

Title 25. Health Services
Part 1. Department of State Health Services
Chapter 289. Radiation Control
Subchapter D. General
Amendments §§289.201 - 289.202
Subchapter F. License Regulations
Amendments §§289.251 - 289.253 and 289.255 - 289.257

Proposed Preamble

The Executive Commissioner of the Health and Human Services Commission, on behalf of the Department of State Health Services (department), proposes amendments to §289.201 concerning general provisions for radioactive material; §289.202 concerning standards for protection against radiation from radioactive materials; §289.251 concerning exemptions, general licenses, and general license acknowledgements; §289.252 concerning licensing of radioactive material; §289.253 concerning radiation safety requirements for well logging service operations and tracer studies; §289.255 concerning radiation safety requirements and licensing and registration procedures for industrial radiography; §289.256 concerning medical and veterinary use of radioactive material; and §289.257 concerning packaging and transportation of radioactive material.

BACKGROUND AND PURPOSE

Numerous amendments to §§289.201, 289.202, 289.251, 289.252, and 289.255 - 289.257 are necessary to comply with compatibility requirements of the United States Nuclear Regulatory Commission (NRC). The amendments are the result of the NRC's adoption of requirements for: record keeping; general and specific licenses; training and experience; financial assurance; exemptions to training requirements for radiation safety officers, authorized medical physicists, or authorized nuclear pharmacists; and advance notification to Native American tribes of the transportation of certain types of radioactive wastes. Amendments to §289.253 primarily delete well-logging screenout discard requirements which are under the jurisdiction of the Texas Commission on Environmental Quality (TCEQ).

Changes to §289.257(dd) regarding fees assessed for low level radioactive waste (LLRW) shippers are proposed to comply with Senate Bill (SB) 347, 83rd Legislature, Regular Session, 2013, a portion of which is codified at Health and Safety Code, §401.307. This new legislation increases both the maximum and the minimum amounts to be held in the state's total perpetual care account (PCA) for radiation. The cap of the state's PCA was raised from \$500,000 to \$100 million, effective September 1, 2013. When the balance of the state's PCA, to which both the department and the TCEQ now contribute, totals \$100 million, further collection of fees is to be suspended. Among the fees the department collects is a fee of \$10 per cubic foot for LLRW originating in Texas or being shipped into a licensed Texas LLRW disposal facility. These fees are deposited to the department's radiation PCA. If and when the balance of the state's PCA falls to \$50 million or less, this LLRW shippers' fee is to be reinstated. In addition, this shippers' fee is to be suspended from imposition against a party state compact waste generator when the total

of these fees reaches \$500,000, and to be reinstated if and when the total of these fees is reduced to \$350,000 or less.

Senate Bill 347 also added a provision for utilizing PCA funds for first responder training in counties through which transportation of LLRW occurs.

Other amendments to §§289.201 - 289.202, 289.251 - 289.253, and 289.255 - 289.257 update and/or correct: rule citation references; terminology; form names; and minor grammatical, typographical, formatting, language consistency, and unit of measure errors.

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). Sections 289.201 - 289.202, 289.251 - 289.253, and 289.255 - 289.257, have been reviewed and the department has determined that the reasons for adopting these sections continue to exist because rules on this subject are needed.

SECTION-BY-SECTION SUMMARY

The definition in §289.201(b)(21) is revised due to a formatting error in the equation " $(H_E, 50 = \sum_{w_T, H_T, 50})$."...the "50" should be a subscript number instead of regular text as it appears in the TAC.

To maintain rules that are compatible with the NRC, §289.201(b)(115) corrects a rule cross-reference regarding the packaging and transportation rule.

Section 289.202(p) adds clarifying language for site surveys relating to subsurface residual radioactivity and survey record keeping to maintain rules that are compatible with the NRC and, as an agreement state, Texas must adopt them.

Section 289.202(ee) and (jj) corrects rule cross-references regarding the packaging and transportation rule, §289.257, because as an agreement state, Texas must adopt rules compatible to the NRC rules.

Concerning §289.202(ddd)(1)(A), rule references to §289.253 (relating to Radiation Safety Requirements for Well Logging Service Operations and Tracer Studies) and §289.259 (relating to Licensing of Naturally Occurring Radioactive Material) are added to accurately reflect the complete list of rules that are applicable to decommissioning of facilities for license termination.

To maintain rules that are compatible with the NRC, new §289.202(ddd)(2)(B) - (D) and (3)(A)(iv) adds specific requirements for financial assurance, planning, and residual radioactivity relating to radiological requirements for unrestricted use and alternate requirements for license termination.

New §289.202(ddd)(5)(B) adds language to clarify the requirements for minimization of contamination from residual radioactivity during preparation for license termination because as an agreement state, Texas must adopt rules compatible to the NRC rules.

The figure in §289.202(ggg)(5), regarding time requirements for record keeping, was revised to remove the words "Subsection" and "of this subsection" to simplify language and to change the form names from "BRC Form" to "RC Form" to reflect the current Radiation Control program name and to be consistent with form nomenclature used throughout the chapter.

