

**REGULATORY GUIDE B2**

**COMPLYING WITH TITLE B - MEDICAL FACILITIES**



S.C. Department of Health and  
Environmental Control

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## **REGULATORY GUIDE B2 COMPLYING WITH TITLE B - MEDICAL FACILITIES**

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.

### **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. 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 accepted shielding plan and any changes in the ownership of the facility.

### **SHIELDING PLANS**

(See RHB 4.4)

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, IV, VII, or IX vendor. After the equipment has been installed, "as-built" drawings and an area survey (if applicable) are required to be submitted. The shielding plan must be accompanied by a \$62.50 Shielding Plan Review fee.

A shielding plan is required in the following situations:

- 1) An existing x-ray machine or control generator is replaced with a unit that has increased capabilities;
- 2) Any mobile or portable units used in a single location for more than 5 consecutive days;
- 3) Any space utilized as a radiation area for more than 5 consecutive days.

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.

### **PERSONNEL MONITORING**

(See RHB 3.12)

Personnel monitoring is required in the following situations:

- 1) When an employee is likely to receive greater than 10% of their occupational dose limit for one year. (See RHB 3.4, RHB 3.7, and RHB 3.8);
- 2) When an individual enters a high radiation area;
- 3) Personnel working with medical fluoroscopic equipment;
- 4) Declared pregnant workers who request an additional badge for monitoring doses underneath lead aprons;
- 5) When the Department deems it necessary.

Personnel monitoring badges must be returned for processing within 45 days of the end of the monitoring period. Direct read dosimeters must be read according to manufacturer specifications. The Registrant must document explanations of any late, absent, or unused badges and maintain these records for Departmental review.

When a protective lead apron is worn by the operator and a personnel monitoring device is used, the monitoring device must be worn at the collar outside of the apron. When two monitoring devices are worn (one outside and one under the apron), the one outside will be considered the permanent record for the individual.

The Radiation Safety Officer may decide that an Effective Dose Equivalent be used as the permanent record. Protective equipment must be used by those individuals utilizing the EDE. The use of protective equipment

must be documented and this documentation must be reviewed periodically by the RSO. The RSO must make periodic visits to observe adherence to proper radiation safety practices. These visits must be documented and this documentation must be available for Departmental review. The Department may immediately revoke EDE approval if a violation of RHB 3.12.5 occurs.

The personnel monitoring devices used to determine compliance with occupational dose limits must be processed by a vendor which possesses current personnel dosimetry accreditation from the National Voluntary Laboratory Accreditation Program (NVLAP) of the National Institute of Standards and Technology (NIST). The accreditation must be for the type of radiation for which the individual wearing the device is monitored.

Each registrant must maintain records showing the radiation exposure for each person that is required to be monitored. Adjustments to the dose of permanent record must be determined by the Radiation Safety Officer.

Personnel monitoring records must be retained indefinitely or until this Department authorizes their disposal, even if the service is discontinued.

### **PRIOR OCCUPATIONAL EXPOSURE**

(See RHB 3.20)

Each registrant has the responsibility to determine the occupation radiation dose received within the current year for any new individual who enters the facility's restricted or controlled area. This may be done through signed written statements or previous personnel monitoring reports for the individual. The registrant must maintain these records for 5 years after the termination of the registration.

### **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. Each facility must ensure that the total dose received by the employee at both locations does not exceed the occupational limits.

### **TRAINING PLANS**

(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, and 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.

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.

## **QUALITY ASSURANCE**

(See RHB 4.2.16)

A quality assurance program should include equipment performance tests (initial or annual calibrations) of the x-ray system and repeat analysis. It is each registrant's responsibility to evaluate the performance of their x-ray imaging systems and tailor their quality assurance plan accordingly.

### **1) Equipment Performance Tests (Calibrations)**

Equipment performance testing for each x-ray unit must be performed, by a registered vendor, at the time of installation, annually, and at any time the Department deems necessary. Equipment performance test results must include numerical data. It must also include an indication of Pass/Fail or Compliant/Non-compliant. Any items found to be non-compliant must be corrected within 60 days of receiving the report. Records showing the equipment performance testing and the correction of any non-compliant items found must be retained for five years or until the next Departmental inspection, whichever is later.

**Refer to Part IV-Appendix F for the list of the minimum criteria for equipment performance testing.**

**A list of registered vendors is available at our website, [www.scdhec.gov](http://www.scdhec.gov).**

### **2) Repeat analysis program.**

A repeat is any radiograph that has been retaken, thereby exposing the patient to additional radiation, due to some error, breakdown, or degradation in the radiographic process.

Each registrant must establish a repeat analysis program. The analysis must be performed at least quarterly and include, at a minimum, the overall repeat rate (%) and the cause for repeats. Repeat analysis records must be maintained for two years or until the next Department inspection, whichever is later.

Repeat Rate Equation:  $[\text{total \# of repeats} / \text{total \# of films}] \times 100 = \text{repeat rate\%}$

Facilities with a single operator may document reasons for repeats on the patient log in lieu of calculating a repeat analysis rate.

### **3) Image Processing:**

#### **A. Manual Film Processing Systems**

(See RHB 4.2.17.1)

When a facility performs manual film processing, the following items are required:

- 1) The darkroom must be light tight to the dark adapted eye (RHB 4.2.16.2);
- 2) Processing tanks that are mechanically rigid and corrosion resistant;
- 3) A dedicated darkroom thermometer to adjust the film processing time according to

- solution temperature;
- 4) A dedicated darkroom timer with an adjustable preset function to adjust film processing time according to solution temperature;
  - 5) Documentation to show when film processing chemicals are changed;
    - a) This documentation must be maintained for two years or until the next Department inspection, whichever is later.
  - 6) If a safelight is used, it needs to be adequate for the film speed; and
  - 7) A time-temperature developing chart.

