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 fees.

BACKGROUND AND PURPOSE

The department is directed in House Bill (HB) 1, the General Appropriations Act (82nd Legislature, Regular Session, 2011), Rider 59 to evaluate regulatory programs in Consumer Protection Services, which includes the Radiation Control Program, to determine whether new fees can be assessed or existing fees increased in order to equal or exceed the appropriations to these programs and the associated "other direct and indirect costs" appropriated in this Act. The department collects fees to recover the costs of implementing the radiation control regulatory program, in accordance with Health and Safety Code, §401.301(b), and is directed to recover 100% of those regulatory costs but not to exceed actual expenses. It is also authorized to collect fees under §401.302 from each nuclear reactor or other fixed nuclear facility in the state that uses special nuclear material.

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 costs above revenue for the specific program; and the cost of impacted permits compared to other similar permits.

Additional costs of administration and enforcement of the program, were also evaluated to determine the direct and indirect costs imposed on the Licensing, Inspection, Incident and Investigation, Policy/Standards/Quality Assurance (PSQA), and Enforcement Programs due to a United States Nuclear Regulatory Commission (NRC) mandated implementation of increased controls (IC) requirements in June 2006, for all licensees that possess risk-sensitive quantities of radioactive material, resulting in a significant increase in direct and indirect costs and program workloads. As an agreement state, Texas must adopt rules that are compatible with the NRC. The following criteria and tasks were evaluated to determine what increase in fees would be necessary to recover 100% of the additional time required and increased costs incurred by the affected department program areas: Entire Radiation Program to draft and obtain approval for new regulations that had to be compatible with NRC requirements; Radiation Program to review, comment and prepare for additional rules and requirements being developed by the NRC; Licensing Program to provide guidance to all affected licensees; draft appropriate license conditions, amend affected licenses and mail amended licenses; Inspection Program to conduct and document separate and ongoing inspections to establish compliance with the IC regulations

for source security, the completion of personnel background checks and fingerprinting requirements for materials users, and for the protection of sensitive information from unauthorized access; Inspection Program to complete pre-licensing inspections; Licensing Program to complete verifications in NRC's National Source Tracking System; Inspection Program to complete pre-licensing security inspections; Incident and Investigation Program to investigate complaints and incidents involving the use or storage of risk-sensitive quantities; PSQA to process and review the IC reports, mail compliance correspondence, and refer significant violations to the Enforcement Unit with a proposal to assess administrative penalties; and Enforcement Unit to evaluate individual situations, draft and mail preliminary reports, schedule and conduct informal conferences with licensees, and draft and mail agreed orders.

The amendment increases the fees for certification of mammography systems and mammography machines used in interventional breast radiography to be commensurate with comparable United States Food and Drug Administration (FDA) fees.

The rule revision increases the fees for mammography accreditation to reflect an increase in the amount the American College of Radiology charges the department to perform image reviews.

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). Section 289.204 has been reviewed and the department has determined that the reasons for adopting this section continues to exist because a rule on this subject is needed.

SECTION-BY-SECTION SUMMARY

Amendments to §289.204 contain increases in fees for radioactive material licenses, evaluation of a sealed source and/or device, certification of mammography systems and mammography machines used for interventional breast radiography, accreditation of mammography facilities, and certificates of registration. In addition, the fees in §289.204(e) - (g) and (j) have been adjusted for administrative convenience.

The $5,920 fee contained in §289.204(e) for a two-year sealed neutron generator target radioactive material license is a 191.75% fee increase to recover department costs for the extensive time required for the technical review of additional requirements placed on neutron generators which is a category of radioactive material license that is comparable to the well logging license category.

The fees contained in §289.204(e) for radioactive materials licenses are increased by 100% for these categories of license: two-year fee of $1,410 for gauge general license acknowledgement (GLA) and two-year fee of $5,970 for research and development. Including overhead expenses per employee, the entire revenue from GLA fees are currently allocated to the Licensing and GLA Self-Inspection program leaving nothing to cover costs associated with Inspection, PQSA, Incident and Investigation, and Enforcement. The license review for a research and development

license is part of the Advanced Technology Licensing Program and is generally more technically challenging to review and administer, therefore requiring substantial time.

