

REGULATORY GUIDE B2

COMPLYING WITH TITLE B - MEDICAL FACILITIES



SC DEPARTMENT *of*
ENVIRONMENTAL
SERVICES

September 2025

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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 SCDES Form 0845 "Facility Registration Approval Request" along with the non-refundable application fee of \$62.50. This form may be submitted by email to XRayFRA-ShieldingPlans@des.sc.gov or mailed to 2600 Bull Street, Columbia, SC 29201. Fees may be paid by check, or an invoice will be issued after the application is received. Applications are processed in the order received, with a typical turnaround time of 15 business days (excluding weekends and holidays) once a complete submission and payment are received. As the Department transitions to electronic correspondence, all approval letters and documentation will be delivered electronically. Please maintain digital records, as paper copies will not be mailed.

A FACILITY SHALL NOT INSTALL AN X-RAY PRODUCING MACHINE UNTIL THE DEPARTMENT HAS ISSUED A FACILITY REGISTRATION APPROVAL.

If a facility relocates, SCDES Form 4262 "Report of Change" must be submitted to the Department within thirty (30) calendar days. This form may be submitted by email to XRayRegistration@des.sc.gov or mailed to 2600 Bull Street, Columbia, SC 29201. Facility Registration Approval is not transferable to a new owner or additional locations. A new Facility Registration Approval and associated 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.

REGISTERING EQUIPMENT

(See RHB 2.5)

All x-ray equipment must be registered with the Department within thirty (30) calendar days of installation by submitting SCDES Form 0819 "Registration and/or Deletion of X-ray Producing Machines." This form may be submitted by email to XRayRegistration@des.sc.gov or mailed to 2600 Bull Street, Columbia, SC 29201. The Department will issue a registration sticker for each control panel. Stickers must be affixed in a clearly visible location to indicate the facility's registration status.

See Regulatory Guide B1 for additional details on registration requirements.

REPORT OF CHANGE

(See RHB 2.6)

Registrants are required to notify the Department in writing within thirty (30) calendar days of any change affecting the facility or its registration. Changes that must be reported include, but are not limited to:

- 1) Change in location address or mailing address.
- 2) Name change.
- 3) Change of facility contact information.
- 4) Change of billing contact information.
- 5) Radiation Safety Officer (RSO) change.

Submit changes on SCDES Form 4262 "Report of Change" by email to XRRegistration@des.sc.gov or by mail to 2600 Bull Street, Columbia, SC 29201.

If the name change is the result of a change of ownership, a new Facility Registration Approval Request (SCDES Form 0845) and applicable fee are required.

SHIELDING PLANS

(See RHB 4.4)

A radiation shielding plan is required for applicable x-ray installations. Shielding plans must be prepared and submitted by a registered vendor (Class III, IV, VII, VIII, or IX, depending on application type).

To request review, complete and submit SCDES Form 0846 "Shielding Plan Review Application," the shielding plan, and supporting documents along with the non-refundable \$62.50 fee. Submit by email to XRRegistration@des.sc.gov or by mail to 2600 Bull Street, Columbia, SC 29201. Fees may be paid by check, or an invoice will be issued after the application is received. Applications are processed in the order received, with a typical turnaround time of 15 business days (excluding weekends and holidays) once a complete submission and payment are received.

Shielding plans are required for:

- 1) All diagnostic medical x-ray units installed at new facilities
- 2) Relocation of a unit within a facility or the relocation of a facility to a new physical address.
- 3) Table bone density units (or area survey if prior approval is granted).
- 4) Mobile and portable radiographic units with a permanent cassette holder as addressed in RHB 4.4.4.6.
- 5) Any space utilized as a radiation area for a period of five (5) or more consecutive days.

Shielding plans may be required for:

- 1) Modifications to an existing accepted installation, such as moving the operator's barrier, or installing vertical cassette holder.
- 2) Changes to an accepted plan that may affect the shielding requirements, such as changing the film/screen system used, etc.

Within thirty (30) calendar days of installation, a radiation area survey must be completed and submitted along with SCDES Form 4112 "As-Built/Area Survey Submission Form". Submit by email to XRayFRA-ShieldingPlans@des.sc.gov or by mail to 2600 Bull Street, Columbia, SC 29201. The survey must include a scale drawing of the x-ray room indicating the composition of the walls, floor, ceiling, windows, and doors, and the placement of the x-ray equipment, including the table, control, and vertical cassette holder, if provided. The survey shall include an evaluation of the adequacy of each protective barrier to include the ceiling and the floor, the operator's location, and if film is used, the film storage area. The survey shall include the date performed, the legible signature of the person performing the survey, and a certification that the shielding is adequate.

