

Regulation 61-64

X-Rays (Title B)

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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 to use, receive, own, or possess x-ray equipment unless the facility is registered with the Department and is operated in compliance with all applicable provisions.

1.2.4 It shall be unlawful to use hand-held non-image intensified fluoroscopic screens.

1.2.5 It shall be unlawful to use plastic pointed position indicating devices on intraoral dental systems.

1.2.6 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.

1.2.7 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.

1.2.8 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.

1.2.9 It shall be unlawful for a person other than a licensed practitioner of the healing arts as defined by the South Carolina Department of Labor, Licensing, and Regulation 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.

1.2.10 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.

1.2.11 It shall be unlawful to use a mammographic imaging system not specifically designed by the manufacturer for imaging of the breast.

1.2.12 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 45 CFR 46, 21 CFR 50 and 21 CFR 56.

1.2.13 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 persons shall be registered with the Department in accordance with RHB 2.6.

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.

1.3.4 The Department is authorized by law to enter and inspect property in order to determine compliance with Department regulations. Such entry and inspection falls under the health oversight activities exception of the Health Information Portability and Accountability Act (HIPAA). Therefore, when protected health information is necessary for determining compliance with Department regulations, protected health information may be used and disclosed to the Department without the subject's authorization.

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.

1.4.4 Radiation Survey Instruments

1.4.4.1 The radiation survey instrument used shall have a minimum operation range consistent with the radiation field being measured.

1.4.4.2 Each radiation survey instrument shall be maintained annually.

1.4.4.2.1 Each radiation survey instrument used for equipment performance testing and radiation area surveys shall be calibrated at intervals not to exceed 24 months and after each instrument servicing.

1.4.4.2.2 Each radiation survey instrument shall be calibrated such that the accuracy is within 20 percent or within the manufacturer specifications, whichever is less, and traceable to a national standard that can be demonstrated.

1.4.4.2.3 Each radiation survey instrument shall be calibrated at two or more widely separated points, other than zero, on each scale.

1.4.4.2.4 Records of these calibrations shall be maintained for inspection by this Department.

1.4.4.3 The manufacturer's instructions of the survey instrument shall be made available to the instrument users. This shall include any restrictions of the operating techniques required for the proper operation of the instrument.

1.4.4.3.1 The registrant shall adhere to the manufacturer's instructions in all respects.

1.4.4.3.2 The user shall be able to demonstrate familiarity and competence with these instructions.

1.4.4.3.3 The operator shall check each survey instrument with a dedicated check source each day of use to ensure the instrument is operating properly.

1.4.4.4 Calibration radiation measurements required by Part VI shall be performed using a dosimetry system:

1.4.4.4.1 Having a calibration factor traceable to a national standard;

1.4.4.4.2 Calibrated within the preceding 24 months and after any servicing that may have affected its calibration;

1.4.4.4.3 Calibrated in such a fashion that an uncertainty can be stated for the radiation quantities monitored by the system; and

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 the sale and operation of x-ray producing equipment not specifically covered in these regulations, the seller shall submit for review and approval to the Department a listing of manufacturer's specifications for the equipment, an analysis of exposure rates for the equipment, independent peer reviewed radiation safety studies of the equipment, training materials in the use of the equipment, and verification of compliance with the United States Food and Drug Administration. In addition, the seller shall provide the written operating procedures and user's manual of the equipment. Guidance documents regarding new modalities may be found on the Department's website.

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 Develop and implement 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, with respect to action that has been taken or planned to correct the violation.

1.7.2.1 Mammography Violation Response

1.7.2.1.1 If the MQSA (Mammography Quality Standards Act) report results in a Level 1, repeat Level 1, or repeat Level 2 finding, a written Corrective Action Plan shall be provided to the Department within 15 calendar days of the date of citation.

1.7.2.1.2 If the MQSA report results in a Level 2 or repeat Level 3 finding, a written Corrective Action Plan shall be provided to the Department within 30 calendar days of the date of citation.

1.7.2.2 All Other Violation Response

1.7.2.2.1 A written Corrective Action Plan shall be provided in writing within twenty (20) calendar days from the date of citation with respect to action that is planned to correct the violation.

1.7.2.2.2 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.

1.7.3 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.

1.7.4 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, 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 Regulations 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 comply with 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, and beam limiting devices;

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, equipment performance tests, 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; until the next Department inspection; or until the registrant no longer possesses the equipment.

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 model number, serial number, shielding acceptance number (if applicable), date of last equipment performance test, 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, fax, or electronic mail 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 judgment, 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 twenty four (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 fifteen (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 (10) years and three (3) 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 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 occupational or 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 1.13.4.3. 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 1.13.4.1 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 (11-70)	\$25,000-5,000	\$15,000-5,000	\$10,000-2,500
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
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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, Willfulness, 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 (\$25,000.00) 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. (4.2.11.2)

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. (7.5.1)

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. (4.2.13.2)

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. (4.2.2, 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. (4.2.11)

Two or more incidents on three consecutive inspections of failing to perform required equipment performance tests, surveys, 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. (4.2.11.1)

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 five percent (5%), or the sum of the excess length and width of greater than six percent (6%). (4.9.2.2)

Initiating or conducting a healing arts screening program without prior approval from the Department. (4.2.11.2)

Failing to provide a safety device on open-beam configuration analytical x-ray equipment. (7.5.1)

ESEs that vary from the average ESE by more than a factor of 2, as determined by Appendix D of Part IV. (4.2.13.2)

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 where 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 workers, 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. (4.2.12.4)

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. (4.2.13.2)

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. (7.4.5.5)

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. (4.4.3)

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. (7.5.6.2)

Two or more incidents on two consecutive inspections of failure to control access to equipment, or failure to control access to restricted areas. (7.5.3)

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. (4.2.2.4, 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. (3.12.2)

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 facility's operating conditions. (4.2.3)

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. (4.2.16.4)

Two or more incidents on two consecutive inspections of failing to perform densitometric and sensitometric testing if required by RHB 4.2.17.2.7.

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 4.2.2.6 or RHB 6.3.3.8.

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.

1.16 Any person to whom an order is issued may appeal it pursuant to applicable law, including S.C. Code Title 44, Chapter 1; and Title 1, Chapter 23.

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 Facility Application Fee. Each registrant shall pay a non-refundable application fee of sixty two dollars and fifty cents 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 sixty two dollars and fifty cents per x-ray control upon submission of any shielding plan. A shielding plan acceptance shall not be issued until payment of the review fee.

2.3.3 Vendor Application Fee. Each vendor shall pay a non-refundable application fee of sixty two-dollars and fifty cents upon submission of the initial Business Registration Approval Request form. A vendor registration approval shall not be issued until payment of the application fee.

2.3.4 Out-of-State Facility Application Fee. Any person proposing to bring an x-ray machine into the State, for any temporary use, shall pay a non-refundable application fee of sixty-two dollars and fifty cents upon submission of the initial Out-of-State Facility Form. An Out-of-State Facility approval shall not be issued until payment of the application 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 A shielding plan, if required by RHB 4.4 or 8.12.2;

2.4.1.1.5 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 An operating schedule, indicating when and where the equipment will be used;

2.4.2.1.5 A radiation area survey as required by RHB 4.4 or 8.12.2;

2.4.2.1.6 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 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 Out of State Facility. Any person proposing to bring an x-ray producing machine into the State, for any temporary use, shall meet the provisions of this Subpart.

2.4.4.1 Prior to entering the state, the Out of State Facility shall submit to the Department the following information:

2.4.4.1.1 Facility Name and Mailing Address where correspondence may be sent;

2.4.4.1.2 The name of the radiation safety officer responsible for radiation protection, and the individual's qualifications to serve in such a capacity;

2.4.4.1.3 Type and make of x-ray equipment to be utilized; and

2.4.4.1.4 A radiation area survey, as required by RHB 4.4 or 8.12.2.

2.4.4.2 An operating schedule, indicating when and where the equipment will be used, shall be submitted to the Department 5-days prior to equipment use in the State.

2.4.5 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 installation. Registration shall be made on the form 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 confirmed 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.

2.6.1.1 In-house personnel employed by a facility or corporation shall be exempt from the registration requirement, provided such personnel:

2.6.1.1.1 Shall meet the education, training, and experience requirements for the appropriate vendor Class and

2.6.1.1.2 Shall exclusively service one facility or corporation.

2.6.1.2 Documentation of education, training, and experience for in-house service personnel shall be maintained by the facility or corporation and available for Department review.

2.6.2 Application for vendor registration shall be completed on forms 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, if registering as a Class II vendor;

2.6.2.6 A sample of a shielding plan, if registering as a Class III, Class IV, Class VII, or Class IX 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 Class I - Direct sale and transfer of radiation machines and machine components to end users;

2.6.4.2 Class II - Installation or servicing of radiation machines and associated radiation machine components;

2.6.4.2.1 Class II-A - Installation of radiation machines and associated radiation machine components;

2.6.4.2.2 Class II-B - Servicing of radiation machines and associated radiation machine components;

2.6.4.2.3 Class II-C - Perform "Equipment Performance Tests" as outlined in RHB 4.2.16. Refer to Appendix F;

2.6.4.3 Class III - Diagnostic radiographic facility and shielding design;

2.6.4.4 Class IV - Diagnostic fluoroscopic facility and shielding design;

2.6.4.5 Class V - Diagnostic area radiation survey, e.g., shielding evaluation;

2.6.4.6 Class VI - Radiation instrument calibration;

2.6.4.7 Class VII - Therapeutic facility and shielding design, area radiation surveys, or calibration;

2.6.4.8 Class VIII - General health physics consulting, non-healing arts, e.g., independent diagnostic radiation output measurements, dose analysis, design of safety programs and radiation safety training programs, facility and shielding design, area radiation surveys, and acting as the radiation safety officer;

2.6.4.9 Class IX - General health physics consulting, healing arts, e.g., independent diagnostic radiation output measurements, dose analysis, design of safety programs and radiation safety training programs, facility and shielding design, area radiation surveys, equipment performance tests, and acting as the radiation safety officer; 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 that would render the information contained on the company and/or employee registration form no longer accurate. Changes shall include, but not be limited to, changes in employee's status, new employees, and in vendor Class or services.

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 - A, B, or C - 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 Documented manufacturer's equipment school of service, testing, 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 a minimum of three months of experience in installation, service, and/or testing of radiation machines and machine components.

2.6.6.3 Class III - Diagnostic radiographic facility and shielding design:

2.6.6.3.1 Documented training in principles of radiation protection;

2.6.6.3.2 Documented 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 Documented training in principles of radiation protection;

2.6.6.4.2 Documented 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 Documented training in principles of radiation protection;

2.6.6.5.2 Documented training in shielding evaluation; and

2.6.6.5.3 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 if instrument calibration is done utilizing radioactive materials 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; and

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 - General health physics, non-healing arts, e.g., independent diagnostic radiation output measurements, dose analysis, design of safety programs, and radiation safety training programs, facility and shielding design, area radiation surveys, and acting as the radiation safety officer;

2.6.6.8.1 One year experience in non-healing arts facility design and area radiation surveys.

2.6.6.8.2 Baccalaureate degree in physical science (e.g., physics, chemistry or radiologic science), engineering or related field and two years of progressive experience in medical or health physics; or

2.6.6.8.3 Baccalaureate degree in physical science (e.g., physics, chemistry or radiologic science), engineering or related field and two years graduate training in medical or health physics; or

2.6.6.8.4 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.

2.6.6.9 Class IX - General health physics consulting, healing arts, e.g., independent diagnostic radiation output measurements, dose analysis, design of safety programs, and radiation safety training programs,

facility and shielding design, area radiation surveys, equipment performance tests, and acting as the radiation safety officer:

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; or

2.6.6.9.2 Baccalaureate degree in a physical science (e.g., physics, chemistry or radiologic science), engineering or related field and two years graduate training in medical or health physics; 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.

2.6.6.9.4 All training requirements of RHB 2.6.6.2, 2.6.6.3, 2.6.6.4, 2.6.6.5, 2.6.6.7, as applicable. Any person registered prior to the effective date of this regulation as a vendor of this Class shall meet the education, training, and experience requirements no later than 24 months after the effective date of these regulations.

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.

