

REGULATORY GUIDE B5
COMPLYING WITH TITLE B - VENDORS



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Table of Contents

| | |
|---|-----------|
| REGISTRATION..... | 3 |
| <i>I. Class I.....</i> | <i>3</i> |
| <i>II. Class II.....</i> | <i>3</i> |
| <i>III. Class III.....</i> | <i>3</i> |
| <i>IV. Class IV.....</i> | <i>3</i> |
| <i>V. Class V.....</i> | <i>3</i> |
| <i>VI. Class VI.....</i> | <i>4</i> |
| <i>VII. Class VII.....</i> | <i>4</i> |
| <i>VIII. Class VIII.....</i> | <i>4</i> |
| <i>IX. Class IX.....</i> | <i>4</i> |
| REPORT OF CHANGE | 4 |
| TRAINING AND EDUCATIONAL REQUIREMENTS..... | 4 |
| VENDOR OBLIGATIONS | 7 |
| ANNUAL FEES | 9 |
| QUESTIONS..... | 10 |
| REGULATORY GUIDES | 10 |

REGULATORY GUIDE B5 COMPLYING WITH TITLE B - VENDORS

Any person who provides x-ray equipment services in South Carolina is required to be registered with the Department. Providers of x-ray services (vendors) are regulated under Regulation 61-64, X-Rays (Title B). This guide is intended to assist vendors in complying with Title B regulations.

REGISTRATION

(See RHB 2.6)

Anyone who sells, leases, installs, or offers to sell, lease, or install x-ray machines or components of x-ray machines is required to be registered with the Department. In addition, anyone who furnishes or offers to furnish any equipment services must be registered **prior to** doing so.

Both the business and the employees must be registered with the Department. The Business registration form may be obtained from the Department or at <http://www.scdhec.gov/health/radhlth>. Each vendor must pay a non-refundable vendor application fee of \$62.50 upon submission of the initial Business Registration Approval Request form.

X-ray equipment services that require registration are shown below. Each type of service is designated with a Class level as shown. Registration is granted by the class number as follows:

I. Class I

Direct sale and transfer of radiation machines and machine components to end users.

II. Class II

Installation or servicing of radiation machines and associated machine components. You must choose one or all of the sub-classes:

- II-A- Installation of radiation machines and associated radiation machine components
- II-B- Servicing of radiation machines and associated radiation machine components
- II-C- Perform "Equipment Performance Tests" as outlined in RHB 4.2.16. Refer to Appendix F. If performing Equipment Performance Tests, you must submit a sample of the equipment performance test procedures and forms.

III. Class III

Diagnostic radiographic facility and shielding design

- Must submit a sample of a shielding plan.

IV. Class IV

Diagnostic fluoroscopic facility and shielding design

- Must submit a sample of a shielding plan.

V. Class V

Diagnostic area radiation survey, e.g., shielding evaluation.

VI. Class VI

Radiation instrument calibration.

VII. Class VII

Therapeutic facility and shielding design, area radiation surveys, or calibration.

- Must submit a sample of a shielding plan.

VIII. Class VIII

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

IX. Class IX

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

- Must submit a sample of a shielding plan and sample of an equipment performance tests.

***Additional information may be required in order to process an application.**

Any branch office of a vendor is considered to be a separate entity and must be registered separately.

REPORT OF CHANGE

(See RHB 2.6.5)

Vendors who are registered must notify the Department, in writing, within thirty (30) days of any changes that would render the information contained on the company and/or employee registration form no longer accurate. This includes change of address, change of phone numbers, change of employee status, addition of new employees, changes in services provided, etc.

TRAINING AND EDUCATIONAL REQUIREMENTS

(See RHB 2.6.6)

Each person registered with the Department must be qualified by reason of education, training, and experience to provide the services for which registration is requested. Listed below are minimum qualifications for specific types of services.

For the purpose of registration, the required work experience may be gained while working for a manufacturer or while under the direct supervision of a vendor registered in the particular class. Any person registered prior to the effective date of this regulation as a vendor shall meet the education, training, and experience requirements of this part no later than 24 months after the effective date of these regulations.

All training must be documented (on the job training will be accepted if issued on company letterhead). Please be aware that on the job training must be factual as required by RHB 1.12.2 "Material False Statements."

1) **Class I** - Sales of radiation machines and machine components to end users. The applicant must certify knowledge of familiarity with the rules and regulations which govern the possession, installation, and use of x-ray equipment in South Carolina.

2) **Class II** - Installation and service of radiation machines and components. This includes the making of diagnostic radiation output measurements to verify performance associated with the installation or service.

a) Manufacturer's equipment school for service, or equivalent training;

b) Maintenance and installation for the type of machine use (e.g., dental intraoral, medical diagnostic or medical fluoroscopic) or equivalent training;

c) Training in principles of radiation protection; and three to six months of experience in installation and service of radiation machines and components;

3) **Class III** - Diagnostic radiographic facility and shielding design.

a) Documented training in principles of radiation protection, and

b) Documented training in shielding design, and

c) One year of experience in diagnostic radiographic facility and shielding design for the specific type of machine application.

