

**Department of State Health Services
Agenda Item for State Health Services Council
January 30-31, 2008**

Agenda Item Title:

Amendment of 25 TAC, §289.204, Rule Relating to Fees for Certificates of Registration, Radioactive Material Licenses, Emergency Planning and Implementation, and Other Regulatory Services

Amendment of 25 TAC, §289.226, Rule Relating to Registration of Radiation Machine Use and Services

Amendment of 25 TAC, §289.232, Rule Relating to Radiation Control Regulations for Dental Radiation Machines

Amendment of 25 TAC, §289.233, Rule Relating to Radiation Control Regulations for Radiation Machines Used in Veterinary Medicine

Amendment of 25 TAC, §289.301, Rule Relating to Registration and Radiation Safety Requirements for Lasers and Intense-Pulsed Light Devices

Agenda Number: 4k

Recommended Council Action:

For Discussion Only

For Discussion and Action by the Council

Background:

The Radiation Control Program is in the Division for Regulatory Services and provides a regulatory program to protect and promote the physical and environmental health of the citizens of Texas. The regulatory program includes licensing, registration, inspection, enforcement and emergency response functions for the use of radioactive material and radiation machines. The Radiation Control Program is entirely fee funded from fees charged for licenses and registrations that it issues.

Summary:

The revisions to §§289.204, 289.226, 289.232, 289.233, and 289.301 will not affect licensees and registrants because the changes do not require licensees and registrants to alter their business practices in order to comply with the revisions. There will be no adverse economic impact on those persons regulated.

Concerning §289.204 relating to fees for certificates of registration, radioactive material licenses, emergency planning and implementation, and other regulatory services, changes are needed due to House Bill (HB) 2285 of the 80th Legislative Session, which eliminated the need for a two-year permit term, but the fees will continue to be paid every two years. In addition, the fee amounts for the industrial radiographer certification and examinations that were previously revised in §289.255 of this title (relating to Radiation Safety Requirements and Licensing and Registration Procedures for Industrial Radiography) in 2007, are being updated in this revised section to be consistent with §289.255 of this title.

The changes also delete the schedule of fees, adjustment of fees, and one-time fee adjustments for uranium recovery and byproduct material disposal facility licenses, and remove references to the rules concerning licensing of radioactive waste processing and storage facilities and licensing of uranium recovery and byproduct material disposal facilities. The deletions are due to the transfer of the regulatory authority for licensing and inspection of low-level waste processing and uranium recovery and disposal from the department to the Texas Commission on Environmental Quality, as a result of Senate Bill 1604 of the 80th Legislative Session. As a result of HB 2285 amending Health and Safety Code §401.301(f), the department is prohibited from assessing fees on local law enforcement agencies for the registration of x-ray machines used for security screening, which will result in a loss of revenue to the state.

Concerning §289.226 relating to registration of radiation machine use and services, although revisions will eliminate the two-year permit term due to HB 2285, the fees will continue to be paid every two years. The revision also includes

updating the names of several Texas medical and professional boards; adding clarifying language regarding changes in inventory of radiation machines, and correcting referenced rule citations.

Concerning §289.232 relating to radiation control regulations for dental radiation machines, amendments to eliminate the two-year permit term are necessary due to HB 2285 but the fees will continue to be paid every two years. Additionally, the fee amounts for certificates of registration for radiation machines used in dentistry that were previously revised in §289.204 of this title in 2006, are being updated in this revised section to be consistent with §289.204 of this title. The amendments also update the following: the names of several Texas medical and professional boards; hearing and enforcement procedure requirements, and exposure reproducibility requirements for consistency with other comparable rules of this chapter. In addition, the table of half-value layer for selected kilovolt peak is revised to state the correct values.

Concerning §289.233 relating to radiation control regulations for radiation machines used in veterinary medicine, changes are needed due to HB 2285, which eliminated the need for a two-year permit term but the fees will continue to be paid every two years. Additionally, the fee amounts for certificates of registration for radiation machines used in veterinary medicine that were previously revised in §289.204 of this title in 2006, are being updated in this revised section to be consistent with §289.204 of this title. The changes update: the names of several Texas medical and professional boards; make the hearing and enforcement procedure requirements consistent with other comparable rules of this chapter; and remove language regarding changes in categories of veterinary radiation machines.

Concerning §289.301 relating to registration and radiation safety requirements for lasers and intense-pulsed light devices, although the two-year permit term will be eliminated as a result of HB 2285, the fees will continue to be paid every two years. In addition, the amendment adds clarifying language regarding inventory of lasers and corrects referenced citations.

The rules also comply with the mandatory four-year review of the agency rules in accordance with Government Code, §2001.039.

Summary of Input from Stakeholder Groups:

The rules will be posted for review and comment to the Radiation Control website (www.dshs.state.tx.us/radiation/draft.shtm).

The proposed rules were reviewed by the Texas Radiation Advisory Board (TRAB) at their October 13, 2007, meeting in Austin, Texas. TRAB recommended that the proposed rules for §§289.204, 289.226, 289.232, 289.233, and 289.301 be forwarded to the State Health Services Council for consideration as proposed rules.

Proposed Motion: Motion to recommend HHSC approval for publication of rules contained in agenda item #4k.

Agenda Item Approved by Assistant Commissioner/Director: Kathryn C. Perkins **Date:** 12/28/07

Person Presenting: Cindy Cardwell **Program:** Environmental and Consumer Safety Section **Phone No:** 834-6770

Final CAM Approved by Consumer Affairs: RMM **Date:** 12/28/07

TITLE 25. HEALTH SERVICES
Part 1. DEPARTMENT OF STATE HEALTH SERVICES
Chapter 289. Radiation Control
Subchapter D. General
Amendment §289.204
Subchapter E. Registration Regulations
Amendment §289.226
Amendment §289.232
Amendment §289.233
Subchapter G. Registration Regulations
Amendment §289.301

Proposed Preamble

The Executive Commissioner of the Health and Human Services Commission on behalf of the Department of State Health Services (department) proposes the amendment of §289.204 concerning fees for certificates of registration, radioactive material licenses, emergency planning and implementation, and other regulatory services, the amendment of §289.226 concerning registration of radiation machine use and services, the amendment of §289.232 concerning radiation control regulations for dental radiation machines, the amendment of §289.233 concerning radiation control regulations for radiation machines used in veterinary medicine, and amendment of §289.301 concerning registration and radiation safety requirements for lasers and intense-pulsed light devices.

BACKGROUND AND PURPOSE

The amendment of §289.204 is necessary to clarify that although House Bill (HB) 2285 (80th Legislature, 2007) amending Health and Safety Code, §12.0112(b)(2) removed the two-year term for radiation permits, the fees will continue to be paid every two years. As a result of Senate Bill (SB) 1604 (80th Legislature, 2007) amending Health and Safety Code §401.011, the section is revised to delete the applicable fees, definition, rule requirements, and rule citations related to the licensing and inspection of low-level waste processing and uranium recovery and disposal since the regulatory authority for these items has been transferred from the department to the Texas Commission on Environmental Quality (TCEQ). In addition, the fee amounts for the industrial radiographer certification and examinations that were previously revised in §289.255 of this title (relating to Radiation Safety Requirements and Licensing and Registration Procedures for Industrial Radiography) in 2007, are being updated in this revised section to be consistent with §289.255 of this title. As a result of HB 2285 amending Health and Safety Code §401.301(f), the department is prohibited from assessing fees on local law enforcement agencies for the registration of x-ray machines used for security screening therefore resulting in a loss of revenue to the state. The department has determined that it is able to absorb the lost revenues and will not attempt to recoup the loss by increasing fees for the remaining industrial x-ray machine registrants. Other minor grammatical changes are also made.

Section 289.226 is being amended as a result of HB 2285 remove the administrative review and two-year term requirements of radiation permits and, therefore, reinstate the previous

requirements for renewal of certificates of registration for radiation machines. In addition, the section is revised to update the names of several Texas medical and professional boards, update the titles of a few referenced sections, and correct referenced citations. Other minor grammatical changes are also made.

Due to HB 2285, the amendment of §289.232 is necessary to remove the administrative review and two-year term requirements of radiation permits and therefore reinstate the previous requirements for renewal of certificates of registration for radiation machines used in dentistry. This revised section also updates the department name and the names of several Texas medical and professional boards and corrects referenced citations. Several definitions, requirements concerning enforcement and hearings procedures, and a form are also revised to be consistent with language used throughout this chapter. Additionally, the fee amounts for certificates of registration for radiation machines used in dentistry that were previously revised in §289.204 of this title in 2006, are being updated in this revised section to be consistent with §289.204 of this title. The table concerning the half-value layer for selected kilovolt peaks is revised to state the correct values, and other minor grammatical corrections are also made.

Due to HB 2285, §289.233 is revised to remove the administrative review and two-year term requirements of radiation permits and therefore reinstate the previous requirements for renewal of certificates of registration for radiation machines used in veterinary medicine. Section 289.233 updates the department name and the names of several Texas medical and professional boards, clarifies a couple of radiation machine requirements, and corrects referenced citations. Several definitions, requirements concerning enforcement and hearings procedures, and a form are also revised to be consistent with language used throughout this chapter. Additionally, the fee amounts for certificates of registration for radiation machines used in veterinary medicine that were previously revised in §289.204 of this title in 2006, are being updated in this revised section to be consistent with §289.204 of this title. Other minor grammatical changes are also made.

The amendment of §289.301 is necessary to remove the administrative review and two-year term requirements of radiation permits and, therefore, reinstate the previous requirements for renewal of certificates of registration for laser machines, due to HB 2285. Section 289.301 is also revised to update the names of several Texas medical and professional boards, clarify requirements for protection against Class 3b or 4 lasers and intense-pulsed light device radiation, and correct reference citations and a few minor grammatical inconsistencies.

Government Code, §2001.039, requires that each state agency review and consider for readoption each rule adopted by that agency pursuant to the Government Code, Chapter 2001 (Administrative Procedure Act). Sections 289.204, 289.226, 289.232, 289.233, and 289.301 have been reviewed and the department has determined that the reasons for adopting these sections continue to exist because rules on these subjects are needed.

SECTION-BY-SECTION SUMMARY

Due to SB 1604 amending Health and Safety Code, §401.011, the regulatory authority for the applicable licensing and inspection of low-level waste processing and uranium recovery and

disposal responsibilities have been transferred from the department to the TCEQ and, therefore, the following changes have been made: §289.204(b)(1)(A) deletes reference to §289.254 of this title (relating to Licensing of Radioactive Waste Processing and Storage Facilities), and §289.260 of this title (relating to Licensing of Uranium Recovery and Byproduct Material Disposal Facilities); the definition of “post closure” in §289.204(c)(7) is deleted; §289.204(d)(1) and (2) delete reference to “subsection (m)”; and current §289.204(m) regarding the schedule of fees for uranium recovery and byproduct material disposal facility licenses, §289.204(n) regarding adjustments to fees for uranium recovery and byproduct material disposal facility licenses, and §289.204(o) regarding one-time fee adjustments for uranium recovery and byproduct material disposal facility licenses are deleted, therefore renumbering the subsequent subsection.

Although HB 2285 removed the two-year term for radiation permits, the fees for radiation permits will continue to be paid every two years and therefore, the following changes have been made: Section 289.204(d)(2) revises the second and third sentences to read “The fee shall be paid every two years based on the month listed as the expiration month on the license or general license acknowledgement and shall be paid in full on or before the last day of the expiration month;” in §289.204(d)(3), the second and third sentences are revised to read “The fee shall be paid every two years based on the month listed as the expiration month on the certificate of registration and shall be paid in full on or before the last day of the expiration month;” and §289.204(l)(2) is changed to read “In any case where the agency finds that a licensee or registrant has failed to pay a fee prescribed by this section by the due date, the agency may implement compliance procedures as provided in §289.205 of this title (relating to Hearing and Enforcement Procedures).”

In §289.204(h)(2) relating to fees for accreditation of mammography facilities, current subparagraph (G) is deleted because the department no longer incurs a cost for replacement of thermoluminescent dosimeters. Subsequent subparagraphs are renumbered.