In addition, the fees contained in §289.204(e) for radioactive materials licenses are increased by 50% for these categories of license that must comply with NRC's increased controls requirements: gauge (fixed), industrial radiography (fixed facility and temporary field site), self-contained and unshielded irradiator, medical therapy (sealed and unsealed source), diagnostic nuclear medicine, remote controlled brachytherapy device (includes low dose-rate and high dose-rate remote afterloaders and intravenous brachytherapy), well logging, and other specific licenses, ranging from a two-year fee of $2,980 for an "other specific license" to a two-year fee of $17,870 for an industrial radiography temporary field site license.

The fees contained in §289.204(e) for radioactive materials licenses are increased by 15% for these categories of license: accelerator (used for production of radioactive material), agency-accepted training course (involving possession of radioactive material), bone mineral analyzer, broad license, survey instrument calibration service, calibration/reference source, fixed and mobile decontamination service, demonstration/sales, environmental laboratory, eye applicator, fine leak testing device, fixed multi-beam teletherapy, x-ray fluorescence, hand-held light intensifying imaging device, gas chromatograph, gauge (spinning pipe-thickness/portable), installer, repair, or maintenance, in-vitro use of radioactive material, in-vitro test kit manufacturer, leak test service, manufacturing and commercial distribution (processor of radioactive material, other manufacturing and commercial distribution, commercial distribution only, limited manufacturing for loose material), mineral recovery (byproduct material), mobile scanning service, naturally occurring radioactive material (commercial processing), nuclear pharmacy, pacemaker, pipe joint collar marker, radiopharmaceutical manufacturing, source material, special nuclear material, teletherapy, tracer studies (used in other than oil and gas industry wellbores), and tracer studies (used in oil and gas industry wellbores), ranging from a two-year fee of $1,090 for an in-vitro use of radioactive material license to a two-year fee of $76,930 for a mineral recovery (byproduct material) license.

In §289.204(e), the license fee categories for civil defense and waste processing (Class I exempt, Class I, Class II, and Class III) have been deleted because they are obsolete and/or the department no longer has the authority to regulate.

Fees contained in §289.204(f) for evaluation of a sealed source and/or device are increased by 15%, ranging from $2,660 for an amendment requiring re-evaluation of a sealed source to $10,650 for an initial evaluation of a device. In addition, a new $1,000 record maintenance fee, beginning one year after initial sealed source and device authorization listing and every two years thereafter, is added to §289.204(f)(3).

The fees in §289.204(g) for certification of mammography systems and mammography machines used in interventional breast radiography are increased by 15% for a one-year fee of $2,010 for mammography systems, one-year fee of $490 for mammography machines used in interventional breast radiography, and one-year fee of $240 for each additional machine for mammography systems and mammography machines used in interventional breast radiography.

The fees for accreditation of mammography facilities in §289.204(h)(2)(A) - (C) and (F) are increased to reflect an increase in the amount the American College of Radiology charges the department to perform image reviews. The accreditation fee for the first mammography machine is increased from $980 to $1025. The accreditation fee for each additional mammography machine is increased from $585 to $610. The fee for re-evaluation of clinical images is increased from $305 to $330. The fee for reinstatement of a mammography machine is increased from $585 to $610. A new $330 fee is added in §289.204(h)(2)(H) to recover department costs for the review of clinical images for dual modality mammography machines, if registrants choose to utilize this type of machine. Subsequent subparagraphs are renumbered.

In §289.204(h)(2)(D), the fee for re-evaluation of phantom images is decreased from $340 to $300 because the department no longer performs thermoluminescent dosimeter replacements.

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.

The $1,910 fee contained in §289.204(j) for a two-year certificate of registration for accelerators is reflective of a 225% fee increase to recover department costs for a steady increase in the number of applications and the extensive time required for the technical review of operating and safety procedures and shielding calculations for this category of radiation machine which is a category of radiation machine that is comparable to the computerized tomography radiation machine category.

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, radiographic machines only, industrial radiography, other industrial machines, morgues and educational facilities with machines for non-human use, laser (medical/research/academic and industrial/services/entertainment), and other radiation machine services. The fees for these categories range from a two-year fee of $230 for laser (medical/research/academic) to a two-year fee of $3,280 for industrial radiography temporary job sites.

The fees contained in §289.204(j) for certificates of registration are increased by 10% for these categories of machine type or use: podiatric radiographic only, dental radiographic only, veterinary, and minimal threat machines. The fees for these categories range from a two-year fee of $290 for minimal threat machines to $420 for podiatric radiographic machines.

