

|  |
| --- |
| Regulatory Guide 4.5Veterinary and Animal Research Facilities |
| Consumer Protection Division Radiation Program |
| January 2023 |

Table of Contents

[GUIDE FOR THE USE OF RADIATION MACHINES IN VETERINARY MEDICINE AND ANIMAL RESEARCH 3](#_Toc86317980)

[REGULATORY REQUIREMENTS 5](#_Toc86317981)

[TEXAS RADIATION REGULATIONS 5](#_Toc86317982)

[REGISTRATION AND FEE REQUIREMENTS 5](#_Toc86317983)

[RADIATION SAFETY OFFICER (RSO) 6](#_Toc86317984)

[DEPARTMENT INSPECTIONS AND NOTIFICATIONS 6](#_Toc86317985)

[VETERINARY EQUIPMENT PERFORMANCE EVALUATIONS (EPE) 7](#_Toc86317986)

[EQUIPMENT INVENTORY 8](#_Toc86317987)

[SECURITY AND CONTROL OF RADIATION MACHINES 8](#_Toc86317988)

[REQUIRED OPERATING AND SAFETY PROCEDURES 8](#_Toc86317989)

[SECTION 1 - POSTING NOTICES, INSTRUCTIONS, AND REPORTS TO WORKERS AND POSTING A RADIATION AREA 8](#_Toc86317990)

[SECTION 2 - INDIVIDUAL DOSIMETRY MONITORING REQUIREMENTS/DOSE LIMITS TO OPERATORS 10](#_Toc86317991)

[SECTION 3 – OPERATING AND SAFETY PROCEDURES 11](#_Toc86317992)

[SECTION 4 – QUALITY ASSURANCE AND QUALITY CONTROL 12](#_Toc86317993)

[APPENDIX A 15](#_Toc86317994)

[APPENDIX B 18](#_Toc86317995)

[APPENDIX C 19](#_Toc86317996)

[APPENDIX D 20](#_Toc86317997)

[APPENDIX E 21](#_Toc86317998)

[APPENDIX F 23](#_Toc86317999)

# GUIDE FOR THE USE OF RADIATION MACHINES IN VETERINARY MEDICINE AND ANIMAL RESEARCH

When any facility in Texas uses a radiation machine, the facility must meet specific Texas rules for the safe operation of a radiation source. The rules for using a radiation source in Texas can be found in Title 25, Chapter 289 of the Texas Administrative Code (TAC). Different sections in this chapter address various requirements for users of radiation sources. Specific requirements for veterinary use of radiation machines are addressed in 25 TAC §289.233. The use of radiation machines on non-living animals is considered industrial use, which is regulated under §289.228.

This guide focuses on the administrative and operational requirements for using a radiation machine in a veterinary practice in Texas and provides generalized procedures for using a radiation machine. You must write procedures specific to your facility and your machine to address each requirement. Using the sections of this guide that apply, you may create your unique operating and safety procedures. This guide may also be used to develop operating and safety procedures for facilities with mobile veterinary services.

A facility using radiation machines only on non-living animals must follow the requirements for industrial radiation machines. Some parts of this guide apply to such research activities. Some of the following sections will discuss requirements for animal research.

This guide is an aid for the registrant to provide the information required by **§289.233 (j)(2) Operating and safety procedures**. If you are a sole practitioner and sole operator, and you are the only occupationally exposed individual, then you are exempt from **§289.233(j)(2)** and do not have to maintain written operating and safety procedures.

Regulatory guides may be reproduced by using the Radiation Control web page at <http://dshs.texas.gov/radiation/x-ray/regulatory-guides.aspx>

This manual is a guide for you to establish procedures that will minimize radiation exposure to your employees and your clients. This guidance is provided to help you comply with the Texas Department of State Health Services (DSHS) Radiation Control rules. The Certificate of Registration (COR) issued by the department contains conditions and restrictions that apply to the operation of the x-ray machines in the registered facility and the list of the sections in 25 TAC Chapter 289 that apply to the registration.

The Texas Department of State Health Services, Radiation Control considers each facility’s compliance with the law and rules when determining whether to issue or renew a license or certificate of registration or to take enforcement actions. The Department publishes Regulatory Guides as supplemental information to assist persons with compliance under the Texas Radiation Control Act. The DSHS regulatory guides provide examples of appropriate conduct and explain inspection and evaluation procedures for applicants, licensees, registrants, and other persons. Regulatory Guides are NOT substitutes for the existing law and rules. Each person is responsible for compliance with the law and regulations, but compliance with the regulatory guides is not required. Applicants, licensees, or registrants may choose to comply with the law and rules through policies and procedures that differ from those in the guides.