2.6.7 Any branch office of a vendor shall be considered a separate entity and shall be registered separately pursuant to RHB 2.6.

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 forms furnished by the Department and 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.

2.7.2 No person shall make, sell, lease, transfer, lend, maintain, calibrate, test, 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.

2.7.2.1 Any vendor acting as a Radiation Safety Officer on behalf of a registered facility shall be registered as a Class VIII or IX vendor and shall meet all applicable parts of this regulation.

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 and the legible signature of the person performing the service. 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.

2.7.3.6.1 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.

2.7.3.6.2 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.

2.7.3.6.3 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.

2.7.3.6.4 The equipment performance test record shall include a summary of findings and recommendations for necessary improvements and/or corrective actions.

2.7.3.6.5 The record of equipment performance shall include the date that the testing was performed; the legible signature of the person performing the service; manufacturer, model number, serial number, and the calibration date of the instrument used to perform the test; the manufacturer, serial number, model number, and location of the equipment.

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. All provisions of RHB 1.4.4 apply.

RHB 2.8 Out of State Facilities.

2.8.1 No person shall bring any radiation machine into the state, for any temporary use, unless such person has given a written notice to the agency at least five working days before the machine is to be used in the state. The notice shall include the type of radiation machine; the nature, duration, and scope of use; and the exact location(s) where the radiation machine is to be used. If, for a specific case, the five working day period would impose an undue hardship on the person, he may, upon application to the agency, obtain permission to proceed sooner.

2.8.2 Such facilities shall meet all applicable parts of this regulation.

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 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:

2.9.3.1 Call to the attention of the registrant in writing the facts or conduct which may warrant these actions, and

2.9.3.2 Provide an opportunity for the registrant to demonstrate or achieve compliance with all regulations.

2.9.4 The Department may terminate a registration upon written request submitted by the registrant to the Department.

2.9.5 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 and Out of State Facilities 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, out of state facility, 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. Chapter 7, Nuclear Energy, Article 1, Atomic Energy and Radiation Control Act, Section 13-7-45, (A)(1) requires the Department to establish a schedule for the collection of annual fees for the licensing, registration, and certification of users of sources of ionizing radiation.

Type of Equipment	Fee
Radiographic	\$131
Fluoroscopic	\$131
Combination Rad/Fluoro	\$231
Dental	\$93.50
Therapy (medical)	\$156
Diffraction	\$99.75
X-ray Fluorescence	\$99.75
Accelerator (industrial)	\$156
Electron Microscope	\$68.50
Spectrograph	\$99.75
Cephalometer	\$131
Panoramic	\$81
Cabinet X-ray	\$124.75

CT Scanner, and/or PET/CT, SPECT, Dental CT	\$131
C-Arm Fluoroscopic	\$131
Mammography	(See RHB 5.6)
Stereotactic Mammography	\$131
Baggage Checker	\$99.75
Bone Densitometer	\$131
Lithotripter	\$131
Simulator	\$131
Other	\$131
Out of State Facilities	\$187.25
Vendors and Installers	\$187.25

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 Authority and Responsibility for the 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.

3.3.4 The registrant shall provide the Radiation Safety Officer sufficient authority, organizational freedom, time, resources, and management prerogative, to:

3.3.4.1 Identify radiation safety problems;

3.3.4.2 Initiate, recommend, or provide corrective actions;

3.3.4.3 Stop unsafe operations; and,

3.3.4.4 Verify implementation of corrective actions.

3.3.5 The registrant shall establish either monthly or quarterly investigative limits to ensure individuals will not exceed annual occupational exposure limits.

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:

3.4.1.1.1 The total effective dose equivalent being equal to 5 rem (0.05 Sv); or

3.4.1.1.2 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).

3.4.1.2 The annual limits to the lens of the eye, to the skin, and to the extremities which are:

3.4.1.2.1 An eye dose equivalent of 15 rem (0.15 Sv), and

3.4.1.2.2 A shallow dose equivalent of 50 rem (0.5 Sv) to the skin or to any extremity.

3.4.1.3 Any individual exceeding his/her annual occupational exposure limit shall not be exposed to additional occupational radiation for the remainder of the calendar year.

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

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.

RHB 3.12 Personnel Monitoring

3.12.1 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:

3.12.1.1 Holding current personnel dosimetry accreditation from the National Voluntary Laboratory Accreditation Program (NVLAP) of the National Institute of Standards and Technology; and

3.12.1.2 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.

3.12.2 Exposure of a personnel monitoring device to deceptively indicate a dose delivered to an individual is prohibited.

3.12.3 Personnel Monitoring Devices.

3.12.3.1 Personnel Monitoring (or other dosimeters approved by the Department) shall meet the following requirements:

3.12.3.1.1 The monitoring device shall be assigned to and worn only by one individual;
and

3.12.3.1.2 When a lead apron is worn, the monitoring device shall be worn at the collar, outside the apron; and

3.12.3.1.3 If a personnel monitoring device is lost or damaged, the worker shall cease work immediately until a replacement badge is provided and the exposure is calculated for the time period from issuance to loss or damage of the badge. In the event a replacement badge is not available, the Radiation Safety Officer shall be contact immediately to evaluate the probable radiation exposure to the worker until a replacement device is received; and

3.12.3.1.4 The Registrant shall ensure that personnel monitoring devices are returned within 45 days of the end of the monitoring period. Direct read dosimeters must be read according to the manufacturer specifications and the results from the readings recorded and available for departmental review; and

3.12.3.1.5 Documentation providing explanation of any late, absent or unused personnel monitoring devices must be recorded and available for Departmental review; and

3.12.3.1.6 Personnel monitoring devices must be worn in accordance with manufacturer guidelines.

3.12.3.2 Control badges are used to measure background radiation. They shall be stored away from the radiation area. Control badges are not to be worn as a personnel monitoring device. Ensure the control badge is returned with the lot of badges with which it was issued.

3.12.3.3 Upon departmental approval, area monitors may be used in place of personnel monitoring devices.

3.12.4 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:

3.12.4.1 Each registrant shall monitor occupational exposure to radiation and shall supply and require the use of individual monitoring devices by:

3.12.4.1.1 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

3.12.4.1.2 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

3.12.4.1.3 Individuals entering a high or very high radiation area.

3.12.4.1.3.1 Personnel monitoring devices shall be worn appropriately by personnel working with medical fluoroscopic equipment.

3.12.4.1.4 Such other individuals as the Department deems necessary.

3.12.5 Determination of Dose

3.12.5.1 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.

3.12.5.2 The Radiation Safety Officer may give consideration that an Effective Dose Equivalent be used as the permanent record provided that all provisions of RHB 3.3 apply. The Radiation Safety Officer must ensure individuals utilizing the Effective Dose Equivalent shall meet the following requirements:

3.12.5.2.1 Protective equipment must be used. The use of protective equipment shall be routinely documented in each room and this documentation shall periodically be reviewed by the Radiation Safety Officer, or other responsible persons to determine if it is being completed correctly.

3.12.5.2.2 Periodic visits must be made by the radiation safety officer or his designee for personal observation adherence to proper radiation safety practices. Documentation of these reviews must be available for Departmental review.

3.12.5.2.3 The Department may immediately revoke the use of the Effective Dose Equivalent upon determination that a violation of RHB 3.12.5 has occurred.

3.12.5.3 Adjustments to the dose of permanent record shall be determined by the Radiation Safety Officer prior to any changes to the record. Records of these actions shall be maintained for Departmental review.

3.12.6 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. The fetal badge shall be processed and evaluated on a monthly basis, at a minimum.

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.

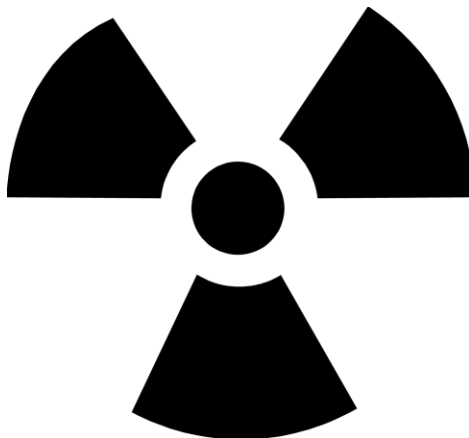
3.13.3 The registrant may apply to the Department for approval of alternative methods for controlling access to high radiation areas.

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.

3.17.3 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 3.18 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 3 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 termination of the registration.

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 determine the occupational radiation dose received during the current year.

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 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, letter, or other electronic means. 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 a clear and legible record, of all the information required. The record shall show each period in which the individual received occupational exposure to radiation. For each period for which the registrant obtains reports, the registrant shall use the dose shown in the report in preparing the record. For any period in which the registrant does not obtain a report, the registrant shall place a notation on the record 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 until the Department terminates each pertinent registration requiring this record. The registrant shall retain records for 5 years after the termination of the registration.

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.

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 Notification of Incidents.

3.24.1 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:

3.24.1.1 A total effective dose equivalent of 25 rem (0.25 Sv) or more; or

3.24.1.2 An eye dose equivalent of 75 rem (0.75 Sv) or more; or

3.24.1.3 A shallow dose equivalent to the skin or extremities or a total organ dose equivalent of 250 rad (2.5 Gy) or more; or

3.24.2 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:

3.24.2.1 A total effective dose equivalent exceeding 5 rem (0.05 Sv); or

3.24.2.2 An eye dose equivalent exceeding 15 rem (0.15 Sv); or

3.24.2.3 A shallow dose equivalent to the skin or extremities or a total organ dose equivalent exceeding 50 rem (0.5 Sv); or

3.24.3 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.

3.24.4 Registrants shall make the reports required by this Part to the Department by telephone, telegram, mailgram, or facsimile to the Department.

3.24.5 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 3.25 Reports of Exposures and Radiation Levels Exceeding the Limits.

3.25.1 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:

3.25.1.1 Any incident for which notification is required by RHB 3.25;

3.25.1.2 Doses in excess of any of the following:

3.25.1.2.1 The occupational dose limits for adults in RHB 3.4;

3.25.1.2.2 The occupational dose limits for a minor in RHB 3.7;

3.25.1.2.3 The limits for an embryo/fetus of a declared pregnant woman in RHB 3.8; or

3.25.1.2.4 The limits for an individual member of the public in RHB 3.9.

3.25.2 The written report shall include the following:

3.25.2.1 A description of the extent of exposure of individuals to radiation, including, as appropriate:

3.25.2.1.1 Estimates of each individual's dose; and

3.25.2.1.2 The levels of radiation involved; and

3.25.2.1.3 The cause of the elevated exposures or dose rates; and

3.25.2.1.4 Corrective steps taken or planned to ensure against a recurrence, including the schedule for achieving conformance with applicable limits.

3.25.2.2 For each individual exposed: the name 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.

3.25.3 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 3.26 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 3.27 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 3.28 Notifications and Reports to Individuals.

3.28.1 Requirements for notification and reports to individuals of exposure to radiation are specified in RHB 10.4.

3.28.2 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 3.29 Storage and Control of Radiation Sources

3.29.1 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.

3.29.2 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 3.30 Reports of Stolen, Lost, or Missing Radiation Sources.

3.30.1 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.

3.30.2 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:

3.30.2.1 A description of the registered source of radiation involved, including the manufacturer, model and serial number, type and maximum energy of radiation emitted;

3.30.2.2 A description of the circumstances under which the loss or theft occurred; and

3.30.2.3 A statement of disposition, or probable disposition, of the registered source of radiation involved; and

3.30.2.4 Actions that have been taken, or will be taken, to recover the source of radiation; and

3.30.2.5 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.

3.30.3 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 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.

4.2.2 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.

4.2.2.1 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.

4.2.2.2 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.

4.2.2.3 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.

4.2.2.4 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.

4.2.2.5 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.

4.2.2.6 The registrant shall display each operator's current South Carolina Radiation Quality Standards Association certificate or the registrant may post a notice to the public that these certificates are available for review upon request. The certificate or posting shall be displayed in public view, not obstructed by any barrier, equipment, or other object.

4.2.2.7 The registrant shall ensure that each operator has received facility specific training to include the equipment and operating conditions. Documentation of this training for each operator shall be made available for Departmental review.

4.2.2.8 Dentists and their auxiliaries who meet the requirements of the South Carolina Dental Practice Act are exempt from the requirements of 4.2.2.1 through 4.2.2.6.

