



TO: Health and Human Services Commission
Executive Council

DATE: December 6, 2018

FROM: Chuck Flynn, Radiation Unit Manager, Policy,
Standards and Quality Assurance Section,
Consumer Protection Division

AGENDA ITEM: 2.d

SUBJECT: Radiation Control Regulations for Dental Radiation Machines

BACKGROUND: Federal Legislative Other: Program Initiative

The Radiation Control Program in the Consumer Protection Division protects and promotes the physical and environmental health of Texans. The program includes licensing, registration, inspection, enforcement, and emergency response functions for the use of radioactive material and radiation machines. The program regulates approximately 1,600 licensees and 16,000 registrants.

The program routinely monitors complaints received and resolved, numbers of new and renewed registrations, numbers of disciplinary actions taken, and violation trends. The number of complaints received, enforcement actions taken, inspections performed, and registration actions are monitored on a quarterly basis. The program charges fees for issuing licenses and registrations and is entirely fee funded.

The repeal of Title 25, Texas Administrative Code (TAC) §289.232 and new §289.232 are necessary due to extensive revisions made throughout the section. The changes correct rule citation references, define registrant responsibilities, and mirror registration requirements in 25 TAC §289.226, concerning registration of radiation machine use and services. In addition, updates to the new section reflect fee requirements in 25 TAC §289.204, concerning fees for certificates of registration, radioactive material licenses, emergency planning and implementation, and other regulatory services.

Other changes to §289.232 include updates to be compatible with the Code of Federal Regulations on x-ray machine technical requirements.

ISSUES AND ALTERNATIVES:

Several comments received resulted in changes to the proposed new rule. However, there are concerns about consultants being in attendance at inspections and concerns that inspector training requirements were removed from rule.

Program staff realize that it is not always possible to wait for a consultant as not all inspections are announced in order for DSHS to comply with the rule. The requirements regarding inspector training are not usually placed in rule. Inspector training requirements and standards are detailed in the Radiation Control Program policies and procedures manual.

STAKEHOLDER INVOLVEMENT:

The draft rule changes were posted on the Radiation Control web site. (www.dshs.texas.gov/radiation). Stakeholders and DSHS staff were notified of the draft rules and given the opportunity to comment and feedback was received from individuals and groups. A public meeting was held on March 19, 2018, to accept verbal comments. Comments were reviewed by DSHS Radiation staff and some of the commenters' suggestions were included in the draft rule.

The Medical Committee of the Texas Radiation Advisory Board (TRAB) reviewed the draft proposed rules at its June 22, 2018, meeting. TRAB reviewed the draft proposed rules at its September 28, 2018, meeting and recommended that the proposed repeal and new rule be forwarded to the HHSC Executive Council for consideration.

The proposed rules will be made available on the Radiation Control website during the 30-day comment period while published in the *Texas Register*. Notification of the availability of the proposed rules and the opportunity to comment will be given to stakeholders and appropriate DSHS staff using email/list servers.

FISCAL IMPACT:

None

SERVICES IMPACT STATEMENT:

The public benefit anticipated as the result of the repeal and new rule is to ensure continued enhanced protection of the public, patients, workers, and the environment from unnecessary exposure to radiation by ensuring that the rules are clear and specific.

RULE DEVELOPMENT SCHEDULE:

December 6, 2018	Present to HHSC Executive Council
December 2018	Publish proposed rules in <i>Texas Register</i>
February 2019	Publish adopted rules in <i>Texas Register</i>
March 2019	Effective date

Proposed Preamble

The Executive Commissioner of the Health and Human Services Commission, on behalf of the Department of State Health Services (DSHS), proposes the repeal of §289.232 and new §289.232, concerning Radiation Control Regulations for Dental Radiation Machines.

BACKGROUND AND PURPOSE

The repeal and replacement with the new section are necessary due to extensive revisions made throughout the new section. The changes correct rule citation references, define registrant responsibilities, and mirror registration requirements in Title 25, Texas Administrative Code (TAC), §289.226, concerning the registration of radiation machine use and services. In addition, the new section is updated to reflect fee requirements in Title 25, TAC, §289.204, concerning fees for certificates of registration, radioactive material licenses, emergency planning and implementation, and other regulatory services.

Other changes to §289.232 include updating the rules to be compatible with the Code of Federal Regulations (CFR) on x-ray machine technical requirements; reorganizing current requirements; adding new requirements from staff and stakeholder input; adding and clarifying definitions; and updating terminology. Changes to the section strengthen qualifications for radiation safety officers; require radiation safety officers to review operating and safety procedures at intervals not to exceed 12 months; clarify inspection compliance and hearing procedures; and clarify the requirement for an equipment performance evaluation be performed on radiation machines within 30 days of installation or reinstallation. In addition, the changes clarify timelines and requirements for equipment performance evaluations on the x-ray units; add safety requirements to Operating and Safety Procedures; add requirements for controlling operator's occupational radiation exposure; and strengthen the requirements for digital imaging.

Texas Government Code, §2001.039, requires that each state agency review and consider for readoption each rule adopted by that agency pursuant to the Texas Government Code, Chapter 2001 (Administrative Procedure Act). Section 289.232 has been reviewed and DSHS has determined that the reasons for adopting the section continue to exist because a rule on this subject is needed to protect public health and safety and to fulfill DSHS's statutory responsibilities as the state's Radiation Control Agency.

In accordance with Texas Health and Safety Code, §401.064, DSHS has solicited recommendations from the State Board of Dental Examiners

(Dental Board) regarding rules for the inspections of dental electronic products. On March 19, 2018, a representative of the Dental Board attended a public meeting seeking comments from stakeholders; no recommendations were offered by the Dental Board on the proposed draft rules.

SECTION-BY-SECTION SUMMARY

Section 289.232(a)(1) adds language to update fee requirements located in subsection (h) of this section and §289.204 of this title.

Section 289.232(a)(4) adds language to clarify that the use of radiation machines can only be operated by individuals who have received proper instructions in the safe use of radiation machines.

Section 289.232(b)(5) adds applicable requirements in §289.203 of this title (relating to Notice, 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), and §289.205 of this title (relating to Hearing and Enforcement Procedures) to ensure all registrants are complying with agency rules.

Section 289.232(c)(1) and (2), concerning the use of radiation machines, relocates the language previously in subsection (i).

New language in §289.232(c)(3) requires a new prohibition stating that no person can cause the operation of a radiation machine to result in an exposure of an individual to the useful beam for training, demonstration, or other non-healing arts purposes.

New language in §289.232(c)(4) requires a new prohibition that states an individual cannot hold the tube or tube housing assembly support during a radiographic exposure. Hand-held radiation machines can be held only in the manner specified by the manufacturer recommendation.

Section 289.232(d) does not include the definitions for "Entrance exposure," "Licensed Medical Physicist," "Licensing state," and "Non-certified equipment" from former §289.232(c).

Section 289.232(d) adds new definitions for "Air kerma," "Applicant," "Attenuate," "Committed effective dose equivalent," "Consultant," "Effective dose equivalent," and "Equipment performance evaluations (EPE)."

Section 289.232(d) revises definitions for "Certified radiation machines," "Control panel," "Deep dose equivalent," "Dose," "Dose equivalent," "Dose limits," "Entrance exposure (Entrance air kerma)," "Exposure," "Exposure rate (air kerma rate)," "Gray," "Half-value layer," "Image receptor," "Individual monitoring devices," "Inspection," "Institutional Review Board," "Mobile service operation," "Occupational dose," "Party," "Phototimer," "Protective barrier," "Public dose," and "Radiation machine." The definitions of "Stationary radiation machine" and "Portable radiation machine" were in the previous rule as stand-alone definitions and are moved under "Radiation" to include the different types of radiation machines in one definition. Also, the definitions of "Hand-held radiation machine" and "Mobile radiation machine" are added as new types of radiation machines. The section also revises definitions for "Rem," "Research and development," "Severity level," "Shallow dose equivalent (H_s) (that applies to the external exposure of the skin of the whole body or the skin of an extremity)," "Source of radiation," "Technique chart," "Technique factors," "Total effective dose equivalent," "Worker," "X-ray control panel," and "X-ray field."

Since the section has been renumbered, Figure 25 TAC §289.232(d)(20) replaces the former Figure 25 TAC §289.232(c)(17), Coefficient of variation or C, to reflect the renumbering of the section.

Section 289.232(e)(4) adds language to require that on-site storage is secure from unauthorized use or removal and require that a radiation machine shall meet all requirements of this section before resuming use of the machine for human use.

Section 289.232(e)(6) adds language to require that if a person takes possession of a radiation machine by default of payment and the radiation machine is energized, it shall be in accordance with this chapter.

Section 289.232(e)(8) adds language to clarify that hand-held portable radiation machines shall be held according to manufacturer's specifications.

Section 289.232(e)(10) adds language to specify that registrants are required to perform equipment performance evaluation tests and deletes "Bureau of Radiation Control" and replaces it with "Department of State Health Services, Radiation Control."

Section 289.232(f)(2) deletes the word "telegram" and replaces the word "telefacsimile" with "facsimile."

Section 289.232(h)(1)(A) and (B) replaces the fee "\$330" with the language "specified in §289.204 of this title, as amended."

Section 289.232(h)(1)(B)(i) replaces the language “authorized on a single certificate of registration, the registrant will pay an additional \$90” with “where radiation machines or services are authorized under the same registration, there will be an additional charge of 30% of the applicable fee.”

Section 289.232(h)(1)(B)(ii) removes the language from the previous rule “If this certificate of registration also has additional authorized use sites, the registrant shall pay an additional 30% of the highest fee category.”

Section 289.232(h)(1)(C) replaces the language “\$330 fee” with “non-refundable fee specified in §289.204 of this title, as amended.”

Section 289.232(h)(2)(A) and (B) revises the language to reflect the rule reference concerning fees to “§289.204 of this title, as amended.”

Section 289.232(i)(1)(A) adds language to clarify that initial registrations with multiple radiation machine use locations shall complete a separate application for each use location under the registration.

Section 289.232(i)(1)(C) adds language to clarify that the agency may abandon the application and return the original application if it is incomplete 60 days after the submission. Once the application has been abandoned, the applicant will cease use of all radiation machines.

Section 289.232(i)(1)(E) adds language to strengthen the qualifications and specific duties for the radiation safety officer.

Section 289.232(i)(1)(E)(ii)(III)(-f-) replaces the “Texas State Board of Physician Assistant Examiners” with “Texas Physician Assistant Board.”

Section 289.232(i)(1)(F) replaces the language “further statements in order to enable the agency” with “additional information.”

Section 289.232(i)(1)(H) adds language to specify that an application will not be accepted for filing or processing before the full amount of the fee payment specified in §289.204 of this title.

New §289.232(i)(3)(C) requires the registrant to provide additional information to the agency to determine whether the certificate of registration should be modified.

New §289.232(i)(5)(B) states that the registrant shall designate a qualified individual as the radiation safety officer and shall ensure the individual continually performs the responsibilities of the radiation safety officer.

New §289.232(i)(5)(C) requires persons using radiation machines for mobile services shall have a valid certificate of registration issued by the agency before initiation of the mobile services.

New §289.232(i)(5)(D) requires that for a new certificate of registration, no person shall use radiation machines unless they have applied for registration within 30 days after beginning use of the radiation machine.

New §289.232(i)(5)(F) requires that no person shall provide radiation machine services for a person who does not have evidence of a completed application for registration or a valid certificate of registration issued by the agency except for the initial installation for a new certificate of registration and the registrant is authorized for demonstration and sale of a radiation machine.

Section 289.232(i)(5)(K)(i) revises the required amount of time a loaner radiation machine may be used from 60 days to 30 days.

New §289.232(i)(5)(K)(i)(III) requires the registrant to perform an equipment performance evaluation on loaner radiation machines.

New §289.232(i)(5)(K)(ii) specifies that persons who do not hold a valid certificate of registration may use loaner radiation machines for human use up to 30 days by or under the supervision of a dentist licensed by Texas Board of Dental Examiners, before applying for a certificate of registration.

Section 289.232(i)(6)(A) adds language to require that a written termination request of the certificate of registration shall be signed by the radiation safety officer, owner, or an individual authorized to act on behalf of the registrant.

Section 289.232(i)(8)(G) revises the duration of the reciprocal recognition from one year to two years from the date it is granted. A new request for a reciprocity shall be submitted to the agency every two years and should include the items in §289.232(i)(8)(A).

Section 289.232(j)(2) and (j)(2)(A) adds safety requirements to specify that procedures shall be read by and accessible to each individual prior to operating a radiation machine and reviewed annually not to exceed a 12-month period.

Section 289.232(j)(2)(B)(viii) replaces the language “digital image processing” with “digital imaging acquisition system protocols.”

Section 289.232(j)(3)(A)(i)(V) replaces the National Council on Radiation Protection and Measurements (NCRP) language “No. 91 “Recommendations on Limits for Exposure to Ionizing Radiation” (June 1, 1987)” with “No. 116 ‘Limitation of Exposure to Radiation’ (March 31, 1993).”

Section 289.232(j)(3)(A)(v) adds requirements for controlling the operator’s occupational radiation exposure.

Figure 25 TAC §289.232(j)(4)(A) replaces former figure 25 TAC §289.232(i)(5)(A) to reflect the renumbering of the section for the radiation caution signs.

Figure 25 TAC §289.232(j)(4)(B)(i)(I) replaces former figure 25 TAC §289.232(i)(5)(B)(iii) to reflect the renumbering of the section for the Form 232-1 for Notice to Employees.

New §289.232(j)(4)(E)(iii) adds language regarding the proper storage of hand-held dental radiation machines.

New §289.232(j)(5)(A)(ii)(I)(-b-) adds language “unless prevented by the design of the certified radiation machine,” concerning technique and exposure factors.

Section 289.232(j)(5)(A)(ii)(III), adds the sentence “In addition, a signal audible to the operator shall indicate that the exposure has terminated,” concerning technique and exposure factors.

Figure 25 TAC §289.232(j)(5)(E)(i)(I) replaces former figure 25 TAC §289.232(i)(6)(E)(i)(I), the Half-Value Layer for Selected kVp Table, to reflect a new column and data titled, “Intraoral dental systems manufactured before or on June 10, 2006” to compare to the existing column newly titled, “Intraoral dental systems manufactured after June 10, 2006.”

New §289.232(j)(5)(J), concerning equipment performance evaluations, relocates the language from previous subsection (b)(3).

New §289.232(j)(5)(J)(i) specifies requirements of an equipment performance evaluation to be performed on radiation machines within 30 days after initial installation or reinstallation of a radiation machine, and

after repairs of a radiation machine component that would affect the radiation output.

New figure 25 TAC in §289.232(j)(5)(J)(ii) adds a table to define the requirement for the frequency of an equipment performance evaluation for dental x-ray and CT systems.

New figure 25 TAC in §289.232(j)(5)(J)(x) adds a table for “Radiographic Entrance Exposure Limits (Air Kerma Limits)” to clarify the limits in mR (Exposure Limits) and mGy (Air Kerma Limits).

Section 289.232(j)(5)(J)(xi) adds language to clarify how measurements of the radiation output for a radiation machine shall be performed.

New §289.232(j)(5)(J)(xii) requires registrants to verify and record that all dosimetry equipment meets the requirements of §289.232(j)(5)(J)(xi).

New §289.232(j)(6)(B) adds Title 21, CFR, for the regulation requirements for facilities with radiation machines with investigational device exemptions that are involved in clinical studies.

Section 289.232(j)(8) adds the language “All modifications of components or installation of components must be approved by the manufacturer,” concerning radiation machines for dental facilities.

Section 289.232(j)(12)(A) replaces the word “darkroom” with “processing area” for clarification.

Section 289.232(j)(14)(B) adds language to the digital imaging quality assurance/quality control (QA/QC) protocol stating that “if a protocol cannot be established by the manufacturer, it shall be developed and implemented by the registrant.”

New §289.232(j)(14)(B)(i) requires that the QA/QC protocol shall include image quality testing for, but not limited to, spatial resolution, noise and contrast by using a commercially purchased testing tool or an inanimate object of at least three varying densities.

New §289.232(j)(14)(B)(i)(I) requires that the QA/QC digital images shall be acquired with each image receptor at an interval not to exceed three months.

New §289.232(j)(14)(B)(i)(II) requires that the QA/QC test images shall be compared to previous test images to assess degradation of image quality.

