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| Regulatory Guide 4.3Facilities for the Healing Arts, Podiatry, and Chiropractic Medicine |
| Consumer Protection DivisionRadiation Program |
|  June 2020 |

Table of Contents

[GUIDE FOR THE PREPARATION OF OPERATING AND SAFETY PROCEDURES FOR THE HEALING ARTS OF MEDICINE, PODIATRY, AND CHIROPRACTIC 2](#_Toc19624723)

[DEPARTMENT INSPECTIONS AND NOTIFICATIONS 3](#_Toc19624724)

[REGULATIONS 3](#_Toc19624725)

[REGISTRATION AND FEES 4](#_Toc19624726)

[EQUIPMENT PERFORMANCE EVALUATIONS (EPE) 4](#_Toc19624727)

[RADIATION SAFETY OFFICER (RSO) 5](#_Toc19624728)

[OPERATOR REQUIREMENTS 5](#_Toc19624729)

[INDIVIDUAL MONITORING REQUIREMENTS/DOSE TO OPERATORS 6](#_Toc19624730)

[USE OF PROTECTIVE DEVICES 7](#_Toc19624731)

[HOLDING OF PATIENTS AND/OR IMAGE RECEPTOR 8](#_Toc19624732)

[POSTING NOTICES, INSTRUCTIONS, REPORTS TO WORKERS, AND POSTING A RADIATION AREA 8](#_Toc19624733)

[OPERATION OF THE X-RAY UNIT 9](#_Toc19624734)

[DIGITAL IMAGING ACQUISITION SYSTEMS 10](#_Toc19624735)

[FILM PROCESSING 10](#_Toc19624736)

[ALTERNATIVE PROCESSING SYSTEMS 11](#_Toc19624737)

[EQUIPMENT INVENTORY 11](#_Toc19624738)

[APPENDIX A 12](#_Toc19624739)

[APPENDIX B 13](#_Toc19624740)

[APPENDIX C 14](#_Toc19624741)

[APPENDIX D 15](#_Toc19624742)

[APPENDIX E 16](#_Toc19624743)

[APPENDIX F 18](#_Toc19624744)

[APPENDIX G 19](#_Toc19624745)

[APPENDIX H 21](#_Toc19624746)

[APPENDIX I 22](#_Toc19624747)

# GUIDE FOR THE PREPARATION OF OPERATING AND SAFETY PROCEDURES FOR THE HEALING ARTS OF MEDICINE, PODIATRY, AND CHIROPRACTIC

The purpose of this guide is to provide an outline of the subjects to be addressed in the written operating and safety procedures required by 25 Texas Administrative Code §289.227(i)(2).

You can use this template by entering the information that is applicable and unique to your facility, removing information that does not apply to your facility. Other formats are acceptable, however, information required by §289.227(i)(2) must be included.

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**OPERATING AND SAFETY PROCEDURES FOR**

**\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_**

**(Name of Facility)**

This manual establishes procedures that will minimize radiation exposure to patients and employees. These procedures are provided to comply with rules enforced by the Texas Department of State Health Services (DSHS) Radiation Control. The certificate of registration contains conditions and restrictions that apply to the operation of the x-ray machines in this facility as well as a listing of the sections of the rules that apply. These rules are available for your review in/at **(specify location)**

|  |  |
| --- | --- |
| Regulatory Guides are issued to describe and make available acceptable methods of implementing specific sections of **Title 25 Texas Administrative Code Chapter 289, Texas Regulations for Control of Radiation**, to delineate techniques used by the staff in evaluating specific issues, or to provide guidance to applicants, licensees, or registrants. Regulatory Guides are **NOT** substitutes for regulations and compliance with them is not required. Methods and solutions different from those set out in the guides will be acceptable if they provide a basis for the Texas Department of State Health Services, Radiation Control, to make necessary determinations to issue or continue a license or certificate of registration. | Comments and suggestions for improvements in these Regulatory Guides are encouraged at all times and they will be revised, as appropriate, to accommodate comments and to reflect new information or experience. Comments should be sent to the Radiation Policy/Standards/Quality Assurance Group, Texas Department of State Health Services, P.O. Box 149347 Austin, Tx 78714-9347Regulatory guides may be reproduced or may be obtained by contacting the agency at (512) 834-6659 or accessing the Radiation Control web page at <http://dshs.texas.gov/radiation/x-ray/regulatory-guides.aspx> |