Comments and suggestions for improvements in these Regulatory Guides are always encouraged, and they will be revised, as appropriate, to accommodate comments and to reflect new information or experience. Comments should be sent to the Radiation Operations Group, Texas Department of State Health Services, CPDrulecomments@dshs.texas.gov

# REGULATORY REQUIREMENTS

## TEXAS RADIATION REGULATIONS

The Texas Radiation Control Act, Health and Safety Code, Chapter 401, authorizes DSHS to develop and enforce rules on the use of radiation sources. Title 25 of the Texas Administrative Code (TAC) §289.233 applies to veterinary facilities and users of veterinary x-ray machines. Other rule sections of Chapter 289 have additional requirements and are listed at §289.233(b)(5) and (6).

All operators of veterinary x-ray machines are required to read these rules and understand the requirements and restrictions that apply to using a veterinary x-ray machine as part of their education and training.

Under §289.228, a facility using radiation machines only on non-living animals must follow some of the same requirements that veterinary facilities follow. The area requirements (limiting radiation levels, performing surveys, and posting radiation warning signs), operating and safety procedure requirements, personnel requirements (required instructions and radiation monitoring), and record-keeping requirements are similar to §289.233. However, §289.228 has unique requirements for operator approval, safety equipment, extremity monitoring, and record keeping. The operating and safety procedures for a facility using radiation machines only on non-living animals must include these special requirements.

Section 289.228 requires a facility using radiation machines only on non-living animals to follow §289.203 of this title (relating to Notices, Instructions, and Reports to Workers; Inspections), §289.204 of this title (relating to Fees for Certificates of Registration, Radioactive Material Licenses, Emergency Planning and Implementation, and Other Regulatory Services), §289.205 of this title (relating to Hearing and Enforcement Procedures), §289.226 of this title (relating to Registration of Radiation Machine Use and Services), and §289.231 of this title (relating to General Provisions and Standards for Protection Against Machine-Produced Radiation).

The rules must be available to operators in physical or electronic form. The current rules are available at <https://dshs.texas.gov/radiation/laws-rules.aspx>.

## REGISTRATION AND FEE REQUIREMENTS

Any veterinary facility or animal research facility that uses radiation machines must register within 30 days after beginning the use of the machine **[§289.233(i)(1)(B) and §289.226(a)(2)].** Mobile services require authorization before providing mobile services **[§289.233(i)(2)].**

Operation of a class IIIb or a class IV laser also requires registration according to 25 TAC §289.301 Registration and Radiation Safety Requirements for Lasers and Intense-Pulsed Light Devices.

[The registration fees can be found here.](https://www.dshs.texas.gov/sites/default/files/radiation/pdffiles/Rules/204_fn_9_2014.pdf)

If your address or other contact information changes, or if you add machines not authorized on your COR, you must notify the Department within 30 days **[§289.233(i)(5)(G) and §289.226(m)(7)]**. Form RC 226-2 is available to notify the Department about a new registration or update your registration information (<https://dshs.texas.gov/radiation/x-ray/medical-faq.aspx>). You must also inform the Department when you cease doing business or sell your practice to terminate your COR (Form RC-17R).

Veterinary CORs do not expire and registration fees are due every two years. Failure to pay registration fees may result in the revocation of your COR.
Penalties may be imposed if you continue to use the radiation machine with a revoked or expired COR.

Also, be aware that a COR does not transfer to a new business owner when you sell your business. When you are selling or buying a practice, the seller must terminate their COR, and the buyer must apply for and receive a new COR in most cases. Additional information can be found at <https://dshs.texas.gov/radiation/x-ray/veterinary.aspx>.

**Note**: Failure to register, maintain your registration information, or pay your registration fees may result in administrative penalties. It is important to keep your registration information current so that the Department can contact you.

## RADIATION SAFETY OFFICER (RSO)

Every registrant must have a Radiation Safety Officer (RSO) designated on the application for a COR. **[§289.233(i)(1)(E****) and §289.226(e)]** The RSO is responsible for the radiation safety program. If you change the RSO for your facility, you must notify the Department.

The RSO must have the authority to enforce safe practices at your facility. To be qualified to be an RSO for veterinary facilities, a person must know about the hazards of working with an x-ray machine, have an education related to ionizing radiation safety, or have experience using the x-ray machine at a veterinary facility.

