Texas Department of State Health Services
Radiation Safety Licensing Branch

REGULATORY GUIDE 4.3

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

1. Introduction

Operating and safety procedures are required by 25 Texas Administrative Code (TAC) §289.227(i)(2). The model procedures in this regulatory guide are generalized. You must write procedures that are specific for your facility. By using the sections of this guide that apply, you may create your unique set of operating and safety procedures. This guide may also be used to develop operating and safety procedures for facilities with mobile services. Although other formats are acceptable, information contained in §289.227(t) must be included in your operating and safety procedures. Individuals who are sole practitioners and sole operators and the only occupationally exposed individual are exempt from the requirement to have and implement written operating and safety procedures.

II. Sample Operating and Safety Procedures

OPERATING AND SAFETY PROCEDURES
FOR

_____
(name of facility)

This manual establishes procedures that will minimize radiation exposure to patients and employees. They are provided to comply with rules enforced by the Texas Department of State Health Services (DSHS), Radiation Control. The rules require that each x-ray facility be registered with 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) [See §289.203(b)].

The rules require that a Radiation Safety Officer (RSO) be designated. The RSO has the responsibility and authority for assuring safe radiation practices and serves as the contact person between this facility and the DSHS, Radiation Control. Direct all your questions or concerns on radiation safety to the RSO for this facility, (specify name) [See §289.226(e)(2)].

A. Operator and Patient Safety

1. Credentialing Requirements for Operators of X-ray Machines

All operators of x-ray machines, including fluoroscopy, must meet the appropriate credentialing requirements of the Medical Radiologic Technologist (MRT) Certification Act, Texas Occupations Code, Chapter 601. [See §289.227(i)(5)]. [For information about credentialing, contact the MRT Program at 512-834-6617].

2. Individual Monitoring Requirements [See §289.231(n)(1) and (s)(3)] 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 such as a film badge or thermoluminescent dosimeter. 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 [See §289.231(n)(1)(C)].

a. Individual monitoring devices must be worn at the unshielded location of the whole body likely to receive the highest exposure. When a protective apron is worn, the location of the individual monitoring device is typically at the neck (collar) [See §289.231(q)(1)(B)].

b. Additional individual monitoring devices used for monitoring the dose to the embryo/fetus of a declared pregnant woman must be located at the waist under any protective apron being worn by the woman [See §289.231(q)(1)(C)].

c. The individual monitoring device shall be assigned to and must be worn only by one individual [See §289.231(q)(1)(A)].

d. When wearing a protective apron during fluoroscopy procedures, multiple individual monitoring devices may be worn. When multiple devices are worn, occupational doses shall be determined in accordance with §289.231(m)(3)(C).

e. If multiple individual monitoring devices are worn by a declared pregnant woman, dose to the embryo/fetus and the occupational dose to the woman shall be determined in accordance with §289.231(m)(1)(D)(iv).

f. Individual monitoring devices that are not being worn and the control monitoring device will be stored in an area that is away from rooms where radiation machines are in use. This is in/at (specify location).

g. (specify name) is responsible for the occupational dose records and exchanging the individual monitoring devices on (specify exchange dates). The individual monitoring device readings (film badge reports) are located in/at (specify posting or records location).

h. If you are working for another employer and receive an occupational dose, you should report that dose to the RSO so that it can be included in your annual record of occupational dose.

3. Use of Protective Devices

a. Use protective devices, such as lead aprons, gloves, and shields, to reduce exposure to radiation and keep radiation exposure as low as reasonably achievable (ALARA). Protective devices must be used or provided in the following situations:

(i) when it is necessary for an individual other than the patient to remain in the room or hold a patient [See §289.227(i)(4), (i)(8)(B)];

(ii) when a patient must hold the image receptor [See §289.227(i)(8)(D)];

(iii) when it is necessary to protect other patients who cannot be moved out of the room (Examples: critical care areas, emergency rooms, or trauma units) or [See §289.227(i)(12)]; or

(iv) when the gonads are in or within 5 centimeters of the x-ray beam, shields must be used unless the use of the shield interferes with the diagnostic procedure [See §289.227(i)(13)].

b. If fluoroscopic procedures are being 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 0.5 mm lead equivalent material [See§289.227(m)(8)].

c. Protective device(s) is/are stored in/at (specify location).

d. Protective devices shall be checked annually for defects, such as holes, cracks, or tears. This check can be done by visually inspecting or feeling the protective devices or may also be done by x-raying these items. A record will be kept of this check [See Appendix C]. 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 [See §289.227(i)(4)(B)].