New §289.232(k)(1)(A) adds language to require registrants to maintain records at each site, including sites authorized by the certificate of registration, conditions, and sites for mobile services. These records may be maintained in electronic format and shall be accessible to radiation machine operators during working hours.

Figure 25 TAC §289.232(k)(1)(K)(i)(II) replaces former figure 25 TAC §289.232(j)(1)(L)(i)(II) to reflect the renumbering of the section for information that falls under an exception to the Texas Public Information Act.

Figure 25 TAC §289.232(k)(2)(A) replaces former figure 25 TAC §289.232(k)(1)(X)(i) to reflect the renumbering of the section and includes the following changes.

Figure 25 TAC §289.232(k)(2)(A)(i), (iii), (vi), (vii), (viii), (xi), (xii) and (xiii) changes language on the time intervals for keeping records/documents from "Until next on-site inspection" to "Until next routine on-site inspection."

Figure 25 TAC §289.232(k)(2)(A)(iv) adds "25 TAC" to the name of the record/document to state "25 TAC §289.232."

Figure 25 TAC §289.232(k)(2)(A)(viii) adds a new record/document name "Records of machine corrections or repairs."

Figure 25 TAC §289.232(k)(2)(A)(ix), replaces the name of record/document "Equipment Performance Evaluation Tests" with the name of record/document "Equipment Performance Evaluations." Also, the time interval for keeping Equipment Performance Evaluations records/documents is changed from 4 years to 10 years.

Figure 25 TAC §289.232(k)(2)(A)(xi), changes the name of the record/document from "Automatic and Manual Film Processing Records" to "Film Processing Records and Corrections."

Figure 25 TAC §289.232(k)(2)(A)(xii) changes the name of the record/document from "Alternative Film Processing Records" to "Alternative Processing System Records."

Figure 25 TAC §289.232(k)(2)(A)(xiv) changes the name of the record/document from "Records at Additional Authorized Use Locations" to "Records at Additional Authorized Sites."

Section 289.232(k)(3)(B)(i) adds language to clarify that radiation administered for healing arts purposes is an exception to reporting an event involving a radiation machine.

Section 289.232(k)(3)(D)(ii) adds language for registrants to provide an annual written report to each worker of their estimated dose received in that monitoring year if the individual's occupational dose exceeds 100 mrem (1 mSv) total effective dose equivalent or 100 mrem (1mSv) to any individual organ or tissue or the individual requests his or her annual dose report in writing.

Figure 25 TAC §289.232(l)(3)(D)(iii)(II) replaces former figure for 25 TAC §289.232(k)(2)(D)(iii)(II) to reflect the renumbering of the section for Base Administrative Penalties.

Language relating to inspector training is not included in this rule as those training requirements are now detailed in the Radiation Control Program policies and procedures manual.

Other changes to §289.232 correct language in order to be consistent throughout the section and chapter, update rule references, and correct verbiage use and abbreviations for measurements.

FISCAL NOTE

Donna Sheppard, Chief Financial Officer, has determined that for each year of the first five years that the sections are in effect, there will be no fiscal implications to state or local government as a result of enforcing and administering the sections as proposed.

GOVERNMENT GROWTH IMPACT STATEMENT

DSHS has determined that during the first five years that the rules will be in effect:

- (1) the proposed rules will not create or eliminate a government program;
- (2) implementation of the proposed rules will not affect the number of employee positions;
- (3) implementation of the proposed rules will not require an increase or decrease in future legislative appropriations;
- (4) the proposed rules will not affect fees paid to the agency;
- (5) the proposed rules will create a new rule, but only to replace the repealed rule;
- (6) the proposed new rule will expand and repeal an existing rule;

- (7) the proposed rules will not change the number of individuals subject to the rules; and
- (8) the proposed rules will not affect the state's economy.

SMALL BUSINESS, MICRO-BUSINESS, AND RURAL COMMUNITY IMPACT ANALYSIS

Donna Sheppard has also determined that there will be no adverse economic impact on small businesses, micro-businesses, or rural communities required to comply with the sections as proposed. Small businesses, micro-businesses, and rural communities will not be required to alter their business practices in order to comply with the sections.

ECONOMIC COSTS TO PERSONS AND IMPACT ON LOCAL EMPLOYMENT

There are no anticipated economic costs to persons who are required to comply with the sections as proposed. There is no anticipated negative impact on local employment.

COSTS TO REGULATED PERSONS

Texas Government Code, §2001.0045 does not apply to these rules because these rules are necessary to protect the health, safety, and welfare of the residents of Texas.

PUBLIC BENEFIT

Kirk Cole, Interim Associate Commissioner, Consumer Protection Division, has determined that for each year of the first five years the sections are in effect, the public will benefit from adoption of the sections. The public benefit anticipated as the result of enforcing or administering the sections are to ensure continued enhanced protection of the public, patients, workers, and the environment from unnecessary exposure to radiation by ensuring that the rule is clear and specific.

REGULATORY ANALYSIS

DSHS has determined that this proposal is not a "major environmental rule" as defined by Texas Government Code, §2001.0225. "Major environmental rule" is defined to mean a rule the specific intent of which is to protect the environment or reduce risk to human health from environmental exposure and that may adversely affect, in a material way, the economy, a sector of the economy, productivity, competition, jobs, the environment or the public health and safety of a state or a sector of the state. This proposal is not

specifically intended to protect the environment or reduce risks to human health from environmental exposure.

TAKING IMPACT ASSESSMENT

DSHS has determined that the proposed repeal and new rule do not restrict or limit an owner's right to his or her property that would otherwise exist in the absence of government action and, therefore, do not constitute a taking under Texas Government Code, §2007.043.

PUBLIC HEARING

A public hearing to receive comments on the proposal will be scheduled after publication in the *Texas Register* and will be held at the Department of State Health Services, Exchange Building, 8407 Wall Street, Austin, Texas 78754. The meeting date will be posted on the Radiation Control website (www.dshs.texas.gov/radiation). Please contact Chuck Flynn at (512) 834-6655, or by email at Chuck.Flynn@dshs.texas.gov if you have questions.

PUBLIC COMMENT

Written comments on the proposal may be submitted to Chuck Flynn, Radiation Unit Manager, Policy, Standards, and Quality Assurance Section, Consumer Protection Division, Texas Department of State Health Services, Mail Code 1987, P.O. Box 149347, Austin, TX 78714-9347; (512) 834-6655 or by email to CPDRuleComments@dshs.texas.gov. Please indicate "Comments on Chapter 289 Proposed Dental Rule" in the subject line.

To be considered, comments must be submitted no later than 30 days following publication of the proposal in the *Texas Register*. If the last day to submit comments falls on a weekend or a holiday, comments must be postmarked, shipped, or emailed before midnight on the following business day to be considered.

STATUTORY AUTHORITY

The repeal and new rule are authorized by Texas Health and Safety Code, Chapter 401, which provides for DSHS radiation control rules and regulatory program to be compatible with federal standards and regulation; §401.051, which provides the required authority to adopt rules and guidelines relating to the control of sources of radiation; §401.103, which provides authority for licensing and registration for transportation of sources of radiation; §401.224, which provides rulemaking authority relating to the packaging of radioactive waste; and Government Code, §531.0055; and Texas Health and

Safety Code, §1001.075, which authorizes the Executive Commissioner of the Health and Human Services Commission to adopt rules and policies for the operation and provision of health and human services by DSHS and for the administration of Texas Health and Safety Code, Chapter 1001. The review of the rules implements Texas Government Code, §2001.039, regarding review of existing rules.

The repeal and new rule implement Texas Health and Safety Code, Chapters 401 and 1001; and Texas Government Code, Chapter 531.

The agency hereby certifies that this proposal has been reviewed by legal counsel and found to be a valid exercise of the agency's legal authority.

TITLE 25 HEALTH SERVICES
PART 1 DEPARTMENT OF STATE HEALTH SERVICES
CHAPTER 289 RADIATION CONTROL
SUBCHAPTER E REGISTRATION REGULATIONS

The full text of the repealed rule for §289.232 can be viewed here:

**§289.232. Radiation Control Regulations for Dental Radiation
Machines.**

[http://texreg.sos.state.tx.us/public/readtac\\$ext.TacPage?sl=R&app=9&p_dir=&p_rloc=&p_tloc=&p_ploc=&pg=1&p_tac=&ti=25&pt=1&ch=289&rl=232](http://texreg.sos.state.tx.us/public/readtac$ext.TacPage?sl=R&app=9&p_dir=&p_rloc=&p_tloc=&p_ploc=&pg=1&p_tac=&ti=25&pt=1&ch=289&rl=232)

TITLE 25 HEALTH SERVICES
PART 1 DEPARTMENT OF STATE HEALTH SERVICES
CHAPTER 289 RADIATION CONTROL
SUBCHAPTER E REGISTRATION REGULATIONS

§289.232. Radiation Control Regulations for Dental Radiation Machines.

(a) Purpose. This section establishes the requirements for the use of dental radiation machines.

(1) Fees for certificates of registration for dental facilities and provisions for their payment will be processed in accordance with subsection (h) of this section or §289.204 of this title (relating to Fees for Certificates of Registration, Radioactive Material Licenses, Emergency Planning and Implementation, and Other Regulatory Services), as amended.

(2) Requirements of persons using radiation machines are as follows.

(A) No person shall use radiation machines except as authorized in a certificate of registration issued by the agency in accordance with the requirements of this section.

(B) A person who receives, possesses, uses, owns, or acquires radiation machines before receiving a certificate of registration is subject to the requirements of this chapter.

(3) Requirements intended to control the receipt, possession, use, and transfer of radiation machines by any person so the total dose to an individual, including doses resulting from all sources of radiation other than background radiation, does not exceed the standards for protection against radiation prescribed in this chapter. However, nothing in this section shall be construed as limiting actions that may be necessary to protect health and safety in an emergency.

(4) Requirements for the use of radiation machines include that the registrant shall ensure the requirements of this section are met in the operation of such radiation machines and only persons who have received proper instructions in the safe use of radiation machines shall be permitted to operate the radiation machines.

(5) Requirements for specific record keeping and general provisions for records and reports are included in this section.

(6) Requirements for providing notices to employees and instructions and options available to such individuals in connection with agency inspections of registrants to determine compliance with the provisions of the Texas Radiation Control Act, Health and Safety Code, Chapter 401, and requirements of this section, orders, and certificates of registration issued thereunder regarding radiological working conditions.

(7) Governing of the following in accordance with the Texas Radiation Control Act, Health and Safety Code, Chapter 401; the Texas Administrative Procedure Act, Texas Government Code, Chapter 2001; Title 1, Texas Administrative Code, Chapter 155; and the Formal Hearing Procedures, §§1.21, 1.23, 1.25, and 1.27 of this title:

(A) proceedings for the granting, denying, renewing, transferring, amending, suspending, revoking, or annulling of a certificate of registration;

(B) determining compliance with or granting of exemptions from requirements of this section, an order, or a condition of the certificate of registration;

(C) assessing administrative penalties; and

(D) determining propriety of other agency orders.

(b) Scope.

(1) Except as specifically provided in other sections of this chapter, this section applies to persons who receive, possess, use, or transfer dental radiation machines.

(A) The dose limits in this section do not apply to doses due to background radiation, to exposure of patients to radiation for dental diagnosis, to exposure from individuals administered radioactive material and released in accordance with this chapter, or to voluntary participation in medical research programs.

(B) No radiation may be deliberately applied to human beings except by or under the supervision of a dentist licensed by the Texas State Board of Dental Examiners.

(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) Dental radiation machines located in a facility that also has other healing arts radiation machines will be inspected at the intervals specified in §289.231(II)(2) of this title (relating to General Provisions and Standards for Protection Against Machine-Produced Radiation).

(4) The agency may, by requirements in this chapter, an order, or a condition of the certificate of registration, impose upon any registrant such requirements in addition to those established in this section as it deems appropriate or necessary to minimize danger to public health and safety or the environment.

(5) Registrants who are also specifically licensed by the agency to receive, possess, use, and transfer radioactive materials shall also comply with the applicable requirements of §289.201 of this title (relating to General Provisions for Radioactive Material), §289.202 of this title (relating to Standards for Protection Against Radiation from Radioactive Materials), §289.203 of this title (relating to Notice, Instructions, and Reports to Workers; Inspections), §289.204 of this title, §289.205 of this title (relating to Hearing and Enforcement Procedures), §289.252 of this title (relating to Licensing of Radioactive Material), §289.256 of this title (relating to Medical and Veterinary Use of Radioactive Material), and §289.257 of this title (relating to Packaging and Transportation of Radioactive Material).

(c) Prohibitions.

(1) The agency may prohibit use of radiation machines that pose significant threat or endanger occupational and public health and safety, in accordance with subsections (a) - (g) and (l)(3) of this section.

(2) Individuals shall not be exposed to the useful beam except for healing arts purposes authorized by a dentist. This provision specifically prohibits deliberate exposure for the following purposes:

(A) exposure of an individual for training, demonstration, or other non-healing arts purposes; or

(B) exposure of an individual for research except as authorized by subsection (j)(6) of this section.

(3) No person shall cause the operation of a radiation machine that results in exposure of an individual to the useful beam for training, demonstration, or other non-healing arts purposes.

(4) In no case shall an individual hold the tube or tube housing assembly support during any radiographic exposure. Hand-held radiation machines shall be held only in the manner specified by manufacturer recommendation.

(d) Definitions. The following words and terms when used in this section shall have the following meaning, unless the context clearly indicates otherwise.

(1) Absorbed dose--The energy imparted by ionizing radiation per unit mass of irradiated material. The units of absorbed dose are the gray (Gy) and the rad.

(2) Accessible surface--The external surface of the enclosure or housing provided by the manufacturer.

(3) Act--Texas Radiation Control Act, Health and Safety Code, Chapter 401.

(4) Administrative law judge (ALJ)--A judge employed by the State Office of Administrative Hearings.

(5) Administrative penalty--A monetary penalty assessed by the agency in accordance with Health and Safety Code, §401.384, to emphasize the need for lasting remedial action and to deter future violations.

(6) Adult--An individual 18 or more years of age.

(7) Agency--The Department of State Health Services or its successor.

(8) Agreement State--Any state with which the United States Nuclear Regulatory Commission (NRC) has entered into an effective agreement under §274b of the Atomic Energy Act of 1954 (42 United States Code et seq.), as amended (73 Stat. 689).

(9) Air kerma--The kinetic energy released in air by ionizing radiation. Kerma is the quotient of dE by dM, where dE is the sum of the initial kinetic energies of all the charged ionizing particles liberated by uncharged ionizing particles in air of mass dM. The SI unit of air kerma is joule per kilogram and the special name for the unit of kerma is the gray. For purposes of this section, when exposure in air measured in roentgen (R) is to be converted to

dose in air measured in gray, a nationally recognized standard air conversion factor shall be used.

(10) Applicant--A person seeking a certificate of registration issued in accordance with the provisions of the Act and the requirements in this section.

(11) As low as is reasonably achievable (ALARA)--Making every reasonable effort to maintain exposures to radiation as far below the dose limits in this section as is practical, consistent with the purpose for which the registered activity is undertaken, taking into account the state of technology, the economics of improvements in relation to the state of technology, the economics of improvements in relation to benefits to the public health and safety, and other societal and socioeconomic considerations, and in relation to utilization of ionizing radiation and radiation machines in the public interest.

(12) Attenuate--To reduce the exposure rate (air kerma rate) upon passage of radiation through matter.

(13) Automatic exposure control--A device that automatically controls one or more technique factors in order to obtain a required quantity of radiation at preselected locations (See definition for phototimer).

(14) Background radiation--Radiation from cosmic sources; non-technologically enhanced naturally occurring radioactive material, including radon, except as a decay product of source or special nuclear material, and including global fallout as it exists in the environment from the testing of nuclear explosive devices or from past nuclear accidents, such as Chernobyl, that contribute to background radiation and are not under the control of the registrant. "Background radiation" does not include radiation from sources of radiation regulated by the agency.

(15) Barrier--(See definition for protective barrier.)

(16) Beam-limiting device--A device that provides a means to restrict the dimensions of the x-ray field.

(17) Beam quality (diagnostic x-ray)--A term that describes the penetrating power of the x-ray beam. This is identified numerically by half-value layer and is influenced by kilovolt peak (kVp) and filtration.

