Personally perform an appropriate history and physical examination, make a diagnosis, and formulate a therapeutic plan. This process must be documented appropriately; and

(2) Discuss with the patient the diagnosis and the evidence for it, and the risks and benefits of various treatment options; and

(3) Insure the availability of the physician or coverage for the patient for appropriate follow-up care.

B. Prescribing for a patient whom the physician has not personally examined may be suitable under certain circumstances. These may include, but not be limited to, admission orders for a newly hospitalized patient, prescribing for a patient of another physician for whom the prescriber is taking call, prescribing for a patient examined by a licensed advanced practice registered nurse, a physician assistant or other physician extender authorized by law and supervised by the physician, or continuing medication on a short-term basis for a new patient prior to the patient's first appointment.

C. Prescribing drugs to individuals the physician has never met based solely on answers to a set of questions, as is common in Internet or toll-free telephone prescribing, is inappropriate and unprofessional.

D. Section 40-47-200(F)(8) of the South Carolina Medical Practice Act authorizes the Board to discipline a licensed South Carolina physician who is guilty of engaging in dishonorable, unethical or unprofessional conduct that is likely to deceive, defraud, or harm the public.

Fiscal Impact Statement: No additional funds will be incurred by the State or any political subdivision.

Document No. 2526

DEPARTMENT OF LABOR, LICENSING AND REGULATION
BOARD OF EXAMINERS FOR THE LICENSURE OF PROFESSIONAL COUNSELORS, MARRIAGE AND FAMILY THERAPISTS, AND PSYCHO-EDUCATIONAL SPECIALISTS

CHAPTER 36

Statutory Authority: 1976 Code Section 40-75-05, et seq.

Synopsis:

Revisions have been made to include psycho-educational specialists and to clarify educational and experience requirements for licensed professional counselors, marriage and family therapists, licensed professional counselor interns, marriage and family therapy interns, licensed professional counselor supervisors, and marriage and family therapy supervisors, as well as practitioners who diagnose and treat serious disorders.

These regulations also include an impaired practitioners program and provide a code of ethics for each group of licensees.

Instructions: Amend current regulations, by replacing them in their entirety with new regulations as they appear in the text below.

Text:

Article 1
Definitions.

36-01. Definitions.

Definitions found in Section 40-75-20 apply to this chapter.

(1) "SUPERVISION" MEANS FACE-TO-FACE CONTACT BETWEEN A SUPERVISOR AND AN INTERN OR OTHER PERSON REQUIRING SUPERVISION UNDER THIS CHAPTER DURING WHICH TIME THE PERSON SUPERVISED APPRISES THE SUPERVISOR OF THE DIAGNOSIS

AND TREATMENT OF EACH CLIENT, THE CLIENTS' CASE IS DISCUSSED, THE SUPERVISOR PROVIDES THE SUPERVISED PERSON WITH OVERSIGHT AND GUIDANCE IN DIAGNOSING, TREATING, AND DEALING WITH CLIENTS, AND THE SUPERVISOR EVALUATES THE SUPERVISED PERSON'S PERFORMANCE. THE FOCUS OF A SUPERVISION SESSION IS ON RAW DATA FROM CLINICAL WORK WHICH IS MADE DIRECTLY AVAILABLE TO THE SUPERVISOR THROUGH SUCH MEANS AS WRITTEN CLINICAL MATERIALS, DIRECT (LIVE) OBSERVATION, CO-THERAPY, AUDIO AND VIDEO RECORDINGS, AND LIVE SUPERVISION. SUPERVISION IS A PROCESS CLEARLY DISTINGUISHABLE FROM PERSONAL PSYCHOTHERAPY AND IS CONTRASTED IN ORDER TO SERVE PROFESSIONAL GOALS. THE MAJOR FOCUS IN SUPERVISION OF SUPERVISORS IS ON THE DEVELOPMENT OF SUPERVISORY ABILITIES AS OPPOSED TO AN EXCLUSIVE FOCUS ON CLINICAL SKILLS.

(2) "Group supervision" means a regularly scheduled meeting of not more than six (6) supervisees, and an approved supervisor, for a minimum of one and one half (1½) hours.

(3) "Individual supervision" means a meeting of one (1) or two (2) supervisees with a supervisor for a period of at least a one (1) hour session.

(4) "Internship" means a distinctly defined, post-degree, supervised curricular experience intended to enable and to refine and enhance basic skills, develop more advanced therapy skills, and integrate professional knowledge and skills appropriate to the individual's initial professional placement. Internship licensure status provides an opportunity, under supervision, for the individual to perform all the activities that a regularly employed staff member in the setting would be expected to perform.

(5) "Continuing education" means an organized educational program designed to expand a licensee's knowledge base beyond the basic entry level educational requirements for professional counselors, marriage and family therapists, and psycho-educational specialists.

(6) "Contact hour" means a minimum of fifty (50) minutes of instruction.

(7) "Impairment" means impairment of mental and/or physical ability to practice according to acceptable and prevailing standards of care including, but not limited to, habitual or excessive use or abuse of drugs, alcohol, or other substances that impair ability to practice. Impairment includes inability to practice in accordance with such standards, and treatment, monitoring, and supervision.

(8) "Relapse" means any use of alcohol or of a drug or substance that may impair ability to practice during or after any approved treatment program, except pursuant to the directions of a treating physician who has knowledge of the patient's history and the disease of addiction, or pursuant to the direction of a physician in a medical emergency.

(9) "Approved treatment provider" means a treatment provider approved by the Board.

(10) "Sobriety" means abstinence from alcohol, and from drugs or substances that may impair ability to practice, except pursuant to the directions of a treating physician who has knowledge of the patient's history and the disease of addiction, or pursuant to the direction of a physician in a medical emergency.

(11) "Qualified licensed mental health practitioner" means a person licensed as a Professional Counselor Supervisor, Marriage and Family Therapy Supervisor, Psychologist, or Medical Doctor who possesses the knowledge and expertise necessary to provide a supervised person with guidance and direction, in a structured program, to gain knowledge and skills associated with the diagnosis and treatment of serious problems as categorized in standard diagnostic nomenclature.

(12) "DSM" means the Diagnostic and Statistical Manual of Mental Disorders.

(13) "Serious Problems" are those disorders as categorized in standard diagnostic nomenclature such as the DSM with the exception of codes assigned to normal lifecycle transitional conflicts.

Article 2
Officers of Board; Meetings.
36-02. Officers of Board.

At the first meeting of each calendar year, the Board shall elect from among its professional members a president, vice-president, and other officers as the Board determines necessary.

36-03. Meetings.

(1) The Board shall meet at least two (2) times a year and at other times upon the call of the president or a majority of the Board members.

(2) A majority of the members of the Board constitutes a quorum; however, if there is a vacancy on the Board, a majority of the members serving constitutes a quorum.

(3) Board members are required to attend meetings or to provide proper notice and justification of inability to do so. Unexcused absences from meetings may result in removal from the Board as provided in Section 1-3-240. Affirmative action by the Board is required to approve an excused absence and the status of an absence as excused or unexcused is entirely within the Board's discretion.

Article 3

Licensing Provisions.

36-04. General Licensing Provisions for Professional Counselor Interns.

An applicant for initial licensure as a professional counselor intern must:

(1) submit an application on forms approved by the Board, along with the required fee; and

(2) submit evidence of successful completion of a graduate degree with a minimum of forty-eight (48) graduate semester hours primarily in counseling or related discipline from a college or university accredited by the Commission on the Colleges of the Southern Association of Colleges and Schools, one of its transferring regional associations, the Association of Theological Schools in the United States and Canada, or a regionally-accredited institution of higher learning subsequent to receiving the graduate degree, along with evidence of an earned master's degree, specialist's degree or doctoral degree. On graduate transcript the applicant must demonstrate successful completion of one (1) three-hour graduate level course in each of the following areas:

(a) Human growth and development: coursework content providing an understanding of the nature and needs of individuals at all developmental levels, normal and abnormal human behavior, personality theory, and learning theory (all) within cultural contexts; and

(b) Social and cultural foundations: coursework content providing an understanding of societal changes and trends, human roles, societal subgroups, social mores and interaction patterns, and differing lifestyles; and

(c) Helping relationships: coursework content providing an understanding of philosophic bases of helping processes, counseling theories and their applications, helping skills, consultation theories and applications, helper self-understanding and self-development, and facilitation of client or consultee change; and

(d) Groups: coursework content providing an understanding of group development, dynamics, and counseling theories; group leadership styles, group counseling methods and skills, and other group approaches; and

(e) Lifestyle and career development: coursework content providing an understanding of career development theories, occupational and educational information sources and systems, career and leisure counseling, guidance, and education; lifestyle and career decision-making; and career development program planning, resources, and evaluation; and

(f) Appraisal: coursework content providing an understanding of group and individual education and psychometric theories and approaches to appraisal, data, and information gathering methods, validity and reliability, psychometric statistics, factors influencing appraisals, and use of appraisal results in helping processes; and

(g) Research and evaluation: coursework content providing an understanding of types of research, basic statistics, research report development, research implementation, program evaluation, needs assessment, and ethical and legal considerations; and

(h) Professional orientation: coursework content providing an understanding of professional roles and functions, professional goals and objectives, professional organizations and associations, professional history and trends, ethical and legal standards, professional preparation standards, and professional credentialing; and

(i) Psychopathology: coursework content providing an understanding of psychopathology, abnormal psychology, abnormal behavior, etiology dynamics, and treatment of abnormal behavior; and

(j) Diagnostics: coursework content providing an understanding of the diagnostics of Psychopathology; and

(k) Practicum: a minimum of one (1) supervised one hundred fifty (150) hour counseling practicum; and

(3) submit evidence of a passing score on an examination approved by the Board; and

(4) submit a supervision plan, satisfactory to the Board, designed to take effect after notice of a passing score on the required examination.

36-04.1 Specific training required for interns to assess and treat serious problems as categorized in standard diagnostic nomenclature.

In order for any person licensed as a Licensed Professional Counselor Intern to assess and treat serious problems as described in standard diagnostic nomenclature, a Licensed Professional Counselor Intern must have satisfied the following requirements:

(1) In addition to the academic course requirements outlined in Section 36-04(2)(a-k) above, obtained a minimum of three (3) graduate semester hours in Psychopathology in academic training from a college or university approved by the Board. This course must provide an understanding of psychopathology, abnormal psychology, abnormal behavior, etiology dynamics, and treatment of abnormal behavior; and

(2) In addition to the academic course requirements outlined in Section 36-04 (2) (a-k) above, obtained a minimum of three (3) graduate semester hours in Diagnostics in academic training from a college or university approved by the Board. This course must provide an understanding of the diagnostics of psychopathology; and

(3) Completed a practicum as part of a degree program, as required in Section 36-04(2)(k) above, that dealt directly with the assessment and treatment of more serious problems as categorized in standard diagnostic nomenclature; and

(4) Completed an internship, as part of a degree program, of at least six hundred (600) hours under the supervision of a qualified licensed mental health practitioner where experience assessing and treating clients with the more serious problems as categorized in standard diagnostic nomenclature is obtained.

36-05. General Licensing Provisions for Licensed Professional Counselors.

An applicant for licensure as a professional counselor must:

(1) submit an application on forms approved by the Board, along with the required fee; and

(2) hold a current, active, and unrestricted professional counselor intern license; and

(3) submit evidence satisfactory to the Board of a minimum of two thousand (2000) hours of supervised clinical experience in the practice of professional counseling performed over a period of not less than two (2) years under the supervision of a licensed professional counselor supervisor or other qualified licensed mental health practitioner as provided in Section 36-05.1. The experience must include a minimum of one thousand five hundred (1500) hours of direct counseling with individuals, couples, families, or groups and a minimum of one hundred fifty (150) hours spent in immediate supervision with the licensed professional counselor supervisor, including one hundred (100) hours of individual supervision and fifty (50) hours of either individual or group supervision. A maximum of five hundred (500) hours of experience gained prior to the award of a graduate degree may be included in the total required experience; and

(4) submit evidence that the supervision plan has been completed, including a recommendation by the licensed professional counselor supervisor, on forms approved by the Board.

36-05.1 Specific training required for persons licensed as Professional Counselors to assess and treat serious problems as categorized in standard diagnostic nomenclature.

In order for any person licensed as a Licensed Professional Counselor to assess and treat serious problems as described in standard diagnostic nomenclature, a Licensed Professional Counselor must have satisfied the following requirements:

(A)(1) The licensee will have acquired a minimum of twelve (12) graduate hours to ensure a level of competency in the area of specialty, including;

(a) a minimum of three (3) graduate semester hours in Psychopathology in academic training from a college or university approved by the Board. This course must provide the practitioner with an understanding of psychopathology, abnormal psychology, abnormal behavior, etiology dynamics, and treatment of abnormal behavior; and

(b) a minimum of three (3) graduate semester hours in Diagnostics in academic training from a college or university approved by the Board. This course must provide the practitioner with an understanding of the diagnostics of psychopathology; and

(2) The licensee must have completed a minimum of two thousand (2000) hours of post-degree supervised clinical experience performed over a period not less than two (2) years with an emphasis in the treatment of serious problems as categorized in standard diagnostic nomenclature, under the supervision of a qualified licensed mental health practitioner approved by the Board. The experience must include a minimum of two thousand (2000) hours of direct counseling with individuals, couples, families, or groups and a minimum of one hundred fifty (150) hours spent in immediate supervision with the supervisor, including one hundred (100) hours of individual supervision and fifty (50) hours of either individual or group supervision. A maximum of five hundred (500) hours of experience gained prior to the award of a graduate degree may be included in the total required experience.

