Regulation 61-65

Particle Accelerators (Title C)

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S.C. Department of Health and Environmental Control

2600 Bull Street | Columbia, SC 29201

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PART I
GENERAL PROVISIONS

RHC 1.1. Purpose and Scope.

1.1.1 These regulations establish procedures for the registration and the use of particle accelerators.

1.1.2 Except as otherwise specifically provided, these regulations apply to all persons who develop, manufacture, receive, possess, use, transfer, own, or acquire any industrial use particle accelerator.

1.1.3 In addition to the requirements of this Regulation, all registrants are subject to the requirements of Parts I, II, III, VIII, and X of R.61-64, X-Rays (Title B). Registrants engaged in the healing arts are subject to the requirements of Part VI of R.61-64, X-Rays (Title B). Registrants whose operations result in the production of radioactive material are also subject to the requirements of R.61-63, Radioactive Materials (Title A).

RHC 1.2. Prohibited Use.

1.2.1 It shall be unlawful to use, receive, own, or possess a particle accelerator unless the facility is registered with the Department and is operated in compliance with all applicable provisions.

1.2.2 No person, in any advertisement, shall refer to the fact that any particle accelerator facility, particle accelerator, or any activity under these regulations has been approved by the Department.

1.2.3 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.

1.2.4 No person shall make, sell, lease, transfer, lend, repair, or install a particle accelerator 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. Also, such persons shall be registered with the Department in accordance with RHC 2.5

RHC 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 particle accelerators and the premises and facilities wherein such particle accelerators 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.

RHC 1.4. Tests 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 Particle accelerators;

1.4.2.2 Facilities wherein particle accelerators 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 particle accelerators.

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 and repair.

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 operating properly. Documentation of these checks shall be maintained for Department review.

1.4.5 Records of all calibrations and instrumentation checks shall be retained for five years or until the next Department inspection, whichever is later.

RHC 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 life, health, or property. Applications for exemptions shall specify why such exemptions are 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 "Occupational Dose Limits for Adults" of R.61-64, X-Rays (Title B).

1.5.2.2 The dose to an individual member of the public will not exceed those specified in "Dose Limits for Individual Members of the Public" of R.61-64, X-Rays (Title B).

1.5.2.3 There is no significant hazard to life or property.

RHC 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 radiation 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 particle accelerators;

1.6.4.4 Ensure that surveys are made, procedures are carried out, and radiation safety instructions are given as required by these regulations.

RHC 1.7. Violations.

1.7.1 The Department may obtain an injunction or other court order prohibiting any violation or any provision of the Act or any regulation or order issued thereunder. Any person who willfully violates any provision of the Act or any regulation or order issued thereunder shall be guilty of a misdemeanor and, upon conviction, shall be punished by fine or imprisonment or both, as provided by the Act.

1.7.2 Any person found in violation of any regulation shall notify the Department, in writing, within 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 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 RHC 1.11.

RHC 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 registrant 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.

1.8.3 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.

RHC 1.9. Records.

1.9.1 Each registrant shall keep records showing the receipt, transfer, use, storage, and disposal of all particle accelerators and major components. These records shall be maintained by the registrant until disposal is authorized by the Department. All records shall be readily available at the facility for Department review. Additional record requirements are specified elsewhere in these regulations.

1.9.2 The registrant shall maintain the following information for each particle accelerator system for inspection by the Department:

1.9.2.1 Model and serial numbers of all tubes and controls;

1.9.2.2 Records of surveys, maintenance, and modifications performed on the particle accelerator(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;

1.9.2.3 A copy of all correspondence with the Department regarding that particle accelerator system.

1.9.3 Each registrant shall maintain a current inventory listing that indicates the model number, serial number, and location and status of each control. The inventory listing shall be made available to the Department upon request.

1.9.4 All records required by these regulations shall be accurate and true.

RHC 1.10. Communications.

1.10.1 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, SC 29201

1.10.2 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.

RHC 1.11. Administration of Civil Penalties.