4.2.3 The operator shall be able to demonstrate familiarity and competence with the facility's operating conditions.

4.2.4 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.

4.2.5 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.

4.2.6 For general radiographic systems not equipped with an operational anatomic programming option, protocols shall be documented and readily available to the operator. At a minimum, these protocols shall include:

4.2.6.1 Patient's body part and anatomical size, or body part thickness or age (for pediatrics), versus technique factors to be used;

4.2.6.2 Source to image receptor distance (SID) to be used (except for dental intra-oral radiography) and

4.2.6.3 If an AEC system is operated in a manual mode, the technique chart shall specify the requirements of RHB 4.2.6.1 and RHB 4.2.6.2.

4.2.6.4 The technique chart shall accurately reflect techniques currently in use at the facility.

4.2.7 A sign shall be posted 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.

4.2.8 The effectiveness of protective equipment and apparel 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.

4.2.9 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.

4.2.9.1 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.

4.2.9.2 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 0.25 mm lead equivalent material.

4.2.9.3 Persons 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 and when feasible shall be so positioned that the nearest portion of the body is at least 2 meters from both the tube head and the nearest edge of the image receptor.

4.2.9.4 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 3.4 of these regulations, additional protective devices may be required by the Department.

4.2.10 Shielding of not less than 0.5 mm lead equivalent material shall be used for patients during x-ray procedures except in cases where the shielding would interfere with the diagnostic image desired.

4.2.11 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:

4.2.11.1 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.

4.2.11.2 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.

4.2.12 When a patient or film must be provided with auxiliary support during a radiation exposure:

4.2.12.1 Mechanical holding devices shall be used when the technique permits.

4.2.12.2 The facility shall indicate the requirements for selecting a holder, and the procedure the holder shall follow.

4.2.12.3 The human holder shall be instructed in personal radiation safety and shall be protected as required by 4.2.9.

4.2.12.4 No person shall be used routinely to hold patients or film. All requirements of RHB 4.2.14 and 4.2.15 apply.

4.2.12.5 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.

4.2.12.6 When practical, a pregnant female shall not be used to hold film or patients.

4.2.12.7 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.

4.2.13 Procedures and auxiliary equipment designed to minimize patient and personnel exposure shall be used.

4.2.13.1 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.

4.2.13.2 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 shall be used by the registrant in evaluating patient exposure.

4.2.13.3 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. Portable or mobile dental equipment, not to include handheld, shall be exempt from this regulation.

4.2.13.4 Radiologic technologists performing fluoroscopy as a localizing procedure shall be monitored by the supervising radiologist who is personally and immediately available.

4.2.14 Personnel Monitoring

4.2.14.1 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:

4.2.14.1.1 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:

4.2.14.1.2 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 3.12.5.

4.2.14.1.3 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.

4.2.14.2 Exposure of a personnel monitoring device to falsely indicate a dose delivered to an individual is prohibited.

4.2.14.3 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 lead apron, when such apron is worn.

4.2.15 X-ray Log.

4.2.15.1 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; identification of the operator performing the examination; and the dates the examinations were performed.

4.2.15.2 When the examination is performed using any type of fluoroscopy, the log shall include a record 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 or instrument guided radiation therapy units.

4.2.15.3 X-ray log records shall be maintained for two years or until the next Department inspection, whichever is later.

4.2.15.4 Logs are not required for dental or veterinary x-ray equipment.

4.2.16 Quality Assurance

4.2.16.1 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 or until the next Department inspection, whichever is later. Equipment performance tests are to be performed:

4.2.16.1.1 At the time installation at all facilities, including veterinary facilities, or

4.2.16.1.2 Within thirty (30) days of installation, provided that the manufacturer's specified testing is performed at the time of installation and before patient use.

4.2.16.1.3 At the following specified intervals thereafter:

4.2.16.1.3.1 Dental intraoral and dental extraoral units shall be tested every two years. Dental computed tomography and dental handheld units shall be tested annually.

4.2.16.1.3.2 All medical x-ray equipment, including fluoroscopic, computed 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.

4.2.16.1.3.3 Veterinary facilities are required to have equipment performance tests performed at the time of installation, every five years, and at any time the Department deems necessary.

4.2.16.1.4 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.

4.2.16.2 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.

4.2.16.3 If grids are used between the patient and the image receptor to decrease scatter to the film and improve contrast the grid shall:

4.2.16.3.1 Be positioned properly, i.e., tube side facing the right direction, and grid centered to the central ray,

4.2.16.3.2 If of the focused type, be of the proper focal distance for the SID's being used.

4.2.16.4 Repeat Analysis.

4.2.16.4.1 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.

4.2.16.4.2 The repeat analysis shall be done at least quarterly. Records shall be maintained for two years or until the next Department inspection, whichever is later.

4.2.16.4.3 Facilities with a single operator may document reasons for repeats on the patient log in lieu of a repeat analysis rate.

4.2.16.4.4 Registrants possessing dental or veterinary x-ray equipment are exempt from this requirement.

4.2.17 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:

4.2.17.1 Manual Film Processing Systems

4.2.17.1.1 Processing tanks shall be constructed of mechanically rigid, corrosion resistant material.

4.2.17.1.2 A dedicated darkroom thermometer shall be used. The thermometer shall be used to adjust the film processing time according to solution temperature.

4.2.17.1.3 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.

4.2.17.1.4 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.

4.2.17.1.5 Safelight. If a safelight is used, it shall be adequate for the film speed(s) and the darkroom operating procedures used to prevent fogging of unprocessed film.

4.2.17.1.6 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 ½
25.0	77	2 ½
24.4	76	3
23.9	75	3
23.3	74	3 ½
22.8	73	3 ½
22.2	72	4
21.7	71	4
21.1	70	4 ½

20.6	69	4 ½
20.0	68	5
19.4	67	5
18.9	66	5 ½
18.3	65	6
17.8	64	6 ½
17.2	63	7
16.7	62	8
16.1	61	8 ½
15.6	60	9 ½

4.2.17.1.7 Radiographs shall not be "sight developed."

4.2.17.2 Automated Processors and Other Closed Processing Systems.

4.2.17.2.1 The temperature of film processing chemicals shall be appropriate for the type of film(s) being processed at the film transport speed selected.

4.2.17.2.2 The film processing chemicals used and their replenishing rate (if applicable) shall be appropriate for the film transport speed selected.

4.2.17.2.3 Documentation shall be kept of the frequency at which film processing chemicals are changed. At a minimum, the interval recommended by the chemical manufacturer shall be used.

4.2.17.2.4 Safelight. If a safelight is used, it shall be adequate for the film speed(s) and the darkroom operating procedures used to prevent fogging of unprocessed film.

4.2.17.2.5 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.

4.2.17.2.6 The specified developer temperature shall be available.

4.2.17.2.7 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.

4.2.17.2.8 Densitometric and sensitometric performance testing.

4.2.17.2.8.1 Densitometric and sensitometric performance testing of the processor is required of facilities that process more than 250 films per week.

4.2.17.2.8.2 Control limits shall be established for each parameter monitored. Provisions for correctable action shall be undertaken whenever the pre-established control limits are exceeded.

4.2.17.2.8.3 Documentation of testing must be maintained for at least two years or until the next Department inspection, whichever is later.

4.2.17.2.8.4 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.

4.2.17.2.8.5 Facilities that operate 24 hours per day must perform the required testing once each day.

4.2.17.2.8.6 Registrants possessing dental or veterinary x-ray equipment are exempt from this requirement.

4.2.17.2.9 Records of processor maintenance shall be kept for at least two years or until the next Department inspection, whichever is later.

4.2.17.3 Other Requirements

4.2.17.3.1 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.

4.2.17.3.2 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.

4.2.17.3.3 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.

4.2.17.4 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.

4.2.17.5 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: "WARNING: This x-ray unit may be dangerous to patient and operator unless safe exposure factors and operating instructions are observed."

4.3.1.1 The warning label shall be legible and its view unobstructed.

4.3.2 Battery Charge Indicator. On battery-powered generators, visual means shall be provided on the control panel to indicate that the battery is adequately charged.

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 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.

4.3.5 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 that is not listed in Table I, linear interpolation or extrapolation may be made.

TABLE I

Design Operating Range (kVp)	Measured Potential (kVp)	Specified Dental Systems (mm Al)	All other Diagnostic (mm Al)
30 to 50	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.

4.3.7.1 This indication shall be on both the X-ray control and at or near the tube housing assembly.

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, whether manual or automatic exposure control, shall be indicated before the exposure begins. This requirement may be met by permanent markings on equipment having fixed technique factors.

4.3.9.2 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.

4.3.12 Imaging Systems other than Screen/Film. The provisions of this part are in addition to, and not in substitution for, applicable provisions of these regulations.

4.3.12.1 Users of digital imaging acquisition systems shall follow protocol established by the manufacturer of the digital imaging acquisition system. Records documenting adherence to this protocol shall be kept for at least two years or until the next Department inspection, whichever is later.

4.3.12.2 The manufacturer's current operating manual shall be available for Department review.

RHB 4.4 Shielding.

4.4.1 Shielding Plan Required.

4.4.1.1 Prior to construction of a new facility, modification, or renovation of an existing x-ray facility, or replacement of an x-ray machine, the floor plans and equipment arrangement shall be reviewed by a Class III, Class IV, Class VII, or Class IX vendor and submitted to the Department for review and acceptance.

4.4.1.2 A shielding plan shall be required for any space utilized as a radiation area for a period of greater than five (5) consecutive days.

4.4.2 Equipment Replacement.

4.4.2.1 A shielding plan is not required upon the replacement of an existing x-ray machine, control, or generator with like equipment and when there are no other changes which would render the original shielding plan inaccurate, as determined by a Class III, Class IV, Class V, Class VII, Class VIII or Class IX vendor. The appropriate vendor shall notify the Department regarding such replacement. A form shall be provided by the Department for this notification and shall be exempt from RHB 2.3.2.

4.4.2.2 A shielding plan shall be required when a facility replaces an existing x-ray machine or control generator with a unit with increased capabilities which would render the original shielding plan inaccurate, as determined by a Class III, Class IV, Class V, Class VII, Class VIII or Class IX vendor, or when the original shielding plan is not available.

4.4.2.3 A shielding plan shall be required when the parameters of the original shielding plan change to an extent so as to render the original shielding plan inaccurate, as determined by a Class III, Class IV, Class V, Class VII, Class VIII or Class IX vendor.

4.4.3 X-ray equipment shall not be installed or operated before a shielding plan for the unit has been reviewed and accepted by the Department.

4.4.4 Shielding Plan Requirements.

4.4.4.1 The registrant shall submit plans and a report, including any recommendations and all basic assumptions used, from the vendor to the Department. Applicable fees shall be submitted in accordance with RHB 2.3.2. In order for the Department to accept the submitted shielding plan, the information listed in Appendix B shall be submitted. The design considerations listed in Appendix C shall be followed.

4.4.4.2 Each installation shall be provided with such primary barriers and secondary 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 the National Council of Radiation Protection and Measurements, Report Number 147, "Structural Shielding Design for Medical X-ray Imaging Facilities;" the National Council of Radiation Protection and Measurements, Report Number 145, "Radiation Protection in Dentistry;" the National Council of Radiation Protection and Measurements, Report Number 151, "Structural Shielding Design and Evaluation for Megavoltage X- and Gamma-Ray Radiotherapy Facilities," or an equivalent reference.

4.4.4.3 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.

4.4.4.4 Secondary barriers shall be provided in all wall, floor and ceiling areas not having primary barriers.

4.4.4.5 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 that has been scattered only once.

4.4.4.6 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.

4.4.5 The acceptance 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.

4.4.6 Area Surveys. The registrant shall have a radiation area survey performed by a Class V, Class VII, or Class IX vendor, registered with the Department.

4.4.6.1 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.

4.4.6.2 A copy of the radiation area survey shall be submitted to the Department within thirty days after installation of the x-ray equipment.

4.4.6.3 Any deviation from the accepted shielding plan shall be documented and evaluated for adequacy.

4.4.6.4 The Department may determine that a survey is not required for some installations.

4.4.7 "As-built" Drawings.

4.4.7.1 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.

