

REGULATORY GUIDE B5

COMPLYING WITH TITLE B - VENDORS



South Carolina Department of Health
and Environmental Control

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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-Ray (Title B), Rules and Regulations for Radiation Control. This guide is intended to assist vendors in complying with Title B.

REGISTRATION (see RHB 2.6)

Each person who is engaged in the business of selling, leasing, or installing or offering to sell, lease, or install x-ray machines or components is required to be registered with the Department. In addition, each person who is engaged in the business of furnishing or offering to furnish any equipment services must also be registered.

Registration with the Department is required **prior to** furnishing or offering to furnish any services.

Both the business and the employees must be registered with the Department. Business (DHEC 823) and employee (DHEC 824) registration forms may be obtained from the Department or at <http://www.scdhec.gov/health/radhlth/x-ray.htm>. Each vendor must pay a non-refundable registration 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:

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

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

- Denote whether your company will be performing the Equipment Performance Test as required by Title B or doing routine servicing (repair, preventive maintenance, etc).
- If performing Equipment Performance Tests you must submit a sample of the equipment performance test procedures and forms.

Class III - Diagnostic radiographic facility and shielding design.

- Must submit a sample of a shielding plan.

Class IV - Diagnostic fluoroscopic facility and shielding design.

- Must submit a sample of a shielding plan.

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

Class VI - Radiation instrument calibration.

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

- Must submit a sample of a shielding plan.

Class VIII - Personnel dosimetry services.

Class IX - General health physics consulting, e.g., independent diagnostic radiation output measurements,

dose analysis, design of safety programs and radiation safety training programs, non-healing arts facility and shielding design, and area radiation surveys.

- Must submit a sample of a shielding plan.

*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 DHEC forms 824 and 825 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 the Material False Statements of Title B RHB 1.12.2

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, and

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

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 includes 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** - Personnel dosimetry service. The applicant must hold current personnel dosimetry service accreditation from the National Voluntary Laboratory Accreditation Program (NVLAP) of the National Institute of Standards and Technology or use NVLAP accredited dosimetry.

9) **Class IX** - General health physics consulting. This includes independent diagnostic radiation output measurements, dose analysis, design of safety programs, and radiation safety training programs, non-healing arts facility and shielding design, and area radiation surveys.

a) Baccalaureate degree in a physical science, engineering, or related field, and two years of progressive experience in medical or health physics; or

b) Baccalaureate degree in a physical 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 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.

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 DHEC form 823, available from 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 a FDA 2579 form is required to be submitted for an installation, the FDA 2579 forms should be submitted along with the corresponding DHEC form 823. 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, 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 approved 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 approved 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, 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 the legible signature of the person who performed the service.

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, 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:

- 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. If any items listed in Part IV, Appendix F are marked as “Fail” or “Noncompliant” and the vendor does not repair or recalibrate the x-ray machine to a “Pass” or “Compliant” status, the vendor shall forward a copy of the report to the Department within ninety (90) days of this testing.

- The date the testing was performed, the legible signature of the person who performed the testing and the manufacturer, model number, serial number, and location of the equipment.
- If recommendations are included in the report they must be clearly indicated as recommendations.

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 2.7.5 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 \$156.25. 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 fifty dollars. 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 fifty dollars, and an additional penalty of one hundred dollars, if the registrant is otherwise in good standing and presents to the Department a satisfactory explanation for his failure to pay the required 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
(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 - Vendor Registration and Responsibilities
- B6 - 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

Visit our web site at: <http://www.scdhec.net/health/radh1th>