(B) A LICENSEE ENGAGED IN THE ASSESSMENT AND TREATMENT OF SERIOUS PROBLEMS AS CATEGORIZED IN STANDARD DIAGNOSTIC NOMENCLATURE PRIOR TO THE EFFECTIVE DATE OF THESE REGULATIONS SHALL BE AUTHORIZED TO CONTINUE ENGAGING IN SUCH PRACTICE PROVIDED THAT THE LICENSEE HAS MADE PROPER APPLICATION TO THE BOARD FOR DESIGNATION NOT LATER THAN ONE YEAR AFTER THE EFFECTIVE DATE OF THESE REGULATIONS; AND:

(1) has completed, within three (3) years after the effective date of these regulations, a minimum of three graduate semester hours in Psychopathology in academic training from a college or university approved by the Board. This course must provide the practitioner with an understanding of psychopathology, abnormal psychology, abnormal behavior, etiology dynamics, and treatment of abnormal behavior; and

(2) has completed, within three (3) years after the effective date of these regulations, a minimum of three graduate semester hours in Diagnostics in academic training from a college or university approved by the Board. This course must provide the practitioner with an understanding of the diagnostics of psychopathology; and

(C) Upon application to the Board and satisfactory proof of compliance with all applicable requirements to assess and treat serious problems as categorized in standard diagnostic nomenclature, the Board shall designate that the licensee is authorized to assess and treat the more serious problems as categorized in standard diagnostic nomenclature for which the licensee has met the requirements.

36-06. General Licensing Provisions for Licensed Professional Counselor Supervisors.

An applicant for licensure as a professional counselor supervisor must:

(1) submit an application on forms approved by the Board, along with the required fee; and

(2) hold a current, active, and unrestricted South Carolina Professional Counselor License. For supervisors initially licensed after July 1, 1998, a current South Carolina Professional Counselor License is a requirement for renewal and the lapse of a South Carolina Professional Counselor License shall cause the Professional Counselor Supervisor License to lapse. For supervisors initially licensed prior to July 1, 1998, a current South Carolina Professional Counselor License is not required for the continuation of supervisory activities under a current supervisor's license; however, the supervisor may not also engage in the practice of Professional Counseling unless a current, active, and unrestricted Professional Counselor License is first obtained; and

(3) submit evidence acceptable to the Board of at least five (5) years of continuous clinical experience immediately preceding the application. Continuous clinical experience is any counseling experience gained as in

certification by the National Board for Certified Counselors (NBCC), National Association of Alcoholism and Drug Abuse Counselors (NAADAC), or South Carolina Association of Alcoholism and Drug Abuse Counselors (SCAADAC) or a licensed professional counselor; and

(4) submit evidence acceptable to the Board of at least two (2) years supervising the clinical casework of other NBCC, NAADAC, or SCAADAC certified counselors or licensed counselors; and

(5) submit evidence of a minimum of thirty-six (36) hours of individual supervision, by a Board licensed supervisor, of the applicant's supervision of at least two (2) licensed professional counselor interns; and

(6) submit evidence of a minimum of thirty (30) contact hours of formal academic training or continuing education in supervision oriented to their discipline.

36-07. General Licensing Provisions for Marriage and Family Therapy Interns.

An applicant for initial licensure as a marriage and family therapy intern must:

(1) submit an application on forms approved by the Board, along with the required fee; and

(2) submit evidence of successful completion of a minimum of forty-eight (48) graduate semester hours in marriage and family therapy from a college or university accredited by the Commission on the Colleges of the Southern Association of Colleges and Schools, one (1) of its transferring regional associations, the Association of Theological Schools in the United States and Canada, a post-degree program accredited by the Commission on Accreditation for Marriage and Family Therapy Education, or a regionally accredited institution of higher learning subsequent to receiving the graduate degree, along with evidence of an earned master's degree, specialist's degree, or doctoral degree. The applicant must demonstrate successful completion of:

(a) a minimum of nine (9) graduate semester hours in theoretical foundations. The coursework content in this area must enable students to conceptualize and distinguish the critical epistemological issues in marriage and family therapy. The material in this area must be related conceptually to clinical concerns. The applicant must demonstrate completion of an introductory course including historical development, theoretical foundations, and contemporary conceptual directions in the field of marriage and family therapy of at least three (3) graduate semester hours as part of this requirement; and

(b) a minimum of fifteen (15) graduate semester hours in clinical practice. The coursework content in this area must address marriage and family therapy practice and be related conceptually to theory. Coursework in this area must focus on assessment, including marriage and family therapy methods and major mental health assessment methods and instruments, and must provide a comprehensive survey and substantive understanding of the major models of marriage and family therapy, as well as address a wide variety of clinical problems. Coursework must educate students about appropriate collaboration with related disciplines, and must include three (3) semester hours of psychopathology, abnormal psychology, abnormal behavior, etiology dynamics or treatment of abnormal behavior, and three (3) semester hours of diagnostics of psychopathology; and

(c) a minimum of six (6) graduate semester hours in individual development and family relations. The coursework content in this area must include significant material on individual development, family development, and family relationships. Coursework must include significant material on issues of sexuality as it relates to marriage and family therapy theory and practice. Sexual dysfunctions and difficulties, as well as individual development, gender, multi-cultural and sexual orientation, as related to marriage and family therapy theory and practice must be included; and

(d) a minimum of three (3) graduate semester hours in professional identity, legal, and ethical issues. The coursework in this area must include information about legal responsibilities and liabilities in the practice of marriage and family therapy. The coursework must include research, family law, confidentiality issues, and codes of ethics; and

(e) a minimum of three (3) graduate semester hours in research. The coursework content in this area must include significant material on research in marriage and family therapy. This area must focus on research methodology, data analysis, and the evaluation of research; and

(f) a minimum of nine (9) graduate semester hours in clinical experience. The coursework content in this area must include client contact and clinical supervision with individuals, couples, and families in a clinical setting. The clinical experience must include a minimum of three hundred (300) hours of face to face client contact, one half (1/2) of which must be relational. A minimum of fifty (50) hours of clinical supervision must be provided by a marriage and family therapy supervisor; and

(3) submit evidence of a passing score on an examination approved by the Board; and

(4) submit a supervision plan, satisfactory to the Board, designed to take effect after notice of a passing score on the required examination.

36-08. General Licensing Provisions for Marriage and Family Therapists.

An applicant for licensure as a Marriage and Family Therapist must:

(1) submit an application on forms approved by the Board, along with the required fee; and

(2) hold a current, active, and unrestricted Marriage and Family Therapy Intern license unless applying under the provisions of Section 36-11; and

(3) submit evidence satisfactory to the Board of a minimum of twelve hundred (1200) hours of supervised clinical experience in the practice of marriage and family therapy performed over a period of not less than two (2) years under the supervision of a licensed marriage and family therapy supervisor. The experience must include a minimum of one thousand (1000) hours of direct client contact with individuals, couples, families, or groups and a minimum of two hundred (200) hours spent in immediate supervision with the licensed marriage and family therapy supervisor, including one hundred (100) hours of individual supervision. A maximum of five hundred (500) hours of experience gained prior to the award of a graduate degree may be included in the total required experience; and

(4) submit evidence that the supervision plan has been completed, including a recommendation by the licensed marriage and family therapy supervisor, on forms approved by the Board.

36-09. General Licensing Provisions for Licensed Marriage and Family Therapy Supervisors.

An applicant for licensure as a marriage and family therapy supervisor must:

(1) submit an application on forms approved by the Board, along with the required fee; and

(2) hold a current, active, and unrestricted South Carolina Marriage and Family Therapy License. For supervisors initially licensed after July 1, 1998, a current South Carolina Marriage and Family Therapy License is a requirement for renewal and the lapse of a South Carolina Marriage and Family Therapy License shall cause the Marriage and Family Therapy Supervisor License to lapse. For supervisors initially licensed prior to July 1, 1998, a current South Carolina Marriage and Family Therapy License is not required for the continuation of supervisory activities under a current supervisor's license; however, the supervisor may not also engage in the practice of Marriage and Family Therapy unless a current, active, and unrestricted Marriage and Family Therapy License is first obtained; and

(3) submit evidence acceptable to the Board of at least five (5) years of continuous clinical experience immediately preceding the application including one hundred eighty (180) hours of clinical supervision under a licensed Marriage and Family Therapy Supervisor; and

(4) submit evidence of a minimum of thirty-six (36) hours of individual supervision of the applicant's supervision of at least two (2) marriage and family therapy interns; and

(5) submit evidence of a minimum of three (3) semester hours of graduate study in supervision.

36-10. General Licensing Provisions for Psycho-educational Specialists.

An applicant for initial licensure as a psycho-educational specialist must:

(1) submit an application on forms approved by the Board, along with the required fee; and

(2) submit evidence of successful completion of an earned master's degree plus thirty (30) graduate semester hours, or an earned sixty (60) graduate semester hour master's degree, or a sixty (60) graduate semester hour specialist's degree, or a doctoral degree in school psychology from an institution of higher education whose program is approved by the National Association of School Psychologists or the American Psychological Association or a program which the Board finds to be substantially equivalent. A substantially equivalent program must include an earned master's, specialist's, or doctoral degree in an applied area of psychology, education, or behavioral sciences from a regionally accredited institution, completion of at least sixty (60) graduate semester hours, and substantial preparation, including coursework, in the following areas:

(a) psychological foundations, including biological bases of behavior; human learning; child and adolescent development; social/cultural bases of behavior; and individual differences (exceptionalities/psychopathology of children and youth); and

(b) educational foundations, including organization and operation of schools; and instructional/remedial design; and

(c) assessment and intervention, including diverse methods of individual assessment that can be linked to intervention; direct intervention including counseling and behavior analysis/intervention; and indirect intervention including a consultation with school personnel and families; and

(d) statistics and research methodologies; and

(e) professional school psychology, including history and foundations of school psychology; legal and ethical issues; professional issues and standards; alternative models of service delivery; emergent technologies; and roles and functions of school psychologists; and

(f) a one-year twelve hundred (1200) hour internship, at least one-half (1/2) of which must be in an approved school setting. The internship shall include a full range of psycho-educational services supervised by a licensed psycho-educational specialist or certified or licensed school psychologist. If a portion of the internship is completed in a non-school setting, supervision may be provided by a psychologist appropriately credentialed for that setting as approved by the Board. The possession of a National Certified School Psychologist (NCSP) credential issued after January 1, 1988 shall be evidence of completion of a satisfactory program as provided above; and

(3) provide evidence satisfactory to the Board of certification by the South Carolina Department of Education in school psychology level II or III; and

(4) provide evidence satisfactory to the Board that the applicant has successfully served as a certified school psychologist for at least two (2) years in a school or comparable setting. After January 1, 2000, one (1) year must have been under the supervision of a licensed psycho-educational specialist. One (1) year of experience is defined as full-time employment for one (1) contract year of at least one hundred ninety (190) work days. Two (2) consecutive years of half-time work may, at the discretion of the Board, be deemed to be equivalent to one (1) full year of experience. The experience must include provision of a full range of services to children, youth, and families. Experience acquired under a provisional or temporary certificate in school psychology, or in a pre-degree practicum or internship, may not count toward this experience requirement; and

(5) submit evidence of a passing score on an examination approved by the Board.

36-11. Licensure by Endorsement.

An applicant for licensure as a professional counselor, marriage and family therapist, or psycho-educational specialist by endorsement must:

(1) hold a current, active, and unrestricted license under the laws of another state or territory that had requirements that were, at the date of licensure, equivalent to the requirements in effect at the time of application in South Carolina; and

(2) submit an application on a form approved by the Board, along with the required fee; and

(3) provide other documentation, as required by the Board.

36-12. Reactivation of Expired Licenses.

(1) A licensed professional counselor, marriage and family therapist, or psycho-educational specialist whose license has been expired for at least one (1) year, but less than six (6) years, may reactivate the license upon application, along with the required fee, and demonstration of evidence satisfactory to the Board on a form approved by the Board of the requisite continuing education hours for each year during which the license was expired. The Board may, in its discretion, require supervised experience or additional training as a condition of reactivation. The Board for good cause may waive any part of this continuing education requirement upon appropriate conditions.

(2) A licensed professional counselor, marriage and family therapist, or psycho-educational specialist whose license has been expired for more than six (6) years must re-apply and meet all of the requirements, at the time of application, for licensure.