Concerning §289.251(b), rule references to §289.254 (relating to Licensing of Radioactive Waste Processing and Storage Facilities) and §289.260 (relating to Licensing of Uranium Recovery and Byproduct Material Disposal Facilities) are deleted because the regulatory authority for licensing and inspection of low-level waste processing and uranium recovery and disposal was transferred from the department to the TCEQ as a result of SB 1604, 80th Legislative Session, 2007.

To maintain rules that are compatible with the NRC's, new §289.251(e)(3)(A)(i)(II) - (IV) adds exemptions for static elimination devices, ion generating tubes designed for ionization of air, and devices authorized before October 23, 2012, for use under a general license. Clause (i) is subsequently renumbered.

Concerning new §289.251(e)(3)(A)(i)(VI) and (VII), the words "manufactured before December 17, 2007" are added to the exemptions for balances of precision containing tritium and marine compasses containing tritium gas because, as an agreement state, Texas must adopt rules compatible to the NRC rules.

To maintain rules that are compatible with the NRC's, §289.251(e)(3)(A)(i) deletes current subclauses (IV), (VI) and (IX) relating to exemptions for certain items containing radioactive material, specifically, automobile shift quadrants, thermostat dials and pointers, and spark gap irradiators.

New §289.251(e)(3)(A)(i)(IX)(-b-) is added to clarify the requirements for ionizing radiation measuring instruments containing a source of radioactive material used for internal calibration or standardization to maintain rules that are compatible with the NRC's.

New §289.251(e)(3)(A)(iii) adds language to specify that a person shall apply for a specific license in accordance with Title 10, CFR, §32.14, for any person who desires to apply radioactive material to, or to incorporate radioactive material into, the products exempted in subparagraph (A) to be compatible with the NRC rules.

To maintain rules that are compatible with the NRC's, the words "initially transfer for sale or," "initially," and "initial" are added to §289.251(e)(3)(B)(i) relating to the distribution of self-luminous products containing tritium, krypton-85, promethium-147, or radium-226. In addition, language is added to allow for an exception to the rule requirements.

New §289.251(e)(3)(B)(ii) is added to clarify that a licensing requirement for any person who desires to manufacture, process or produce, or initially transfer for sale or distribution self-luminous products containing tritium, krypton-85, promethium-147, or radium-226 shall apply for a specific license to be issued exclusively by the NRC as an item of compatibility with the NRC rules.

Current §289.251(e)(3)(B)(ii) is deleted removing the exemption for articles acquired prior to January 1, 1986, containing less than 0.1 microcuries of radium-226 to maintain rules that are compatible with the NRC's.

The exemption for self-luminous products containing tritium, krypton-85, or promethium-147 used in products for frivolous purposes or in toys or adornments is moved from §289.251(e)(3)(B)(i) to new (e)(3)(B)(iii) because, as an agreement state, Texas must adopt rules compatible to the NRC rules.

Concerning §289.251(e)(3)(C)(i), the words "to the extent" and "health, safety" are added and the word "life" is removed along with the words "from fires or airborne hazards provided that" to clarify the exemption for gas and aerosol detectors containing radioactive material to be compatible with the NRC rules.

References to "§289.252 of this title" are deleted from §289.251(e)(3)(C)(i)(I) and (II), because the regulation of manufacturing, processing, producing, or initially transferring for sale or distribution of gas and aerosol detectors containing radioactive material are exclusive to NRC jurisdiction.

To maintain rules that are compatible with the NRC's, new §289.251(e)(3)(C)(i)(IV) is added to clarify that any person who desires to manufacture, process or produce gas and aerosol detectors containing radioactive material, shall apply for a specific license and certificate of registration to be issued exclusively by the NRC.

New §289.251(e)(3)(D) is added to allow an exemption for certain industrial devices containing radioactive material used for the purpose of detecting, measuring, gauging or controlling thickness, density, level, interface location, radiation, leakage, or qualitative or quantitative chemical composition, or for producing an ionized atmosphere. This addition is made as an item of compatibility with the NRC rules.

The words "manufactured prior to November 30, 2007" are added to §289.251(f)(4)(K)(i) regarding the issuance of a general license for certain items and self-luminous products containing radium-226 because, as an agreement state, Texas must adopt rules compatible to the NRC's.

New §289.251(f)(4)(K)(ii)(IV) and (V) adds requirements for exporting and disposing of certain items and self-luminous products containing radium-226 to maintain rules compatible with the NRC's.

Concerning new §289.251(f)(4)(K)(ii)(VI), language is added to require that a general licensee respond to written requests from the department to provide information relating to the general license for certain items and self-luminous products containing radium-226 as an item of compatibility with the NRC rules.

New §289.252(d)(9) - (12) adds requirements regarding filing an application for specific licenses for distributing and identifying sealed sources and/or devices because, as an agreement state, Texas must adopt rules compatible to the NRC rules. The subsection is subsequently renumbered.