The RSO is responsible for creating and updating the written operating and safety procedures. The procedures for using radiation sources must follow “As Low As Reasonably Achievable (ALARA)” practices to minimize exposure to your workers and clients. The RSO is responsible for investigating and reporting excessive radiation exposure or any loss of an x-ray machine and ensuring all the records required by this rule are kept current for inspection by the Department. **[§289.233(i)(1)(E)(iv) and §289.226(e)]**

## DEPARTMENT INSPECTIONS AND NOTIFICATIONS

The Department is authorized to perform an inspection of public or private property to determine if radiation machines are being used in a manner that meets the requirements of the Texas Radiation Control Act (Health and Safety Code, Chapter 401), the requirements of 25 TAC 289, your COR, and any compliance orders issued by the Department.

Your inspection may be conducted with an on-site inspection by a Department inspector or by completing a Remote Inspection Form (RIF). RIFs must be completed and submitted before the due date to avoid violations and penalties. Department inspections are not announced; however, Department inspectors will work with the registrant to complete the inspection with as little interference as possible to the facility’s routine.

If you receive a Notice of Violation (NOV) resulting from an inspection, you must respond by following the instructions in the NOV letter. Administrative penalties may be incurred if you do not respond to an NOV by the provided deadline.

## VETERINARY EQUIPMENT PERFORMANCE EVALUATIONS (EPE)

An Equipment Performance Evaluation (EPE) is required for all radiation machines used for veterinary medicine. The EPE process measures the radiation output from the x-ray machine and verifies that the machine is working according to the original manufacturer’s specifications **[§289.233(j)(5)(N)]**.

An EPE is required within 30 days of a machine’s installation, reinstallation, or within 30 days of any service to the x-ray unit that could potentially change the radiation output of the machine. Both the service company that installed the machine and the registrant who bought the machine is responsible for the 30-day EPE. The installer must install the machine according to the manufacturer’s specifications. The 30-day EPE ensures that the installation or repair was done correctly.

Machines registered at a veterinary facility must also have an EPE done every five years on or before the date of the previous EPE. **[§289.233(j)(5)(N)(i)(IV)]** This test ensures the machine continues to meet the manufacturer’s original specifications. Machines used for non-living animal research do not require a periodic EPE.

EPEs (or any service) may only be performed by service companies registered by the Department. The EPE must be documented and available for review by the Department.**[§289.233(j)(5)(N)(iii) through (vii)].**

The measurement of radiation output on a radiation machine can only be done by a service company registered in Texas. Radiation output measurement on a fluoroscopic machine, a C.T. machine, or a radiation therapy unit must be done by a Licensed Medical Physicist (LMP) registered as a service company with the Department. The LMP must use a calibrated dosimetry system.

If your facility has fluoroscopy, computed tomography, or radiation therapy machines, the rule has special requirements for each type in **§289.233(j)(6), (7), and (8)**, respectively.

If a system fails to meet regulatory specifications, the facility has 30 days to begin the repair, and must be completed within 90 days. Any exceptions must be reviewed and approved by the Department. **[§289.233(j)(5)(M)]**

## EQUIPMENT INVENTORY

An inventory of all radiation machines must be taken at an interval not to exceed one year. It must include the manufacturer’s name, model, control panel serial number, and the radiation machine's location (ex. room name/number).

## SECURITY AND CONTROL OF RADIATION MACHINES

The facility must have control procedures in place that prevent an unauthorized person from operating an x-ray machine or removing an x-ray machine. Examples of administrative controls are written procedures to lock doors to the work area when staff is not present or written procedures to lock a handheld x-ray machine in a cabinet when not in use. **[§289.233(j)(4)(H)]**

## REQUIRED OPERATING AND SAFETY PROCEDURES

The following is a list of procedures that are required explicitly by §289.233 for veterinary facilities. Each registrant must have written procedures that ensure the facility meets Texas regulations and provides for the safe use of radiation sources. This guide is broken into sections describing the regulatory requirements of §289.233 and shows where the requirement can be found.

## SECTION 1 - POSTING NOTICES, INSTRUCTIONS, AND REPORTS TO WORKERS AND POSTING A RADIATION AREA

To let employees know about the requirements for using a radiation source, §289.233 requires the veterinary facilities and §289.228 requires research facilities to post certain information in an area where all employees can read it. The following documents must be made available to employees:

* Any applicable section of 25 TAC 289 that pertains to your business, as listed on your COR.
* The Certificate of Registration (COR).
* The Operating Procedures that apply to the work listed on the COR.
* Any Notice of Violation (NOV) or Compliance Order issued by the Department must be posted, as well as the registrant’s response to an NOV that describes the corrective actions taken.
* RC. Form 233-2 “Notice to Employees” must be posted in a location accessible by all employees.