4.4.7.2 Any deviation from the accepted shielding plan shall be documented and evaluated for adequacy by a Class III, Class IV, Class VII, or Class IX vendor.

4.4.8 Bone Density And Mammography Installations.

4.4.8.1 Prior to installation of new or replacement equipment:

4.4.8.1.1 A shielding plan shall be submitted to the Department for review and acceptance or;

4.4.8.1.2 A written request shall be made by a Class V, Class VII, or Class IX vendor registered with the Department to perform a post-install survey in lieu of a shielding plan. All provisions of RHB 4.4.6 apply.

4.4.8.1.3 Applicable fee shall be submitted in accordance with RHB 2.3.2.

4.4.9 After installation of a radiation machine, the facility shall maintain for inspection by the Department:

4.4.9.1 A copy of the shielding plan, as required by RHB 4.4,

4.4.9.2 A copy of the Department's acceptance letter, and

4.4.9.3 A copy of the area survey or "as-built" drawing, as required by RHB 4.4.6 or 4.4.7.

RHB 4.5 Intraoral Dental Radiographic Installations. In addition to the provisions of RHB 4.3, 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 Position Indication Device (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 (T_{max}) minus the minimum exposure period (T_{min}) when 4 timer tests are performed: $\overline{T} \geq 5 (T_{max} - T_{min})$.

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 For mobile and portable x-ray systems, the exposure switch shall meet the requirements of 4.5.4.2.2.

4.5.4.2.4 Visual and/or audible indication, observable at or from the operator's protected position, shall be provided whenever x-rays are initiated and 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 (\bar{E}) is greater than or equal to 5 times the maximum exposure (E_{max}) minus the minimum exposure (E_{min}): $\bar{E} \geq 5 (E_{max} - E_{min})$.

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 and secondary barriers for all areas struck by the useful beam, as required by RHB 4.4.4.2.

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 between adjacent areas shall be securely interlocked in a functional, permanent manner.

4.5.11.4 Shielding plans are not required for intraoral dental radiographic installations.

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 4.4 and 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 Dental CT

4.6.3.1 Where applicable, all provisions of RHB 4.4 and 4.11 apply, except RHB 4.11.2.3.

4.6.4 Hand-Held Intraoral Equipment

4.6.4.1 The hand-held x-ray system shall be equipped with a non-removable backscatter shield of not less than 0.25 mm lead equivalent and 15.2 cm (6 inches) in diameter that is positioned as close as practicable to the distal end of the position indication device.

4.6.4.2 The facility shall maintain documentation that each operator has completed training as specified by the manufacturer, and approved by the Department.

4.6.4.3 The facility shall adopt and follow protocols provided by the manufacturer and approved by the Department regarding the safe operation of the device.

4.6.4.4 When operating a hand-held intraoral dental radiographic unit, operators shall wear a 0.25 mm lead equivalent apron and thyroid collar.

4.6.4.5 If the operator has difficulty in holding the device stationary during the exposure, the operator shall use a stand to immobilize the device.

4.6.4.6 The registrant shall secure the hand-held device from unauthorized removal or use.

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 does not 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 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.

4.7.4.2.4 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.

4.7.4.2.5 Automatic Exposure Controls. When an automatic exposure control is provided:

4.7.4.2.5.1 Indication shall be made on the control panel when this mode of operation is selected;

4.7.4.2.5.2 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;

4.7.4.2.5.3 The minimum exposure time for all equipment other than that specified in 4.7.4.2.5.2 shall be equal to or less than one-sixtieth (1/60) second or a time interval required to deliver 5 mAs, whichever is greater;

4.7.4.2.5.4 Either the product of peak x-ray tube potential, current, and exposure time shall be limited to not more than 60 kW 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

4.7.4.2.5.5 A visible signal shall indicate when an exposure has been terminated at the limits required by 4.7.4.2.5.4, and manual resetting shall be required before further automatically timed exposures can be made.

4.7.4.2.6 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 (T_{\max}) minus the minimum exposure period (T_{\min}) 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 (E_{\max}) minus the minimum exposure (E_{\min}): $\overline{E} \geq 5 (E_{\max} - E_{\min})$.

4.7.6 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.

4.7.7 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.

4.7.7.1 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: $[X_1 - X_2] < 0.10 (X_1 + X_2)$; where X_1 and X_2 are the average C/kg/mAs (or mR/mAs) values obtained at any two tube current settings.

4.7.7.2 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: $[X_1 - X_2] < 0.10 (X_1 + X_2)$; where X_1 and X_2 are the average C/kg/mAs (or mR/mAs) values obtained at any two mAs selector settings.

4.7.7.3 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 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.

4.7.8 Light Localization.

4.7.8.1 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.

4.7.8.2 Exemptions to RHB 4.7.8.1 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.

4.7.9 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.

4.7.10 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)(1)(ii). A log book of such maintenance shall be maintained for inspection by the Department.

4.7.11 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.

4.7.12 Positive Beam Limitation. For units having an operable positive beam limitation (PBL) system, the following requirements must be met:

4.7.12.1 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

4.7.12.2 The sum of the length and width differences, without regard to sign, shall not exceed 4 percent of the SID.

4.7.12.3 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.

4.7.12.4 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 and any change of image receptor size or SID must cause the automatic return.

4.7.12.5 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.

4.7.13 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).

4.7.14 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 4.7.14 apply, except 4.7.12 and 4.7.4.2.2.

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 in a single location for a period of greater than five consecutive days 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 6 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 thirty-eight (38) centimeters on stationary fluoroscopic systems manufactured on or after August 1, 1974.

4.9.1.2 thirty-five and one half (35.5) centimeters on stationary fluoroscopic systems manufactured prior to August 1, 1974.

4.9.1.3 thirty (30) centimeters on all mobile and portable fluoroscopes, and

4.9.1.4 twenty (20) centimeters for mobile fluoroscopes used for specific surgical procedures. If removable, the appropriate spacer shall be replaced after the specific surgical procedure application is complete.

4.9.1.4.1 For stationary, mobile, or portable fluoroscopes manufactured on or after June 10, 2006, having a maximum source-image receptor distance of less than forty-five (45) cm, means shall be provided to limit the source-skin distance to not less than nineteen (19) cm. Such systems shall be labeled for extremity use only.

4.9.1.4.2 For those systems intended for specific surgical applications that would be prohibited at the source-skin distance specified above, provisions may be made for operation at shorter source-skin distances but in no case less than ten (10) cm.

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. 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.

4.9.4.1.2 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 C-arm type of fluoroscope having an SID less than 45 centimeters, the exposure rate shall be measured at the minimum SSD.

4.9.4.3.6 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.

4.9.4.3.7 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 4.2.16.1. 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.

4.9.4.3.8 Conditions of measurement of maximum 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, mA, and other selectable parameters shall be adjusted to those settings which give the maximum entrance exposure rate.

4.9.4.3.8.3 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.

4.9.4.3.8.4 Testing shall be performed in each mode used clinically.

4.9.4.3.9 Conditions of measurement of typical entrance exposure rate are as follows:

4.9.4.3.9.1 The measurement shall be made under the conditions that satisfy the requirements of RHB 4.9.4.3.

4.9.4.3.9.2 The kVp and mA shall be typical of clinical use of the x-ray system.

4.9.4.3.9.3 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.

4.9.4.3.9.4 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 4.2.9.2.

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 (\bar{T}) shall be greater than or equal to 5 times the maximum exposure period (T_{max}) minus the minimum exposure period (T_{min}) when 4 timer tests are performed: $\bar{T} \geq 5 (T_{max} - T_{min})$.

4.9.9.3 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 (\bar{E}) is greater than or equal to 5 times the maximum exposure (E_{max}) minus the minimum exposure (E_{min}): $\bar{E} \geq 5 (E_{max} - E_{min})$.

4.9.10 Mobile and Portable fluoroscopic x-ray systems which are used in a single location for a period of greater than five consecutive days shall be considered a stationary fluoroscopic system, 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 4.2.16, 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 (\bar{T}) shall be greater than or equal to 5 times the maximum exposure period (T_{max}) minus the minimum exposure period (T_{min}) when 4 timer tests are performed: $\bar{T} \geq 5(T_{max} - T_{min})$.

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 (\bar{E}) is greater than or equal to 5 times the maximum exposure (E_{max}) minus the minimum exposure (E_{min}): $\bar{E} \geq 5(E_{max} - E_{min})$.

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 a shielding plan, as required by RHB 4.4 to the Department for review and acceptance.

4.10.2.2 Peripheral units are exempt from 4.10.2.1.

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, 4.2.7, and 10.2.1 apply.

4.10.4.3 Operators. All provisions of RHB 4.2.2 apply.

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.

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 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 Viewing Systems.

4.11.2.4.1 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.

4.11.2.4.2 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 Records of equipment performance tests 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 one of 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 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.

4.11.5 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 4.2.2, 4.2.7, 4.2.10, and 4.2.11. No person other than a licensed practitioner or an adequately trained individual, as required by RHB 4.12.22, shall use equipment emitting ionizing radiation for diagnostic purposes.

4.12.2 Radiation Protection. All provisions of RHB 4.2.9 apply, except 4.2.9.3.

4.12.3 Holding of Patients and Films. All provisions of RHB 4.2.12 apply. In addition:

4.12.3.1 Each human holder in a veterinary facility shall utilize protective apparel.

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 and lead gloves are not utilized, then ring badges shall also be provided and worn.

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 (\bar{T}) shall be greater than or equal to 5 times the maximum exposure period (T_{max}) minus the minimum exposure period (T_{min}) when 4 timer test are performed: $\bar{T} \geq 5 (T_{max} - T_{min})$.

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 (\bar{E}) is greater than or equal to 5 times the maximum exposure (E_{max}) minus the minimum exposure (E_{min}): $\bar{E} \geq 5 (E_{max} - E_{min})$.

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 Exemptions to RHB 4.12.16.1 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 apparel 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 - Where applicable, all provisions of RHB 4.11 apply.

4.12.21 Veterinary Dental Systems— Where applicable, all provisions of RHB 4.5 apply.

4.12.22 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.

4.12.22.1 The registrant shall require persons operating registered equipment and associate equipment and/or holding patients to receive, at a minimum, instruction in the following areas:

4.12.22.1.1 Radiation Protection. Training in radiation protection shall include, but is not limited to, protective clothing; patient holding; time, distance, and shielding; radiation protection standards; and the biological effects of radiation.

4.12.22.1.2 Darkroom Techniques/Digital Imaging Acquisition Systems. Training in darkroom techniques shall include, but is not limited to, developing chemicals; film protection; cassettes; and screens. Training in digital imaging acquisition systems shall follow protocol established by the manufacturer of the digital imaging acquisition system.

4.12.22.1.3 Machine Safety. Training in machine safety shall include machine functions; safety procedures; and recognizing problems.

4.12.22.1.4 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.

4.12.22.2 Instruction required by 4.12.22.1 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.

RHB 4.13 Medical Specimen Unit.

4.13.1 Administrative Requirements. All provisions of RHB 4.2.2.7 apply.

4.13.2 Radiation Protection. Upon installation, the medical specimen 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 areas adjacent to the unit shall also be performed at least annually, and after any repair, modification, or maintenance on the system. Documentation of the surveys shall be maintained for inspection by the Department.

4.13.3 Tests of all safety devices such as interlocks shall be conducted annually for medical specimen units. Documentation of such tests shall be maintained for inspection by the Department.

4.13.4 Radiation emitted from the medical specimen unit shall not exceed 0.5 milliRoentgens per hour at an point five centimeters from the external surface.

4.13.5 When not in operation the medical specimen unit shall be secured.

Part IV - 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.

Part IV - Appendix B

Information on Radiation Shielding Required for Plan Review. The following information must be provided to the Department for review and acceptance of a shielding plan:

1. Plans shall show, at 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) An accurate drawing 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 type of x-ray equipment and the maximum technique factors.

f) 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. The use of filmless systems shall be indicated in writing.

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 the shielding will continue to remain adequate.

3. Individual barrier radiation shielding specifications and descriptions of all assumptions that were used in the shielding calculations.

