

**REGULATORY GUIDE B9**

**COMPLYING WITH TITLE B - VETERINARY FACILITIES**



South Carolina Department of Health  
and Environmental Control

# TABLE OF CONTENTS

<b>FACILITY REGISTRATION APPROVAL.....</b>	<b>3</b>
<b>SHIELDING PLANS.....</b>	<b>4</b>
<b>REGISTERING EQUIPMENT.....</b>	<b>3</b>
<b>OPERATING PROCEDURES.....</b>	<b>4</b>
POLICIES AND PROCEDURES FOR PATIENT HOLDING AND OPERATOR PROTECTION.....	4
POLICIES AND PROCEDURES FOR PREGNANT WORKERS.....	4
POLICIES AND PROCEDURES FOR PERSONNEL MONITORING.....	4
PROCEDURES FOR TRAINING NEW EMPLOYEES.....	5
METHODS FOR QUALITY ASSURANCE.....	5
<b>PERSONNEL MONITORING.....</b>	<b>5</b>
<b>PRIOR OCCUPATIONAL EXPOSURE.....</b>	<b>6</b>
<b>OCCUPATIONAL EXPOSURE AT MULTIPLE FACILITIES.....</b>	<b>6</b>
<b>TRAINING PLANS.....</b>	<b>6</b>
<b>QUALITY ASSURANCE.....</b>	<b>7</b>
STANDARDS FOR PERFORMANCE OF THE X-RAY SYSTEM AND ASSOCIATED COMPONENTS.....	8
STANDARDS FOR PROCESSING.....	9
<b>MANUAL FILM PROCESSING.....</b>	<b>9</b>
<b>AUTOMATIC FILM PROCESSING.....</b>	<b>9</b>
<b>OTHER FILM PROCESSING REQUIREMENTS.....</b>	<b>10</b>
<b>NON FILM BASED IMAGING SYSTEMS.....</b>	<b>10</b>
<b>ADMINISTRATIVE REQUIREMENTS.....</b>	<b>10</b>
<b>OVEREXPOSURES.....</b>	<b>11</b>
<b>RECORDS.....</b>	<b>11</b>
<b>INSPECTIONS.....</b>	<b>11</b>
<b>CHECKLIST FOR DHEC INSPECTION.....</b>	<b>14</b>

## **REGULATORY GUIDE B9 COMPLYING WITH TITLE B - VETERINARY FACILITIES**

Each veterinary facility that is registered with the Department is required to comply with Regulation 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). The facility where the installation will be shall submit any application and shielding review fees as required by RHB 2.3. To receive a Facility Registration Approval, complete and return the FRA request form DHEC 0845 along with the application fee, including the following information:

- 1) Facility Name, Location Address, and Mailing Address
- 2) The name of the Radiation Safety Officer (RSO) who is responsible for radiation protection and the individual's qualifications to serve in this capacity
- 3) Manufacturer, model #, and type and make of x-ray equipment to be installed. For example:
  - i. Siemens Polydoros 80 Rad/Fluoro unit
  - ii. Belmont Model 071 Dental unit
- 4) The name, address, and contact person of the company selling and installing the equipment. If more than one company is involved, then provide the information for all companies.
- 5) Operating policies and procedures. See below under "Operating Procedures"
- 6) A shielding plan, if required. Shielding review fees must accompany the shielding plan.
- 7) There is a \$62.50 non-refundable fee required for registration of new facilities.
- 8) The application fee must be submitted with the facility registration approval request. The \$62.50 should be sent in the form of a check or money order made out to SCDHEC.
- 9) After review and approval of this information and receipt of application and shielding review fees, the Department will issue a Facility Registration Approval.

### **SHIELDING PLANS** (See RHB 4.4)

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 or a Class IV vendor. After the equipment is installed, "as-built" drawings and the area survey (if applicable) are required to be submitted. See Regulatory Guide B6 for assistance. The shielding plan must be accompanied by a \$62.50 Shielding Plan Review fee.

A shielding plan is required for mobile or portable units used in a single location for more than a week.