(18) Certificate of registration--A form of permission given by the agency to an applicant who has met the requirements for registration set out in the Act and this chapter.

(19) Certified radiation machines--Radiation machines that have been certified in accordance with Title 21, Code of Federal Regulations (CFR).

(20) Coefficient of variation or C--The ratio of the standard deviation to the mean value of a population of observations. It is estimated using the following equation:

Figure: 25 TAC §289.232(d)(20)

(21) Collective dose--The sum of the individual doses received in a given period by a specified population from exposure to a specified source of radiation.

(22) Commissioner--The Commissioner of the Department of State Health Services.

(23) Committed effective dose equivalent ($H_{E,50}$)--The sum of the products of the weighting factors applicable to each of the body organs or tissues that are irradiated and the committed dose equivalent to these organs or tissues ($H_{E,50} = \sum W_T H_{T,50}$).

(24) Contested case--A proceeding in which the agency determines the legal rights, duties, or privileges of a party after an opportunity for adjudicative hearing.

(25) Continuous pressure type switch--A switch so constructed that a circuit closing contact can be maintained only by continuous pressure on the switch by the operator.

(26) Consultant--An individual who is not routinely engaged in work under the registrant who provides advice related to compliance with this chapter.

(27) Control panel--The part of the radiation machine where the switches, knobs, push buttons, and other hardware necessary for manually setting the technique factors are located.

(28) Declared pregnant woman--A woman who has voluntarily informed the registrant, in writing, of her pregnancy and the estimated date of conception. The declaration remains in effect until the declared pregnant

woman voluntarily withdraws the declaration in writing or is no longer pregnant.

(29) Deep dose equivalent (H_d), that applies to external whole body exposure--The dose equivalent at a tissue depth of 1 centimeter (1000 milligrams per square centimeter).

(30) Dentist--An individual licensed by the Texas State Board of Dental Examiners.

(31) Diagnostic source assembly--The tube housing assembly with a beam-limiting device attached.

(32) Director--The director of the radiation control program under the agency's jurisdiction.

(33) Dose--A generic term that means absorbed dose, dose equivalent, or total effective dose equivalent. For purposes of this section, "radiation dose" is an equivalent term.

(34) Dose equivalent (H_t)--The product of the absorbed dose in tissue, quality factor, and all other necessary modifying factors at the location of interest. The units of dose equivalent are the sievert (Sv) and rem.

(35) Dose limits--The permissible upper bounds of radiation doses established in accordance with this chapter. For purposes of this section, "limits" is an equivalent term.

(36) Effective dose equivalent (H_E)--The sum of the products of the dose equivalent to the organ or tissue (H_T) and the weighting factors (W_T) applicable to each of the body organs or tissues that are irradiated ($H_E = \sum W_T H_T$).

(37) Embryo/fetus--The developing human organism from conception until the time of birth.

(38) Entrance exposure (Entrance air kerma)--The entrance exposure in air expressed in roentgens or the entrance dose in air (air kerma) expressed in gray, measured at the point where the center of the useful beam enters the patient.

(39) Equipment performance evaluations (EPE)--Required testing performed by a registered service provider at a specified interval to ensure radiation machines operate in compliance with this chapter.

(40) Exposure--The quotient of dQ by dm where "dQ" is the absolute value of the total charge of the ions of one sign produced in air when all the electrons (negatrons and positrons) liberated by photons in a volume element of air having mass "dm" are completely stopped in air. The International System of Units (SI) unit of exposure is the coulomb per kilogram. The roentgen is the special unit of exposure. For purposes of this section, this term is used as a noun.

(41) Exposure rate (air kerma rate)--The exposure per unit of time. For purposes of this section, "air kerma rate" is an equivalent term.

(42) External dose--That portion of the dose equivalent received from any source of radiation outside the body.

(43) Extremity--Hand, elbow, arm below the elbow, foot, knee, and leg below the knee. The arm above the elbow and the leg above the knee are considered part of the whole body.

(44) Field emission equipment--Equipment that uses an x-ray tube in which electron emission from the cathode is due solely to the action of an electric field.

(45) Filter--Material placed in the useful beam to absorb selected radiations preferentially.

(46) Gray (Gy)--The SI unit of absorbed dose. One gray is equal to an absorbed dose of one joule per kilogram or 100 rad.

(47) Half-value layer (HVL)--The thickness of a specified material that attenuates the beam of radiation to an extent such that the exposure rate (air kerma rate) is reduced to one-half of its original value.

(48) Healing arts--Any system, treatment, operation, diagnosis, prescription, or practice for the ascertainment, cure, relief, palliation, adjustment, or correction of any human disease, ailment, deformity, injury, or unhealthy or abnormal physical or mental condition.

(49) Hearing--A proceeding to examine an application or other matter before the agency in order to adjudicate rights, duties, or privileges.

(50) Human use--For exposure to x-ray radiation from radiation machines, the external administration of radiation to human beings for

healing arts purposes or research or development specifically authorized by the agency.

(51) Image receptor--Any device, such as a fluorescent screen, radiographic film, or digital sensor that transforms incident x-ray photons either into a visible image or into another form that can be made into a visible image by further transformations.

(52) Individual--Any human being.

(53) Individual monitoring--The assessment of dose equivalent to an individual by the use of:

(A) individual monitoring devices; or

(B) survey data.

(54) Individual monitoring devices--Devices designed to be worn by a single individual for the assessment of dose equivalent. For purposes of this section, "personnel dosimeter," "dosimeter," and "personnel monitoring equipment" are equivalent terms. Examples of individual monitoring devices include, but are not limited to, film badges, thermoluminescence dosimeters, optically stimulated luminescence dosimeters, pocket ionization chambers (pocket dosimeters), and electronic personal dosimeters.

(55) Informal conference--A meeting held by the agency with a person to discuss the following:

(A) safety, safeguards, or environmental problems;

(B) compliance with regulatory or registration condition requirements;

(C) proposed corrective measures, including, but not limited to, schedules for implementation; and

(D) enforcement options available to the agency.

(56) Inspection--An official thorough examination or observation, including, but not limited to, records, tests, surveys, and monitoring to effectively determine compliance with the Act and requirements of this section, orders, and conditions of the agency.

(57) Institutional Review Board (IRB)--Any board, committee, or other group formally designated by an institution to review, approve the initiation

of, and conduct periodic review of biomedical research involving human subjects.

(58) Ionizing radiation--Any electromagnetic or particulate radiation capable of producing ions, directly or indirectly, in its passage through matter. Ionizing radiation includes gamma rays and x-rays, alpha and beta particles, high-speed electrons, neutrons, and other nuclear particles.

(59) kV--Kilovolt.

(60) kVp--Kilovolt peak (See definition for peak tube potential).

(61) kWs--Kilowatt-second. It is equivalent to 10^3 watt-second, where 1 watt-second = 1 kilovolt x 1 milliampere x 1 second.

(62) Lead equivalent--The thickness of lead affording the same attenuation, under specified conditions, as the material in question.

(63) Leakage radiation--Radiation emanating from the diagnostic assembly except for the useful beam and radiation produced when the exposure switch or timer is not activated.

(64) Lens dose equivalent--The external dose equivalent to the lens of the eye at a tissue depth of 0.3 centimeters (300 milligrams per square centimeter).

(65) License--A form of permission given by the agency to an applicant who has met the requirements for licensing set out in the Act and this chapter.

(66) Licensed material--Radioactive material received, possessed, used, or transferred under a general or specific license issued by the agency.

(67) Licensee--Any person who is licensed by the agency in accordance with the Act and this chapter.

(68) mA--Milliampere.

(69) mAs--Milliampere-second.

(70) Medical research--The investigation of various health risks and diseases.

(71) Member of the public--Any individual, except when that individual is receiving an occupational dose.

(72) Minor--An individual less than 18 years of age.

(73) Mobile service operation--The provision of radiation machines and personnel at temporary locations for limited time periods.

(74) Monitoring--The measurement of radiation and the use of the results of these measurements to evaluate potential exposures and doses. For purposes of this section, "radiation monitoring" and "radiation protection monitoring" are equivalent terms.

(75) Notice of violation--A written statement prepared by the agency of one or more alleged infringements of a legally binding requirement.

(76) Occupational dose--The dose received by an individual in the course of employment in which the individual's assigned duties involve exposure to radiation from licensed/registered and unlicensed/unregistered sources of radiation, whether in the possession of the licensee/registrant or other person. Occupational dose does not include dose received from background radiation, from any medical administration the individual has received, from exposure to individuals administered radioactive material and released in accordance with this section, from voluntary participation in medical research programs, or as a member of the public.

(77) Order--A specific directive contained in a legal document issued by the agency.

(78) Party--A person designated as such by the ALJ. A party may consist of the following:

(A) the agency;

(B) an applicant, licensee, registrant, accredited mammography facility, or certified industrial radiographer; and

(C) any person affected.

(79) Patient--An individual subjected to dental examination, diagnosis, or treatment.

(80) Peak tube potential--The maximum value of the potential difference in kilovolts across the x-ray tube during an exposure.

(81) Person--Any individual, corporation, partnership, firm, association, trust, estate, public or private institution, group, agency, local government, any other state or political subdivision or agency thereof, or any other legal entity, and any legal successor, representative, agent, or agency of the foregoing, other than the United States Nuclear Regulatory Commission, and other than federal government agencies licensed or exempted by the United States Nuclear Regulatory Commission.

(82) Personnel monitoring equipment--(See definition for individual monitoring devices).

(83) Phototimer--A method for controlling radiation exposures to image receptors by the amount of radiation that reaches a radiation detection device. The radiation detection device is part of an electronic circuit that controls the duration of time the tube is activated (See definition for automatic exposure control).

(84) Primary protective barrier--(See definition for protective barrier).

(85) Protective barrier--A barrier of radiation absorbing materials used to reduce radiation exposure. The types of protective barriers are as follows:

(A) primary protective barrier--A barrier sufficient to attenuate the useful beam to the required degree; or

(B) secondary protective barrier--A barrier sufficient to attenuate the stray radiation to the required degree.

(86) Public dose--The dose received by a member of the public from exposure to radiation from licensed/registered and unlicensed/unregistered sources of radiation, whether in the possession of the licensee/registrant or other person. It does not include occupational dose or doses received from background radiation, from any medical administration the individual has received, from exposure to individuals administered radioactive material and released in accordance with this section, or from voluntary participation in medical research programs, or as a member of the public.

(87) Rad--The special unit of absorbed dose. One rad is equal to an absorbed dose of 100 ergs per gram or 0.01 joule per kilogram (0.01 Gy).

(88) Radiation--One or more of the following:

(A) gamma and x-rays, alpha and beta particles, and other atomic or nuclear particles or rays;

(B) radiation emitted to energy density levels that could reasonably cause bodily harm from an electronic device; or

(C) sonic, ultrasonic, or infrasonic waves from any electronic device or resulting from the operation of an electronic circuit in an electronic device in the energy range to reasonably cause detectable bodily harm.

(89) Radiation area--Any area, accessible to individuals, in which radiation levels could result in an individual receiving a dose equivalent in excess of 0.005 rem (0.05 millisievert) in one hour at 30 centimeters from the radiation machine or from any surface that the radiation penetrates.

(90) Radiation machine--An x-ray system, subsystem, or component capable of producing ionizing radiation except those devices with radioactive material as the only source of radiation. For purposes of this section, "radiation machine," "x-ray equipment," "x-ray system," and "x-ray unit" are equivalent terms. Types of radiation machines include, but are not limited to:

(A) Stationary radiation machine--A radiation machine that is installed in a fixed location.

(B) Hand-held radiation machine--A radiation machine that is designed to be hand-held during operation.

(C) Portable radiation machine--A radiation machine that is mounted on a permanent base with wheels or casters for moving while completely assembled, including a hand-carried radiation machine that is designed to be mounted on a support while operating.

(D) Mobile radiation machine--A radiation machine that is transported in a vehicle to be used at various temporary locations.

(91) Radiation safety officer (RSO)--An individual who has a knowledge of and the authority and responsibility to apply appropriate radiation protection rules, standards, and practices, who shall be specifically authorized on a certificate of registration, and who is the primary contact with the agency.

(92) Radiograph--An image receptor on which the image is created directly or indirectly by an x-ray exposure and results in a permanent record.

(93) Registrant--Any person issued a certificate of registration by the agency in accordance with the Act and this chapter.

(94) Regulation--(See definition for rule).

(95) Rem--The special unit of any of the quantities expressed as dose equivalent. The dose equivalent in rem (sievert (Sv) is equal to the absorbed dose in rad or gray multiplied by the quality factor (1 rem = 0.01 Sv).

(96) Remote inspection--An examination by the agency of information submitted by the registrant on a form provided by the agency.

(97) Research and development--Research and development is defined as:

(A) theoretical analysis, exploration, or experimentation; or

(B) the extension of investigative findings and theories of a scientific or technical nature into practical application for experimental and demonstration purposes, including the experimental production and testing of models, devices, equipment, radiation machines, materials, and processes.

(98) Restricted area--An area, access to which is limited by the registrant for protecting individuals against undue risks from exposure to radiation. Restricted area does not include areas used as residential quarters, but separate rooms in a residential building may be set apart as a restricted area.

(99) Roentgen (R)--The special unit of exposure. One roentgen (R) equals 2.58×10^{-4} coulombs per kilogram of air. (See definition for exposure.)

(100) Rule--Any agency statement of general applicability that implements, interprets, or prescribes law or policy, or describes the procedure or practice requirements of an agency. The term includes the amendment or repeal of a section but does not include statements concerning the internal management or organization of any agency and does not affect private rights or procedures. The word "rule" was formerly referred to as "regulation."

(101) Scattered radiation--Radiation that has been deviated in direction during passage through matter.

(102) Secondary protective barrier--(See definition for protective barrier).

(103) Severity level--A classification of violations based on relative seriousness of each violation and the significance of the effect of the violation on the occupational or public health or safety or the environment.

(104) Shallow dose equivalent (H_s) (that applies to the external exposure of the skin of the whole body or the skin of an extremity)--The dose equivalent at a tissue depth of 0.007 centimeters (7 milligrams per square centimeter).

(105) SI--The abbreviation for the International System of Units.

(106) Sievert--The SI unit of any of the quantities expressed as dose equivalent. The dose equivalent in sievert is equal to the absorbed dose in gray multiplied by the quality factor (1 sievert = 100 rem).

(107) Source of radiation--Any radioactive material or device that is capable of emitting or producing ionizing radiation.

(108) Source-to-image receptor distance--The distance from the source to the center of the input surface of the image receptor.

(109) Source-to-skin distance--The distance from the source to the skin of the patient.

(110) Special units--The conventional units historically used by registrants, i.e., rad (absorbed dose), and rem (dose equivalent).

(111) Stray radiation--The sum of leakage and scattered radiation.

(112) Supervision--The delegating of the task of applying radiation in accordance with this section to persons not licensed in dentistry, who perform tasks under the dentist's control. The dentist assumes full responsibility for these tasks and shall assure that the tasks will be administered correctly.

(113) Survey--An evaluation of the radiological conditions and potential hazards incident to the production, use, transfer, and disposal of radiation machines. When appropriate, such survey includes, but is not limited to, tests, physical examination of location of equipment or radiation machines, and measurements of levels of radiation present, and evaluation of administrative and engineered controls.

(114) Technique chart--A chart that provides technical factors, anatomical examination, and patient size for examination being performed needed to make clinical radiographs when the radiation machine is in manual mode.

(115) Technique factors--The conditions of operation that are specified as follows:

(A) for capacitor energy storage equipment, peak tube potential in kilovolt and quantity of charge in milliampere-second;

(B) for field emission equipment rated for pulsed operation, peak tube potential in kilovolt and number of x-ray pulses; and

(C) for all other radiation machines, peak tube potential in kilovolt and either tube current in milliamperes and exposure time in seconds or the product of tube current and exposure time in milliampere-second.

(116) Termination--A release by the agency of the obligations and authorizations of the registrant under the terms of the certificate of registration. It does not relieve a person of duties and responsibilities imposed by law or rule.

(117) Texas Regulations for Control of Radiation --All sections of Chapter 289 of this title.

(118) Total effective dose equivalent--The sum of the effective dose equivalent (for external exposures) and the committed effective dose equivalent (for internal exposures).