(3) Any applicant for reactivation shall submit a notarized affidavit certifying that they have not been engaged in the practice of counseling, marriage and family therapy, or psycho-education outside of the school setting during the period their license was not in a current status.

Article 4

Continuing Education.

36-13. Continuing Education Requirements for Professional Counselors and Marriage and Family Therapists.

(1) Persons licensed as professional counselors or marriage and family therapists shall complete forty (40) hours of continuing education related to their respective professional license during every two-year licensure period. Persons licensed both as professional counselors and marriage and family therapists must complete fifty (50) hours of formal continuing education during every two-year licensure period as a condition of renewal of their licenses. Of the fifty (50) hours, at least twenty-five (25) hours must be related to each discipline. Persons licensed as professional counselor supervisors or marriage and family therapy supervisors must complete ten (10) hours of formal continuing education in supervision of their discipline during every two-year licensure period as a condition of renewal of their license. Persons licensed both as professional counselor supervisors and marriage and family therapy supervisors must complete ten (10) hours of formal continuing education in supervision, at least five (5) hours of which must be in supervision of each discipline. A maximum of fifteen (15) hours may be obtained through informal continuing education, as long as the activity is approved in advance by the Board.

(2) Any formal continuing education activity sponsored by a professional counselor certifying body, marriage and family therapy certifying body, NAADAC, or SCAADAC approved by the Board as a continuing education sponsoring body, or one of its regional or state divisions, is automatically approved for the formal continuing education requirement.

(3) Unapproved sponsoring organizations must request advance approval on Board-approved forms ninety (90) days prior to each continuing education event. In order to request approval, the sponsoring organization must submit an agenda of the session, the curriculum vitae of all presenters and a copy of the evaluation documents.

(4) The Board may approve informal continuing education using the following guidelines:

(a) a first time presentation of a paper, workshop, or seminar for a national, regional, statewide, or other professional meeting may be approved for a maximum of five (5) continuing education hours; and

(b) a published paper in a referred journal may be approved for a maximum of five (5) continuing education hours and may be used only once; and

(c) preparation of a new or related course for an educational institution or organization may be approved for a maximum of five (5) continuing education hours; and

(d) individual self-study to include use of audio-visual materials, reading of professional journals and books, and participation in professional study and discussion groups may be approved based on the number of hours recommended by the sponsoring organization or the number of hours engaged in the activity for a total of fifteen (15) hours during each two-year licensure period.

(5) No hours may be carried forward from the renewal period in which they were earned.

36-14. Continuing Education Requirements for Psycho-educational Specialists.

(1) Persons licensed as psycho-educational specialists shall complete forty (40) hours of continuing education related to their professional licensure during every two-year licensure period.

(2) Continuing education credit may be awarded for documented completion of the following activities:

(a) a minimum of twenty (20) continuing education hours in workshops, conferences, formal in-service training, college or university courses, and teaching and training activities. A maximum of ten (10) hours may be awarded for attendance at workshops, conferences, or in-service training. For teaching and training activities, credit may be awarded only for the first time the content is taught and limited to a maximum of ten (10) hours; or

(b) a maximum of twenty (20) continuing education hours in research and publications, supervision of interns, post-graduate supervised experiences, program planning/evaluation, self-study, and professional organizational leadership. A maximum of ten (10) hours may be awarded for unpublished research. A maximum of twenty (20) hours may be awarded for research and publication or presentation. A maximum of ten (10) hours may be awarded for articles published or posters presented. Each project may be claimed only once. A maximum of twenty (20) hours may be awarded for supervision of interns. No more than one (1) post-graduate supervised experience may be claimed in any renewal period. A maximum of fifteen (15) hours may be awarded for program planning/evaluation. A maximum of twenty (20) hours may be awarded for self-study. No more than one (1) activity may be counted per organization per year and a maximum of ten (10) hours may be awarded in professional organization leadership.

Article 5

Fees.

36-15. Fees.

(A) Fees are as follows:

(1) Application Fee	
(a) Intern Application (not to exceed)	$ 150.00
(b) All other applications (not to exceed)	$ 200.00
(2) After August 31, 2001 - Biennial license renewal	
(a) Interns (not to exceed)	$ 200.00
(b) Professional Counselors (not to exceed)	$ 200.00
(c) Marriage and Family Therapists (not to exceed)	$ 200.00
(d) Psycho-educational Specialists (not to exceed)	$ 200.00
(e) Professional Counselor Supervisors (not to exceed)	$ 150.00
(f) Marriage and Family Therapy Supervisors (not to exceed)	$ 150.00
(3) Late Renewal Penalty (1 through 3 months)	$ 50.00
Late Renewal Penalty (4 through 12 months)	$ 100.00
(4) Reactivation Fee	$ 300.00 + renewal
(5) Examination Fee (not to exceed)	$ 300.00
(6) Examination Score Verification or License Verification (not to exceed)	$ 15.00
(7) Application for Continuing Education sponsor (not to exceed)	$ 100.00
(8) Continuing Education Sponsorship Renewal (not to exceed)	$ 50.00 (annually)
(9) License verification to another state (not to exceed)	$ 20.00
(10) Name change and new license (not to exceed)	$ 25.00
(11) Duplication license (not to exceed)	$ 25.00
(12) Returned check charge	$ 25.00

(or as otherwise established by law as administrative costs for returned checks)

(B) All fees are nonrefundable.

Article 6

Treatment for impaired practitioners.

36-16. Identification of Impaired Practitioners.

(A) Any person licensed under Title 40, Chapter 75 of the Code of Laws of South Carolina shall report to the Board any belief that a practitioner suffers from an impairment that does presently or in the future may affect the ability of the practitioner to competently practice, unless:

(1) the individual, or the organization of which the individual is a part, is a treatment provider approved by the Board; and

(a) the practitioner maintains participation in treatment or aftercare; and

(b) the practitioner, if currently undergoing an inpatient treatment program, is not practicing and is following the guidelines set forth by the treatment program. If the practitioner is an out-patient, is maintaining sobriety and is enrolled in an approved aftercare program; or

(2) the individual is a member of an impaired practitioner committee, or the equivalent, established by a hospital or similar institution or its staff, or is a representative or agent of a committee or program sponsored by a professional association of individuals licensed under Title 40, Chapter 75 of the Code of Laws to provide peer assistance to practitioners with substance abuse problems; and

(a) the practitioner has been referred for examination to an approved treatment program; and

(b) the practitioner cooperates with the referral for examination and any determination that he should enter treatment; and

(c) the practitioner's ability to practice competently has not been affected; or

(3) the individual maintains a good faith belief that:

(a) the practitioner has been referred for examination to an approved treatment program; and

(b) the practitioner cooperates with the referral for examination and any determination that he should enter treatment; and

(c) the practitioner's ability to practice competently has not been affected; or

(4) the individual is otherwise prohibited from reporting to the Board by state or federal law.

(B) For purposes of this section, a reason to believe or a belief does not require absolute certainty or complete unquestioning acceptance; but only an opinion that an impairment exists based upon firsthand knowledge, or reliable information.

(C) Any report required by this section shall be made to the Board within forty-eight (48) hours.

36-17. Treatment of Complaints Pertaining to Impaired Practitioners.

(A) An individual who accepts the privilege of practicing under Title 40, Chapter 75 of the South Carolina Code of Laws in this State is subject to oversight by the Board. By filing an application or being licensed by the Board, the individual shall be deemed to give consent to submit to a mental or physical examination when ordered to do so by the Board in writing, and to have waived all objections to the admissibility of testimony or examination of reports that constitute privileged communications. Failure of the individual to submit to a mental or physical examination order by the Board constitutes an admission of the allegations against the individual licensee unless the failure is due to circumstances beyond the individual's control.

(B) When the Board receives information by the filing of a complaint, or upon its own information, that a licensee's ability to practice has fallen below the acceptable and prevailing standards of care because of habitual or excessive use or abuse of drugs, alcohol, or other substances and other physical or mental impairments that affect the ability to practice, the Board may order the licensee to submit to a mental or physical examination conducted by a designee of the Board for the purpose of determining if there is an impairment that poses a threat to the licensee's well-being or the treatment of a client whom the licensee serves.

(C) If the Board determines that the individual's ability to practice is impaired, the Board shall suspend or place restrictions on the individual's license to practice, or deny the individual's application, and require the individual to submit to treatment, as a condition for initial, continued, reinstated, or renewed licensure to practice.

(D) In cases where the Board has not initiated disciplinary action, the following general pattern of action shall be followed:

(1) upon identification by the Board of reason to believe that a licensee or applicant is impaired it may compel an examination or examinations; and

(2) if the examination or examinations fail to disclose impairment, no action shall be initiated unless other investigation produces reliable, substantial, and probative evidence demonstrating impairment; and

(3) if the examination discloses impairment, or if the Board has other reliable, substantial, and probative evidence demonstrating impairment, including, but not limited to, evidence of relapse after the completion of inpatient or outpatient treatment, the Board shall initiate proceedings to suspend the license or deny licensure of the applicant; and

(4) before being eligible to apply for reinstatement of a license suspended under this section, the practitioner must demonstrate to the Board that a resumption of practice may be made in compliance with acceptable and prevailing standards of care under the provisions of an unrestricted license. Such demonstrations shall include, but shall not be limited to, the following:

(a) certification from a treatment provider approved by the Board that the practitioner has successfully completed any required inpatient treatment; and

(b) evidence of continuing full compliance with an aftercare contract or consent agreement; and

(c) two (2) written reports indicating that the individual's ability to practice has been assessed and that he has been found capable of practicing according to acceptable and prevailing standards of care. The reports shall be made by individuals or providers approved by the Board for making such assessments and shall describe the basis for this determination; and

(5) when the impaired practitioner resumes practice after reinstatement of his license, the Board shall require continued monitoring of the practitioner. This monitoring shall include, but not be limited to, compliance with any written consent agreement entered into before reinstatement or compliance with conditions imposed by the Board order after a hearing, and, upon termination of the consent agreement, submission by the practitioner to the Board, for at least two (2) years, of annual written progress reports made under penalty of perjury stating whether the license holder has maintained sobriety.

(E) In cases where the Board has initiated a disciplinary action, the general pattern of action described above shall be followed, except that:

(1) if the Board imposes a period of ineligibility for licensure, the individual shall not be eligible for a license reinstatement until the period has lapsed; or

(2) if the Board imposes an indefinite period of ineligibility, licensure, or license reinstatement shall depend upon successful completion of the requirements and determination by the Board that the period of suspension or ineligibility served is commensurate with the violations found.

36-18. Impaired Practitioner Treatment Programs.

(A) The Board may contract with providers of impaired treatment programs, or refer practitioners to Board-approved programs, receive and evaluate reports of suspected impairment from any source, intervene in cases of verified impairment, monitor treatment and rehabilitation of the impairment, provide post-treatment monitoring, and support and provide other functions as necessary to carry out the provisions of this regulation.

(B) The Board-approved treatment programs shall be provided with all relevant information from the Board and other sources regarding a practitioner referred to the program, including but not limited to, the potential impairment. The program shall report in a timely fashion any impaired professional counselor, marriage and family therapist, or psycho-educational specialist who refuses to cooperate with an evaluation or investigation, or who refuses to submit to treatment or rehabilitation, or whose impairment is not substantially alleviated through treatment or who, in the opinion of the evaluators, is unable to practice professional counseling, marriage and family therapy, or psycho-education with reasonable skill and safety.

(C) All Board-approved programs must:

(1) report to the Board the name of any impaired practitioner who fails to enter treatment within forty-eight (48) hours following the provider's determination that the practitioner needs treatment; and

(2) require every practitioner who enters treatment to agree to a treatment contract establishing the terms of treatment and aftercare, including any required supervision or restrictions of practice during treatment or aftercare; and

(3) require a practitioner to suspend practice upon entry into any required inpatient treatment; and

(4) report to the Board any failure by an impaired practitioner to comply with the terms of the treatment contract during inpatient or outpatient treatment or aftercare; and

(5) report to the Board the resumption of practice of any impaired practitioner before the treatment provider has made a clear determination that the practitioner is capable of practicing according to acceptable and prevailing standards of care; and

(6) require a practitioner who resumes practice after completion of treatment to comply with an aftercare contract that meets the requirements of rules adopted by the Board for approval of treatment providers.

Article 7

Codes of Ethics

36-19. Code of Ethics for Professional Counselors.

(A) General.

(1) Professional Counselors shall engage in continuous efforts to improve professional practices, services, and research and shall be guided in their work by evidence of the best professional practices.

(2) Professional Counselors shall recognize their responsibility to the clients they serve and the institutions in which the services are performed and shall strive to assist the respective agency, organization, or institution in providing competent and ethical professional services. The acceptance of employment in an institution shall mean that the Professional Counselor is in agreement with the general policies and principles of the institution and that the professional activities of the Professional Counselor are in accord with the objectives of the institution. If the Professional Counselor and the employer do not agree and cannot reach agreement on policies that are consistent with appropriate counselor ethical practice that is conducive to client growth and development, the Professional Counselor shall terminate his employment and strive to change the unethical practice through appropriate professional organizations.

