

TITLE 25. HEALTH SERVICES
Part 1. DEPARTMENT OF STATE HEALTH SERVICES
Chapter 289. Radiation Control
Subchapter D. General
Amendment §289.204

Proposed Preamble

The Executive Commissioner of the Health and Human Services Commission on behalf of the Department of State Health Services (department) proposes an amendment to §289.204, concerning Radiation Control fees.

BACKGROUND AND PURPOSE

The Texas Legislature passed the General Appropriations Act, Senate Bill 1, 79th Legislature, Regular Session (2005). Article II, Rider 85 makes a portion of the appropriation contingent upon collection of fees above the Comptroller of Public Accounts' Biennial Revenue estimate. To meet these requirements, a cost recovery fee is included in this amendment.

The radiation control program was evaluated to determine the level of increase in fees based on the following criteria: the date of the last fee increase for the specific program area; the percentage of revenue above costs for the specific program; and the cost of permits compared to other similar permits. Additional costs of administration and enforcement of the program, due to a recent legislative increase in pay, longevity pay, and travel reimbursement, were also evaluated to determine the direct and indirect costs of each program.

SECTION-BY-SECTION SUMMARY

The amendment adds references to §289.232 (relating to Radiation Control Regulations for Dental Radiation Machines) and §289.233 (relating to Radiation Control Regulations for Radiation Machines Used in Veterinary Medicine) in §289.204(b)(1)(C) for clarification and adds "and Intense-Pulsed Light Devices" after "Lasers)" at the end of the subparagraph to state the correct title of the rule being cited.

In addition, the amendment changes the agency name from "Texas Department of Health/Bureau of Radiation Control" to "Department of State Health Services/Radiation Control" to state the new department name in §289.204(d)(8).

Amendments to §289.204 contain increases in fees for certificates of registration, radioactive material licenses, emergency planning and implementation, and other regulatory services. Specifically, the categories of fees contained in §289.204(e) for radioactive materials licenses increase by 28%, ranging from a two-year fee of \$704 for a gauge general license acknowledgement to a two-year fee of \$273,800 for a Class III waste processing license. Fees contained in §289.204(f) for evaluation of a sealed source or device increase by 28%, ranging from \$2,309 for an amendment requiring reevaluation of a sealed source to \$9,258 for an initial

evaluation of a device. Fees contained in §289.204(m) for uranium recovery and byproduct material disposal facility licenses are also increased by 28% and range from a two-year fee of \$52,012 for an in situ license in post-closure to a two-year fee of \$463,096 for a new application for a conventional uranium recovery license. In addition, the one-time fee adjustments contained in §289.204(o) for uranium recovery and byproduct material disposal facility licenses are increased by 28% and range from \$11,235 for the addition of a wellfield on contiguous property to \$71,651 for addition of an in situ satellite site. The fees contained in §289.204(j) for certificates of registration are increased by 15% for these categories of machine type or use: computerized tomography, fluoroscopy, accelerators, radiographic machines only, industrial radiography, other industrial machines, morgues and educational facilities with machines for non-human use, and other radiation machine services. The fees for these categories range from a two-year fee of \$253 for radiation machine services to a two-year fee of \$1,656 for computerized tomography. The fees contained in §289.204(j) for certificates of registration are increased by 10% for these categories of machine type or use: dental radiographic only, podiatric radiographic only, veterinary, and minimal threat machines. The fees for these categories range from a two-year fee of \$264 for podiatric radiographic machines to \$374 for minimal threat machines.

Section §289.204(j) adds language to clarify that the fees specified in this section are the applicable fees for persons using only dental radiographic machines and for persons using veterinary radiographic machines, including computerized tomography, fluoroscopy, and accelerators.

FISCAL NOTE

Susan E. Tennyson, Section Director, Environmental and Consumer Safety Section, has determined that for each fiscal year of the first five years that the section will be in effect, there will be fiscal implications to state or local governments as a result of enforcing and administering the section as proposed. The effect on state government will be an increase in revenue to the state of \$923,991 in 2006 and \$1,385,987 in 2007 through 2010. These additional revenues will offset the increased costs associated with the legislative increase in pay, longevity pay, and travel reimbursement. State and local government entities that are licensed or registered with the department for possession of radioactive material or radiation machines will be required to pay the increased fee as specified in the rule.