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

1.11.1.1 The seriousness of the violation(s);

1.11.1.2 Previous compliance history;

1.11.1.3 The amount necessary to deter future violations;

1.11.1.4 Efforts to correct the violation; and

1.11.1.5 Any other mitigating or enhancing factors.

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

1.11.2.1 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.

1.11.2.2 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.

1.11.2.3 Minor. Violations that are of minor safety significance, or which represent a minor deviation from the requirements of this regulation.

1.11.2.4 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.

1.11.3 Application. Adjustments to the values listed in RHC 1.11.4.1 under each severity level may be made for the presence or absence of the following factors:

1.11.3.1 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.

1.11.3.2 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.

1.11.3.3 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.

1.11.3.4 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.

1.11.3.5 Multiple Occurrences. The civil penalty may be increased where multiple examples of a particular violation are identified during the inspection period.

1.11.3.6 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.

1.11.4 The Department shall issue civil penalties according to the following schedule:

1.11.4.1 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

Deviation from Requirement: Potential for Harm:	Major (11-30)	Moderate (4-10)	Minor (1-3)
Moderate (6-10)	$10,000-2,500	$7,500-1,000	$5,000-500
Minor (0-5)	$5,000-1,000	$3,000-500	$2,500-250

Calculation of Base Penalty:

Each violation is assigned a relative point value as follows: Potential for Harm- 0-70, with 70 being maximum harm; Deviation from Requirement- 1-30, with 30 being the maximum deviation. Add the two values together, convert to a decimal value (15 to .15, for example), and multiply by the maximum per day per violation per civil penalty ($25,000). This is the base civil penalty per violation. The base penalty may be increased for repeat violations, multi-day penalties, or degree of recalcitrance, willfulness, negligence, or indifference.

Minimum Increase for Repeat Violations Found on Follow-up Inspections or Reinspections

Second Offense (First Follow-up Inspection or First Reinspection)	15%
Third Offense (Second Follow-up Inspection or Second Reinspection)	30%
Fourth Offense (Third Follow-up Inspection or Third Reinspection)	45%
Fifth and Subsequent Offenses	60%

Multi-Day Penalties:

Increase penalty 1% to 7% for each day of noncompliance.

Degree of Recalcitrance, Willfulness, Negligence, or Indifference:

Increase Penalty 10% to 50%.

1.11.4.2 The Department reserves the right to impose a civil penalty up to Twenty- five Thousand Dollars ($25,000) 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:

1.11.4.2.1 Two or more incidents of workers receiving excess radiation exposures, when such exposures are contrary to the occupational dose limits for adults as set forth in the provisions of Part III of R.61-64, X-Rays (Title B).

1.11.4.2.2 Two or more incidents of members of the general public, or non-radiation workers, receiving excess radiation exposures contrary to the dose limits for individual members of the public as set forth in the provisions of Part III of R.61-64, X-Rays (Title B).

1.11.4.2.3 Two or more incidents on two consecutive inspections of failing to perform required surveys, tests, checks, calibrations or evaluations. (RHC 1.4)

1.11.4.2.4 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. (RHC 2.5.3)

PART II
REGISTRATION PROCEDURE

RHC 2.1. Purpose and Scope.

This part provides for the registration of industrial use particle accelerators (controls and tubes) and facilities.

2.1.1 Except as specifically exempted in RHC 2.2, each person who develops, manufactures, receives, possesses, uses, transfers, owns, or acquires any industrial use particle accelerator 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.

RHC 2.2. Exemptions.

2.2.1 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.

2.2.2 Electronic equipment producing radiation incidental to its operation for other purposes is exempt from the registration requirements of this Part if dose equivalent rate averaged over an area of 10 square centimeters does not exceed 0.5 mrem per hour at 5 centimeters from any accessible surface of such equipment. The production, testing, or factory servicing of such equipment is not exempt.

2.2.3 Any facility where a federal agency has exclusive jurisdiction is exempt from the requirements of this Part.

2.2.4 Particle accelerators while in transit or storage incident thereto are exempt from the requirements of this Part.

RHC 2.3. Facility Registration Approval.

