

REGULATORY GUIDE B1

REGISTRATION OF X-RAY FACILITIES AND EQUIPMENT



S.C. Department of Health and
Environmental Control

March 2017

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REGULATORY GUIDE B1 REGISTRATION OF X-RAY FACILITIES AND EQUIPMENT

Each facility that has x-ray equipment must be registered with the Department. Registration of x-ray facilities and equipment is regulated under Regulation 61-64, X-Rays (Title B). Registration is a two-step process:

- Step 1: Facility Registration Approval
- Step 2: Equipment Registration

FACILITY REGISTRATION APPROVAL

(See RHB 2.4)

Prior to installing an x-ray machine, a facility must apply to the Department for a Facility Registration Approval (FRA). To receive a Facility Registration Approval, complete and return the FRA request form DHEC 0845 along with the non-refundable application fee of \$62.50.

A FACILITY SHALL NOT INSTALL OR CAUSE TO BE INSTALLED AN X-RAY PRODUCING MACHINE UNTIL THE DEPARTMENT HAS ISSUED A FACILITY REGISTRATION APPROVAL.

If a facility moves to a new location, a letter must be submitted to the Department stating the new location address and any updated facility contact information. Facility Registration Approval is not transferable to a new owner or any additional locations. A new Facility Registration Approval and processing fees are required for the acquisition of an existing facility.

Please note that certain types of equipment require a shielding plan prior to installation in accordance with RHB 4.4. See Regulatory Guide B6 or contact the Department for assistance.

EQUIPMENT REGISTRATION

(See RHB 2.5)

When the Facility Registration Approval is issued, equipment registration forms, DHEC form 819, will be sent to the facility. After the x-ray equipment is operational, the facility has thirty (30) days to return the completed equipment registration forms.

After receiving the equipment registration forms, the Department registers the controls and tubes, and issues an invoice for registration fees. Fees will be prorated for the remainder of the calendar year based upon the schedule of fees which is found in RHB 2.10. Registration fees must be paid within thirty (30) days. A copy of the registration form will be returned to you for your records.

Upon registration of a control, the Department will send the facility a registration sticker to be placed on each control. The registration sticker indicates the registration status of the facility and the control.

ANNUAL FEES

(See RHB 2.10)

Any person issued or granted a registration for the possession and use of x-ray machines must pay an annual

registration fee per machine tube. 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.

LEASING OF EQUIPMENT

(See RHB 2.5.5)

When a facility leases x-ray equipment, it is the facility's responsibility to register the equipment and to ensure that the equipment is maintained to meet Title B regulations.

REPORT OF CHANGE

(See RHB 2.5.3)

Facilities must report to the Department, within thirty (30) days, any changes of status affecting any x-ray machine or facility. Report of a change of status must be made in writing. Changes that must be reported include but are not limited to:

- 1) Change in location address or mailing address.
- 2) Acquiring, selling, or transferring any x-ray machine.
- 3) Change in facility ownership.

OUT OF STATE FACILITIES

(See RHB 2.3.4, RHB 2.4.4 and RHB 2.8)

Prior to bringing an x-ray machine into the State, for any temporary use, a company must apply to the Department for an Out-of-State Facility Registration Approval. Out-of-state facilities must pay a non-refundable application fee of \$62.50 upon submission of the Out-of-State Facility Registration Approval Request Form. An Out-of-State Facility approval shall not be issued until payment of the application fee.

Out of state facilities shall pay an annual flat fee set by RHB 2.10.6. Annual registration fees are due by January 15 of each year.

Before bringing any radiation machine into the state, written notice must be provided to the agency at least five working days before the machine is to be used in the state. The notice shall include the type of radiation machine; the nature, duration, and scope of use; and the exact location(s) where the radiation machine is to be used. If, for a specific case, the five working day period would impose an undue hardship on the person, he may, upon application to the agency, obtain permission to proceed sooner.

The Out-of-State Facility is required to comply with all applicable parts of Title B.

DEMONSTRATION, LOANER, AND TEMPORARY UNITS

Prior notification must be given to the Department before equipment demonstrations are conducted. If a facility that is not currently registered with the Department makes the decision to acquire the unit, it is the facility's responsibility to immediately apply for Facility Registration Approval. If the facility has a current Facility Registration Approval and decides to acquire the demonstration unit, the facility must register the unit within 30 days of installation.

For loaner and temporary units utilized during equipment replacement or room renovations, the provider of the unit must be registered with the Department. It is the facility's responsibility to verify the equipment provider's registration. The facility and the x-ray equipment provider must notify the Department prior to the use of loaner and temporary units. Information, such as the most recent equipment performance testing and surveys, must be available for Departmental review.

DEMONSTRATION, LOANER AND TEMPORARY UNITS MUST MEET AND BE USED IN ACCORDANCE WITH ALL APPLICABLE TITLE B REGULATIONS.

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 - 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

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