In §289.204(i), the fee amounts for the industrial radiographer certification and examinations that were previously revised in §289.255 of this title in 2007, are being updated in this revised section to be consistent with §289.255 of this title. In §289.204(j), the sentence “As of the effective date of this section, the fees for the dental radiographic only category and the veterinary category, as specified in the following schedule, are the applicable fees for those categories.” is deleted because the fees addressed in this sentence are now included specifically in §§289.232 and 289.233.

In §289.226(b)(3) and (5), the titles of several referenced sections are updated to state the correct titles. The following subsections are revised to update the names of several Texas medical and professional boards: §289.226(b)(11), (f)(7), and (t)(1)(B)(i)(II)(-g-)(-1-) and (-3-). Section 289.226(i)(4) updates the rule citation to be consistent with the recently revised §289.255 of this title. The words “that results in a change in inventory as specified in subsection (m)(1)(C) of this section” are added to §289.226(n)(2) to clarify the notification requirements to the department for persons who sell, lease, lend, dispose, assemble, install, or otherwise transfer radiation machines in the state.

Due to HB 2285, §289.226(o) and (q) are revised and renumbered to reflect the deletion of all requirements relevant to the administrative review and two-year term requirements of radiation permits and, therefore, reinstate the previous requirements for renewal of certificates of registration for radiation machines.

Section 289.232(b)(3) changes the referenced rule citations to state the correct citations. The following subsections and definitions are revised and/or deleted to change the department name from “Texas Department of Health” to “Department of State Health Services”, and/or to change the Radiation Control Program name from “Bureau of Radiation Control” to “Radiation Control” as a result of the 2004 department and Radiation Control Program name changes and reorganization: §289.232(c)(7); current (c)(15); new (c)(19) and (27); §289.232(e)(1); §289.232(g)(1)(D); figure for §289.232(i)(5)(B)(iii); figure for §289.232(j)(1)(L)(i)(II); and subsequent definitions are renumbered. In addition, the following subsections are deleted and/or changed to be consistent with language used in other sections of this chapter: current §289.232(c)(31); new §289.232(c)(48); renumbered §289.232(c)(71); language and figure for §289.232(i)(5)(B)(iii); §289.232(j)(2)(C)(iii); §289.232(k)(2)(C)(i), (v), and (vi); §289.232(k)(2)(D)(iii)(III) and (IV); §289.232(k)(2)(E)(ii)(I)(-d-) and (-f-); §289.232(k)(2)(E)(ii)(II)(-a-) through (-c-); and §289.232(k)(2)(G)(iv).

In §289.232(g)(1)(A) through (C), the fee amounts for certificates of registration for radiation machines used in dentistry that were previously revised in §289.204 of this title in 2006, are being updated in this revised section to be consistent with §289.204 of this title. Sections 289.232(g)(1)(B)(ii), 289.232(g)(1)(C); 289.232(h)(1)(D); and 289.232(i)(6)(L) update the referenced citations to state the correct citations.

Although HB 2285 removed the two-year term for radiation permits, the fees for radiation permits will continue to be paid every two years and therefore, the following changes have been made: §289.232(g)(1)(B) revises the second and third sentences to read “The fee shall be paid every two years based on the month listed as the expiration month on the certificate of registration and shall be paid in full on or before the last day of the expiration month” and §289.232(g)(2)(B) is changed to read “In any case where the agency finds that a registrant has failed to pay a fee prescribed by this section by the due date, the agency may implement compliance procedures as provided in subsection (k)(2)(C) of this section.”

Due to HB 2285, §289.232(h)(6) and new (8) are revised and renumbered to reflect the deletion of all requirements relevant to the administrative review and two-year term requirements of radiation permits and therefore reinstate the previous requirements for renewal of certificates of registration for radiation machines used in dentistry. Subsequent paragraphs are renumbered.

Current §289.232(i)(5)(C) is deleted as this information is redundant with language in §289.232(i)(5)(B)(iii). Subsequent subparagraphs are renumbered. The table for §289.232(i)(6)(E)(i)(I) concerning the half-value layer for selected kilovolt peaks is revised to state the correct values. Additionally, §289.232(i)(6)(I) deletes the word “interval” and replaces it with “output” before “reproducibility” to be technically correct. Section 289.232(j)(2)(C)(i)(II)(-c-) adds the words “certificate of” before the word “registration” to be consistent with language used throughout this section.

Section 289.233(c) adds language to be consistent with other sections of this chapter. The following subsections and definitions are revised and/or deleted to change the department name from “Texas Department of Health” to “Department of State Health Services” and/or to change the Radiation Control Program name from “Bureau of Radiation Control” to “Radiation Control” as a result of the 2004 department and Radiation Control Program name changes and reorganization: §289.233(c)(7); current (c)(17); new (c)(20); §289.233(e)(1); §289.233(g)(1)(D); figure for §289.233(i)(3)(F)(vii); figure for §289.232(i)(4)(B)(iii); figure for §289.233(j)(1)(K)(i)(II); and subsequent definitions are renumbered. In addition, the following subsections are deleted and/or changed to be consistent with language used in other sections of this chapter: current §289.233(c)(34); new §289.233(c)(52); renumbered §289.233(c)(68); §289.233(g)(1)(A); language and figure for §289.233(i)(4)(B)(iii); §289.233(j)(3)(C)(iii); §289.233(k)(2)(C)(i), (v), (vi), and (vii); §289.233(k)(2)(D)(iii)(III) and (IV); §289.233(k)(2)(E)(ii)(I)(-d-) and (-f-); and §289.233(k)(2)(E)(ii)(II)(-a-) through (-c-).

In §289.233(g)(1)(A) through (C), the fee amounts for certificates of registration for radiation machines used in veterinary medicine that were previously revised in §289.204 of this title in 2006, are being updated in this revised section to be consistent with §289.204 of this title. Section §289.233(g)(1)(C) updates the referenced citation to state the correct citations.

Although HB 2285 removed the two-year term for radiation permits, the fees for radiation permits will continue to be paid every two years and therefore, the following changes have been made: §289.233(g)(1)(B) revises the second and third sentences to read “The fee shall be paid every two years based on the month listed as the expiration month on the certificate of registration and shall be paid in full on or before the last day of the expiration month”, and §289.233(g)(2)(B) is changed to read “In any case where the agency finds that a registrant has failed to pay a fee prescribed by this section by the due date, the agency may implement compliance procedures as provided in subsection (k)(2) of this section.”

Due to HB 2285, §289.233(h)(6) and new (8) are revised and renumbered to reflect the deletion of all requirements relevant to the administrative review and two-year term requirements of radiation permits and therefore reinstate the previous requirements for renewal of certificates of registration for radiation machines used in veterinary medicine. Subsequent paragraphs are renumbered.

Section §289.233(i)(5)(H)(iv)(II) deletes the words “for circular image receptors” after the words “image receptor” to be technically correct. Language is added as new §289.233(i)(5)(N)(v) to clarify that fluoroscopic x-ray systems shall comply with the additional requirements stated in §289.233(i)(6). Section 289.233(j)(3)(C)(i)(II)(-e-) adds the words “certificate of” before the word “registration” to be consistent with language used throughout this section.

In §289.301(a)(2) the word “laser” is replaced with the word “lasers” to be grammatically correct. The definition for “continuous wave” in §289.301(d)(14) replaces “>=” with “≥” to correctly represent the mathematical symbol. The definition for §289.301(d)(36) updates the names of two Texas medical and professional boards. Section 289.301(j)(3) adds “Class 3B and 4” before the word “lasers” to clarify the type of lasers in their possession that should be

inventoried. Section 289.301(j)(3)(E) and (4)(B) replaces “in accordance with subsection (d)(35)” with “as defined in subsection (d)(38)” to be grammatically correct and to state the correct rule citation.

Due to HB 2285, §289.301(k) and (m) are revised and renumbered to reflect the deletion of all requirements relevant to the administrative review and two-year term requirements of radiation permits and therefore reinstate the previous requirements for renewal of certificates of registration for laser machines.

Section 289.301(r)(2) adds the words “presently being used or listed on the registrant’s current inventory,” before the words “shall be provided” to clarify which lasers the registrant needs to provide written instructions for safe use. The sentence “The instructions to personnel shall be maintained in accordance with subsection (ee) of this section for inspection by the agency.” is added at the end of this paragraph to direct the registrant to maintain records of the written instructions for safe use for inspection by the agency.

Section 289.301(t)(1)(E) and §289.301(w) add language to inform the registrant of where in the section recordkeeping intervals are listed for the maintenance of records required in this section. Section 289.301(x) adds language to clarify that the registrant shall maintain current records/documents required by this subsection for inspection by the agency. In addition, the figure for §289.301(ee) is revised to add language to clarify which lasers the registrant needs to provide written instructions for safe use.

FISCAL NOTE

Susan E. Tennyson, Section Director, Environmental and Consumer Safety Section, has determined that for each year of the first five-year period that §§289.226, 289.232, 289.233, and 289.301 are in effect, there will be no fiscal implications to the state or local government as a result of enforcing and administering the sections as proposed. However, concerning §289.204, Ms. Tennyson has determined that there will be fiscal implications to state government which will be a decrease in revenue to the state of \$11,691 for calendar years 2008, 2010, and 2012 and a decrease in revenue to the state of \$3,486 for calendar years 2009 and 2011, due to the department being prohibited from assessing fees on local law enforcement agencies for the registration of x-ray machines used for security screening, as a result of HB 2285 amending Health and Safety Code §401.301(f). The department has determined that it is able to absorb the lost revenues and will not attempt to recoup the loss by increasing fees for the remaining industrial x-ray machine registrants. Implementation of proposed §289.204 will not result in any fiscal implications for local governments.

SMALL AND MICRO-BUSINESS IMPACT ANALYSIS

Ms. Tennyson has also determined that there will be no effect on small businesses or micro-businesses required to comply with the sections as proposed. This was determined by interpretation of the rules that small businesses and micro-businesses will not be required to alter their business practices in order to comply with the sections. 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.

STATEMENT OF NO ADVERSE ECONOMIC IMPACT

Pursuant to the requirement of §2006.002(c) of the Government Code (amended by HB 3430, 80th Legislature), the department has determined that none of the proposed changes “may have an adverse economic effect on small businesses subject to the proposed rule.” This determination is made because there will be no adverse economic impact to any regulated entity subject to the proposed rule as further discussed in the Small and Micro-Business Economic Impact Analysis above.

PUBLIC BENEFIT

Ms. Tennyson has also 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 §§289.204, 289.226, 289.232, 289.233, and 289.301 is to ensure continued protection of the public, workers, and the environment from unnecessary exposure to radiation by ensuring that the department is able to properly enforce the state’s radiation protection rules.

REGULATORY ANALYSIS

The department has determined that this proposal is not a “major environmental rule” as defined by 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.

TAKINGS IMPACT ASSESSMENT

The department has determined that the proposed amendments 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 Government Code, §2007.043.

PUBLIC COMMENT

Comments on the proposal may be submitted to Cindy Cardwell, Radiation Group, Policy/Standards/Quality Assurance Unit, Division for Regulatory Services, Environmental and Consumer Safety Section, Department of State Health Services, 1100 West 49th Street, Austin, Texas 78756, 512/834-6770, extension 2239, or by email to Cindy.Cardwell@dshs.state.tx.us. Comments will be accepted for 30 days following publication of the proposal in the *Texas Register*.

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.state.tx.us/radiation). Please contact Cindy Cardwell at (512) 834-6770, extension 2239, or Cindy.Cardwell@dshs.state.tx.us if you have questions.

LEGAL CERTIFICATION

The Department of State Health Services General Counsel, Lisa Hernandez, certifies that the proposed rules have been reviewed by legal counsel and found to be within the state agencies' authority to adopt.