(119) Traceable to a national standard--This indicates that a quantity or a measurement has been compared to a national standard, for example, the National Institute of Standards and Technology, directly or indirectly through one or more intermediate steps and that all comparisons have been documented.

(120) Tube--An x-ray tube, unless otherwise specified.

(121) Tube housing assembly--The tube housing with tube installed. It includes high-voltage and/or filament transformers and other appropriate elements when such are contained within the tube housing.

(122) Unrestricted area (uncontrolled area)--An area, access to which is neither limited nor controlled by the registrant. For purposes of this section, "uncontrolled area" is an equivalent term.

(123) Useful beam--Radiation that passes through the window, aperture, core, or other collimating device of the source housing. Also referred to as the primary x-ray beam.

(124) Violation--An infringement of any rule, license or registration condition, order of the agency, or any provision of the Act.

(125) Whole body--For purposes of external exposure, head, trunk, including male gonads, arms above the elbow, or legs above the knee.

(126) Worker--An individual engaged in work under the certificate of registration issued by the agency.

(127) X-ray control panel--A device that controls input power to the x-ray high-voltage generator or the x-ray tube. It includes components such as timers, phototimers, automatic brightness stabilizers, and similar devices that control the technique factors of an x-ray exposure.

(128) X-ray field--That area of the intersection of the useful beam and any one of the set of planes parallel to and including the plane of the image receptor, whose perimeter is the locus of points at which the exposure rate (air kerma rate) is one-fourth of the maximum in the intersection.

(129) X-ray high-voltage generator--A device that transforms electrical energy from the potential supplied by the x-ray control to the tube operating potential. The device may also include means for transforming alternating current to direct current, filament transformers for the x-ray tubes, high-voltage switches, electrical protective devices, and other appropriate elements.

(130) X-ray system--An assemblage of components for the controlled production of x-rays. It includes, minimally, an x-ray high-voltage generator, an x-ray control, a tube housing assembly, a beam-limiting device, and the necessary supporting structures. Additional components that function with the system are considered integral parts of the system.

(131) X-ray subsystem--Any combination of two or more components of an x-ray system.

(132) X-ray tube--Any electron tube that is designed to be used primarily for the production of x-rays.

(133) Year--The period of time beginning in January used to determine compliance with the provisions of this chapter. The registrant may change the starting date of the year used to determine compliance by the registrant if the change is made at the beginning of the year and that no day is omitted or duplicated in consecutive years.

(e) Exemptions.

(1) The agency may, upon application or upon its own initiative, exempt a source of radiation or a kind of use or user from the requirements of this section if the agency determines that the law does not prohibit the exemption and it will not result in a significant risk to public health or safety or the environment. In determining such exemptions, the agency will consider:

(A) state of technology;

(B) economic considerations in relation to benefits to the public health and safety; and

(C) other societal, socioeconomic, or public health and safety considerations.

(2) Electronic equipment that produces radiation incidental to its operation for other purposes is exempt from the registration and notification requirements of this section, if the dose equivalent rate averaged over an area of 10 square centimeters does not exceed 0.5 millirem (5 microsieverts) per hour at 5 centimeters from any accessible surface of such equipment. The production, testing, or factory servicing of such equipment shall not be exempt.

(3) Radiation machines in transit or in storage incident to transit are exempt from the requirements of this section. This exemption does not apply to the providers of radiation machines for mobile services.

(4) Facilities that have placed all radiation machines in storage, including on-site storage secured from unauthorized use or removal, and have notified the agency in writing, are exempt from the requirements of this section. This exemption is void if any radiation machine is energized resulting in the production of radiation. Before resuming use of the radiation machine for human use, the radiation machine shall meet all requirements of this section.

(5) Inoperable radiation machines are exempt from the requirements of this section. For the purposes of this section, an inoperable radiation machine means a radiation machine that cannot be energized when connected to a power supply without repair or modification.

(6) A person that takes possession of a radiation machine as the result of foreclosure, bankruptcy, or other default of payment may possess the radiation machine without registering it. If the radiation machine is energized, it shall be in accordance with this chapter.

(7) No individual monitoring shall be required for personnel operating only dental radiation machines for dental diagnostic purposes.

(8) Portable radiation machines designed to be hand-held are exempt from the requirements of subsections (c)(4) and (j)(5)(C) of this section. The portable radiation machines shall be held according to manufacturer's specifications.

(9) Individuals who are sole practitioners and sole operators, and the only occupationally exposed individual are exempt from the following requirements:

(A) operating and safety procedures specified in subsection (j)(2) of this section;

(B) instruction to workers specified in subsection (j)(3)(D) of this section; and

(C) posting of notices to workers specified in subsection (j)(4)(B) and (C) of this section.

(10) In accordance with Texas Occupations Code, §258.054, dental practices are exempt from the Medical Physics Practice Act, Texas Occupations Code, Chapter 602. Registrants required to have EPE tests performed in accordance with subsection (j)(5)(J) of this section may select any qualified person authorized by registration through the Department of State Health Services, Radiation Control.

(f) Communications.

(1) Except where otherwise specified, all communications and reports concerning this chapter and applications filed under the communications and reports should be mailed by postal service to Radiation Control, Department of State Health Services, P.O. Box 149347, MC 2003, Austin, Texas, 78714-

9347. Communications, reports, and applications may be delivered in person to the agency's office located at 8407 Wall Street, Austin, Texas, 78754.

(2) Documents received by the agency will be deemed to have been received on the date of the postmark, facsimile, or other electronic media transmission.

(g) Interpretations. Except as specifically authorized by the agency in writing, no interpretation of the meaning of this chapter by any officer or employee of the agency other than a written legal interpretation by the agency, will be considered binding upon the agency.

(h) Fees for certificates of registration for dental facilities.

(1) Payment of fees.

(A) Each application for a certificate of registration shall be accompanied by a nonrefundable fee specified in §289.204 of this title, as amended. No application will be accepted for filing or processed before payment of the full amount specified.

(B) A nonrefundable fee specified in §289.204 of this title, as amended, shall be paid for each certificate of registration for radiation machines used in dentistry. The fee shall be paid every two years and shall be paid in full and on or before the due date stated on the invoice.

(i) For each additional use location where radiation machines or services are authorized under the same registration, there will be an additional charge of 30% of the applicable fee.

(ii) In the case of a single certificate of registration that authorizes more than one category of radiation machine use, the category listed in §289.204 of this title that is assigned the higher fee will be used.

(C) Each application for reciprocal recognition of an out-of-state registration in accordance with subsection (i)(8) of this section shall be accompanied by the non-refundable fee specified in §289.204 of this title, as amended, provided that no such fee has been submitted within 24 months of the date of commencement of the proposed activity.

(D) Fee payments shall be in cash or by check or money order made payable to the Department of State Health Services. The payments may be made by personal delivery to the central office, Radiation Control, Department of State Health Services, 1100 West 49th Street, Austin, Texas,

78756-3199 or mailed to Radiation Control, Department of State Health Services, P.O. Box 149347, MC 2003, Austin, Texas, 78714-9347.

(2) Failure to pay prescribed fees.

(A) In any case where the agency finds that an applicant for a certificate of registration has failed to pay the non-refundable fee prescribed in §289.204 of this title, as amended, the agency will not process that application until such fee is paid.

(B) In any case where the agency finds that a registrant has failed to pay a fee prescribed by §289.204 of this title, as amended, by the due date, the agency may implement compliance procedures as provided in subsection (l)(3)(C) of this section.

(3) Electronic fee payments. Renewal payments may be processed through www.texas.gov or another electronic payment system specified by the agency. For all types of electronic fee payments, the agency will collect additional fees, in amounts determined by www.texas.gov to recover costs associated with electronic payment processing.

(i) Registration of radiation machine use.

(1) Application for registration of radiation machines.

(A) Application for registration shall be completed on forms prescribed by the agency and shall contain all the information required by the form and accompanying instructions. For initial registrations with multiple radiation machine use locations, a separate application shall be completed for each use location under the registration.

(B) Each person having a radiation machine used in dentistry shall apply for registration with the agency within 30 days after beginning use of the radiation machine, except for mobile services that shall be registered in accordance with paragraph (2) of this subsection and clinical trial evaluations that shall be registered in accordance with paragraph (5)(K) of this subsection.

(C) If the application is incomplete 60 days after submission, the agency may abandon the application and return the original application. The applicant will cease use of all radiation machines once the application has been abandoned.

(D) The applicant shall ensure that radiation machines will be operated by individuals qualified by reason of training and experience to use the radiation machines for the purpose requested in accordance with this section in such a manner as to minimize danger to occupational and public health and safety.

(E) A radiation safety officer shall be designated on each application form. The qualifications of that individual shall be submitted to the agency with the application. The radiation safety officer shall meet the applicable qualifications of clause (i) of this subparagraph and carry out the responsibilities specified in clause (v) of this subparagraph.

(i) The radiation safety officer shall have the following qualifications:

(I) knowledge of potential hazards and emergency precautions;
and

(II) educational courses completed that relate to ionizing radiation safety or a radiation safety officer course; or

(III) experience in the use and familiarity of the type of radiation machine used; and

(ii) In addition to the qualifications in clause (i) of this subparagraph, documentation of the following shall be submitted to the agency:

(I) for dentist radiation safety officers, a dental licensing board number and their signature on the application;

(II) for a practitioner radiation safety officer, documentation of a licensing board number; or

(III) for non-practitioner radiation safety officers, any one of the following:

(-a-) evidence of a valid general certificate issued under the Medical Radiologic Technologist Certification Act, Texas Occupations Code, Chapter 601, and at least two years of supervised experience or supervised use of radiation machines;

(-b-) evidence of a valid limited general certificate issued under the Medical Radiologic Technologist Certification Act, Texas

Occupations Code, Chapter 601, and at least four years of supervised experience or supervised use of radiation machines;

(-c-) evidence of registry by the American Registry of Radiologic Technologists and at least two years of supervised experience or supervised use of radiation machines;

(-d-) evidence of associate degree in radiologic technology, health physics, or nuclear technology, and at least two years of supervised experience or supervised use of radiation machines;

(-e-) evidence of registration with the Texas Board of Nursing as a Registered Nurse and at least two years of supervised experience or supervised use of radiation machines in the respective specialty;

(-f-) evidence of registration with the Texas Physician Assistant Board, and at least two years of supervised use of radiation machines in the respective specialty;

_____ (-g-) evidence of:

(-1-) registration with the Texas State Board of Dental Examiners to perform radiologic procedures under a dentist's instruction and direction or evidence of a valid certificate as a registered dental hygienist; and

(-2-) at least four years of supervised use of radiation machines in the respective dentist's specialty;

(-h-) evidence of bachelor's (or higher) degree in a natural or physical science, health physics, radiological science, nuclear medicine, or nuclear engineering; or

(-i-) evidence of a current Texas license under the Medical Physics Practice Act, Texas Occupations Code, Chapter 602, in medical health physics, diagnostic medical physics, or nuclear medical physics for diagnostic x-ray facilities.

(iii) Academic institutions and research and development facilities shall have radiation safety officers who are faculty or staff members in radiation protection, radiation engineering, or related disciplines. (This individual may also serve as the radiation safety officer over the dental section of the facility.)

(iv) The radiation safety officer identified on a certificate of registration for use of dental radiation machines issued before September 1, 1993, need not comply with the qualification requirements in this subsection.

(v) Specific duties of the radiation safety officer include, but are not limited to, the following:

(I) establishing and overseeing operating and safety procedures that maintain radiation exposures as low as reasonably achievable, and reviewing the procedures at intervals not to exceed 12 months to ensure that the procedures are current and conform with this section;

(II) investigating and reporting to the agency each:

(-a-) known or suspected case of radiation exposure to an individual or radiation level detected in excess of limits established by this section; and

(-b-) theft or loss of radiation machines, determining the cause, and taking steps to prevent its recurrence;

(III) assuming control and having the authority to institute corrective actions, including shutdown of operations when necessary in emergencies or unsafe conditions;

(IV) making and maintaining records as required by this section;
and

(V) ensuring that personnel are adequately trained and complying with this section, the conditions of the certificate of registration, and the operating and safety procedures of the registrant.

(F) At any time after the filing of the original application, the agency may require additional information to determine whether the certificate of registration is issued or denied.

(G) An application for a certificate of registration may include a request for a certificate of registration authorizing one or more activities or radiation machine use locations. If an application includes a request for an additional authorization other than use of a dental radiation machine, compliance with other applicable sections of this chapter will be required.

(H) Each application for a certificate of registration shall be accompanied by the fee prescribed in §289.204 of this title, as amended. No application will be accepted for filing or processed before payment of the full amount specified.

(I) Each application shall be accompanied by a completed RC Form 226-1, Business Information Form that shall contain the legal name of the entity or business. The form can be found at <http://dshts.texas.gov/radiation/x-ray/medical-faq.aspx>. Unless exempt in accordance with the Business and Commerce Code, Chapter 71, the applicant shall:

(i) be authorized to conduct business in the State of Texas as listed on the Texas Secretary of State (SOS) web site; and

(ii) file an assumed name certificate with the Texas SOS if using an assumed name in their application or the office of the county clerk in the county where the business is located.

(J) An application for use of a dental radiation machine shall be signed by a licensed dentist. The signature of the administrator, president, or chief executive officer will be accepted in lieu of a licensed dentist's signature if the facility has more than one licensed dentist who may direct the operation of radiation machines. The application shall also be signed by the radiation safety officer.

(K) Applications and documents submitted to the agency may be made available for public inspection except that the agency may withhold any document or part thereof from public inspection in accordance with subsection (k)(1)(J) and (K) of this section.

(2) Application for registration of mobile service operation used in dentistry. In addition to the requirements of paragraph (1) of this subsection, each applicant shall apply for and receive authorization from the agency for mobile service operation before beginning mobile service operation. The following shall be submitted:

(A) An established main location where the radiation machines and related compliance documents and records will be maintained for inspection. This shall be a street address, not a post office box number.

(B) A sketch or description of the normal configuration of each radiation machine's use, including the operator's position and any ancillary personnel's location during exposures. If a mobile van is used with a fixed

radiation machine inside, furnish the floor plan indicating protective shielding and the operator's position.

(C) A current copy of the applicant's operating and safety procedures regarding radiological practices for protection of patients, operators, employees, and the public.

(3) Issuance of certificate of registration.

(A) A certificate of registration will be approved if the agency determines that an application meets the requirements of the Act and the requirements of this chapter. The certificate of registration authorizes the proposed activity and contains the conditions and limitations, as the agency deems appropriate or necessary.

(B) The agency may incorporate in the certificate of registration at the time of issuance, or thereafter by amendment, additional requirements and conditions concerning the registrant's possession, use, and transfer of radiation machines subject to this chapter, as it deems appropriate or necessary in order to:

(i) minimize danger to occupational and public health and safety;

(ii) require additional records and the keeping of additional records as may be appropriate or necessary; and

(iii) prevent loss or theft of radiation machines subject to this chapter.

(C) The agency may request, and the registrant shall provide, additional information after the certificate of registration has been issued to enable the agency to determine whether the certificate of registration should be modified in accordance with paragraph (7) of this subsection.

(4) Terms and conditions of certificates of registration.

(A) Each certificate of registration issued in accordance with this section shall be subject to the applicable provisions of the Act, now or hereafter in effect, and to the applicable requirements of this chapter and orders of the agency.

(B) No certificate of registration issued or granted under this section shall be transferred, assigned, or in any manner disposed of, either

voluntarily or involuntarily, to any person unless the agency authorizes the transfer in writing.

(C) Each person registered by the agency for radiation machine use in accordance with this section shall confine use and possession of the radiation machine registered to the locations and purposes authorized in the certificate of registration.

(D) In making a determination whether to grant, deny, amend, revoke, suspend, or restrict a certificate of registration, the agency may consider the technical competence and compliance history of an applicant or holder of a certificate of registration. After an opportunity for a hearing, the agency shall deny an application for a certificate of registration or an amendment to a certificate of registration if the applicant's compliance history reveals that at least three agency actions have been issued against the applicant, within the previous six years, that assess administrative or civil penalties against the applicant, or that revoke or suspend the certificate of registration.

(5) Responsibilities of the registrant.

(A) The registrant is responsible for complying with this section and the conditions of the certificate of registration.

(B) The registrant shall designate an individual qualified in accordance with paragraph (1)(E)(i) of this subsection as the radiation safety officer and shall ensure the individual continually performs the duties of the radiation safety officer as identified in paragraph (1)(E)(v) of this subsection.

