

**Department of State Health Services  
Agenda Item for State Health Services Council  
October 5, 2006**

**Agenda Item Title:**

Amend 25 TAC §289.204, Rule Relating to Radiation Control Fees for Certificates of Registration, Radioactive Material Licenses, Emergency Planning and Implementation, and Other Regulatory Services (specifically mammography certification and accreditation fees).

**Agenda Number: 3g**

**Recommended Council Action:**

For Discussion Only

For Discussion and Action by the Council

**Background:** Radiation Control 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.

**Summary:** Title 25, Texas Administrative Code, §289.204, is revised to increase the radiation control fees for mammography certification and accreditation. The revision is necessary because the Department of State Health Services (department) is applying to the United States Food and Drug Administration (FDA) to become a certifying body for mammography facilities. Currently, the department has a contract with the FDA for the department to perform inspections. The FDA bills individual facilities for the cost of those inspections. When the department becomes a certifying body, the contract with the FDA will not be extended and fees for performing inspections as well as fees for the certification process will be incorporated into one certification fee paid to the agency by each facility. Increases to the mammography accreditation fees reflect increases to costs charged to the agency for services provided by the American College of Radiology (ACR). The department contracts with the ACR to provide quality assurance reviews of mammography films for accreditation.

**Summary of Stakeholder Input to Date (including advisory committees):** The rule will be made available on the Radiation Control website ([www.dshs.state.tx.us/radiation](http://www.dshs.state.tx.us/radiation)) and Radiation Control stakeholders were provided notification of the proposed rule for their review and comment. The proposed rule was reviewed by the Texas Radiation Advisory Board (TRAB) at the August 19, 2006, meeting in Austin, Texas. The TRAB recommended that the proposed rule be forwarded to the department's State Health Services Council for consideration as a proposed rule.

**Proposed Motion:** Motion to recommend HHSC approval for publication of rules contained in the agenda item # 3g.

**Agenda Item Approved by:** Vicki Cowling

**Presented by:** Cindy Cardwell, 834-6770, ext. 2239 **Title:** Manager, Radiation Group

**Program/Division:** Policy/Standards/Quality Assurance Unit, Environmental & Consumer Safety Section

**Contact Name/Phone:** Cathy Fontaine-834-6688, ext. 2245

**Date Submitted**

8/16/06

## 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, specifically mammography certification and accreditation fees.

#### BACKGROUND AND PURPOSE

The amendment to §289.204 is necessary because the department is applying to the United States Food and Drug Administration (FDA) to become a certifying body for mammography facilities. Currently, the department has a contract with the FDA for the department to perform inspections and the FDA bills individual facilities for the cost of those inspections. When the department becomes a certifying body, the contract with the FDA will not be extended and fees for performing inspections as well as fees for the certification process will be incorporated into one certification fee paid to the department by each facility. In addition, the department has fees for mammography accreditation. Increases to the mammography accreditation fees reflect increases to costs charged to the department for services provided by the American College of Radiology (ACR). The department contracts with the ACR to provide quality assurance reviews of mammography films for accreditation. Additional costs of administration and enforcement of the program, due to a recent legislative increase in pay, longevity pay, and travel reimbursement, were also included in the evaluation to determine the direct and indirect costs of each program.

#### SECTION-BY-SECTION SUMMARY

In §289.204(b)(1)(C), the amendment changes references to §289.230 (relating to Certification of Mammography Systems and Mammography Machines Used for Interventional Breast Radiography) to state the correct title of the rule being cited, and adds reference to §289.234 (relating to Mammography Accreditation) to appropriately reflect a new rule section. Amendments to §289.204(g) clarify the subsection title and add language stating that no application will be accepted for filing or processed prior to payment of the full amount specified. Section 289.204(g)(1) reflects changes in the fees charged to a facility for certification. Currently a facility pays a \$422 certification fee to the department and a \$1,749 inspection fee to the FDA for a total of \$2,171. When the department becomes a certifying body, fees for performing inspections as well as fees for the certification process will be incorporated into one certification fee of \$1,745 paid to the department by each facility. Certifications with more than one machine (system) on the same certification will be charged an additional \$204 for each additional machine. Section 289.204(g)(2) changes the annual fee to \$1,745 with an additional charge of \$204 for each additional machine on the certification.

Language is added to §289.204(g)(3)(A) to clarify that the fee for mammography machines used for interventional breast radiography is \$422. Certifications with more than one interventional breast radiography machine on the same certification will be charged an additional \$204 for each additional machine. In §289.204(g)(3)(B), the annual fee for mammography machines used for interventional breast radiography is \$422 with an additional \$204 charged for each additional machine on the certification.

In §289.204(h)(2)(A)-(B), the cost of quality assurance reviews of mammography films by the ACR is increasing. The accreditation fee will increase from \$880 to \$980 for the first machine. The fee for each additional machine will increase from \$490 to \$585. Other fees charged by the ACR are also increasing. In §289.204(h)(2)(C), the fee for re-evaluation of clinical images is changing from \$270 to \$305. In §289.204(h)(2)(D), the fee for phantom image review is increasing from \$210 to \$340. The fee for reinstatement of mammography machines in §289.204(h)(2)(F) is changing from \$610 to \$585. Section §289.204(h)(2)(G) reflects a \$5 increase in the amount for processing thermoluminescent dosimeters.