(3) Professional Counselors shall engage in ethical behavior at all times and shall take immediate action to report unethical behavior by professional associates to the Board or other appropriate authority.

(4) Professional Counselors must refuse remuneration for consultation or counseling with persons who are entitled to these services through the counselor's employing institution or agency and shall not divert to their private practices, without the mutual consent of the institution and the client, legitimate clients in their primary agencies, or the institutions with which they are affiliated.

(5) In establishing fees, Professional Counselors shall consider the financial status of clients, and if the established fee is inappropriate, must provide assistance to the client in finding comparable services at an acceptable cost. Professional Counselors shall not enter into any agreement wherein counseling services are exchanged as barter.

(6) Professional Counselors shall offer only professional services for which they are trained or have supervised experience. No diagnosis, assessment, or treatment shall be performed without prior training or supervision. Professional Counselors shall correct any misrepresentation of their qualifications by others.

(7) Professional Counselors shall recognize their limitations and provide services or use techniques for which they are qualified by training and/or supervision. Professional Counselors shall recognize the need for and seek continuing education to assure competent services.

(8) Professional Counselors must be aware of the intimacy in the counseling relationship and maintain respect for the client and must not engage in activities that seek to meet their personal or professional needs at the expense of the client.

(9) Professional Counselors shall not engage in personal, social, organizational, financial, or political activities which might lead to a misuse of their influence.

(10) Professional Counselors shall not engage in sexual intimacy with clients and shall not be sexually, physically, or romantically intimate with clients, nor engage in sexual, physical, or romantic intimacy with clients within two (2) years after terminating the counseling relationship.

(11) Professional Counselors shall not engage in sexual harassment or other unwelcome comments, gestures, or physical contact of a sexual nature, nor shall they condone such conduct in others.

(12) Professional Counselors shall guard the individual rights and personal dignity of their clients in the counseling relationship through an awareness of the impact of stereotyping and unwarranted discrimination.

(13) Professional Counselors shall be accountable at all times for their behavior and must be aware that all actions and behaviors reflect on professional integrity and, when inappropriate, can damage the public trust in the counseling profession. To protect public confidence in the counseling profession, Professional Counselors shall avoid behavior that is clearly in violation of accepted moral and legal standards.

(14) Professional Counselors shall observe this Code of Ethics in all products and services offered, including but not limited to classroom instruction, public lectures, demonstrations, written articles, radio, and television programs.

(15) Professional Counselors must withdraw from the practice of counseling if the mental or physical condition of the Counselor renders it unlikely that a professional relationship can be maintained.

(B) Counseling Relationship.

(1) Professional Counselors shall respect the integrity and promote the welfare of clients, whether they are assisted individually, in family units, or in group counseling. In group settings, the Professional Counselor shall be responsible for taking reasonable precautions to protect individuals from physical and/or psychological trauma resulting from interaction within the group.

(2) Professional Counselors shall take into account the traditions and practices of other professional disciplines with whom they work and cooperate fully with them. If a person is receiving similar services from another professional, Professional Counselors shall not offer their own services directly to such a person. If a Professional Counselor is contacted by a person who is already receiving similar services from another professional, the Professional Counselor must carefully consider that professional relationship and the client's welfare and proceed with caution and sensitivity to the therapeutic needs of the client. When Professional Counselors learn that their clients are in a professional relationship with another mental health professional, the Professional Counselor must request release from the client to inform the other mental health professional of their relationship with the client and strive to establish positive and collaborative professional relationships that are in the best interest of the client. Professional Counselors shall discuss these issues with the client and the mental health professional so as to minimize the risk of confusion and conflict and encourage clients to inform other professionals of the new professional relationship.

(3) PROFESSIONAL COUNSELORS MAY CONSULT WITH ANY OTHER PROFESSIONALLY COMPETENT PERSON ABOUT A CLIENT AND SHALL INFORM THE CLIENT OF THIS

POSSIBILITY. PROFESSIONAL COUNSELORS MUST AVOID PLACING A CONSULTANT IN A CONFLICT-OF-INTEREST SITUATION THAT WOULD PRECLUDE THE CONSULTANT SERVING AS A PROPER PARTY TO THE EFFORTS TO ASSIST THE CLIENT.

(4) Professional Counselors may share confidential information when there is a clear and imminent danger to the client and others, as provided by law.

(5) Professional Counselors shall maintain records of the counseling relationship which may include interview notes, test data, correspondence, audio or visual tape recordings, electronic data storage, and other documents. Records shall contain accurate factual data, and the physical record are the property of the Professional Counselor or their employers. Professional Counselors shall maintain records in accordance with the policy of the Board.

(6) Professional Counselors shall ensure that all data maintained in electronic storage are secure. Stored data shall be limited to information that is appropriate and necessary for the services provided and accessible only to appropriate staff members involved in the provision of services. Professional Counselors shall ensure that the electronically stored data are destroyed when the information is no longer of value in providing services or required as part of the client's record.

(7) Professional Counselors shall disguise identifying information derived from a client relationship when that information is used in training or research. Any data which cannot be disguised may be used only as expressly authorized by the client's informed consent.

(8) Professional Counselors shall inform clients of the purposes, goals, techniques, procedures, limitations, potential risks, and benefits of services to be performed, and clearly indicate limitations that may affect the relationship as well as any other pertinent information. Professional Counselors must take reasonable steps to ensure that clients understand the implications of any diagnosis, the intended use of tests and reports, methods of treatment, and safety precautions that must be taken in their use, fees, and billing arrangements.

(9) Professional Counselors who have an administrative, supervisory, and/or evaluative relationship with individuals seeking counseling services shall not serve as the counselor and shall refer the individual to other professionals. Exceptions may be made only in instances where an individual's situation warrants counseling intervention and another alternative is not available. Dual relationships that might impair the counselor's objectivity and professional judgment must be avoided and/or the counseling relationship terminated through referral to a competent professional.

(10) When a Professional Counselor determines an inability to be of professional assistance to a potential or existing client, the counselor must, respectively, not initiate the counseling relationship or immediately terminate the relationship. In either event, the counselor must suggest appropriate alternatives and be knowledgeable about referral resources so that a satisfactory referral can be initiated. If the client declines the referral, the counselor shall not be obligated to continue the relationship.

(11) When engaging in intensive, short-term counseling, a Professional Counselor shall ensure that professional assistance is available at normal costs to clients during and following the short-term counseling.

(12) Professional Counselors who employ electronic means in which the counselor and client are not in immediate proximity must present clients with local sources of care before establishing a continued short or long-term relationship.

(13) Professional Counselors shall obtain legal authorization to practice in any jurisdiction in which they maintain an electronic presence via the internet or other electronic means.

(14) Professional Counselors shall ensure that clients are intellectually, emotionally, and physically compatible with computer applications used by the counselor and understand their purpose and operation.

(15) Professional Counselors shall maintain client confidentiality as provided by law.

(16) Professional Counselors shall screen prospective group counseling participants to ensure compatibility with group objectives.

(C) Measurement and Evaluation.

(1) Professional Counselors shall recognize the limits of their competence and perform only those assessment functions for which they have received appropriate training or supervision.

(2) Professional Counselors who utilize assessment instruments to assist them with diagnoses must have appropriate training and skills in educational and mental measurement, validation criteria, test research, and guidelines for test development and use.

(3) Professional Counselors shall provide instrument specific orientation or information to an examinee prior to and following the administration of assessment instruments or techniques so that the results may be placed in proper perspective with other relevant factors. The purpose of testing and the explicit use of the results must be disclosed to an examinee prior to testing.

(4) Professional Counselors shall carefully evaluate the specific theoretical bases and characteristics, validity, reliability, and appropriateness of an instrument in selecting the instrument or techniques for use in a given situation or with a particular client.

(5) Professional Counselors must provide accurate information and avoid false claims or misconceptions concerning the meaning of an instrument's reliability and validity terms when making statements to the public about assessment instruments or techniques.

(6) Professional Counselors shall follow the directions and researched procedures for selection, administration, and interpretation of all evaluation instruments and use them only within proper contexts.

(7) Professional Counselors shall be cautious when interpreting the results of instruments that possess insufficient technical data, and must explicitly state to examinees the specific limitations and purposes for the use of such instruments.

(8) Professional Counselors shall proceed cautiously when attempting to evaluate and interpret performance of any person who cannot be appropriately compared to the norms for the instruments.

(9) Professional Counselors shall maintain test security.

(10) Professional Counselors shall consider psychometric limitations when selecting and using an instrument, and must be cognizant of the limitations when interpreting the results.

(11) Professional Counselors shall ensure that appropriate interpretation accompanies any release of individual or group test data and shall obtain explicit prior understanding and consent when releasing results.

(12) Professional Counselors shall ensure that computer-generated test administration and scoring programs function properly thereby providing clients with accurate test results.

(13) Professional Counselors who develop computer-based test interpretations to support the assessment process shall ensure that the validity of the interpretations is established prior to the commercial distribution of the computer application.

(14) Professional Counselors shall recognize that test results may become obsolete and avoid the misuse of obsolete data.

(D) Research and Publication.

(1) Professional Counselors shall adhere to applicable legal and professional guidelines on research with human subjects.

(2) In planning research activities involving human subjects, Professional Counselors shall be aware of and responsive to all pertinent ethical principles and ensure that the research problem, design, and execution are in full compliance with any pertinent institutional or governmental regulations.

(3) The ultimate responsibility for ethical research lies with the principal researcher, although others involved in the research activities are ethically obligated and responsible for their own actions.

(4) Professional Counselors who conduct research with human subjects are responsible for the welfare of the subjects throughout the experiment and must take all reasonable precautions to avoid causing injurious psychological, physical, or social effects on their subjects.

(5) Professional Counselors who conduct research shall abide by the basic elements of informed consent:

(a) a fair explanation of the procedures to be followed, including an identification of those which are experimental; and

(b) a description of the attendant discomforts and risks; and

(c) a description of the benefits to be expected; and

(d) disclosure of appropriate alternative procedures that would be advantageous for subjects with an offer to answer any inquiries concerning the procedures; and

(e) an instruction that subjects are free to withdraw their consent and to discontinue participation in the project or activity at any time.

(6) When reporting research results, explicit mention shall be made of all the variables and conditions known to the investigator that may have affected the outcome of the study or the interpretation of the data.

(7) Professional Counselors who conduct and report research investigations shall do so in a manner that minimizes the possibility that the results will be misleading.

(8) Professional Counselors shall give credit through joint authorship, acknowledgment, footnote statements, or other appropriate means to those who have contributed to the research and/or publication, in accordance with such contributions.

(9) Professional Counselors shall communicate to other counselors the results of any research judged to be of professional value.

(E) Consulting.

(1) Professional Counselors, acting as consultants, must have a high degree of self awareness of their own values, knowledge, skills, limitations, and needs in entering a helping relationship that involves human and/or organizational change. The focus of the consulting relationship must be on the issues to be resolved and not on the persons presenting the problem.

(2) In the consulting relationship, the Professional Counselor and the client must understand and agree upon the problem definition, subsequent goals, and predicted consequences of interventions selected.

(3) Professional Counselors acting as consultants must be reasonably certain that they, or the organization represented, have the necessary competencies and resources for giving the kind of help that is needed or that may develop later, and that appropriate referral resources are available.

(4) Professional Counselors in a consulting relationship must encourage and cultivate client adaptability and growth toward self-direction. Professional Counselors must maintain this role consistently and not become a decision maker for clients or create a future dependency on the consultant.

(F) Private Practice.

(1) In advertising services as a private practitioner, Professional Counselors must advertise in a manner that accurately informs the public of the professional services, expertise, and techniques of counseling available.

(2) Professional Counselors who assume an executive leadership role in a private practice organization shall not permit their names to be used in professional notices during periods of time when they are not actively engaged in the private practice of counseling unless their executive roles are clearly stated.

(3) Professional Counselors shall make available their highest degree (described by discipline), type and level of certification, and/or license, address, telephone number, office hours, type and/or description of services, and other relevant information. Listed information must not contain false, inaccurate, misleading, partial, out-of-context, or otherwise deceptive material or statements.

(4) Professional Counselors who are involved in a partnership/corporation with other certified counselors and/or other professionals, must clearly specify all relevant specialities of each member of the partnership or corporation.

36-20. Code of Ethics for Marriage and Family Therapists.

(A) Responsibility to Clients.

(1) Marriage and Family Therapists shall not discriminate against or refuse professional service to anyone on the basis of race, gender, religion, national origin, or sexual orientation.

(2) Marriage and Family Therapists shall not exploit the trust and dependency of clients and shall avoid dual relationships with clients that could impair professional judgment or increase the risk of exploitation. When a dual relationship cannot be avoided, therapists shall take appropriate professional precautions to ensure judgment is not impaired and no exploitation occurs. Marriage and Family Therapists shall not engage in sexual relationships with clients and shall not engage in sexual relationships with former clients for at least two (2) years following the termination of therapy.