(C) Persons using radiation machines in accordance with subsection (i)(2) of this section, concerning application for mobile services, shall have a valid certificate of registration issued by the agency before initiation of the mobile services.

(D) Other than the initial installation of the first radiation machine for a new certificate of registration, no person shall use a radiation machine unless the person has applied for registration within 30 days after beginning use of the radiation machine in accordance with subsection (i)(1)(B) of this section.

(E) No registrant shall engage any person for services described in §289.226(b)(11) of this title (relating to Registration of Radiation Machine Use and Services) until such person provides to the registrant evidence of registration with the agency.

(F) No person shall provide radiation machine services for a person who cannot produce evidence of a completed application for registration or a valid certificate of registration issued by the agency except for:

(i) the initial installation of the first radiation machine for a new certificate of registration; and

(ii) the registrant authorized for demonstration and sale may demonstrate a radiation machine in accordance with paragraph (5)(D) of this subsection, except as prohibited by subsection (c) of this section.

(G) The registrant shall notify the agency in writing of any changes that would render the information contained in the application for registration or the certificate of registration inaccurate. The notification shall be in writing and signed by an authorized representative.

(i) Notification is required within 30 days after the following changes:

(I) legal business name;

(II) mailing address;

(III) street address where radiation machine will be used;

(IV) additional radiation machine location;

(V) radiation safety officer; or

(VI) name and registration number of the contracted "provider of equipment," registered in accordance with §289.226 of this title.

(ii) The registrant shall notify the agency within 30 days after changes in the radiation machines that include:

(I) any change in the category of radiation machine type or type of use as authorized in the certificate of registration (for example, addition of a computerized tomography radiation machine); or

(II) any increase in the number of radiation machines authorized by the certificate of registration in any radiation machine type or type of use category.

(H) The registrant, or the parent company, shall notify the agency, in writing, immediately following the filing of a voluntary or involuntary petition for bankruptcy. This notification shall include:

(i) the bankruptcy court in which the petition for bankruptcy was filed; and

(ii) the case name and number, and date of filing the petition.

(I) The registrant shall inventory all radiation machines in the registrant's possession at an interval not to exceed one year.

(i) The inventory shall include:

(I) manufacturer's name;

(II) model and serial number of the control panel; and

(III) location of all radiation machines, for example, room number.

(ii) Records of the inventory shall be made and maintained in accordance with subsection (k)(2) of this section for inspection by the agency.

(J) Receipt, transfer, and disposal of radiation machines.

(i) The registrant shall make and maintain records of receipt, transfer, and disposal of radiation machines. The records shall include the following:

(I) manufacturer's name and model and serial number from the control panel;

(II) date of the receipt, transfer, and disposal;

(III) name and address of person the radiation machines received from, transferred to, or disposed of; and

(IV) name of the individual recording the information.

(ii) Records of receipt, transfer, and disposal of radiation machines shall be made and maintained in accordance with subsection (k)(2) of this section for inspection by the agency.

(K) The following criteria applies to loaner radiation machines.

(i) For persons having a valid certificate of registration, loaner radiation machines may be used for up to 30 days. If the loaner radiation machine is used for more than 30 days, the registrant is required, within the next 30 days, to complete the following:

(I) notify the agency of any change in the category of radiation machine type or type of use as authorized in the certificate of registration (for example, addition of a computerized tomography radiation machine); or

(II) notify the agency of any increase in the number of radiation machines authorized by the certificate of registration in any radiation machine type or type of use category; and

(III) perform an EPE on the radiation machines in accordance with subsection (j)(5)(J) of this section.

(ii) For persons who do not hold a valid certificate of registration, loaner radiation machines may be used for human use up to 30 days, by or under the supervision of a dentist licensed by Texas State Board of Dental Examiners, before applying for a certificate of registration in accordance with this section.

(6) Termination of certificates of registration. When a registrant decides to terminate all activities involving radiation machines authorized under the certificate of registration, the registrant shall notify the agency immediately and:

(A) request termination of the certificate of registration in writing. The request shall be signed by the radiation safety officer, owner, or an individual authorized to act on behalf of the registrant;

(B) submit to the agency a record of the disposition of the radiation machines and, if transferred, to whom transferred; and

(C) pay any outstanding fees in accordance with subsection (h) of this section.

(7) Modification, suspension, and revocation of certificates of registration.

(A) The terms and conditions of all certificates of registration shall be subject to revision or modification. A certificate of registration may be

suspended or revoked by reason of amendments to the Act, by reason of requirements of this chapter or orders issued by the agency.

(B) Any certificate of registration may be revoked, suspended, or modified, in whole or in part in accordance with subsection (l)(3)(C)(iii) of this section.

(C) Each certificate of registration revoked by the agency ends at the end of the day on the date of the agency's final determination to revoke the certificate of registration, or on the revocation date stated in the determination, or as otherwise provided by the agency order.

(D) Except in cases in which the occupational and public health or safety requires otherwise, no certificate of registration shall be suspended or revoked unless, before the institution of proceedings therefore, facts or conduct that may warrant such action shall have been called to the attention of the registrant in writing and the registrant shall have been afforded an opportunity to demonstrate compliance with all lawful requirements.

(8) Reciprocal recognition of out-of-state certificates of registration.

(A) Whenever any radiation machine is to be brought into the State of Texas for any temporary use, the person proposing to bring the radiation machine into the state shall apply for and receive a notice from the agency granting reciprocal recognition before beginning operations. The request for reciprocity shall include the following:

(i) completed RC Form 226-1 (Business Information Form);

(ii) completed RC Form 252-3 (Notice of Intent to Work in Texas Under Reciprocity);

(iii) name and Texas licensing board number of the dentist if the radiation machines are used on humans;

(iv) copy of the applicant's current state certificate of registration or equivalent document;

(v) copy of the applicant's current operating and safety procedures pertinent to the proposed use;

(vi) fee as specified in subsection (h)(1) of this section; and

(vii) qualifications of personnel who will be operating the radiation machines.

(B) Upon a determination that the request for reciprocity meets the requirements of the agency, the agency may issue a notice granting reciprocal recognition authorizing the proposed radiation machine use.

(C) Once reciprocity is granted, the out-of-state registrant shall file a RC Form 252-3 with the agency before each entry into the state. This form shall be filed at least three working days before the radiation machine is used in the state. At determination of the agency, the out-of-state registrant may, for a specific case, obtain permission to proceed sooner if the three-day period would impose an undue hardship.

(D) When radiation machines are used as authorized under reciprocity, the out-of-state registrant shall have the following in its possession at all times for inspection by the agency:

(i) completed RC Form 252-3;

(ii) copy of the notice from the agency granting reciprocity;

(iii) copy of the out-of-state registrant's operating and safety procedures; and

(iv) copy of the applicable rules as specified in the notice granting reciprocity.

(E) If the state from which the radiation machine is proposed to be brought does not issue certificates of registration or equivalent documents, a certificate of registration shall be obtained from the agency in accordance with the requirements of this section.

(F) The agency may withdraw, limit, or qualify its acceptance of any certificate of registration or equivalent document issued by another agency upon determining that such action is necessary in order to prevent undue hazard to occupational and public health and safety or property or environment.

(G) Reciprocal recognition will expire two years from the date it is granted. A new request for reciprocity shall be submitted to the agency every two years and the items in subparagraph (A) of this paragraph shall be included.

(H) Radiation services provided by a person from out-of-state will not be granted reciprocity. Whenever radiation services are to be provided by a person from out-of-state, that person shall apply for and receive a certificate of registration from the agency before providing radiation services. The application shall be filed in accordance with this subsection, as applicable.

(j) Use of radiation machines.

(1) As low as reasonably achievable. Persons shall use, to the extent practical, procedures and engineering controls based upon sound radiation protection principles to achieve occupational doses and public doses that are as low as reasonably achievable.

(2) Operating and safety procedures. Each registrant shall have and implement written operating and safety procedures. These procedures shall be read by and accessible to each individual before operating a radiation machine, including any restrictions of the operating technique required for the safe operation of the particular radiation machine.

(A) The registrant shall ensure and document that each individual has read the operating and safety procedures before operating a radiation machine and reviewed the procedures annually not to exceed 12 months. This documentation shall be maintained in accordance with subsection (k)(2) of this section for inspection by the agency. The documentation shall include the following:

(i) name and signature of individual;

(ii) date individual read the operating and safety procedures; and

(iii) initials of the radiation safety officer.

(B) The operating and safety procedures shall include, but are not limited to, the following procedures as applicable:

(i) ordering x-ray exams in accordance with subsection (b)(1)(A) and (B) of this section;

(ii) providing radiation dose requirements in accordance with paragraph (3)(A) of this subsection;

(iii) instructing workers in accordance with paragraph (3)(D) of this subsection;

(iv) posting notices to workers in accordance with paragraph (4)(B) of this subsection;

(v) posting of a radiation area in accordance with paragraph (4)(C) and (D) of this subsection;

(vi) using a technique chart in accordance with paragraph (5)(A) of this subsection;

(vii) holding of patients or film in accordance with paragraph (11)(A) and (B) of this subsection and subsection (c)(4) of this section;

(viii) following film for processing program or digital imaging acquisition system protocols in accordance with paragraphs (12) - (14) of this subsection;

(ix) notifying and reporting to individuals in accordance with subsection (k)(2) and (3) of this section; and

(x) ensuring security and control of radiation machines in accordance with paragraph (4)(E)(i) of this subsection.

(3) Personnel requirements.

(A) Occupational dose limits.

(i) The registrant shall control the occupational dose to individuals, to the following dose limits.

(I) An annual limit shall be the total effective dose equivalent being equal to 5 rems (0.05 sievert).

(II) The annual limits to the lens of the eye, to the skin of the whole body, and to the skin of any extremities shall be:

(-a-) a lens dose equivalent of 15 rems (0.15 sievert); and

(-b-) a shallow dose equivalent of 50 rems (0.5 sievert) to the skin of the whole body or to the skin of any extremity.

(III) The annual limits for a minor shall be 10% of the annual occupational dose limits specified in subclauses (I) and (II) of this clause.

(IV) If a woman declares her pregnancy, the registrant shall ensure that the dose equivalent to an embryo/fetus during the entire pregnancy, due to occupational exposure of a declared pregnant woman, does not exceed 0.5 rem (5 millisievert). If a woman chooses not to declare pregnancy, the occupational dose limits specified in subclauses (I) and (II) of this clause are applicable to the woman.

(V) The registrant shall make efforts to avoid substantial variation above a uniform monthly exposure rate (air kerma rate) to a declared pregnant woman to satisfy the limit in clause (i) of this subparagraph. The National Council on Radiation Protection and Measurements recommended in NCRP Report No. 116 "Limitation of Exposure to Radiation" (March 31, 1993) that no more than 0.05 rem (0.5 mSv) to the embryo/fetus be received in any one month.

(ii) The assigned deep dose equivalent shall be for the portion of the body receiving the highest exposure. The assigned shallow dose equivalent shall be the dose averaged over the contiguous 10 cm² of the skin receiving the highest exposure.

(iii) The deep dose equivalent, lens dose equivalent, and shallow dose equivalent may be assessed from surveys or radiation measurements for demonstrating compliance with the occupational dose limits.

(iv) The registrant shall reduce the dose that an individual may be allowed to receive in the current year by the amount of occupational dose received from radiation machines or radioactive materials while employed by any other person.

(v) The agency may impose additional requirements for controlling occupational exposure to restrict or assess the collective dose.

(B) Dose limits for individual members of the public.

(i) Each registrant shall conduct operations so that:

(I) the total effective dose equivalent to individual members of the public from exposure to radiation from radiation machines does not exceed 0.5 rem (5 millisieverts) in a year, exclusive of the dose contribution from background radiation, exposure of patients to radiation for medical diagnosis or therapy, or to voluntary participation in medical research programs; and

(II) the dose in any unrestricted area from external sources does not exceed 0.002 rem (0.02 millisieverts) in any one hour.

(ii) If the registrant permits members of the public to have access to restricted areas, the limits for members of the public continue to apply to those individuals.

(iii) The agency may impose additional restrictions on radiation levels in unrestricted areas in order to restrict the collective dose.

(C) Occupational doses from other sources of radiation. Individuals who receive occupational doses from sources of radiation other than dental radiation machines may be required to comply with the requirements of §289.231(n) and (q) - (s) of this title.

(D) Instructions to workers. The registrant shall provide instructions to radiation workers before beginning initial work in restricted areas. These instructions shall include the following:

(i) precautions or procedures to minimize exposure;

(ii) the applicable provisions of agency requirements and certificates of registration for the protection of personnel from exposures to radiation occurring in such areas; and

(iii) the radiation worker's responsibility to report promptly to the registrant any condition that may constitute, lead to, or cause a violation of agency requirements or certificate of registration conditions, or unnecessary exposure to radiation.

(4) Facility requirements.

(A) Caution signs. Unless otherwise authorized by the agency, the standard radiation symbol prescribed shall use the colors magenta, purple or black on yellow background. The standard radiation symbol prescribed is the three-bladed design as follows:

Figure: 25 TAC §289.232(j)(4)(A)

(i) the cross-hatched area of the symbol is to be magenta, purple, or black; and

(ii) the background of the symbol is to be yellow.

(B) Posting of notices to workers.

(i) Each registrant shall post current copies of the following documents:

(I) RC Form 232-1, "Notice to Employees," or an equivalent document containing at least the same wording as RC Form 232-1; and

Figure: 25 TAC §289.232(j)(4)(B)(i)(I)

(II) a notice that describes the following documents and states where the documents may be examined:

(-a-) a copy of this section;

(-b-) the certificate of registration and conditions or documents incorporated into the certificate of registration by reference and amendments thereto;

(-c-) the operating procedures applicable to work under the certificate of registration; and

(-d-) any notice of violation, if applicable, involving radiological working conditions, or order issued in accordance with subsections (b) and (I)(3) of this section and documentation of the corrections of any violations.

(ii) Documents, notices, or forms posted in accordance with this subsection shall:

(I) appear in an area visible to all workers to permit individuals engaged in work under the certificate of registration to observe the documents on the way to or from any particular work location to which the document applies;

(II) be conspicuous; and

(III) be replaced if defaced or altered.

(C) Posting requirements. The registrant shall post each radiation area with a conspicuous sign or signs bearing the radiation symbol and the words "CAUTION, RADIATION AREA."

(D) Exceptions to posting requirements. Registrants are exempt from the posting of the radiation area requirements in subparagraph (C) of this paragraph if the operator has continuous surveillance and access control of the radiation area.

(E) Security and control of radiation machines.

(i) The registrant shall establish a protocol to ensure radiation machines are secure from unauthorized removal.

(ii) The registrant shall use devices and administrative procedures to prevent unauthorized use of radiation machines.

(iii) Any person using hand-held dental radiation machines shall ensure proper storage of the unit to include:

(I) securing the unit against theft or unauthorized use; and

(II) storing the unit in locked cabinets, storage rooms or work areas when not under immediate supervision of authorized users.

(5) Radiation machine requirements.

(A) Technique chart.

(i) A technique chart relevant to the particular radiation machine shall be provided or electronically displayed near the control panel and used by all operators.

(ii) Technique and exposure indicators.

(I) The technique factors to be used during an exposure shall be indicated before the exposure begins except:

(-a-) when automatic exposure controls are used, in which case the technique factors that are set before the exposure shall be indicated; or

(-b-) unless prevented by the design of the certified radiation machine.

(II) On radiation machines having fixed technique factors, the requirement of subclause (I) of this clause may be met by permanent markings.

(III) The x-ray control shall provide visual indication of the production of x-rays. In addition, a signal audible to the operator shall indicate that the exposure has terminated.

(IV) The indicated technique factors shall be accurate to within manufacturer's specifications. If these specifications are not available from the manufacturer, the factors shall be accurate to within plus or minus 10% of the indicated setting.

(B) Labeling radiation machines. Each registrant shall ensure that each radiation machine is labeled in a conspicuous manner that cautions individuals that radiation is produced when it is energized. This label shall be affixed in a clearly visible location on the face of the radiation machine.

(C) Mechanical support of tube head. The tube housing assembly shall be adjusted to remain stable during an exposure unless tube housing movement is a designed function of the radiation machine.

(D) Battery charge indicator. On battery-powered x-ray generators, visual means shall be provided on the control panel to indicate whether the battery is in a state of charge adequate for proper operation.