A shielding plan is not required upon the replacement of an x-ray **control or generator** 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, VII, VIII, or IX vendor. The vendor must notify the Department on SCDES Form 2779 "Control/Generator Replacement Notification (CGRN)". Submit by email to XRayFRA-ShieldingPlans@des.sc.gov or by mail to 2600 Bull Street, Columbia, SC 29201. No fee is required for the submission of the CGRN form. This notification must be submitted to the Department withing thirty (30) calendar days of such replacement.

A shielding plan **is required** when a facility replaces an existing x-ray system.

See Regulatory Guide B6 for additional details on shielding requirements 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 forty-five (45) days of the end of the monitoring period. All dosimeters must be read at least quarterly, the results from the readings recorded and evaluated for compliance with RHB 3.3.2 and 3.4 and be available for Departmental review. 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 (EDE) 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 or his/her designee must make periodic semi-annual visits, at a minimum, 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 and/or attempt to obtain records of prior occupation dose for five (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 (5) 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.

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 (2) 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 with 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 (2) years or until the next Department inspection; and
- 3) Film developing solutions are prepared in accordance with 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 (2) years or until the next Department inspection, whichever is later.

ADMINISTRATIVE REQUIREMENTS

(See RHB 3.15, RHB 4.2.6.4, RBH 4.2.7, RHB 4.3.1, RHB 11.2.3, and RHB 4.2.8)

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. The symbol shall be magenta, purple, or black, and the background shall be yellow. 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 3.15 & 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 automatic exposure control (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 (2) years or until the next Department inspection, whichever is later.

- 6) 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.des.sc.gov.
- 7) 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 (2) years, or until the next Department inspection, whichever is later. (See RHB 4.2.8)

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 prescribing physician, allied health personnel and the patient's referring physician), the patient's identification number, a brief description of the misadministration, the effect on the patient, what improvements are needed to prevent recurrence, and the action taken to prevent recurrence. The records of misadministration must be maintained for three (3) 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 30 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, tests, 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. Records shall be maintained for five (5) years, until the next Department inspection, or until the registrant no longer possesses the equipment (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)
- Records of shielding plans and area surveys (RHB 4.4 & 4.4.6)
- Any other records of routine checks, quality control, or testing that may be required.

INSPECTIONS

The Department conducts routine **unannounced** 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 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 will be included in this report.

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. Each violation must be addressed individually. It will not suffice to simply state that all violations have been corrected. After the Department has received the sixty (60) day notification and accepted the corrective action, a compliance letter will be sent to the facility.

QUESTIONS

If you have questions, please feel free to call, email, or write:

SC Department of Environmental Services
 Radiation Protection Program
 2600 Bull Street
 Columbia, SC 29201
 PHONE: (803) 545-4400
 FAX: (803) 545-4412

EMAIL –

REGISTRATIONS: XRayRegistration@des.sc.gov

FACILITY REGISTRATION APPROVALS AND SHIELDING PLANS: XRayFRA-ShieldingPlans@des.sc.gov

COMPLIANCE: XRayCompliance@des.sc.gov

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 - Personnel Security Screening Systems

B9 - Complying with Title B - Veterinary Facilities

B10 - Complying with Title B - Hospitals

Visit our website at: <https://des.sc.gov/programs/bureau-land-waste-management/radiation-protection-program/x-ray-regulations>

CHECKLIST FOR SCDES INSPECTION

Medical Facility

Please have available the following records for the SCDES Inspector:

- ___ Records from x-ray performance testing, including equipment performance tests and service records
- ___ Documentation that all x-ray equipment operators have machine specific training on equipment at the facility
- ___ SCRQSA certificates for x-ray operators (not applicable for licensed practitioners)
- ___ Personnel monitoring reports, if applicable.
- ___ 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 SCDES Inspector the following items:

- ___ Posted pregnancy warning signs
- ___ Posted radiation area signs
- ___ Posted "Notice to Employees"
- ___ Posted technique charts
- ___ Patient log
- ___ Copy of shielding plans and area survey/as-built drawings