(3) Marriage and Family Therapists shall not use their professional relationships with clients to further their own interests.

(4) Marriage and Family Therapists shall respect the right of clients to make decisions and help them to understand the consequences of their decisions. Therapists shall clearly advise clients that a decision as to marital status is the responsibility of the client.

(5) Marriage and Family Therapists shall continue therapeutic relationships so long as is reasonably clear that clients are benefitting from the relationship.

(6) Marriage and Family Therapists shall assist persons in obtaining other therapeutic services if the therapist is unable or unwilling, for appropriate reasons, to provide professional help.

(7) Marriage and Family Therapists shall not abandon or neglect clients in treatment without making reasonable arrangements for the continuation of such treatment.

(8) Marriage and Family Therapists shall obtain written informed consent from clients before videotaping, audio recording, or permitting third party observation.

(B) Confidentiality.

(1) Marriage and Family Therapists shall not disclose client confidences except as mandated by law or described in this chapter.

(2) Marriage and Family Therapists may use client and/or clinical materials in teaching, writing, and public presentations only if the client has executed a written waiver or when appropriate steps have been taken to protect the identity of the client.

(3) Marriage and Family Therapists shall store or dispose of all client records in a manner that will protect confidentiality.

(C) Professional Competence and Integrity.

(1) Marriage and Family Therapists shall immediately notify all appropriate agencies, including, but not limited to the Board, of any criminal conviction; of any conduct which may lead to a conviction; any actions disciplining or expelling them from any professional organization; suspension, revocation, or other discipline by any regulatory body; of incompetency due to physical or mental causes or the abuse of alcohol or other substances.

(2) Marriage and Family Therapists shall seek appropriate professional assistance for their personal problems or conflicts that may impair work performance or clinical judgment.

(3) Marriage and Family Therapists who function as teachers, supervisors, or researchers shall maintain the highest standards of scholarship and present accurate information.

(4) Marriage and Family Therapists shall remain abreast of new developments in knowledge and practice through educational activities.

(5) Marriage and Family Therapists shall not engage in sexual or other harassment or exploitation of clients, students, trainees, supervisees, employees, colleagues, research subjects, or actual or potential witnesses or complainants in investigations and ethical proceedings.

(6) Marriage and Family Therapists shall not diagnose, treat, or advise on problems outside the recognized boundaries of their competence, as established by the Board.

(7) Marriage and Family Therapists shall make every effort to prevent the distortion or misuse of their clinical and research findings.

(8) Marriage and Family Therapists shall exercise special care when making public their professional recommendations and opinions through testimony or other public statements.

(D) Responsibility to Students, Employees, and Supervisees.

(1) Marriage and Family Therapists shall not exploit the trust and dependency of students, employees, and supervisees and shall avoid dual relationships that could impair professional judgment or increase the risk of exploitation. When a dual relationship cannot be avoided, therapists shall take appropriate professional precautions to ensure judgment is not impaired and no exploitation occurs. A Marriage and Family Therapist shall not provide therapy to an employee, student or supervisee. Sexual intimacy with students, or supervisees is prohibited.

(2) Marriage and Family Therapists shall not permit students, employees, or supervisees to perform or hold themselves out as competent to perform professional services beyond their training, level of experience, and competence.

(3) Marriage and Family Therapists shall not disclose supervisee confidences except as mandated by law and described in this chapter.

(E) Responsibility to Research Participants.

(1) Marriage and Family Therapists functioning as investigators shall make careful examinations of ethical acceptability in planning studies. To the extent that services to research participants may be compromised by participation in research, Marriage and Family Therapists shall seek the ethical advice of qualified professionals not directly involved in the investigation and observe safeguards to protect the rights of the research participants.

(2) Marriage and Family Therapists functioning as investigators shall inform research participants of all aspects of the research that might reasonably be expected to influence willingness to participate. Marriage and Family Therapists shall be sensitive to the possibility of diminished consent when participants are receiving clinical services, have impairments which limit understanding and/or communication, or when participants are children.

(3) Marriage and Family Therapists functioning as investigators shall respect participants' freedom to decline participation in or to withdraw from a research study at any time. This obligation requires special thought and consideration when Marriage and Family Therapists or other members of the research team are in positions of authority or influence over participants. Therapists shall make every effort to avoid dual relationships with research participants that could impair professional judgment or increase the risk of exploitation.

(4) Marriage and Family Therapists shall maintain confidentiality during any investigation unless there is a waiver obtained in writing. When the possibility exists that others, including family members, may obtain access to such information, this possibility, together with the plan for protecting confidentiality, is explained as part of the procedure for obtaining informed consent.

(F) Responsibility to the Profession.

(1) Marriage and Family Therapists shall maintain the standards of the profession when acting as members or employees of organizations.

(2) Marriage and Family Therapists shall assign publication credit to those who have contributed to a publication in proportion to their contributions and in accordance with customary professional publication practices.

(3) Marriage and Family Therapists who are the authors of books shall cite persons to whom credit for original ideas is due.

(4) Marriage and Family Therapists who are the authors of books or other materials published or distributed by an organization shall take reasonable precautions to ensure that the organization promotes and advertises the materials accurately and factually.

(5) Marriage and Family Therapists should participate in activities that contribute to a better community and society, including devoting a portion of their professional activity to services for which there is little or no financial return.

(6) Marriage and Family Therapists should be concerned with developing laws and regulations pertaining to the practice of marriage and family therapy that serve the public interest, and with altering such laws and regulations that are not in the public interest.

(7) Marriage and Family Therapists should encourage public participation in the design and delivery of professional services and in the regulation of practitioners.

(G) Financial Arrangements.

(1) Marriage and Family Therapists shall not offer or accept payment for referrals.

(2) Marriage and Family Therapists shall not charge excessive fees for services and shall not barter therapy services.

(3) Marriage and Family Therapists shall disclose their fees to clients and supervisees at the initiation of services.

(4) Marriage and Family Therapists shall represent facts truthfully to clients, third party payors, and supervisees regarding the services rendered.

(H) Advertising.

(1) Marriage and Family Therapists shall accurately represent their competence, education, training, and experience relevant to their practice of marriage and family therapy.

(2) Marriage and Family Therapists shall assure that advertisements and publications in any media conveys information that is necessary for the public to make an appropriate selection of professional services.

(3) Marriage and Family Therapists shall not use a name which could mislead the public concerning the identity, responsibility, source, and status of those practicing under that name and shall not hold themselves out as being partners or associates of a firm when they are not.

(4) Marriage and Family Therapists shall not use any professional identification if it includes any statement or claim that is false, fraudulent, misleading, or deceptive. A statement is false, fraudulent, misleading, or deceptive if it:

(a) contains any material misrepresentation of fact; or

(b) fails to state any material fact necessary to make the statement, in light of all circumstances, not misleading; or

(c) is intended to or is likely to create an unjustified expectation.

(5) Marriage and Family Therapists shall correct, wherever possible, false, misleading, or inaccurate information and representations made by others concerning the therapist's qualifications, services, or products.

(6) Marriage and Family Therapists shall insure that the qualifications of persons in their employ are represented in a manner that is not false, misleading, or deceptive.

(7) Marriage and Family Therapists may represent themselves as specializing within a limited area of marriage and family therapy, but shall not advertise specialization in any area unless they have the education and supervised experience in settings which meet recognized professional standards to practice in that specialty area.

36-21. Code of Ethics for Psycho-educational Specialists.

(A) Professional Competency.

(1) Psycho-educational Specialists shall recognize the strengths and limitations of their training and experience and engage only in practices for which they are qualified.

(2) Psycho-educational Specialists shall represent competence levels, education, training, and experience accurately and in a professional manner.

(3) Psycho-educational Specialists shall not use affiliations with persons, associations, or institutions to imply a level of professional competence exceeding that actually achieved.

(4) Psycho-educational Specialists shall enlist the assistance of other specialists in supervisory, consultative, or referral roles as appropriate in providing services.

(5) Psycho-educational Specialists shall refrain from any activity in which their personal problems or conflicts may interfere with professional effectiveness. Competent assistance is sought to alleviate conflicts in professional relationships.

(B) Professional Relationships and Responsibilities.

(1) Psycho-educational Specialists shall apply their professional expertise for the purpose of promoting improvement in the quality of life for students, their families, and the school community.

(2) Psycho-educational Specialists shall respect all persons and must be sensitive to physical, mental, emotional, political, economic, social, cultural, ethnic, and racial characteristics, gender and sexual orientation, and religion.

(3) Psycho-educational Specialists shall be responsible for the direction and nature of their personal loyalties or objectives. When these commitments may influence a professional relationship, the Psycho-educational Specialist shall inform all concerned persons of relevant issues in advance.

(4) Psycho-educational Specialists shall maintain professional relationships with students, parents, the school, and community. Parents and students must be fully informed about all relevant aspects of services in advance, taking into account language and cultural differences, cognitive capabilities, developmental level, and age so that the explanation may be understood by the student, parent, or guardian.

(5) Psycho-educational Specialists shall attempt to resolve situations in which there are divided or conflicting interests in a manner which is mutually beneficial and protective of the rights of all parties involved.

(6) Psycho-educational Specialists shall not exploit clients through professional relationships nor condone these actions in their colleagues. All individuals, including students, clients, employees, colleagues, and research participants, shall not be exposed to deliberate comments, gestures, or physical contacts of a sexual nature. Psycho-educational Specialists shall not harass or demean others based on personal characteristics nor engage in sexual relationships with their students, supervisees, trainees, or past or present clients.

(7) Psycho-educational Specialists shall not enter into personal or business relationships with students/clients or their parents.

(8) Psycho-educational Specialists shall notify the Board if aware of a suspected detrimental or unethical practice of another professional.

(9) Psycho-educational Specialists shall respect the confidentiality of information obtained during their professional work and reveal this information only with the informed consent of the client, or the client's parent or legal guardian, except as provided by law.

(C) Students.

(1) Psycho-educational Specialists shall engage only in professional practices which maintain the dignity and integrity of students and other clients.

(2) Psycho-educational Specialists shall explain important aspects of their professional relationships with students and clients in a clear, understandable manner, including the reason why services were requested, who will receive information about the services provided, and the possible outcomes.

(3) When a child initiates services, Psycho-educational Specialists shall respect the right of the student or client to initiate, participate in, or discontinue services voluntarily. When another party initiates services, the Psycho-educational Specialists shall make every effort to secure voluntary participation of the child/student.

(4) Psycho-educational Specialists shall discuss recommendations, including all alternatives available.

(D) Parents, Legal Guardians, and Appointed Surrogates.

(1) Psycho-educational Specialists shall explain all services to parents in a clear, understandable manner, and explain options taking into account the values and capabilities of each parent. Provision of services by interns, practicum students, and other unlicensed personnel must be explained and agreed to in advance.

(2) Psycho-educational Specialists shall assure that there is direct parent contact prior to seeing the student/client on an on-going basis. Frank and prompt reporting to the parent of findings and progress shall be made so long as it conforms to the limits of confidentiality.

(3) Psycho-educational Specialists shall encourage and promote parental participation in designing services provided to their children, including when appropriate, linking interventions between the school and the home, tailoring parental involvement to the skills of the family, and helping parents to gain the skills needed to help their children.

(4) Psycho-educational Specialists shall respect the wishes of parents who object to services and attempt to guide parents to alternative community resources.

(5) Psycho-educational Specialists shall discuss recommendations and plans for assisting the student/client with the parent. The discussion must include alternatives associated with each set of plans, showing respect for the ethnic/cultural values of the family. The parents must be advised as to sources of help available at school and in the community.

(6) Psycho-educational Specialists shall discuss the rights of parents and students regarding creation, modification, storage, and disposal of confidential materials.

(E) Service Delivery.

(1) Psycho-educational Specialists shall be knowledgeable of the organization, philosophy, goals, objections, and methodologies of the setting in which they are employed.

(2) Psycho-educational Specialists shall recognize that an understanding of the goals, processes, and legal requirements of their particular workplace is essential for effective functioning within that setting.

(3) Psycho-educational Specialists shall become integral members of the client systems to which they are assigned.

(4) Psycho-educational Specialists providing services to several different groups must disclose potential conflicts of interest to all parties.

(F) Community.

(1) Psycho-educational Specialists shall not engage in or condone practices that discriminate against clients based on race, handicap, age, gender, sexual orientation, religion, national origin, economic status, or native language.

(2) Psycho-educational Specialists shall avoid any action that could violate or diminish the civil or legal rights of clients.

(3) Psycho-educational Specialists shall adhere to federal, state, and local laws and ordinances governing their practice.

(G) Related Professional.

(1) Psycho-educational Specialists shall cooperate with other professional disciplines in relationships based on mutual respect.

(2) Psycho-educational Specialists shall encourage and support the use of all resources to best serve the interests of students and clients.