(E) Beam quality. The following requirements apply to beam quality.

(i) Half-value layer.

(I) The half-value layer of the useful beam for a given x-ray tube potential shall not be less than the values shown in the following table. If it is necessary to determine such half-value layer at an x-ray tube potential that is not listed in the table, linear interpolation may be made.

Figure: 25 TAC §289.232(j)(5)(E)(i)(I)

(II) For capacitor energy storage equipment, compliance with the requirements of this subparagraph shall be determined with the maximum quantity of charge per exposure.

(ii) Filtration controls.

(I) For radiation machines that have variable kilovolt peak and variable filtration for the useful beam, a device shall link the kilovolt peak selector with the filters and shall prevent an exposure unless the minimum

amount of filtration required by clause (i) of this subparagraph is in the useful beam for the given kilovolt peak that has been selected.

(II) Any other radiation machine having removable filters shall be required to have the minimum amount of filtration as required by clause (i)(I) of this subparagraph permanently located in the useful beam during each exposure.

(F) Multiple tubes. Where two or more radiographic tubes are controlled by one exposure switch, the tube or tubes that have been selected shall be clearly indicated before initiation of the exposure. This indication shall be both on the x-ray control panel and at or near the tube housing assembly that has been selected.

(G) X-ray control. An x-ray control shall be incorporated into each radiation machine such that an exposure can be terminated by the operator at any time, except for exposures of 0.5 second or less. The exposure switch shall be of the continuous pressure type.

(H) Radiation machines needing correction or repair. The correction or repair shall begin within 30 days following the failure and the registrant shall perform or cause to be performed the correction or repair according to a designated plan. Correction or repair shall be completed no longer than 90 days from discovery unless authorized in writing by the agency.

(I) Records of radiation machine corrections or repairs. The registrant shall maintain records of corrections or repairs and any tests, measurements or numerical readings listed in subparagraph (J) of this paragraph in accordance with subsection (k)(2) of this section for inspection by the agency.

(J) Equipment performance evaluations (EPE).

(i) For all dental radiation machines, the registrant shall perform, or cause to be performed, EPE tests for each item specified in clauses (vi) - (xi) of this subparagraph as follows:

(I) within 30 days after initial installation of radiation machines:

(II) within 30 days after reinstallation of a radiation machine;

and

(III) within 30 days after repair of a radiation machine component that would affect the radiation output that includes, but is not limited to, the timer, tube, and power supply.

(ii) Frequency of EPE. For x-ray and CT systems, an EPE shall be performed at the frequency listed in the following table.

Figure: 25 TAC §289.232(j)(5)(J)(ii)

(iii) Records of the EPE results shall be available for inspection by the agency and shall include the following:

(I) measurements and numerical readings;

(II) indication of pass or fail for each test; and

(III) maintenance by the registrant in accordance with subsection (k)(2) of this section for inspection by the agency.

(iv) Radiation machines needing correction or repair. If a radiation machine requires correction or repair following an EPE, the correction or repair shall begin within 30 days following the failure and the registrant shall perform or cause to be performed the correction or repair according to a designated plan. Correction or repair shall be completed no longer than 90 days from discovery unless authorized in writing by the agency.

(v) Timer.

(I) The accuracy of the timer shall meet the manufacturer's specifications. If the manufacturer's specifications are not obtainable, the timer accuracy shall be plus or minus 10% of the indicated time with testing performed at 0.5 second.

(II) Means shall be provided to terminate the exposure at a preset time interval, a preset product of current and time, a preset number of pulses, or a preset radiation exposure to the image receptor. In addition, it shall not be possible to make an exposure when the timer is set to a "zero" or "off" position if either position is provided.

(vi) Exposure reproducibility. When all technique factors are held constant, including control panel selections associated with automatic exposure control systems, the coefficient of variation of exposure for both manual and automatic exposure control systems shall not exceed 0.05. This requirement applies to clinically used techniques.

(vii) Kilovolt peak. If the registrant possesses documentation of the appropriate manufacturer's kilovolt peak specifications, the radiation machine shall meet those specifications. If the registrant does not possess documentation of the appropriate manufacturer's kilovolt peak specifications, the indicated kilovolt peak shall be accurate to within plus or minus 10% of the indicated settings. For radiation machines with fewer than three fixed kilovolt peak settings, the radiation machine shall be checked at those settings.

(viii) Tube stability. The x-ray tube shall remain physically stable during exposures. In cases where tubes are designed to move during exposure, the registrant shall assure proper and free movement of the radiation machine.

(ix) Collimation. Field limitation shall meet the requirements of paragraphs (9) and (10) of this subsection.

(x) Entrance exposure limits (air kerma limits) for dental facilities. The in-air exposure (entrance air kerma) for an adult bite wing view shall be determined from the exposure technique used by the registrant for the average adult patient. The in-air exposure (entrance air kerma) for intraoral (bite wing) dental radiography shall not exceed the following entrance exposure limits (air kerma limits):

Figure: 25 TAC §289.232(j)(5)(J)(x)

(xi) Measurements of the radiation output for a radiation machine. Measurements of the radiation output for a radiation machine shall be performed with a calibrated dosimetry system in accordance with the following.

(I) The dosimetry system calibration shall be traceable to a national standard.

(II) Dosimetry systems shall be calibrated within 24 months from the date of the prior calibration.

(xii) Record of dosimetry system calibration. The registrant shall verify all dosimetry equipment meets the requirements of clause (xi) of this subparagraph.

(6) Dental research.

(A) Any research using radiation machines on humans shall be approved by an Investigational Review Board (IRB) as required by Title 45, CFR, Part 46, and Title 21, CFR, Part 56. The IRB shall include at least one licensed dentist to direct any use of radiation in accordance with this section.

(B) Facilities with radiation machines with investigational device exemptions that are involved in clinical studies shall comply with primary regulations that govern the conduct of clinical studies and that apply to the manufacturers, sponsors, clinical investigators, institutional review boards, and the medical device. These regulations include the following:

(i) 21 CFR, Part 812, Investigational Device Exemptions;

(ii) 21 CFR, Part 50, Protection of Human Subjects

(iii) 21 CFR, Part 56, Institutional Review Boards

(iv) 21 CFR, Part 54, Financial Disclosure by Clinical Investigators;

and

(v) 21 CFR, Part 820, Subpart C, Design Controls of the Quality System Regulation.

(7) Educational facilities. Facilities conducting training using non-humans are held to all the requirements of this section except for paragraph (5)(J) of this subsection concerning EPE and for paragraphs (12) and (13) of this subsection concerning image processing.

(8) Certified radiation machines for dental facilities. The registrant shall not make, nor cause to be made, any modification of components or installations of components certified in accordance with the United States Food and Drug Administration Title 21, CFR, Part 1020, "Performance Standards for Ionizing Radiation Emitting Products," as amended, in any manner that could cause the installations or the components to fail to meet the requirements of the applicable parts of the standards specified in Title 21, CFR, Part 1020, except where a variance has been granted by the Director, Center for Devices and Radiological Health, United States Food and Drug Administration. A copy of the variance shall be maintained by the registrant in accordance with subsection (k)(2) of this section for inspection by the agency. All modifications of components or installation of components must be approved by the manufacturer.

(9) Additional requirements for dental intraoral radiation machines.

(A) Source-to-skin distance. Radiation machines designed for use with an intraoral image receptor shall be provided with means to limit source-to-skin distance to not less than:

(i) 18 centimeters if operable above 50 kilovolt peak; or

(ii) 10 centimeters if not operable above 50 kilovolt peak.

(B) Field limitation. Radiation machines designed for use with an intraoral image receptor shall be provided with means to limit the x-ray beam such that:

(i) if the minimum source-to-skin distance is 18 centimeters or more, the x-ray field at the minimum source-to-skin distance shall be restricted to a dimension of no more than seven centimeters; and

(ii) if the minimum source-to-skin distance is less than 18 centimeters, the x-ray field at the minimum source-to-skin distance shall be restricted to a dimension of no more than six centimeters.

(10) Additional requirements for dental extraoral radiation machines.

(A) Dental panoramic radiation machines shall be provided with means to restrict the x-ray beam to the following:

(i) the imaging slit in the transverse axis; and

(ii) no more than a total of 0.5 inches larger than the imaging slit in the vertical axis.

(B) All other dental extraoral radiation machines (e.g., cephalometric) shall be provided with means to restrict the x-ray field to the image receptor. The x-ray field shall not exceed the image receptor by more than:

(i) 2.0% of the source-to-image receptor distance for the length or width of the image receptor for rectangular collimation; or

(ii) 2.0% of the source-to-image receptor distance for the diagonal of the image receptor for circular or polygon collimation.

(11) Additional operational controls.

(A) When a patient or image receptor must be held in position during radiography, mechanical supporting or restraining devices shall be used

when the exam permits except in individual cases in which the registrant has determined that the holding devices are contraindicated.

(B) The registrant's written operating and safety procedures required by paragraph (2) of this subsection shall include the following:

(i) a list of circumstances in which mechanical holding devices cannot be routinely utilized; and

(ii) a procedure used for selecting an individual to hold or support the patient or image receptor.

(C) The operator position during the exposure shall be such that the operator's exposure is as low as reasonably achievable and the operator is a minimum of six feet from the useful beam or behind a protective barrier. The operator shall maintain verbal, aural, and visual contact with the patient.

(12) Automatic and manual film processing for dental facilities and mobile dental services.

(A) Films shall be developed in accordance with the time-temperature relationships recommended by the film manufacturer. The specified developer temperature for automatic processing and the time-temperature chart for manual processing shall be posted in the processing area. If the registrant determines an alternate time-temperature relationship is more appropriate for a specific facility, that time-temperature relationship shall be documented and posted.

(B) Chemicals shall be replaced according to the chemical manufacturer or supplier's recommendations or at an interval not to exceed three months.

(C) Darkroom light leak tests shall be performed at intervals not to exceed six months.

(D) Lighting in the film processing/loading area shall be maintained with the filter, bulb wattage, and distances recommended by the film manufacturer for that film emulsion or with products that provide an equivalent level of protection against fogging.

(E) Corrections or repairs of the light leaks or other deficiencies in subparagraphs (B) - (D) of this paragraph shall be initiated within 72 hours after discovery and completed no longer than 15 days from detection of the deficiency unless a longer time is authorized by the agency. Records of the

corrections or repairs shall include the date and initials of the individual performing these functions and the registrant shall maintain the records in accordance with subsection (k)(2) of this section for inspection by the agency.

(F) Documentation of the items in subparagraphs (B), (C), and (E) of this paragraph shall be maintained at the site where performed and shall include the date and initials of the individual completing these items. These records shall be made and maintained in accordance with subsection (k)(2) of this section for inspection by the agency.

(13) Alternative processing systems. Users of daylight processing systems, laser processors, self-processing film systems, or other alternative processing systems shall follow manufacturer's recommendations for image processing. Documentation that the registrant is following manufacturer's recommendations shall include the date and initials of the individual completing the document and shall be made and maintained at the authorized use location where performed in accordance with subsection (k)(2) of this section for inspection by the agency.

(14) Digital imaging acquisition systems.

(A) Users of digital imaging acquisition systems shall follow quality assurance/quality control (QA/QC) protocol for digital imaging established by the manufacturer.

(i) The registrant shall include the protocols established in paragraph (2) of this subsection in its operating and safety procedures.

(ii) The registrant shall document the frequency at which the quality assurance/quality control protocol is performed. Documentation shall:

(I) include the date and initials of the individual completing the document and the images acquired; and

(II) be maintained and available at the authorized use location where performed in accordance with subsection (k)(2) of this section for inspection by the agency.

(B) If a protocol cannot be established by the manufacturer, it shall be developed and implemented by the registrant.

(i) The QA/QC protocol, as developed and implemented by the registrant, 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.

(I) Images shall be acquired with each x-ray image receptor at an interval not to exceed three months.

(II) Test images shall be compared to previous test images to assess degradation of image quality.

(III) If a radiation machine or components of the digital imaging acquisition system require correction or repair following a quality test, the correction or repair shall begin within 30 days following the failure and the registrant shall perform or cause to be performed the correction or repair according to a designated plan. Correction or repair shall be completed no longer than 90 days from discovery unless authorized in writing by the agency.

(ii) The registrant shall include the protocols established in paragraph (2) of this subsection in its operating and safety procedures.

(iii) The registrant shall document the frequency at which the quality assurance/quality control protocol is performed. Documentation shall:

(I) include the date and initials of the individual completing the document and the images acquired; and

(II) be maintained and available at the authorized use location where performed in accordance with subsection (k)(2) of this section for inspection by the agency.

(k) Records and reports.

(1) General provisions for records and reports.

(A) Each registrant shall maintain records at each site, including sites authorized by the certificate of registration, conditions, and records sites for mobile services. The records shall include those specified in paragraph (2) of this subsection and shall be maintained at the time interval indicated for inspection by the agency. These records may be maintained in electronic format. These records shall be accessible to radiation machine operators during working hours.

(B) All records required by this section shall be accurate and factual.

(C) Each registrant shall use the SI units gray, sievert, and coulomb per kilogram, or the special units rad, rem, and roentgen, including multiples and subdivisions, and shall clearly indicate the units of all quantities on records required by this section.

(D) The registrant shall make a clear distinction among the quantities entered on the records required by this section, such as, total effective dose equivalent, shallow dose equivalent, lens dose equivalent, and deep dose equivalent.

(E) Each record required by this section shall be legible throughout the specified retention period.

(F) The record shall be the original, a reproduced copy, or a microform, if the authorized personnel authenticate the copy or microform and that the microform is capable of producing a clear copy throughout the required retention period.

(G) The record may also be stored in electronic format with the capability for producing legible, accurate, and complete records during the required retention period.

(H) The registrant shall maintain adequate safeguards against tampering with and loss of records.

(I) Copies of records required in subsections (i)(5)(I) and (J), (j)(5)(J), and (j)(12)(F) of this section and by certificate of registration condition that are relevant to operations at an additional authorized use location shall be maintained at that location in addition to the main site specified on a certificate of registration in accordance with subsection (k)(2) of this section.

(J) Subject to the limitations provided in the Texas Public Information Act, Government Code, Chapter 552, all information and data collected, assembled, or maintained by the agency are public records open to inspection and copying during regular office hours.

(K) Any person who submits written information or data to the agency and requests that the information be considered confidential, privileged, or otherwise not available to the public under the Texas Public Information Act, shall justify such request in writing, including statutes and cases where applicable, addressed to the agency.

(i) Documents containing information that is claimed to fall within an exception to the Texas Public Information Act shall be marked to indicate that fact. Markings shall be placed on the document on origination or submission.

(I) The words "NOT AN OPEN RECORD" shall be placed conspicuously at the top and bottom of each page containing information claimed to fall within one of the exceptions.

(II) The following wording shall be placed at the bottom of the front cover and title page, or first page of text if there is no front cover or title page:

Figure: 25 TAC §289.232(k)(1)(K)(i)(II)

(ii) The agency requests, whenever possible, that all information submitted under the claim of an exception to the Texas Public Information Act be extracted from the main body of the application and submitted as a separate annex or appendix to the application.

(iii) Failure to comply with any of the procedures that are described in clauses (i) and (ii) of this subparagraph may result in all information in the agency file being disclosed upon an open records request.

(L) The agency will determine whether information falls within one of the exceptions to the Texas Public Information Act. The agency will determine whether there has been a previous determination that the information falls within one of the exceptions to the Texas Public Information Act. If there has been no previous determination and the agency believes that the information falls within one of the exceptions, an opinion of the Attorney General will be requested. If the agency agrees in writing to the request, the information shall not be open for public inspection unless the Attorney General's office subsequently determines that it is not an exception.

(M) Requests for information.

(i) All requests for open records information shall be in writing and refer to documents currently in possession of the agency.

(ii) The agency will determine whether the information may be released or whether it falls within an exception to the Texas Public Information Act.

(I) The agency may take a reasonable period to determine whether information falls within one of the exceptions to the Texas Public Information Act.

(II) If the information is determined to be public, it will be presented for inspection and copies of documents will be furnished within a reasonable period. A fee will be charged to recover agency costs for copies.

(iii) Original copies of public records may not be removed from the agency. Under no circumstances shall material be removed from existing records.

(2) Records requirements.