2.3.1 Any facility planning to install a particle accelerator (fixed or mobile) shall meet the following provisions:

2.3.1.1 Prior to installation of any particle accelerator, the facility where the installation will be shall submit to the Department the following information:

2.3.1.1.1 Facility Name, Location Address, and Mailing Address;

2.3.1.1.2 The name of the Radiation Safety Officer and the individual's qualifications to serve in such a capacity;

2.3.1.1.3 Type and make of particle accelerator to be installed;

2.3.1.1.4 Operating procedures as required by RHC 3.3;

2.3.1.1.5 A training plan as required by RHC 3.2;

2.3.1.1.6 The name, address, and contact person of the company selling and installing the equipment. If more than one company is involved in the sale and/or installation, then the above information shall be provided for all companies involved.

2.3.1.2 Upon review and approval of the above information, the Department shall issue a facility registration approval.

2.3.1.3 A facility shall not install or cause to be installed any particle accelerator until the Department has issued a facility registration approval.

RHC 2.4. Equipment Registration Requirements, Users of Particle Accelerators.

2.4.1 Initial Equipment Registration. Every person possessing a particle accelerator shall register the machine's control and tubes with the Department within 30 days of the date of acquisition. Registration shall be made on Form DHEC 819 furnished by the Department.

2.4.1.1 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.

2.4.1.2 When a control is removed from a facility, the facility shall remove the registration sticker.

2.4.1.3 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 RHC 2.5.3.

2.4.2 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.

2.4.3 Report of Change. The registrant shall report to the Department, within 30 days, any changes of status affecting any particle accelerator or facility. Report of a change of status shall be made in writing and forwarded to the Department.

2.4.4 Verification of Service Representative. Each registrant shall require any person furnishing particle accelerator servicing or services as described in this Part to provide evidence that he/she has been registered with the Department as a vendor in accordance with these regulations.

RHC 2.5. Vendor Registration and Obligation.

2.5.1 Each person who is a) engaged in the business of selling, leasing, or installing particle accelerators or machine components; or b) offering to sell, lease, or install particle accelerators or machine components; or c) engaged in the business of furnishing or offering to furnish any equipment services in South Carolina shall apply for registration as a vendor with the Department within 30 days following the effective dates of these regulations or thereafter prior to furnishing or offering to furnish any such services.

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

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

2.5.1.1.2 Shall exclusively service one facility or corporation.

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

2.5.2 Any person who sells, leases, transfers, lends, moves, assembles or installs particle accelerators in South Carolina shall notify the Department of the following within 30 days of the transaction:

2.5.2.1 The name and address of persons who have received the machine;

2.5.2.2 The manufacturer, control model and serial number, and tube(s) model and serial number of each particle accelerator transferred; and

2.5.2.3 The date of transfer of each particle accelerator.

2.5.2.4 Notification to the Department shall be made on DHEC Form 823. A DHEC 823 form shall be submitted to the Department each month by Class I and Class II vendors, as outlined in Part II "Registration of X-Ray Machines and Services" of R.61-64, X-Rays (Title B), regardless of whether a particle accelerator was sold that month.

2.5.3 No person shall make, sell, lease, transfer, lend, maintain, repair, assemble, reassemble, reinstall or install particle accelerators 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.

2.5.4 Each vendor shall maintain records for review by the Department. These records shall include, at a minimum:

2.5.4.1 All information required by RHC 2.5;

2.5.4.2 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;

2.5.4.3 Records of any routine maintenance, repair, alterations, or reassembly of particle accelerators. 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;

2.5.4.4 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.

2.5.5 All records required by this Part shall be maintained by the vendor for review by the Department. Training records shall be retained for personnel currently acting in any role as described in this Part. All other records shall be retained for five years. All records shall be accurate and factual.

2.5.6 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.

2.5.6.1 Survey meters used for radiation area surveys shall be calibrated at intervals not to exceed 12 months and after each instrument servicing.

RHC 2.6. Modification, Revocation, Termination of Registrants.

2.6.1 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:

2.6.1.1 Amendments to the Act;

2.6.1.2 Rules and regulations adopted pursuant to provisions of the Act; or

2.6.1.3 Orders issued by the Department.

2.6.2 Any registration may be revoked, suspended, or modified in whole or part:

2.6.2.1 For any material false statement in the application or in any statement of fact required by provisions of this Part;

2.6.2.2 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

2.6.2.3 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.