STATUTORY AUTHORITY

The proposed amendments are authorized by Health and Safety Code, §12.0111, which requires the department to charge fees for issuing or renewing a license; Health and Safety Code, §401.301, which allows the department to collect fees for radiation control licenses and registrations that it issues; Health and Safety Code, §401.051, which provides the Executive Commissioner of the Health and Human Services Commission with authority to adopt rules and guidelines relating to the control of radiation; and Government Code, §531.0055, and Health and Safety Code, §1001.075, which authorize 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 the department and for the administration of Health and Safety Code, Chapter 1001. The review of the rules implements Government Code, §2001.039.

The proposed amendments affect the Health and Safety Code, Chapters 12, 401, and 1001; and Government Code, Chapters 531 and 2001.

LEGEND: (Proposed Amendments)

Single-Underline = Proposed new language

[Bold Print and Brackets] = Current language proposed for deletion

Regular Print = Current language

(No change.) = No changes are being considered for designated subdivisions

§289.204. Fees for Certificates of Registration, Radioactive Material Licenses, Emergency Planning and Implementation, and Other Regulatory Services.

(a) (No change.)

(b) Scope. Except as otherwise specifically provided, the requirements in this section apply to any person who is the following:

(1) an applicant for, or holder of:

(A) a radioactive material license issued in accordance with §289.252 of this title (relating to Licensing of Radioactive Material), **[\$289.254 of this title (relating to Licensing of Radioactive Waste Processing and Storage Facilities),] or** §289.259 of this title (relating to Licensing of Naturally Occurring Radioactive Material (NORM)), **or §289.260 of this title (relating to Licensing of Uranium Recovery and Byproduct Material Disposal Facilities)];** or

(B) - (C) (No change.)

(2) - (3) (No change.)

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

(1) - (5) (No change.)

[(6) Post-closure - The time period after which closure activities have been completed by the conventional mill licensee and prior to transfer of land ownership of tailings disposal sites to the State of Texas or the United States of America and termination of the license or after which confirmatory surveys have been conducted by the agency of an in-situ facility and before termination of the license or site.]

(6) **[(7)]** Processor of radioactive material **[Radioactive Material]** - A manufacturer/distributor who converts normal form radioactive material into special form or a manufacturer/distributor of radioactive sealed sources.

(d) Payment of fees.

(1) Each application for a specific license, general license acknowledgement, or certificate of registration for which a fee is prescribed in subsections (e), (g), or (j), **or (m)** of

this section shall be accompanied by a nonrefundable fee equal to the appropriate fee. Each request for evaluation of a sealed source and/or device shall be accompanied by a nonrefundable fee prescribed in subsection (f) of this section. Each application for accreditation of a mammography facility shall be accompanied by a nonrefundable fee prescribed in subsection (h) of this section. Each application for an industrial radiographer certification and an industrial radiographer examination shall be accompanied by a nonrefundable and non-transferable fee prescribed in subsection (i) of this section.

(A) - (C) (No change.)

(2) A nonrefundable fee, in accordance with subsection (e) [**and (m)**] of this section shall be paid for each radioactive material license and/or for each general license acknowledgement. The fee shall be paid every two years based on the month listed as the expiration month on [**for the two-year term of**] the license or general license acknowledgement and [**The fee**] shall be paid in full on or before the last day of the expiration month [**and year of the license or general license acknowledgement**]. In the case of a single license that authorizes more than one category of use, the fee shall be the prescribed fee for the highest license category plus 25% of the applicable prescribed fee for each additional license category authorized.

(3) A nonrefundable fee, in accordance with subsection (j) of this section, shall be paid for each certificate of registration for radiation machines and/or services, or sources of laser radiation. The fee shall be paid every two years based on the month listed as the expiration month on [**for the two-year term of**] the certificate of registration and [**The fee**] shall be paid in full on or before the last day of the expiration month [**and year of the certificate of registration**].

(4) - (9) (No change.)

(e) - (g) (No change.)

(h) Fees for accreditation of mammography facilities.

(1) (No change.)

(2) Fees for accreditation of mammography facilities are as follows.

(A) - (F) (No change.)

[(**G**) **The fee for replacement of thermoluminescent dosimeters (TLD)**
is \$75.]

(G) [(**H**)] Each facility for which a targeted clinical image review is required will be charged for actual expenses to the agency arising from the visit.

~~(H)~~ **[(I)]** Each facility for which an on-site visit due to three denials of accreditation is required will be charged for actual expenses to the agency arising from such visit.

~~(I)~~ **[(J)]** Payment of the fees in subparagraphs ~~(G)~~ and ~~(H)~~ **[(H) and (I)]** of this paragraph shall be made within 60 days following the date of invoice.

(i) Fees for industrial radiographer certification and for radiographer certification examinations.

(1) The nonrefundable and non-transferable application fee for examination shall be \$120 **[\$25]** and shall be submitted to the agency with the application for examination.

(2) The nonrefundable application fee for radiographer certification shall be \$110 **[\$100]** and shall be submitted to the agency with the application for radiographer certification.

(j) Schedule of fees for certificates of registration for radiation machines, lasers, and services. The following schedule contains the fees for certificates of registration for radiation machines, lasers, and services. **[As of the effective date of this section, the fees for the dental radiographic only category and the veterinary category, as specified in the following schedule, are the applicable fees for those categories.]**

Figure: 25 TAC §289.204(j) (No change.)

(k) (No change.)

(l) Failure to pay prescribed fees.

(1) (No change.)

(2) In any case where the agency finds that a licensee or registrant has failed to pay a fee prescribed by this section by the due date, **[the license or certificate of registration expires and]** the agency may implement compliance procedures as provided in §289.205 of this title (relating to Hearing and Enforcement Procedures).

(3) (No change.)

[(m) Schedule of fees for uranium recovery and byproduct material disposal facility licenses. The following schedule contains the fees for uranium recovery and byproduct material disposal facility licenses:]

[Figure: 25 TAC §289.204(m)]

[(n) Adjustments to fees for uranium recovery and byproduct material disposal facility licenses.]

[(1) If additional noncontiguous uranium recovery facility sites are authorized under the same license, the appropriate fee shall be increased by 25% for each additional site for an operational year and 50% for closure only.]

[(2) If an authorization for disposal of byproduct material is added to a license, the appropriate fee shall be increased by 25%.]

[(o) One-time fee adjustments for uranium recovery and byproduct material disposal facility licenses. For the addition of the following items after an environmental assessment has been completed on a facility, a one-time fee corresponding to the item shall be paid:]

[(1) \$28,658 for in situ wellfield on noncontiguous property;]

[(2) \$71,651 for in situ satellite;]

[(3) \$11,235 for wellfield on contiguous property;]

[(4) \$50,756 for non-vacuum dryer; or]

[(5) \$71,651 for disposal (including processing, if applicable) of byproduct material.]

[(m) [(p)] Fees for Texas Online participation. For all applications and renewal applications, the department is authorized to collect subscription and convenience fees, in amounts determined by the Texas Online Authority, to recover costs associated with application and renewal application processing through Texas Online.

§289.226. Registration of Radiation Machine Use and Services.

(a) (No change.)

(b) Scope.

(1) - (2) (No change.)

(3) Registrants using analytical and other industrial radiation machines, such as x-ray equipment used for cathodoluminescence, ion implantation, gauging, or electron beam welding, are subject to the requirements of §289.228 of this title (relating to Radiation Safety Requirements for **[Analytical and Other]** Industrial Radiation Machines).

(4) (No change.)

(5) Registrants using mammography radiation machines are also subject to the requirements of §289.230 of this title (relating to Certification of Mammography Systems and

Machines Used for Interventional Breast Radiography and §289.234 of this title (relating to Mammography Accreditation) [Accreditation of Mammography Facilities].

(6) - (10) (No change.)

(11) For purposes of this section, a practitioner of the healing arts is a person licensed to practice healing arts by either the Texas Medical Board [**Texas State Board of Medical Examiners**] as a physician, the Texas Board of Chiropractic Examiners, or the Texas State Board of Podiatric Medicine [**Texas State Board of Podiatry Examiners**].

(c) - (e) (No change.)

(f) Application for registration for human use of radiation machines. In addition to the requirements of subsection (e) of this section, each applicant shall comply with the following.

(1) - (6) (No change.)

(7) An application for accelerators or therapeutic radiation machines for human use shall be signed by a practitioner licensed by the Texas Medical Board [**Texas State Board of Medical Examiners**]. The signature of the administrator, president, or chief executive officer will be accepted in lieu of a licensed practitioner's signature if the facility has more than one licensed practitioner who may direct the operation of radiation machines. The application shall also be signed by the RSO if the RSO is someone other than the licensed practitioner. Each applicant shall submit operating and safety procedures as described in §289.229(h)(1)(D) of this title and a description of the proposed facilities in accordance with the following:

(A) - (B) (No change.)

(g) (No change.)

(h) Application for registration of healing arts screening and medical research.

(1) (No change.)

(2) In addition to the requirements of subsections (e) and (f) of this section, any research using radiation machines on humans shall be approved by an Institutional Review Board (IRB) as required by Title 45, Code of Federal Regulations (CFR) [**CFR**], Part 46 and Title 21, CFR, Part 56. The IRB shall include at least one practitioner of the healing arts to direct any use of radiation in accordance with §289.231(b)(1) of this title.

(i) Application for registration of radiation machines for non-human use, including use in morgues. In addition to the requirements of subsection (e) of this section, each applicant shall comply with the following.

(1) - (3) (No change.)

(4) Each applicant for use of radiation machines in industrial radiographic operations shall submit the information required in §289.255(t)(1) [~~§289.255(u)(7)~~] of this title before beginning use of the machine(s).

(5) (No change.)

(j) Application for registration of radiation machine services. In addition to the requirements of subsection (e) of this section, each applicant shall comply with the following.

(1) Each person who intends to provide radiation services described in subsection [subsections] (b)(10) of this section shall apply for and receive a certificate of registration from the agency before providing such service.

(2) - (8) (No change.)

(k) - (m) (No change.)

(n) Sale, lease, loan, installation, assembly, disposal, and transfer of radiation machines.

(1) (No change.)

(2) Any person who sells, leases, lends, disposes, assembles, installs, or otherwise transfers radiation machines in the state that results in a change in inventory as specified in subsection (m)(1)(C) of this section shall notify the agency of the following information within 30 days of such action:

(A) - (C) (No change.)

(3) (No change.)

(o) Expiration of certificates of registration [**and administrative renewal**].

(1) [**Effective September 1, 2004, the term of the certificate of registration is two years.**] Except as provided by subsection (q) of this section, each certificate of registration expires at the end of the day, in the month and year stated in the certificate of registration. [**Except for subsection (q)(5) of this section, upon payment of the fee required by §289.204 of this title and if the agency does not deny the renewal in accordance with subsection (l)(4) of this section, the certificate of registration will be administratively renewed. The requirements in this subsection are subject to the provisions of Government Code, §2001.054.**]

[(2) **If the fee is not paid and the certificate of registration is not renewed in accordance with paragraph (1) of this subsection, the certificate of registration expires, and the registrant is in violation of the requirements in this chapter and is subject to administrative penalties in accordance with §289.205 of this title.**]

[(A) If the registrant pays the fee required by §289.204 of this title within 30 days after expiration of the certificate of registration, the certificate of registration will be reinstated and the registrant will not be required to file an application in accordance with subsection (e) of this section.]

[(B) If the registrant fails to pay the fee within 30 days after expiration of the certificate of registration, the registrant shall file an application in accordance with subsection (e) of this section.]

(2) [(3)] If a registrant does not submit an application for renewal of [fails to pay the fee required by §289.204 of this title and] the certificate of registration in accordance with subsection (q) of this section, as applicable [is not renewed], the registrant shall on or before the expiration date specified in the certificate of registration:

(A) terminate use of all radiation machines and/or terminate radiation machine servicing or radiation services; **[and]**

(B) submit to the agency a record of the disposition of the radiation machines, if applicable, and if transferred, to whom it was transferred, within 30 days following the expiration date; and **[.]**

(C) pay any outstanding fees in accordance with §289.204 of this title.

(3) [(4)] Expiration of the certificate of registration does not relieve the registrant of the requirements of this chapter.

