

TITLE 25 HEALTH SERVICES
Part 1. DEPARTMENT OF STATE HEALTH SERVICES
Chapter 289. Radiation Control
Subchapter E. Registration Regulations
New §289.226
Repeal §289.226

Proposed Preamble

The Executive Commissioner of Health and Human Services Commission, on behalf of the Department of State Health Services (department), proposes the repeal of §289.226 and new §289.226, concerning the registration of radiation machine use and services.

BACKGROUND AND PURPOSE

This proposal undertakes to correct rule citation references; update terminology to be consistent with current technology; update form names and names of professional boards; clarify that radiation machines used in veterinary medicine are required to have equipment performance evaluations performed; clarify language to differentiate between physician and certified physician; clarify that an entity under the jurisdiction of the federal government is not held to the requirements of this section; add transmission microscopes to the exemption section; and clarify that lasers, laser services, laser hair removal facilities, laser hair removal training programs, and laser hair removal individuals are required to submit separate applications for registration.

The proposal will permit therapeutic radiation machines operating at or above 1 MeV to be energized for purposes of installation and acceptance testing before receiving a certificate of registration; add requirements to apply for and receive a registration for electronic brachytherapy devices; require healing arts screening programs to determine a method for patients to select a physician for follow-up for those who do not have a physician; update the minimum education and training requirements for persons performing radiation machine assembly, installation or repair; and clarify that linear accelerators and healing arts screening procedures shall be registered prior to human use.

In addition, the proposal will clarify that a person providing radiation machine services shall ensure that the person transferring, or having a radiation machine installed, shall have evidence of a completed application for registration or be in possession of a current certificate of registration; require the registrant to notify the department within 30 days of a new use location to be added to the certificate of registration; require providers of radiation machines to maintain a log of machines provided; and prohibit demonstration of radiation machines on humans unless by or under the direction of a practitioner.

The proposal will require the radiation safety officer to review operating and safety procedures at intervals not to exceed 12 months; require an equipment performance evaluation to be performed on radiation machines within 30 days of installation or re-installation; clarify the duties of the physicist when supervising a non-physicist that collects entrance exposure data; allow the option for the request for termination of the certificate of registration to be signed by the radiation safety

officer, owner, or an individual authorized to act on behalf of the registrant; require research using radiation machines on humans to be approved by an Investigational Review Board; extend the interval for reciprocity requests from 1 year to 2 years; and add language to require the retention of records for training and experience of service providers to until termination of registration or 5 years after the individual terminates employment.

In addition, this rule proposal satisfies the four-year review of agency rules in Government Code, §2001.039, which requires that each state agency review every four years its rules and consider for re adoption each rule adopted by that agency pursuant to the Government Code, Chapter 2001 (Administrative Procedure Act). Section 289.226 has been reviewed in its entirety and the department has determined that the reasons for adopting new §289.226 continue to exist.

SECTION-BY-SECTION SUMMARY

Throughout new §289.226 minor grammatical and typographical corrections are made, technical terminology is updated, rule reference citations are corrected and/or updated; and rule text extensively reorganized. In addition, form names and names of professional boards are updated.

Concerning §289.226(b)(11)(G), the phrase "and on machines used in veterinary medicine" is added to clarify that radiation services include completion of equipment performance evaluations on veterinary radiation machines.

Section 289.226(b)(14) and (15) add clarifying language to differentiate between the definition of a "physician" and a "certified physician" for purposes of the rule.

Section 289.226(b)(16) adds language to clarify that an entity under the jurisdiction of the federal government is not held to the requirements of this section.

In reference to §289.226(d)(5), the term "transmission microscopes" is added to include that they are exempt from the requirements of this section.

Concerning §289.226(e)(5), language is added to clarify that a separate application is required for lasers, laser services, laser hair removal facilities, laser hair removal training programs, and laser hair removal individuals.

In reference to §289.226(f)(1)(B), language is added to permit a person to energize an accelerator for purposes of installation and acceptance testing before receiving a certificate of registration.