(3) Psycho-educational Specialists shall explain their field and their professional competencies, including roles, assignments, and working relationships to other professionals.

(4) Psycho-educational Specialists shall cooperate and coordinate with other professionals and agencies with the rights and needs of their clients in mind and must promote coordination of services.

(5) Psycho-educational Specialists shall refer a student or client to another professional for services whenever a condition is identified which is outside the professional's competencies or scope of practice.

(6) Psycho-educational Specialists shall ensure that all relevant and appropriate individuals, including the student/client when appropriate, are notified when transferring the intervention responsibility.

(H) Other Psycho-educational Specialists.

(1) Psycho-educational Specialists who employ, supervise, or train other professionals shall provide continuing professional development and must provide appropriate working conditions, fair and timely evaluations, and constructive consultation.

(2) Psycho-educational Specialists who supervise interns shall be responsible for all professional practices of the supervisee and assure the students/clients and the profession that the intern is adequately supervised.

(I) Advocacy.

(1) Psycho-educational Specialists shall be responsible to students/clients when acting as advocates for their rights and welfare.

(2) Psycho-educational Specialists shall communicate to the school administration and staff service options, taking into consideration the primary concern for protecting the rights and welfare of students.

(J) Assessment and Intervention.

(1) Psycho-educational Specialists shall maintain the highest standards for educational and psycho-educational assessment.

(2) In conducting psycho-educational, educational, or behavioral evaluations, or in providing therapy, counseling, or consultation services, Psycho-educational Specialists must give consideration to individual integrity and individual differences.

(3) Psycho-educational Specialists shall respect the differences in age, gender, sexual orientation, and socioeconomic, cultural and ethnic backgrounds and must select and use appropriate assessment or treatment procedures, techniques, and strategies.

(4) Psycho-educational Specialists must maintain knowledge about the validity and reliability of their instruments and techniques so as to choose those that have up-to-date standardization data and are applicable and appropriate for the benefit of the student/client.

(5) Psycho-educational Specialists shall not condone the use of psycho-educational assessment techniques, or the mis-use of the information these techniques provide, by unqualified persons in any way, including teaching, sponsorship, or supervision.

(6) Psycho-educational Specialists shall develop interventions which are appropriate to the presenting problems and are consistent with data collected and must modify or terminate the treatment plan when the data indicate the plan is not achieving the desire goals.

(K) Use of Materials and Technology.

(1) Psycho-educational Specialists shall maintain test security, preventing the release of underlying principles and specific content that would undermine the use of the device, and shall be responsible for the security requirements specific to each instrument used.

(2) Psycho-educational Specialists shall abide by all copyright laws and obtain permission from the authors before reproducing un-copyrighted published instruments.

(3) Psycho-educational Specialists shall obtain written prior consent or remove identifying data presented in public lectures or publications.

(4) When producing materials for consultation, intervention, teaching, public lectures, or publication, Psycho-educational Specialists shall acknowledge sources and assign credit to those whose ideas are reflected in the product.

(5) Psycho-educational Specialists shall not promote or encourage inappropriate use of computer generated test analyses or reports and must select scoring and interpretation services on the basis of accuracy and professional alignment with the underlying decision rules.

(6) Psycho-educational Specialists shall bear responsibility for any technological services used. All ethical and legal principles regarding confidentiality, privacy, and responsibility for decisions apply to the Psycho-educational Specialist and cannot be transferred to equipment, software companies, or data processing departments.

(7) Technological devices shall be used to improve the quality of client services.

(L) Research, Publication, and Presentation.

(1) Psycho-educational Specialists shall, when designing and implementing research in schools, employ research methodology, subject selection techniques, data gathering methods, and analysis and reporting techniques which are grounded in sound research practice.

(2) Psycho-educational Specialists working in agencies without review committees shall have peer review prior to initiating research.

(3) In publishing reports of their research, Psycho-educational Specialists shall provide discussion of limitations of their data and acknowledge existence of disconfirming data, as well as alternate hypotheses and explanations of their findings.

(M) Relationships with School Districts.

(1) Psycho-educational Specialists employed in both the public and private sector shall separate their roles and protect and completely inform the consumer of all potential conflicts of interest or concerns.

(2) Psycho-educational Specialists shall not accept any form of remuneration from clients who are entitled to the same service provided by the same Psycho-educational Specialists while working in the public sector. This prohibition includes students who attend the non-public schools within the public school assignment area.

(3) Psycho-educational Specialists in private practice shall inform parents of any free school psycho-educational services available from the public or private schools prior to delivering such services for remuneration.

(4) Psycho-educational Specialists shall conduct all private practice outside of the hours of contracted public employment.

(5) Psycho-educational Specialists engaged in private practice shall not use tests, materials, equipment, facilities, secretarial assistance, or other services belonging to the public sector employer, unless approved in advance through a written agreement.

(6) Psycho-educational Specialists shall not barter psycho-educational services.

(N) Service Delivery.

(1) Psycho-educational Specialists shall conclude a financial agreement in advance of service delivery.

(2) Psycho-educational Specialists shall ensure to the best of their ability that the client clearly understands the financial agreement.

(3) Psycho-educational Specialists shall not give or receive any remuneration for referring clients for professional services.

(4) Psycho-educational Specialists in private practice shall adhere to the conditions of a contract until service thereunder has been performed, the contract has been terminated by mutual consent, or has otherwise been legally terminated.

(5) Psycho-educational Specialists shall not engage in personal diagnosis and therapy by means of public lectures, newspaper columns, magazine articles, radio or television programs, or mail.

(O) Announcements/Advertising.

(1) Psycho-educational Specialists shall present accurate representations of training, experience, services provided, and affiliations, and shall advertise these in a restrained manner.

(2) Listings in telephone directories shall be limited to name, highest relevant degree, state certification/licensure status as provided for by statute, address, telephone number, brief identification of major areas of practice, office hours, appropriate fee information, foreign languages spoken, policy regarding third party payments, and license number.

(3) Announcements of services by Psycho-educational Specialists in private practice shall be made in a formal, professional manner, using the guidelines for advertising in the telephone directory. In addition, clear statements of purposes with unequivocal descriptions of the experiences to be provided shall be given, along with education, training, and experience of all staff members appropriately specified.

(4) Psycho-educational Specialists in private practice shall not directly solicit clients for individual diagnosis or therapy.

(5) PSYCHO-EDUCATIONAL SPECIALISTS SHALL NOT COMPENSATE IN ANY MANNER A REPRESENTATIVE OF THE PRESS, RADIO, OR TELEVISION IN RETURN FOR PROFESSIONAL PUBLICITY IN A NEWS ITEM.

FISCAL IMPACT STATEMENT: **THERE WILL BE NO ADDITIONAL COST INCURRED BY THE STATE OR ANY POLITICAL SUBDIVISION.**

Document No. 2579
DEPARTMENT OF LABOR, LICENSING AND REGULATION
REAL ESTATE APPRAISERS BOARD
CHAPTER 137
Statutory Authority: 1976 Code Section 40-60-60

Synopsis:

The Real Estate Appraisers Board is proposing to amend its existing regulations to be consistent with the recently enacted practice act. The proposed regulations include, but are not limited to, new provisions for mass appraiser qualifications and licensure as well as revision of current regulations codified at South Carolina Regulations Chapter 137. The revision of current regulations also includes deleting repetitious language that is in the statute.

Instructions: Amend current regulations by repealing current regulations and replacing them with new regulations as it appears in the text below.

TEXT:

137-100.01. Appraisal Experience Point System.
A point system shall be utilized by the Board to evaluate the appraisal experience of applicants. The evaluation method converts hours spent in appraisal activity to points earned for appraisal experience.

137-100.02. Qualifications.
(A) In order to qualify as a state apprentice, licensed or certified appraiser, an applicant must meet the requirements set forth below, as well as any requirements established by the Appraiser Qualifications Board and the Appraisal Standards Board of the Appraisal Foundation, as subsequently endorsed by the Appraisal Subcommittee pursuant to Title XI of the Financial Institutions Reform Recovery, and Enforcement Act of 1989:
(B) In order to qualify as an appraiser apprentice, an applicant must have received 75 hours of classroom education covering at least thirty (30) hours in an L-1 category course(s) (Introduction to Real Estate Appraisal), at least thirty (30) hours in an L-2 category course(s) (Valuation Procedures), and at least fifteen (15) hours in an L-3 category course (Uniform Standards of Professional Appraisal Practice).
(C) In order to qualify to become a state licensed real estate appraiser, an applicant:

1. must have received ninety (90) hours of classroom education covering at least thirty (30) hours in an L-1 category course(s) (Introduction to Real Estate Appraisal), at least thirty (30) hours in an L-2 category course(s) (Valuation Procedures), and at least fifteen (15) hours in an L-3 category course (Uniform Standards of Professional Appraisal Practice) and at least fifteen (15) hours in a CR category course (Applied Residential Property Valuation); and

2. must have earned a minimum of two hundred fifty (250) experience points in appraising either residential or nonresidential properties; however, the maximum number of points which an applicant can earn in review (field, documentary, or desk) appraisal experience is limited to one hundred twenty-five (125) points. Qualifying experience must be of a variety sufficient to demonstrate competency in all USPAP recognized approaches to value; and

3. must have at least twenty-four (24) months of real estate appraisal experience; and

4. must stand for and pass an exam administered or approved by the Board.

(D) In order to qualify to become a state certified residential real estate appraiser, an applicant:

1. must have received one hundred twenty (120) hours of classroom education covering thirty hours in an L-1 category course(s) (Introduction to Real Estate Appraisal), at least thirty (30) hours in an L-2 category course(s) (Valuation Procedures), and at least fifteen (15) hours in an L-3 category course (Uniform Standards of

Professional Appraisal Practice), at least fifteen (15) hours in a CR category (Applied Residential Property Valuation) and at least thirty (30) hours in a C-1 category course(s) (Introduction to Income Property Appraising);

2. must have earned a minimum of three hundred twelve and one-half (312.5) experience points in appraising either residential or nonresidential properties; however, the maximum number of points which an applicant can earn in review (field, documentary, or desk) appraisal experience is limited to one hundred fifty six and one quarter (156.25) points. Qualifying experience must be of a variety sufficient to demonstrate competency in all USPAP recognized approaches to value;

3. must have at least twenty-four (24) months of real estate appraisal experience; and

4. must stand for and pass an exam administered or approved by the Board.

(E) In order to qualify to become a state certified general real estate appraiser, an applicant:

1. must have received one hundred eighty (180) hours of classroom education covering thirty hours (30) in an L-1 category course(s) (Introduction to Real Estate Appraisal), at least thirty (30) hours in an L-2 category course(s) (Valuation Procedures), at least fifteen (15) hours in an L-3 category course (Uniform Standards of Professional Appraisal Practice), at least fifteen (15) hours in a CR category course (Applied Residential Property Valuation), at least thirty (30) hours in a C-1 category course(s) (Introduction to Income Property Appraising), at least thirty (30) hours in a C-2 category course(s) (Advanced Income Capitalization Procedures) and thirty hours in a C-3 category course(s) (Applied Income Property Valuation).

2. must have earned a minimum of three hundred seventy-five (375) experience points, fifty (50%) percent of which must come from appraising nonresidential properties. The fifty maximum number of points which an applicant can earn in review (field, documentary, or desk) appraisal experience is limited to one hundred eighty-seven and one-half (187.50) points. Qualifying experience must be of a variety sufficient to demonstrate competency in all USPAP recognized approaches to value;

3. must have at least thirty (30) months of real estate appraisal experience; and

4. must stand for and pass an exam administered or approved by the Board.

(F) The Board may waive the examination requirements for those applicants who are currently licensed or certified in another state upon proof that the applicant has successfully passed an Appraisal Qualifications Board approved exam which served as a requirement for licensure or certification in the state where he is currently licensed or certified.

137-100.03. Residential Appraisal Categories.

The following categories pertain to various forms of appraiser involvement and the point values which may be awarded by the Board when evaluating residential appraisal experience:

Category	Points Assigned
(A) Sole Appraiser - refers to appraisal reports which were completed and signed by only one person.	1.0
(B) Co-Appraiser – refers to appraisal reports in which more than one appraiser worked on the report. To qualify for this category, applicants must have performed more than fifty percent (50%) of the work on an appraisal. Applicants may receive experience credit for the appraisal even if this work was reviewed by a supervising appraiser who signed the appraisal report. However, in those instances where an applicant has not signed an appraisal report and claims experience credit, the applicant must submit with the application a written statement from the supervising appraiser which verifies that the applicant performed more than fifty percent (50%) of the work on specified appraisal assignments. In addition, the name of the individual providing significant professional assistance must be acknowledged in the appraisal report.	.75
(C) Field Review – refers to a review of an appraisal. In order to qualify for field review experience credit, the applicant must have conducted a physical inspection of the property, as well as verified the data and checked the calculations contained in the appraisal under review. In addition, in order to qualify for experience credit in this category, an applicant must have prepared a written report recommending the acceptance, revision, or rejection of the appraisal under review.	.50

(D) Documentary or Desk Review - refers to a review of an appraisal performed by another person (including a person under the applicant's supervision) but does not include a physical inspection of the subject property. In order to qualify for experience credit in this category, an applicant must have thoroughly and critically reviewed all portions of the appraisal report and recommended the acceptance, revision, or rejection of the appraisal under review.	.25
(E) Condemnation Partial Acquisition - refers to appraisals performed on properties involved in condemnation proceedings. In order to qualify for experience credit in this category, a partial acquisition appraisal must be performed and an evaluation of both the before and after value must be given. A total acquisition under condemnation proceedings would not fall under this category.	1.25

1. 137-100.04. Residential Point Values.