Part IV - 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, excluding mammography equipment and intraoral dental. 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:

i) Be so placed that the operator can view the patient during any exposure, and

ii) The device shall be so placed that the operator can have full view of any occupant of the room and shall 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:

i) It shall have a viewing area of at least 1 square foot (0.0929 m²)

ii) 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 (0.457m) from the edge of the booth.

iii) 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:

i) The camera shall be so located as to accomplish the general requirements of this Part, and

ii) There shall be an alternate viewing system as a backup for the primary system.

5. Alternative Design Criteria. 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 acceptance as long as the same degree of safety is being met.

Part IV - Appendix D

Average Patient Exposure Guide

Medical ESE's

Compliance with RHB 4.2.13.2 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%. Facilities utilizing digital imaging systems shall not exceed the ESE Limits as outlined for a 200 speed system.

ESE Limits

Projection	Thickness	200 Speed/Digital	400 Speed
PA Chest – Grid - Non Grid	23 cm	12 - 38 7 - 23	7 - 23 2 - 8
AP Abdomen	23 cm	245 - 735	150 – 450
AP Lumbar Spine	23 cm	225 - 675	175 - 525
Full Spine (AP)	23 cm	130 - 390	72 - 218
AP Cervical Spine	13 cm	67 - 203	47 - 142
Lateral Skull	15 cm	72 - 218	35 - 105
Ret Pyelogram (AP)	23 cm	297-893	297-893
Thoracic Spine (AP)	23 cm	204-612	204-612
DP Foot	8 cm	37 - 111	37 - 111
Cephalometric	15 cm	15 - 45	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.

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 4.2.13.2 shall be considered met if the patient's exposure at skin entrance (ESE) is within the limits shown. Facilities utilizing digital imaging systems shall not exceed the ESE Limits as outlined for a “D” speed film system.

kVp	"D" Speed Film and Digital	"E" and "F" Speed Film
	ESE Limits	ESE Limits
50	340-690	176-384
55	280-600	152-324
60	248-528	132-276
65	216-480	112-240
70	192-420	96-204
75	136-312	80-168
80	120-276	72-144
85	104-240	64-126
90	96-216	56-108
95	88-192	48-64
100	80-168	40-56

Part IV - 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

Part IV - Appendix F

Minimum Criteria for Performance Tests

The following items must be tested. Each item tested must include an indication of Pass/Fail, Compliant/Non-compliant, as required by RHB 2.7.3.6. Items marked with an asterisk (*) 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 4.2.16.1. Each record of equipment performance testing shall be legible and include company name, service person name, and the date of the test, and all applicable requirements of RHB 2.7.3.6.6.

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 (4.7.7)
5. kVp accuracy (4.7.6)
6. Timer reproducibility and accuracy (4.7.4.2.6, 4.7.6)
7. X-ray beam/image receptor centering (4.7.1.7)
8. Collimator light illuminance (4.7.8)
9. Actual vs. indicated collimator field sizes (4.7.1.5, 4.8.6)
10. Positive beam limitation function, if operable (4.7.12)
11. Visual and audible indication of exposure (4.7.4.2.4)
12. Minimum field size (4.7.14)
13. Patient exposure at skin entrance, for most common exams performed at the facility (except veterinary facilities) (4.2.13.2)
14. Proper function of automatic exposure control devices, including AEC reproducibility, kV compensation, and minimum response time (4.7.4.2.5)
15. Grid uniformity and alignment (4.2.16.3)
16. Integrity of lead aprons, gloves, and other protective clothing (4.2.8)*
17. Actual vs. Indicated Source to Image Distance (SID), for all clinically used SIDs (4.7.11)
18. Beam size(s) for fixed collimation, if applicable (4.7.3)
19. X-ray control placement (Appendix C, 3a)

These items must be checked upon initial installation and after any maintenance or repair that could affect its status:

1. Adherence to the accepted 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 (4.7.4.2.3) 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. Cumulative timer function (4.9.7.1)
 5. Control of scattered radiation (4.9.8)
 6. High contrast resolution and low contrast performance
 7. Minimum source to skin distance, upon initial installation (4.9.1)
 8. Spot film beam size (4.9.2.3.2)
 9. Spot film beam centering (4.9.2.3.4)
 10. Spot film exposure reproducibility (4.9.9.3)
 11. Spot film mA/mAs linearity (4.7.7)
 12. Spot film timer reproducibility and accuracy (4.9.9.2, 4.7.6)
 13. Proper function of spot film automatic exposure control devices, including AEC reproducibility, kV compensation, and minimum response time (4.7.4.2.5)
 14. Half-value layer (HVL) (4.3.5)
 15. Cinefluorographic exposure rates (4.9.4)
 16. Integrity of lead aprons, gloves, and other protective clothing (4.2.8)*
 17. Integrity of bucky slot cover shielding and lead drapes (4.2.8)*
 18. Continuous indication of kV and mA during fluoroscopy (4.9.6)
 19. X-ray control placement (Appendix C, 3a)

These items must be checked upon initial installation and after any maintenance or repair that could affect its status:

1. Adherence to the accepted shielding plan (4.4) (Visual inspection of layout of equipment, location of exposure button, location of film, etc.)
2. Primary Barrier Transmission (4.9.5)

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 (4.7.7)
5. kVp accuracy (4.7.6)
6. Timer reproducibility and accuracy (4.7.4.2.6, 4.7.6)
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 (4.7.12)
10. Visual and audible indication of exposure (4.5.4.2.4)
11. Proper function of automatic exposure control devices, including AEC reproducibility, kV compensation, and minimum response time (4.7.4.2.5)
12. Grid uniformity and alignment (4.2.16.3)
13. Integrity of lead aprons, gloves, and other protective clothing (4.2.8)*
14. Actual vs. Indicated Source to Image Distance (SID), for all clinically used SIDs (4.7.11)
15. 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)

16. Cumulative timer function (4.9.7.1)
17. Measurement of scattered radiation (4.9.8)
18. High contrast resolution and low contrast performance
19. Minimum source to skin distance, upon initial installation (4.9.1)
20. X-ray control placement (Appendix C, 3a)

These items must be checked upon initial installation and after any maintenance or repair that could affect its status: Adherence to the accepted 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, and dental CT where applicable)

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. X-ray control placement (Appendix C, 3a)
10. Integrity of lead aprons, gloves, and other protective clothing (4.2.8)*

These items must be checked upon initial installation and after any maintenance or repair that could affect its status: Adherence to the accepted 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 (4.5.4.2.4)
7. Patient exposure at skin entrance, bitewing and/or periapicals (4.2.13.2)
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 (4.2.8)*
11. X-ray control placement (4.5.4.2)

These items must be checked upon initial installation and after any maintenance or repair that could affect its status:

1. Adherence to the accepted 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)

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.

5.1.2.2.4 The mobile mammography facility meets the requirements of RHB 2.3 and 2.4.

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. 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 accreditation 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 FDA. 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 Director of Health Regulation 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 \$1031 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 \$231 per mammographic tube for each additional tube.

5.6.2 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.

5.6.5 Follow-up Inspection Fees

5.6.5.1 In the event that the Department deems a follow-up inspection necessary, an inspection fee of \$500 shall be assessed upon the completion of the follow-up inspection.

5.6.5.2 The follow-up inspection invoice shall be issued in conjunction with the follow-up inspection report.

5.6.5.3 Payment of the follow-up inspection fee shall be due within thirty (30) calendar days of the date of the follow-up inspection fee invoice.

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 a 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.

5.7.1.3.1.1 Any physician added to a facility after April 28, 1999, must provide documentation of initial qualifications. This documentation must be maintained by the facility for Department review.

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 4.2.2 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 2.6.1. Unless the alternative initial qualifications in RHB 5.7.3.2 apply, the medical physicist must:

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 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 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.

5.8.15 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 5.9.4.2, 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 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.

5.11.2 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 maximum compression force for the initial power drive shall be between 111 newtons (25 pounds) and 209 newtons (45 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 Width(mm)	Measured Dimensions 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 (\bar{E}) is greater than or equal to 5 times the maximum exposure (E_{max}) minus the minimum exposure (E_{min}): $\bar{E} \geq 5(E_{max} - E_{min})$. 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 (\bar{T}) shall be greater than or equal to 5 times the maximum exposure period (T_{max}) minus the minimum

exposure period (T_{min}) when 4 timer tests are performed: $\bar{T} \geq 5 (T_{max} - T_{min})$. 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 4.2.16 and film processing requirements of 4.2.17.2 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 or RHB 5.11.7; 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 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 is installed, 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 and 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 other relevant 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 Director of Health Regulation 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 completion of corrective action required by the report. Documentation of corrective action, required as a result of the survey, must 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 conditions. All mammography facilities shall meet the requirements of RHB 4.2.3.

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.

Part V - 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 (BSA). 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 device's 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.

Part V - 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 9.172.

- 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 masses 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 film in the processor used for clinical mammography films.
- h) Examine the processed image for areas of non-uniformity 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 fibrils 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.

Part V - 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/AI
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 All facilities utilizing therapy equipment shall meet the shielding requirements specified in RHB 4.4.

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 the Radiation Safety Officer, 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 Policies and procedures for pregnant workers; NRC Regulatory Guide 8.13, "Instruction Concerning Prenatal Radiation Exposure" should be used for guidance concerning pregnant workers;

6.3.2.1.1.2 Policies and procedures for personnel monitoring;

6.3.2.1.1.3 Policies and procedures for training new employees; and

6.3.2.1.1.4 Policies and procedures for identifying and reporting misadministrations, as defined by RHB 9.153.

6.3.2.1.1.5 Policies and procedures for quality assurance addressing annual equipment performance testing on radiation therapy simulators and CT scanners used for treatment planning.

6.3.2.1.2 Emergency Procedures. The emergency procedures shall include 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 Radiation Quality Standards Association. 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. The registrant may also post a notice to the public that South Carolina Radiation Quality Standards Association certificates are available for review upon request.

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. Documentation of this training for each operator shall be made available for Departmental review.

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 Training for Therapeutic Radiation Machine Authorized Users.

6.3.4.1 For any therapeutic radiation machine covered in Part VI the registrant shall require the authorized user to be a licensed practitioner who;

6.3.4.1.1 Is certified in:

6.3.4.1.1.1 Radiation Oncology or therapeutic radiology by the American Board of Radiology or Radiology (combined diagnostic and therapeutic radiology program) by the American Board of Radiology prior to 1976; or

6.3.4.1.1.2 Radiation oncology by the American Osteopathic Board of Radiology; or

6.3.4.1.1.3 Radiology, with specialization in radiotherapy, as a British “Fellow of the Faculty of Radiology” or “Fellow of the Royal College of Radiology”; or

6.3.4.1.1.4 Therapeutic radiology by the Canadian Royal College of Physicians and Surgeons; or

6.3.4.1.2 Is in the active practice of therapeutic radiology and has completed 200 hours of instruction in basic radiation techniques applicable to the use of an external beam radiation therapy unit, five hundred (500) hours of supervised work experience, and a minimum of three (3) years of supervised clinical experience.

6.3.4.1.2.1 To satisfy the requirement for instruction, the classroom and laboratory training shall include radiation physics and instrumentation, radiation protection, mathematics pertaining to the use and measurement of ionization radiation, and radiation biology.

6.3.4.1.2.2 To satisfy the requirement for supervised work experience, training shall be under the supervision of an authorized user and shall include review of the full calibration measurements and periodic quality assurance checks, evaluation of prepared treatment plans and calculation of treatment times/patient treatment settings, using administrative controls to prevent misadministrations, implementing emergency procedures to be followed in the event of the abnormal operation of an external beam radiation therapy unit or console, and checking and using radiation survey meters.

6.3.4.1.2.3 To satisfy the requirement for a period of supervised clinical experience, training shall include one (1) year in a formal training program approved by the Residency Review Committee for Radiology of the Accreditation Council for Graduate Medical Education or the Committee on Postdoctoral Training of the American Osteopathic Association and an additional two (2) years of clinical experience in therapeutic radiology under the supervision of an authorized user. The supervised clinical experience shall include:

6.3.4.1.2.3.1 Examining individuals and reviewing their case histories to determine their suitability for external beam radiation therapy treatment, and any limitations/contraindications;

6.3.4.1.2.3.2 Selecting proper dose and how it is to be administered;

6.3.4.1.2.3.3 Calculating the therapeutic radiation machine doses and collaborating with the authorized user in the review of patients’ progress and consideration of the need to modify originally prescribed doses and/or treatment plans as warranted by patients’ reaction to radiation; and

6.3.4.1.2.3.4 Post-administration follow-up and review of case histories.

6.3.4.2 The registrant shall maintain a record of all training for each authorized user. Such records shall be made available for Departmental inspection.