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

All x-ray equipment is required to be registered with the Department within thirty (30) days of acquisition. See Regulatory Guide B1 for assistance in registering equipment. The registrant is also required to report, in writing, any changes that affect the x-ray facility or x-ray equipment. This includes change of location or mailing address, acquiring or disposing of x-ray equipment, changes in operating procedures that may affect an approved shielding plan and any changes in the accepted operating procedures. In addition, upon registration of equipment (a control), the Department shall issue the facility a registration sticker to be placed on each control. The registration stickers shall be placed on the control panel in a clearly visible location.

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

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

- 1) **Policies and Procedures for Patient Holding and Operator Protection.** The procedures must state whether or not, as a matter of policy, animals and/or films will be held at that facility. The availability and use of restraining devices must be addressed. If human holders are used for animals and/or films, then the procedures must address the use of protective apparel. The process used to select the human holder must be described. If animals and/or films are routinely held, the procedures must include how the facility will ensure that no one person is routinely used to hold animals and/or films. Pregnant females should not be used to hold animals and/or films.

Each veterinary facility must have protective apparel available in the area of the x-ray unit. The lead aprons and gloves must be at least .5 mm lead and the operating procedures must indicate this lead equivalency will be used. Protective apparel must be checked annually for cracks and holes that could compromise the radiation protection they provide. Documentation of this testing must be kept for two years or until the next Department inspection, whichever is later.

The procedures must address operator protection. If a permanent or mobile operator's barrier is not used, then the procedures must address the use of protective apparel, and where the operator will be standing during exposures.

- 2) **Policies and Procedures for Pregnant Workers.** Procedures to be followed when a worker declares her pregnancy must be included, as well as methods of informing workers of the total exposure received during gestation. If a facility has policies to change the work assignments of pregnant workers, then those policies must be stated. The Nuclear Regulatory Commission's Regulatory Guide 8.13, "Instruction Concerning Prenatal Radiation Exposure" should be used for guidance concerning pregnant workers. This guide is available from the Superintendent of Documents, U.S. Government Printing Office, P.O. Box 37082, Washington, D.C. 20013-7082.
- 3) **Policies and Procedures for Personnel Monitoring.** 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.

Operating procedures must state whether or not personnel monitoring devices will be used at the facility. The procedures must tell employees how to correctly use personnel monitoring devices and how to care for personnel monitoring devices. The name of the person responsible for distribution, collection, and records of badges must be stated. The location of control badges must be given. The policies for reporting and investigating over-exposures must be stated. A prohibition against intentionally exposing any control or personnel badge must be included. Procedures must also be included instructing workers on how they may obtain the results from the monitoring.

- 4) **Procedures for Training New Employees.** See "Training Plans."
- 5) **Methods for Quality Assurance.** The procedures must state the methods that the facility will use to assure that they are producing quality radiographs. At a minimum, the following items must be addressed in the quality assurance plan: Equipment Performance tests (initial) and Standards for Processing. See below under "Quality Assurance."

### **PERSONNEL MONITORING** (See RHB 4.12.3.2 and RHB 3.12)

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, 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.

When facility personnel wear protective lead apparel, and a personnel monitoring device is used, the monitoring device shall 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 registrant shall receive Departmental approval prior to using an Effective Dose Equivalent (EDE) as the permanent record for an individual. Requests to the Department must include reasons for the request, written procedures detailing protective apparel and equipment to be used and procedures to ensure these are used at all times, current ALARA limits, Radiation Protection Program review records, and personnel monitoring records. The Department may immediately revoke EDE approval if the terms or conditions of the written approval are not met or if a violation of Title B Part III occurs.

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.

The registrant must maintain records showing the radiation exposure for each person that is required to be monitored. Prior Departmental approval is required for any changes to the dose of permanent record. Calculated doses from lost or damaged badges are excluded from this requirement. The records must be preserved indefinitely, or until the Department authorizes their disposal. The records may be maintained on microfilm.

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

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

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

If an employee is likely to receive a dose in excess of 50% of the annual allowable dose, the exposure that an employee receives at any one facility must be recorded by each facility at which the employee works. The simplest way to achieve compliance with this requirement would be for each facility to provide the employee with a monitoring badge to be worn only at that particular facility. Then, total occupational dose could be tracked, as well as doses received at individual facilities.