# DEPARTMENT INSPECTIONS AND NOTIFICATIONS

The department is authorized to perform an inspection of a public or private property to determine if radiation machines are being used according to the Texas Radiation Control Act, Health and Safety Code, Chapter 401, requirements of this section, orders, or certificates of registration issued thereunder regarding radiological working conditions. Department inspections are not announced.

# REGULATIONS

1. The Texas Radiation Control Act, Health and Safety Code, Chapter 401, authorizes DSHS to develop and enforce rules dealing with the use of radiation sources. Title 25 of the Texas Administrative Code (TAC) Section §289.227 applies to medical faculties of the healing arts, podiatry, and chiropractic and users of x-ray machines. In order for workers to be aware of the requirements of these regulations, a copy must be available for them.
2. All operators of x-ray machines in this facility are required to read these rules and understand the requirements and restrictions that apply to using an x-ray machine.
3. The rules must be available to operators in physical or electronic form.
4. The Certificate of Registration conditions, restrictions, and sections of rules that apply, and the text of the Rules are available for review in/at **(specify location).**

# REGISTRATION AND FEES

1. Any medical facility that uses radiation machines must register within 30 days after beginning use of the machine **[§289.226(f)(1)(A)].** Mobile service operations must receive authorization prior to conducting services **[§289.226(g)]**
2. Registrants who are also registered by the agency to receive, possess, acquire, transfer, or use class IIIb and class IV lasers shall also comply with the requirements of **§289.301** of this title (relating to Registration and Radiation Safety Requirements for Lasers and Intense-Pulsed Light Devices).
3. A complete list of fees for certificates of registration can be found in **§289.204**.

# EQUIPMENT PERFORMANCE EVALUATIONS (EPE)

1. An Equipment Performance Evaluation (EPE) is required to test that the radiation output from an x-ray machine is at an appropriate level and that the machine is working according to the manufacturer’s specifications. An EPE is required within 30 days of a machines installation or within 30 days of service that may change the radiation output of the machine. **[§289.227(o)(2)]**
2. EPE’s may only be performed by licensed medical physicists authorized by the department with a certificate of registration. The EPE must be documented and available for review by the department. The EPE must test the following items **[§289.227(o)(6)].**
	1. Timer accuracy and operation of the exposure switch
	2. Exposure reproducibility
	3. Kilovoltage Accuracy
	4. Tube Stability
	5. Collimation
	6. Entrance Exposure Limits

If an EPE shows that a system fails to meet regulatory specifications, the facility has 30 days to begin repair and the repair must be completed within 90 days. Exceptions may be approved by the department.

# RADIATION SAFETY OFFICER (RSO)

1. The rule requires that a Radiation Safety Officer (RSO) be designated on the application for registration. **[§289.226(e)(2)]**
2. The RSO has the responsibility and authority to assure and enforce safe practices when using radiation machines. RSO’s are expected to have knowledge of the hazards of working with an x-ray machine, education related to ionizing radiation safety, or experience in the use of the x-ray machine at the facility.

The RSO is responsible for establishing and maintaining operating and safety procedures so radiation exposure is as low as is reasonably achievable (ALARA). RSO’s are also responsible for investigating and reporting excessive radiation exposure or any loss of an x-ray machine. The RSO is considered the person responsible for the radiation safety program of facilities using x-ray machines. **[§289.232(i)(1)(E)(v)]**

The RSO for this facility is **(specify name)\_ .** Direct all questions and concerns to the RSO.

