REGULATORY GUIDE B8
COMPLYING WITH TITLE B - BONE DENSITOMETERS

S.C. Department of Health and Environmental Control

March 2017

Table of Contents

REGULATORY GUIDE B8
COMPLYING WITH TITLE B – BONE DENSITOMETERS

Each medical facility that is registered with the Department is required to comply with Regulations 61-64, X-Rays (Title B), which are the regulations concerning x-ray equipment. This guide is intended to assist the medical facility in complying with Title B regulations.

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.

SHIELDING PLANS

(See RHB 4.4)
Table units - A shielding plan or radiation area survey, which is acceptable only if prior approval is given, is required for table units. Shielding plans must be submitted and accepted by this Department prior to installation. The facility must indicate in writing that an area survey will be performed and submitted to this Department within 30 days of installation. Both shielding plans and requests for post installation radiation area surveys require the submission of a shielding review fee of $62.50.

Peripheral units - A shielding plan or survey is **not** required for peripheral units. The bone densitometer must be located in a controlled area.

A shielding plan is not required upon the replacement of x-ray equipment with like equipment and when there are no other changes that would render the original shielding plan inaccurate. This must be determined by a Class III, IV, V, VII, VIII, or IX vendor. The vendor must notify the Department on DHEC Form 2779. No fee is required for the submission of an equipment notification form. This notification must be submitted to the Department prior to the replacement.

Please see Regulatory Guide B6 or contact the Department for assistance.

REGISTERING EQUIPMENT

(See RHB 2.5)

All x-ray equipment is required to be registered with the Department within thirty (30) days of installation. See Regulatory Guide B1 for assistance in registering equipment. In addition, upon registration of equipment (a control), the Department shall issue the facility a registration sticker to be placed on each control. The registration stickers shall be placed on the control panel in a clearly visible location.

REPORT OF CHANGE

(See RHB 2.5.3)

The registrant is required to report, in writing, any changes that affect the x-ray facility or x-ray equipment. This includes change of location or mailing address, acquiring or disposing of x-ray equipment, changes in operating conditions that may affect an approved shielding plan, or any change in ownership of the facility.

TRAINING

(See RHB 4.2.2)

Each medical facility is required by RHB 4.2.2 to ensure that all x-ray operators possess a current, valid certificate from the South Carolina Radiation Quality Standards Association (SCRQSA). Each operator's current certificate must be displayed in public view. The registrant may also post a notice to the public that SCRQSA Certificates are available for review upon request. Licensed practitioners (physicians, chiropractors, podiatrists, etc.) are exempt from the certification requirements.

An operator is defined as one who applies ionizing radiation to humans for diagnostic purposes. An operator also includes anyone who performs x-ray exam setups, patient positioning, or technique selection.

Each operator, including physicians, is also required to receive training specific to the equipment and operating conditions of the facility. This training must be documented for each operator and maintained at the facility.

ADMINISTRATIVE REQUIREMENTS

(See RHB 4.10.4)

The following items are required:

- Radiation area signs. Each entrance into a radiation area must be posted with a radiation area sign.
- A sign shall be posted, so as to be easily seen by the patient, to the effect that if there is a pregnancy or the possibility of a pregnancy, the physician shall be notified.

- A "Notice to Employees" sign (SC-RHA-20) must be posted in an area where it can be reviewed by all employees. A copy of this form is available on the DHEC website.
- The x-ray control must have a label on it which states "WARNING: This x-ray unit may be dangerous to patient and operator unless safe exposure factors and operating instructions are observed."
- A patient log is required at each facility. The patient log must show the patient's name, the type of examination, identification of the operator performing the examination, and the dates the examinations were performed (See RHB 4.2.15).

Please note that all bone density examinations must be prescribed by a licensed practitioner (See RHB 4.2.11).

DIAGNOSTIC MISADMINISTRATIONS

(See RHB 1.11)

Misadministration is the administration of radiation to the wrong patient or performance of a diagnostic procedure other than that ordered by a prescribing licensed practitioner.

