

**REGULATORY GUIDE B8**

**COMPLYING WITH TITLE B - BONE DENSITOMETERS**



South Carolina Department of Health  
and Environmental Control

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## 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). 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.

#### **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 approved by this Department prior to installation, or 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.

## **REGISTERING EQUIPMENT** (See RHB 2.5)

All x-ray equipment is required to be registered with the Department within thirty (30) days of acquisition. See Regulatory Guide B1 for assistance in registering equipment. The registrant is also 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 procedures that may affect an approved shielding plan and any changes in the accepted operating procedures. 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.

## **REQUIREMENTS FOR OPERATING PROCEDURES** (See RHB 4.2.3)

All facilities are required to have written operating procedures available to all x-ray operators. Each registrant shall maintain documentation indicating that each operator has read and agrees to adhere to the operating procedures and shows competency in operating the x-ray equipment. Generic procedures obtained from vendors shall be modified to reflect the actual practices of the facility. The procedures must include the following items, as a minimum:

- 1) **Policies and Procedures for Patient Holding.** The procedures must state whether or not, as a matter of policy, patients and/or films will be held at that facility. Whenever possible, an adult accompanying the patient should be used for holding. Pregnant females should not be used to hold a patient. Methods for protecting the human holder, such as wearing lead aprons and gloves, may be included. If a facility is required to routinely hold patients and/or films, then procedures to ensure that no one person is used routinely to hold patients must be included. If an employee may be required to hold patients or films more than three times a quarter, then the procedures must also address personnel monitoring of human holders.
- 2) **Policies and Procedures for Pregnant Workers.** Procedures to be followed when a worker declares her pregnancy should be included, as well as methods of informing workers of the total exposure received during gestation. The Nuclear Regulatory Commission's Regulatory Guide 8.13, "Instruction Concerning Prenatal Radiation Exposure" should be used for guidance concerning pregnant workers. This guide is available from the Superintendent of Documents, U.S. Government Printing Office, P.O. Box 37082, Washington, D.C. 20013-7082.
- 3) **Policies and Procedures Regarding the Use of Gonadal Shielding.** The proper use and placement of gonadal shielding must be addressed. If such shielding interferes with individual projections, then those projections should be specified.

The lead aprons and gloves must be checked annually for cracks and holes that could compromise the radiation protection they provide. Documentation of this testing shall be kept for two years or until the next Department inspection.

- 4) **Policies and Procedures for Pregnant Patients.** The procedures should include methods for determining possible patient pregnancy. Prescription of x-ray examinations of pregnant or possibly pregnant patients shall assure that medical consideration has been given to possible fetal exposure and appropriate measures are taken. X-ray techniques for minimizing fetal exposure should be included.

Methods of determining fetal exposure and procedures to follow for advising the woman and her practitioner of the exposure received by the fetus may also be included.

- 5) **Policies and Procedures for Personnel Monitoring.** See "Personnel Monitoring." The operating procedures must state whether or not personnel monitoring devices will be used at the facility. The procedures may tell employees how to correctly use personnel monitoring devices and how to care for personnel monitoring devices. The name of the person responsible for distribution, collection, and records of badges may be stated. The location of control badges may be given. The policies for reporting and investigating over-exposures should be stated. A prohibition against intentionally exposing any control or personnel badge should be included. Procedures may also be included instructing workers on how they may obtain the results from the monitoring.
- 6) **Procedures for Training New Employees.** See "Training." The procedures must include a statement indicating that all operators, other than licensed practitioners, will be certified by the South Carolina Radiation Quality Standards Association (SCRQSA). For more information, contact the SCRQSA at (877) 771-6141 or visit their website at [www.scrqsa.org](http://www.scrqsa.org).
- 7) **Methods for Quality Assurance.** The procedures must state the methods that the facility will use to assure that they are producing quality radiographs. The items that may be, but are not limited to be addressed are (a) Equipment Performance tests of the x-ray system (b) a repeat analysis program and (c) standards for processing. See "Quality Assurance."

#### **PRIOR OCCUPATIONAL EXPOSURE** (See RHB 3.20)

Each registrant has the responsibility to require an employee to disclose their previous occupational dose prior to working at the registrant's facility. The registrant must obtain a written, signed statement that states either that the worker had no prior occupational dose during the current calendar quarter or states the nature and amount of any prior occupational dose during the current calendar quarter. For the purpose of this statement, the current calendar quarter is interpreted to mean the most recently available calendar quarter. The registrant must maintain these written statements until the Department authorizes their disposal.

