

**REGULATORY GUIDE B5**

**COMPLYING WITH TITLE B - VENDORS**



SC DEPARTMENT *of*  
**ENVIRONMENTAL  
SERVICES**

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## **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 2.7)

Anyone who sells, leases, assembles, installs, or offers to sell, lease, assemble, 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 SCDES Form 0824 "Business Registration" may be obtained from the Department or at [www.des.sc.gov](http://www.des.sc.gov). Each vendor must pay a non-refundable vendor application fee of \$62.50 upon submission of the SCDES Form 0824 "Business Registration". A SCDES Form 0825 "Vendor Employee Registration" must be provided with each SCDES Form 0825. The forms can be submitted to [XRayVendors@des.sc.gov](mailto:XRayVendors@des.sc.gov) or mailed to 2600 Bull Street, Columbia, SC 29201. Fees may be paid by check or an invoice will be issued after the application is received. Applications are processed in the order received, with a typical turnaround time of 15 business days (excluding weekends and holidays) once a complete submission and payment are received. As the Department transitions to electronic correspondence, all approval letters and documentation will be delivered electronically. Please maintain digital records, as paper copies will not be mailed.

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:

#### **1. Class I**

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

#### **2. Class II**

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

- II-A- Installation and assembly 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.

#### **3. Class III**

Medical shielding design and area radiation surveys (e.g., shielding evaluation)

- Must submit a sample of a shielding plan and an area survey.

**4. Class IV**

Non-Medical (e.g., Industrial or Analytical) shielding design and area radiation surveys (e.g., shielding evaluation)

- Must submit a sample of a shielding plan and an area survey.

**5. Class VI**

Radiation instrument calibration.

**6. Class VII**

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

- Must submit a sample of a shielding plan and area survey.

**7. 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.

**8. 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 2.7.7)

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. Changes that must be reported include, but are not limited to:

- 1) Name change
- 2) Ownership change
- 3) Change in location address or mailing address.
- 4) Change of contact information (e.g., phone numbers, email address, etc.).
- 5) Change of employee status
- 6) Addition of new employees
- 7) Changes in services provided

Report of changes can be made in writing to [XRayVendors@des.sc.gov](mailto:XRayVendors@des.sc.gov) or mailed to 2600 Bull Street, Columbia, SC 29201.

If the name change is the result of a change of ownership, a new SCDES Form 0824 "Business Registration" and applicable fee are required.

## **TRAINING AND EDUCATIONAL REQUIREMENTS**

(See RHB 2.7.8)

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.

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 "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, assembly, service, and testing of radiation machines and components. This includes the making of diagnostic radiation output measurements to verify performance associated with the installation or service.

a) Experience or education providing familiarity with the type of equipment to be serviced.

b) Training in radiation safety to include principles of radiation protection.

c) Six (6) months of supervised installation, assembly, service, and/or testing of the type of equipment to be serviced.

d) And one (1) of the following:

- One (1) year of documented formal training from the manufacturer's school, military technical training school, or other courses in radiation machine installation, assembly or repair, or an equivalent combination of training and experience.
- An associate's degree in biomedical equipment technology with specialized training in radiation producing devices.
- A bachelor's degree in electrical engineering with specialized training in radiation producing devices.

3) **Class III** – Medical shielding design and area radiation surveys (e.g., shielding evaluation)

- a) Documented training in principles of radiation protection.
- b) Documented training in shielding design and shielding evaluation.
- c) One (1) year of experience in medical shielding design for the specific machine application.
- d) One (1) year of experience performing area radiation surveys.

4) **Class IV** - Non-Medical (e.g., Industrial or Analytical) shielding design and area radiation surveys (e.g., shielding evaluation)

- a) Documented training in principles of radiation protection.
- b) Documented training in shielding design and shielding evaluation.
- c) One (1) year of experience in non-medical shielding design for the specific type of machine application.
- d) One (1) year of experience performing area radiation surveys.

5) **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.
- b) Training in principles of radiation protection.
- c) One (1) year experience in an instrument calibration laboratory.
- d) Must submit a description of the procedures that will be utilized in performing instrument calibrations.