A diagnostic misadministration requires the registrant shall promptly investigate its cause and make a record for Department review. The record must contain the names of all individuals involved in the misadministration (including the physician, allied health personnel, the patient, and the patient's referring physician), the patient's identification number, a brief description of the event, the effect on the patient, and the action taken, if any, to prevent recurrence. The records of misadministration must be maintained for three years for diagnostic misadministrations.

RECORDS

(See RHB 1.10)

The registrant is required to maintain all records required to comply with or show compliance with Title B. These records include:

- Records showing receipt, transfer, use, storage, and disposal of all sources of radiation. (RHB 1.10.1)
- Records showing model and serial numbers of all tubes and controls. (RHB 1.10.2.1)
- Records of surveys, equipment performance tests (to include corrective action), maintenance, and modifications performed on the x-ray system and components, with the names of persons who performed such services. (RHB 1.10.2.4)
- Copies of all correspondence with the Department. (RHB 1.10.2.5)
- Records of misadministrations. (RHB 1.11.2)
- Records of prior occupational dose for employees (RHB 3.20)
- Records of personnel monitoring results. (RHB 3.22.1)
- Records of employee training to include operator certification. (RHB 4.2.2 & 4.2.2.7)
- X-ray logs. (RHB 4.2.15)
- A shielding plan accepted by the Department and any required area surveys or as-built drawings. (RHB 4.4)
- Any other records of routine checks, quality control, or testing that may be required.

INSPECTIONS

The Department conducts routine periodic inspections of x-ray facilities. The Department will also conduct inspections if a complaint is received or if a facility requests an inspection. If violations are found on an inspection, a follow-up inspection may be conducted if the Department deems it necessary. Inspections by the Department are mandatory and **the Department has the right to make unannounced inspections.**

The inspection consists of checking/verifying the operation of the x-ray equipment and reviewing records as outlined in the attached checklist. The facility can greatly assist the Department inspector by using the attached inspection checklist to ensure that all records are available for review. The checklist also contains some questions that will be asked by the inspector. At the conclusion of the inspection, the inspector will conduct an exit interview to discuss items of non-compliance as well as any other items the inspector deems relevant.

The inspector may leave an inspection report at the conclusion of the inspection or a written report will be mailed to the facility. Any violations and/or recommendations will be included in this report. After receiving the report, the facility has twenty days to respond, in writing, to the Department. This twenty day notification must indicate the corrective action that will be taken to correct any violations. The Department will respond, in writing, to the twenty day notification as needed.

All corrections must be made within sixty (60) days of receipt of the inspection report. The facility must notify the Department, in writing, by this date that corrections have been made. Corrective action must be described for each violation. The facility has the option of accepting Departmental recommendations. Each violation and recommendation must be addressed individually. It will not suffice to simply state that all violations and recommendations have been corrected. If a facility chooses not to accept a recommendation made by the Department, the facility should state so in their response. After the Department has received the sixty day notification and accepted the corrective action, a Completed Corrective Action letter will be sent to the facility.

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
B11 - Complying with Title B - Therapy

Visit our web site at: www.scdhec.gov/Health/FHPF/HealthFacilityRegulationsLisensing/X-RayFacilitiesRadioactiveMaterials/X-RayFacilities/

CHECKLIST FOR DHEC INSPECTION

Bone Densitometer

Please have available the following records for the DHEC inspector:

_____ Personnel monitoring reports

_____ Records of previous occupational dose for employees and records of dose for employees who work at other facilities

_____ Patient logs

_____ Documentation of operator training. (SCRQSA certificates and facility specific training)

_____ Misadministration records

_____ A list of all operators of the x-ray equipment. This includes routine operators, as well as back-up operators and part-time operators. Indicate on the list the title of each operator, such as RT, RN, etc., and SCRQSA certificate number.

Please be familiar with, and be prepared to show the DHEC inspector the following items:

_____ Posted radiation area signs

_____ Posted pregnancy posters

_____ Posted Notice to Employees

_____ Patient Log