

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 No person, in any advertisement, shall refer to the fact that any x-ray facility, x-ray machine, or any activity under these regulations has been approved by the Department.

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

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

1.2.7 The use of any source of radiation may be prohibited when it is determined by the Department to be detrimental to public health and safety.

1.2.8 It shall be unlawful to use hand-held radiographic or fluoroscopic imaging devices, or hand-held therapy units, except for contact therapy units operated according to Part VI of these regulations.

1.2.9 It shall be unlawful to use fluoroscopy for positioning a patient for radiographic imaging, except when done by a licensed practitioner of the healing arts, or except for radiation therapy simulators.

1.2.10 It shall be unlawful for a person other than a licensed practitioner of the healing arts 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.

1.2.11 It shall be unlawful to use direct exposure x-ray film (without intensifying screens) for all radiological imaging other than intraoral dental radiography, therapeutic portal imaging, and industrial radiography.

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

1.2.13 It shall be unlawful to intentionally expose a human to electronically produced ionizing radiation except for healing arts purposes, or as part of a research protocol authorized by an institutional review board conforming to 21 CFR 50 and 21 CFR 56.

1.2.14 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 2.5.

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 shall be calibrated at intervals not to exceed 12 months and after each instrument servicing.

1.4.4.2.2 Each radiation survey instrument shall be calibrated such that accuracy within 20 percent traceable to a national standard 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 Each radiation survey instrument shall be calibrated according to manufacturer's specifications.

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

1.4.4.3 The registrant shall make available to survey instrument users the manufacturer's instructions of the survey instrument including any restrictions of the operating techniques required for the proper operation of the particular 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 Documentation must be maintained, indicating that the user has read and agrees to adhere to the operating instructions.

1.4.4.3.4 The operator shall check each survey instrument for proper operation with a dedicated check source each day of use to ensure the instrument is operation properly. Documentation of these checks shall be maintained for Department review.

RHB 1.5 Exemptions.

1.5.1 The Department may, upon application by any user, or upon its own initiative grant such exemptions from the requirements of these regulations as it determines are authorized by law, and will not result in undue hazard to health, life, or property. Applications for exemptions shall specify why such exemption is necessary.

1.5.2 Before granting an exemption, the Department shall determine that there is reasonable and adequate assurance that:

1.5.2.1 The occupational dose to any individual adult will not exceed those specified in RHB 3.4.

1.5.2.2 The dose to an individual member of the public will not exceed those specified in RHB 3.9.

1.5.2.3 There is no significant hazard to life or property.

RHB 1.6 Additional Requirements.

1.6.1 The Department may, by rule, regulation, or order, impose upon any registrant such requirements in addition to those established in these regulations as it deems appropriate or necessary to minimize danger to public health and safety or property.

1.6.2 The Department is authorized to inspect and investigate the premises and operations and personnel of any radiation installation, whether or not such installation is required to be registered by the Department, for the purpose of studying and evaluating the health hazard(s) caused by the use and operation of such machines and material.

1.6.3 Equipment Not Covered In Regulations. Prior to operation of x-ray producing equipment not specifically covered in these regulations, the facility and the vendor shall submit for review and approval to the Department a listing of manufacturer's specifications for the equipment, an analysis of exposure rates around the equipment, and written operating procedures describing how the equipment is to be used.

1.6.4 Radiation Safety Officer. The registrant shall designate an individual who will be responsible for radiation protection at the facility. Such individual shall:

1.6.4.1 Be qualified by training and experience concerning all hazards and precautions involved in operating the equipment for which he is responsible;

1.6.4.2 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 wilfully violates any provision of the Act or any regulation or order issued thereunder shall be guilty of a misdemeanor and, upon conviction, shall be punished by fine or imprisonment or both, as provided by the Act.

1.7.2 Any person found in violation of any regulation shall notify the Department, in writing, within twenty (20) calendar days, from the date of citation with respect to action that has been taken or planned to correct the violation.

1.7.3 All violations shall be corrected within sixty (60) calendar days from the date of citation. The Department shall be notified in writing of all action taken to correct the violations.

1.7.4 The Department is authorized to hold public hearings, compel attendance of witnesses, make findings of fact and determinations and to assess fines and civil penalties relating to violations of the provisions of the Act or any regulation, temporary or permanent order, or final determination of the Department.

1.7.5 The Department may impose a civil penalty not to exceed Twenty-five Thousand Dollars (\$25,000) on a person who violates a provision of the Act, rules, regulations, or orders issued. Each day of continued violation shall constitute a separate offense in computing the civil penalty. Civil penalties shall be assessed as specified in RHB 1.13.

RHB 1.8 Enforcement.

