

TITLE 25 HEALTH SERVICES
PART 1 DEPARTMENT OF STATE HEALTH SERVICES
CHAPTER 289 RADIATION CONTROL
SUBCHAPTER E REGISTRATION REGULATION

PROPOSED PREAMBLE

The Executive Commissioner of the Texas Health and Human Services Commission (HHSC), on behalf of the Department of State Health Services (DSHS), proposes an amendment to §289.226, concerning Registration of Radiation Machine Use and Services.

BACKGROUND AND PURPOSE

The purpose of the amendment is to correct rule citation references and define registrant responsibilities. Other changes to §289.226 include clarifying rule requirements as suggested by staff and stakeholders and updating terminology. The amendment clarifies qualifications for radiation safety officers (RSOs), requires RSOs to review operating and safety procedures at least annually, and clarifies the service company responsibility to perform equipment performance evaluations on radiation machines within 30 days of installation or repair that affects radiation output. In addition, the amendment adds safety requirements to Operating and Safety Procedures and strengthens the requirements for quality control of digital imaging. Minor editorial changes were made to create less ambiguity within the amendment.

Texas Government Code, §2001.039, requires that each state agency review and consider for re-adoption each rule adopted by that agency pursuant to the Texas Government Code, Chapter 2001 (Administrative Procedure Act). Section 289.226 has been reviewed and DSHS has determined that the reasons for adopting the section continue to exist because a rule on this subject is needed to protect public health and safety and to fulfill DSHS's statutory responsibilities as the state's Radiation Control Agency.

SECTION-BY-SECTION SUMMARY

The term "department" replaces the former term "agency" throughout §289.226 for consistency with the use of "department" in 25 Texas Administrative Code.

Amended §289.226(a)(2) modifies the requirements for the registration of person using radiation machines. Subsection (a)(2)(A) adds a requirement that no person can use a radiation machine unless they have a certificate of registration.

Amended §289.226(b)(11)(B) adds the measurement of air kerma for a machine registered under §289.229 as a service that requires registration as a service company.

Amended §289.226(b)(11)(E) clarifies that any company that must energize a radiation machine for demonstration or sale of radiation machines or image acquisition systems must register as a service company.

Amended §289.226(b)(16) defines the term "veterinary-use" for this section.

Amended §289.226(c)(1) adds a prohibition that no person shall be exposed to useful beam for training, demonstration, or other non-healing arts purposes.

Amended §289.226(c)(3) adds a prohibition that radiation machines must be designated for human-use or veterinary-use but cannot be designated as both, unless performing research or approval is granted by the agency.

Amended §289.226(d)(8) adds an exemption for bone densitometry systems from the requirement to perform equipment performance evaluations.

Amended §289.226(e)(3)(B) adds qualifications for approval of a RSO according to facility types.

Amended §289.226(e)(3)(B)(i)(II) adds qualifications for approval of a non-practitioner to become an RSO.

Amended §289.226(e)(3)(B)(i)(III) adds qualifications for approval of a person to become an RSO without being a licensed practitioner or having radiation machine-related credentials.

Amended §289.226(e)(3)(B)(i)(III)(-a-) adds the list of credentials that a person must have in order to become an RSO without being a licensed practitioner or having radiation machine-related credentials.

Amended §289.226(e)(3)(B)(i)(III)(-b-) adds additional documentation that must be provided to qualify as a non-practitioner RSO without radiation machine-related credentials.

Amended §289.226(e)(3)(B)(ii) requires academic institutions or research and development facilities to have RSOs who are faculty or staff members with a bachelor's degree or higher in a radiation-related field and at least two years of supervised experience in the use of radiation machines.

Amended §289.226(e)(3)(B)(ii)(I) and (II) lists documentation required for §289.226(e)(3)(B)(ii).

Amended §289.226(e)(3)(E) adds stipulation that DSHS may determine that a person, who otherwise meets the RSO requirements of this section, may be unqualified based on the person's regulatory compliance history.