SMALL AND MICRO-BUSINESS IMPACT ANALYSIS

Ms. Tennyson has also determined that there are anticipated economic costs to small businesses or micro-businesses required to comply with the section as proposed. Small businesses or micro-businesses that have a license to possess radioactive material will have an increase of 28% in the two-year license fee. Small businesses or micro-businesses that have a certificate of registration will have a 15% increase in the two-year registration fee if they use a radiation machine in the following categories of machine type or use: computerized tomography, fluoroscopy, accelerators, radiographic machines only, industrial radiography, other industrial machines, morgues and educational facilities with machines for non-human use, and other radiation machine services. Small businesses or micro-businesses that have a certificate of registration

will have a 10% increase in the two-year registration fee if they use a radiation machine in the following categories of machine type or use: dental radiographic only, podiatric radiographic only, veterinary, and minimal threat machines. There is no anticipated negative impact on local employment.

PUBLIC BENEFIT

In addition, Ms. Tennyson has also determined that for each year of the first five years the section is in effect, the public will benefit from adoption of the sections. The public benefit anticipated as a result of enforcing or administering the section is to generate funding to operate the radiation control program to ensure continued protection of the public, workers, and the environment from unnecessary exposure to radiation.

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 amendment does 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, does not constitute a taking under Government Code, §2007.043.

PUBLIC COMMENT

Comments on the proposal may be submitted to Cindy Cardwell, Environmental and Consumer Safety Section, Radiation Group, Policy/Standards/Quality Assurance Unit, Division of Regulatory Services, Department of State Health Services, 1100 West 49th Street, Austin, Texas 78756, 512/834-6688, 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 web site (www.tdh.state.tx.us/radiation). Please contact Cindy Cardwell at (512) 834-6688, extension 2239, or cindy.cardwell@dshs.state.tx.us if you have questions.

STATUTORY AUTHORITY

The proposed amendment to §289.204 is 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, §401.302, which allows the department to collect fees from each nuclear reactor or other fixed nuclear facility in the state that uses special nuclear material; 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 Chapter 1001, Health and Safety Code.

The proposed amendment affects the Health and Safety Code, Chapters 12, 401, and 1001; and Government Code, Chapter 531.

LEGAL CERTIFICATON

The Department of State Health Services General Counsel, Cathy Campbell, certifies that the proposed rule has been reviewed by legal counsel and found to be within the state agencies' authority to adopt.

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)-(B) (No change.)

(C) a certificate of registration for radiation machines and/or services, or sources of laser radiation, issued in accordance with §289.226 of this title (relating to Registration of Radiation Machine Use and Services), §289.230 of this title (relating to Certification of Mammography Systems and Accreditation of Mammography Facilities), a certificate of registration for dental radiation machines in accordance with §289.232 (relating to Radiation Control Regulations for Dental Radiation Machines), a certificate of registration for radiation machines used in veterinary medicine in accordance with §289.233 (relating to Radiation Control Regulations for Radiation Machines Used in Veterinary Medicine), or §289.301 of this title (relating to Registration and Radiation Safety Requirements for Lasers and Intense-Pulsed Light Devices); or

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

(c) (No change.)

(d) Payment of fees.

(1)-(7) (No change.)

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(8) 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, Radiation Control [Bureau of Radiation Control], Department of State Health Services, [Texas Department of Health] 1100 West 49th Street, Austin, Texas, or mailed to Radiation Control, Department of State Health Services [the Bureau of Radiation Control, Texas Department of Health], 1100 West 49th Street, Austin, Texas, 78756-3189.

(9) (No change.)

(e) Schedule of fees for radioactive material licenses. The following schedule contains the fees for radioactive material licenses:

Figure: 25 TAC §289.204(e) [**Figure: 25 TAC §289.204(e)**]

(f) Fee for evaluation of a sealed source and/or device.

(1) Each time a manufacturer submits a request for evaluation of a unique sealed source, one of the following fees shall be paid:

(A) for an initial evaluation, a fee of \$4,626 [**\$3,614**]; or

(B) for an amendment requiring re-evaluation, a fee of \$2,309 [**\$1,804**].

