



REGULATORY GUIDE 4.6

TEXAS DEPARTMENT OF STATE HEALTH SERVICES
RADIATION SAFETY LICENSING BRANCH (RSLB)

GUIDE FOR THE PREPARATION OF OPERATING AND SAFETY PROCEDURES FOR ACCELERATORS, THERAPEUTIC RADIATION MACHINES, AND SIMULATORS

I. Introduction

Operating and safety procedures are required by 25 Texas Administrative Code (TAC) §289.229(f)(3)(B) for research and development and industrial accelerators and §289.229(h)(1)(G) for therapeutic radiation machines used in the healing arts and veterinary medicine. The model procedures in this regulatory guide are generalized. **Procedures must be written that are specific for your facility.** By using the sections of this guide that apply, a unique set of operating and safety procedures may be created. Although other formats are acceptable, information contained in §289.229(f)(3)(B) for research and development and industrial accelerators and §289.229(h)(1)(G) for therapeutic radiation machines must be included in your operating and safety procedures.

II. Sample Operating and Safety Procedures

OPERATING AND SAFETY PROCEDURES FOR

(name of facility)

A. General requirements for research and development, industrial accelerators, therapeutic radiation machines, and simulators.

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 facility using accelerators and/or simulators be registered with DSHS, Radiation Control.

The certificate of registration contains conditions and restrictions that apply to the operation of the radiation 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) [§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 RSO name). [§289.226(e)(2)].

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 Machine Source Group, Texas Department of State Health Services, 1100 W. 49th Street, Austin, Texas 78756-3189.

Regulatory guides may be reproduced or may be obtained by accessing the Radiation Control web page at www.dshs.state.tx.us/radiation/regguide.shtm.

A. (Continued):

1. Personnel Monitoring Requirements

- (a). 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 50 millirem during the entire pregnancy must also use an individual monitoring device. [§289.231(n)]
- (b). The individual monitoring device shall be assigned to and must be worn only by one individual [§289.231(q)(1)(A)].
- (c). 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). [§289.231(q)(1)(B)]
- (d). 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 [§289.231(q)(1)(C)]. 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 the rules. [§289.231(m)(1)(D)(iv)].
- (e). 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).
- (f). (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).
- (g). If you are working for another employer and receive an occupational dose, report that dose to the RSO so that it can be included in your annual record of occupational dose.

2. 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)) [§289.203(b)].
- (c). Your rights and obligations as a radiation worker are found in §289.203(c),(d), and (e) of the rules.
- (d). The room(s) in which the radiation machine(s) is/are located and operated is a radiation area and is restricted [§289.231(x)].

3. Radiation incidents, overexposures, and therapy events (medical misadministrations).

The following incidents, overexposures, or medical misadministrations should immediately be reported to the RSO.

- (i). stolen, lost, or missing radiation machines [§289.231(gg)];

- (ii). overexposures [§289.231(hh)]; and
 - (iii). therapy events (misadministrations) [§289.229(i) and (j)].
4. Training and credentialing for operators of equipment.
- (a). Operators of accelerators used in research and development and industrial operations shall receive instruction in and demonstrate competence with the following [§289.229(f)(4)]: This will be accomplished by (name method, i.e., classes, one-on-one-instruction by the RSO, reading and testing).
 - (i). operating and safety procedures;
 - (ii). radiation warning and safety devices;
 - (iii). identification of hazards associated with use of the equipment; and
 - (iv). procedures for reporting an actual or suspected overexposure.

A record shall be maintained for agency inspection. [See Appendix A].

- (b). Individuals who operate radiation machines for human use shall meet the appropriate credentialing requirements of rules issued in accordance with the Medical Radiologic Technologist Certification Act, Texas Occupations Code, Chapter 601. Copies of the credentialing document shall be maintained at each facility where the individual is working. They will be kept at (name location) [§289.229(h)(1)(C)].
- B. Requirements for accelerators used in research and development and industrial operations. [§289.229(f)(3)(B)]:
1. The methods used to secure the accelerator from unauthorized use include (list methods specific to this facility and operation); and
 2. The procedures for testing interlocks, entrance controls, and alarm systems include (list procedures specific to this facility to include):
 - (a). all interlocks shall be tested for proper operation on (date)(time) by (name).
 - (b). All visible or audible alarms shall be tested for proper operation on (date)(time) by (name).