2.6.3 An order of revocation may be appealed pursuant to applicable law, including S.C. Code Title 44, Chapter 1; and Title 1, Chapter 23.

2.6.4 Except in cases of willfulness or those in which the public health, interest, or safety requires otherwise, prior to the institution of proceedings for modification, revocation, or suspension of a registrant, the Department shall:

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

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

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

2.6.6 The provisions of this Part shall apply to both registration of particle accelerators and registration of particle accelerator services (vendors).

RHB 2.7. Annual Fees.

2.7.1 Any person issued or granted a registration for the possession and use of particle accelerator(s) shall pay an annual registration fee. 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.

2.7.2 Persons failing to pay the fees required by RHC 2.7.1 by March 15 of that year shall also pay a penalty of 50 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.

2.7.3 A registrant suspended for failure to pay the required fee under RHC 2.7.2 may be reinstated by the Department upon payment of the required fee, the penalty of 50 Dollars and an additional penalty of 100 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.

2.7.4 Payment of fees shall be made in accordance with the instructions of a "Statement of Fees Due" issued annually by the Department.

2.7.5 Fees required by RHC 2.7.1 for a particle accelerator, 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.

2.7.6 Schedule of Fees. The fee schedule pursuant to Part II "Annual Fees" of R.61-64, X-Rays (Title B) shall be used by the Department to determine the annual fee due.

PART III
RADIATION SAFETY REQUIREMENTS FOR RADIATION SAFETY OFFICERS AND OPERATORS

RHC 3.1. Minimum Personnel Radiation Safety Requirements for Radiation Safety Officers and Operators.

3.1.1 No registrant shall permit any individual to act as a Radiation Safety Officer until such person:

3.1.1.1 Has been instructed in the subjects outlined in RHC 3.2 of this Part;

3.1.1.2 Has received copies of and instruction in these regulations and the registrant's operating and emergency procedures and shall have demonstrated understanding thereof; and

3.1.1.3 Has demonstrated competence to use the particle accelerator, related handling tools, and survey instruments that will be employed in the assignment.

3.1.2 No registrant shall permit any individual to act as an operator until such person:

3.1.2.1 Has been instructed in the subjects outlined in RHC 3.2 of this Part;

3.1.2.2 Has received copies of and instruction in these regulations and the registrant's operating and emergency procedures and shall have demonstrated understanding thereof; and

3.1.2.3 Has demonstrated competence to use, under the personal supervision of the Radiation Safety Officer, the particle accelerator, related handling tools, and survey instruments that will be employed in his assignment.

3.1.2.4 The registrant shall have all training procedures and testing documented in writing and available for the Department's review.

3.1.3 Maintenance personnel performing any activities involving a particle accelerator shall have minimum training as outlined in RHC 3.1.2 of this Part.

RHC 3.2. Minimum Subjects to be Covered in Training Radiation Safety Officers and Operators.

3.2.1 No registrant shall permit any individual to act as an operator of a particle accelerator until such individual has been instructed in radiation safety and shall have demonstrated an understanding in the following:

3.2.1.1 Fundamentals of Radiation Safety:

3.2.1.1.1 Characteristics of ionizing radiation;

3.2.1.1.2 Units of radiation dose (rem or Sievert);

3.2.1.1.3 Hazards of exposure to radiation;

3.2.1.1.4 Levels of radiation from sources of radiation;

3.2.1.1.5 Methods of controlling radiation dose;

3.2.1.1.5.1 Working time;

3.2.1.1.5.2 Working distances; and

3.2.1.1.5.3 Shielding.

3.2.1.2 Radiation Detection Instrumentation to be Used:

3.2.1.2.1 Use of radiation survey instruments;

3.2.1.2.1.1 Operation;

3.2.1.2.1.2 Calibration; and

3.2.1.2.1.3 Limitations.

3.2.1.2.2 Survey techniques; and

3.2.1.2.3 Use of personnel monitoring equipment:

3.2.1.2.3.1 Film badges or other approved dosimeters; and

3.2.1.2.3.2 Pocket dosimeters or pocket chambers, if applicable.

3.2.1.3 Operation and control of particle accelerators and interlock systems.

3.2.1.4 The requirements of pertinent state regulations.

3.2.1.5 The registrant's written operating and emergency procedures.

RHC 3.3. Operating and Emergency Procedures.