# OPERATOR REQUIREMENTS

All operators of x-ray machines must meet the appropriate credentialing requirements of the Medical Radiological Technologist (MRT) Certification Act, Texas Occupations Code, Chapter 601, or the appropriate practitioner’s regulatory body.

For information about credentialing, contact the

Texas Medical Board: 800-248-4062 http://www.tmb.state.tx.us/

Texas Board of Nursing: 512-305-7400 https://www.bon.texas.gov/

# INDIVIDUAL MONITORING REQUIREMENTS/DOSE TO OPERATORS

1. All occupational dose limits are found in **§289.231(m)**.
2. Any adult who is likely to receive a dose from occupational exposure to radiation in excess of 500 millirem in a year must use an individual monitoring device. **[§289.231(n)(1)(A)]**
3. Declared pregnant women who are likely to receive a dose from occupational exposure to radiation in excess of 100 millirem during the entire pregnancy must also use an individual monitoring device. **[§289.231(n)(1)(C)]**
4. If a woman voluntarily informs the RSO in writing of her pregnancy, the facility must ensure that the dose to the embryo/fetus does not exceed 0.5 rem (500 mrem) during the entire pregnancy. **[§289.231(c)(12) & §289.231(m)(1)(D)]**
5. If a declared pregnant woman is wearing multiple individual monitoring devices, dose to the embryo/fetus and the occupational doses shall be determined in accordance with **§289.231(m)(1)(D)(iv).**

If an additional individual monitoring device is used for monitoring the dose to the embryo/fetus of a declared pregnant woman, it shall be located at the waist under any protective apron being worn by the woman. **[§289.231(q)(1)(C)]**

1. Individual monitoring devices used for monitoring the dose to the whole body must be worn at the unshielded location where it will receive the highest exposure. When an apron is worn, the individual monitoring device must be worn outside of apron around neck (collar). **[§289.231(q)(1)(B)]**
2. Individual monitoring devices must be assigned to and worn by only one individual. **[§289.231(q)(1)(A)]**
3. If an individual works for another employer, they will provide a copy of the dosimetry report to the RSO to be included in the yearly record of occupational dose.
4. Individual monitoring devices not in use and the control badge will be stored away from rooms where radiation machines are in use. They are located in/at **\_\_(specify location)\_\_**.
5. **\_ (Specify name)\_\_** is responsible for the occupational dose records and exchanging the individual monitoring devices on **\_\_(specify exchange dates)**.
6. The individual monitoring device readings (dosimetry reports) are located in/at **\_\_(specify location)\_\_**.
7. If an individual suspects overexposure or a radiation incident, they must immediately notify the RSO. **[§289.231(hh)]**

# USE OF PROTECTIVE DEVICES

1. Protective devices, such as lead aprons, gloves, and shields, must be used to keep radiation exposure as low as reasonably achievable (ALARA). **[§289.227(i)(4)]**
2. Protective devices must be checked yearly for defects such as holes, cracks, or tears. This check can be done by visual or tactile means, or x-ray imaging. If defect is found at the time of the yearly check or any other time, notify the RSO and remove the device from service until it can be repaired or replaced. **[§289.227(i)(4)(B)]**
3. A record of the yearly check for defects of protective devices will be maintained. The record is located in/at **\_\_(specify location)\_\_**.
4. Protective device(s) is/are stored in/at **\_\_(specify location) \_**.
5. Protective devices must be used/provided in the following situations:
6. When necessary for an individual, other than the patient, to remain in room or hold a patient. **[§289.227(i)(8)(B)]**
7. When a patient must hold the image receptor. **[§289.227(i)(8)(C)]**
8. To protect other patients who cannot be moved out of the room. **[§289.227(i)(12)]**
9. When gonads are in or within 5 centimeters of the x-ray beam unless the shield interferes with the diagnostic procedure. **[§289.227(i)(13)]**