(2) Each time a manufacturer submits a request for evaluation of a unique device, one of the following fees shall be paid:

(A) for an initial evaluation, a fee of \$9,258 [**\$7,233**]; or

(B) for an amendment requiring re-evaluation, a fee of \$4,632 [**\$3,619**].

(3) (No change.)

(g)-(i) (No change.)

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(j) Schedule of fees for certificates of registration for radiation machines, lasers, and services. **[The fee for certificates of registration for dental radiation machines is specified in §289.232 of this title. The fee for certificates of registration for radiation machines used in veterinary medicine is specified in §289.233 of this title.]** The following schedule contains the fees for certificates of registration for radiation machines, lasers, and services. [:] As of January 1, 2006, 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) **[Figure: 25 TAC §289.204(j)]**

(k)-(l) (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) **[Figure: 25 TAC §289.204(m)]**

(n) (No change.)

(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 [**\$22,389**] for in situ wellfield on noncontiguous property;
- (2) \$71,651 [**\$55,977**] for in situ satellite;
- (3) \$11,235 [**\$8,777**] for wellfield on contiguous property;
- (4) \$50,756 [**\$39,653**] for non-vacuum dryer; or
- (5) \$71,651 [**\$55,977**] for disposal (including processing, if applicable) of byproduct material.

(p) (No change.)

Category of License	Fee
(1) Accelerator (used for Production of Radioactive Material)	\$15,319.00
(2) Agency-Accepted Training Course (Involving Possession of Radioactive Material)	\$3,676.00
(3) Bone Mineral Analyzer	\$1,987.00
(4) Broad License	\$20,698.00
(5) Calibration Service (Survey Instrument)	\$1,690.00
(6) Calibration/Reference Source	\$1,267.00
(7) Civil Defense	\$1,987.00
(8) Decontamination Service	
(A) Fixed Site	\$25,597.00
(B) Mobile	\$8,392.00
(9) Demonstration/Sales	\$3,830.00
(10) Environmental Laboratory	\$1,564.00
(11) Eye Applicator	\$1,564.00
(12) Fine Leak Testing Device	\$4,815.00
(13) Fixed Multi-Beam Teletherapy	\$8,617.00
(14) X-Ray Fluorescence	\$1,987.00
(15) Hand-held Light Intensifying Imaging Device	\$1,987.00
(16) Gas Chromatograph	\$1,846.00

Category of License	Fee
(17) Gauge	
(A) Spinning Pipe-Thickness/Portable	\$2,816.00
(B) Fixed	\$2,268.00
(18) General License Acknowledgement-Gauge	\$704.00
(19) Industrial Radiography (Fixed Facility)	\$5,660.00
(20) Industrial Radiography (Temporary Field Site)	\$11,912.00
(21) Installer, Repair, or Maintenance	\$3,126.00
(22) Irradiator (Self-Contained)	\$3,126.00
(23) Irradiator (Unshielded)	\$19,261.00
(24) In-Vitro Use of Radioactive Material	\$945.00
(25) In-Vitro Test Kit Manufacturer	\$4,915.00
(26) Leak Test Service	\$1,846.00
(27) Manufacturing and Commercial Distribution	
(A) Processor of Radioactive Material	\$48,745.00
(B) Other Manufacturing and Commercial Distribution	\$7,941.00
(C) Commercial Distribution Only	\$3,676.00
(D) Limited Manufacturing (loose material)	\$7,096.00
(28) Medical Therapy (Sealed Source)	\$2,703.00
(29) Medical Therapy (Unsealed Source)	\$2,268.00
(30) Mineral Recovery (Byproduct Material)	\$66,895.00
(31) Mobile Scanning Service	\$4,393.00