(p) (No change.)

(q) Renewal **[Technical renewal]** of certificate of registration.

(1) An [If required by the certificate of registration, an] application for [technical] renewal of a certificate of registration shall be filed in accordance with subsection (e) of this section and applicable paragraphs of subsections (f) - (j) of this section. [An application for a technical renewal of a certificate of registration shall be submitted to the agency by the date specified in the certificate of registration. If the registrant fails to apply and pay the fee required by §289.204 of this title, or the agency does not approve the application in accordance with subsection (k)(1) of this section, the certificate of registration expires and the registrant is in violation of the requirements in this chapter and is subject to administrative penalties in accordance with §289.205 of this title. The registrant shall comply with the requirements of subsection (o)(3)(A)-(B) of this section.]

[(2) Expiration of the certificate of registration does not relieve the registrant of the requirements of this chapter.]

(2) [(3)] If a registrant files an application for a [technical] renewal in proper form before the existing certificate of registration expires [and pays the fee required by

§289.204 of this title], such existing certificate of registration shall not expire until the application status has been determined by the agency.

[(4) An application for technical renewal of a certificate of registration will be approved if the agency determines that the requirements of subsection (e) of this section and applicable paragraphs of subsections (f) - (j) of this section have been satisfied.]

[(5) When the date for administrative renewal in accordance with subsection (o)(1) of this section and the date for the technical renewal in accordance with paragraph (1) of this subsection occur at the same time, the certificate of registration will be renewed if the fee required by §289.204 of this title is paid, the technical renewal is approved by the agency in accordance with paragraph (4) of this subsection, and the agency does not deny the renewal in accordance with subsection (l)(4) of this section.]

[(6) When the date for the administrative renewal in accordance with subsection (o)(1) of this section and the date for the technical renewal in accordance with paragraph (1) of this subsection occur at the same time, the certificate of registration renewal may be denied by the agency if any one of the following conditions apply:]

[(A) the fee required by §289.204 of this title is not paid;]

[(B) the agency denies the renewal in accordance with subsection (l)(4) of this section; or]

[(C) the agency does not approve the technical renewal in accordance with paragraph (4) of this subsection.]

[(7) The requirements in this subsection are subject to the provisions of Government Code, §2001.054.]

(r) - (s) (No change.)

(t) Appendices.

(1) Requirements for RSOs for registrants.

(A) (No change.)

(B) Specific requirements for RSOs by facility are as follows.

(i) Healing arts facilities shall have:

(I) (No change.)

(II) non-practitioner RSOs with the following:

(-a-) - (-f-) (No change.)

(-g-) evidence of:

(-1-) registration with the Texas Medical Board [**Texas State Board of Medical Examiners**] performing radiologic procedures under a physician's instruction and direction;

(-2-) (No change.)

(-3-) registration with the Texas State Board of Podiatric Medicine [**Texas State Board of Podiatry Examiners**] performing radiologic procedures under a podiatrist's instruction and direction; and

(-4-) (No change.)

(-h-) - (-j-) (No change.)

(ii) - (iii) (No change.)

(C) (No change.)

(2) - (4) (No change.)

§289.232. Radiation Control Regulations for Dental Radiation Machines.

(a) (No change.)

(b) Scope.

(1) - (2) (No change.)

(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) [**§289.231(II)(1)**] of this title (relating to General Provisions and Standards for Protection Against Machine-Produced Radiation) and equipment performance evaluations shall be performed at the interval specified for a medical facility in subsection §289.227(o)(1) [**§289.227(q)(1)**] of this title (relating to Use of Radiation Machines in the Healing Arts and Veterinary Medicine).

(4) - (5) (No change.)

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

(1) - (6) (No change.)

(7) Agency - The Department of State Health Services [**Texas Department of Health**] or its successor.

(8) - (14) (No change.)

[(15) Board - The Texas Board of Health or its successor.]

(15) [(16)] 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 Texas Radiation Control Act and this section.

(16) [(17)] Certified equipment - Equipment that has been certified in accordance with Title 21, Code of Federal Regulations.

(17) [(18)] 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(c)(17) [**Figure: 25 TAC §289.232(c)(18)**]

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

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

(20) - (26) (No change.)

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

(28) [(27)] Dose - For external exposure to x-ray radiation from radiation machines, 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.

(29) [(28)] Dose equivalent - 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.

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

(31) [(30)] Embryo/fetus - The developing human organism from conception until the time of birth.

[(31) Enforcement 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.]

(32) - (47) (No change.)

(48) 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.

(49) [(48)] Inspection - An official examination and/or observation including, but not limited to, records, tests, surveys, and monitoring to determine compliance with the Texas Radiation Control Act and agency rules, orders, requirements, and conditions of the certificate of registration.

(50) [(49)] Institutional Review Board - 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.

(51) [(50)] 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.

(52) [(51)] kV - Kilovolt.

(53) [(52)] kVp - Kilovolt peak (See definition for peak tube potential).

(54) [(53)] kW - Kilowatt-second. It is equivalent to 10^3 watt-second, where 1 watt-second = 1 kilovolt x 1 milliampere x 1 second.

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

(56) [(55)] 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.

(57) [(56)] 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).

(58) [(57)] License - A form of permission given by the agency to an applicant who has met the requirements for licensing set out in the Texas Radiation Control Act and this chapter.

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

(60) [(59)] Licensed medical physicist - An individual holding a current Texas license under the Medical Physics Practice Act, Texas Occupations Code, Chapter 602.

(61) [(60)] Licensee - Any person who is licensed by the agency in accordance with the Texas Radiation Control Act and this chapter.

(62) [(61)] Licensing state - Any state with rules equivalent to the Suggested State Regulations for Control of Radiation relating to, and having an effective program for, the regulatory control of naturally occurring or accelerator-produced radioactive material (NARM) and has been designated as such by the Conference of Radiation Control Program Directors, Inc.

(63) [(62)] mA - Milliampere.

(64) [(63)] mAs - Milliampere-second.

(65) [(64)] Medical research - The investigation of various health risks and diseases.

(66) [(65)] Member of the public - Any individual, except when that individual is receiving an occupational dose.

(67) [(66)] Minor - An individual less than 18 years of age.

(68) [(67)] Mobile service operation - The provision of radiation machines and personnel at temporary sites for limited time periods. The radiation machines may be fixed

inside a motorized vehicle or may be a portable radiation machine that may be removed from the vehicle and taken into a facility for use.

(69) [(68)] Monitoring - The measurement of radiation and the use of the results of these measurements to evaluate potential exposures and doses. For purposes of this chapter, “radiation monitoring” and “radiation protection monitoring” are equivalent terms.

(70) [(69)] Non-certified equipment - Equipment manufactured and assembled prior to certification requirements of Title 21, Code of Federal Regulations (CFR), effective as specified in Title 21, CFR, §1020.30(a).

(71) [(70)] Notice of violation - A written statement prepared by the agency of one or more alleged infringements of a legally binding requirement. **[The notice requires the person receiving the notice to provide a written statement describing the following:]**

[(A) corrective steps taken by the person and the results achieved;]

[(B) corrective steps to be taken to prevent recurrence; and]

[(C) the projected date for achieving full compliance. The agency may require responses to notices of violation to be under oath.]

(72) [(71)] 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 chapter or from voluntary participation in medical research programs, or as a member of the public.

(73) [(72)] Order - A specific directive contained in a legal document issued by the agency.

(74) [(73)] Party - A person designated as such by the ALJ. A party may consist of the following:

(A) the agency; and

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

(75) [(74)] Patient - An individual subjected to dental examination, diagnosis, or treatment.

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

(77) [(76)] 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.

(78) [(77)] Personnel monitoring equipment - (See definition for individual monitoring devices).

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

(80) [(79)] Portable x-ray equipment - (See definition for x-ray equipment).

(81) [(80)] Primary protective barrier - (See definition for protective barrier).

(82) [(81)] 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.

(83) [(82)] 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 chapter or from voluntary participation in medical research programs, or as a member of the public.

(84) [(83)] 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 gray).

(85) [(84)] 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.

(86) [(85)] 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.

(87) [(86)] Radiation machine - Any device capable of producing ionizing radiation except those devices with radioactive material as the only source of radiation.

(88) [(87)] Radiation safety officer - 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.

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

(90) [(89)] Registrant - Any person issued a certificate of registration by the agency in accordance with the Texas Radiation Control Act and this chapter.

(91) [(90)] Regulation (See definition for rule).

(92) [(91)] Rem - The special unit of any of the quantities expressed as dose equivalent. The dose equivalent in rem is equal to the absorbed dose in rad multiplied by the quality factor (1 rem = 0.01 sievert).

(93) [(92)] Remote inspection - An examination by the agency of information submitted by the registrant on a form provided by the agency.

(94) [(93)] 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, materials, and processes.

(95) [(94)] Restricted area - An area, access to which is limited by the registrant for the purpose of 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.

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

(97) [(96)] 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 prior section but does not include statements concerning only the internal management or organization of any agency and not affecting private rights or procedures. The word “rule” was formerly referred to as “regulation.”

(98) [(97)] Scattered radiation - Radiation that has been deviated in direction during passage through matter.

(99) [(98)] Secondary protective barrier (See definition for protective barrier).

(100) [(99)] 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.

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

(102) [(101)] SI - The abbreviation for the International System of Units.

(103) [(102)] 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).

(104) [(103)] Source of radiation - Any radioactive material, or any device or equipment emitting or capable of producing radiation.

(105) [(104)] Source-to-image receptor distance - The distance from the source to the center of the input surface of the image receptor.

(106) [(105)] Source-to-skin distance - The distance from the source to the skin of the patient.

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

(108) [(107)] Stationary x-ray equipment - (See definition for x-ray equipment).

(109) [(108)] Stray radiation - The sum of leakage and scattered radiation.

(110) [(109)] 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.

(111) [(110)] Survey - An evaluation of the radiological conditions and potential hazards incident to the production, use, transfer, and/or 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/or engineered controls.

(112) [(111)] Technique chart - A chart that provides all necessary generator control settings and geometry needed to make clinical radiographs when the radiation machine is in manual mode.

(113) [(112)] 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 milliamperes-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 equipment, 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 milliamperes-second.

(114) [(113)] 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.

(115) [(114)] Texas Regulations for Control of Radiation (TRCR) - All sections of Title 25 Texas Administrative Code, Chapter 289.

(116) [(115)] Total effective dose equivalent - For external exposures only to x-ray radiation from radiation machines, the total effective dose equivalent is equal to the deep dose equivalent.

(117) [(116)] 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.

(118) [(117)] Tube - An x-ray tube, unless otherwise specified.

(119) [(118)] 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.

(120) [(119)] 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.

(121) [(120)] Useful beam - Radiation that passes through the window, aperture, core, or other collimating device of the source housing. Also referred to as the primary beam.

(122) [(121)] Violation - An infringement of any rule, license or registration condition, order of the agency, or any provision of the Texas Radiation Control Act.

(123) [(122)] X-ray control - A device that controls input power to the x-ray high-voltage generator and/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.

(124) [(123)] X-ray equipment - An x-ray system, subsystem, or component thereof. For the purposes of this rule, types of x-ray equipment are as follows:

(A) portable x-ray equipment - x-ray equipment mounted on a permanent base with wheels and/or casters for moving while completely assembled or equipment designed to be hand-carried; or

(B) stationary x-ray equipment - x-ray equipment that is installed in a fixed location.

(125) [(124)] 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 is one-fourth of the maximum in the intersection.

(126) [(125)] 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.

(127) [(126)] 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.

(128) [(127)] X-ray subsystem - Any combination of two or more components of an x-ray system.

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

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

(131) [(130)] Worker - An individual engaged in work under a certificate of registration issued by the agency and controlled by a registrant, but does not include the registrant.

(132) [(131)] 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 provided that the change is made at the beginning of the year and that no day is omitted or duplicated in consecutive years.

(d) (No change.)

(e) Communications.