## FISCAL NOTE

Susan E. Tennyson, Section Director, Environmental and Consumer Safety Section, has determined that for each calendar year of the first five years the section is in effect, there will be fiscal implications to the state as a result of enforcing or administering the section as proposed. The effect on state government will be an increase in revenue to the state of \$0 the first calendar year and \$675,262 each year for calendar years two through five due to the increase in certification and accreditation fees. The additional revenue will offset the increased costs associated with assuming the costs of mammography inspections formerly performed under contract with the FDA at a cost of \$530,440, and the legislative increase in pay, longevity pay, and travel reimbursement.

Presently, a facility pays a \$422 certification fee to the department and a \$1,749 inspection fee to the FDA for a total of \$2,171. When the department becomes a certifying body, the contract with the FDA will not be extended and fees for performing inspections as well as fees for the certification process will be incorporated into one certification fee paid to the department by each facility. This fee is \$1,745. In addition, the FDA will charge each facility a \$509 overhead fee for maintaining the national support structure. The total of both fees will be \$2,254 for an increase of \$83 or 3.8% to each facility for certification.

For facilities accredited with the department, fees charged to the department for quality assurance reviews of mammography films for accreditation by the ACR are increasing. The accreditation fee will increase from \$880 to \$980 for the first machine. The fee for each additional machine will increase from \$490 to \$585. The fees for other accreditation services will increase by a range of 11% to 59%.

State and local government entities that are registered with the department for possession of mammography radiation machines will be required to pay the increased certification fee as specified in the rule. All facilities in Texas and state and local government entities have a choice of accrediting with the department or with the ACR.

## 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. There will be an increase in the certification fees for businesses or persons required to maintain a mammography certification from \$422 to \$1,745 per year. Presently, a facility pays a \$422 certification fee to the department and a \$1,749 inspection fee to the FDA for a total of \$2,171. When the department becomes a certifying body, the contract with the FDA will not be extended and fees for performing inspections as well as fees for the certification process will be incorporated into one certification fee paid to the department by each facility. This fee is \$1,745. In addition, the FDA will charge each facility a \$509 overhead fee for maintaining the national support structure. The total of both fees will be \$2,254 for an increase of \$83 or 3.8% to each facility for certification. There will be an increase in the accreditation fees for businesses or persons who choose mammography accreditation with the department. The current accreditation fee of \$880 for the first machine will be increased to \$980. The fee for each additional machine will increase from \$490 to \$585. Facilities in Texas have a choice of accrediting with the department or with the ACR. 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 amended section. The public benefit anticipated as a result of enforcing or administering the section is to generate funding to operate the radiation control mammography and certification programs to ensure continued provision of safe, properly operating mammography systems for patients and 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. This proposal is not specifically intended to protect the environment or reduce risks to human health from environmental exposure.

## 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) 834-6770, extension 2239, or by email to [Cindy.Cardwell@dshs.state.tx.us](mailto: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](http://www.dshs.state.tx.us/radiation)). Please contact Cindy Cardwell at (512) 834-6770, extension 2239, or by email to [Cindy.Cardwell@dshs.state.tx.us](mailto:Cindy.Cardwell@dshs.state.tx.us), if you have questions.

## LEGAL CERTIFICATION

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.

## 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 registrations that it issues; §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 necessary 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 proposed amendment affects the Health and Safety Code, Chapters 12, 401, and 1001; and Government Code, Chapter 531.

LEGEND: (Proposed Amendment)

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 the 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 Mammography Machines Used for Interventional Breast Radiography), **[§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 of this title (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 of this title (relating to Radiation Control Regulations for Radiation Machines Used in Veterinary Medicine), §289.234 of this title (relating to Mammography Accreditation), 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) - (f) (No change.)

(g) Fees for certification of mammography systems and mammography machines used for interventional breast radiography. No application will be accepted for filing or processed prior to payment of the full amount specified in paragraph (1) of this subsection.

(1) An application for certification of mammography systems shall be accompanied by a nonrefundable fee of \$1,745 [**\$422 for each unit**]. Additional mammography systems that have not been assigned a separate United States Food and Drug Administration (FDA) identification number shall be authorized on the same certification. A nonrefundable fee of \$204 for each additional mammography system on the same certification shall be included in the nonrefundable application fee.

(2) The annual fee for mammography systems is \$1,745 [**\$422 for each unit**]. A fee of \$204 for each additional mammography system on the same certification shall be included in the annual fee.

(3) Fees for mammography machines used for interventional breast radiography shall be as follows:

(A) An application for certification of machines used for interventional breast radiography shall be accompanied by a nonrefundable fee of \$422. A nonrefundable fee of \$204 for each additional machine used for interventional breast radiography on the same certification shall be included in the nonrefundable application fee.

(B) The annual fee for machines used for interventional breast radiography is \$422. A fee of \$204 for each additional machine used for interventional breast radiography on the same certification shall be included in the annual fee.

(h) Fees for accreditation of mammography facilities.

(1) (No change.)

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

(A) The accreditation fee for the first mammography machine is \$980 [**\$880**].

(B) The accreditation fee for each additional mammography machine is \$585 [**\$490**].

(C) The fee for re-evaluation of clinical images due to failure during the accreditation process is \$305 [**\$270**] per mammography machine.

(D) The fee for re-evaluation of phantom images due to failure during the accreditation process is \$340 [**\$210**] per machine.

(E) (No change.)

(F) The fee for reinstatement of a mammography machine is \$585 [**\$610**].

(G) The fee for replacement of thermoluminescent dosimeters (TLD) is \$75 [**\$70**].

(H) - (J) (No change.)

(i) - (p) (No change.)