### **TRAINING PLANS** (See RHB 4.12.22)

Each veterinary facility is required by RHB 4.12.22 to ensure that all x-ray operators are adequately instructed in safe operating procedures and competent in the safe use of the x-ray equipment. The Department will assess operator training by reviewing the training plan of each veterinary facility. Therefore, each facility must establish a training plan to ensure instruction in the areas specified in RHB 4.12.22. The training plan must document the following items:

1. According to Title B regulations the minimum required subjects that must be covered in operator training are as follows:
  - 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.
  - b) Dark Room Instruction. Instruction in this area must include:
    - 1) Use of developing chemicals.
    - 2) Film storage and protection.
    - 3) Care of screens and cassettes.
  - 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 according to the facility's training plan must begin within 30 days after employment.
  3. If required training was obtained from a seminar or workshop, an agenda of the seminar or workshop shall be maintained as proof of training.
  4. Facility Specific Training must be provided for each operator for each type of exam to be performed and each type of equipment to be used. The facility must assess the types of exams that will be performed and tailor their training program appropriately.

Documentation of all operator training will be reviewed as part of the routine inspection and at any time deemed necessary by the Department.

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)

The following items must be checked, at a minimum, for the Department to consider the quality assurance program acceptable. These items are not inclusive of all items that could be addressed in a quality assurance program. It is the registrant's responsibility to evaluate the performance of their x-ray imaging systems and tailor their quality assurance program accordingly. Quality assurance testing might be performed by a combination of an x-ray vendor and the facility. X-ray vendors used to perform quality assurance monitoring must be registered with the Department to provide these services. A list of registered vendors is available from the Department.

The following items should be contained in the quality assurance manual, as appropriate:

- 1) A list of the parameters to be monitored, the frequency of monitoring, and the limits that require corrective action to be taken.
- 2) Procedures for monitoring each parameter.
- 3) Procedures for corrective action.
- 4) A list of the records, along with sample forms, that the facility is using. Notations should be made concerning the length of time that each type of record is kept before discarding.
- 5) Results of acceptance testing of new equipment.

As previously stated, the two items that must be addressed in a quality assurance plan are (1) equipment performance tests (initial) of the x-ray system, and (2) standards for processing.

- 1) **Equipment Performance Tests of the X-ray System and Associated Components (Calibrations).** Written standards must be established for the proper performance of each x-ray imaging system under the registrant's control. These tests are required to be performed at the time of installation, every five years, after any major repair, and at any time the Department deems necessary to ensure compliance with the standards. Equipment performance tests must include numerical data. Items found to be non-compliant during these tests must be corrected within sixty (60) days of receipt of the report. Records showing the test results and the correction of non-compliant items found must be retained for five years.

If a portable unit is returned to the manufacturer, the unit must be tested once it is returned to the facility. Testing completed prior to return shipment to the facility will not be acceptable.

The following items, as appropriate, should be included in the x-ray system standards for radiographic equipment. Items marked with an asterisk (\*) indicate that this item may be tested by the vendor or the facility.

- Half-value layer (HVL)
- X-ray field/light field alignment
- Exposure reproducibility
- mA/mAs linearity
- kVp accuracy
- Timer reproducibility and accuracy
- X-ray beam/image receptor centering
- Collimator light illuminance
- Actual vs. indicated collimator field sizes
- Positive beam limitation function, if operable
- Visual and audible indication of exposure
- Capacitor discharge radiation levels, if appropriate
- Minimum field size
- Proper function of automatic exposure control devices, including AEC reproducibility, kV compensation, and minimum response time
- Grid uniformity and alignment
- Integrity of lead aprons, gloves, and other protective clothing \*
- Actual vs. Indicated Source to Image Distance (SID), for all clinically used SIDs
- Beam size(s) for fixed collimation, if applicable

These items must be checked upon initial installation and after any maintenance or repair that could affect their status:

- Adherence to the approved shielding plan (Visual inspection of layout of equipment, location of exposure button, location of film, etc.)
- Minimum source to skin distance on mobile radiographic units