Because brachytherapy devices are a new radiation therapy technology that is now regulated, §289.226(f)(6) adds requirements for each person having the device to apply for and receive a certificate of registration from the department before using the device on humans.

Wording in §289.226(h)(2)(H)(i) adds requirements for persons performing healing arts screening to establish a method for patients to ensure proper follow-up care if the screening reveals a condition requiring treatment to select a physician if the patient does not already have one to ensure proper follow-up care if the screening reveals a condition requiring treatment.

In §289.226(j)(5)(A)(iii)(I) - (III), a combination of training and experience is added for those with less formal training, but have additional years of supervised experience, to meet registration compliance requirements for the assembly, installation, and repair of radiation machines.

Section 289.226(m)(3) adds language to clarify that registration of the radiation machines is required prior to use.

Wording is added in §289.226(m)(6) to clarify that a person providing radiation machine services shall ensure that the person transferring, or having a radiation machine installed, shall have evidence of a completed application for registration or be in possession of a current certificate of registration.

Section 289.226(m)(7)(A)(iii) adds language to require that the person notify the department within 30 days if a radiation machine is installed at another use location so the department may document the site of the radiation machine and update the certificate of registration accordingly.

Concerning §289.226(m)(12)(B)(i) - (iii), language is added to require that the provider of radiation machines maintain a log of each machine provided to include the date, and name and registration number of the customer.

For health and safety purposes, §289.226(m)(13)(C) adds a requirement that explicitly prohibits demonstration of radiation machines on humans unless performed by or under the direction of a practitioner of the healing arts.

Section 289.226(n)(1)(A) adds language to require that the radiation safety officer review the operating and safety procedures at intervals not to exceed 12 months to ensure the procedures are current and compliant with rule.

For operator and patient safety, new language is added in §289.226(o)(5) to clarify that an equipment performance evaluation shall be performed on all radiation machines within 30 days of installation, re-installation, or after the repair of a component that might affect the radiation output.

Section 289.226(o)(7)(A) - (B) adds language to clarify the duties of the physicist when supervising a non-physicist in connection with the collection of entrance exposure data.

Section 289.226(q)(1)(A) adds language to permit the registrant's radiation safety officer, owner, or an individual authorized to act on behalf of the registrant, to sign a request for termination of the certificate of registration.

Language is added in §289.226(t)(7) to extend from 1 year to 2 years from the date granted, the reciprocal recognition of a registration from another jurisdiction.

Section 289.226(u) adds language to require that any research using radiation machines on humans is to be approved by an Investigational Review Board to comply with Title 45, Code of Federal Regulations (CFR), Part 46 and Title 21, CFR, Part 56.

The retention period for records of training and experience for the figure referenced in §289.226(v)(1) item (A) is extended to, "until termination of registration or 5 years after the individual terminates employment with the facility," so that pertinent records will be available at the time of inspection by the department.

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 government as a result of enforcing and administering the sections as proposed.

SMALL AND MICRO-BUSINESS IMPACT ANALYSIS

Ms. Tennyson also has determined that there will be no adverse economic impact on small businesses or micro-businesses required to comply with the sections as proposed. This is 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.

ECONOMIC COSTS TO PERSONS AND IMPACT ON LOCAL EMPLOYMENT

There are no anticipated costs to persons who are required to comply with the sections as proposed. There is no anticipated negative impact on local employment.

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 adoption of the sections. The public benefit anticipated as the result of enforcing or administering these sections is to ensure continued, enhanced protection of the public, patients, workers, and the environment from unnecessary exposure to radiation by ensuring that the rule is clear and specific.

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.

TAKING IMPACT ASSESSMENT

The department has determined that the proposal 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, TX 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; 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 repeal and new rule affect Health and Safety Code, Chapters 401 and 1001; and Government Code, Chapter 531.

Section for Repeal.

§289.226. Registration of Radiation Machine Use and Services.