3.3.1 The registrant shall have written operating and emergency procedures. These procedures shall include instruction in:

3.3.1.1 The handling and use of particle accelerators to be employed such that no person is likely to be exposed to radiation doses in excess of the occupational dose limits established in Part III "Standards for Protection Against Radiation" of R.61-64, X-Rays (Title B);

3.3.1.2 Methods and occasions for conducting radiation surveys;

3.3.1.3 Methods for controlling access to radiation areas;

3.3.1.4 Methods for locking and securing particle accelerators when not in use or in storage;

3.3.1.5 Personnel monitoring and the use of personnel monitoring equipment, including steps that must be taken by radiation personnel in the event a pocket dosimeter is found to be off-scale;

3.3.1.6 The proper handling of exposed personnel;

3.3.1.7 Minimizing exposure of individuals in the event of an accident;

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

3.3.1.9 Maintenance of records.

RHC 3.4. Authority and Responsibility for the Radiation Safety Officer.

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

3.4.1.1 Identify radiation safety problems;

3.4.1.2 Initiate, recommend, or provide corrective actions;

3.4.1.3 Stop unsafe operations; and

3.4.1.4 Verify implementation of corrective actions.

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

PART IV
PERSONNEL MONITORING REQUIREMENTS

RHC 4.1. Personnel Monitoring.

4.1.1 No registrant shall permit any individual to act as a Radiation Safety Officer or as an operator unless, at all times during radiographic operations, each such person wears a film badge, thermoluminescent dosimeter (TLD), or other dosimeter approved by the Department.

4.1.2 All provisions of Part III "Standards for Protection Against Radiation" of R.61-64, X-Rays (Title B) apply.

PART V
SHIELDING AND SAFETY DESIGN REQUIREMENTS

RHC 5.1. Shielding.

5.1.1 A qualified expert, acceptable to the Department, shall be consulted in the design of a particle accelerator installation and called upon to perform a radiation survey when the accelerator is first capable of producing radiation.

5.1.2 Each particle accelerator installation shall be provided with such primary and secondary barriers as are necessary to assure compliance with occupational dose limits as outlined in Part III "Standards for Protection Against Radiation" of R.61-64, X-Rays (Title B).

PART VI
PARTICLE ACCELERATOR CONTROLS AND INTERLOCK SYSTEMS

RHC 6.1. Particle Accelerator Controls and Interlock Systems.

6.1.1 Instrumentation, readouts, and controls on the particle accelerator control console shall be clearly identified and easily discernible.

6.1.2 Accelerator controls shall be equipped with one or more of the following:

6.1.2.1 A keyswitch or other device which will render the console inoperative when the key or device is removed or;

6.1.2.2 A password protected computer system.

6.1.3 Each entrance into a target room or other high radiation area shall be equipped with multiple safety interlocks that shut down the machine under conditions of barrier penetration.

6.1.4 Each safety interlock shall be on a circuit which shall allow it to operate independently of all other safety interlocks.

6.1.5 All shielding that is temporary, movable, or detachable shall be interlocked.

6.1.6 All safety interlocks shall be designed so that any defect or component failure in the safety interlock system prevents operation of the accelerator.

6.1.7 When a safety interlock system has been tripped, it shall only be possible to resume operation of the accelerator by manually resetting controls at the position where the safety interlock has been tripped and, lastly, at the main control console.

6.1.8 A scram button or other emergency power cutoff switch shall be located and easily identifiable in all high radiation areas. Such a cutoff switch shall include a manual reset so that the accelerator cannot be restarted from the accelerator control console without resetting the cutoff switch.

RHC 6.2. Warning Devices.