(1) Except where otherwise specified, all communications and reports concerning this chapter and applications filed under them should be mailed by postal service to **[the Bureau of] Radiation Control, Department of State Health Services [Texas Department of Health]**, 1100 West 49th Street, Austin, Texas, 78756-3189. Communications, reports, and applications may be delivered in person to the agency's office located at 8407 Wall Street, Austin, Texas.

(2) (No change.)

(f) (No change.)

(g) 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 of \$330 [**\$300**]. No application will be accepted for filing or processed prior to payment of the full amount specified.

(B) A nonrefundable fee of \$330 [**\$300**] shall be paid for each certificate of registration for radiation machines used in dentistry. The fee shall be paid every two years based on the month listed as the expiration month on [**for the two-year term of**] the certificate

of registration ~~and~~. **The fee**] shall be paid in full on or before the last day of the expiration month **[and year of the certificate of registration]**.

(i) (No change.)

(ii) In the case of a single certificate of registration that authorizes more than one category of use, the category listed in ~~§289.204(j)~~ **[\$289.204(h)]** of this title (relating to Fees for Certificates of Registration, Radioactive Material Licenses, Emergency Planning and Implementation, and Other Regulatory Services) and assigned the higher fee will be used. If this certificate of registration also has additional authorized use sites, the registrant shall pay an additional 30% of the highest fee category.

(C) Each application for reciprocal recognition of an out-of-state registration in accordance with subsection ~~(h)(10)~~ **[(h)(9)]** of this section shall be accompanied by the ~~\$330~~ **[\$300]** fee, 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 **[Texas Department of Health]**. The payments may be made by personal delivery to the central office, **[Bureau of]** Radiation Control, Department of State Health Services **[Texas Department of Health]**, 1100 West 49th Street, Austin, Texas, or mailed to the **[Bureau of]** Radiation Control, Department of State Health Services **[Texas Department of Health]**, 1100 West 49th Street, Austin, Texas, 78756-3189.

(2) Failure to pay prescribed fees.

(A) (No change.)

(B) In any case where the agency finds that a registrant has failed to pay a fee prescribed by this section by the due date, **[the certificate of registration expires and]** the agency may implement compliance procedures as provided in subsection (k)(2)(C) of this section.

(3) (No change.)

(h) Registration of Radiation Machine Use.

(1) Application for registration.

(A) - (C) (No change.)

(D) 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 requirements of paragraph ~~(11)~~ **[(10)]** of this subsection and carry out the responsibilities of paragraph ~~(12)~~ **[(11)]** of this subsection.

(E) - (K) (No change.)

(2) - (5) (No change.)

(6) Expiration of certificates of registration.

(A) Except as provided by paragraph (8) of this subsection, each **[Effective September 1, 2004, the term of the certificate of registration is two years. Each]** certificate of registration expires at the end of the day, in the month and year stated in the certificate of registration. **[Upon payment of the fee required by subsection (g)(1)(B) of this section, and if the agency does not deny the renewal in accordance with subsection (h)(4)(F) of this section, the certificate of registration will be renewed].**

[(B) If the fee is not paid and the certificate of registration is not renewed in accordance with subparagraph (A) of this paragraph, the certificate of registration expires, and the registrant is in violation of the requirements in this chapter and is subject to administrative penalties in accordance with §289.205 of this title.]

[(i) If the registrant pays the fee required by §289.204 of this title within 30 days after expiration of the certificate of registration, the certificate of registration will be reinstated and the registrant will not be required to file an application in accordance with subsection (h) of this section.]

[(ii) If the registrant fails to pay the fee within 30 days after expiration of the certificate of registration, the registrant shall file an application in accordance with subsection (h) of this section.]

(B) [(C)] If a registrant does not submit an application for renewal of the certificate of registration in accordance with paragraph (8) of this subsection, as applicable, the registrant shall on or before the expiration date specified in the certificate of registration [pay the fee required by subsection (g) of this section and the certificate of registration is not renewed, the registrant shall]:

(i) terminate use of all radiation machines within 30 days following the expiration date; **[and]**

(ii) submit to the agency a record of the disposition of the radiation machines and if transferred, to whom transferred, within 30 days following the expiration date; and **[.]**

(iii) pay any outstanding fees in accordance with subsection (g) of this section.

(C) [(D)] Expiration of the certificate of registration does not relieve the registrant of the requirements of this chapter.

(7) (No change.)

(8) Renewal of certificate of registration.

(A) An application for renewal of registration shall be filed in accordance with paragraph (1) or (2) of this subsection, as applicable.

(B) If a registrant files an application in proper form before the existing certificate of registration expires, such existing certificate of registration shall not expire until the application status has been determined by the agency.

(9) [(8)] Modification, suspension, and revocation of certificate 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, for any of the following:

(i) any material false statement in the application or any statement of fact required under 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 terms and conditions of the Act, this chapter, 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.

(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, prior to 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.

(10) [(9)] Reciprocal recognition of out-of-state certificates of registration.

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

- (i) completed BRC Form 226-1 (Business Information Form);
- (ii) completed BRC 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 to irradiate 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) the fee as specified in subsection (g)(2) of this section; and
- (vii) qualifications of personnel who will be operating the 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 use.

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

(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 BRC 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.

(G) Reciprocal recognition will expire one year from the date it is granted. A new request for reciprocity shall be submitted to the agency each year. Reciprocity requests made after the initial request shall include only the following:

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

(ii) completed BRC 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 to irradiate 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) the fee as specified in subsection (g)(1) of this section; and

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

(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.

(11) [(10)] A radiation safety officer (RSO) shall be designated on each application form. The qualifications of that individual shall be submitted to the agency with the application.

(A) The RSO shall have the following qualifications:

- (i) knowledge of potential hazards and emergency precautions; and
- (ii) completed educational courses related to ionizing radiation safety or a radiation safety officer course; or
- (iii) experience in the use and familiarity of the type of equipment used; and

(B) In addition to the qualifications in subparagraph (A) of this paragraph, documentation of the following shall be submitted to the agency:

(i) dentist radiation safety officers shall provide documentation of licensing board number and their signature on the application; or

(ii) non-practitioner radiation safety officers shall provide any one of the following:

(I) 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 use of radiation machines;

(II) 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 use of radiation machines;

(III) evidence of registry by the American Registry of Radiologic Technologists (ARRT) or the American Registry of Clinical Radiologic Technologists (ARCRT) and at least two years of supervised use of radiation machines;

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

(V) evidence of registration with the Board of Nurse Examiners as a Registered Nurse or a Registered Nurse with an extended scope of practice (Nurse Practitioner) performing radiologic procedures, and at least two years of supervised use of radiation machines in the respective practitioners' specialty;

(VI) evidence of registration with the Texas State Board of Physician Assistant Examiners, and at least two years of supervised use of radiation machines in the respective practitioners' specialty;

(VII) evidence of:

(-a-) 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

(-b-) at least four years of supervised use of radiation machines in the respective dentists' specialty;

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

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

(C) Academic institutions and/or 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).

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

(12) [(11)] Responsibilities of radiation safety officers. Specific duties of the radiation safety officer include, but are not limited to, the following:

(A) establishing and overseeing operating and safety procedures that maintain radiation exposures as low as reasonably achievable, and to review them regularly to ensure that the procedures are current and conform with this section;

(B) investigating and reporting to the agency each known or suspected case of radiation exposure to an individual or radiation level detected in excess of limits established by this section and each theft or loss of radiation machines, determining the cause, and taking steps to prevent its recurrence;

(C) having a thorough knowledge of management policies and administrative procedures of the registrant;

(D) assuming control and having the authority to institute corrective actions including shut-down of operations when necessary in emergency situations or unsafe conditions;

(E) maintaining records as required by this section; and

(F) 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.

(i) Use of Dental Radiation Machines.

(1) - (4) (No change.)

(5) Facility requirements.

(A) (No change.)

(B) Posting of notices to workers.

(i) - (ii) (No change.)

(iii) The following form, BRC [Bureau of Radiation Control (BRC)] Form 232-1, “Notice to Employees,” which is found at the end of the section, [as contained in subparagraph (C) of this paragraph,] or an equivalent document containing at least the same wording as BRC Form 232-1, shall be posted by each registrant as required by this section.

Figure: 25 TAC §289.232(i)(5)(B)(iii)

(iv) (No change.)

[(C) Notice to employees. The following form, or an equivalent as stated in subparagraph (B)(ii) of this paragraph, shall be posted.]

[Figure: 25 TAC §289.232(i)(5)(C)]

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

(6) Radiation machine requirements.

(A) - (D) (No change.)

(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 I. If it is necessary to determine such half-value layer at an x-ray tube potential that is not listed in Table I, linear interpolation may be made.

Figure: 25 TAC §289.232(i)(6)(E)(i)(I) [Figure: 25 TAC §289.232(i)(6)(E)(i)(I)]

(II) (No change.)

(ii) - (iii) (No change.)

(F) - (H) (No change.)

(I) Exposure output [interval] 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.

(J) - (K) (No change.)

(L) Collimation. Field limitation shall meet the requirements of paragraphs (11) and (12) [paragraph (12)] of this subsection.

(M) - (N) (No change.)

(7) - (16) (No change.)

(j) Records and reports.

(1) General provisions for records and reports.

(A) - (K) (No change.)

(L) 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) (No change.)

(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(j)(1)(L)(i)(II) [Figure: 25 TAC §289.232(j)(1)(L)(i)(II)]

(ii) - (iii) (No change.)

(M) - (N) (No change.)

(2) Reports.

(A) - (B) (No change.)

(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) (No change.)

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

(-a-) - (-d-) (No change.)

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

(III) (No change.)

(ii) (No change.)

(iii) Each report filed in accordance with subparagraph (C)(i) of this paragraph shall include for each individual exposed: the name, a unique identification number [social security number], and date of birth. With respect to the limit for the embryo/fetus in subsection (i)(4)(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.

(iv) (No change.)

(D) (No change.)

(k) Compliance and hearing procedures.

(1) (No change.)

(2) Hearing and enforcement procedures.

(A) - (B) (No change.)

(C) Compliance procedures for registrants and other persons.

(i) A registrant or other person who commits a violation(s) 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) - (iv) (No change.)

(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 meeting to discuss the following with the agency: [enforcement conference.]

(I) methods and schedules for correcting the violation(s); or

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

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

(vii) - (ix) (No change.)

(D) Assessment of Administrative Penalties.

(i) - (ii) (No change.)

(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) - (II) (No change.)

(III) Adjustments to the [severity levels and] percentages of base amounts in Table IIB may be made for the presence or absence of the following factors:

(-a-) - (-f-) (No change.)

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

(iv) (No change.)

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

(i) (No change.)

(ii) Criteria to elevate or reduce severity levels.

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

(-a-) - (-c-) (No change.)

(-d-) a violation was willful or grossly negligent; [**This means the violation was the result of careless regard for requirements, deception, or other indications of willfulness by the registrant or employees of the registrant; or**]

(-e-) compliance history; or[.]

(-f-) other mitigating factors.

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

(-a-) the registrant identified and corrected the violation prior to the agency inspection; [**or**]

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

(-c-) other mitigating factors.

(iii) (No change.)

(F) (No change.)

(G) Emergency orders.

(i) - (iii) (No change.)

(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 of the date of the order.

(I) - (II) (No change.)

(-a-) - (-e-) (No change.)

(III) (No change.)

(H) (No change.)

Figure: 25 TAC §289.232(c)(17)

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

where : s = estimated standard deviation of the population

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

X_i = ith observation in sample

n = number of observations in sample

Department of State Health Services
1100 West 49th Street
Austin, Texas 78756-3189

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 must furnish to you, upon your written request, an annual written report of your exposure to radiation.
 - (b) your employer must give you a written report 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 must set forth the specific grounds for the notice, and must 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.