#### **OCCUPATIONAL EXPOSURE AT MULTIPLE FACILITIES** (See RHB 3.4.4)

If an employee is likely to receive a dose in excess of 50% of the annual allowable dose, the exposure that an employee receives at any facility must be recorded by each facility at which the employee works. The simplest way to achieve compliance with this requirement would be for an employee to be provided with a monitor to be worn at all facilities where employment occurs, and an individual monitor issued by each facility. Then, total occupational dose could be tracked, as well as doses received at individual facilities.

#### **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 or therapeutic purposes. An operator also includes anyone who performs x-ray exam setups, patient positioning, technique selection, therapy treatment setups, setting of treatment parameters, verification of treatment accessories, or documents daily treatments for a patient's chart.

Each operator, including physicians, is also required to receive training specific to the equipment and procedures in use at the facility, including machine specific training, use of personnel monitoring devices, quality assurance procedures, and the operating procedures required by RHB 4.2.3. This training must be documented for each operator and maintained at the facility. For new employees, this training must begin within 30 days after employment.

The training records will be checked as part of the routine inspection by the Department. In addition, the Department may request at any time to review the training records of an employee.

#### **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 must be posted in a conspicuous area that notifies patients to inform the technologist if they are pregnant or might be pregnant.
- 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.
- Approval for Screening – Screening is defined as "testing using x-ray machines for the detection or evaluation of health indications when such tests are not specifically and individually ordered by a licensed practitioner of the healing arts legally authorized to prescribe such x-ray tests for the purpose of diagnosis or treatment." A screening program cannot be initiated without prior approval from the Department. The Department is not approving bone density screening programs at this time.

#### **MISADMINISTRATIONS** (See RHB 1.11)

Misadministration means the administration of radiation to the wrong patient or performance of a diagnostic or therapeutic procedure other than that ordered by a prescribing licensed practitioner (3) a therapeutic radiation dose from a source such that errors in the source calibration, time of exposure, or treatment geometry result in a calculated total treatment dose differing from the total prescribed treatment dose by more than 20 percent, (4) a therapeutic

radiation dose from a source such that errors in the source calibration, time of exposure, or treatment geometry result in a calculated total treatment dose differing from the total prescribed treatment dose by more than 10 percent, when the treatment consists of three or fewer fractions, or (5) when the calculated weekly treatment dose exceeds the weekly prescribed dose by 30 percent or more of the weekly prescribed dose.

Situations that would not constitute misadministration would include, for example, incorrect ordering of an exam, such as ordering a lateral chest x-ray when a PA chest x-ray was desired. Another example that is not misadministration would be if, after review of films from an exam, a radiologist who was not the original ordering physician decides that additional views are necessary to adequately image the area of interest. Repeat films performed due to patient motion, processing errors or problems, incorrect patient positioning, or improper radiographic technique selection are not considered misadministrations.

Each registrant must retain records of misadministrations. The record must contain the name of all individuals involved in the misadministration (including the physician, allied health personnel, the patient, and the patient's referring physician), the patient's social security number or 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 and ten years for therapy misadministrations.

The action that a registrant must take in response to a misadministration depends on the type of misadministration that occurs. When a misadministration involves a diagnostic procedure, the registrant shall promptly investigate its cause, make a record for Department review, and maintain the records for three years.

### **OVEREXPOSURES** (See RHB 3.24 and RHB 3.25)

The registrant is required to report to the Department any exposure of an individual in excess of any limit in the regulations. The registrant is also required to report any radiation levels in an unrestricted area that are in excess of 10 times any limit in the regulations. The time frame for reporting overexposures depends on the exposure that an individual receives. Immediate, 24 hour, and/or thirty day written notification may be required. See RHB 3.24 concerning radiation levels and the requirements for reporting.

### **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, controls, and beam limiting devices. (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)
- Repeat analysis records. (RHB 4.2.16.4)
- A scale drawing of the x-ray room showing occupancies of surrounding areas, and composition of all walls, or results of an area survey performed by a Class IX vendor showing radiation levels around the room. (RHB 4.4.6)
- 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 severity of the violations warrants it. Inspections by the Department are mandatory, but every attempt will be made to accommodate patient schedules. **The Department does have 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. Generally, an inspection requires use of the x-ray equipment for about one hour per control. At the conclusion of the inspection, the inspector will conduct an exit interview to discuss items of non-compliance.

The inspector may leave an inspection report at the conclusion of the inspection or send a written report to the facility within approximately two weeks of the inspection. 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 - 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>**

**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.
- \_\_\_ Operating procedures. (Including a written policy on Pregnant Workers, Pregnant Patients, Patient Holding, Personnel Monitoring, Training Procedures, and Quality Assurance)

**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