2. The following point values may be awarded by the Board concerning property types when evaluating residential appraisal experience:

Type of Appraisal	POINTS ASSIGNED
1. Appraisal of Single-Family (one unit dwelling)	1.0
2. Appraisal of Multi-Family (two-four units)	2.0
3. Appraisal of Vacant Residential Lot	.5
4. Appraisal of Rural Residential Land (10-50 acres)	2.0

137-100.05. Nonresidential Point Values.

THE FOLLOWING POINT VALUES MAY BE AWARDED BY THE BOARD CONCERNING PROPERTY TYPES WHEN EVALUATING NONRESIDENTIAL APPRAISAL EXPERIENCE:

Type of Appraisal	POINTS ASSIGNED
A. Vacant Land: (Undeveloped nonresidential tracts, residential multi-family sites, commercial sites, industrial sites, lands in transition, etc.)	2.5
B. Rural/Agricultural:	
(51 to 250 acres)	2.5
(more than 250 acres)	4.0
C. Residential Multi-Family (5-12 units): (apartments, condominiums, townhouses, mobile home parks, etc.)	5.0
D. Residential Multi-Family (13 units or more): (Apartments, condominiums, townhouses, mobile home parks, etc.) [Add 1 point for proposed project projections.]	7.0
E. Commercial Single-Tenant: (Office building, retail store, restaurant, service station, bank, day-care center, etc.)	5.0
F. Commercial Multi-Tenant: (Office building, shopping center, hotel/motel, etc.) [Add 1 point for proposed projections.]	8.0
G. Industrial: (Warehouse, manufacturing plant, etc.)	
Under 20,000 square feet	5.0

	20,000 square feet or more	9.0
H.	Institutional:	7.0
	(Nursing home, hospital, school, church, government building, etc.)	

137-100.06. Nonresidential Appraisal Categories.

THE FOLLOWING CATEGORIES PERTAIN TO VARIOUS FORMS OF APPRAISER INVOLVEMENT AND THE POINT VALUES WHICH MAY BE AWARDED BY THE BOARD WHEN EVALUATING NONRESIDENTIAL APPRAISAL EXPERIENCE:

Type of Appraisal	Points Assigned
A. Sole Appraiser – refers to appraisal reports which were completed and signed by only one person.	1.0
B. Co-Appraiser – refers to appraisal reports in which more than one appraiser worked on the report. To qualify for this category, applicants must have performed more than fifty percent (50%) of the work on an appraisal. Applicants may receive experience credit for the appraisal even if this work was reviewed by a supervising appraiser who signed the appraisal report. However, in those instances where an applicant has not signed an appraisal report and claims experience credit, the applicant must submit with the application a written statement from the supervising appraiser which verifies that the applicant performed more than fifty percent (50%) of the work on specified appraisal assignments.	.75
C. Field Review – refers to a review of an appraisal. In order to qualify for field review experience credit, the applicant must have conducted a physical inspection of the property, as well as verified the data and checked the calculations contained in the appraisal under review. In addition, in order to qualify for experience credit in this category, an applicant must have prepared a written report recommending the acceptance, revision, or rejection of the appraisal under review.	.50
D. Documentary or Desk Review - refers to a review of an appraisal performed by another person but does not require a physical inspection of the subject property. In order to qualify for experience credit in this category, an applicant must have thoroughly and critically reviewed all portions of the appraisal report and recommended the acceptance, revision, or rejection of the appraisal under review.	.25
E. Condemnation Partial Acquisition - refers to appraisals performed on properties involved in condemnation proceeding. In order to qualify for experience credit in this category, a partial acquisition appraisal must be performed and an evaluation of both the before and after value must be given. A total acquisition under condemnation proceedings would not fall under this category.	1.25

137-100.07. Other Appraisal Experience.

(A) Applicants may receive credit for appraisals of other types of real property not listed in these Regulations. The Board may, on an individual basis, determine the amount of credit to be awarded for such appraisals based on information provided to the Board by the applicant.

(B) Experience credit may be awarded for mass appraisal activity provided such activity is in compliance with the standards set forth in the Uniform Standards of Professional Appraisal Practice. However, the maximum

number of experience points an applicant will be awarded for mass appraisal activity is forty percent (40%), of which no more than fifty (50) points may be earned through review appraisals.

(C) Mass appraisal experience will not be awarded for activity performed by individuals commonly referred to as "listers." The duties these individuals perform are typically limited to the location of real property, measurement of improvements relative to such things as number of bedrooms and bathrooms, siding, decks, or other miscellaneous information. Such activity does not, in and of itself, apply the methods and techniques utilized in the appraisal process and consequently will not be credited as appraisal experience.

(D) Duties performed by listers are not considered regulated appraisal activity and therefore listers are not required to become licensed or certified under the South Carolina Real Estate Appraiser License and Certification Act.

137-200.01. Mass Appraisal Activity.

(A) Appraisal experience may be obtained through mass appraisal activity when applicants can demonstrate that after receiving information supplied by the lister the person claiming mass appraisal experience credit inspected the subject property, determined the quality or classification of the property, estimated the depreciation of the improvements, determined the land or lot value based on market sales of comparable properties adjusted to the subject property, and reviewed the estimated value of the property against comparable sales in order to ensure the value estimate approximated market value.

(B) Ad valorem appraisal experience may be obtained through individual property appraisals utilizing the entire appraisal process.

137-200.02. Residential Mass Appraisals.

THE FOLLOWING CATEGORIES PERTAIN TO VARIOUS FORMS OF APPRAISER INVOLVEMENT AND THE POINT VALUES WHICH MAY BE AWARDED BY THE BOARD WHEN EVALUATING RESIDENTIAL MASS APPRAISAL EXPERIENCE:

(A) Sole Appraiser - refers to appraisals which were completed by only one person.

Type of Appraisal		Points Assigned
1. Single-Family	New	.25
(one-unit dwelling)	Update	.05
2. Multi-Family	New	.25
(two-four units)	Update	.067
3. Residential Lots	New	.02
(4 lots or less)	Update	.02
4. Rural Residential Land	New	.167
(50 acres or less)	Update	.10

(B) Co-Appraiser refers to appraisals in which more than one appraiser worked as a team. To qualify for this category, applicants must have performed at least fifty percent (50%) of the work on an appraisal.

Type of Appraisal		**Points Assigned**
1. Single-Family	New	.188
(one unit dwelling)	Update	.038
2. Multi-Family	New	.188
(two-four units)	Update	.05
3. Residential Lots	New	.015
(4 lots or less)	Update	.015
4. Rural Residential Land	New	.125
(50 acres or less)	Update	.075

REGULATION 137-200.03. NONRESIDENTIAL MASS APPRAISALS.

THE FOLLOWING CATEGORIES PERTAIN TO VARIOUS FORMS OF APPRAISER

INVOLVEMENT AND THE POINT VALUES WHICH MAY BE AWARDED BY THE BOARD WHEN EVALUATING NONRESIDENTIAL MASS APPRAISAL EXPERIENCE:

(A) Sole Appraiser refers to an appraisal which was completed by only one person.

Type of Appraisal		Points Assigned
1. Vacant Land	New	.067
	Update	.04
2. Rural Agricultural	New	.167
(51 acres to 250 acres)	Update	.10
3. Rural Agricultural	New	.20
(more than 250 acres)	Update	.125
4. Multi-Family	New	1.0
(5-12 units)	Update	.25
5. Multi-Family	New	1.5
(13 or more units)	Update	.33
6. Commercial	New	1.0
(single tenant)	Update	.25
7. Commercial	New	2.0
(multi-tenant)	Update	1.0
8. Industrial	New	1.0
(under 20,000 square	Update	.75
9. Industrial	New	1.5
(more than 20,000 square	Update	1.0
10. Institutional	New	1.5
	Update	.33

(B) Co-Appraiser refers to an appraisal in which two or more appraisers worked together as a team. To qualify for this category, applicants must have performed at least fifty percent (50%) of the work on an appraisal.

Type of Appraisal		Points Assigned
1. Vacant Land	New	.05
	Update	.03
2. Rural Agricultural	New	.125
(51 acres to 250 acres)	Update	.075
3. Rural Agricultural	New	.150
(more than 250 acres)	Update	.094
4. Multi-Family	New	.75
(5-12 units)	Update	.188
5. Multi-Family	New	1.125
(13 or more units)	Update	.248
6. Commercial	New	.75
(single tenant)	Update	.188
7. Commercial	New	1.5
(multi-tenant)	Update	.75
8. Industrial	New	.75
(under 20,000 square feet)	Update	.563
9. Industrial	New	1.125
(more than 20,000 square feet)	Update	.75
10. Institutional	New	1.125
	Update	.248

REGULATION 137-200.04. MASS APPRAISAL EXPERIENCE VERIFICATION.

Persons claiming mass appraisal experience must provide a statement of verification of the experience claimed. This verification should be completed by the applicant's supervisor or employer where the mass appraisal experience was required.

Regulation 137-500.01. Continuing Education.

(A) All appraisers, including appraiser apprentices, prior to their first and all subsequent renewals of their authorization to engage in real estate appraisal activity, must complete the continuing education requirement of at least fourteen (14) classroom hours of approved instruction.

(B) CONTINUING EDUCATION IS TO BE REPORTED ON A FORM APPROVED BY THE BOARD AND MUST HAVE ALL SUPPORTING DOCUMENTATION ATTACHED. TO ENSURE THAT IT IS RECORDED PRIOR TO THE RENEWAL DEADLINE OF JUNE 30 AND DOES NOT DELAY AN APPRAISER'S RENEWAL, IT SHOULD BE RECEIVED BY THE BOARD NO LATER THAN JUNE 1 OF EACH YEAR. THE BOARD CANNOT GUARANTEE THAT A RENEWAL WILL BE PROCESSED PRIOR TO THE EXPIRATION DATE OF JUNE 30 IF FORMS ARE RECEIVED AFTER JUNE 1. ANY CONTINUING EDUCATION REPORTS SUBMITTED AFTER AUGUST 31 WILL BE SUBJECT TO A LATE FEE.

(C) Approved qualifying courses may be used to meet the continuing education requirement provided that the following conditions are met:

1. Qualifying courses taken after July 1, 1992, must be on the approved list.

2. The level of the course must be above the appraiser's current status [e.g. a licensed appraiser may receive continuing education credit for taking a C-level (C-1, C-2 or C-3 course).

3. Credit will not be given for the same category course taken within a three-year (3) period with the exception of The Uniform Standards of Professional Appraiser Practice which may be taken annually.

4. The Uniform Standards of Professional Appraiser Practice ("L-3"category course)must be taken by all appraisers at least every five (5) years.

5. A certified residential appraiser may receive continuing education credit for taking a CR level course if it is substantially different in content from the one for which he received qualifying credit.

6. A certified general appraiser may receive continuing education credit for taking a C-3 category course if it is substantially different in content from the one for which he received qualifying credit.

(D) Appraisers may request that they receive credit for continuing education for a course taken that has not been approved by the Board. Credit will be granted only if the appraiser provides satisfactory proof of course completion and the Board finds that the course meets the criteria set for continuing education courses with regard to subject matter, course length, instructor qualification and student attendance. Requests for continuing education credit for non-approved courses must be made on a form approved by the Board and must be submitted along with a non-refundable fee.

(E) Up to twenty-eight (28) continuing education credits may be carried forward for two (2) years to meet the annual continuing education requirement.

(F) Appraisers who received their authority to engage in real estate appraisal activity in South Carolina through either a reciprocal agreement with their state of residence or as a non-resident South Carolina appraiser may meet the continuing education requirements by providing evidence that they have met the continuing education requirements of their state of residence. Such real estate appraisal requirements must meet South Carolina's minimum hour requirements and be approved by the regulatory agency in their state.

(G) Submission of false or misleading information is grounds for immediate revocation of the appraiser's authority to practice and other disciplinary actions.

(H) Approved instructors may receive continuing education credit for teaching continuing education courses, subject to Board approval. Credit will not be given for the same continuing education course taught within a five-year (5) period.

Regulation 137-900.01. Educational Providers - Approval Required.

(A) Providers seeking approval to offer and conduct appraiser qualifying instruction (prelicensing/precertification) and/or continuing education instruction must make application on a form approved by the Board. Upon approval, the South Carolina Appraisers Board will issue a Certificate of Approval prior to the commencement of any instruction.