Category of License	Fee
(32) Naturally Occurring Radioactive Material (NORM)-Commercial Processing	\$25,597.00
(33) Nuclear Medicine (Diagnostic)	\$2,409.00
(34) Nuclear Pharmacy	\$7,096.00
(35) Neutron Generator Target	
(A) Sealed	\$2,028.00
(B) Unsealed	\$4,055.00
(36) Pacemaker	\$1,142.00
(37) Pipe Joint Collar Marker	\$2,268.00
(38) Radiopharmaceutical Manufacturing	\$20,979.00
(39) Remote Controlled Brachytherapy Device (Includes Low Dose-Rate and High Dose-Rate Remote Afterloaders and Intravenous Brachytherapy)	\$3,548.00
(40) Research and/or Development	\$2,985.00
(41) Source Material	\$3,830.00
(42) Special Nuclear Material	\$2,268.00
(43) Teletherapy	\$3,548.00
(44) Tracer Studies (Used in Other Than Oil and Gas Industry Wellbores)	\$6,533.00
(45) Tracer Studies (Used in Oil and Gas Industry Wellbores)	\$3,942.00
(46) Waste Processing-Class I Exempt	\$3,830.00
(47) Waste Processing-Class I	\$39,959.00
(48) Waste Processing-Class II	\$94,661.00

Category of License	Fee
(49) Waste Processing-Class III	\$273,800.00
(50) Well Logging	\$3,942.00
(51) Other Specific License	\$1,987.00
(52) Additional Authorized Use Sites Where Radioactive Material Is Stored Or Used Under Same License Or Where Only Records Are Stored	25% of Applicable Fee Not To Exceed 50 Additional sites
(53) Reciprocity	Fee of Applicable Category

Category of Machine/Type of Use	Fee
(1) Computerized Tomography (CT)	\$1,656.00
(2) Fluoroscopy	\$816.00
(3) Accelerator, Simulator, or Other Therapeutic Radiation Machine	\$586.00
(4) Radiographic Machines Only	\$517.00
(5) Podiatric Radiographic Only	\$374.00
(6) Dental Radiographic Only	\$330.00
(7) Veterinary, Including CT, Fluoroscopy, and Accelerators	\$264.00
(8) Industrial Radiography	
(A) Fixed Facility	\$1,702.00
(B) Temporary Job Sites	\$2,852.00
(9) Other Industrial	\$575.00
(A) Diffraction	
(B) Computerized Tomography	
(C) Fluoroscopy	
(D) Flash Radiography	
(E) Hand-held Light Intensifying Image Devices	
(10) Morgues and Educational Facilities Utilizing Radiation Machines for Non- human Use, Including CT, Fluoroscopy, and Accelerators	\$575.00
(11) Minimal Threat Radiation Machines as Specified in 25 TAC §289.231(II)(3) of this Title	\$264.00
(A) Cathodoluminescence	
(B) Electron Beam Welding	
(C) Fluorescence X-Ray	
(D) Gauge - X-Ray	
(E) Ion Implantation	
(F) Package X-Ray	
(G) Particle Size Analyzer - X-Ray	
(H) Cabinet X-Ray (Certified)	
(I) Other	

Category of Machine/Type of Use	Fee
(12) Exposure Rate or Dose Measurements performed by a Licensed Medical Physicist as Specified in 25 TAC §289.226(b)(9)	\$253.00
(13) Services as Specified in 25 TAC §289.226(b)(10) (A) Exposure Rate or Dose Measurements (B) Radiation Machine Output Measurements (C) Agency-Accepted Training Courses (D) Calibration (E) Demonstration/Sales (F) Assembly, Installation or Repair (G) Equipment Performance Evaluations on Dental Radiation Machines (H) Provider of Equipment	\$253.00
(14) Laser - Medical/Research/Academic	\$200.00
(15) Laser - Industrial/Services/Entertainment	\$340.00
(16) Reciprocity	Fee of Applicable Category
(17) Additional Authorized Use Location Where Radiation Machines or Services are Authorized Under the Same Registration	30% of Applicable Fee

Figure: 25 TAC §289.204(m)

	License Category	New Application	Operational Status	Closure Only	Post-Closure
(a)	Conventional	\$463,096		\$121,859	\$104,023
(b)	In Situ	\$322,633	\$121,859	\$121,859	\$52,012
(c)	Heap Leach	\$325,910			
(d)	Disposal Only	\$374,729	\$121,859	\$121,859	\$104,023