

REGULATORY GUIDE B3
COMPLYING WITH TITLE B - DENTAL FACILITIES



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REGULATORY GUIDE B3 COMPLYING WITH TITLE B – DENTAL FACILITIES

Each dental 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 dental 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 by submitting equipment registration forms, DHEC form 819. Upon registration of equipment (a control), the Department shall issue the facility a registration sticker to be placed on each control panel in a clearly visible location.

See Regulatory Guide B1 for assistance in registering equipment.

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, 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 to the Department for review and acceptance. The shielding plan must be reviewed by a Class III, Class IV, or Class IX vendor. The shielding plan must be accompanied by a \$62.50 Shielding Plan Review fee.

A shielding plan is required for the following types of x-ray units in dental facilities:

- 1) Cephalometric
- 2) Combination Panoramic/Cephalometric
- 3) TMJ
- 4) Dental CT

A shielding plan is required when the replaced unit has increased capabilities that would render the original shielding plan inaccurate. This must be determined by a Class III, IV, V, VII, VIII, or IX vendor.

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.

Intraoral dental units and panoramic units do not require shielding plans.

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

PASS THROUGHS

(See RHB 4.5.11.3)

Each unit that is installed so that it may be shared between rooms shall be installed so that its pass through is securely interlocked in a functional, permanent manner. In other words, if the tube is being used in one room, a means must be available to keep the unit from operating if the door in the cabinet to the other room is open.

HAND-HELD INTRAORAL EQUIPMENT

(See RHB 4.6.4)

Intraoral Hand-held dental equipment requires a variance approval from the Department. The variance approval must be obtained prior to the use, sale or purchase of the device for routine use.

The following requirements must be followed for the use of intraoral hand-held dental equipment:

- 1) The unit must be equipped with a non-removable backscatter shield of not less than 0.25 mm lead equivalent and 15.2 cm (6 inches) in diameter that is positioned as close as practicable to the distal end of the position indication device.
- 2) The facility must maintain documentation that each operator has completed training as specified by the manufacturer, and approved by the Department.
- 3) The facility shall adopt and follow protocols provided by the manufacturer and approved by the Department regarding the safe operation of the device.

- 4) When operating a hand-held intraoral dental radiographic unit, operators shall wear a 0.25 mm lead equivalent apron and thyroid collar.
- 5) If the operator has difficulty in holding the device stationary during the exposure, the operator shall use a stand to immobilize the device.
- 6) The registrant shall secure the hand-held device from unauthorized removal or use.

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 (Reference RHB 3.4 and RHB 3.7)
- 2) When an individual operates a Dental CT
- 3) Declared pregnant workers who request an additional badge for monitoring doses underneath lead aprons (Reference RHB 3.8)
- 4) Personnel who have been operating a Nomad unit for 6 months or less
- 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.

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 the 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 dental facility is required by RHB 4.2.2.8 to ensure that all x-ray operators meet the requirements of the South Carolina Dental Practice Act. Regulation 39-16 Dental Radiography states, "On or after July 1, 1985, all personnel in a dental office who place and expose radiographic films shall have successfully completed a structured course of training in radiation safety." Lead dentist shall ensure that all personnel who expose radiograph films/x-rays meet the requirements of the South Carolina Dental Practice Act regarding the receipt of training in radiographic safety from a Board-approved certification program.

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.

QUALITY ASSURANCE

(See RHB 4.2.16)

Registrants must tailor their quality assurance plan according to their x-ray imaging and processing systems. In most facilities, the quality assurance testing will be performed by a combination of the facility and an x-ray vendor. The facility must use a vendor that is registered with the Department to provide these services.

A list of registered vendors is available at our website, www.scdhec.gov.

The two items that should be addressed in a quality assurance plan are:

1) Equipment Performance Tests

Equipment performance testing for each x-ray unit must be performed, by a registered vendor, at the time of installation; every two years for dental intraoral units, panoramic units and cephalometric units; annually for handheld intraoral units and Dental CT units; 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.

NOTE: Facilities using cephalometric and/or dental CT units should refer to Regulatory Guide B2 "Medical Facilities" for assistance in setting standards for performance of the x-ray equipment. Cephalometric units are considered medical units by the Department and are subject to the requirements for medical units. "Cone beam" or Dental CT units are considered computed tomography units by the Department and are subject to the requirements for CT units.

2) 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

(See RHB 4.6.1.1 and RHB 3.15 and RHB 3.16 and RHB 4.2.6.4)

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. Only rooms containing cephalometric or dental CT units are considered to be radiation areas.

- 2) Technique charts. A technique chart must be posted at each control panel for units without built-in settings. The chart must state the patient's body part and anatomical size versus technique factors (kVp, mA, and time) to be used (RHB 4.2.6).
- 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 (RHB 4.3.1)
- 5) 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.
- 6) 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)

Misadministration, in a dental office, is the administration of radiation to the wrong patient or the performance of a diagnostic procedure other than that ordered by a prescribing dentist.

Incorrect ordering of an exam, such as ordering a periapical x-ray when a bitewing x-ray was desired is a situation that would not constitute a misadministration. Another example that is not misadministration would be if, after review of films from an exam, a dentist 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.

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, and major components (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 test (to include corrective action), maintenance, and modifications performed on the x-ray system(s), with the names of persons who performed such services. Records shall be maintained for five 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 1.11.3)
- Records of prior occupational dose for employees (RHB 3.20)
- Records of personnel monitoring results (RHB 3.22)
- Records of employee training to include operator certification (RHB 4.2.2.7)
- 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) (For cephalometric and dental CT units only.)
- Any other records of routine checks or testing that are required to be carried out.

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, but every attempt will be made to accommodate patient schedules. Generally, an inspection requires use of a dental x-ray unit for about thirty minutes per tube. **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. 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

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

CHECKLIST FOR DHEC INSPECTION

Please have available the following records for the DHEC 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.
- ___ Verification that all x-ray operators have received training that meets SC Dental Practice Act requirements. Please have the lead Dentist sign the Facility General Information Form to indicate compliance.
- ___ Documentation of protective apparel inspection/testing.
- ___ Personnel monitoring reports, if applicable.
- ___ Records of previous occupational dose for employees, if applicable.
- ___ Records of occupational dose for employees working at multiple locations, if applicable.
- ___ Records/documentation from processor maintenance and cassette cleaning if applicable.

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

- ___ Posted technique charts at each control
- ___ Posted pregnancy posters
- ___ Posted radiation area signs, if required
- ___ Posted "Notice to Employees"
- ___ Copy of shielding plan and area survey/as-built drawing, if required