Figure: 25 TAC §289.232(i)(6)(E)(i)(I)

TABLE I. HALF-VALUE LAYER FOR SELECTED KILOVOLT PEAK

X-ray tube voltage (kilovolt peak)		Measure Half-Value Layer (millimeters of aluminum)
Designed operating range	Measured operating potential	
Below 51-----	30	1.5
	40	1.5
	50	1.5
51 to 70-----	51	1.5
	60	1.5
	70	1.5
Above 70-----	71	2.1
	80	2.3
	90	2.5
	100	2.7
	110	3.0
	120	3.2
	130	3.5
	140	3.8
150	4.1	

Figure: 25 TAC §289.232(j)(1)(L)(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)”

§289.233. Radiation Control Regulations for Radiation Machines Used in Veterinary Medicine.

(a) - (b) (No change.)

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

(1) - (6) (No change.)

(7) Agency - The Department of State Health Services [**Texas Department of Health**] or its successor.

(8) - (16) (No change.)

[(17) Board - The Texas Board of Health or its successor.]

(17) [(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.

(18) [(19)] 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 §289.233(c)(18) [**Figure: 25 TAC §289.233(c)(19)**]

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

Services. (20) Commissioner - The Commissioner of the Department of State Health

(21) - (33) (No change.)

[(34) Enforcement 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.]

(34) [(35)] 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 SI unit of exposure is the coulomb per kilogram (C/kg). The roentgen is the special unit of exposure. For purposes of this chapter, this term is used as a noun.

(35) [(36)] Exposure rate - The exposure per unit of time.

(36) [(37)] External dose - That portion of the DE received from any source of radiation outside the body.

(37) [(38)] 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.

(38) [(39)] 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.

(39) [(40)] Field size - The dimensions along the major axes of an area in a plane perpendicular to the central axis of the beam at the normal treatment or examination source to image distance and defined by the intersection of the major axes and the 50% isodose line.

(40) [(41)] Filter - Material placed in the useful beam to preferentially absorb selected radiation.

(41) [(42)] Fluoroscopic imaging assembly - A subsystem in which x-ray photons produce a fluoroscopic image. It includes the image receptors such as the image intensifier and

spot-film device, electrical interlocks, if any, and structural material providing linkage between the image receptor and diagnostic source assembly.

(42) [(43)] Gray (Gy) - The SI unit of absorbed dose. One gray is equal to an absorbed dose of 1 joule per kilogram (J/kg) or 100 rad.

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

(44) [(45)] 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.

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

(46) [(47)] High radiation area - An area, accessible to individuals, in which radiation levels from radiation machines external to the body could result in an individual receiving a DE in excess of 0.1 rem (1 millisievert (mSv)) in one hour at 30 cm from any source of radiation or from any surface that the radiation penetrates.

(47) [(48)] Image intensifier - A device, installed in its housing, that instantaneously converts an x-ray pattern into a corresponding light image of higher energy density.

(48) [(49)] Image receptor - Any device, such as a fluorescent screen or radiographic film, 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.

(49) [(50)] Individual - Any human being.

(50) [(51)] Individual monitoring - The assessment of DE to an individual by the use of:

(A) individual monitoring devices; or

(B) survey data.

(51) [(52)] Individual monitoring devices - Devices designed to be worn by a single individual for the assessment of DE. For purposes of this chapter, “personnel dosimeter” and “dosimeter” are equivalent terms. Examples of individual monitoring devices include, but are not limited to, film badges, thermoluminescence dosimeters (TLDs), optically stimulated luminescence dosimeters (OSLs), pocket ionization chambers (pocket dosimeters), and electronic personal dosimeters.

(52) 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.

(53) - (67) (No change.)

(68) Notice of violation - A written statement prepared by the agency of one or more alleged infringements of a legally binding requirement. **[The notice requires the person receiving the notice to provide a written statement describing the following:]**

[(A) corrective steps taken by the registrant and the results achieved;]

[(B) corrective steps to be taken to prevent recurrence; and]

[(C) the projected date for achieving full compliance. The agency may require responses to notices of violation to be under oath.]

(69) - (136) (No change.)

(d) (No change.)

(e) Communications.

(1) Except where otherwise specified, all communications and reports concerning this chapter and applications filed under them should be addressed to **[the Bureau of]** Radiation Control, Department of State Health Services [Texas Department of Health], 1100 West 49th Street, Austin, Texas, 78756-3189. Communications, reports, and applications may be delivered in person to the agency's office located at 8407 Wall Street, Austin, Texas.

(2) (No change.)

(f) (No change.)

(g) Fees for certificates of registration for veterinary facilities.

(1) Payment of fees.

(A) Each application for a certificate of registration shall be accompanied by a nonrefundable fee of \$264 [**\$240**]. No application will be accepted for filing or processed prior to payment of the full amount specified.

(B) A nonrefundable fee of \$264 shall be paid for each certificate of registration for radiation machines used in veterinary medicine. The fee shall be paid every two years based on the month listed as the expiration month on [for the two-year term of] the certificate of registration and[. The fee] shall be paid in full on or before the last day of the expiration month **[and year of the certificate of registration]**. In the case of a single certificate of registration that authorizes more than one category of use, the category listed in §289.204(j) [**§289.204(h)**] of this title (relating to Fees for Certificates of Registration, Radioactive Material Licenses, Emergency Planning and Implementation, and Other Regulatory Services) and assigned the higher fee will be used. For each additional use location on a single certificate of registration, the registrant shall pay an additional \$72.

(C) Each application for reciprocal recognition of an out-of-state registration in accordance with subsection (h)(10) [(h)(9)] of this section shall be accompanied by the \$264 [**\$240**] fee, 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 [Texas Department of Health]. The payments may be made by personal delivery to the central office, **[Bureau of]** Radiation Control, Department of State Health Services [Texas Department of Health], 1100 West 49th Street, Austin, Texas, or mailed to **[the Bureau of]** Radiation Control, Department of State Health Services [Texas Department of Health], 1100 West 49th Street, Austin, Texas, 78756-3189.

(2) Failure to pay prescribed fees.

(A) (No change.)

(B) In any case where the agency finds that a registrant has failed to pay a fee prescribed by this section by the due date, **[the certificate of registration has expired and]** the agency may implement compliance procedures as provided in subsection (k)(2) of this section.

(3) (No change.)

(h) Registration of radiation machine use.

(1) - (5) (No change.)

(6) Expiration of certificates of registration.

(A) Except as provided by paragraph (8) of this subsection, each [Effective September 1, 2004, the term of the certificate of registration is two years. Each]

certificate of registration expires at the end of the day, in the month and year stated in the certificate of registration. **[Upon payment of the fee required by subsection (g) of this section and if the agency does not deny the renewal in accordance with paragraph (4)(D) of this subsection, the certificate of registration will be renewed.]**

[(B) If the fee is not paid and the certificate of registration is not renewed in accordance with subparagraph (A) of this paragraph, the certificate of registration expires, and the registrant is in violation of the requirements in this chapter and is subject to administrative penalties in accordance with subsection (k)(2)(D) of this section.]

[(i) If the registrant pays the fee required by subsection (g) of this section within 30 days after expiration of the certificate of registration, the certificate of registration will be reinstated and the registrant will not be required to file an application in accordance with subsection (h) of this section.]

[(ii) If the registrant fails to pay the fee within 30 days after expiration of the certificate of registration, the registrant shall file an application in accordance with subsection (h) of this section.]

(B) [(C)] If a registrant does not submit an application for renewal of the certificate of registration in accordance with paragraph (8) of this subsection, as applicable, the registrant shall on or before the expiration date specified in the certificate of registration [fails to pay the fee required by subsection (g) of this section and the certificate of registration is not renewed, the registrant shall]:

(i) terminate use of all radiation machines within 30 days following the expiration date; **[and]**

(ii) submit to the agency a record of the disposition of the radiation machines and if transferred, to whom transferred within 30 days following the expiration date; and[.]

(iii) pay any outstanding fees in accordance with subsection (g) of this section.

(C) [(D)] Expiration of the certificate of registration does not relieve the registrant of the requirements of this chapter.

(7) (No change.)

(8) Renewal of certificate of registration.

(A) An application for renewal of registration shall be filed in accordance with paragraph (1) or (2) of this subsection, as applicable.

(B) If a registrant files an application in proper form before the existing certificate of registration expires, such existing certificate of registration shall not expire until the application status has been determined by the agency.

(9) [(8)] 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, for any of the following:

(i) any material false statement in the application or any statement of fact required under 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 terms and conditions of the Act, this chapter, 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.

(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, prior to 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.

(10) [(9)] Reciprocal recognition for out-of-state certificates of registration.

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

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

- (ii) completed BRC Form 252-3 (Notice of Intent to Work in Texas Under Reciprocity);
- (iii) copy of the applicant's current state certificate of registration or equivalent document;
- (iv) copy of the applicant's current operating and safety procedures pertinent to the proposed use; and
- (v) fee as specified in subsection (g) of this section.

(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 use.

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

(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 BRC 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.

(G) Reciprocal recognition will expire one year from the date it is granted. A new request for reciprocity shall be submitted to the agency each year. Reciprocity requests made after the initial request shall include only the following:

- (i) a completed BRC Form 226-1;
- (ii) a completed BRC Form 252-3;
- (iii) the fee as specified in subsection (g) of this section; and
- (iv) copy of the applicant's current state certificate of registration or equivalent document; and
- (v) copy of the applicant's current operating and safety procedures pertinent to the proposed use.

(i) Use of radiation machines for veterinary medicine.

(1) - (2) (No change.)

(3) Personnel requirements.

(A) - (E) (No change.)

(F) Determination of occupational dose for the current year.

(i) - (vi) (No change.)

(vii) Occupational exposure form. The following BRC Form 233-1 (Occupational Exposure Record for a Monitoring Period), is to be used to document occupational exposures for a monitoring period.

Figure: 25 TAC §289.233(i)(3)(F)(vii) [Figure: 25 TAC §289.233(i)(3)(F)(vii)]

(G) - (L) (No change.)

(4) Facility requirements.

(A) (No change.)

(B) Posting of notices to workers.

(i) - (ii) (No change.)

(iii) The following form, BRC [Bureau of Radiation Control (BRC)] Form 233-2, “Notice to Employees,” which is found at the end of the section, or an equivalent document containing at least the same wording as BRC Form 233-2.

Figure: 25 TAC §289.233(i)(4)(B)(iii) [Figure: 25 TAC §289.233(i)(4)(B)(iii)]

(iv) (No change.)

(C) - (H) (No change.)

(5) Radiation Machine Requirements.

(A) - (G) (No change.)

(H) Beam limiting devices. Beam limiting devices shall do the following:

(i) - (iii) (No change.)

(iv) limit the x-ray field such that the x-ray field shall not exceed:

(I) (No change.)

(II) 2.0% of the SID for the diagonal of the image receptor [for circular image receptors]; and

(v) (No change.)

(I) - (M) (No change.)

(N) Equipment performance evaluations.

(i) - (iv) (No change.)

(v) Fluoroscopic x-ray systems shall comply with the additional requirements specified in paragraph (6) of this subsection.

(6) - (11) (No change.)

(j) Records and reports.

(1) General provisions for records and reports.

(A) - (J) (No change.)

(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) (No change.)

(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 §289.233(j)(1)(K)(i)(II) [Figure: 25 TAC §289.233(j)(1)(K)(i)(II)]

(ii) - (iii) (No change.)

(L) - (P) (No change.)

(2) (No change.)

(3) Reports.

(A) - (B) (No change.)

(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) (No change.)

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

(-a-) - (-d-) (No change.)

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

(III) (No change.)

(ii) (No change.)

(iii) Each report filed in accordance with clause (i) of this subparagraph shall include for each individual exposed: the name, a unique identification number [social security number], and date of birth. With respect to the limit for the embryo/fetus in subsection (i)(3)(A)(i)(IV) 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.

(iv) (No change.)

(D) (No change.)

(k) Compliance and hearing procedures.

(1) (No change.)

(2) Hearing and enforcement procedures.

(A) - (B) (No change.)

(C) Compliance procedures for registrants and other persons.

(i) A registrant or other person who commits a violation(s) 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) - (iv) (No change.)

(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 meeting [enforcement conference] to discuss the following with the agency:

(I) - (II) (No change.)