Section 289.204(m) is deleted and replaced with new language to provide the updated references for electronic payment transactions.

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 approximately $1,392,776 in 2012 and approximately $2,089,165 in 2013 through 2016. The department provides the estimated increase in revenue based on the following assumptions: (1) proposed fee increases become effective January 1, 2012; (2) half of the radioactive material licenses and half of the certificates of registration will be billed each year; (3) although the proposed rule includes fee increases for mammography certification and accreditation, these fees are dedicated general revenue which means that the fees collected will remain with the department; (4) although the proposed rule decreases the mammography accreditation fee for re-evaluation of phantom images, this fee is dedicated general revenue which means that the fees collected will remain with the department; and (5) proposed rule does not include increases for industrial radiographer certification and exam administration because these fees are not assessed on a two-year basis like the other licenses and certificates of registration issued by the department and the fees collected from these regulatory efforts are not necessarily recurring. These additional revenues will ensure the department is recovering 100% of regulatory costs to continue implementation of the Radiation Control Program. 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 will be adverse economic impact to small businesses, micro-businesses, or persons required to comply with the section as proposed. The impact will be the same as for larger businesses listed in the Section-By-Section Summary and will range from 10-225% increase in fees depending on the type of radioactive material license or certificate of registration. As a general rule, small and micro-businesses will possess radioactive material licenses, certification of mammography systems and mammography machines used for interventional breast radiography, accreditation of mammography facilities, certificates of registration, and/or request evaluation of a sealed source and/or device, expected to increase in the 10-50% range.

IMPACT ON LOCAL EMPLOYMENT

There is no anticipated negative impact on local employment.

REGULATORY FLEXIBILITY ANALYSIS

HB 1, the General Appropriations Act, Rider 59 directs the department to evaluate regulatory programs in Consumer Protection Services, which includes the Radiation Control Program, to determine whether new fees can be assessed or existing fees increased in order to equal or

exceed the appropriations to these programs and the associated "other direct and indirect costs" appropriated in this Act. Rider 59 directs the department to adopt rules to implement the provisions of the bill. The department collects fees to recover the costs of implementing the radiation control regulatory program, in accordance with Health and Safety Code, §401.301(b), and is directed to recover 100% of those regulatory costs but not to exceed actual expenses. To allow exceptions to the fees for small businesses or micro-businesses would cause the department either to fail to collect 100% of actual regulatory costs or shift a disproportionate burden to larger businesses. Chapter 401 makes no exceptions from the permitting requirements based on business size of the entity. As a general rule, small and micro-businesses will possess radioactive material licenses, certification of mammography systems and mammography machines used for interventional breast radiography, accreditation of mammography facilities, certificates of registration, and/or request evaluation of a sealed source and/or device, expected to increase in the 10-50% range.

Concerning the mammography certification and accreditation fee increases, small businesses or micro-businesses, have to be certified and accredited, per Title 21, Code of Federal Regulations, Part 900, if they choose to provide mammography services. Mammography certification can only be obtained through the department for Texas facilities under the United States Food and Drug Administration, Mammography Quality Standards Act (MQSA) States as Certifiers (SAC) provision. However, mammography accreditation can be obtained through the department or the American College of Radiology. Although the department's accreditation fees are less than those of the American College of Radiology, small businesses or micro-businesses, have the option to obtain mammography accreditation through the American College of Radiology.

Therefore, small businesses or micro-businesses will incur the costs of complying with the fees in §289.204(e) - (h) and (j).

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 section. 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 Barbara J. Taylor, Radiation Group, Policy/Standards/Quality Assurance Unit, Division of Regulatory Services, Environmental and Consumer Safety Section, Department of State Health Services, Mail Code 1987, P. O. Box 149347, Austin, Texas 78714-9347, (512) 834-6770, extension 2010, or by email to BarbaraJ.Taylor@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 Barbara J. Taylor at (512) 834-6770, extension 2010, or BarbaraJ.Taylor@dshs.state.tx.us if you have questions.

LEGAL CERTIFICATON

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

STATUTORY AUTHORITY

The amendment is authorized by HB 1, the General Appropriations Act (82nd Legislature, Regular Session), Rider 59; 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 Health and Safety Code, Chapter 1001. The review of the rule implements Government Code, §2001.039.

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