(A) Each registrant shall maintain the following records at each site, including authorized records sites for mobile services, at the time intervals specified and make available to the agency for inspection. The records may be maintained in electronic format.

Figure: 25 TAC §289.232(k)(2)(A)

(B) For radiation machines authorized for mobile service, copies of the records specified in the table in subparagraph (A)(iii)-(v) of this paragraph shall be maintained with the radiation machine in accordance with subparagraph (A) of this paragraph for inspection by the agency. If on-board processors are utilized, image processing records shall also be made on board in accordance with subsection (j)(12), (13), and (14) of this section and maintained in accordance with subparagraph (A) of this paragraph for inspection by the agency.

(C) For authorized records sites for mobile services, copies of the records specified in subparagraph (A)(ii) and (vi)-(xii) of this paragraph shall be maintained in accordance with subparagraph (A) of this paragraph for inspection by the agency.

(3) Reports.

(A) Reports of stolen, lost, or missing radiation machines.

(i) Each registrant shall report to the agency by telephone a stolen, lost, or missing radiation machine immediately after its occurrence becomes known to the registrant.

(ii) Within 30 days after making the telephone report, each registrant required to make a report according to clause (i) of this subparagraph shall make a written report to the agency that includes the following information:

(I) a description of the radiation machine involved, including the manufacturer name, model and serial number;

(II) a description of the circumstances under which the loss or theft occurred;

(III) actions that have been taken, or will be taken, to recover the radiation machine; and

(IV) procedures or measures that have been, or will be, adopted to ensure against a recurrence of the loss or theft of radiation machines.

(iii) Subsequent to filing the written report, the registrant shall also report additional information pertaining to the loss or theft within 30 days after the registrant learns of such information.

(iv) The registrant shall prepare any report filed with the agency in accordance with this subsection so that names of individuals who may have received exposure to radiation are stated in a separate and detachable portion of the report.

(B) Reports of incidents.

(i) Notwithstanding other requirements for notification, each registrant shall immediately report each event involving a radiation machine possessed by the registrant that may have caused or threatens to cause an individual, except radiation administered for healing arts purposes, to receive:

(I) a total effective dose equivalent of 25 rems (0.25 sievert) or more;

(II) a lens dose equivalent of 75 rems (0.75 sievert) or more; or

(III) a shallow dose equivalent to the skin of the whole body or to the skin of any extremities of 250 rads (2.5 grays) or more.

(ii) Within 24 hours of discovery of the event, each registrant shall report to the agency each event involving loss of control of a radiation

machine possessed by the registrant that may have caused, or threatens to cause an individual to receive, in a period of 24 hours:

(I) a total effective dose equivalent exceeding 5 rems (0.05 sievert);

(II) a lens dose equivalent exceeding 15 rems (0.15 sievert); or

(III) a shallow dose equivalent to the skin of the whole body or to the skin of any extremities exceeding 50 rems (0.5 sievert).

(iii) Registrants shall make the initial notification reports required by clauses (i) and (ii) of this subparagraph by telephone to the agency and shall confirm the initial notification report within 24 hours by facsimile or other electronic media to the agency.

(iv) The registrant shall prepare each report filed with the agency in accordance with this section so that names of individuals who have received exposure to sources of radiation are stated in a separate and detachable portion of the report.

(C) Reports of exposures and radiation levels exceeding the limits.

(i) In addition to the notification required by subparagraph (B) of this paragraph, each registrant shall submit a written report within 30 days after learning of any of the following occurrences:

(I) incidents for which notification are required by subparagraph (B) of this paragraph;

(II) doses in excess of any of the following:

(-a-) the occupational dose limits for adults in subsection (j)(3)(A)(i) of this section;

(-b-) the occupational dose limits for a minor in subsection (j)(3)(A)(i)(III) of this section;

(-c-) the limits for an embryo/fetus of a declared pregnant woman in subsection (j)(3)(A)(i)(IV) and (V) of this section;

(-d-) the limits for an individual member of the public in subsection (j)(3)(B) of this section; or

(-e-) any applicable limit in the certificate of registration;

(III) levels of radiation in:

(-a-) a restricted area in excess of applicable limits in the certificate of registration; or

(-b-) an unrestricted area in excess of 10 times the applicable limit set forth in this section or in the certificate of registration conditions, whether or not involving exposure of any individual in excess of the limits in subsection (j)(3)(B) of this section.

(ii) Each report required by clause (i) of this subparagraph shall describe the extent of exposure of individuals to radiation, including, as appropriate:

(I) estimates of each individual's dose;

(II) the levels of radiation involved;

(III) the cause of the elevated exposures, dose rates; and

(IV) corrective steps taken or planned to ensure against a recurrence, including the schedule for achieving conformance with applicable limits, and associated registration conditions.

(iii) Each report filed in accordance with clause (i) of this subparagraph shall include, for each individual exposed, the name, a unique identification number, and date of birth. With respect to the limit for the embryo/fetus in subsection (j)(3)(A)(i)(IV) and (V) of this section, the identifiers should be those of the declared pregnant woman. The report shall be prepared so that this information is stated in a separate and detachable portion of the report.

(D) Reports to individuals of exposures.

(i) If applicable, radiation exposure data for an individual shall be reported to the individual as specified in this paragraph. The information reported shall include data and results obtained in accordance with requirements of this section, orders, certificate of registration conditions, as shown in records made and maintained by the registrant in accordance with this subsection. Each notification and report shall:

(I) be in writing;

(II) include appropriate identifying data such as the name of the registrant, the name of the individual, and the individual's identification number;

(III) include the individual's exposure information; and

(IV) contain the following statement: "This report is furnished to you under the provisions of the Texas Regulations for Control of Radiation, 25 Texas Administrative Code §289.232(j)(3)(A) - (C). You should preserve this report for further reference."

(ii) If applicable, each registrant shall provide an annual written report to advise each worker of the worker's estimated dose, received in that monitoring year, as shown in records made and maintained by the registrant in accordance with subparagraph (C) of this paragraph if:

(I) the individual's occupational dose exceeds 100 mrem (1 mSv) total effective dose equivalent or 100 mrem (1 mSv) to any individual organ or tissue; or

(II) the individual requests his or her annual dose report in writing.

(iii) When a registrant is required in accordance with subparagraphs (B) and (C) of this paragraph to report to the agency any exposure of an identified occupationally exposed individual, or an identified member of the public, to radiation, the registrant shall also notify the individual and provide the individual with a copy of the report submitted to the agency, including the information required by clause (i) of this subparagraph. Such reports shall be transmitted no later than the transmittal to the agency.

(l) Compliance and hearing procedures.

(1) Inspections. The agency may enter public or private property at reasonable times to determine whether, in a matter under the agency's jurisdiction, there is compliance with the Act, the requirements of this section, certificate of registration conditions, and orders issued by the agency.

(A) Each registrant shall perform, upon instructions from the agency, or shall permit the agency to perform such reasonable surveys, as the agency deems appropriate or necessary, including, but not limited to, surveys of:

(i) radiation machines;

(ii) facilities where radiation machines are used; and

(iii) other radiation machines and devices used in connection with utilization of radiation machines.

(B) The routine inspection interval for dental facilities is four years. On-site inspections and remote inspections may be alternated as determined by the agency. The inspection interval specified is based upon the average number of health-related violations per inspection, as determined from compliance history data. Registrant's having certificates of registration authorizing multiple radiation machine use categories will be inspected on-site at the most frequent interval specified for the radiation machine uses authorized.

(i) Notwithstanding the inspection interval specified in this subparagraph, the agency may inspect registrants more frequently due to:

(I) the persistence or severity of violations found during an inspection;

(II) investigation of an incident or complaint concerning the facility;

(III) a request for an inspection by a worker in accordance with paragraph (2) of this subsection;

(IV) any change in a facility or radiation machine that might cause a significant increase in radiation output or hazard; or

(V) a mutual agreement between the agency and registrant.

(ii) The agency will conduct inspections of dental radiation machines in a manner designed to cause as little disruption of a dental practice as is practicable.

(C) On-site Inspections.

(i) Each registrant shall afford to the agency at all reasonable times opportunity to inspect materials, radiation machines, activities, facilities, premises, and records in accordance with this section.

(ii) During an inspection, agency inspectors may obtain and retain paper or electronic copies of requested documentation in accordance with this section.

(iii) Each registrant shall make available to the agency for inspection records made and maintained in accordance with this section.

(iv) Agency inspectors may consult privately with workers concerning matters of occupational radiation protection and other matters related to applicable provisions of agency regulations and certificates of registration to the extent the inspectors deem necessary for the conduct of an inspection.

(v) An employee who routinely is engaged in work under control of the registrant, operating the radiation machines for healing arts purposes, shall be made available to operate the radiation machines at the time of the inspection and engage in the inspection process.

(vi) Notwithstanding the other provisions of this section, agency inspectors are authorized to refuse to permit accompaniment by any individual who interferes, delays, or causes to be delayed an inspection.

(D) For remote inspection of dental radiation machines, each registrant shall:

(i) respond to a request from the agency for a remote inspection;

(ii) complete the remote inspection forms in accordance with the instructions included with the forms; and

(iii) return to the agency the completed remote inspection forms, including documentation of the most recent EPE performed in accordance with subsection (j)(5)(J) of this section and an inventory in accordance with subsection (i)(5)(I) of this section by the deadline indicated on the forms.

(E) During the course of an inspection, any worker may privately inform the inspectors, either verbally or in writing, any past or present condition which that individual has reason to believe may have contributed to or caused any violation of the Act, the requirements in this section, certificate of registration conditions, or any unnecessary exposure of an individual to radiation from any radiation machine source of radiation under the registrant's control. Any such notice in writing shall comply with the requirements of paragraph (2) of this subsection.

(F) The provisions of subparagraph (E) of this paragraph shall not be interpreted as authorization to disregard instructions in accordance with subsection (j)(3)(D) of this section.

(2) Complaints. Any worker or representative of a worker who believes that a violation of the Act, the requirements of this section, or certificate of registration conditions exists or has occurred in work under a certificate of registration with regard to radiological working conditions in which the worker is engaged, may request an inspection by giving notice of the alleged violation to the agency. Any such notice shall be in writing, shall set forth the specific grounds for the notice, and the worker or representative of the worker shall sign the notice. A copy shall be provided to the registrant by the agency no later than at the time of inspection except that, upon the request of the worker giving such notice, the worker's name and the name of individual referred to therein shall not appear in such copy or on any record published, released, or made available by the agency, except for good cause shown.

(A) If, upon receipt of such notice, the agency determines that the request meets the requirements set forth in this paragraph, and that there are reasonable grounds to believe that the alleged violation exists or has occurred, an inspection shall be made as soon as practicable to determine if such alleged violation exists or has occurred. Inspections in accordance with this section need not be limited to matters referred in the request.

(B) No registrant, contractor or subcontractor of a registrant shall discharge or in any manner discriminate against any worker because of the following:

(i) such worker has filed any request or instituted or caused to be instituted any proceeding under this section;

(ii) such worker has testified or is about to testify in any such proceeding; or

(iii) because of the exercise by such worker on behalf of that individual or others of any option afforded by this section.

(C) Inspections not warranted.

(i) If the agency determines, with respect to a request under subparagraphs (A) and (B) of this paragraph, that an inspection is not warranted because there are no reasonable grounds to believe that a violation exists or has occurred, the agency shall notify the requestor in

writing of such determination. The requestor may obtain review of such determination in accordance with the provisions of the Act and the Government Code, Chapters 2001 and 2002.

(ii) If the agency determines that an inspection is not warranted because the requirements of this paragraph have not been met, the agency shall notify the requestor in writing of such determination. Such determination shall be without prejudice to the filing of a new request meeting the requirements of this paragraph.

(D) Agency inspectors are required to have special training in the design and uses of medical x-ray equipment. Inspector training requirements and standards will be detailed in the Radiation Control Program policies and procedures manual.

(3) Hearing and enforcement procedures.

(A) Violations.

(i) A court injunction or agency order may be issued prohibiting any violation of any provision of the Act or any requirement of this section or order issued thereunder.

(ii) Any person who violates any provision of the Act or any requirement of this section or order issued thereunder may be subject to civil or administrative penalties.

(iii) Such person may also be guilty of a misdemeanor and upon conviction, may be punished by fine or imprisonment or both, as provided by law.

(B) Denial of an application for a certificate of registration.

(i) When the agency contemplates denial of an application for certificate of registration as outlined in subparagraph (A)(i) of this paragraph, the registrant shall be afforded the opportunity for a hearing. Notice of the denial shall be delivered to the registrant by mail, addressed to the last known address of the registrant.

(ii) Any applicant or registrant against whom the agency contemplates denial of an application may request a hearing by submitting a written request to the director within 30 days after service of the notice or date of mailing.

(I) The written request for a hearing shall contain the following:

(-a-) statement requesting a hearing; and

(-b-) name and address of the applicant or registrant.

(II) Failure to submit a written request for a hearing within 30 days after notice is sent will render the agency action final.

(C) Compliance procedures for registrants and other persons.

(i) A registrant or other person who commits a violation will be issued a notice of violation. The person receiving the notice shall provide the agency with a written statement and supporting documentation by the date stated in the notice describing the following:

(I) steps taken by the person and the results achieved;

(II) corrective steps to be taken to prevent recurrence; and

(III) the date when full compliance was or is expected to be achieved. The agency may require responses to notices of violation to be under oath.

(ii) The terms and conditions of all certificates of registration shall be subject to amendment or modification. A certificate of registration may be modified, suspended, or revoked by reason of amendments to the Act, or for violation of the Act, the requirements of this section, a condition of the certificate of registration, or an order of the agency.

(iii) Any certificate of registration may be modified, suspended, or revoked in whole or in part, for any of the following:

(I) any material false statement in the application or any statement of fact required in accordance with provisions of the Act;

(II) conditions revealed by such application or statement of fact or any report, record, or inspection, or other means that would warrant the agency to refuse to grant a certificate of registration on an original application;

(III) violation of, or failure to observe any of the applicable terms and conditions of the Act, this section, or of the certificate of registration, or order of the agency; or

(IV) existing conditions that constitute a substantial threat to the public health or safety or the environment.

(iv) If another state or federal entity takes an action such as modification, revocation, or suspension of the certificate of registration, the agency may take a similar action against the registrant.

(v) When the agency determines that the action provided for in clause (viii) of this subparagraph or subparagraph (D) of this paragraph is not to be taken immediately, the agency may offer the registrant an opportunity to attend an informal conference to discuss the following with the agency:

(I) methods and schedules for correcting the violations; or

(II) methods and schedules for showing compliance with applicable provisions of the Act, the requirements of this section, certificate of registration conditions, or any orders of the agency.

(vi) Notice of any informal conference shall be delivered by personal service, or certified mail, addressed to the last known address. An informal conference is not a prerequisite for the action to be taken in accordance with clause (viii) of this subparagraph or subparagraph (D) of this paragraph.

(vii) Except in cases in which the occupational and public health or safety requires otherwise, no certificate of registration shall be suspended or revoked unless, before the institution of proceedings therefore, facts or conduct that may warrant such action shall have been called to the attention of the registrant in writing, and the registrant shall have been afforded an opportunity to demonstrate compliance with all lawful requirements.

(viii) When the agency contemplates modification, suspension, or revocation of the certificate of registration, the registrant shall be afforded the opportunity for a hearing. Notice of the contemplated action, along with a complaint, shall be given to the registrant by personal service or certified mail, addressed to the last known address.

(ix) Any applicant or registrant against whom the agency contemplates an action described in clause (viii) of this subparagraph may request a hearing by submitting a written request to the director within 30 days after service of the notice.

(I) The written request for a hearing shall contain the following:

(-a-) statement requesting a hearing;

(-b-) name, address, and identification number of the registrant against whom the action is being taken.

(II) Failure to submit a written request for a hearing within 30 days after notice is sent will render the agency action final.

(D) Assessment of administrative penalties.

(i) When the agency determines that monetary penalties are appropriate, proposals for assessment of and hearings on administrative penalties shall be made in accordance with Health and Safety Code, §401.384; Title 1, Texas Administrative Code, Chapter 155; and applicable sections of the Formal Hearing Procedures, §§1.21, 1.23, 1.25, and 1.27 of this title.

(ii) Assessment of administrative penalties shall be based on the following criteria:

(I) the seriousness of the violations;

(II) previous compliance history;

(III) the amount necessary to deter future violations;

(IV) efforts to correct the violations; and

(V) any other mitigating or enhancing factors.