Amended §289.226(e)(5) removes laser, laser services, laser hair removal facilities, laser hair removal training programs, and laser hair removal individuals since these programs have moved to the Texas Department of Licensing and Regulation.

Amended §289.226(e)(7) clarifies the reference for registration fees that can be found at §289.204 of this title.

Amended §289.226(e)(8)(B) clarifies that applications must file an assumed names certificate with the Texas Secretary of State instead of with the county clerk in the county where the business is located.

Amended §289.226(f)(1)(B) adds electronic brachytherapy machines to the list of accelerators that must apply for and receive a certificate of registration before using the machine.

Amended §289.226(f)(5) clarifies documentation and credentials required for registration of accelerators, therapeutic radiation machines, and electronic brachytherapy devices used on humans.

Amended §289.226(h)(2)(G) removes the requirement to provide training data for approval of registration for healing arts screening.

Amended §289.226(h)(3) adds the requirement that screening standards and procedures shall meet national standards such as those recommended by the American College of Radiology or other national standards.

Amended §289.226(i)(2) adds reference to §289.255 of this title for industrial radiographic operations.

Amended §289.226(i)(3) adds that the applicant must receive a certificate of registration from the agency before operating industrial radiographic machines.

Amended §289.226(m)(3) adds electronic brachytherapy machines to the list of machines that require agency approval before using the machine.

Amended §289.226(m)(13)(C) adds that companies who provide demonstrations and sales of radiation machines may never expose individuals to a useful beam except for healing arts purposes and unless such exposure has been specifically and individually ordered by a licensed practitioner of the healing arts.

Amended §289.226(m)(13)(C)(i)-(iii) adds specific examples in which deliberate exposure of humans to the useful beam is strictly prohibited.

Amended §289.226(m)(13)(E) states that a service company that demonstrates radiation machines for healing arts purposes must perform and document machine testing to meet the requirements of §289.227 of this title.

Amended §289.226(n)(1)(A)(i) revises the requirement that RSOs must review the chapter and policies and procedures at an interval not to exceed 12 months to ensure procedures are current and conform with the chapter.

Amended §289.226(n)(1)(A)(ii) adds that RSOs are responsible for the facility's compliance with the rules.

Amended §289.226(n)(1)(E) makes the RSO responsible to ensure corrective actions for violations issued by the agency are implemented to avoid repeat violations.

Amended §289.226(n)(3) adds that the RSO shall make entries of the dosimetry monitoring records from subsection (n)(1)(B) of this section at intervals not to exceed 30 days after receipt of a monitoring report.

Amended §289.226(o)(5)(B) corrects rule citation references.

Amended §289.226(o)(7)(D) adds requirements that a radiation machine must have the entrance exposure re-tested after the machine has been repaired or adjusted by a registered service company.

Amended §289.226(o)(7)(E) adds that the licensed medical physicist (LMP) or service company performing equipment performance evaluations (EPEs) must submit results to the facility within 30 days after completion of testing.

Amended §289.226(o)(7)(E)(i)-(ix) adds documentation that must be included on an EPE report.

Amended §289.226(o)(7)(F) adds that an LMP or service company must maintain records of EPEs according to the length of time the facility is required to maintain records.

Amended §289.226(o)(7)(G)(i)-(ii) adds that dosimetry system available for use must be calibrated by the National Institute for Standards and Technology or by an American Association of Physicists in Medicine Accredited Dosimetry Calibration Laboratory and the calibration must have been completed within the previous 24 months and after any servicing that may have affected the system calibration.

Amended §289.226(t)(1)(C) adds RSO qualifications to the list of documents required for approval of reciprocal recognition of out-of-state certificates of registration.

Amended Figure §289.226(v)(1) to include record retention requirements that are currently in other sections of 25 Texas Administrative Code Chapter 289.

FISCAL NOTE

Donna Sheppard, Chief Financial Officer, has determined that for each year of the first five years that the rule will be in effect, enforcing or administering the rule does not have foreseeable implications relating to costs or revenues of state or local governments.