- Proper indication of multiple tubes on units so equipped
- 2) **Standards for Processing.** The following items should be checked as components of the final diagnostic image obtained. Again, these items are not all inclusive, and should be tailored to meet the individual facility conditions.
- a) Evaluation of screens, cassettes, and grids. Procedures should be included for cleaning and maintenance of cassettes and screens and checks of screen condition. Documentation of these cleanings must be kept for 2 years or until the next inspection.
  - b) Processor quality assurance. The quality assurance plan should address the care, maintenance, and cleaning of the processor, temperature measurement, replenishment rates, water flow rates, and residual fixer testing. Records of processor maintenance must be kept for 2 years or until the next inspection by the Department.
  - c) Evaluation of darkroom and film. Film base plus fog should be tested, along with darkroom fog conditions. Darkrooms must be light tight to the dark adapted eye, and should be free from dust and dirt. If a safelight is used, it must be adequate for the film speed and darkroom procedures used to prevent fogging of unprocessed film.

For new facilities, the quality assurance plan will be reviewed by the Department before registration of the x-ray equipment. For existing facilities, the quality assurance plan will be reviewed at the first inspection after the effective date of the regulations.

Records of quality assurance testing and monitoring will be reviewed on each routine inspection. Facilities must maintain records of all testing and checks performed. These records must be maintained for 2 years or until the next inspection by the Department which ever is the later.

### **MANUAL FILM PROCESSING** (See RHB 4.2.17.1)

When a facility performs manual film processing, the following items are required to be used by the facility:

- 1) Processing tanks that are mechanically rigid and corrosion resistant
- 2) A dedicated darkroom thermometer to measure developer temperature  
The developer temperature must be within 60° F and 80° F (16° C to 27° C).
- 3) A dedicated darkroom timer to set film processing time
- 4) Documentation to show when the film processing chemicals are changed
- 5) A functional darkroom safelight compatible with the type of film being used
- 6) A time-temperature developing chart.

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

### **SIGHT DEVELOPING OF RADIOGRAPHS IS NOT ACCEPTABLE FOR PROCESSING FILMS.**

### **AUTOMATIC FILM PROCESSING** (See RHB 4.2.17.2)

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

- 1) Processing chemical temperatures consistent with the type of film(s) being processed.
- 2) Appropriate film processing chemicals and replenishment rates
- 3) A functional darkroom safelight compatible with the type of film(s) being used
- 4) Film immersion times consistent with the developer temperature
- 5) The specified developer temperature must be immediately available

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

### **OTHER FILM PROCESSING REQUIREMENTS** (See RHB 4.2.17.3)

Film pass boxes must be "light-tight" and incorporate adequate shielding to prevent fogging of undeveloped film from stray radiation. Film must be stored in a cool, dry place protected from stray radiation. Film in open packages must be stored in a light tight container. Film should not be stored where it can be exposed to chemical fumes or radiation. Film that is expired or outdated shall not be used, unless it has been properly stored, and passes a sensitometric test for base + fog, and speed.

Film cassettes and intensifying screens must be inspected in accordance with the facility's approved operating procedures. They must be cleaned and replaced as necessary to best assure radiographs of good diagnostic quality. Documentation of these inspections and cleanings must be maintained for 2 years or until the next inspection by this Department which ever is the later.

Film developing solutions must be properly stored; they should never be allowed to freeze. They must be prepared according to the directions given by the manufacturer, and maintained in strength by replenishment or renewal.

### **NON FILMED BASED IMAGING SYSTEMS** (See RHB 4.3.12)

Users of digital imaging acquisition systems must follow protocols established by the manufacturer of the digital system.

The manufacturer's current operating manual must be available for Department review.

### **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, such as a restroom with an entrance from a hall and the x-ray room. (See RHB 3.16)
- 2) Technique charts. (See RHB 4.2.6) A technique chart must be posted at each control panel, which states the following information:
  - The patient's body part and anatomical size versus technique factors to be used
  - The type and size of film or the film-screen combination to be used
  - The source to image distance (SID) to be used
  - For automatic exposure control systems, the appropriate exposure detector(s) must be

specified. For automatic exposure control systems, there must also be available a technique chart to be used when the equipment is operated in a non-automatic mode.