These postings must appear in a sufficient number of places to permit individuals engaged in work under the COR to observe them on the way to or from the radiation work area. The posting must be clearly visible. If posting these documents is not practicable, the registrant must post a notice that describes where employees may find these documents. If any of the documents become outdated, defaced, or otherwise unusable, they must be replaced.

All individuals likely to receive an occupational dose over 100mR (1 mSv) in a year must be given specific instructions as follows **[see** **§289.233(j)(3)(G) for veterinary facilities and §289.231(n) for research facilities]**:

* kept informed of the storage, transfer, or use of sources of radiation in the licensee’s or registrant’s workplace;
* the health protection problems associated with exposure to sources of radiation. The individual must understand ALARA principles and how to use protective equipment such as lead aprons and gloves;
* the regulatory requirements of §289.233 and other related rule sections;
* their responsibility to report any condition that may cause a violation of agency rules or COR conditions,
* their responsibility to report unnecessary exposure to sources of radiation;
* the appropriate response to warnings made in the event of any radiation accident or emergency, and
* informed of the radiation exposure reporting requirements to workers.

These instructions need to be sufficient for the types and amounts of radiation sources used at the clinic to prevent potential radiological health protection problems.

Certain reports must be given to workers **[see §289.233(j)(2)(B) for veterinary facilities and §289.231(ii) for research facilities]**. If any radiation worker receives more than 500 millirem of annual exposure, the RSO is required to provide that radiation worker with a report of their radiation exposure. Reports must also be provided to any radiation worker who asks. The report must contain certain information, such as the worker’s name and the dose measurement from the monitoring badge. Additional requirements can be found at **§289.233(k)(3)(D) for veterinary facilities and §289.231(jj) for research facilities**.

If an incident happens where there is a high exposure to an individual (25 rem or more to the whole body, 75 rem to the eye, or 250 rad to the skin), it must be reported immediately. Exposures below these levels that still exceed the dose limits for a radiation worker must be reported within 24 hours. Lastly, if any report shows that an occupational, fetal, or public dose limit or radiation area limit has been exceeded, the information must be given to the radiation worker as appropriate. Any incident report must also go to the Department **[See §289.233(k) for veterinary facilities and §289.231(hh) for research facilities]**.

Areas, where radiation sources are used, must be posted with appropriate signs to let workers and your clients know about potential radiation exposure. The warning signs are different depending on the level of radiation that could exist. The signs must be visible and obvious to anyone in the area.

|  |  |
| --- | --- |
| Radiation Levels | Sign Required |
| Exposure rate > 5 millirem/hr | "CAUTION, RADIATION AREA" sign bearing the radiation symbol |
| Exposure rate > 100 millirem/hr | "CAUTION, HIGH RADIATION AREA" sign bearing the radiation symbol |
| Absorbed dose > 500 rad/hr | "GRAVE DANGER, VERY HIGH RADIATION AREA" sign bearing the radiation symbol. |

A registrant is not required to post radiation warning signs in areas or rooms containing radiation machines if the radiation machines are constantly under the surveillance and control of the operator **and** the area or room is a restricted area subject to the registrant's control.

## SECTION 2 - INDIVIDUAL DOSIMETRY MONITORING REQUIREMENTS/DOSE LIMITS FOR OPERATORS

As a registrant, you are responsible for measuring and monitoring the radiation levels from your machine so that annual exposure limits are not exceeded for either workers or the public. Texas rule sets limits on the amount of radiation a worker or member of the public (your client) may receive. Your procedures must be written so that radiation exposure to everyone is not only below these limits but also as low as possible each time the source is used **[§289.233(j)(3) and §289.228(f)]**.

To know the amount of radiation that your radiation workers receive, you must use dosimeters to measure the occupational dose. Dosimeters may also be used to measure radiation levels in the unrestricted areas accessible to your clients. Any radiation worker who is likely to receive a dose from occupational exposure to radiation over 500 millirem in a year (about 42 millirem a month) must be monitored with an individual dosimetry monitoring device such as a film badge or thermoluminescent dosimeter. Worn correctly, these devices will measure the radiation exposure to the radiation worker. The dosimeters are exchanged every month or quarter, and a report is sent to you concerning the radiation measured for the wear period.

