

Title 25. Health Services
Part 1. Department of State Health Services
Chapter 289. Radiation Control
Subchapter E. Registration Regulations
Repeal §289.227
New §289.227

Proposed Preamble

The Executive Commissioner of the Health and Human Services Commission, on behalf of the Department of State Health Services (department), proposes the repeal of §289.227 and new §289.227, concerning the use of radiation machines in the healing arts.

BACKGROUND AND PURPOSE

The repeal and new §289.227 are the result of extensive revisions made throughout the section, reorganization of current requirements, and the addition of new requirements generated during six draft revisions involving stakeholder input. More specifically, this proposal undertakes to: add definitions for fluoroscopically-guided interventional procedures and reference levels; revise the kilovolt peak half-value layer table; change the requirements for calibration of the dosimetry system used to measure radiation output; add requirements for the development of a radiation protocol committee for facilities that perform fluoroscopically-guided interventional procedures; add requirements for the development of a radiation safety awareness training program for the use of fluoroscopy radiation machines; add requirements for the development of a radiation protocol committee for facilities that perform computed tomography procedures; require an equipment performance evaluation at installation and re-installation of radiation machines; revise equipment performance evaluation intervals; change record keeping intervals; add new record retention requirements; correct rule citation references; and update terminology to be consistent with and reflect current technology.

The department determined these new requirements should be put in place because of the increased incidence of radiation over-exposures in other states resulting from the improper use in the healing arts of fluoroscopy and computed tomography radiation machines. In so doing, the department is taking a proactive approach by requiring, among other things, that users of these machines receive radiation safety training specific to these machines and procedures so that the risk of dangerous and unnecessary radiation over-exposures is reduced in connection with performing fluoroscopically-guided interventional procedures and computed tomography procedures.

Government Code, §2001.039, requires that each state agency review and consider for re-adoption each rule adopted by that agency pursuant to the Government Code, Chapter 2001 (Administrative Procedure Act). Section 289.227 has been reviewed and the department has determined that the reasons for adopting this section continues to exist because of the continuing

and increasing need to employ radiation safety procedures in connection with the use of radiation machines in the healing arts.

SECTION-BY-SECTION SUMMARY

New §289.227(b)(4), concerning the Health Insurance Portability and Accountability Act (HIPAA) of 1996, 45 Code of Federal Regulations (CFR), Parts 160 and 164, informs users of radiation machines for the healing arts that full compliance shall be achieved concerning privacy standards under HIPAA.

New §289.227(e)(36), a definition for "Fluoroscopically-Guided Interventional Procedures" describes when a new rule requirement for a radiation protocol committee is triggered and includes a list to assist the registrant in identifying some of the procedures that would be considered fluoroscopically-guided interventional procedures.

New §289.227(e)(76), a definition for "Reference level" allows registrants to determine if acceptable image quality can be achieved at a lower radiation output and provides a benchmark for comparison of imaging equipment performance.

Concerning §289.227(k)(4)(A)(i), the kilovolt peak half-value layer table, achieves consistency with 21 CFR, Part 1020.

In reference to §289.227(m)(3)(D)(i), (n)(3)(A)(ii), and (o)(1), the 12-month interval for performance of radiation output measurements, entrance exposure rates, and equipment performance evaluations on computed tomography and fluoroscopy radiation machines, is revised from annually to "not to exceed 14 months" to provide the physicist or facility with sufficient time to permit coordination of this testing with that also required for other types of radiation machines.

New §289.227(i)(14) deletes the requirement for an intercomparison of the dosimetry system to avoid possible inaccurate results.

Section 289.227(m)(9) requires registrants of facilities that perform fluoroscopically-guided interventional procedures to create a radiation protocol committee to establish and implement fluoroscopically-guided interventional protocols to ensure that radiation machine reference levels are set and monitored and that action is taken if the reference levels are exceeded.

New §289.227(m)(9)(E)(iii), which requires that the radiation safety awareness training for physicians performing fluoroscopically-guided interventional procedures be completed within two years from the effective date of the rule, and provides the physicians with sufficient time to complete the training.

After two years, new §289.227(m)(9)(E)(iv) requires physicians to complete the radiation safety awareness training prior to performing fluoroscopically-guided interventional procedures to

ensure that physicians practicing in this area are aware of the safety measures to be implemented for the safe use of radiation machines during these particular procedures.

As a time and cost saving measure, new §289.227(m)(9)(v) allows the 8 hours of Category 1 Continuing Medical Education Unit (CMEU) training in radiation safety awareness to be obtained through web-based online training.

New §289.227(n)(6) requires registrants of facilities that perform computed tomography procedures to create a radiation protocol committee to establish and implement computed tomography system protocols to ensure that radiation machine reference levels are set and monitored and that action is taken if the reference levels are exceeded.

New §289.227(o)(2) requires that an equipment performance evaluation be performed at the time of installation or re-installation for each radiation machine to document that all required parameters of the x-ray system are tested and that the system is operating within established limits.

Throughout new §289.227, minor grammatical and typographical corrections are made, technical terminology is updated, and rule reference citations are corrected and/or updated.