6.3.5 Control.

6.3.5.1 The radiation safety officer shall maintain a current list of all personnel who are qualified to service the therapeutic equipment.

6.3.5.2 No registrant shall permit a therapeutic unit to operate at any time with a safety interlock bypassed, except for necessary testing.

6.3.5.3 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.

6.3.5.4 No individual other than the patient shall be in the therapy room during irradiation.

6.3.6 Technique indicators. Instrumentation readouts and controls on the therapy control console must be clearly identified and easily discernable.

6.3.7 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.

6.3.8 No therapeutic machine shall be left unattended unless it is secured against unauthorized use.

RHB 6.4 Therapeutic X-ray Systems of Less than 1 MeV.

6.4.1 Equipment requirements.

6.4.1.1 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 Contact Therapy	Leakage Limit 100 mR/hr	Measurement Location 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	0.1 percent of 1 R in 1 hr.	1 m from source useful beam or

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 May 25, 2001, shall meet the requirements of RHB 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. 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 May 25, 2001, 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 RHB 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 RHB 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 these regulations. Each radiation survey instrument shall meet the requirements of RHB 1.4.4.

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 meet the requirements of RHB 1.4.4.

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 RHB 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 RHB 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 RHB 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 RHB 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 RHB 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 RHB 6.4.4.2 and RHB 6.4.4.3 have been met.

RHB 6.5 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 RHB 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 RHB 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 May 25, 2001, 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 Electron Beam in MeV	X-ray Absorbed Dose As a Fraction of Maximum Absorbed Dose
1	0.03
15	0.05
35	0.10
50	0.20

6.5.4.2 Compliance with RHB 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 RHB 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 RHB 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 RHB 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 May 25, 2001, 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 RHB 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 RHB 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 RHB 6.2 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 RHB 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 RHB 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 RHB 6.6.3 shall meet the requirements of RHB 1.4.4.

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 RHB 6.6.3.1 and dosimetry system calibrations under RHB 6.6.3.3 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 RHB 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 in 6.6.3.

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 RHB 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 RHB 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 Part VII 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 Hand-Held Analytical X-ray Equipment.

Hand-held analytical x-ray equipment shall be exempt from the other requirements of Part VII except that they:

7.3.1 Shall be registered with the Department;

7.3.2 Shall only be operated by personnel who have completed documented training as outlined in RHB 7.9;

7.3.3 Shall have an interlock system that prevents the operation of the unit unless the x-ray exit port is in contact with or in close proximity to the item being irradiated;

7.3.4 Shall be operated in accordance with the manufacturer's specifications;

7.3.5 Shall have operating procedures in accordance with RHB 7.10.

RHB 7.4 General Requirements for all Analytical X-ray Equipment.

7.4.1 Registration. All requirements of RHB 2.3 and 2.4 apply.

7.4.2 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.

7.4.3 Labeling. All analytical x-ray equipment shall be labeled with a readily discernible sign or signs bearing the radiation symbol, and

7.4.3.1 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.

7.4.3.2 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.

7.4.4 Warning Lights.

7.4.4.1 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.

7.4.4.2 Warning lights shall have fail-safe characteristics.

7.4.5 Safety Devices.

7.4.5.1 Any temporary alteration to safety devices, such as by-passing interlocks or removing shielding shall be:

7.4.5.1.1 Approved in advance by the radiation safety officer.

7.4.5.1.2 Specified in writing and posted near the x-ray tube housing.

7.4.5.1.3 Terminated as soon as possible.

7.4.5.1.4 Documented and the documentation maintained for inspection by the Department. This documentation shall contain: the nature of the alteration, and the signature and date of the individuals who made the alteration and who restored the unit to original condition.

7.4.5.2 Tests of all safety devices such as interlocks, shutters, and warning lights shall be conducted annually for all operable analytical x-ray equipment. Documentation of such tests shall be maintained for inspection by the Department.

7.4.5.3 The inspection and testing of safety devices shall not be a substitute for a radiation area survey.

7.4.5.4 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.

7.4.5.5 Unused ports on radiation source housings shall be secured in the closed position in a manner to prevent inadvertent opening.

7.4.6 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 per hour.

7.4.7 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 per hour.

7.4.8 Radiation in excess of the limits specified in RHB 7.4.6 and RHB 7.4.7 shall be eliminated prior to using the analytical x-ray equipment.

7.4.9 Repair or Modification of X-ray Tube System. Except as specified in 7.3.5.1, 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 7.5 Additional Requirements for Open Beam Configuration X-ray Equipment.

7.5.1 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:

7.5.1.1 A description of the various safety devices that have been evaluated;

7.5.1.2 The reason each of these devices cannot be used;

7.5.1.3 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; and

7.5.1.4 The procedure for notifying proper persons in the event of an accident. This list shall include the names, addresses, and telephone numbers.

7.5.2 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.

7.5.3 When not in use, equipment shall be secured in such a manner as to be inoperable by unauthorized persons.

7.5.4 Warning Devices. Open-beam configuration x-ray equipment shall be provided with a readily discernible indication of:

7.5.4.1 X-ray tube status (ON-OFF) located near the radiation source housing, if the primary beam is controlled in this manner, or

7.5.4.2 Shutter status (OPEN-CLOSED) located near each port on the radiation source housing, if the primary beam is controlled in this manner.

7.5.5 Warning devices shall be labeled so that their purpose is easily identified.

7.5.6 Warning devices shall have fail-safe characteristics.

7.5.6.1 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.

7.5.6.2 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.

7.5.7 Operating Procedures. The registrant shall create and make available to x-ray operators written operating procedures. The procedures shall include, but not be limited to:

7.5.7.1 Policies and procedures for personnel monitoring.

7.5.7.2 Policies and procedures for controlling access to radiation areas.

7.5.7.3 Policies and procedures for locking and securing the x-ray unit.

7.5.7.4 Policies and procedures for pregnant employees.

7.5.7.5 Policies and procedures for training new employees.

7.5.8 Operator training.

7.5.8.1 No person shall be permitted to operate, repair, modify, or maintain x-ray equipment unless such person has received instruction and demonstrated competence in:

7.5.8.1.1 Identification of radiation hazards associated with the use of the equipment;

7.5.8.1.2 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;

7.5.8.1.3 Proper operation of the equipment per manufacturer's guidelines and registrant's written operating procedures;

7.5.8.1.4 Radiation survey instruments: operation, calibration, limitations, and survey techniques, if applicable;

7.5.8.1.5 Characteristics of ionizing radiation;

7.5.8.1.6 Methods of controlling radiation dose;

7.5.8.1.7 Units of radiation dose;

7.5.8.1.8 Personnel monitoring and the use of personnel monitoring equipment;

7.5.8.1.9 Symptoms of an acute localized exposure and;

7.5.8.1.10 Proper procedures for reporting an actual or suspected overexposure.

7.5.8.1.11 The regulations contained in this Part, and the applicable sections of Part III.

7.5.8.2 Instruction and demonstration of competence shall be documented in writing and these records shall be available for review.

RHB 7.6 Additional Requirements for Enclosed Beam X-ray Equipment. To include stationary, mobile, and portable units.

7.6.1 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.

7.6.2 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 properly functioning interlock.

RHB 7.7 Area Requirements for All Analytical X-ray Equipment.

7.7.1 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 3.4. These levels shall be met at any specified tube rating.

7.7.2 Surveys, Tests and Inspections. Radiation surveys, as required by RHB 1.4 of all analytical x-ray systems to show compliance with RHB 7.7.1 shall be performed and records kept and available for review:

7.7.2.1 Upon installation of the equipment and at least once every twelve (12) months thereafter.

7.7.2.2 Following any change in the initial arrangement, number, or type of local components in the system.

7.7.2.3 Following any change in operating parameters.

7.7.2.4 Following any maintenance requiring the disassembly or removal of a local component of the system.

7.7.2.5 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.

7.7.2.6 Any time a visual inspection of the local components in the system reveals an abnormal condition.

7.7.2.7 Whenever monitoring devices show a significant increase over the previous monitoring period or the readings are approaching the radiation dose limits.

7.7.3 Radiation survey measurements shall not be required if a registrant can demonstrate compliance to the satisfaction of the Department with 7.7.1 in some other manner. Upon approval by the Department, an area monitor or monitors may be used in place of an annual radiation survey. The area monitor shall be

placed on the unit and changed on at least a quarterly basis. The results shall be documented and available for review. If an area monitor result shows a substantial increase over previous results, perform a documented investigation including a radiation area survey.

7.7.4 Tests and inspections of all safety devices shall be performed at least yearly to ensure their proper operation. The results shall be documented and available for review in accordance with RHB 1.10.2.4.

RHB 7.8 Radiation Survey Instruments. All provisions of RHB 1.4.4 apply.

RHB 7.9 Minimum Personnel Radiation Safety Requirements For Radiation Safety Officers and Operators.

7.9.1 No registrant shall permit any individual to act as a radiation safety officer until such person:

7.9.1.1 Has been instructed in the subjects outlined in RHB 7.9.2 of this Part;

7.9.1.2 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

7.9.1.3 Has demonstrated competence to use the X-ray machine, related handling tools, and survey instruments which will be employed in the assignment.

7.9.2 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:

7.9.2.1 Identification of radiation hazards associated with the use of the equipment;

7.9.2.2 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;

7.9.2.3 Proper operation of the equipment per manufacturer's guidelines and registrant's written operating procedures as specified in RHB 7.10;

7.9.2.4 Characteristics of ionizing radiation;

7.9.2.5 Personnel and/or area monitoring and the use of personnel and/or area monitoring equipment, if applicable.

7.9.3 Instruction and demonstration of competence shall be documented in writing and these records shall be available for review.

RHB 7.10 Operating Procedures

7.10.1 The registrant shall create and make available to x-ray operators written operating procedures. The procedures shall include, but not be limited to:

7.10.1.1 Policies and procedures for personnel and/or area monitoring;

7.10.1.2 Policies and procedures for pregnant employees;

7.10.1.3 Policies and procedures for training new employees;

7.10.1.4 Methods and occasions for conducting radiation surveys;

7.10.1.5 Methods for controlling access to radiographic areas;

7.10.1.6 Methods for locking and securing X-ray machines, when not in use or in storage;

7.10.1.7 Maintenance of records.

7.10.2 A copy of operator training provided as required by RHB 7.9 and a copy of operating procedures as required by RHB 7.10 shall be provided to the Department upon request.

RHB 7.11 Personnel Monitoring.

7.11.1 Personnel monitoring shall be required as outlined in RHB 3.12.

7.11.2 Finger or wrist dosimetric devices shall be provided to and shall be used by:

7.11.2.1 Analytical x-ray equipment workers using systems having an open-beam configuration and not equipped with a safety device; and

7.11.2.2 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.

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. All provisions of RHB 1.4.4 apply.

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 and Posting Requirements.

8.6.1 Registration. Each facility shall meet the requirements of RHB 2.3 and 2.4 of these regulations.

8.6.2 Posting. Areas in which radiography is being performed shall be conspicuously posted as required by RHB 3.15 and 3.16.

RHB 8.7 Minimum Personnel 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 the 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 Part III of 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 annually, 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 dosimeters approved by the Department. All provisions of Part III of these Regulations apply.

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 Special Requirements for Certain Industrial Radiographic Techniques.

8.12.1 Cabinet Radiography.

8.12.1.1 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.

8.12.1.2 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.

8.12.1.3 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.

8.12.1.4 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.

8.12.1.5 The insertion of any part of the human body through any port into the primary beam or through any aperture shall not be possible.

8.12.1.6 Interlocks.

8.12.1.6.1 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.

8.12.1.6.2 Each access panel shall have at least one safety interlock.

8.12.1.6.3 Following interruption of x-ray generation by the functioning of any safety interlock, use of a control provided in accordance with RHB 8.12.1.8.2 shall be necessary for resumption of x-ray generation.