There are two key concepts of wearing a radiation dosimeter: the dosimeter must be assigned to and worn by only one radiation worker, and the dosimeter must be worn at the unshielded location of the whole body likely to receive the highest exposure. **[§289.233(j)(3)(E)(i)and §289.231(m)(2)]** When a protective apron is worn, the location of the individual monitoring device is typically at the neck (collar), outside of the protective apron, except for the fetal monitoring dosimeter (see below). Operators of machines with open beam configuration must also wear finger dosimetry devices if the machine does not have safety devices. **[§289.228(h)(3)]**

A woman may choose to “declare” her pregnancy to her employer so that the radiation dose to the fetus is monitored. A declared pregnant woman who is likely to receive a dose from occupational exposure to radiation over one millisievert (100 mrem) during the entire pregnancy must be monitored with an embryo/fetus dosimetry monitoring device in addition to her personal dosimeter. **[§289.233(j)(3)(A)(i)(IV) and §289.231(m)(1)(D)]** The dosimeter used for monitoring the dose to the embryo/fetus must be located at the waist under any protective apron worn by the woman. **[§289.233(j)(3)(E)(i)(III)]**

If a radiation worker receives an occupational dose (i.e., wears a dosimeter) at another facility, the radiation worker should report that dose to the RSO so that it can be included in the annual record of occupational dose.

Dosimeters may also be used to record the radiation levels in unrestricted areas affected by the radiation source. **[§289.233(j)(3)(D) and §289.231(p)]**These “area” dosimeters will have their measurements reported with the radiation worker’s measurements.

## SECTION 3 – OPERATING AND SAFETY PROCEDURES

This section contains regulatory requirements related to the operation of a radiation machine in a veterinary facility or an animal research facility. One of the primary prohibitions in §289.233 is that a radiation machine registered at a veterinary facility should never be used to x-ray a person. Human-use machines are tested, so they do not exceed radiation exposure limits to the patient. Veterinary machines are not tested the same way and are unsafe for human use. The rules also state that a radiation machine operated under a veterinary registration can only be used when an exam is ordered by a Texas-licensed veterinarian**[§289.233(b)(1)(C)]**.

The operator is not allowed to hold the x-ray tube or tube housing assembly during an x-ray exam. The only exceptions are when the radiation machine is designed to be held during exposure and only when the operator follows the manufacturer’s procedures. **[§289.233(c)(3)]** Please note that not all radiation machines sold on the internet will meet the radiation machine requirements of §289.233.

Protective Devices, such as lead aprons, gloves, and shields, must be used to reduce radiation exposure to staff and clients, as appropriate. Protective devices (aprons, gloves, etc.) used at a veterinary facility must be checked annually for defects, such as holes, cracks, or tears. This check can be done by a visual and tactile inspection of the protective devices or by x-raying these items. A record must be kept of this check **[Appendix D]**. If a defect is found at the time of the annual check or on any other occasion, notify the RSO and remove the device from service until it can be repaired or replaced **[§289.233(j)(3)(H)(ii)]**. If fluoroscopic procedures are performed, protective devices (lead drapes, hinged sliding panels) shall be in place. If sterile fields or special procedures prohibit the use of protective devices, all individuals in the fluoroscopic room must wear protective aprons of 0.35 mm lead equivalent **[§289.233(j)(6)(C)(ii)(I)]**.

A technique chart shows the correct machine settings for different imaging exams. The technique settings should be the lowest settings necessary to get the best image quality for the exam. The technique chart for each radiation machine used at the facility must be posted or displayed on or near the control panel. All operators must use the technique chart. **[§289.233(j)(5)(A)]** This practice ensures that the image quality will remain consistent and that the radiation exposure in the area of the machine is as low as reasonably possible.

The operator must be positioned so their exposure is as low as reasonably achievable. To achieve this, the operator must be at least six feet from the source of radiation or behind a protective barrier **[§289.233(j)(3)(K)]**.

When an animal or image receptor must be held in position during an exam, you must use mechanical supporting or restraining devices, as appropriate, whenever the exam permits [**§289.233(j)(3)(J)]**. If there are exams that do not permit the use of a mechanical device, then the facility must have written procedures for when and how to hold an animal or image receptor. These written procedures must identify who will assist the operator. It is important to use proper collimation and the proper protective equipment to reduce radiation exposure to the person holding the animal or image receptor.

The facility’s responsibility is to ensure that radiation machines are operated by individuals qualified by training and experience to use x-ray machines safely. **[See §289.233(i)(1)(D) and §289.228(h)(1)]** All workers must be aware of each radiation source and be made aware of all procedures involved with radiation sources. Your workers’ training level will depend on how their duties are related to your radiation source.

## SECTION 4 – QUALITY ASSURANCE AND QUALITY CONTROL

The purpose of any imaging quality assurance/quality control (QA/QC) program is to ensure that the x-ray imaging system used at a veterinary registration produces a diagnostic image consistently. The goal is to identify any image degradation that would result in a missed diagnosis or the need for a repeat x-ray exposure. A QA/QC program consists of tests that are done consistently and repeated on a regular schedule. If a test fails, the system needs to be adjusted or repaired. You should follow the QA/QC tests present in your imaging system operator’s manual, which may not be the same manual as your radiation machine.