(vi) Notice of any informal meeting [enforcement conference] shall be delivered by personal service, or certified mail, addressed to the last known address. An informal meeting [enforcement conference] is not a prerequisite for the action to be taken in

accordance with [under] 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, prior to 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 [accorded] an opportunity to demonstrate compliance with all lawful requirements.

(viii) - (ix) (No change.)

(D) Assessment of administrative penalties.

(i) - (ii) (No change.)

(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) - (II) (No change.)

(III) Adjustments to the **[severity levels and]** percentages of base amounts in Table IIB may be made for the presence or absence of the following factors:

(-a-) - (-f-) (No change.)

(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 chapter, order, certificate of registration issued in accordance with [under] the Act. Each day a violation continues may be considered a separate violation for purposes of penalty assessment.

(iv) (No change.)

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

(i) (No change.)

(ii) Criteria to elevate or reduce severity levels.

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

(-a-) - (-c-) (No change.)

(-d-) a violation was willful or grossly negligent;
This means the violation was the result of careless regard for requirements, deception, or other indications of willfulness by the registrant or employees of the registrant; or]

(-e-) compliance history; or;

(-f-) other mitigating factors.

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

(-a-) the registrant identified and corrected the violation prior to the agency inspection; [**or**]

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

(-c-) other mitigating factors.

(iii) (No change.)

(F) - (H) (No change.)

Figure: 25 TAC §289.233(c)(18)

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

where : s = estimated standard deviation of the population

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

X_i = ith observation in sample

n = number of observations in sample

BRC Form 233-1				Department of State Health Services/Radiation Control								
OCCUPATIONAL EXPOSURE RECORD FOR A MONITORING PERIOD												
1. NAME (LAST, FIRST, MIDDLE INITIAL)				2. IDENTIFICATION NUMBER		3. ID TYPE		4. SEX <input type="checkbox"/> MALE <input type="checkbox"/> FEMALE		5. DATE OF BIRTH		
6. MONITORING PERIOD			7. LICENSEE OR REGISTRANT NAME				8. LICENSE OR REGISTRATION NUMBER(S)		9A. RECORD ESTIMATE		9B. ROUTINE PSE	
INTAKES				DOSES (in rem)								
10A. RADIONUCLIDE	10B. CLASS	10C. MODE	10D. INTAKE IN μ Ci									
				DEEP DOSE EQUIVALENT (DDE)							11.	
				EYE DOSE EQUIVALENT TO THE LENS OF THE EYE (LDE)							12.	
				SHALLOW DOSE EQUIVALENT, WHOLE BODY (SDE,WB)							13.	
				SHALLOW DOSE EQUIVALENT, MAX EXTREMITY (SDE,ME)							14.	
				COMMITTED EFFECTIVE DOSE EQUIVALENT (CEDE)							15.	
				COMMITTED DOSE EQUIVALENT, MAXIMALLY EXPOSED ORGAN (CDE)							16.	
				TOTAL EFFECTIVE DOSE EQUIVALENT <i>(BLOCKS 11 + 15) (TEDE)</i>							17.	
				TOTAL ORGAN DOSE EQUIVALENT, MAX ORGAN <i>(BLOCKS 11 + 16) (TODE)</i>							18.	
				19. COMMENTS								
20. SIGNATURE -- LICENSEE OR REGISTRANT										21. DATE PREPARED		

Figure: 25 TAC §289.233(i)(4)(B)(iii)

INSTRUCTIONS AND ADDITIONAL INFORMATION PERTINENT TO THE COMPLETION OF BRC FORM 233-1 <i>(All doses should be stated in rems)</i>																
<p>1. Type or print the full name of the monitored individual in the order of last name (include "Jr," "Sr," "III," etc.), first name, middle initial (if applicable).</p> <p>2. Enter the individual's identification number, including punctuation. This number should be the 9-digit social security number if at all possible. If the individual has no social security number, enter the number from another official identification such as a passport or work permit.</p> <p>3. Enter the code for the type of identification used as shown below:</p> <table border="0"> <tr> <td><u>CODE</u></td> <td><u>ID TYPE</u></td> </tr> <tr> <td>SSN</td> <td>U.S. Social Security Number</td> </tr> <tr> <td>PPN</td> <td>Passport Number</td> </tr> <tr> <td>CSI</td> <td>Canadian Social Insurance Number</td> </tr> <tr> <td>WPN</td> <td>Work Permit Number</td> </tr> <tr> <td>IND</td> <td>INDEX Identification Number</td> </tr> <tr> <td>OTH</td> <td>Other</td> </tr> </table> <p>4. Check the box that denotes the sex of the individual being monitored.</p> <p>5. Enter the date of birth of the individual being monitored in the format MM/DD/YY.</p> <p>6. Enter the monitoring period for which this report is filed. The format should be MM/DD/YY - MM/DD/YY.</p> <p>7. Enter the name of the licensee or registrant.</p> <p>8. Enter the Agency license or registration number or numbers.</p> <p>9A. Place an "X" in Record or Estimate. Choose "Record" if the dose data listed represent a final determination of the dose received to the best of the licensee's or registrant's knowledge. Choose "Estimate" only if the listed dose data are preliminary and will be superseded by a final determination resulting in a subsequent report. An example of such an instance would be dose data based on self-reading dosimeter results and the licensee intends to assign the record dose on the basis of TLD results that are not yet available.</p> <p>9B. Place an "X" in either Routine or PSE. Choose "Routine" if the data represent the results of monitoring for routine exposures. Choose "PSE" if the listed dose data represents the results of monitoring of planned special exposures received during the monitoring</p>	<u>CODE</u>	<u>ID TYPE</u>	SSN	U.S. Social Security Number	PPN	Passport Number	CSI	Canadian Social Insurance Number	WPN	Work Permit Number	IND	INDEX Identification Number	OTH	Other	<p>period. If more than one PSE was received in a single year, the licensee or registrant should sum them and report the total of all PSEs.</p> <p>10A. Enter the symbol for each radionuclide that resulted in an internal exposure recorded for the individual, using the format "Xx-###x," for instance, Cs-137 or Tc-99m.</p> <p>10B. Enter the lung clearance class as listed in Appendix B to Part D (D, W, Y, V, or O for other) for all intakes by inhalation.</p> <p>10C. Enter the mode of intake. For inhalation, enter "H." For absorption through the skin, enter "B." For oral ingestion, enter "G." For injection, enter "J."</p> <p>10D. Enter the intake of each radionuclide in μCi.</p> <p>11. Enter the deep dose equivalent (DDE) to the whole body.</p> <p>12. Enter the eye dose equivalent (LDE) recorded for the lens of the eye.</p> <p>13. Enter the shallow dose equivalent recorded for the skin of the whole body (SDE,WB).</p> <p>14. Enter the shallow dose equivalent recorded for the skin of the extremity receiving the maximum dose (SDE,ME).</p> <p>15. Enter the committed effective dose equivalent (CEDE) or "NR" for "Not Required" or "NC" for "Not Calculated".</p> <p>16. Enter the committed dose equivalent (CDE) recorded for the maximally exposed organ or "NR" for "Not Required" or "NC" for "Not Calculated".</p> <p>17. Enter the total effective dose equivalent (TEDE). The TEDE is the sum of items 11 and 15.</p> <p>18. Enter the total organ dose equivalent (TODE) for the maximally exposed organ. The TODE is the sum of items 11 and 16.</p>	<p>19. COMMENTS. In the space provided, enter additional information that might be needed to determine compliance with limits. An example might be to enter the note that the SDE,ME was the result of exposure from a discrete hot particle. Another possibility would be to indicate that an overexposed report has been sent to the Agency in reference to the exposure report.</p> <p>20. Signature of the person designated to represent the licensee or registrant.</p> <p>21. Enter the date this form was prepared.</p>
<u>CODE</u>	<u>ID TYPE</u>															
SSN	U.S. Social Security Number															
PPN	Passport Number															
CSI	Canadian Social Insurance Number															
WPN	Work Permit Number															
IND	INDEX Identification Number															
OTH	Other															

Department of State Health Services
1100 West 49th Street
Austin, Texas 78756-3189

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 as 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) §289.233(i)(3)(A) of this title (relating to Radiation Control Regulations for Radiation Machines Used in Veterinary Medicine). This subsection specifies limits on exposure to radiation.

2. If you work where individual monitoring devices are provided in accordance with 25 TAC §282.233(i)(3)(B) of this title;
(b) your employer must furnish to you, upon your written request, an annual written report of your exposure to radiation; and
(a) your employer must 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 must set forth the specific grounds for the notice, and must 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 violation as described above.

POSTING REQUIREMENT

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 §289.233 (relating to Radiation Control Regulations for Radiation Machines Used in Veterinary Medicine), to permit employees to observe a copy on the way to or from their place of employment.

Figure: 25 TAC §289.233(j)(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)

which 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)”

§289.301. Registration and Radiation Safety Requirements for Lasers and Intense-Pulsed Light Devices.

(a) Purpose.

(1) (No change.)

(2) This section establishes requirements for the registration of persons who receive, possess, acquire, transfer, or use Class 3b (IIIb), International Electrotechnical Commission (IEC) Class 3B and Class 4 (IV), IEC Class 4 lasers in the healing arts, veterinary medicine, industry, academic, research and development institutions, and of persons who are in the business of providing laser services. No person shall use Class 3b (IIIb), IEC Class 3B or 4 (IV), IEC Class 4 lasers or perform laser services except as authorized in a certificate of laser registration issued by the agency in accordance with the requirements of this section. Class 1 (I) lasers [**laser**], IEC Class 1 and 1M, Class 2 (II) lasers [**laser**], IEC Class 2 and 2M, and Class 3a (IIIa) lasers [**laser**], IEC Class 3R and IPL devices are not required to be registered. However, use of Class 1 (I) lasers [**laser**], IEC Class 1 and 1M, Class 2 (II) lasers [**laser**], IEC Class 2 and 2M, and Class 3a (IIIa) lasers [**laser**], IEC Class 3R and IPL devices are subject to other applicable requirements in this section.

(b) Scope.

(1) - (4) (No change.)

(5) In addition to the requirements of this section, all registrants authorized to use Class 3b and Class 4 lasers are subject to the following requirements:

(A) (No change.)

(B) §289.204 of this title (relating to Fees for Certificates of Registration, Radioactive Material Licenses, Emergency Planning and Implementation, and Other Regulatory Services);

(C) - (D) (No change.)

(c) (No change.)

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

(1) - (13) (No change.)

(14) Continuous wave - The output of a laser that is operated in a continuous rather than a pulsed mode. In this section, a laser operating with a continuous output for a period of \geq [\geq] 0.25 seconds is regarded as a continuous wave laser.

(15) - (35) (No change.)

(36) Practitioner of the healing arts (practitioner) - For the purposes of this section, a person licensed to practice the healing arts by either the Texas Medical Board [**Texas State Board of Medical Examiners**] as a physician; the Texas State Board of Dental Examiners; the Texas Board of Chiropractic Examiners; or the Texas State Board of Pediatric Medicine [**Texas State Board of Podiatry Examiners**]. A practitioner's use of a laser is limited to his/her scope of professional practice as determined by the appropriate licensing agency.

(37) - (47) (No change.)

(e) - (i) (No change.)

(j) Responsibilities of registrant.

(1) - (2) (No change.)

(3) Each registrant shall inventory all Class 3B and 4 lasers in their possession at an interval not to exceed one year. The inventory record shall be maintained for inspection by the agency in accordance with subsection (ee) of this section and shall include:

(A) - (D) (No change.)

(E) if using a provider of lasers as defined in subsection (d)(38) **[in accordance with subsection (d)(35)]** of this section, a statement with the inventory that the registrant is using lasers provided by a provider of lasers.

(4) Notification to the agency is required within 30 days of the following:

(A) (No change.)

(B) if the registrant begins or terminates the use of a provider of lasers as defined in subsection (d)(38) **[in accordance with subsection (d)(35)]** of this section.

(5) - (8) (No change.)

(k) Expiration of certificates of laser registration **[and administrative renewal]**.

