

**REGULATORY GUIDE B9**

**COMPLYING WITH TITLE B - VETERINARY FACILITIES**



S.C. Department of Health and  
Environmental Control

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## **REGULATORY GUIDE B9**

### **COMPLYING WITH TITLE B - VETERINARY FACILITIES**

Each Veterinary 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 veterinary 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 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 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 are used in a single location for more than 5 consecutive days;
- 3) Any space is 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 and RHB 4.12.3.2)

Each veterinary facility that holds patients is required to provide personnel monitoring devices. If the human holder's hands are in or near the primary beam and lead gloves are not utilized, then ring badges must also be provided. In addition, if a declared pregnant worker requests an additional badge for monitoring doses underneath lead aprons, then the additional badge **must** be provided to her.

**The personnel 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.**

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.

Personnel monitoring devices must be returned for processing within 45 days of the end of the monitoring period. Direct read dosimeters must be read according to the manufacturer specifications and the results from the readings must be recorded and available for departmental review. The Registrant must document explanations of any late, absent, or unused badges and maintain these records for Departmental review. Personnel monitoring records must be retained indefinitely or until this Department authorizes their disposal, even if the service is discontinued.

The 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 prior to any changes to the record.

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 4.12.22)

Each veterinary facility is required by RHB 4.12.22 to ensure that all x-ray operators and holders are adequately instructed in safe operating procedures and competent in the safe use of the x-ray equipment. Requirements for each operator and holder are as follows:

1. According to Title B regulations the minimum required subjects that must be covered in operator training are:
  - a) **Radiation Protection.** Instruction in this area must include:
    - 1) Radiation protection standards.
    - 2) Principles of time, distance, and shielding.
    - 3) Use of protective apparel.
    - 4) The radiation protection aspects of patient holding.
    - 5) The biological effects of radiation.
  - b) **Dark Room/ Digital Imaging Instruction.** Instruction in this area must include:
    - 1) Use of developing chemicals.
    - 2) Film storage and protection.
    - 3) Care of screens and cassettes.
    - 4) Manufacturer's protocol of digital imaging system.
  - c) **Machine Safety and Operation.** Instruction in this area must include:
    - 1) All aspects of machine functions for which the operator will be responsible, for example the effect of kV and mA on radiographic image.
    - 2) Safety features and safety procedures associated with the x-ray unit.

- 3) How to recognize problems associated with the x-ray unit.
- 4) Factors affecting radiographic images.
- 5) Specific instruction on the equipment that the operator will use.

d) **General Operating Procedures.** Instruction in this area must include:

- 1) Anatomy as it relates to the types of exams that the operator will be performing.
- 2) Patient positioning for the types of exams that the operator will perform.
- 3) The proper selection of radiographic techniques.
- 4) Proper use of collimating devices.
- 5) Design, use, and interpretations of personnel monitoring devices.
- 6) The quality assurance procedures in place at the facility, and how to carry out and interpret those procedures.

2. Training of employees must begin within 30 days after employment.
3. Facility Specific Training must be provided for each operator and holder. This must include training for each type of exam to be performed and for each type of equipment to be used.
4. Written documentation must be maintained of all training for each operator and holder. This documentation must be made available for Departmental review.

Employees who are licensed veterinary technologists are considered to meet the basic training requirements. Additional instruction, Facility Specific Training, would still be required in areas unique to the facility's operations.

## **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 veterinary x-ray unit must be performed, by a registered vendor, at the time of installation, every five years, 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) 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) 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)
- 4) 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).
- 5) 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.



## **OVEREXPOSURES**

(See RHB 3.24)

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 and controls. (RHB 1.10.2.1)
- Records of surveys, equipment performance tests (to include corrective action), maintenance, and modifications performed on the x-ray system and components, with the names of persons who performed such services. (RHB 1.10.2.4)
- Copies of all correspondence with the Department (RHB 1.10.2.5)
- Records of 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 4.12.22)
- 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**

### **Veterinary Facility**

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

- \_\_\_ Records from x-ray equipment performance testing, including calibration and service records
- \_\_\_ Documentation of training for all x-ray equipment operators and animal holders
- \_\_\_ Personnel monitoring reports
- \_\_\_ Records of previous occupational dose for employees
- \_\_\_ Records of occupational dose for employees working at multiple facilities/locations, if applicable
- \_\_\_ Records/documentation from processor maintenance, cassette cleaning, or digital imaging QA
- \_\_\_ Documentation of annual protective apparel inspection/testing

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

- \_\_\_ Posted radiation area signs
- \_\_\_ Posted "Notice to Employees"
- \_\_\_ Posted technique charts
- \_\_\_ Copy of shielding plans and area survey/as-built drawings