### Digital Imaging System

If your system does not have manufacturer’s procedures for a QA/QC program, the rule requires that basic QA/QC testing is done using a phantom. A phantom can be any common object that shows at least three distinct densities when imaged on your system. Using the same object as a phantom for each test is recommended to avoid a test failure. The first image is saved as the standard when performing a QA/QC test with a phantom. QA/QC test images are taken quarterly and are compared to the standard image. An image quality test should be repeated with the same phantom in the same position with the same technique factors each time. **[§289.233(c)(2)]** Never use a person or any part of a person as a phantom. The test fails if the QA/QC image shows a different density or contrast from the standard.

When using the imaging system manufacturer’s written procedures for your QA/QC program, they must be included in the safety and operating procedures for the facility **[§289.233(j)(12)(A)]**. The QA/QC program must state how often the test will be done and how the results are logged. The log must have the date of the test, the results of the test, and who did the test. Phantom images must be kept for review by the Department.

If a manufacturer’s written procedures are not available, the facility must establish a written QA/QC program that incorporates the requirements listed below. **[§289.233(j)(12)(B)]**

1. The QA/QC program shall include image quality testing for, but not limited to, spatial resolution, noise, artifacts, and contrast. A facility can use a commercially purchased testing tool or an inanimate object of at least three varying densities.
2. Image quality testing must be done at least every three months.
3. Digital QA/QC testing should be conducted with the same phantom or inanimate object and the same technique factors (machine settings) each time.
4. Test images shall be compared to previous test images to assess the degradation of image quality (spatial resolution, noise, artifacts, and contrast).
5. If an imaging test fails, the facility has 30 days to initiate repair of the system and 90 days to complete the repair.
6. The test results must be documented, and the documentation must include the date of the test and the initials of who performed the test. Any images created for QA/QC testing must also be retained for review at the authorized use location. **[see Appendix F]**
7. Digital QA/QC testing shall never be conducted using a human subject.

### Automatic and Manual Film Processing

QA/QC for film processing involves monitoring the temperature of the chemicals used and the darkroom conditions where the film is developed. The facility procedures must be written to ensure the requirements in this section are met. **[****§289.233(j)(10)]**

Automatic and manual film processing must be done according to the time-temperature relationships recommended by the film manufacturer. Variations in chemical temperature can greatly affect image quality. For automatic processing, the developer temperature must be posted in the film processing area. For manual processing, the time-temperature chart must be posted in the processing area. Chemicals must be replaced according to the manufacturer’s recommendations or at least every three months.

Darkroom conditions must be tested at least every six months. Lighting in a darkroom must be with “safelights” that do not expose the film. Any light leaking into the darkroom will cause fogging of the film that is being developed and reduce image quality. The safelight in the darkroom must be the recommended bulb, filter, and distance from the work area. Light leaks or the wrong bulb/filter in the safelight must be corrected. The steps to correct darkroom test failures must begin within 72 hours of discovery and must be completed within 15 days.

Radiation fields will also cause the film to fog, so unexposed film must be stored in a low-radiation area.

### Alternative Processing Systems

If the facility uses daylight processing systems, laser processors, self-processing film units, or other alternative processing systems, processing must be done according to the manufacturer’s recommendations for that processing system. **[§289.233(j)(11)]**

# APPENDIX A

**SAMPLE OPERATING AND SAFETY PROCEDURES**

Radiation Safety Program for

 **(Name of Facility)**

The RSO listed on the registration for this facility is: **(specify a name)**

**Direct all radiation-related questions and concerns to the RSO.**

The certificate of registration, operating and safety procedures, and any notices of violations involving radiological working conditions and corrective actions are located: **(specify a location)**

The room(s) in which the x-ray unit(s) is located and operated is a radiation area and is restricted (choose one of the following sentences).

[ ]  The Radiation area is designated by “Caution, Radiation Area” signs. **[§289.233(j)(4)(A)]**

---or---

[ ]  This facility is not required to post “Caution, Radiation Area” signs because the operators have continuous surveillance and control of the radiation area. **[§289.233(j)(4)(D)]**

**Dosimetry Monitoring**

1. Dosimeters (Check the appropriate box for your program)

[ ]  Radiation monitoring dosimeters are worn by employees. The dosimeter supplier is **(specify name),** and the dosimeters are exchanged **(specify exchange frequency).**

OR

 [ ]  Employees do not wear radiation monitoring dosimeters. Employees do not receive more than 500mR (5 mSv) annual exposure.