- 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." (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 the DHEC website.

### **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**

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 aluminum equivalent filtration of the useful beam for all x-ray units, including any routine variation (RHB 1.10.2.3)
- 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 (RHB 4.2.2.7 and 4.2.3)
- A scale drawing of the x-ray room showing occupancies of surrounding areas, and composition of all walls, or results of an area survey performed by a Class IX vendor showing radiation levels around the room (RHB 4.4.6)

- Any other records of routine checks, quality control, or testing that are required.

## **INSPECTIONS**

The Department conducts routine periodic inspections of x-ray facilities. The Department will also conduct inspections if a complaint is received, or if a facility requests an inspection. If violations are found on an inspection, a follow-up inspection may be conducted if the severity of the violations warrants it. The Department may also inspect newly installed, Food and Drug Administration (FDA) certified units for compliance with FDA regulations. Inspections by the Department are mandatory, but every attempt will be made to accommodate patient schedules. **The Department does have the right to make unannounced inspections.**

The inspection consists of checking/verifying the operation of the x-ray equipment and reviewing records as outlined in the attached checklist. The facility can greatly assist the Department inspector by using the attached inspection checklist to ensure that all records are available for review. The checklist also contains some questions that will be asked by the inspector. Generally, an inspection requires use of the x-ray equipment for about one hour per control. At the conclusion of the inspection, the inspector will conduct an exit interview to discuss items of non-compliance.

The inspector may leave an inspection report at the conclusion of the inspection or send a written report to the facility within approximately two weeks of the inspection. Any violations and/or recommendations will be included in this report. After receiving the report, the facility has twenty days to respond, in writing, to the Department. This twenty day notification must indicate the corrective action that will be taken to correct any violations. The Department will respond, in writing, to the twenty day notification as needed.

All corrections must be made within sixty (60) days of receipt of the inspection report. The facility must notify the Department, in writing, by this date that corrections have been made. Corrective action must be described for each violation. The facility has the option of accepting Departmental recommendations. Each violation and recommendation must be addressed individually. It will not suffice to simply state that all violations and recommendations have been corrected. If a facility chooses not to accept a recommendation made by the Department, the facility should state so in their response. After the Department has received the sixty day notification and accepted the corrective action, a Completed Corrective Action letter will be sent to the facility.

## **QUESTIONS**

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

SC Department of Health and Environmental Control  
Bureau of Radiological Health  
2600 Bull Street  
Columbia, SC 29201  
(803) 545-4400  
FAX (803) 545-4412

## **REGULATORY GUIDES**

B1 - Registration of X-ray Facilities and Equipment  
B2 - Complying with Title B - Medical Facilities

- B3 - Complying with Title B - Dental Facilities
- B4 - Complying with Title B - Facilities Utilizing Analytical or Industrial X-ray Equipment
- B5 - Vendor Registration and Responsibilities
- B6 - Shielding Plans
- B7 - Complying with Title B - Mammography
- B8 - Complying with Title B - Bone Densitometers
- B9 - Complying with Title B - Veterinary Facilities
- B10 - Complying with Title B - Hospitals

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**Checklist for DHEC Inspection**  
**Veterinary Facility**

**Please have available the following records for the DHEC inspector:**

- \_\_\_\_\_ Records from x-ray equipment performance testing, including initial calibration and service records
- \_\_\_\_\_ Written operating procedures that address (Patient Holding, Pregnant Workers, Personnel Monitoring, Training Plan, Quality Assurance)
- \_\_\_\_\_ Documentation of all x-ray equipment operators to adhere to the Operating Procedures and have Machine Specific training on equipment in the office
- \_\_\_\_\_ 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
- \_\_\_\_\_ Documentation of annual lead apron testing or inspection

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

- \_\_\_\_\_ Posted radiation area signs
- \_\_\_\_\_ Posted technique charts
- \_\_\_\_\_ Posted "Notice to Employees"