6.2.1 Each location designated as a high radiation area, and each entrance to such location shall be equipped with easily observable warning lights that operate when, and only when, radiation is being produced.

6.2.2 Each high radiation area shall have an audible warning device which shall be activated for 15 seconds prior to the possible creation of such high radiation area. Such warning devices shall be clearly discernible in all high radiation areas.

6.2.3 Barriers, temporary or otherwise, and pathways leading to high radiation areas shall be posted in accordance with Part III "Standards for Protection Against Radiation" of R.61- 64, X-Rays (Title B).

RHC 6.3. Methods of Operation.

6.3.1 The name(s) of the operator, as outlined in Part III of these regulations, shall be displayed at the control of each particle accelerator. Only the operator(s) whose name is displayed shall operate the particle accelerator.

6.3.2 Particle accelerators, when not in operation, shall be secured to prevent unauthorized use.

6.3.3 The safety interlock system shall not be used to turn off the accelerator beam except in an emergency.

6.3.4 All safety and warning devices, including interlocks, shall be checked for proper operation at intervals not to exceed three months. Results of such tests shall be maintained at the accelerator facility for inspection by the Department.

6.3.5 Electrical circuit diagrams of the accelerator and the associated safety interlock systems shall be kept current and maintained for inspection by the Department and shall be available to the operator at each accelerator facility.

6.3.6 If, for any reason, it is necessary to intentionally bypass a safety interlock or interlocks, such action shall be:

6.3.6.1 Authorized by the Radiation Safety Committee or Radiation Safety Officer;

6.3.6.2 Recorded in a permanent log and a notice posted at the accelerator control console; and

6.3.6.3 Terminated as soon as possible.

6.3.7 A copy of the current operating and the emergency procedures shall be maintained at the accelerator control panel.

RHC 6.4. Radiation Monitoring Requirements.

6.4.1 There shall be available at each particle accelerator facility appropriate portable monitoring equipment which is operable and has been appropriately calibrated for the radiation energy levels being produced at the facility.

6.4.2 A radiation protection survey shall be performed and documented by a qualified expert, acceptable to the Department, at intervals not to exceed three months and when changes have been made in shielding, operation, equipment, workload, or occupancy of adjacent areas.

6.4.2.1 All surveys shall be made in accordance with the written procedures established by a qualified expert acceptable to the Department and the Radiation Safety Officer.

6.4.2.2 All surveys shall include a diagram of the machine and adjacent areas including, but not limited to, the operator's area at the control panel.

6.4.2.3 All survey results shall be recorded using quantified units of radiation at each survey point.

6.4.3 Radiation levels in all high radiation areas shall be continuously monitored. The monitoring devices shall be electrically independent of the accelerator control and safety interlock systems and capable of providing a readout at the control panel.

6.4.4 Personnel entering a target room or high radiation area shall use a radiation monitor capable of producing an audible alarm or "chirp" in the presence of radiation. The alarm shall be fully functional and checked for operability in accordance with RHC 6.4.6.

6.4.5 All area monitors and survey instruments shall be calibrated at intervals not to exceed one year and after each servicing and repair.

6.4.6 The operator shall check each survey instrument for proper operation with a dedicated check source each day in which the instrument is used to ensure the instrument is operating properly.

6.4.7 Whenever applicable, periodic surveys shall be made to determine the amount of airborne particulate radioactivity present.

6.4.8 Whenever applicable, periodic smear surveys shall be made to determine the degree of contamination.

6.4.9 Records of all radiation protection surveys, calibrations, and instrumentation tests shall be maintained at the accelerator facility for inspection by the Department. The registrant shall retain these records for five years or until the next Department inspection, whichever is later.

PART VII
VENTILATION SYSTEMS

RHC 7.1. Ventilation Systems.

7.1.1 Ventilation systems shall be provided to ensure that personnel entering any area where airborne radioactivity may be produced will not be exposed to airborne radioactive material in excess of those limits specified in R.61-63, Radioactive Materials (Title A).

