

REGULATORY GUIDE B1

REGISTRATION OF X-RAY FACILITIES AND EQUIPMENT

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**South Carolina Department of Health
and Environmental Control**

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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). The facility where the installation will be shall submit any application and shielding review fees as required by RHB 2.3. To receive a Facility Registration Approval, complete and return the FRA request form DHEC 0845 along with the application fee, including the following information:

- 1) Facility Name, Location Address, and Mailing Address
- 2) The name of the Radiation Safety Officer (RSO) who is responsible for radiation protection and the individual's qualifications to serve in this capacity
- 3) Manufacturer, model #, and type and make of x-ray equipment to be installed. For example:
 - i. Siemens Polydoros 80 Rad/Fluoro unit
 - ii. Belmont Model 071 Dental unit
- 4) The name, address, and contact person of the company selling and installing the equipment. If more than one company is involved, then provide the information for all companies.
- 5) Operating policies and procedures See below under "Operating Procedures"
- 6) A shielding plan, if required. Shielding review fees must accompany the shielding plan.
- 7) There is a \$62.50 non-refundable fee required for registration of new facilities.
- 8) The application fee must be submitted with the facility registration approval request. The \$62.50 should be sent in the form of a check or money order made out to SCDHEC.
- 9) After review and approval of this information and receipt of application and shielding review fees, the Department will issue a Facility Registration Approval.

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

For facilities that routinely replace equipment, the information required in the facility registration approval process will only have to be submitted one time. Only information specific to the equipment being replaced would be required to be submitted. If a facility moves to a new location, a letter must be submitted to the Department stating the same procedures will be used, if a facility does not want to resubmit all of their procedures (unless procedure changes have been made). Facility Registration Approval is not transferable to a new owner or any additional locations.

APPLICATION AND SHIELDING REVIEW FEES (See RHB 2.3)

Upon submission of the Facility Registration Approval Request form, each new facility must pay a non-refundable application fee of \$62.50. A Facility Registration Approval will not be issued until payment of the application fee.

Before construction, a facility is required to submit a radiation shielding plan and a shielding review fee to the Department for review and acceptance. The shielding plan must be reviewed by a Class III or a Class IV vendor. After the equipment is installed, "as-built" drawings and the area survey (if applicable) are required to be submitted. See Regulatory Guide B6 for assistance. The shielding plan must be accompanied by a non-refundable \$62.50 Shielding Plan Review fee.

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.

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. When a control is removed from a facility, the facility shall remove the registration sticker. 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 RHB 2.7.2. In addition, a copy of the registration form will be mailed to you for your records.

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 **will be mailed** 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 State regulations.

REPORTING CHANGES (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:

- 1) Change in location or mailing address.
- 2) Acquiring, selling, or transferring any x-ray machine.
- 3) Change in facility ownership.
- 4) Change of the Radiation Safety Officer.
- 5) Changes to an approved shielding plan. This includes installation of different equipment than that which was approved, addition or deletion of components such as a vertical cassette holder, changes in use or occupancies of areas around the x-ray room, or changes in use such as adding an additional SID, or increasing the workload.

OUT OF STATE FACILITIES (See RHB 2.3, RHB 2.4 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 Approval. Out-of-state facilities shall pay a non-refundable application fee of sixty-two dollars and fifty cents (\$62.50) upon submission of the initial Out-of-State Facility Form. An Out-of-State Facility approval shall not be issued until payment of the application fee.

Any person issued or granted a registration for the possession and use of x-ray machine(s) shall pay an annual registration fee per machine tube. Out of state facilities shall also pay an annual flat fee. Annual registration shall be due by January 15 of each year.

No person shall bring any radiation machine into the state, for any temporary use, unless such person has given a written notice 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 Title B requirements and supply the Department with certain information, such as the most recent performance testing results, a shielding plan, etc.

DEMONSTRATION/LOANER/TEMPORARY UNITS

As a general rule, if a demonstration or loaner x-ray unit is left at your facility for longer than 30 days, then it must be registered with the Department under your facility's name. It is the facility's responsibility to ensure that the provider of the unit is registered with the Department and to inform the Department if the unit is acquired. For demonstrations (such as c-arm fluoroscopic units or mobile radiographic units) conducted at a medical facility already possessing registered x-ray units, it is expected and required for safety precautions, such as the use of lead aprons and personnel monitoring, to be utilized. In some cases, such as for c-arm fluoroscopic units, if the unit is acquired, a shielding plan may be required depending on how and where the unit is to be used. Prior notification must be given to the Department for demonstration to be conducted at facilities not currently registered with the Department. If the decision is made to acquire the unit, it is the facility's responsibility to immediately apply for Facility Registration Approval.

For industrial demonstration units, the vendor must submit written procedures to the Department prior to conducting any x-ray unit demonstration. If the decision is made to acquire the unit, it is the facility's responsibility to notify the

Department and to immediately apply for Facility Registration Approval.

For loaner units, such as temporary mobile units (CT units, cath labs, etc.) utilized during equipment replacement/room renovations, the provider of the unit must be registered with the Department, and it is the facility's responsibility to verify registration. These units are required to meet all applicable Title B regulations. The Department is required to be notified by the facility and the x-ray equipment provider prior to the use of a temporary loaner unit. The x-ray equipment provider is required to comply with all Title B requirements and supply the Department with certain information, such as the most recent performance testing results, a shielding plan, etc.