4) **Class IV** - Diagnostic fluoroscopic facility and shielding design.

a) Documented training in principles of radiation protection, and

b) Documented training in shielding design, and

c) One year of experience in diagnostic fluoroscopic facility and shielding design for the specific type of machine application.

5) **Class V** - Diagnostic area radiation survey, e.g., shielding evaluation.

a) Documented training in principles of radiation protection,

b) Documented training in shielding evaluation, and

c) One year of experience performing area radiation surveys.

6) **Class VI** - Radiation instrument calibration.

- a) The applicant must possess a current radioactive materials license if instrument calibration is done utilizing radioactive materials or registration authorizing radiation instrument calibration, and
- b) Training in principles of radiation protection, and
- c) One year experience in an instrument calibration laboratory, and
- d) Must submit a description of the procedures that will be utilized in performing instrument calibrations.

7) **Class VII** - Therapeutic facility and shielding design, area radiation surveys, or calibration.

- a) Certification by the American Board of Radiology in therapeutic radiological physics, radiological physics, or x-ray and gamma ray physics, or certification by the American Board of Medical Physics, or
- b) Having the following minimum training and experience:
 - Master's or a Doctoral degree in physics, biophysics, radiological physics, health physics, or medical physics; and
 - One year full-time experience in therapeutic radiological physics, and
 - One year full-time experience in a therapeutic facility where the individual's duties involve calibration and spot checks of a medical accelerator, and include personal calibration and spot check of at least one machine.
- c) Must submit a description of the procedures that will be utilized in performing therapeutic calibrations including a list of all guides and references employed.
- d) Must submit a copy of all forms, reports, and documents that will be supplied to registrants, and must submit one sample of each specific type.

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

- a) One year experience in non-healing arts facility design and area radiation surveys
- b) Baccalaureate degree in a physical science, (e.g. physics, chemistry or radiologic science), engineering, or related field, and two years of progressive experience in medical or health physics; or
- c) Baccalaureate degree in a physical science, (e.g. physics, chemistry or radiologic science), engineering, or related field and two years graduate training in medical or health physics; or
- d) Certification by the American Board of Radiology in diagnostic radiological physics, therapeutic radiological physics, radiological physics, roentgen-ray and gamma ray physics, or x-ray and radium physics; certification by the American Board of Health Physics in comprehensive practice, or certification by the American Board of Medical Physics.

9) **Class IX** - General health physics consulting, healing arts, e.g., independent diagnostic radiation output measurements, dose analysis, design of safety programs and radiation safety training programs, facility and shielding design, area radiation surveys, equipment performance tests, and acting as the radiation safety officer

- a) Baccalaureate degree in a physical science, (e.g. physics, chemistry or radiologic science), engineering, or related field, and two years of progressive experience in medical or health physics; or
- b) Baccalaureate degree in a physical science, (e.g. physics, chemistry or radiologic science), engineering, or related field and two years graduate training in medical or health physics; or
- c) Certification by the American Board of Radiology in diagnostic radiological physics, therapeutic radiological physics, radiological physics, roentgen-ray and gamma ray physics, or x-ray and radium physics; certification by the American Board of Health Physics in comprehensive practice, or certification by the American Board of Medical Physics.

For Vendor classes II-V: Companies may submit a comprehensive training plan, addressing the requirements of RHB 2.6.6, which must be completed by all employees. This plan must include all applicable requirements for each class. Training received on the job must be clearly documented and verified by a responsible individual (i.e. Company CEO, President, and RSO). This option may be allowed in lieu of providing training documentation listed in this part. The Department reserves the right to require submission of documentation of all items specified in RHB 2.6.6

VENDOR OBLIGATIONS

(See RHB 2.7)

1) **Notification.** Any person who sells, leases, transfers, lends, moves, assembles, or installs x-ray machines must notify the Department within thirty days of:

- a) The name and address of persons who have received these machines.
- b) The manufacturer, the control and tube(s) model and serial numbers.
- c) The date of transfer of each x-ray machine.

Notifications must be made on forms furnished by the Department. This form must be submitted by each Class I and Class II vendor each month regardless of whether x-ray equipment was sold or installed that month.

If an FDA 2579 form is required to be submitted for an installation, the FDA 2579 forms should be submitted along with the corresponding Monthly Report Form. Submission of an FDA 2579 form does not relieve a vendor from the monthly reporting requirement.