4. Holding of patients and/or film

a. If a patient or film must be supported during a radiation procedure, use a mechanical holding device when circumstances permit. Mechanical devices cannot be routinely used during the following situations in this facility [See §289.227(i)(8)(C)(*i*)].

(1) (list situations)
(2)
(3)

b. If it becomes necessary for an individual to hold a patient or film, the holder should not be pregnant. They must wear protective devices and keep out of the direct beam.

5. Holding of x-ray tubes. The x-ray tube housing shall not be held by an individual during any radiographic exposure [See §289.227(i)(11)].

6. Posting Notices, Instructions, and Reports to Workers; and Posting a Radiation Area

a. Read the "Notice to Employees" sign posted in/at (specify location).

b. The certificate of registration, operating and safety procedures, and any notices of violations involving radiological working conditions are located in/at (specify location(s) [See §289.203(b)].

c. Your rights and obligations as a radiation worker are found in §289.203(c), (d), (e), (f), (g), and (i).

d. The room(s) in which the x-ray machine(s) is/are located and operated is a radiation area and is restricted [See §289.231(x)].

(Choose one of the following sentences)

- The radiation area is designated by "Caution Radiation Area" signs [See §289.231(x)(1)].

- Our facility is not required to post "Caution Radiation Area" signs because our operators have continuous surveillance [See §289.227(d)(3)].

B. Dose to Operators

1. Occupational dose limits are found in §289.231(m)

2. If any employee is pregnant or becomes pregnant, she may voluntarily inform the RSO in writing of the pregnancy [See §289.231(c)(12). If the RSO is informed of the pregnancy, the facility must ensure that the dose to the embryo/fetus does not exceed 0.5 rem (500 mrem) during the entire pregnancy [See §289.231(m)(1)(D)].

3. Radiation Incidents or Overexposure

   If you suspect there has been an excessive exposure or a radiation incident, immediately notify the RSO.

C. Operation of the X-ray Machine and Film Processing

1. Ordering of X-ray Exams

   No x-ray exams shall be taken unless ordered by a __(choose one: name(s) of physician, chiropractor, or podiatrist) [See §289.231(b)(1) and §289.227(b)(1)].

2. Operator Position During Exposure

   a. The operator must be able to continuously see, hear, and communicate with the patient [See §289.227(i)(9)].

   b. During the exposure, the operator must be positioned so that the operator exposure is as low as reasonably achievable (ALARA) and that he/she is at least six feet from the machine or is protected by a lead apron, gloves, or other shielding [See §289.227(i)(10)].

3. Use of a Technique Chart

Use of a technique chart aides in reducing the exposure to the operator and patient and it must be used for all exposures. Our technique charts are displayed in the vicinity of the control panel of each x-ray machine and may be (choose one, two, or all of the following: written; electronically displayed; or graphically displayed) [See §289.227(i)(1)].

4. Restriction and Alignment of the Beam

The useful x-ray beam shall be restricted to the area of clinical interest [See §289.227(l)(1)(A)(i) and §289.227(m)(8)(B)(ii)]. Use the centering and beam limiting devices (collimator) provided on the x-ray machine.

5. Use of Fluoroscopic Machines

a. Reset the 5-minute cumulative timing device before each fluoroscopic procedure [See §289.227(m)(7)(A)].

b. For mobile fluoroscopy (i.e. C-arm) machines, a 30-centimeter (cm) source-to-skin distance (SSD) must be used [See §289.227(m)(6)(A)(*ii*)].

c. A 20-cm SSD (spacer) may be used for mobile fluoroscopy during (list procedures). The following precautionary measures must be used when a 20-cm spacer is utilized: (list measures). Immediately following the procedure, restore the 30-cm SSD [See §289.227(m)(6)(B)].

d. See Section (II)(A)(3)(b) of these procedures for use of protective devices during fluoroscopy.

6. Use of Portable Machines

- Portable x-ray equipment is mounted on a permanent base with wheels and/or casters for moving while completely assembled.