HOLDING OF PATIENTS AND/OR IMAGE RECEPTOR

1. A mechanical holding device must be used when a patient or image receptor must be supported during a radiation procedure. **[§289.227(i)(8)]**

Holding a patient, image receptor or both is only applicable for the following situations in this facility:

**\_\_\_\_\_(List Situations)\_\_\_\_\_\_\_ \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_**

 **\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_**

1. If an individual holds a patient or image receptor, that individual must wear protective shielding devices, must keep out of the direct beam, and should not be pregnant.
2. No individual will hold the x-ray tube or tube housing assembly supports during a radiographic exposure. **[§289.227(i)(11)]**

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

1. All employees must read the “Notice to Employees” sign posted in/at **\_\_(specify location)\_\_**.
2. The Certificate of Registration, operating and safety procedures, and any notices of violations involving radiologic working conditions are located in/at **\_ (specify locations\_** .
3. The rights and obligations of radiation workers are found in **§289.203(c),(d),(e),(f),(g) and (i).**
4. The room(s) in which the x-ray unit(s) is/are 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. [§289.231(x)(1)]**

 **---or---**

* **This facility is not required to post “Caution, Radiation Area” signs because our operators have continuous surveillance and access controls of the radiation area. [§289.227(d)(3) & §289.231(y)]**

# OPERATION OF THE X-RAY UNIT

1. No x-rays will be taken unless ordered by a (choose one: physician, chiropractor, or podiatrist). **[§289.227(b)(1) and §289.231(b)(1)]**

\_\_\_\_**(List names)**\_\_\_\_\_\_\_\_\_\_ \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

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

1. The operator must continually see, hear, and communicate with patient during an x-ray procedure. **[§289.227(i)(9)]**
2. The operator will be positioned so that their exposure is as low as reasonably achievable and that he/she is at least six feet from the source of radiation or is protected by a lead apron, gloves, or other shielding during the exposure. **[§289.227(i)(10)]**
3. A technique chart relevant to the particular radiation machine shall be used by all operators. **[§289.227(i)(1)]**
4. Techniques charts are displayed in the vicinity of the control panel of each x-ray machine and are **\_\_(choose the ones that apply: written, electronically displayed, graphically displayed) \_. [§289.227(i)(1)]**
5. The useful beam must be restricted to the area of clinical interest by using beam limiting devices (collimators). **[§289.227(l)(10(A)(i)]**

# DIGITAL IMAGING ACQUISITION SYSTEMS

1. The purpose of digital quality assurance/quality control (QA/QC) is to ensure the digital acquisition system is functioning as it was designed to and there has not been any image degradation that would result in the need for a repeat x-ray exposure.

2. **[Choose the provision that applies: §289.227(r)]**

* This facility will follow the digital QA/QC protocol established by the manufacturer.
* This facility will establish a written QA/QC protocol, incorporating the following procedures:[If a manufacturer’s QA/QC protocol is not available, DSHS recommends the following]
	+ Test each sensor using a purchased test tool or an inanimate object with at least 3 varying densities to test spatial resolution, noise, and contrast

(Example: Step wedge, phantom)

* + Set an interval for testing not to exceed 3 months.

Digital QA/QC testing should be conducted with the same phantom or inanimate object and the same technical factors (technique) each time.

* + Compare current image(s) with previous images
	+ Take corrective actions, if needed
	+ Document the date of the test, the results of the comparison to previous images, the name of the person performing the test, and any corrective action taken. [see Appendix D]

3. Protocol for QA/QC was established by (choose which one applies): **\_\_manufacturer/facility\_\_**. The QA/QC protocol is located **\_ (specify location).**

4. Records of test(s) will be maintained. The record(s) is/are located in/at **\_(specify location).**

1. Digital QA/QC testing shall never be conducted using a human subject.

# FILM PROCESSING

1. Unexposed film is stored **\_\_(describe location and procedures for storage)\_\_.**

2. Films must be developed by the time and temperature recommended by the x-ray film manufacturer. Specifications are posted in/at **\_\_(specify location)\_\_.**

3. Chemicals will be replaced by **\_(specify name)\_** according to manufacturer’s or chemical supplier’s recommended interval, which is **\_(specify frequency)\_**, or no longer than 3 months.