(iii) Application of administrative penalties. The agency may impose differing levels of penalties for different severity level violations and different classes of users as follows.

(I) Administrative penalties may be imposed for severity level I and II violations. Administrative penalties may be imposed for severity level III, IV, and V violations when the violations are combined with those of higher severity levels or for repeated violations.

(II) The following Tables A and B show the base administrative penalties.

Figure: 25 TAC §289.232(I)(3)(D)(iii)(II)

(III) Adjustments to the percentages of base amounts in Table B may be made for the presence or absence of the following factors:

(-a-) prompt identification and reporting;

(-b-) corrective action to prevent recurrence;

(-c-) compliance history;

(-d-) prior notice of similar event;

(-e-) multiple occurrences; and

(-f-) negligence that resulted in or increased adverse effects.

(IV) The penalty for each violation may be in an amount not to exceed \$10,000 a day for a person who violates the Act or requirements of this section, order, or certificate of registration issued in accordance with the Act. Each day a violation continues may be considered a separate violation for purposes of penalty assessment.

(iv) The agency may conduct settlement negotiations.

(E) Severity levels of violations for registrants or other persons.

(i) Violations for registrants or other persons shall be categorized by one of the following severity levels.

(I) Severity level I are violations that are most significant and may have a significant negative impact on occupational or public health and safety or on the environment.

(II) Severity level II are violations that are very significant and may have a negative impact on occupational or public health and safety or on the environment.

(III) Severity level III are violations that are significant and which, if not corrected, could threaten occupational or public health and safety or the environment.

(IV) Severity level IV are violations that are of more than minor significance, but if left uncorrected, could lead to more serious circumstances.

(V) Severity level V are violations that are of minor safety or environmental significance.

(ii) Criteria to elevate or reduce severity levels.

(I) Severity levels may be elevated to a higher severity level for the following reasons:

(-a-) more than one violation resulted from the same underlying cause;

(-b-) a violation contributed to or was the consequence of the underlying cause, such as a management breakdown or breakdown in the control of registered activities;

(-c-) a violation occurred multiple times between inspections;

(-d-) a violation was willful or grossly negligent;

(-e-) compliance history; or

(-f-) other mitigating factors.

(II) Severity levels may be reduced to a lower level for the following reasons:

(-a-) the registrant identified and corrected the violation before the agency inspection;

(-b-) the registrant's actions corrected the violation and prevented recurrence; or

(-c-) other mitigating factors.

(iii) Examples of severity levels. Examples of severity levels are available upon request to the agency.

(F) Impoundment of radiation machines. Radiation machines shall be subject to impounding in accordance with Health and Safety Code, §401.068 and this paragraph.

(i) In the event of an emergency, the agency shall have the authority to impound or order the impounding of radiation machines

possessed by any person not equipped to observe or failing to observe the provisions of the Act, or any requirements of this section, certificate of registration conditions, or orders issued by the agency. The agency shall submit notice of the action to be published in the *Texas Register* no later than 30 days following the end of the month in which the action was taken.

(ii) At the agency's discretion, the impounded radiation machines may be disposed of by:

(I) returning the radiation machine to a properly registered owner, upon proof of ownership, who did not cause the emergency;

(II) releasing the radiation machine as evidence to police or courts;

(III) returning the radiation machine to a registrant after the emergency is over and settlement of any compliance action; or

(IV) selling, destroying or other disposition within the agency's discretion.

(iii) If agency action is necessary to protect the public health and safety, no prior notice need be given the owner or possessor. If agency action is not necessary to protect the public health and safety, the agency will give written notice to the owner or the possessor of the impounded radiation machine of the intention to dispose of the radiation machine. Notice shall be the same as provided in subparagraph (C)(viii) of this paragraph. The owner or possessor shall have 30 days from the date of personal service or mailing to request a hearing under Title 1, Texas Administrative Code, Chapter 155, and the Formal Hearing Procedures, §§1.21, 1.23, 1.25, and 1.27 of this title, and in accordance with subparagraph (C)(ix) of this paragraph, concerning the intention of the agency. If no hearing is requested within that period, the agency may take the contemplated action, and such action is final.

(iv) Upon agency disposition of a radiation machine, the agency may notify the owner or possessor of any expense the agency may have incurred during the impoundment or disposition and request reimbursement. If the amount is not paid within 60 days from the date of notice, the agency may request the Attorney General to file suit against the owner or possessor for the amount requested.

(v) If the agency determines from the facts available that an impounded radiation machine is abandoned, with no reasonable evidence

showing its owner or possessor, the agency may make such disposition of the radiation machine as it sees fit.

(G) Emergency orders.

(i) When an emergency exists requiring immediate action to protect the public health or safety or the environment, the agency may, without notice or hearing, issue an order citing the existence of such emergency and require that certain actions be taken as the agency directs to meet the emergency. No later than 30 days following the end of the month in which the action was taken, the agency shall submit notice of the action for publication in the *Texas Register*. The action taken will remain in full force and effect unless and until modified by subsequent action of the agency.

(ii) An emergency order takes effect immediately upon service.

(iii) Any person receiving an emergency order shall comply immediately.

(iv) The person receiving the order shall be afforded the opportunity for a hearing on an emergency order. Notice of the action, along with a complaint, shall be given to the person by personal service or certified mail, addressed to the last known address. A hearing shall be held on an emergency order if the person receiving the order submits a written request to the director within 30 days after the date of the order.

(I) The hearing shall be held not less than 10 days nor more than 20 days after receipt of the written application for hearing.

(II) At the conclusion of the hearing and after the proposal for decision is made as provided in the Texas Administrative Procedure Act, Texas Government Code, Chapter 2001, the commissioner shall take one of the following actions:

(-a-) determine that no further action is warranted;

(-b-) amend the certificate of registration;

(-c-) revoke or suspend the certificate of registration;

(-d-) rescind the emergency order; or

(-e-) issue such other order as is appropriate.

(III) The application and hearing shall not delay compliance with the emergency order.

(H) Miscellaneous provisions.

(i) Computation of time. A time established by the requirements of this section shall begin on the first day after the event that invokes the time. When the last day of the period falls on a Saturday, Sunday, or state or federal holiday, the time shall end on the next day that is not a Saturday, Sunday, or state or federal holiday. The time shall expire at 5:00 p.m. of the last day of the computed time.

(ii) Hearing location. Hearings will be held at the offices of the State Office of Administrative Hearings in Austin unless the administrative law judge specifies another location.

(iii) Non-party witness and mileage fees.

(I) A witness or deponent who is not a party (or an employee, agent, or representative of a party) and who is subpoenaed or otherwise compelled to attend an agency hearing or a proceeding to give a deposition, or to produce books, records, papers, accounts, documents, or other objects necessary and proper for the purposes of the hearing or proceeding may receive reimbursement for transportation and other costs at rates established by the current Appropriations Act for state employees.

(II) The person requesting the attendance of the witness or deponent shall deposit with the agency the funds estimated to accrue in accordance with subclause (I) of this clause when filing a motion for the issuance of a subpoena or a commission to take a deposition.

(iv) Service. A return of service by the person who performed personal service, postal return receipt, or proof of mailing to the last known address shall be conclusive evidence of service.

Figure: 25 TAC §289.232(d)(20)

$$C = \frac{s}{\bar{X}} = \frac{1}{\bar{X}} \left[\sum_{i=1}^n \frac{(X_i - \bar{X})^2}{n-1} \right]^{1/2}$$

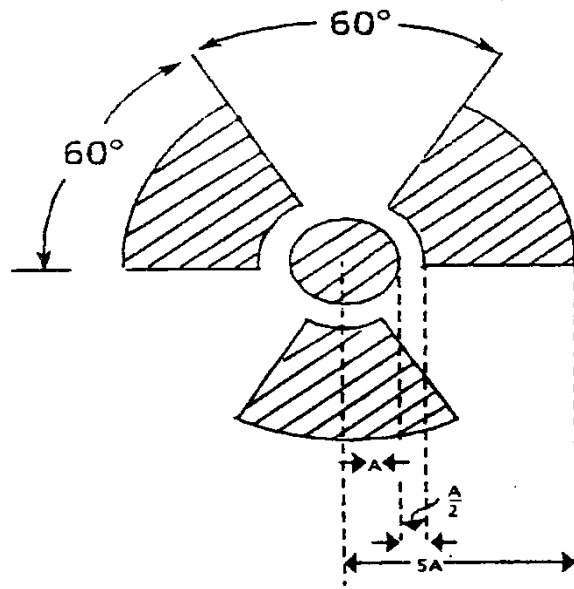
where : s = estimated standard deviation of the population

\bar{X} = mean value of observations in sample

X_i = i th observation in sample

n = number of observations in sample

Figure: 25 TAC §289.232(j)(4)(A)



Department of State Health Services
P.O. Box 149347
Austin, Texas 78714-9347

NOTICE TO EMPLOYEES

TEXAS REGULATIONS FOR CONTROL OF RADIATION

The Department of State Health Services has established standards for your protection against radiation hazards, in accordance with the Texas Radiation Control Act, Health and Safety Code, Chapter 401.

YOUR EMPLOYER'S RESPONSIBILITY

Your employer is required to-

1. Apply these rules to work involving sources of radiation.
2. Post or otherwise make available to you a copy of the Department of State Health Services rules, certificates of registration, notices of violations, and operating procedures that apply to your work, and explain their provisions to you.

YOUR RESPONSIBILITY AS A WORKER

You should familiarize yourself with those provisions of the rules and the operating procedures that apply to your work. You should observe the rules for your own protection and protection of your co-workers.

WHAT IS COVERED BY THESE RULES

1. Limits on exposure to sources of radiation in restricted and unrestricted areas;
2. Measures to be taken after accidental exposure;
3. Individual monitoring devices, surveys, and equipment;
4. Caution signs, labels, and safety interlock equipment;
5. Exposure records and reports;
6. Options for workers regarding agency inspections; and
7. Related matters.

REPORTS ON YOUR RADIATION EXPOSURE HISTORY

1. The rules require that your employer give you a written report if you receive an exposure in excess of any applicable limit set forth in the rules or in the certificate of registration. The basic limits for exposure to employees are set forth in 25 Texas Administrative Code (TAC) §289.232(i)(4)(A) - (C) of this title (relating to Radiation Control Regulations for Dental Radiation Machines.) This subsection specifies limits on exposure to radiation.

2. If you work where individual monitoring devices are provided in accordance with 25 TAC §289.231 of this title (relating to General Provisions and Standards for Protection Against Machine-Produced Radiation);

- (a) your employer shall furnish to you an annual written report of your exposure to radiation if.
 - (1) the individual's occupational dose exceeds 100 mrem (1 mSv) total effective dose equivalent or 100 mrem (1 mSv) to any individual organ or tissue; or
 - (2) the individual requests his or her annual dose report in writing.
- (b) your employer shall give you a written report, upon termination of your employment, of your radiation exposures if you request the information on your radiation exposure in writing.

INSPECTIONS

All licensed or registered activities are subject to inspection by representatives of the Department of State Health Services. In addition, any worker or representative of the workers, who believes that there is a violation of the Texas Radiation Control Act, the rules issued thereunder, or the terms of the employer's license or registration with regard to radiological working conditions in which the worker is engaged, may request an inspection by sending a notice of the alleged violation to the Department of State Health Services. The request shall state the specific grounds for the notice, and shall be signed by the worker or the representative of the workers. During inspections, agency inspectors may confer privately with workers, and any worker may bring to the attention of the inspectors any past or present condition that the individual believes contributed to or caused any violations as described above.

POSTING REQUIREMENTS

Copies of this notice shall be posted in a sufficient number of places in every establishment where employees are employed in activities registered, in accordance with 25 TAC §289.232 (relating to Radiation Control Regulations for Dental Radiation Machines), to permit employees to observe a copy on the way to or from their place of employment.

Applicable section of 25 TAC Chapter 289 may be viewed online, at www.dshs.texas.gov/radiation. Our license and/or certificate of registration and any associated documents, our operation procedures, and any "Notice of Violation" or order issued by the agency may be viewed at the following location: _____

Figure: 25 TAC §289.232(j)(5)(E)(i)(I)

HALF-VALUE LAYER FOR SELECTED kVp

X-ray Tube Voltage (kilovolt peak)		Minimum HVL (mm of aluminum)	
Designed operating range	Measured operating potential	Intraoral dental systems manufactured before or on June 10, 2006	Intraoral dental systems manufactured after June 10, 2006
Below 51	30	0.3	1.5
	40	0.4	1.5
	50	0.5	1.5
51 to 70	51	1.2	1.5
	60	1.3	1.5
	70	1.5	1.5
Above 70	71	2.1	2.1
	80	2.3	2.3
	90	2.5	2.5
	100	2.7	2.7
	110	3.0	3.0
	120	3.2	3.2
	130	3.5	3.5
	140	3.8	3.8
	150	4.1	4.1

Figure: 25 TAC §289.232(j)(5)(J)(ii)

Type of Machine	Frequency
CBCT	Annually not to exceed 14 months from the prior EPE
All other Dental X-ray	Four years from the date of prior EPE

Figure: 25 TAC §289.232(j)(5)(J)(x)

RADIOGRAPHIC ENTRANCE EXPOSURE LIMITS (AIR KERMA LIMITS)

Examination	Kilovolt Peak	Exposure Limit (mR)	(Air Kerma Limit) (mGy)
Adult Intraoral	60 and above	450	(4.5)
Adult Intraoral	Less than 60	600	(6.0)

Figure: 25 TAC §289.232(k)(1)(K)(i)(II)

"INFORMATION FALLING WITHIN EXCEPTION OF THE TEXAS PUBLIC INFORMATION ACT, GOVERNMENT CODE, CHAPTER 552 ---- CONFIDENTIAL

This document contains information submitted to the Department of State Health Services, Radiation Control by

(Name of Company)(Name of Submitter)

that is claimed to fall within the following exception to the Texas Public Information Act, Government Code, Chapter 552, Subchapter C

(Appropriate Subsection)

WITHHOLD FROM PUBLIC DISCLOSURE

(Signature and Title)(Office)(Date)"

Figure: 25 TAC §289.232(k)(2)(A)

RECORDS RETENTION

	Name of Record/Document	Specific Rule Subsection	Time Interval for Keeping Record/Document
(i)	Inventory of all Radiation Machines Possessed	(i)(5)(I)	Until next routine on-site inspection
(ii)	Receipt, Transfer, and Disposal of Each Radiation Machine Possessed	(i)(5)(J)	Until termination of registration
(iii)	Current Operating and Safety Procedures Documentation that all staff who operate the radiation machine(s) have read this document	(j)(2) (j)(2)(A)	Until termination of registration Until next routine on-site inspection
(iv)	Current 25 TAC, §289.232 of this title	(j)(4)(B)(i)(II)(-a-)	Until termination of registration
(v)	Current Certificate of Registration	(j)(4)(B)(i)(II)(-b-)	Until termination of registration
(vi)	Notice of Violation From Last Inspection (if applicable)	(j)(4)(B)(i)(II)(-d-)	Until next routine on-site inspection
(vii)	Documentation of Corrections of any Violations	(j)(4)(B)(i)(II)(-d-)	Until next routine on-site inspection
(viii)	Records of machine corrections or repairs	(j)(5)(I)	Until next routine on-site inspection
(ix)	Equipment Performance Evaluations	(j)(5)(J)(iii)	10 years
(x)	United States Food and Drug Administration Variances	(j)(8)	Until transfer of machines or termination of registration
(xi)	Film Processing Records and Corrections	(j)(12)(F)	Until next routine on-site inspection
(xii)	Alternative Processing System Records	(j)(13)	Until next routine on-site inspection

	Name of Record/Document	Specific Rule Subsection	Time Interval for Keeping Record/Document
(xiii)	Digital Imaging Acquisition System Records	(j)(14)(A)(ii)(II)	Until next routine on-site inspection
(xiv)	Records at Additional Authorized Sites	(k)(1)(I)	While location is authorized on registration

BASE ADMINISTRATIVE PENALTIES

Table A – Base Amounts

Type of User	Amount
All registrants	\$5,000
Other persons not registered	\$10,000

Table B – Percentage of Base Amounts Based on Severity Level of Violation

Severity Level	Percent of Amount Listed in Table A
I	100
II	80
III	50
IV	15
V	5