2) **Installation and servicing.** No person shall make, sell, lease, transfer, lend, maintain, calibrate, test, repair, assemble, reassemble, reinstall, or install x-ray units that do not meet regulations. Vendors shall ensure that the facility it is providing with service or supplies is registered with the Department. Vendor responsibilities for several different situations are discussed below:

a) **Installations.** Facilities are required to have a Facility Registration Approval **before** x-ray equipment is installed. A Facility Registration Approval must be requested by the facility prior to installation. See Regulatory Guide B1 for assisting facilities in this process. It is unlawful for any person to install x-ray producing equipment until the facility acquiring that equipment has received a Facility Registration Approval from the Department. It is the responsibility of the vendor to ensure that the equipment is installed to meet State regulations, and to ensure that it is installed according to the accepted shielding plan. The vendor must document all testing that is performed at the time of installation, and provide the registrant with a copy of that testing at the time of installation.

b) **Shielding plans.** Vendors must ensure that a shielding plan has been accepted prior to installation of equipment. Shielding plans are required for all new installations, and may be required for replacement of existing equipment. The Department must always be contacted when replacing equipment in an existing facility to determine if a new shielding plan is required. The vendor installing equipment and the registrant have a joint responsibility to ensure that a plan is approved prior to installation and to ensure that the equipment is installed according to the approved shielding plan.

c) **Servicing of installed equipment.** A vendor has the responsibility to properly service x-ray equipment and is responsible for informing the registrant if a unit cannot be brought into compliance. Vendors are required to make records of any routine maintenance, calibration, testing, repair, alterations, or reassembly of x-ray equipment, and provide the registrant a copy of these records. These records should include the date of the service along with a legible signature of the person who performed the service. Please refer to Appendix F for a complete list of all testing requirements.

3) **Records.** Each vendor must maintain records for review by the Department. These records must include at a minimum:

a) The name and address of persons who have received x-ray equipment from the vendor whether by sale, lease, transfer, trade, or loan. Also required are the manufacturer, control and tube model and serial number, and the date of transfer.

b) A copy of the shielding plan, if one was required, and if provided by that vendor.

c) Tests performed at the time of installation to ensure that the equipment complies with the regulations.

d) Records of any routine maintenance, repair, alterations, or reassembly of x-ray equipment. These records must include the legible signature of the person performing the installation or service.

e) Names of all employees and their dates of employment with the vendor. Records must also be maintained of training provided to the employees during their term of employment.

f) Records of equipment performance testing. These reports must include the following:

- o Data collected during the testing.
- o The testing of all items listed in Part IV, Appendix F, except as noted in the Appendix.
- o Clear indication of all equipment parameters tested accompanied by a designation such as "Pass/Fail" or "Compliant/Noncompliant" that is easily comprehensible by the facility. Any designation other than "Pass/Fail" or "Compliant/Noncompliant" shall be approved by the Department prior to being used on any equipment performance test.
- o The date the testing was performed, the legible signature of the person who performed the testing, manufacturer, model number, serial number, and the calibration date of the instrument used to perform the test, and the manufacturer, model number, serial number, and location of the equipment.
- o The equipment performance test record shall include a summary of findings and recommendations for necessary improvements and/or corrective actions.

All records required above must be maintained by the vendor until the Department authorizes their disposal. All records shall be accurate and factual.

4) **Instruments.** Vendors shall maintain sufficient calibrated and operable instruments to perform the testing appropriate to the class in which the vendor is registered. See RHB 1.4.4 for required calibration frequencies.

ANNUAL FEES

(See RHB 2.10)

Any person issued or granted a registration as a vendor must pay an annual registration fee. This fee is \$187.25. Annual registration fees are due on January 15 of each year. Persons failing to pay the required fees by March 15 shall also pay a penalty of \$50.00. If the fees are not paid by April 15, the registration will be revoked, and any activities permitted under the authority of the registration must cease immediately. A registration that is revoked for failure to pay the fees may be reinstated by the Department upon payment of the required fees, the penalty of \$50.00, and an additional penalty of \$100.00, if the registrant is otherwise in good standing and presents to the Department a satisfactory explanation for his failure to pay the required fees.

QUESTIONS

If you have questions, please feel free to call or write:

SC Department of Health and Environmental Control
Bureau of Radiological Health
2600 Bull Street
Columbia, SC 29201
PHONE (803) 545-4400
FAX (803) 545-4412

REGULATORY GUIDES

- B1 - Registration of X-ray Facilities and Equipment
- B2 - Complying with Title B - Medical Facilities
- B3 - Complying with Title B - Dental Facilities
- B4 - Complying with Title B - Facilities Utilizing Analytical or Industrial X-ray Equipment
- B5 - Complying with Title B - Vendors
- B6 - X-Ray Facility Shielding Plans
- B7 - Complying with Title B - Mammography
- B8 - Complying with Title B - Bone Densitometers
- B9 - Complying with Title B - Veterinary Facilities
- B10 - Complying with Title B - Hospitals
- B11 - Complying with Title B - Therapy Facilities

Visit our web site at: <http://www.scdhec.gov/Health/FHPF/HealthFacilityRegulationsLicensing/X-RayFacilitiesRadioactiveMaterials/X-RayFacilities/>