1. Unrestricted areas are surveyed or monitored.
2. The “control” dosimetry monitoring device and the employee dosimetry monitoring devices that are not being worn will be stored in an area away from radiation sources. This is in: **(specify location)**
3. The RSO is responsible for the occupational dose records and exchanging the individual dosimetry monitoring devices. The individual monitoring device readings (dosimetry badge reports) are located in: **(specify location)**

**Safety and Operating Procedures**

1. All workers are given instructions to meet the requirements of **[§289.233(j)(3)(G)] (See Appendix B).**
2. Protective devices are provided and checked annually for defects. The log for checking protective devices is located at: **(specify location)**
3. The yearly inventory of all radiation machines is located at: **(specify location)** **(see Appendix C)**
4. The following veterinarians order exams at this facility:

|  |
| --- |
|  |
|  |
|  |
|  |
|  |

1. Techniques charts are displayed on the control panel of each x-ray machine and are: **(choose the ones that apply)**

[ ]  Written

[ ]  Electronically displayed

[ ]  Graphically displayed

1. Mechanical devices for holding the patient or image receptor are used if the exam allows. Procedures for how and when to have a person hold the animal or image receptor are located at: **(specify location)**

**QA/QC Program**

1. This facility uses the following radiographic image system:

[ ]  Digital Image acquisition system

[ ]  Automatic or manual film processing

[ ]  Alternative Image processing

1. Protocol for the QA/QC program is established by (choose which one applies) **(See Appendix F)**:

[ ]  Manufacturer’s procedures to meet **§289.233(j)(10), (11), and (12)**

[ ]  Facility procedures to meet **§289.233(j)(10) and (11)**

1. The written QA/QC program is located at: **(specify location)**
2. Records of test dates and results along with the name of the employee who performed the test are maintained at **(specify location)**
3. Any unexposed film is stored at: **(describe location and procedures for storage)**
4. Films are developed with the time and temperature recommended by the x-ray film manufacturer. Specifications are posted in/at: **(specify location)**
5. Chemicals are replaced by **(specify supplier name)** according to the manufacturer’s or chemical supplier’s recommended interval, which is **(specify frequency)**, or no longer than three months.
6. Safe lights(s) in the film processing/loading area is /are provided under these conditions **(See Appendix E)**:

|  |  |  |
| --- | --- | --- |
| Filter Type | Bulb Wattage | Distance from the work area |
|  |  |  |
|  |  |  |

1. Light leaks around doors, ceiling, or other openings in the darkroom, are reported to the RSO. Repairs are initiated within 72 hours and completed within 15 days from the detection of the fault.
2. Darkroom light leak tests are performed at intervals not to exceed six months. A record of darkroom testing is maintained at **(specify location)**
3. This facility uses (choose from the following if applicable):

[ ]  Daylight Processing

[ ]  Laser Processors

[ ]  Self-processing film systems

[ ]  Other:

1. The manufacturer’s procedures for using the above system are located at: **(specify location)**

# APPENDIX B

**SAMPLE RECORD FOR INSTRUCTIONS OF INDIVIDUALS**

OPERATING AND SAFETY PROCEDURES FOR

**(Name of the Facility)**

**The Operating and Safety Procedures shall be read, signed, and dated by the RSO and all operators annually. [§289.233(j)(2)(A)]**

These procedures have been made available to each individual who operates the x-ray equipment on the date(s) indicated. **[§289.233(j)(2)(A)]**

\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

(Signature of RSO) (Date)

**Equipment Operator Statement:**

I have read these procedures and agree to follow them.

\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

(Signature of Equipment Operator) (Date)

\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

(Signature of Equipment Operator) (Date)

\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

(Signature of Equipment Operator) (Date)

\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

(Signature of Equipment Operator) (Date)

\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

(Signature of Equipment Operator) (Date)

\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

(Signature of Equipment Operator) (Date)

\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

(Signature of Equipment Operator) (Date)

# APPENDIX C

**SAMPLE ANNUAL EQUIPMENT INVENTORY LOG**

|  |  |  |  |
| --- | --- | --- | --- |
| MANUFACTURER | MODEL NUMBER | SERIAL NUMBER | LOCATION |
|  |  |  |  |
|  |  |  |  |
|  |  |  |  |
|  |  |  |  |
|  |  |  |  |
|  |  |  |  |
|  |  |  |  |
|  |  |  |  |
|  |  |  |  |

INITIALS AND DATE: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_INITIALS AND DATE: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

INITIALS AND DATE: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_INITIALS AND DATE: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

INITIALS AND DATE: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_INITIALS AND DATE: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

INITIALS AND DATE: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_INITIALS AND DATE: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