GOVERNMENT GROWTH IMPACT STATEMENT

DSHS has determined that during the first five years that the rule will be in effect:

- (1) the proposed rule will not create or eliminate a government program;
- (2) implementation of the proposed rule will not affect the number of DSHS employee positions;
- (3) implementation of the proposed rule will result in no assumed change in future legislative appropriations;
- (4) the proposed rule will not affect fees paid to DSHS;
- (5) the proposed rule will not create a new rule;
- (6) the proposed rule will expand an existing rule;
- (7) the proposed rule will not change the number of individuals subject to the rule;
- and
- (8) the proposed rule will not affect the state's economy.

SMALL BUSINESS, MICRO-BUSINESS, AND RURAL COMMUNITY IMPACT ANALYSIS

Donna Sheppard has also determined that there will be no significant adverse economic impact on small businesses, micro-businesses, or rural communities required to comply with the section as proposed. The rule does not impose any additional costs on small businesses, micro-businesses, or rural communities that are required to comply with the rule. The proposed rule will not affect fees to businesses. The proposed rule will not result in additional work for DSHS employees or other public entities.

LOCAL EMPLOYMENT IMPACT

The proposed rule will not affect a local economy.

COSTS TO REGULATED PERSONS

Texas Government Code, §2001.0045 does not apply to this rule because this rule is necessary to protect the health, safety, and welfare of the residents of Texas.

PUBLIC BENEFIT AND COST

Stephen Pahl, Associate Commissioner, Consumer Protection Division, has determined that for each year of the first five years the rule is in effect, the public will benefit from adoption of the section. The public benefit anticipated as the result of enforcing or administering the section 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.

Donna Sheppard has also determined that for the first five years the rule is in effect, there are no anticipated economic costs to persons who are required to comply with the proposed rule.

TAKING IMPACT ASSESSMENT

DSHS 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, do not constitute a taking under Texas Government Code, §2007.043.

PUBLIC COMMENT

Written comments on the proposal may be submitted to Brian Vamvakias, Radiation Unit Manager, Policy, Standards, and Quality Assurance Section, Consumer Protection Division, DSHS, Mail Code 1987, P.O. Box 149347, Austin, Texas 78714-9347; Exchange Building, 8407 Wall Street, Austin, Texas 78754, (512) 834-6655 or by email to CPDRuleComments@dshs.texas.gov.

To be considered, comments must be submitted no later than 31 days after the date of this issue of the *Texas Register*. Comments must be: (1) postmarked or shipped before the last day of the comment period; (2) hand-delivered before 5:00 p.m. on the last working day of the comment period; or (3) emailed before midnight on the last day of the comment period. If last day to submit comments falls on a holiday, comments must be postmarked, shipped, or emailed before midnight on the following business day to be accepted. When emailing comments, please indicate "Comments on Proposed Rule 20R029" in the subject line.

STATUTORY AUTHORITY

The amendment is authorized by Texas Health and Safety Code, Chapter 401 (the Texas Radiation Control Act), which provides for DSHS radiation control rules and regulatory program to be compatible with federal standards and regulation; §401.051, which provides the required authority to adopt rules and guidelines relating to the control of sources of radiation; §401.064, which provides for the authority to adopt rules related to inspection of x-ray equipment; §401.101, providing for DSHS registration of facilities possessing sources of radiation; Chapter 401, Subchapter J, which authorizes enforcement of the Act; and Texas Government Code, §531.0055; and Texas Health and Safety Code, §1001.075, which authorizes the Executive Commissioner of HHSC to adopt rules and policies for the operation and provision of health and human services by DSHS and for the administration of Texas Health and Safety Code, Chapter 1001. The review of the rule implements Texas Government Code, §2001.039, regarding review of existing rules.

The amendment will implement Texas Health and Safety Code, Chapters 401 and 1001; and Texas Government Code, Chapter 531.

The agency hereby certifies that this proposal has been reviewed by legal counsel and found to be a valid exercise of the agency's legal authority.

ADDITIONAL INFORMATION

For further information, please call: (512) 834-6655.