FISCAL NOTE

Susan E. Tennyson, Section Director, Environmental and Consumer Safety Section, has determined that for each year of the first five years that the sections are in effect, there will be no fiscal implications to state or local governments as a result of enforcing and administering the section as proposed. However, there will be fiscal implications to state and local government facilities performing fluoroscopically-guided interventional procedures as these entities, like other registrants/applicants, will be required to comply with the new proposed radiation safety awareness training requirements specified in §289.227(m)(9)(E). The cost of compliance is estimated to range from approximately \$200 to \$3,000 depending on the scope, length and number of attendees of the training program. Also, new proposed §289.227(n)(3)(A)(i) requires state and local government facilities that utilize computed tomography systems to have radiation output measurements performed by a licensed medical physicist within 30 days after initial installation or re-installation at a cost ranging from approximately \$350 to \$640 per computed tomography system. This cost and requirement does not apply to currently installed computed tomography systems unless they are moved and re-installed. In addition, state and local government entities that are registered with the department for possession of radiation machines will be required to pay the cost of an equipment performance evaluation to be performed at the time of installation or re-installation as specified in §289.227(o)(1), ranging from approximately \$95 to \$280 per machine depending on the type of x-ray machine tested. This cost and requirement does not apply to currently installed radiation machines unless they are moved and re-installed.

SMALL AND MICRO-BUSINESS IMPACT ANALYSIS

Ms. Tennyson has also determined that there are anticipated adverse economic costs to small businesses, micro-businesses or persons required to comply with the sections as proposed.

Section 289.227(o)(1) adds a requirement that an equipment performance evaluation be performed at the time of installation or re-installation of each radiation machine. This requirement does not apply to a currently installed radiation machine unless it is moved and re-installed.

A survey soliciting information from various x-ray service companies across Texas, revealed the cost for having an equipment performance evaluation performed at installation or re-installation will range from approximately \$95 to \$280 per machine. The cost is dependent on the type of x-ray machine tested.

New requirements are added to §289.227(m)(9) that require facilities performing fluoroscopically-guided interventional procedures to develop a radiation protocol committee that will review radiation exposures produced during specified procedures, determine if changes can be incorporated to reduce radiation exposures to patients, establish radiation safety awareness training for physicians, and provide a benchmark for comparison of imaging equipment performance.

Small and micro-businesses or persons performing fluoroscopically-guided interventional procedures are required to comply with the new proposed radiation safety awareness training requirements specified in §289.227(m)(9)(E). Licensed physicists with a specialty in diagnostic medical physics were solicited to request information concerning the cost of conducting the proposed training. If small and micro-businesses or persons contract a licensed physicist to conduct the proposed training, the cost will range from approximately \$200 to \$3,000. The cost of the proposed training is dependant on the scope, length and number of attendees of the training program.

Also, new proposed §289.227(n)(3)(A)(i) requires small and micro-businesses or persons, that utilize computed tomography systems, to have radiation output measurements performed within 30 days after initial installation or re-installation. This requirement does not apply to currently installed computed tomography systems unless they are moved and re-installed. A survey soliciting information from various licensed medical physicists across Texas revealed a cost ranging from approximately \$350 to \$640 per computed tomography system.

IMPACT ON LOCAL EMPLOYMENT

There is no anticipated negative impact on local employment.

REGULATORY FLEXIBILITY ANALYSIS

Small and micro-businesses or persons will incur the cost for the proposed radiation safety awareness training specified in §289.227(m)(9)(E) only one time, if the facility chooses to have physicians who are employees and have successfully completed the training conduct the training for new staff, instead of contracting with a non-employee/consultant such as a licensed physicist. In addition, small and micro-businesses or persons that have a licensed physicist employed by their facility, will only incur minimal additional costs to have the on-staff physicist conduct the training. The cost of the proposed training conducted by a contracted licensed physicist is dependent on the scope, length and number of attendees of the training program. As a result, small or micro-businesses or persons has significant control over the training costs.

Properly calibrated instruments are required to measure the radiation output and the equipment performance evaluation testing. The measurements must be performed by a registered/licensed person trained in radiation safety. Therefore, small and micro-businesses or persons will incur the cost of complying with equipment performance evaluation testing performed at the time of installation or re-installation of each machine as specified in §289.227(o)(1).

Proposed §289.227(n)(3)(A)(i) requires the radiation output of a computed tomography system to be measured within 30 days after initial installation or re-installation. It was determined that small and micro-businesses or persons will incur the cost for the following reasons: rule requires regulatory compliance for users of computed tomography system; the required measurements shall be performed by a licensed medical physicist and the department has no regulatory authority over fees assessed by physicists for these services. Also, the new rule requires that the measurements are made by the physicist with properly calibrated instruments that are not normally possessed by the registrant.

PUBLIC BENEFIT

In addition, Ms. Tennyson also has determined that for each year of the first five years the sections are in effect, the public will benefit from their adoption. During the past 20 years, medical exposure to ionizing radiation has increased significantly. The added requirements for facilities to establish a radiation protocol committee and radiation awareness training for users will assure appropriate protocols are established and followed and that quality control is achieved thereby reducing radiation dose to patients and workers. The public benefit anticipated as a result of administering and enforcing these sections is enhanced and continued protection of the public, patients, 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 repeal and new §289.227 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 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 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 repeal and new rule are authorized by 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; as well as 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 this rule implements Government Code, §2001.039.

The repeal and new rule affect the Health and Safety Code, Chapters 401 and 1001; and Government Code, Chapters 531 and 2001.

Section for Repeal.

§289.227. Use of Radiation Machines in the Healing Arts.