4. Safe lights(s) in the film processing/loading area is /are provided under these conditions:

Filter Type \_\_\_\_\_\_Bulb Wattage \_\_\_\_Distance from work area \_\_\_\_\_\_

5. Light leaks around doors, ceiling, or other openings in the darkroom, must be reported to the RSO.

6. Darkroom light leak tests must be performed at intervals not to exceed 6 months. A record will be maintained. The record is located in/at **\_(specify location) .**

# ALTERNATIVE PROCESSING SYSTEMS

This facility uses (choose from the following): **\_\_daylight processing systems, laser processors, self-processing film units, or other alternative processing systems\_.** Processing will be done according to the manufacturer’s recommendations, which are located in **\_\_(specify location)\_\_. [§289.227(q)]**

# EQUIPMENT INVENTORY

An inventory of all radiation machines must be taken at an interval not to exceed 1 year and shall include the manufacturer’s name, model and serial number of the control panel, and the location of the radiation machine (ex. room name/number). The yearly inventory of all radiation machines is maintained by  **(name of individual)\_\_.**

# APPENDIX A

SAMPLE RECORD FOR INSTRUCTIONS OF INDIVIDUALS

IN OPERATING AND SAFETY PROCEDURES FOR

**\_\_\_\_\_\_\_\_\_\_(name of facility)\_\_\_\_\_\_\_\_\_\_\_\_**

**The Operating and Safety Procedures shall be read, signed, and dated by the RSO and all operators annually. [§289.227(i)(2)(D)]**

These procedures have been made available to each individual who operates the x-ray equipment on the date(s) indicated. [§289.227(i)(2)(C)]

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

(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 B

SAMPLE YEARLY EQUIPMENT INVENTORY LOG

|  |  |  |  |
| --- | --- | --- | --- |
| MANUFACTURER | MODEL NUMBER | SERIAL NUMBER | LOCATION |
|  |  |  |  |
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INITIALS AND DATE: \_\_\_\_\_\_\_\_\_\_\_\_\_ INITIALS AND DATE: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

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

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

# APPENDIX C

SAMPLE YEARLY CHECK FOR DEFECTS OF PROTECTIVE DEVICES LOG

(LEAD APRONS, GLOVES, THYROID SHIELDS, GONADAL SHIELD)

|  |  |  |  |
| --- | --- | --- | --- |
| List Type of Device | ID#/Letter | List Defects(Holes, Cracks, tears) | Initials/Date |
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# APPENDIX D

SAMPLE QA/QC PROTOCOL FOR DIGITAL ACQUISITION SYSTEMS

1. This facility will follow the protocol established by the **\_\_choose one of the following: the manufacturer, facility\_\_.**

(If established by facility, complete 2-6. If established by manufacturer, the QA/QC manufacturer protocols must be available and used by operators)

2. The following QA/QC test(s) will be performed:

**\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_**

**(Specify technical factors/technique)**

**\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_**

**(Specify interval)**

**\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_**

**(Specify directions of how to perform test)**

3. The parameters should be within **\_\_(specify numerical range)\_\_**. (if applicable)

4. The images of the phantom/testing tool are saved for comparison in/at **\_\_(specify name of file)\_\_.**

5. Document the findings **\_\_(specify location of log)\_\_.**

6. Corrective actions (if needed) are/in **\_\_(specify location of records)\_\_.**

SAMPLE LOG FOR DOCUMENTATION OF QA/QC TESTS:

|  |  |  |  |
| --- | --- | --- | --- |
| Date Performed / Initials | Test Performed | Findings/Results | Corrective Actions Taken (If Applicable) |
|  |  |  |  |
|  |  |  |  |
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# APPENDIX E