INITIALS AND DATE: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_INITIALS AND DATE: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

INITIALS AND DATE: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_INITIALS AND DATE: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

# APPENDIX D

**SAMPLE ANNUAL APRON CHECK LOG**

|  |  |  |
| --- | --- | --- |
| Apron # | Visual/Radiographic check (pass/fail) | Location |
|  |  |  |
|  |  |  |
|  |  |  |
|  |  |  |
|  |  |  |
|  |  |  |
|  |  |  |

INITIALS AND DATE: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_INITIALS AND DATE: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

INITIALS AND DATE: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_NITIALS AND DATE: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

INITIALS AND DATE: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_INITIALS AND DATE: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

INITIALS AND DATE: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_INITIALS AND DATE: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

INITIALS AND DATE: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_INITIALS AND DATE: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

INITIALS AND DATE: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_INITIALS AND DATE: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

INITIALS AND DATE: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_INITIALS AND DATE: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

# APPENDIX E

**SAMPLE DARKROOM LOG**

For calendar year: \_\_\_\_\_\_\_\_\_

Automatic Processor: Model # \_\_\_\_\_\_\_\_\_\_\_ Serial Number: \_\_\_\_\_\_\_\_\_\_\_\_\_

Or

Manual Processing: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Developer temperature: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Chemicals replaced \_\_\_\_\_\_\_\_\_\_\_\_ \_\_\_\_\_\_\_\_\_\_\_\_

(not to exceed 3 months) (initials/date) (initials/date)

 \_\_\_\_\_\_\_\_\_\_\_\_ \_\_\_\_\_\_\_\_\_\_\_\_

 (initials/date) (initials/date)

Darkroom light leak tests \_\_\_\_\_\_\_\_\_\_\_\_ \_\_\_\_\_\_\_\_\_\_\_\_

(not to exceed 6 months) (initials/date) (initials/date)

Light leaks or related deficiencies noted: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ \_\_\_\_\_\_\_\_\_\_\_

 (If applicable) (initials/date)

 \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ \_\_\_\_\_\_\_\_\_\_

 (If applicable) (initials/date)

Corrections of light leaks or related deficiencies (or attach service/work orders)

\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

(If applicable) (initials/date)

\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

(If applicable) (initials/date)

Lighting in film processing/loading area:

Filter type: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Bulb Wattage: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Distance from work surfaces: \_\_\_\_\_\_\_\_\_\_\_

# APPENDIX F

**SAMPLE QA**/**QC PROTOCOL FOR DIGITAL ACQUISITION SYSTEMS**

1. This facility will follow the protocol established by (choose one):

[ ]  **The manufacturer of the digital image acquisition system.**

* + - the QA/QC manufacturer protocols are made available to and are used by the operators.
		- If any test fails, repairs are started within 30 days and completed within 90 days.
		- Records
			* The QA/QC protocols are in the operating and safety procedures.
			* The following information is included with each test:
				+ date and initials of the individual completing the test,
				+ the images acquired,
				+ Technique factor settings
				+ Testing interval
				+ Test limits or the “Pass” or “Fail” conditions (if applicable)
				+ Test results in numerical form, if applicable.
			* The QA/QC records are kept at this facility for inspection by the Department.

[ ]  **The facility.**

* + - The QA/QC program includes image quality testing for:
			* spatial resolution (can you see small objects that are close together),
			* noise (does the object stand out from the background),
			* artifacts (objects on the image caused by a faulty machine or image processor), and
			* contrast (how well do the different densities stand out from each other)
		- The phantom is a commercially purchased testing tool or an inanimate object that shows at least three varying densities when imaged.
			* An image is taken of the same item in the same position every three months, using the same technique factors.
			* Each test image is compared with the very first image of the item for the four image quality tests listed above.
		- If any test fails, repairs are started within 30 days and completed within 90 days.
		- Records
			* The QA/QC protocols are in the operating and safety procedures.
			* The following information is included with each test:
				+ date and initials of the individual completing the test,
				+ the images acquired,
				+ Technique factor settings
				+ Testing interval
				+ Test limits or the “Pass” or “Fail” conditions (if applicable)
				+ Test results in numerical form, if applicable.
			* The QA/QC records are kept at this facility for inspection by the Department.

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| Test Performed | Test Limits | Test Results | Corrective Actions | Date Performed / Initials |
|  |  |  |  |  |
|  |  |  |  |  |
|  |  |  |  |  |
|  |  |  |  |  |
|  |  |  |  |  |
|  |  |  |  |  |
|  |  |  |  |  |
|  |  |  |  |  |
|  |  |  |  |  |

**SAMPLE QA/QC LOG**