8.12.1.6.4 Failure of any single component of the cabinet x-ray system shall not cause failure of more than one required safety interlock.

8.12.1.7 A ground fault, or an accidental electrical grounding of an electrical conductor, shall not result in the generation of x-rays.

8.12.1.8 Controls and indicators for all cabinet x-ray systems. For all systems to which this section is applicable, there shall be provided:

8.12.1.8.1 A key actuated control to insure that x-ray generation is not possible with the key removed.

8.12.1.8.2 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.

8.12.1.8.3 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."

8.12.1.8.4 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."

8.12.1.9 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:

8.12.1.9.1 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.

8.12.1.9.2 No means by which x-ray generation can be initiated from within the cabinet.

8.12.1.9.3 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.

8.12.1.9.4 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.

8.12.1.9.5 Signs indicating the meaning of the warning signals required by RHB 8.12.1.9.3 and 8.12.1.9.4 and containing instructions for the use of the control required by RHB 8.12.1.9.1. These signs shall be legible, accessible to view, and illuminated when the main power control is in the "on" position.

8.12.1.10 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."

8.12.1.11 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.

8.12.1.11.1 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.

8.12.1.11.2 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.

8.12.1.12 Exemptions. To qualify for this exemption, registrant must provide documentation regarding the certified and/or certifiable status of each device.

8.12.1.12.1 Uses of certified and certifiable cabinet x-ray systems are exempt from the requirements of this Part except for the following:

8.12.1.12.1.1 For certified and certifiable cabinet x-ray systems, including those designed to allow admittance of individuals:

8.12.1.12.1.1.1 No registrant shall permit any individual to operate a cabinet x-ray system until the individual has received a copy of and instruction in the operating procedures for the unit. Records that demonstrate compliance with this requirement shall be maintained for Departmental review.

8.12.1.12.1.1.2 Tests for proper operation of interlocks must be conducted and documented at intervals not to exceed six months. Records of these tests shall be maintained in accordance with RHB 1.10.2.4.

8.12.1.12.1.1.3 The registrant shall perform an evaluation of the radiation dose limits to determine compliance with Part III of this Regulation and 21 CFR 1020.40, Cabinet X-ray Systems, at intervals not exceed one year. Records of these evaluations shall be maintained in accordance with RHB 1.10.2.4.

8.12.1.12.1.2 Cabinet x-ray systems shall be maintained in compliance with 21 CFR 1020.40, Cabinet X-ray Systems, and no modification shall be made to the system unless prior Departmental approval has been granted.

8.12.2 Shielded Room Radiography.

8.12.2.1 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.

8.12.2.2 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.

8.12.2.3 Each installation shall be provided with such primary barriers and secondary barriers as are necessary to assure compliance with RHB 3.4, and RHB 3.9.

8.12.2.4 Shielding. All provisions of RHB 4.4 apply.

8.12.3 Field Radiography.

8.12.3.1 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:

8.12.3.2 A description (or make and model number) of each X-ray machine;

8.12.3.3 The identity of the radiographer to whom assigned;

8.12.3.4 The plant or site where used and dates used; and

8.12.3.5 The dates each radiation machine is energized or used and number of exposures made.

8.12.3.6 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.

8.12.3.7 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.

8.12.3.7.1 A physical radiation survey shall be conducted to determine that the radiation machine is "off" prior to each entry into the radiographic exposure area.

8.12.3.7.2 Survey results and records of boundary locations shall be maintained and kept available for inspection by the Department.

8.12.3.8 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:

8.12.3.8.1 Capable of measuring doses from zero to at least 200 milliRoentgen;

8.12.3.8.2 Read and doses recorded daily; and

8.12.3.8.3 Recharged daily or at the start of each shift;

8.12.3.8.4 Reports received from the dosimeter processor and records of the pocket dosimeter and pocket chamber readings shall be maintained for inspection by the Department;

8.12.3.8.5 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.

8.12.4 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.

8.12.4.1 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.

8.12.4.2 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.

8.12.4.3 Radiation levels. The local components of an industrial 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 could result in a dose to an individual present therein in excess of the dose limits given in RHB 3.3.2. These levels shall be met at any specified tube rating.

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., S.C. Code of Laws (1976, 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 (keV), 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 radiography" means industrial radiography conducted in an enclosure or cabinet so shielded that every location on the exterior meets the dose limits as specified in Part III of these Regulations.

9.29 "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.

9.30 "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.

9.31 "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.

9.32 "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.

9.33 "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.

9.34 "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.

9.35 "Cephalometric" means a device intended for the radiographic visualization and measurement of the dimensions of the human head.

9.36 "Certifiable cabinet x-ray system" means an existing uncertified x-ray system that has been modified to meet the certification requirements specified in 21 CFR 1020.40.

9.37 "Certification" means the process of approval of a facility by the Department to provide mammography services.

9.38 "Certified cabinet x-ray system" means an x-ray system that has been certified in accordance with 21 CFR 1010.2 as being manufactured and assembled pursuant to the provisions of 21 CFR 1020.40.

9.39 "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.

9.40 "Certified system" means any x-ray system which has one or more certified component(s).

9.41 "Changeable filters" means any filter, exclusive of inherent filtration, which can be removed from the useful beam through any electronic, mechanical, or physical process.

9.42 "Change of Status" means transfer of ownership, change of address, or disposal of any X-ray system.

9.43 "Clinical image" means a mammogram.

9.44 "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:

$$c = s/\bar{X} = 1/\bar{X} * \Sigma (Xi - \bar{X})^2 / n - 1$$

where:

s = Estimated standard deviation of the population.

\bar{X} = Mean value of observations in sample.

Xi = ith observation in sample.

n = Number of observations in sample.

9.45 "Collimator" means a device or mechanism by which the x-ray beam is restricted in size.

9.46 "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.

9.47 "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).

9.48 "Continuing education unit or continuing education credit" means one contact hour of training.

9.49 "Contact hour" means an hour of training received through direct instruction.

9.50 "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.

9.51 "Coulomb per Kilogram" (C/kg) is the unit of exposure. One Roentgen is equal to 2.58×10^{-4} Coulomb per kilogram. Submultiples of this unit are the milliCoulomb per kilogram (mC/kg) and the microCoulomb per kilogram (uC/kg).

9.52 "CT" (See "Computed Tomography")

9.53 "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.

9.54 "CT Gantry" means the tube housing assemblies, beam-limiting devices, detectors, and the supporting structures and frames which hold these components.

9.55 "Computed Tomography" means the production of a tomogram by the acquisition and computer processing of x-ray transmission data.

9.56 "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.

9.57 "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.

9.58 "Cooling Curve" means the graphical relationship between heat units stored and cooling time.

9.59 "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.

9.60 "Declared pregnant woman" means a woman who has voluntarily informed her employer, in writing, of her pregnancy and the estimated date of conception.

9.61 "Deep-dose equivalent" (Hd), which applies to external whole-body exposure, is the equivalent at a tissue depth of 1 cm (1000 mg/cm²).

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

9.63 "Detector" (See "Radiation detector")

9.64 "Diagnostic mammography" means mammography performed on a patient with:

- (a) Clinical signs, symptoms or physical findings suggestive of breast cancer;
- (b) An abnormal or questionable screening mammogram;
- (c) A history of breast cancer with breast conservation surgery regardless of absence of clinical breast signs, symptoms or physical findings; or

(d) Augmented breast regardless of absence of clinical breast signs, symptoms or physical findings.

9.65 "Diagnostic source assembly" means the tube housing assembly with a beam-limiting device attached.

9.66 "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.

9.67 "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.

9.68 "Diaphragm" means a device or mechanism by which the x-ray beam is restricted in size.

9.69 "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).

9.70 "Direct scattered radiation" means that scattered radiation which has been deviated in direction only by materials irradiated by the useful beam (See "Scattered Radiation").

9.71 "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.

9.72 "Dose" is a generic term which means absorbed dose, dose equivalent, effective dose equivalent, or total effective dose equivalent as defined in these regulations.

9.73 "Dose Equivalent" (HT) 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 are the rem and sievert (Sv).

9.74 "Dose limits" (See Limits)

9.75 "Dose monitoring system" means a system of devices for the detection, measurement, and display of quantities of radiation.

9.76 "Dose monitor unit" means a unit response from the dose monitoring system from which the absorbed dose can be calculated.

9.77 "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.

9.78 "Effective dose equivalent" (HE) is the sum of the products of the dose equivalent to the organ or tissue (HT) and the weighting factors (WT) applicable to each of the body organs or tissues that are irradiated ($HE = \sum w_T HT$).

9.79 "Embryo/fetus" means the developing human organism from conception until the time of birth.

9.80 "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.

9.81 "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.

9.82 "ESE" means the exposure at skin entrance where the center of the useful beam enters the patient.

9.83 "Equipment" (See "X-ray system").

9.84 "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.

9.85 "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.

9.86 "Exposure rate" means the exposure per unit of time, such as R/min and mR/h.

9.87 "External dose" means that portion of the dose equivalent received from radiation sources outside the body.

9.88 "Extremities" means hand, elbow, arm below the elbow, foot, knee, and leg below the knee.

9.89 "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/cm²)

9.90 "Facility" means the location at which one or more x-ray machines are installed or located within one building, vehicle, or under one roof and are under the same administrative control.

9.91 "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.

9.92 "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.

9.93 "FDA" means the Food and Drug Administration.

9.94 "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.

9.95 "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.

9.96 "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.

9.97 "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.

9.98 "Filter" means material placed in the useful beam to preferentially absorb selected radiation.

9.99 "First allowable time" means the earliest time a resident physician is eligible to take the diagnostic radiology boards from an FDA-designated certifying body.

9.100 "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.

9.101 "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.

9.102 "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.

9.103 "Gantry" means that part of the system supporting and allowing possible movements of the radiation head.

9.104 "Gauge" means a mechanism designed and manufactured for the purpose of determining or controlling thickness, density, level, interface location, or qualitative or quantitative 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.

9.105 "General purpose radiographic x-ray system" means any radiographic x-ray which, by design, is not limited to radiographic examination of specific anatomical regions.

9.106 "Gonadal shield" means a protective barrier for the testes or ovaries.

9.107 "The "Gray" is the unit of absorbed dose. It is equal to 1 joule per kilogram. One rad is equal to 1×10^{-2} Gray. Submultiples included in this document are the milliGray (Gy) and the microGray (uGy).

9.108 "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.

9.109 "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.

9.110 "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.

9.111 "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.

9.112 "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.

9.113 "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.

9.114 "HVL" (See "Half-value layer").

9.115 "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.

9.116 "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.

9.117 "Image receptor support" means, for mammographic systems, that part of the system designed to support the image receptor during mammography.

9.118 "Individual" means any human being.

9.119 "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.

9.120 "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.

9.121 "Industrial x-ray equipment" means any machine utilizing x-rays for examination of the macroscopic structure of materials. This includes x-ray equipment used for cabinet radiography, shielded room radiography, field radiography, and gauges.

9.122 "Inherent filtration" means the filtration of the useful beam provided by the permanently installed components of the tube housing assembly.

9.123 "Inoperative" means any x-ray machine or device that is temporarily or permanently rendered incapable of producing x-rays.

9.124 "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.

9.125 "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.

9.126 "Interlock" means a device for precluding access to a high radiation area by automatically reducing the exposure rate upon entry by personnel.

9.127 "Interpreting physician" means a licensed physician who interprets mammograms and who meets the requirements of Section 5.7.1 and 5.25.1.1.

9.128 "Irradiation" means the exposure of matter to ionizing radiation.

9.129 "Isocenter" means the intersection of the collimator axis of rotation and the gantry axis of rotation.

9.130 "Kilovolts peak" (See "Peak tube potential").

9.131 "kV" means kilovolts.

9.132 "kVp" (See "Peak tube potential").

9.133 "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.

9.134 "Leakage radiation (non-diagnostic)" means all radiation coming from within the tube housing complex except the useful beam(s).

9.135 "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.

9.136 "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 milliamperere 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.

9.137 "Licensed practitioner" means an individual with professional specialization who has met the criteria as outlined by the South Carolina Department of Labor, Licensing, and Regulation.

9.138 "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.

9.139 "Limits" or "Dose Limits" means the permissible upper bounds of radiation doses.

9.140 "Linear attenuation coefficient" or " μ " 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.