- Portable x-ray equipment may also be designed to be hand-carried.

During the exposure the operator:

a. must be positioned so that his/her exposure is as low as reasonably achievable (ALARA) [See §289.227(i)(10)] (e.g. 6 feet or more away); and/or
b. must wear lead apron, gloves if necessary, or be protected by

other shielding [See §289.227(i)(4)]; and

c. should never be in line with the direct beam.

7. Film Processing [See Appendix B]

a. Unexposed film is stored __(describe location and procedures for storage)____.

b. Films shall be developed by the time and temperature recommended by the x-ray film manufacturer. These specifications are posted in/at __(specify location)__ [See §289.227(p)(1)].

(i) Check the temperature at the beginning of the work day. Do not process films unless the developer temperature is (specify temperature)___. Manual processing temperature should be checked throughout the work day.

(ii) For automatic processors, run blank films through the processor at the beginning of the work day.

c. Expiration dates on film and chemicals should be checked periodically. New film or chemicals should be rotated so the oldest are used first. Do not use films or chemicals after the expiration date.

d. Chemicals will be replaced by __(specify name)___ according to the manufacturer's or chemical supplier's recommended interval, which is _____(specify frequency)____, or no longer than every three months [See §289.227(p)(2)].

e. Safe light(s) in the film processing/loading area is/are provided under these conditions and should not be changed without authorization from the RSO [See §289.227(p)(4)].

Filter type	_____
Bulb wattage	_____
Distance from work surfaces	_____

f. If you see light leaks around doors, ceilings, or other openings in the darkroom, notify the RSO [See §289.227(p)(3)].

8. Alternative Processing Systems

Our facility uses _____(choose from the following: _____ daylight processing systems, laser processors, self-processing (Polaroid) film units, or other alternative processing systems). Processing will be done according to the manufacturer's recommedations, which are located in ____(specify location)_____ [See §289.227(q)].

9. Digital imaging acquisition systems

Our facility uses a digital imaging acquisition system. Processing will follow the quality assurance/quality control protocol for image processing established by ___(choose one: the manufacturer or our facility)_____. The protocol are located in ____(specify location)_____ [See §289.227(r)].

D. Inventory List [See Appendix D and §289.226(m)(1)(B)].

An annual inventory of all radiation machines is maintained by ____(name of individual)_____.

APPENDIX A

SAMPLE RECORD FOR INSTRUCTION OF INDIVIDUALS IN OPERATING AND SAFETY PROCEDURES FOR

_____(name of facility)_____

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

_____

(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)

APPENDIX B

SAMPLE DARKROOM REQUIREMENTS LOG FOR CALENDER YEAR _____

Automatic processor (Model #, Serial #) _____

OR

Manual processing _____

Developer temperature _____

Chemicals replaced (manufacturer's or chemical supplier's recommendations or every 3 months)	_____ (initials)(date)	_____ (initials)(date)
	_____ (initials)(date)	_____ (initials)(date)
Darkroom light leak tests performed (every 6 months)	_____ (initials)(date)	_____ (initials)(date)

Lighting checked in film processing/loading area:

filter type _____

bulb wattage _____

distance from work surfaces _____

_____ (initials)(date)	_____ (initials)(date)

Light leaks or related deficiencies noted _____(initials)(date)_____

_____(initials)(date)_____

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

_____
(initials) (date)

_____
(initials)(date)

APPENDIX C

SAMPLE PROTECTIVE DEVICES SURVEY
(LEAD APRONS, GLOVES, THYROID SHIELDS, GONADAL SHIELDS)

List Type of Device	ID#/Letter	List Defects (Holes, cracks, tears)	Initials/Date
Lead Apron	#4	Hole, Upper Right	XX 12/12/04
Lead Apron	#6	No defects found	XX 12/12/04
Lead Glove	A	No defects found	XX 12/12/04

APPENDIX D

SAMPLE EQUIPMENT INVENTORY LIST

ANNUAL INVENTORY DATE: _____PAGE ___ OF ___

FACILITY NAME: _____(name of facility)_____

REGISTRATION NO.: R00XXX

MANUFACTURER	MODEL NUMBER	SERIAL NUMBER	LOCATION (EX. : ROOM NO.)
BENNETT	HFQ-450	ABC-123	123