**SIGHT DEVELOPING OF FILMS IS PROHIBITED.**

**Other requirements include:**

- 1) Proper storage of film;
- 2) Cassettes and intensifying screens must be inspected, cleaned, and replaced as necessary. Documentation of this inspection and cleaning must be maintained for two years or until the next Department inspection; and
- 3) Film developing solutions are prepared in accordance to the manufacturer.

The film manufacturer or a vendor registered with the Department should be able to assist facilities in obtaining the items listed above.

**B. Automatic Film Processing Systems**

(See RHB 4.2.17.2)

When a facility uses an automatic process or other closed processing system, the following items are required:

- 1) The darkroom must be light tight to the dark adapted eye (RHB 4.2.16.2);
- 2) The temperature of film processing chemicals must be appropriate for the type of film;
- 3) Film processing chemicals used and their replenishing rate must be appropriate for type of film;
- 4) Documentation to show when film processing chemicals are changed; and
  - a) This documentation must be maintained for two years or until the next Department inspection, whichever is later.
- 5) If a safelight is used, it needs to be adequate for the film speed.

**Other requirements include:**

- 1) Proper storage of film;
- 2) Cassettes and intensifying screens must be inspected, cleaned, and replaced as necessary. Documentation of this inspection and cleaning must be maintained for two years or until the next Department inspection; and
- 3) Film developing solutions are prepared in accordance to the manufacturer.

The film manufacturer or a vendor registered with the Department should be able to assist facilities in obtaining the items listed above.

**C. Digital Imaging Acquisition Systems**

(See RHB 4.3.12)

When a facility uses a digital imaging acquisition system, the following items are required:

- 1) The manufacturer's current operating manual is available for Department review;
- 2) Protocol for image quality established by the manufacturer is followed; and
- 3) Records documenting adherence to the manufacturer's protocol is maintained for two years or until the next Department inspection, whichever is later.

### **ADMINISTRATIVE REQUIREMENTS**

The following items are required to be posted or present at x-ray facilities:

- 1) Radiation area signs. Each entrance into a radiation area must be posted with a radiation area sign. If it is a high radiation area, then it must be posted with a high radiation area sign. This includes any access from outside the room. (See RHB 3.16)
- 2) Technique charts. (See RHB 4.2.6) For systems not equipped with an operational anatomic programming option, a technique chart reflecting the techniques currently in use must be posted at each control panel stating the following:
  - a) The patient's body part and anatomical size versus technique factors to be used. For pediatric patients, the body part thickness versus age may be used.
  - b) The source to image distance (SID) to be used.

**\*If an AEC system is operated in manual mode, the technique chart must specify the above two requirements.**

- 3) 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.
- 4) 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." This label shall be legible and in clear view. (See RHB 4.3.1)
- 5) A patient log is required at each facility. (See RHB 4.2.15) The patient log must include the following:
  - a) The patient's name;
  - b) The type of examination, as denoted on the technique chart;
  - c) The operator performing the examination;
  - d) The date the examination was performed; and
  - e) Fluoroscopy time or number of timer resets, if applicable.

Patient log records must be maintained for two years or until the next Department inspection, whichever is later.

- 6) Fluoroscopic Outputs. Entrance exposure rates for each clinically used fluoroscopic mode must be measured annually by a registered vendor. The current results must be posted where any operator may have ready access to them while using the fluoroscope. (See RHB 4.9.4.3.7)



- 7) A "Notice to Employees" must be posted in an area where it can be reviewed by all employees. A copy of this form is available on our website, [www.scdhec.gov](http://www.scdhec.gov).
- 8) Protective equipment and apparel must be checked at least annually for cracks and holes that could compromise the radiation protection they provide. Records of this testing must be retained for two years, or until the next Department inspection, whichever is later.

### **DIAGNOSTIC MISADMINISTRATIONS**

(See RHB 1.11.2)

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

Repeat films are not considered misadministrations.

A diagnostic misadministration requires the registrant to promptly investigate its cause and make a record for Department review. 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 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 misadministration.

### **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**

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)
- Records of protective equipment and apparel testing. (RHB 4.2.8)
- An accurate 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 Department deems necessary. 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 as well as 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. 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 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 - 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 Facilities

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

## **Checklist for DHEC Inspection**

### **Medical Facility**

#### **Please have available the following records for the DHEC Inspector:**

- \_\_\_ Records from x-ray equipment performance testing service records
- \_\_\_ Documentation that all x-ray operators have machine specific training on facility's x-ray equipment
- \_\_\_ SCRQSA certificates for x-ray operators (not applicable for licensed practitioners)
- \_\_\_ Personnel monitoring reports
- \_\_\_ Records of previous occupational dose for employees
- \_\_\_ Records of occupational dose for employees working at multiple facilities
- \_\_\_ Records of processor maintenance, cassette/screen cleaning
- \_\_\_ Records of digital imaging system quality control and the system manufacturer's current manual
- \_\_\_ Documentation of protective apparel inspection/testing
- \_\_\_ Records of repeat analysis, to include overall repeat rate and reasons for repeats
- \_\_\_ Misadministration records.

#### **Please be familiar with, and prepared to show the DHEC Inspector the following items:**

- \_\_\_ Posted pregnancy warning signs
- \_\_\_ Posted radiation area signs
- \_\_\_ Posted "Notice to Employees"
- \_\_\_ Posted technique charts
- \_\_\_ Posted measured fluoroscopic output rates, if applicable
- \_\_\_ Patient log
- \_\_\_ Copy of shielding plans and area survey/as-built drawings