**CT SYSTEMS and RADIATION PROTOCOL COMMITTEE (RPC) REQUIREMENTS §289.227(n)**

1. A maintenance schedule must be developed, followed, and included with the Operating and Safety Procedures. The maintenance schedule must include, but is not limited to, performing radiation output measurements annually. **[§289.227(n)(3)-(4)]**

 **\_\_(specify what tests and how often they will be performed)\_ .**

Records are located in/at **\_\_\_\_(specify location)\_\_\_\_.**

2. Acquisition of images made for quality control purposes will be obtained with phantoms, using protocols and intervals recommended by **the \_choose one: the manufacturer or by licensed medical physicist) .** These images are maintained by either of the following methods: **\_\_(choose one: photographic copies obtained from the image display or stored in digital form). [§289.227(n)(5)]**

3. Each facility utilizing CT systems shall develop a Radiation Protocol Committee (RPC). **[§289.227(n)(6)]**

4. The members required for the RPC shall include but are not limited to the following individuals: A radiologist or radiation oncologist, licensed medical physicist, the RSO, other individuals as deemed necessary by the registrant.

5. The RPC must meet as often as necessary, but no less than every 14 months in person. For interim meetings, video conferencing or teleconferencing is acceptable. These modes of communication should be used sparingly. Communicating via fax or email only does not satisfy the meeting requirements.

6. The facility must make a record of each RPC meeting to include: the date, name of individuals in attendance, minutes of the meeting, and actions taken.

**(See Appendix H for Sample RPC Attendee Meeting Log)**

RPC meeting records are located in/at **\_\_\_\_(specify location)\_\_\_\_.**

7. The RPC will establish and implement CT systems protocols that include but are not limited to:

* 1. A method to be used to monitor radiation exposure.
	2. A recommended reference level for CT procedures performed.
	3. Actions to be taken for cases when the reference level was exceeded which may include patient follow-up.
	4. A review of the established protocol at an interval not to exceed 14 months. If the RPC revises a protocol, the registrant shall maintain the previous documentation after the revision for inspection by the agency. Protocol is located **\_\_(specify location)\_\_.**

8. Procedures for maintaining records

* 1. The facility must make and maintain a record of radiation output information so the radiation dose to skin may be estimated.
	2. The record must include the following: patient identification, type and date of exam, identification of the CT system used, CTDIvol, DLP; or recommendations as identified in “Comprehensive Methodology for the Evaluation of Radiation Dose in X-ray Computed Tomography. Report of American Association of Physicists in Medicine, Task Group 111; The Future of CT dosimetry, February 2010” may be used to meet compliance.

# APPENDIX F

**FLUOROSCOPY REQUIREMENTS**

**§289.227(m)**

1. All fluoroscopy procedures must be under direct supervision of a medical practitioner.

2. Use of Fluoroscopic Machines:

1. The operator must reset the 5-minute cumulative timing device before each fluoroscopic procedure. [§289.227(m)(7)(A)]
2. For mobile fluoroscopy (i.e C-arm) units, a 30-centimeter(cm) source-to-skin distance (SSD) must be used. [§289.227(m)(6)(A)(ii)]
3. A 20cm spacer may be used for mobile fluoroscopy during \_ (list procedures) \_. The following precautionary measures must be used when a 20 cm spacer is used; \_\_(list measures)\_\_. Immediately following the procedure, the operator shall restore the 30 cm SSD. [§289.227(m)(6)(B)]
4. For stationary or portable C-arm fluoroscopic machines, manufactured on or after June, 10, 2006, having a maximum source-to-skin distance of less than 45 cm, a means to limit the source-to-skin distance to not less than 19 cm must be provided, and such systems will be labeled and used for extremity use only. For systems intended for specific surgical applications, provisions may be made for operation at a shorter source-to-skin distance, but in no case less than 10cm. [§289.227(m)(6)(C)]
5. While a fluoroscopy procedure is being performed, protective barriers (lead drapes, hinged sliding panels) shall be in place. If sterile fields or special procedures prohibit the use of protective barriers, all individuals in the room must wear protective aprons of 0.35mm lead equivalent material and the fluoroscopic field size shall be reduced to the absolute minimum required for the procedure being performed. [§289.227(m)(8)]
6. When wearing a protective apron during fluoroscopy procedures, multiple individual monitoring devices may be worn. Occupational doses shall be determined in accordance to §289.231(m)(3)(C).