(B) Providers teaching courses prior to being approved by the Board will not have their Certificates of Completion recognized by the Board.

Regulation 137-900.02. Exemption From Regulation.

COURSES OFFERED AS PART OF A DEGREE PROGRAM BY AN ACCREDITED COLLEGE OR UNIVERSITY OR A TECHNICAL, COMMUNITY, OR JUNIOR COLLEGE MAY BE DEEMED APPROVED BY THE BOARD IF THEY ARE EQUIVALENT IN HOURS AND SUBJECT MATTER TO THOSE SPECIFIED BY THE BOARD. THESE PROVIDERS ARE EXEMPT FROM REGULATION BY THE BOARD, AND ORIGINAL TRANSCRIPTS OR OTHER PROOF OF COURSE COMPLETION WITH A PASSING GRADE MAY BE RECOGNIZED AND ACCEPTED AS A PREREQUISITE FOR EXAMINATION OR FOR MEETING THE REQUIREMENTS FOR CONTINUING EDUCATION.

Regulation 137-900.03. Providers Of Courses.

(A) Courses offered by an accredited college or university or a technical, community, or junior college but which are not part of a degree program, may be approved if they comply with the regulations of the Board with regard to curriculum, instructors, classroom facilities, hours of attendance, texts, examinations and Certificates of Completion as well as comply with the policies and procedures of the appropriate department of the institution.

(B) Courses offered by other providers may be approved if they comply with the regulations of the Board with regard to curriculum, instructors, classroom facilities, hours of attendance, texts, examinations, Certificates of Completion and if the policies and procedures of the provider are also approved by the Board.

REGULATION 137-900.04. APPLICATION FOR PROVIDER APPROVAL.

(A) Providers of courses must furnish to the Board a completed application and all supporting documentation as required by the Board at least sixty (60) days prior to offering course. Applicable fees must accompany the application.

(B) Other information not submitted with the application, but which is information deemed important to the consideration thereof, may be required by the Board.

(C) If the application is disapproved, reason(s) for disapproval will be detailed and the provider may be given thirty (30) days to cure any deficiencies found. If deficiencies are cured, the application will be approved.

Regulation 137-900.05. Curriculum and Attendance.

(A) Topics for qualifying courses referenced in the South Carolina Real Estate Appraiser License and Certification Act must be broad in scope and must cover various principles, concepts, standards, practices and/or methods that are applicable to the performance of a wide range of appraisal assignments that will commonly be encountered by licenses or certified appraisers in connection with appraisals in federally-related transactions. The courses must be at least fifteen (15) hours and must include an examination pertinent to that educational offering.

(B) The seventy-five (75) hours required for qualifying as a real estate appraiser apprentice must emphasize appraisal of one-to four-unit residential properties and must include content on the following topics:

1. L-1 and L-2 classes must be at least thirty (30) hours each and may include:
   (a) influences on real estate value;
   (b) legal considerations in appraisal;
   (c) types of value;
   (d) economic principles;
   (e) real estate markets and analysis;
   (f) valuation process;
   (g) property description;
   (h) highest and best use analysis;
   (i) appraisal statistical concepts;
   (j) sales comparison approach;
   (k) site value;
   (l) cost approach;
   (m) income approach, including gross rent multiplier analysis, estimation of income and expenses, and operating expense ratios;
   (n) valuation of partial interest.
2. L-3 classes must be at least fifteen (15) hours and include The Uniform Standards of Professional Appraisal Practice.

(C) The ninety (90) hours required for a state licensed real estate appraiser must include content from L-1,L-2, and L-3 courses in addition to fifteen (15) hours of applied real estate appraisal education, known as CR courses.

(D) The one hundred twenty (120) hours required for a state certified residential real estate appraiser must include content from L-1, L-2; L-3 and CR courses, along with the C-1 course which must be thirty (30) hours and must cover direct capitalization under the topic of income approach.

(E) The one hundred eighty (180) hours required for a state certified general real estate appraiser must include content from L-1; L-2, L-3, CR and C-1 course with additional coverage of:

1. C-2 and C-3 classes, which must be at least thirty (30) hours each and may include:

(a) appraisal math and statistics;

(b) income approach, including direct capitalization, operating statement ratios, cash flow estimates, measure of cash flow, and discounted cash flow analysis;

(c) narrative report writing.

(F) Topics for continuing education courses must contribute to the goal of maintaining or increasing the knowledge, skill and competence of real estate appraisers with regard to the performance of real estate appraisals in a manner that best serves the public interest and must be a minimum of two (2) classroom hours in length.

(G) Learning objectives and detailed lesson plans reflecting the course content with time allotments must be furnished to the Board at the time of application for approval, along with copies of all quizzes and examinations for qualifying courses. Examinations and the criteria for such examinations and final grade determination may be developed by each provider based on its individual concepts. The Board may, however, direct alterations in examinations procedures, criteria for passing, and administration whenever deemed necessary.

(H) Providers must identify to the Board the texts to be used in any approved course of instruction. The Board may direct that the school withdraw texts and may require additional instructional materials.

(I) For qualifying courses, providers must establish uniform testing and grading procedures for their quizzes and examinations and must use approved instructors for administering and monitoring all such tests. No proprietor, instructor or any other individual may arbitrarily alter a student's grade or offer to students any re-examination of the same test previously administered. Retake examinations must contain at least eighty percent (80%) new material.

(J) Class meetings must be limited to a maximum of eight (8) hours in any given day. Students must be allowed one ten-minute break each hour and must be allowed at least one thirty-minute break for classes that exceed four (4) hours. Providers must require strict attendance of all classroom hours required by law and must maintain records indicating all student absences.

(K) Providers may offer students failing to meet the minimum-hour requirement make-up sessions as follows:

1. a make-up session offered by the provider consisting of the content covered in the session or hours missed; or

2. a video tape of the class session missed, supervised by the instructor, if not more than twenty percent (20%) of the classroom hours are missed; or

3. attendance of the same class session offered by the provider at a future date.

(L) Each provider shall, upon request by the Board, provide the Board with a roster of students in attendance at an approved course. The roster shall list the course identification number assigned by the Board, provider's name, instructor's name, title, location and dates of course; full legal name, address, phone number social security, number, permit/license/certificate number, if applicable, of each student, along with the number of hours in attendance and final grade, if applicable. Rosters must be verified by an authorized official of the provider.

(M) A Certificate of Completion prescribed by the Board shall be awarded to each course graduate, signed and dated by the authorized official of the provider, and must contain the course identification number assigned by the Board, provider's name and address, title, location, dates and number of hours of the course, full legal name, social security number and license number, if applicable, of the student.

Regulation 137-900.06. Provider, Instructor and Course Renewals.

All provider, course, and instructor approvals expire biennially on August 31 of even-numbered years. If issued in odd-numbered years, they shall be renewed the following year and then biennially thereafter. Renewal forms will be mailed to all approved providers and instructors, and completed forms must be received in the Board's office not later than August 15 to insure renewal by August 31. Renewal fees must accompany the form and a late fee will be charged if received after August 31.

Regulation 137-900.07. Enrollment Agreement Policies and Procedures.

(A) An enrollment agreement must be signed by the provider and student prior to the commencement of classes. A copy of the enrollment agreement containing all policies and procedures must be furnished to the student.

(B) The enrollment agreement must contain, at a minimum the following:

1. The name and address of provider and student;
2. Name of course;
3. Tuition and methods of payment, along with terms of any refund policy. If the provider has no policy for refunding fees, it must so state in writing;
4. Provider's policy for cancellation of scheduled courses;
5. The grade required for passing, methods for testing and final grade determination, if applicable;
6. Total hours of attendance required;
7. Scheduled meeting time, dates and location of course; for absences and for re-taking a failed examination, if applicable; and
8. Statement of non-discrimination in admittance requirements.

Regulation 137-900.08. Other Operating Procedures.

(A) Teaching methods.

Courses must be taught by Board-approved instructors and presented using traditional classroom teaching methods. Correspondence courses will not be approved. Nothing in this section, however, shall prohibit the use of video equipment as a teaching supplement.

(B) Facilities and equipment.

1. All facilities must meet the appropriate building, health and fire codes, must be maintained in a safe and sanitary condition at all times and are subject to inspection and approval by a representative of the Board.
2. Classrooms must be of sufficient size to accommodate comfortably all students enrolled in a course, shall have adequate light, heat, cooling and ventilation, and shall be free of distractions which would disrupt class sessions.
3. Classrooms must contain a chalkboard or other audio-visual aid and desks or worktables sufficient to accommodate all students enrolled in a course.

(C) Advertising.

1. "Advertising" includes any form of public notice, however disseminated. This definition includes all publications and promotional items and efforts which could normally be expected to be seen or heard by prospective students. Examples include but are not limited to: catalogs, flyers, signs, mailing pieces, radio, television, audio-visual, newspaper or any other form of public notice designed to aid in the provider's recruiting and promotional activities. Advertising also includes oral communications.
2. Each provider must maintain high standards in the conduct of its operations, solicitation of its students and in its advertising and promotional material. The use of any unfair or deceptive practice or the making or causing to be made of any false, misleading or deceptive statement in any advertising or promotional material which has the tendency or capacity to mislead or deceive students, prospective students, or the public shall be cause for disciplinary action.
3. The name of the provider must be disclosed in each advertising offering.
4. A provider may not advertise or imply that it is "recommended" or "endorsed" by the South Carolina Real Estate Appraisers Board.

(D) Audit and record keeping.

1. Providers must keep copies of all enrollment agreements, advertising, rosters and attendance records. Such records must be kept for five (5) years and be made available to a representative of the Board upon request.
2. Providers must permit periodic inspections and auditing by a representative of the Board for the purpose of evaluating facilities, course content, instructor performance of any other relevant aspect of the administration and conduct of such course.

(E) Changes.

Proposed changes to name, course content and/or length, texts, instructors, operating policies and procedures must be submitted to and approved by the Board prior to implementation.

(F) Complaints.

PROVIDERS MUST POST IN A CONSPICUOUS PLACE A NOTICE WHICH STATES THE FOLLOWING: "ANY COMPLAINT CONCERNING A BOARD-APPROVED REAL ESTATE APPRAISER COURSE OR INSTRUCTOR SHOULD BE DIRECTED TO THE SOUTH CAROLINA REAL ESTATE APPRAISERS BOARD AT (THE BOARD'S CURRENT ADDRESS)."

RESOLUTION 137-900.09 INSTRUCTORS.

(A) Approved courses held in this state must be taught by Board-approved instructors. Instructors teaching courses which are part of a degree program offered by an accredited college, university, technical college, community college or junior college may be deemed approved by the Board.

(B) Applicants for instructor approval must submit an application form along with supporting documentation as proof of knowledge of subject matter and the ability to teach effectively.

1. As proof of knowledge of the subject matter to be taught, one or more of the following will be considered:

(a) For L-1, L-2, L-3 and CR courses, an active appraiser license or certification issued by the Board or other authority acceptable to the Board, and at least three (3) years of appraisal experience; or

(b) For pre-certification courses, an active state certified general appraiser certificate issued by the Board or other authority acceptable to the Board, and at least three (3) years of nonresidential appraisal experience; or

(c) A college degree in an academic area directly related to the course; or

(d) Previous employment by a state or federal agency performing appraisal work for at least five (5) years immediately preceding application; or

(e) Past experience and/or education acceptable to the Board in a subject area directly related to the course.

2. For continuing education courses acceptable proof of knowledge would also include:

(a) Three (3) years of experience within the past five (5) years directly related to subject matter to be taught; or

(b) Three (3) years of experience within the past five (5) years teaching the subject matter to be taught.

3. As proof of the ability to teach effectively, one or more of the following will be considered:

(a) A current teaching certificate issued by any state department of education (or an equivalent agency);

(b) A four-year undergraduate degree in education; or

(c) Previous experience teaching in schools, seminars or in an equivalent setting for three (3) years within the past five (5) years; or

(d) Serving as a trainee or assistant instructor under the direct supervision of a Board-approved instructor for at least sixty (60) hours; or

(e) Past experience acceptable to the Board in the area of education.

(C) Instructors may be approved by the Board to teach one or more specific subjects or courses as outlined in the South Carolina Real Estate Appraiser License and Certification Act.

(D) An instructor may teach approved courses at locations throughout the State of South Carolina but must notify the board in advance and record his name on the provider's roster.

(E) A fee must accompany the application for each instructor approval.

(F) Other information not submitted with the application, but which is deemed important to the consideration thereof, may be required by the Board.

(G) If the application is disapproved, reason(s) for disapproval will be detailed and the instructor will be given an opportunity to cure any deficiencies found within thirty (30) days. If deficiencies are cured, the application will be approved.

(H) Each instructor must prominently display in the classroom where an approved course is being offered, a copy of Certificate of Approval.

Fiscal Impact Statement: No additional funds will be incurred by the State or any political subdivision.