INSPECTIONS (See RHB 1.3)

After facilities and equipment are registered, the Department conducts inspections according to the following schedule:

- Hospitals - Inspected every year
- Mammography x-ray equipment – Inspected every year
- Dental Facilities - Inspected every 4 years
- All other facilities - Inspected every 2 years

Follow-up inspections are conducted as needed as a response to violations cited upon a previous inspection. The Department may also conduct Federal compliance inspections for the Food and Drug Administration within one year after new equipment is installed, regardless of the inspection schedule listed above.

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/radhlth>



FACILITY REGISTRATION APPROVAL REQUEST

Facility Name: _____

Location Address: _____ Contact person: _____

_____ Phone: _____

Mailing Address: _____ Fax: _____

_____ E-mail: _____

Radiation Safety Officer: _____

Qualifications as RSO: _____

Facility type: _____

Equipment Type: _____

Manufacturer, model #, and type of x-ray equipment to be installed: _____

Digital: Yes or No (please circle) _____

Expected date of installation: _____ Shielding Plan log # if applicable _____

Shielding Vendor's Name, Address, Registration #,
Phone #, and Contact Person:

Installation/Sales Vendor's Name, Address, Registration #,
Phone #, and Contact Person:

Purpose for Request:

- New Facility
- Relocation of existing facility (Existing address and registration # _____)
- Acquisition of an existing facility (Existing facility's name, address, and registration # _____)

ENCLOSE THE FOLLOWING ITEMS WITH THIS FORM:

- Operating Procedures - This request cannot be processed without a copy of your operating procedures.
- Application Fee of \$62.50 - This request cannot be processed without this fee.
- Shielding Plan, if applicable-If shielding plan has already been accepted, put the log number here _____.
- If sending a shielding plan, include the shielding plan review fee of \$62.50.
- Operating Schedule (Mobile Facilities Only).

Signature of RSO: _____

This request cannot be processed without the signature of the RSO.

DHEC USE ONLY: Registration # _____ Check # _____ Amount \$ _____ Date approved _____ By _____

DHEC 0845 (7/2009)

**S.C. DEPARTMENT OF HEALTH AND ENVIRONMENTAL CONTROL
BUREAU OF RADIOLOGICAL HEALTH
FACILITY REGISTRATION APPROVAL REQUEST**

PURPOSE:

This form is for the Facility Registration Approval Request. Any facility planning to install an x-ray producing machine shall apply for and receive a Facility Registration Approval prior to the installation of the x-ray machine.

ITEM BY ITEM INSTRUCTIONS:

Facility Name – This refers to the person or company planning to install the x-ray producing machine.

Location Address – Give the address where the machine will be physically located, if different from the mailing address.

Contact person – The person responsible for the submission of this request.

Phone – Self-explanatory.

Mailing Address – Give the Street, City, State, Zip Code.

Fax – Self-explanatory.

E-mail – Self-explanatory.

Radiation Safety Officer (RSO) – Give the name of the person who will be responsible for radiation protection at the facility.

Qualifications of RSO – List the qualification/training of the RSO.

Facility Type – Indicate the facility type using the list below.

Equipment Type – Indicate the equipment type using the list below.

Manufacturer, model #, and type of x-ray equipment to be installed – Self-explanatory.

Digital – Circle Yes or No.

Expected date of installation – Self-explanatory.

Shielding Plan log # (if applicable) – Give the log # of the accepted shielding plan.

Shielding Vendor – Give the name, address, Registration #, Phone #, and Contact person for the Vendor preparing the shielding plan.

Installation/Sales Vendor – Give the name, address, Registration #, Phone #, and Contact person for the Vendor installing/selling the x-ray equipment.

Purpose for Request – Indicate by checking the appropriate purpose for the request.

Enclose the Following Items with this Form – Indicate by checking the items enclosed with this form.

OFFICE MECHANICS AND FILING:

When the FRA request forms are received, stamp the form and all attachments with the date received. After review and approval, the form and all attachments are placed into the registrant's file, and the FRA approval is returned to the registrant for their records.

Type of Facility

Academic	Private Dental	County Health Department
Private Physician	Dental Clinic	Accelerator Facility
Medical Clinic	Chiropractor	Other (Specify)
Medical Hospital	Podiatrist	
Industry	Veterinarian	
Transportation	Security	
Research	Vendor	
Nursing Home	Prison	

Type of Equipment

Radiographic	Ceph/Dental	Baggage Checker
Fluoroscopic	Electron Microscope	Bone Densitometer
Combination (Rad & Fluoro)	Spectrograph	Pan/Dental - 2 tubes
Dental	Cephalometric	Ceph/Dental – 3 tubes
Therapy	Panoramic	Pan/Ceph – 1 tube
Diffraction	Cabinet X-ray	Pan/Ceph – 2 Tubes
CT scanner	Lithotripter	Other (Specify)
Accelerator	C-arm fluoroscopic	
X-ray Gauge	Mammography	
Simulator	Stereotactic	
X-ray fluorescence (Non-medical)		