6) **Class VII** - Therapeutic facility and shielding design, area radiation surveys, and 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 in therapeutic radiological 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.

- One (1) year full-time experience in therapeutic radiological physics.
- One (1) 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 (1) 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 (1) sample of each specific type (e.g. therapy, accelerator).

7) **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) Master's degree in physics, medical physics, other physical science, engineering or applied mathematics from accredited college or university and have forty (40) hours practical training and/or supervised experience in x-ray physics.

**OR**

- b) Certification by the American Board of Health Physics, American Board of Radiology, or American Board of Medical Physics in the appropriate fields or specialties in which services are provided.
- c) Documented training in principles of radiation protection (as applicable).
- d) Documented training in shielding design and shielding evaluation (as applicable).
- e) One (1) year of experience in non-medical shielding design for the specific type of machine application (as applicable).

8) One (1) year of experience performing area radiation surveys (as applicable). **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) Master's degree in physics, medical physics other physical science, engineering, or applied mathematics from an accredited college or university and have forty (40) hours practical training and/or supervised experience in x-ray physics.

**OR**

- b) Certification by the American Board of Health Physics, American Board of Radiology, or American Board of Medical Physics in the appropriate fields or specialties in which services are provided.
- c) Documented training in principles of radiation protection (as applicable).
- d) Documented training in shielding design and shielding evaluation (as applicable).
- e) One (1) year of experience in medical shielding design for the specific machine application (as applicable).
- f) One (1) year of experience performing area radiation surveys (as applicable).

Medical Physicists for mammography shall meet the requirements specified by RHB 5.9.3.

**For Vendor classes II-IV:** Companies may submit a comprehensive training plan, addressing the requirements of RHB 2.7.6, 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 2.7.6.

## **VENDOR OBLIGATIONS**

(See RHB 2.8)

- 1) **Notification.** Any person who sells, leases, transfers, lends, moves, assembles, or installs x-ray machines must notify the Department within thirty (30) 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 the SCDES Form 0823 "Report of Sale or Installation of X-ray Equipment" by the Department. This form must be submitted by each Class I and Class II-A vendor each 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 to [XRayVendors@des.sc.gov](mailto:XRayVendors@des.sc.gov) or mailed to 2600 Bull Street, Columbia, SC 29201. 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. Facility registration approval questions and information can be directed to XRayFRA-ShieldingPlans@des.sc.gov.

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. Shielding questions and information can be directed to XRayFRA-ShieldingPlans@des.sc.gov.

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 any shielding plans and/or area surveys provided by that vendor, if required.

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:
  - Data collected during the testing.
  - The testing of all items listed in Part IV, Appendix F, except as noted in the Appendix.
  - 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.
  - The date the testing was performed, the facility name, facility location address, facility registration number issued by the Department, 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.
  - The equipment performance test record shall include a summary of findings and recommendations for necessary improvements and/or corrective actions.

A copy of the equipment performance test shall be provided to the facility either at the time of testing or within thirty (30) calendar days of the testing date. 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 2.11)

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 no later than thirty (30) calendar days after the date of the "Statement of Fees Due". Persons failing to pay the required fees within thirty (30) calendar days after payment is due shall also pay a penalty of fifty dollars (\$50.00). If the fees are not paid within sixty (60) calendar days after payment is due, 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 fifty dollars (\$50.00), and an additional penalty of one hundred dollars (\$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 to the above email addresses or:

SC Department of Environmental Services

Radiation Protection Program

2600 Bull Street

Columbia, SC 29201

PHONE (803) 545-4400

FAX (803) 545-4412

EMAIL –

VENDOR CORRESPONDENCE: XRayVendors@des.sc.gov

SHIELDING: XRayFRA-ShieldingPlans@des.sc.gov

### **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 – Personnel Security Screening Systems

B9 - Complying with Title B - Veterinary Facilities

B10 - Complying with Title B – Hospitals

**Visit our website at: <https://des.sc.gov/programs/bureau-land-waste-management/radiation-protection-program/x-ray-regulations>**