7.1.2 A registrant shall not vent, release, or otherwise discharge airborne radioactive material to an unrestricted area which exceeds the limits specified in R.61-63, Radioactive Materials (Title A). Every effort must be made to maintain releases of radioactive material to unrestricted areas as far below these limits as is reasonably achievable.

PART VIII
DEFINITIONS

8.1 "Accelerator facility" (See "Facility").

8.2 "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)].

8.3 "Adult" means an individual 18 or more years of age.

8.4 "Annually" means at intervals not to exceed 12 consecutive months.

8.5 "Calibration" means:

8.5.1 the response or reading of an instrument relative to a series of known radiation values over the range of the instrument; or

8.5.2 the strength of a source of radiation relative to a standard.

8.6 "Dedicated check source" means a source of radiation with a known value used to ensure a survey instrument is operational and responding to the levels of radiation in which it is designed to measure.

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

8.8 "Dose" is a generic term which means absorbed dose, dose equivalent, effective dose equivalent, or total effective dose equivalent.

8.9 "Facility" means the location at which one or more particle accelerators are installed or located within one building, vehicle, or under one roof and are under the same administrative control.

8.10 "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.

8.11 "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 one hour at 30 centimeters from the radiation source or from any surface that the radiation penetrates.

8.12 "Individual" means any human being.

8.13 "Industrial use particle accelerator" means any particle accelerator used for nonhuman applications.

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

8.15 "Investigative limits" means a preset administrative level of radiation exposure over a set time, established by the Radiation Safety Officer or the Radiation Safety Committee, used to prevent an individual from exceeding annual occupational exposure limits.

8.16 "Limits" or "dose limits" means the permissible upper bounds of radiation doses.

8.17 "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.

8.18 "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.

8.19 "Operating procedures" means detailed written instructions including, but not limited to, use of the particle accelerator, 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 the particle accelerator. 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.

8.20 "Operator" means a person qualified by training and experience as defined in RHC 3.2 to assume responsibility for the safe operation of a particle accelerator.

8.21 "Particle accelerator" means any machine capable of accelerating electrons, protons, deuterons, or other nuclear particles in a vacuum and discharging these particles into a medium external to the accelerating device.

8.22 "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.

8.23 "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).

8.24 "Protective barrier" means a barrier of radiation absorbing material(s) used to reduce radiation exposure. The types of protective barriers are as follows:

8.24.1 "Primary protective barrier" means the material, excluding filters, placed in the useful beam, to protect anyone from radiation exposure.

8.24.2 "Secondary protective barrier" means a barrier sufficient to attenuate the stray radiation to the required degree.

8.25 "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.

8.26 "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.

8.27 "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.

8.28 "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.

8.29 "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.

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

8.31 "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 one rem or the absorbed dose in gray equal to one sievert.

8.32 "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.

8.33 "Revocation" means a facility's registration is withdrawn and is required to cease operation of all particle accelerator equipment until such time as the Department deems necessary.

8.34 "Smear survey" means a survey performed to measure the amount of removable contamination.

8.35 "Source of radiation" means any radioactive material or any device or equipment emitting or capable of producing radiation.

8.36 "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.

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

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

8.39 "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.

8.40 "Vendor" means a person who is engaged in the business of selling, leasing, installing, or offering to sell, lease, or install particle accelerators or machine components or is engaged in the business of furnishing or offering to furnish particle accelerator services, which includes, but is not limited to, reinstalling, reassembling, leasing, servicing, maintenance, calibration, and repair of particle accelerator equipment, facility and shielding design, radiation surveys, instrument calibration, personnel dosimetry, processor cleaning and maintenance, and health physics consultations.

8.41 "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 one hour at one 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).

Appendix A

For further requirements outlined for the following topics refer to R.61-64, X-Rays (Title B):

Registration Requirements-Servicing and Services (VENDORS) (Part II)

Out-of-state Facilities (Part II) Radiation Dose Limits (Part III)

Control of Access to High and Very High Radiation Areas (Part III) Caution Signs (Part III)

Posting Requirements (Part III) Notification of Incidents (Part III)

Reports of Exposures and Radiation Levels Exceeding the Limits (Part III)

Notices, Instructions, and Reports to Workers: Inspections (Part X)