(1) **[Effective September 1, 2004, the term of the certificate of registration is two years.]** Except as provided by subsection (m) of this section, each certificate of laser registration expires at the end of the day, in the month and year stated in the certificate of laser registration. **[Except for subsection (m)(5) of this section, upon payment of the fee required by §289.204 of this title and if the agency does not deny the renewal in accordance with subsection (i)(4) of this section, the certificate of laser registration will be administratively renewed. The requirements in this subsection are subject to the provisions of Government Code, §2001.054.]**

[(2) If the fee is not paid and the certificate of laser registration is not renewed in accordance with paragraph (1) of this subsection, the certificate of laser registration expires, and the registrant is in violation of the requirements of this chapter and is subject to administrative penalties in accordance with §289.205 of this title.]

[(A) If the registrant pays the fee required by §289.204 of this title within 30 days after expiration of the certificate of laser registration, the certificate of laser registration will be reinstated and the registrant will not be required to file an application in accordance with subsection (g) of this section.]

[(B) If the registrant fails to pay the fee within 30 days after expiration of the certificate of laser registration, the registrant shall file an application in accordance with subsection (g) of this section.]

(2) [(3)] If a registrant does not submit an application for renewal of the certificate of laser registration in accordance with subsection (m) of this section, as applicable, the registrant shall on or before the expiration date specified in the certificate of laser registration **[fails to pay the fee required by §289.204 of this title and the certificate of laser registration is not renewed, the registrant shall]:**

(A) terminate use of all lasers and/or terminate laser servicing or laser services authorized under the certificate of laser registration;

(B) submit to the agency a record of the disposition of the lasers, if applicable, and if transferred, to whom it was transferred within 30 days following the expiration date; and [.]

(C) pay any outstanding fees in accordance with §289.204 of this title.

(3) [(4)] Expiration of the certificate of laser registration does not relieve the registrant of the requirements of this chapter.

(l) (No change.)

(m) Renewal [**Technical renewal**] of certificate of laser registration.

(1) An [**If required by the certificate of laser registration, an**] application for [**technical**] renewal of a certificate of laser registration shall be filed in accordance with subsection (g)(1)(A)-(B), and (E)-(G) of this section and applicable paragraphs of subsections (g)(2),(4), and (7) of this section. [**An application for a technical renewal of a certificate of laser registration shall be submitted to the agency by the date specified in the certificate of laser registration. If the registrant fails to apply and pay the fee required by §289.204 of this title, or the agency does not approve the application in accordance with subsection (h)(1) of this section, the certificate of laser registration expires and the registrant is in violation of the requirements of this chapter and is subject to administrative penalties in accordance with §289.205 of this title. The registrant shall comply with the requirements of subsection (k)(3) of this section.**]

[(2) Expiration of the certificate of registration does not relieve the registrant of the requirements of this chapter.]

(2) [(3)] If a registrant files an application for a [**technical**] renewal in proper form before the existing certificate of laser registration expires [**and pays the fee required by §289.204 of this title**], such existing certificate of laser registration shall not expire until the application status has been determined by the agency.

[(4) An application for technical renewal of a certificate of laser registration will be approved if the agency determines that the requirements of subsection (g)(1) of this section and the applicable paragraphs of subsection (g)(2)-(8) of this section have been satisfied.]

[(5) When the date for administrative renewal in accordance with subsection (k)(1) of this section and the date for the technical renewal in accordance with paragraph (1) of this subsection occur at the same time, the certificate of laser registration will be renewed if the fee required by §289.204 of this title is paid, the technical renewal is approved by the agency in accordance with paragraph (4) of this subsection, and the agency does not deny the renewal in accordance with subsection (i)(4) of this section.]

[(6) When the date for the administrative renewal in accordance with subsection (k)(1) of this section and the date for the technical renewal in accordance with paragraph (1) of this subsection occur at the same time, the certificate of laser registration renewal may be denied by the agency if any one of the following conditions apply:]

[(A) the fee required by §289.204 of this title is not paid;]

[(B) the agency denies the renewal in accordance with subsection (i)(4) of this section; or]

[(C) the agency does not approve the technical renewal in accordance with paragraph (4) of this subsection.]

[(7) The requirements in this subsection are subject to the provisions of Government Code, §2001.054.]

(n) - (q) (No change.)

(r) Requirements for protection against Class 3b or 4 lasers and IPL device radiation. These requirements are for Class 3b or 4 lasers and IPL devices in their intended mode of operation and include special requirements for service, testing, maintenance, and modification. During some operations, certain engineering controls may be inappropriate. In situations where an engineering control may be inappropriate, for example, during medical procedures or surgery, the LSO shall specify alternate controls to obtain equivalent safety protection.

(1) MPE. Each registrant or user of any laser shall not permit any individual to be exposed to levels of laser or collateral radiation higher than are specified in ANSI Z136.1-2000, Safe Use of Lasers and Title 21, CFR, §1040.10 **[Part 1040.10]** respectively.

(2) Instructions to personnel. Personnel operating each laser presently being used or listed on the registrant's current inventory, shall be provided with written instructions for safe use, including clear warnings and precautions to avoid possible exposure to laser and collateral radiation in excess of the MPE, as delineated in ANSI Z136.1-2000, Safe Use of Lasers and the collateral limits listed in Title 21, CFR, §1040.10 **[Part 1040.10]**. The instructions to personnel shall be maintained in accordance with subsection (ee) of this section for inspection by the agency.

(3) Engineering controls.

(A) - (B) (No change.)

(C) Viewing optics and windows.

(i) All viewing ports, viewing optics, or display screens included as an integral part of an enclosed laser or laser product shall incorporate suitable means, (such as interlocks, filters, or attenuators, to maintain the laser radiation at the viewing position at or

below the applicable MPE as delineated in ANSI Z136.1-2000, Safe Use of Lasers and the collateral limits listed in Title 21, CFR, §1040.10 [Part 1040.10], under any conditions of operation of the laser.

(ii) (No change.)

(D) (No change.)

(E) Controlled area. With a Class 3b laser, except those that allow access only to less than 5 mW visible peak power, or Class 4 laser, a controlled area shall be established when exposure to the laser radiation in excess of the MPE, as delineated in ANSI Z136.1-2000, Safe Use of Lasers or the collateral limits listed in Title 21, CFR, §1040.10 [Part 1040.10] is possible. The controlled area shall meet the following requirements, as applicable.

(i) - (iv) (No change.)

(v) For Class 4 indoor controlled areas, optical paths (for example, windows) from an indoor facility shall be controlled in such a manner as to reduce the transmitted values of the laser radiation to levels at or below the appropriate ocular MPE, as delineated in ANSI Z136.1-2000, Safe Use of Lasers and the collateral limits listed in Title 21, CFR, §1040.10 [Part 1040.10]. [(When the laser beam must exit the indoor controlled area (as in the case of exterior atmospheric beam paths), the operator shall be responsible for ensuring that air traffic is protected from any laser projecting into navigable air space (contact Federal Aviation Administration (FAA) or other appropriate agencies, as necessary) or controlled ground space when the beam irradiance or radiant exposure is above the appropriate MPE, as delineated in ANSI Z136.1-2000, Safe Use of Lasers.

(vi) When the removal of panels or protective covers and/or overriding of interlocks becomes necessary, such as for servicing, testing, or maintenance, and accessible laser radiation exceeds the MPE, as delineated in ANSI Z136.1-2000, Safe Use of Lasers and the collateral limits listed in Title 21, CFR, §1040.10 [Part 1040.10], a temporary controlled area shall be established and posted.

(4) (No change.)

(s) Additional requirements for special lasers and applications.

(1) (No change.)

(2) Laser optical fiber transmission system.

(A) (No change.)

(B) Disconnection of a connector resulting in access to radiation in excess of the applicable MPE limits, as delineated in ANSI Z136.1-2000, Safe Use of Lasers and the collateral limits listed in Title 21, CFR, §1040.10 [Part 1040.10], shall take place in a controlled

area. Except for medical lasers whose manufacture has been approved by the FDA, the use of a tool shall be required for the disconnection of a connector for service and maintenance purposes when the connector is not within a secured enclosure. All connectors shall bear the appropriate label or tag specified in subsection (v)(3) of this section.

(t) Additional requirements for safe operation.

(1) Eye protection. Protective eyewear shall be worn by all individuals with access to Class 3b and/or Class 4 levels of laser radiation. Protective eyewear devices shall meet the following requirements:

(A) - (D) (No change.)

(E) be examined, at intervals not to exceed 12 months, to ensure the reliability of the protective filters and integrity of the protective filter frames. Unreliable eyewear shall be discarded. Documentation of the examination shall be made and maintained in accordance with subsection (ee) of this section for inspection by the agency.

(2) Skin protection. When there is a possibility of exposure to laser radiation that exceeds the MPE limits for skin as specified in ANSI Z136.1-2000 Safe Use of Lasers, the registrant shall require the appropriate use of protective gloves, clothing, or shields.

(u) (No change.)

(v) Caution signs, labels, and posting for lasers and IPL devices.

(1) - (2) (No change.)

(3) Labeling lasers and posting laser facilities. All signs and labels associated with Class 2, 3a, 3b, and 4 lasers shall contain the following wording.

(A) - (D) (No change.)

(E) Lasers, except lasers used in the practice of medicine, shall have a label(s) in close proximity to each aperture through which is emitted accessible laser or collateral radiation in excess of the limits specified in ANSI Z136.1-2000, Safe Use of Lasers and the collateral limits listed in Title 21, CFR, §1040.10 [Part 1040.10], with the following wording as applicable.

(i) - (iii) (No change.)

(F) Each noninterlocked or defeatably interlocked portion of the protective housing or enclosure that is designed to be displaced or removed during normal operation or servicing, and that would permit human access to laser or collateral radiation, shall have labels as follows:

(i) - (ii) (No change.)

(iii) for collateral radiation in excess of the emission limits as described in Title 21, CFR, §1040.10 **[Part 1040.10]**, “CAUTION - HAZARDOUS ELECTROMAGNETIC RADIATION WHEN OPEN” and “CAUTION - HAZARDOUS X-RAY RADIATION” as applicable.

(G) - (I) (No change.)

(4) In lieu of the requirements in paragraphs (1)-(3) of this subsection and subsection (dd) of this section, the agency will accept labeling and signage designated by the following:

(A) Title 21, CFR, §1040.10 **[Part 1040.10]**;

(B) - (C) (No change.)

(w) Surveys. Each registrant shall make or cause to be made such surveys as may be necessary to comply with this section and maintain records of the surveys in accordance with subsection (ee) of this section for inspection by the agency. Surveys shall be performed at intervals not to exceed 12 months, to include but not be limited to the following:

(1) - (5) (No change.)

(x) Records/documents. Each registrant shall maintain current records/documents required by this subsection in accordance with subsection (ee) of this section for inspection by the agency.

(y) - (dd) (No change.)

(ee) Keeping records/documents. The following chart contains time requirements for keeping records/documents:

Figure: 25 TAC §289.301(ee) **[Figure: 25 TAC §289.301(ee)]**

Figure: 25 TAC §289.301(ee)

<u>Specific Subsection</u>	<u>Name of Record</u>	<u>Time Interval Required for Record Keeping</u>
(a)(1)	Current Certificate of Laser Registration	Until termination of Certificate of Laser Registration
(b)(5)	Current 25 TAC §§289.203, 289.204, 289.205, 289.231, 289.301	Until termination of Certificate of Laser Registration
(j)(8)	Receipt, transfer, and disposal	Until termination of Certificate of Laser Registration
(r)(2)	Operator instructions for safe use for laser machines being used at present time	Until termination of Certificate of Laser Registration
(t)(1)(E)	Eye protection	5 years
(y)	Measurements and instrumentation	5 years
(z)	Notification of injury other than a medical event	5 years
(aa)	Reports of injuries	5 years
(bb)	Medical event	5 years
(cc)	Reports of stolen, lost, or missing lasers or IPL devices	Until termination of Certificate of Laser Registration or 5 years for IPL devices