1.8.1 Upon determination by the Department that the Act or these regulations have been violated or that a public health risk exists, the Department will:

1.8.1.1 Provide written notification to the non-compliant facility as soon as possible after violations are noted which:

1.8.1.1.1 Cites each section of the Act or regulations violated.

1.8.1.1.2 Specifies the manner in which the registrant failed to comply.

1.8.1.1.3 Requires submission of a timely and comprehensive corrective action plan, including a time schedule for completion of the plan.

1.8.1.1.4 Establishes a firm time schedule within which a corrective action plan must be submitted. The Department will approve the plan and proposed time schedule for its completion if the plan is adequate.

1.8.1.2 In cases where the registrant fails to comply with the conditions of the written notification, 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; or

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 or until the next Department inspection, whichever is later;

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 24 hours, the registrant shall notify the patient as soon as possible thereafter. The registrant may not delay any appropriate medical care for the patient, including any necessary remedial care as a result of the misadministration, because of any delay in notification.

1.11.1.1 The registrant shall submit a written report to the Department within 15 days after the discovery of the misadministration. The report must not include the patient's name or other information that could lead to identification of the patient. The written report must include the registrant's name; the prescribing physician's name; a brief description of the event; why the event occurred; the effect on the patient; what improvements are needed to prevent recurrence; the action taken to prevent recurrence; whether the registrant notified the patient or the patient's responsible relative or guardian; and if not, why the individual involved was not informed; and if the patient was notified, what information was provided to the patient.

1.11.1.2 The registrant shall furnish the following to the patient within 15 days after discovery of the misadministration if the patient was notified:

1.11.1.2.1 A copy of the report that was submitted to the Department; or

1.11.1.2.2 A brief description of both the event and the consequences, as they may affect the patient, provided a statement is included that the report submitted to the Department can be obtained from the registrant.

1.11.2 Diagnostic Misadministrations. When a misadministration involves a diagnostic procedure, the registrant shall promptly investigate its cause, make a record for the Department review, and maintain the record as directed in RHB 1.11.3.

1.11.3 Each registrant shall retain a record of each therapy misadministration for ten years and three years for each diagnostic misadministration. The record must contain the names of all individuals involved in the event (including the prescribing physician, allied health personnel, the patient, and the patient's referring physician), the patient's social security number or identification number if one has been assigned, a brief description of the event misadministration, the effect on the patient, what improvements are needed to prevent recurrence; and the actions taken to prevent recurrence.

1.11.4 Aside from the notification requirement, nothing in RHB 1.11.1 through 1.11.3 shall affect any rights or duties of registrants and physicians in relation to each other, registrants, patients or responsible relatives or guardians.

RHB 1.12 Communications.

1.12.1 All communications and reports concerning these regulations, and registrations filed thereunder, shall be addressed to the Department at:

SC Department of Health and Environmental Control
Bureau of Radiological Health

2600 Bull Street
Columbia, South Carolina 29201

1.12.2 Material False Statements. It shall be unlawful to make a material false statement to the Department regarding information contained in the application for registration, information pertaining to an inspection or any other information required by any provision of these regulations.

RHB 1.13 Administration of Civil Penalties.

1.13.1 Assessment. Assessment of civil penalties shall be based on the following criteria:

- 1.13.1.1 the seriousness of the violation(s);
- 1.13.1.2 previous compliance history;
- 1.13.1.3 the amount necessary to deter future violations;
- 1.13.1.4 efforts to correct the violation; and
- 1.13.1.5 any other mitigating or enhancing factors.

1.13.2 Severity Levels. The seriousness of violations shall be categorized by one of the following severity levels.

1.13.2.1 Major. Violations that are most significant and have a direct negative impact on 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

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, wilfulness, 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, Wilfulness, Negligence, or Indifference

Increase Penalty 10% to 50%

1.13.4.2 The Department reserves the right to impose a civil penalty up to Twenty-five Thousand Dollars on a person who violates the regulations in such a manner so as to present an imminent hazard to human health and safety. The Twenty-five Thousand Dollar civil penalty may be levied for the following:

1.13.4.2.1 Two or more incidents of workers receiving excess radiation exposures, when such exposures are contrary to the provisions of RHB 3.4.

1.13.4.2.2 Two or more incidents of members of the general public, or non-radiation workers, receiving excess radiation exposures. (3.9)

1.13.4.2.3 Two or more incidents in a one year period of deliberate exposure of an individual except by or under the direct supervision of an individual licensed to engage in the healing arts. (1.2.2)

1.13.4.2.4 Two or more incidents on two consecutive inspections of failing to perform required equipment performance testing, surveys, tests, or evaluations. (1.4)

1.13.4.2.5 Four or more incidents in a one year period of making, selling, leasing, transferring, lending, assembling, or installing equipment without the equipment meeting all applicable regulations when properly placed in operation. (2.7.2)

1.13.4.2.6 Two or more incidents in a five year period of initiating a healing arts screening program without prior approval from the Department. (4.2.11.2)

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 5%, or the sum of the excess length and width of greater than 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 operating procedures. (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.