Regulatory Guide 4.4
Dental Facilities

Consumer Protection Division

Radiation Program

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GUIDE FOR THE PREPARATION OF OPERATING AND SAFETY PROCEDURES FOR DENTISTRY

Operating and safety procedures are required by 25 Texas Administrative Code (TAC) **§289.232(j)(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 **§289.232 (j)(2)(B)** must be included in your operating and safety procedures. If you are a sole practitioner and sole operator, and the only occupationally exposed individual, you are exempt from **§289.232(j)(2)** and do not have to maintain operating and safety procedures

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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 _____ **[See §289.232].**

(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 78714-9347

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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 §289.232 applies to dental facilities and users of dental 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 dental x-ray machines in this facility are required to read these rules and understand the requirements and restrictions that apply to using a dental 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 dental facility that uses intraoral or extraoral radiation machines must register within 30 days after beginning use of the machine **[§289.232(i)(1)].** Mobile service operations must receive authorization prior to conducting services **[§289.232(i)(2)].**

2. Registrants who are also registered by the agency to receive, possess, acquire, transfer, or use class IIIb and class IV lasers in dentistry 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. The fee for a certificate of registration for a facility using only dental radiographic machines is $370. The fee for a certificate of registration for a facility using Class 3B or Class 4 lasers is $230. **[§289.204(j)]**

DENTAL EQUIPMENT PERFORMANCE EVALUATIONS (EPE)

1. An Equipment Performance Evaluation (EPE) is required to test that the radiation output from the dental 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. **[§289.232(j)(5)(J)(i)]** Dental machines (intraoral, panoramic or cephalometric) are also required to have an EPE done every four years. Dental CT systems (those that make a 3D image) must have an EPE done annually, not to exceed 14 months.**[§289.232(j)(5)(J)(ii)]**

2. EPE's may only be performed by service companies 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 **[§289.232(j)(5)(J)(v) through (xi)].** The service company technician will also evaluate that the machine meets the requirements of **§289.232(j)(5)**

    a. Timer accuracy and operation of the exposure switch.
    b. Exposure reproducibility.
    c. Kilovoltage Accuracy.
    d. Tube Stability.
    e. Collimation.
    f. Entrance Exposure Limits.

3. 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) is designated on the application for registration. **[§289.232(i)(1)(E)]**

2. The RSO has the responsibility and authority to assure and enforce safe practices when using dental radiation machines. RSO's for dental facilities 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.

3. 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)]**

4. The RSO listed on the registration for this facility is _____ Direct all questions and concerns to the RSO. (specify name)

OPERATOR REQUIREMENTS

It is responsibility of the facility to ensure that radiation machines will be operated by individuals qualified by reason of training and experience to use dental x-ray machines in a safe manner. **[See §289.232(i)(1)(D)]** The Texas State Board of Dental Examiners requires dental assistants and dental hygienists to have appropriate training before they can take dental x-rays unsupervised. Dental hygienists are considered trained based on their credentials. Dental Assistants must complete an approved training course and be issued a Dental Assistant Radiology License by the State Board of Dental Examiners before taking dental x-rays without supervision.

Please contact the Texas State Board of Dental Examiners at (512)463-6400 (http://tsbde.texas.gov/) for further information.

INDIVIDUAL MONITORING REQUIREMENTS/DOSE TO OPERATORS

1. Radiation exposure monitoring is not required for personnel operating only dental radiation machines for dental diagnostic purposes. The annual exposure to dentists, hygienists or assistants has historically been very low. **[See §289.232(e)(7)]**

2. However, dental facilities are still required to keep the radiation exposure to workers and the public below certain limits.

3. All occupational dose limits are found in **§289.232(j)(3)(A).**

4. A facility that uses dental x-ray machines according to §289.232 should be able to maintain employee radiation exposure and public radiation exposure to levels well below these limits.

5. A woman may choose to "declare" her pregnancy to her employer so that radiation dose to the fetus is monitored. Declared pregnant women who are likely to receive a dose from occupational exposure to radiation in excess of 1 millisievert (100 mrem) during the entire pregnancy must also use an individual monitoring device. **[§289.232(j)(3)(A)(i)(IV)]**

6. 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 5 millisieverts (0.5 rem) during the entire pregnancy. It is also recommended that the fetus dose is restricted to no more than 0.5 Millisieverts (50 mrem) per month. **[§289.232 (j)(3)(A)(i)(V)]**

HOLDING OF PATIENTS AND/OR IMAGE RECEPTOR

1. When a patient or image receptor must be held in position during a dental x-ray, a facility is required to use mechanical supporting or restraining devices if and when the exam permits. **[See §289.232(j)(11)]** Your written operating and safety procedures must describe when a mechanical supporting or restraining device cannot be used and also procedures for selecting who will support or restrain the patient or image receptor.

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

   (List Situations) _____ _____

   _____ _____

2. Neither patient or employee is allowed to hold the x-ray tube or tube housing assembly during a dental x-ray exam. The only exceptions are dental x-ray machines designed to be held during an exposure and only when the operator is following the manufacturer's procedures. **[§289.232(c)(4)]**

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

1. The following documents must be made available to employees:
   a. RC Form 232-1 "Notice to Employees" must be posted so that all employees can read it.
   b. The Certificate of Registration, operating and safety procedures, and any notices of violations involving radiologic working conditions and corrective actions taken must be made available to employees.
   c. Section §289.232 of the Texas Administrative Code, Title 25 must be made available to employees.