9.141 "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 = $100 (V_n - V_l) / V_l$ where

V_n = No load line potential and

V_l = Load line potential.

9.142 "mA" means milliAmpere.

9.143 "Mammogram" means a radiographic image produced through mammography.

9.144 "Mammographic modality" means a technology for radiography of the breast. Examples are screen-film mammography and digital mammography.

9.145 "Mammography" means radiography of the breast.

9.146 "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.

9.147 "Mammography medical outcomes audit" means a systematic collection of mammography results and the comparison of those results with outcomes data.

9.148 "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.

9.149 "mAs" means milliAmpere second.

9.150 "Maximum line current" means the root-mean-square current in the supply line of an x-ray machine operating at its maximum rating.

9.151 "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.

9.152 "Medical device" means an instrument, tool, machine, test kit, or implant that is used to prevent, diagnose, or treat disease or other medical conditions.

9.153 "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.

9.154 "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.

9.155 "Minor" means an individual less than 18 years of age.

9.156 "Misadministration" means the administration of:

9.156.1 Radiation to the wrong patient, wrong treatment site, or wrong mode of treatment;

9.156.2 Performance of a diagnostic or therapeutic procedure other than that ordered by the prescribing physician.

9.156.3 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 than 20 percent.

9.156.4 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.

9.156.5 When the calculated weekly treatment dose exceeds the weekly prescribed dose by 30 percent or more of the weekly prescribed dose.

9.157 "Mobile x-ray equipment" (See "X-ray equipment").

9.158 "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.

9.159 "MQSA" means the federal Mammography Quality Standards Act of 1992.

9.160 "Multi-reading" means two or more physicians, at least one of whom is an interpreting physician, interpreting the same mammogram.

9.161 "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).

9.162 "Moving beam therapy" means radiation therapy with relative displacement of the useful beam or the patient during irradiation. It includes arc therapy, skip therapy, conformational therapy, and rotational therapy.

9.163 "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.

9.164 "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.

9.165 "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.

9.166 "Operating Conditions" means circumstances required to maintain a radiation protection program sufficient to ensure compliance with the provisions of this Regulation. Conditions include, but are not limited to, patient holding, pregnant workers, use of shielding and barriers, pregnant patients, use of personnel monitoring devices, employee training, and quality assurance methods.

9.167 "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.

9.168 "Operative" means any x-ray machine or device that is capable of producing x-rays.

9.169 "Out of State Facility" means any person proposing to bring an x-ray machine into the State for any temporary use.

9.170 "Patient" means an individual or animal subjected to healing arts examination, diagnosis, or treatment, including a mammography evaluation.

9.171 "PBL" (See "Positive Beam Limitation").

9.172 "Peak tube potential" means the maximum value of the potential difference across the x-ray tube during an exposure.

9.173 "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.

9.174 "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).

9.175 "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.

9.176 "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.

9.177 "Phantom image" means a radiographic image of a phantom.

9.178 "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").

9.179 "Physical science" means physics, chemistry, radiation science (including medical physics and health physics) and engineering.

9.180 "PID" (See "Position indicating device").

9.181 "Planned special exposure" means an infrequent exposure to radiation, separate from and in addition to the annual occupational dose limits.

9.182 "Portable x-ray equipment" (See "X-ray equipment").

9.183 "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.

9.184 "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.

9.185 "Positive mammogram" means a mammogram that has an overall assessment of findings that are either "suspicious" or "highly suggestive of malignancy."

9.186 "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.

9.187 "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.

9.188 "Primary protective barrier" (See "Protective barrier").

9.189 "Protective apron" means an apron made of radiation absorbing material used to reduce radiation exposure.

9.190 "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.

9.191 "Protective glove" means a glove made of radiation absorbing materials used to reduce radiation exposure.

9.192 "Provisional certificate" means the provisional certificate described in RHB 5.3.3.

9.193 "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.

9.194 "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.

9.195 "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 5.7 and 5.25.1 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.

9.196 "Quality Assurance" is a program designed to produce high quality radiographs at minimal cost and minimal patient exposure.

9.197 "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.

9.198 "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.

9.199 "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.

9.200 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.)

9.201 "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.

9.202 "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.

9.203 "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.

9.204 "Radiation dose" means dose.

9.205 "Radiation Installation" is any location or facility where radiation machines are used.

9.206 "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.

9.207 "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.

9.208 "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.

9.209 "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.

9.210 "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.

9.211 "Radiographic imaging system" means any system whereby a permanent or temporary image is recorded on an image receptor by the action of ionizing radiation.

9.212 "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:

9.212.1 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;

9.212.2 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.

9.213 "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.

9.214 "Rating" means the operating limits as specified by the component manufacturer.

9.215 "Recording" means producing a permanent form of an image resulting from x-ray photons.

9.216 "Registrant" means any person who is registered with the Department or is legally obligated to register with the Department pursuant to the Act and these regulations.

9.217 "Registration" means registering with the Department in accordance with these regulations and the Act.

9.218 "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 a Unit Dose Equivalent*
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.

9.219 "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.

9.220 "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.

9.221 "Roentgen" (R) is the special unit of exposure. One Roentgen equals 2.58×10^{-4} Coulombs/kilogram of air. (See exposure.)

9.222 "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.

9.223 "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.

9.224 "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.

9.225 "Scan sequence" means a preselected set of two or more scans performed consecutively under preselected CT conditions of operation.

9.226 "Scan time" means the period of time between the beginning and end of x-ray transmission data accumulation for a single scan.

9.227 "Scattered radiation" means radiation that, during passage through matter, has been deviated in direction (See "Direct scattered radiation").

9.228 "Screening mammography" means mammography performed on an asymptomatic patient to detect the presence of breast cancer at an early stage.

9.229 "Secondary dose monitoring system" means a system which will terminate irradiation in the event of failure of the primary system.

9.230 "Secondary protective barrier" (See "Protective barrier").

9.231 "Serious adverse event" means 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.

9.232 "Serious complaint" means a report of a serious adverse event.

9.233 "Shadow tray" means a device attached to the radiation head to support auxiliary beam blocking material.

9.234 "Shallow-dose equivalent" (HS), 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.

9.235 "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.

9.236 "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.

9.237 "SID" (see Source to Image Receptor Distance).

9.238 "Sievert (Sv)" is the unit of dose equivalent. The dose equivalent in 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).

9.239 "Site boundary" means that line beyond which the land or property is not owned, leased, or otherwise controlled by the registrant.

9.240 "Source" means the focal spot of the x-ray tube.

9.241 "Source to image receptor distance (SID)" means the distance from the source to the center of the input surface of the image receptor.

9.242 "Source of radiation" means any device or equipment emitting or capable of producing x- ray radiation.

9.243 "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.

9.244 "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.

9.245 "Spot check" means a procedure which is performed to assure that a previous calibration continues to be valid.

9.246 "Spot film" means a radiograph which is made during a fluoroscopic examination to permanently record conditions which exist during that fluoroscopic procedure.

9.247 "Spot film device" means a device intended to transport or 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.

9.248 "SSD" means the distance between the source and the skin entrance plane of the patient.

9.249 "Standard breast" means a 4.2 centimeter (cm) thick compressed breast consisting of 50 percent glandular and 50 percent adipose tissue.

9.250 "Stationary x-ray equipment" (See "X-ray equipment").

9.251 "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).

9.252 "Stray radiation" means the sum of leakage and scattered radiation.

9.253 "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.

9.254 "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.

9.255 "Survey" in Part V, means an onsite physics consultation and evaluation of a facility's quality assurance program performed by a medical physicist.

9.256 "Target" means that part of a radiation head which by design intercepts a beam of accelerated particles with subsequent emission of other radiation.

9.257 "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.

9.258 "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.

9.259 "Test" means a method for determining the characteristics or condition of sources of radiation or components thereof.

9.260 "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.

9.261 "Time cycle" means the film development time.

9.262 "Tomogram" means the depiction of the x-ray attenuation properties of a section through the body.

9.263 "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).

9.264 "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.

9.265 "Tube" means an x-ray tube, unless otherwise specified.

9.266 "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.

9.267 "Tube housing assembly" means the tube housing with tube installed. It includes high voltage or filament transformers and other appropriate elements when such are contained within the tube housing.

9.268 "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.

9.269 "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.

9.270 "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).

9.271 "Virtual source" means a point from which radiation appears to originate.

9.272 "Whole body" means, for purposes of external exposure, head, trunk (including male gonads), arms above the elbow, or legs above the knee.

9.273 "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.

9.274 "X-ray equipment" means an x-ray system, subsystem, or component thereof.

9.274.1 Mobile means X-ray equipment mounted on a permanent base with wheels or casters for moving while completely assembled.

9.274.2 Portable means X-ray equipment designed to be hand carried.

9.274.3 Stationary means X-ray equipment designed which is installed in a fixed location.

9.274.4 Transportable means X-ray equipment installed in a vehicle or trailer.

9.275 "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.

9.276 "X-ray control" means a device which controls input power to the x-ray high-voltage generator and/or the x-ray tube. It includes equipment such as timers, phototimers, automatic brightness stabilizers, and similar devices, which control the technique factors of an x-ray exposure.

9.277 "X-ray subsystem" means any combination of two or more components of an x-ray system.

9.278 "X-ray tube" means any electron tube which is designed to be used primarily for the production of x-rays.

9.279 "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.

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 Director of Health Regulation 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 complaint 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 Director of Health Regulation, 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 of written authorization from the complainant. After considering all written or oral views present, the Director of Health Regulation 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.

RHB 10.9 Right to inspect and investigate. The Department of Health and Environmental Control is the state agency responsible for the control and regulation of radiation sources. Section 13-7- 40(A), S.C. Code of Laws (1976, as amended). By statute, the Department is authorized to enter, at all reasonable times, private or public property for the purpose of determining whether or not there is compliance with or violation of the provisions of its regulations. Section 13-7-40(A), S.C. Code of Laws (1976, as amended). Because the Department is authorized by law to enter and inspect property in order to determine compliance with Department regulations, such entry and inspection falls under the health oversight activities exception of Health Insurance Portability and Accountability Act (HIPAA). Therefore, where protected health information is necessary for determining compliance with Department regulations, protected health information may be used and disclosed to the Department without the subject's authorization under HIPAA.

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 status as directed by the Conference of Radiation Control Program Directors.

11.2.2 The SCRCL shall perform accredited calibration procedures that will be traceable to the National Institute of Standards and Technology.

11.2.2.1 The SCRCL shall perform yearly proficiency tests under the guidance of, and in coordination with, the National Institute of Standards of Technology.

11.2.3 The SCRCL shall maintain current written operating procedures. The policies of the operating procedures will be followed for all instruments entrusted to the SCRCL for calibration.

11.2.4 Each instrument received shall be surveyed for contamination. Contaminated instruments will not be calibrated at the South Carolina Regional Calibration Laboratory.

11.2.5 Each Geiger-Mueller, Ion Chamber and R Meter will be calibrated at two (2) points on each scale.

RHB 11.3 Fees.

11.3.1 A fee shall be charged for each instrument and probe calibrated at the SCRCL. The following table shall be used by the Department to determine calibration fees:

Type of Instrument	Fees
Geiger-Mueller (GM)	\$75
Ion Chamber	
First mode	\$75
Second mode	\$18.75
R Meter	\$50
MDH 1015 or 1515	
One probe-five calibration points	\$250
Additional probe-five calibration points	\$106.25
MDH 2025	
One probe- five calibration points	\$106.25
Additional probe-five calibration points	\$75
Dosimeter test - analog and digital	\$18.75 Per mode of operation
Replacement Carbon Zinc Batteries	
15 volts (NEDA 220)	Market price plus tax
22.5 volts (NEDA 221)	
22.5 volts (NEDA 215)	
30 volts (NEDA 210)	
67.5 volts (NEDA 416)	

300 volts (NEDA 722)	
Replacement desiccant pellets	Market price plus tax
Minimum handling fee, any instrument-no calibration	\$18.75

11.3.2 Shipping and insurance charges will be added to calibration fees for instruments requiring mail services. Charges will be the same as the cost to the Department.

11.3.3 An invoice for calibrations and other services will be issued to the person or organization requesting the calibration. All fees are due upon receipt of the invoice.