- C. Requirements for accelerators and simulators used only in the healing arts.
1. Use of therapeutic radiation machines in the healing arts or veterinary medicine shall be by or under the supervision of a physician in the healing arts or a veterinarian. [§289.229(b)(1)]. A written directive shall be prepared prior to administration of a therapeutic radiation dose except where a delay to provide a written directive would jeopardize the patient's health. [§289.229 (F)(ii)]
 2. Operator/patient communication. The operator must be able to continuously view and communicate with the patient.
 - therapeutic radiation machines operating below 1 MeV [§289.229(h)(2)(B)]
 - therapeutic radiation machines operating at or above 1MeV [§289.229(h)(3)(B)(iv) and (v)]

- radiation therapy simulators [§289.229(h)(4)(A)(iv)]
- (a). Two-way verbal/aural communication between the patient and the operator at the control panel is established by means of (name method, i.e., intercoms, etc.) .

For treatment involving therapeutic radiation machines operating at or above 1 MeV, other methods of communication shall be used if excessive noise levels or treatment requirements make aural communication impractical. The alternative method is (name method) and has been submitted to and received approval from the Bureau of Radiation Control, Registration on (date).

- (b). (name system used, i.e., windows, mirrors, or closed-circuit television) shall be provided for continual observation of the patient. An alternate viewing system consisting of (name alternate, i.e., windows, mirrors, or closed-circuit television) shall be a backup in the event of failure of the primary system.
- (c). If the viewing system and alternate system described in (b) are both inoperable, treatment shall not be performed until one of the systems is restored. Failure of the verbal/aural communication and/or viewing systems shall be reported to (RSO or alternate in his/her absence).

3. Therapeutic radiation machines shall not be used for irradiation of patients unless full calibration measurements and quality assurance checks have been completed;

Therapeutic radiation machines shall not be used in the administration of radiation therapy if a spot check indicates a significant change in the operating characteristics of a system as specified in the written procedures;

Therapeutic radiation machines shall not be left unattended unless secured by a locking device which will prevent unauthorized use (A computerized password system would also constitute a locking device).

D. Calibrations and spot checks.

- therapeutic radiation machines operating below 1 MeV [§289.229(h)(2)(D)(ii) and(iii)]
- therapeutic radiation machines operating at or above 1MeV [§289.229(h)(3)(C)(ii) and (iii)].
- simulators [§289.229(h)(4)(C)(vi)]

1. Procedures for calibrations were developed by (name physicist) and shall be performed by (name physicist).
2. Spot checks were developed by (name physicist) and are to be performed by (name physicist) or by (name) with a review by a licensed medical physicist with a specialty in therapeutic radiological physics (name physicist) within five treatment days.
3. The following are our procedures (include procedures).

III. Acknowledgement.

Once you have reviewed these operating and safety procedures, sign and date the acknowledgement form [See Appendix D].

APPENDIX A

**SAMPLE RECORD FOR DOCUMENTING
TRAINING AND COMPETENCE IN RESEARCH AND DEVELOPMENT AND INDUSTRIAL
OPERATIONS for**

_____ (name of facility) _____

The following individuals completed training in and demonstrated competence with the items in §289.229(f)(4).

Printed Full Name _____ Date: _____

Printed Full Name _____ Date: _____

Printed Full Name _____ Date: _____

Printed Full Name _____ Date: _____

Printed Full Name _____ Date: _____

Printed Full Name _____ Date: _____

Printed Full Name _____ Date: _____

Printed Full Name _____ Date: _____

Printed Full Name _____ Date: _____

Printed Full Name _____ Date: _____

Printed Full Name _____ Date: _____

Printed Full Name _____ Date: _____

Printed Full Name _____ Date: _____

Printed Full Name _____ Date: _____

Signature of RSO _____

Date: _____

APPENDIX C

SAMPLE DARKROOM REQUIREMENTS LOG
FOR CALENDER YEAR

Automatic processor (Model #, Serial #) _____

Developer temperature _____

Chemicals replaced (manufacturer's/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:
(every 6 months)

filter type _____

bulb wattage _____

distance from work surfaces _____

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

Light leaks or related deficiencies noted

Deficiencies (initials) (date)

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

Corrections (initials) (date)

Corrections (initials) (date)

APPENDIX D

**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.

(Signature of RSO)

(Date)

Equipment Operator Statement:

I have read these procedures and agree to abide by 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)