3. This facility (choose the one applies): **does/does not** perform fluoroscopically- guided interventional (FGI) procedures.

4. If FGI procedures are performed, see Appendix G.

# APPENDIX G

**RADIATION PROTOCOL COMMITTEE (RPC) REQUIREMENTS FOR FLUOROSCOPICALLY INTERVENTIONAL GUIDED (FGI) PROCEDURES §289.227(m)(9)**

1. Each facility utilizing FGI procedures shall develop a Radiation Protocol Committee (RPC).

FGI Procedure – An interventional diagnostic or therapeutic procedure performed via percutaneous or other routes usually with local anesthesia or intravenous sedation, which uses external ionizing radiation in the form of fluoroscopy to localize or characterize a lesion, diagnostic site, or treatment site, to monitor the procedure, and to control and document therapy.

**\_\_(List FGI Procedures performed by the facility)\_\_**

2. The RPC shall meet no less than every 14 months in person. For interim meetings, video conferencing or teleconferencing is acceptable. These modes of communication should be used sparingly. Communicating via fax or email only does not satisfy the meeting requirements.

3. The registrant shall make a record of each RPC meeting to include: The date, name of individuals in attendance, minutes of meeting, and actions taken.

**(See Appendix H for Sample RPC Attendee Meeting Log)**

RPC meeting records are located in/at **\_\_(specify location)\_\_.**

1. Members required for the RPC, but not limited to the following individuals, are: a licensed physician of healing arts, licensed medical physicist, the RSO, other individuals as deemed necessary by the registrant.
2. The RPC will establish and implement FGI protocols that include but are not limited to:

a. A restriction of the use of fluoroscopic systems for interventional purposes.

b. A method to be used to monitor radiation exposure.

c. A recommended reference level for FGI procedures.

d. Actions to be taken for cases when the reference level was exceeded which may include patient follow-up.

e. A review of the established protocol at an interval not to exceed 14 months.

f. If the RPC revises a protocol, the registrant shall maintain the previous documentation after the revision for inspection by the agency.

 Protocols are located **\_\_(specify location)\_\_.**

6. Procedures for maintaining records

a. The facility shall make and maintain a record of radiation output

information so the radiation dose to skin may be estimated.

1. The record shall include the following: patient identification, type and date of exam, identification of the fluoroscopy system used, and cumulative air kerma or dose area product used if the information is available on the fluoroscopic system.
2. If cumulative air kerma or dose area product are not displayed on the fluoroscopic system, the following information is necessary for the record: fluoroscopic mode (such as high-level or pulsed mode of operation), cumulative fluoroscopic exposure time, and number of films or recorded exposures.

# APPENDIX H

**SAMPLE RADIATION PROTOCOL COMMITTEE (RPC) MEETING LOG**

**(Can be used for CT and/or Fluoroscopy RPC Meetings)**

**The following individuals were present at the RPC meeting held on:**

**\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_**

**(Specify Meeting Date)**

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

(Name of attendee) (Title of attendee)

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

(Name of attendee) (Title of attendee)

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

(Name of attendee) (Title of attendee)

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

(Name of attendee) (Title of attendee)

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

(Name of attendee) (Title of attendee)

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

(Name of attendee) (Title of attendee)

**Meeting Minutes:**

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

**Action(s) Taken:**

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

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

# APPENDIX I

**SAMPLE DARKROOM REQUIREMENTS LOG**

**FOR CALENDER 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: \_\_\_\_\_\_\_\_\_\_