2. The required documents can be found in/at:
   (Specify Location)
3. 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. [§289.232(j)(4)(C)]**

   ---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. [§289.232(j)(4)(D)]**

OPERATION OF THE X-RAY UNIT

1. No x-rays shall be taken unless ordered by a dentist licensed by Texas State Board of Dental Examiners. **[§289.232(b)(1)(B)]**

The following dentists order dental exams at this facility:

2. The operator shall continually see, hear, and communicate with patient during a dental exam. **[§289.232(j)(11)(C)]**

3. The operator shall 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 behind a protective barrier. **[§289.232(j)(11)(C)]**

4. A technique chart for each dental radiation machine used at the facility shall be posted next to the control panel or electronically displayed at the control panel. The technique chare must be used by all operators. **[§289.232(j)(5)(A)]**

5. 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)__**.

DIGITAL IMAGING ACQUISITION SYSTEMS

1. The purpose of digital imaging quality assurance/quality control (QA/QC) is to ensure the digital image acquisition system is functioning as it was designed to and there has not been any image degradation that would result in a missed diagnosis or the need for a repeat x-ray exposure.
2. A QA/QC program consists of tests that are repeated on a regular schedule and done in a way that is consistent with way the previous test was performed. For example, an image quality test should be repeated with the same phantom in the same position with the same technique factors each time.

3. It is a serious violation to allow a patient, employee, or contractor to be exposed as a test image subject. All dental radiographs on living humans must be for healing arts purposes only and taken under the order of a licensed dentist. **[§289.232(c)(2)]**

4. The facility has two options to meet regulatory requirements a quality assurance program.
    a. Use the digital QA/QC procedures established and published by the manufacturer of the digital imaging system. Note that this may not be the same manufacturer as your dental x-ray machine.
    b. The procedures for the digital imaging system manufacturer QA/QC program must be included in the operating procedures for the facility.
        I. The procedures must include the frequency that the tests are done.
        II. The test results must be documented, and the documentation must include the date the test was done 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.
    c. If a manufacturer's QA/QC protocol is not available, the facility must establish a written QA/QC protocol, incorporating the following procedures:
        I. The QA/QC protocol shall include image quality testing for, but not limited to, spatial resolution, noise, artifacts and contrast by using a commercially purchased testing tool or an inanimate object of at least three varying densities.
        II. Test images shall be acquired with each x-ray image receptor at an interval not to exceed three months.
        III. Digital QA/QC testing should be conducted with the same phantom or inanimate object and the same technical factors (technique) each time.
        IV. Test images shall be compared to previous test images to assess degradation of image quality.
        V. If an image test fails, the facility has 30 days to initiate repair of the system and 90 days to complete the repair.
        VI. The test results must be documented, and the documentation must include the date the test was done 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 D]**

5. Protocol for QA/QC was established by (choose which one applies): _____ (manufacturer/facility). The QA/QC protocol is located _____ (specify location).
6. Records of test(s) will be maintained. The record(s) is/are located in/at _____ (specify location).

7. 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 shall 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 according to manufacturer's or chemical , supplier's recommended interval, which is _____ 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, shall be reported to the RSO. Repairs must be initiated within 72 hours and completed within 15 days from the detection of the fault.

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

ALTERNATIVE PROCESSING SYSTEMS

If the facility uses daylight processing systems, laser processors, self-processing film units, or other alternative processing systems, processing will be done according to the manufacturer's recommendations for that processing system.

This facility uses **(choose from the following)**:

- Daylight Processing
- Laser Processors
- Self-processing film systems
- Other:_____.

The manufacturer's procedures for using the above system is located at . **[§289.232(j)(13)]**

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 located at_____

Security and Control of Radiation Machines

The facility is required to have control procedures in place that prevent an unauthorized person from operating an x-ray machine or taking an x-ray machine. If an employee is not able to keep a constant eye on the x-ray machines, then the facility must do something to prevent a patient or family member from turning the machine on accidentally. If a facility uses handheld dental machines or portable dental machines, the facility must have procedures that prevent the theft of x-ray machines. Examples of administrative controls are written procedures to lock doors to the work area when staff are not present or written procedures to lock a handheld x-ray machine in a cabinet when not in use. **[§289.232(j)(4)(E)]**

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. [§289.232(j)(2)(A)]

These procedures have been made available to each individual who operates the x-ray equipment on the date(s) indicated. **[§289.232(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 B

SAMPLE YEARLY 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 C

SAMPLE QA/QC PROTOCOL FOR DIGITAL ACQUISITION SYSTEMS

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

    a. the manufacturer of the digital image acquisition system.

    b. The facility.

    (If established by facility, complete 2-6. If established by manufacturer, the QA/QC manufacturer protocols shall be available and used by operators)
2. List the QA/QC tests performed below. For each test, list the following:
    a. Technique factor settings
    b. Testing interval
    c. Test limits or the "Pass" or "Fail" conditions (if applicable)
    d. Test results in numerical form, if applicable.

SAMPLE LOG FOR DOCUMENTATION OF QA/QC TESTS:

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

APPENDIX D

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:_____