Language is added, deleted and revised in §289.252(j) relating to requirements for specific licenses for commercial distribution of radioactive materials in exempt quantities to clarify that NRC has sole regulatory jurisdiction.

Section 289.252(k) relating to requirements for specific licenses for incorporation of byproduct material or naturally accelerator-produced radioactive material is revised to clarify that NRC has sole regulatory jurisdiction.

To maintain rules compatible with the NRC's, §289.252(l), relating to specific licenses for the manufacture and commercial distribution of devices to persons generally licensed in accordance with §289.251(f)(4)(H) of this title, adds paragraph (1)(F) to specify that a device be registered in the Sealed Source and Device Registry.

To be compatible with the NRC rules, the words "or initial transfer" and "or initially transfer" are added in §289.252(m) to clarify the licensing requirements of luminous safety devices containing tritium or promethium-147 for use in aircraft. In addition, the word "commercial" is removed and a rule reference to Title 10, CFR, §32.101, is deleted.

Concerning §289.252(n) and (n)(1), the words "or initial transfer" and "or initially transfer" are added; the term "plutonium" is deleted; and a reference to Title 10, CFR, §32.102, is deleted to be compatible with the NRC rules.

To maintain rules that are compatible with the NRC's, §289.252(n)(2) adds the word "finger" before "pressure" and "filter" before "paper", to provide more specific dry wipe test requirements for calibration sources containing americium-241 or radium-226. In addition, language is deleted regarding the criteria to deem a source to be leaking and therefore not transferrable, and is replaced with language that clarifies that a leaking source shall be rejected and not transferred.

New §289.252(o), relating to specific licenses for the manufacture and commercial distribution of sealed sources or devices containing radioactive material for medical use, adds paragraph (5) to specify that the device be registered in the Sealed Source and Device Registry as an item of compatibility with the NRC rules.

To maintain rules that are compatible with the NRC's, §289.252(q), relating to specific licenses for the manufacture and commercial distribution of ice detection devices, deletes a reference to Title 10, CFR, §32.103.

Section 289.252(v) deletes current language and replaces it with new paragraphs (1) - (10) to incorporate requirements for the regulation of sealed source or device evaluations and registration, including: the request for evaluation; evaluation criteria; safety properties; issuance

of the registration; calibration limits; training and experience; the possibility of an additional review; and inactivation of the registration to maintain rules that are compatible with the NRC's.

New §289.252(x)(3) adds application requirements for the transfer of a specific license to include the identity, technical and financial qualifications of the proposed transferee, and financial assurance for decommissioning information required by subsection (gg) of this section, because as an agreement state, Texas must adopt rules compatible with the NRC rules. The subsection is subsequently renumbered.

To maintain rules that are compatible with the NRC's, §289.252(gg)(4), relating to financial assurance and record keeping for decommissioning, adds new subparagraphs (A) and (B) to provide specific instructions relating to each decommissioning funding plan.

Section 289.253(u)(3) deletes the requirement regarding leak testing of sealed sources relating to tracer studies, specifically discarding well-logging screenouts into Class II disposal wells, because this requirement became the jurisdiction of TCEQ in 2007.

The requirements for individual monitoring during industrial radiographic operations is revised in §289.255(p)(2)(A) because as an agreement state, Texas must adopt rules compatible with the NRC rules.

Concerning §289.255(u)(5)(A), language is added to specify how a copy of the American National Standards Institute, ANSI N432-1980, may be purchased to maintain rules that are compatible with the NRC's.

To maintain rules that are compatible with the NRC's, the phrase "the effective date of this rule" is replaced with "October 24, 2002" in §289.256(l)(1), to accurately reflect the beginning date for the training requirement exemption for a Radiation Safety Officer (RSO), a teletherapy or medical physicist, or a nuclear pharmacist who holds a specific license or permit.

New §289.256(l)(2) adds a training exemption for RSOs, authorized medical physicists, or authorized nuclear pharmacists who hold a specific license or permit obtained between October 24, 2002, and April 29, 2005, as an item of compatibility with the NRC. The subsection is subsequently renumbered.

New §289.256(x)(5) is added to allow an exemption for licensees restricted to only unit doses prepared for the manufacture and distribution of radiopharmaceuticals from certain unit dose determinations to correct an inadvertent deletion of this requirement during the 2011 revision of this section.

To maintain rules that are compatible with the NRC rules, §289.256(jj)(2) is deleted removing training and experience requirements for the use of positron emission tomography radionuclides in imaging and localization studies. The subsection is subsequently renumbered.

Section 289.256 is revised to incorporate and modify classroom and laboratory training requirements that are designated as items of compatibility with the NRC and, as an agreement

state, Texas must adopt them. Revisions are reflected in new §289.256(jj)(3)(A)(v) and current (nn)(2)(A)(v), (oo)(3)(A)(v), (pp)(3)(A)(v), (qq)(4)(A)(v), (zz)(2)(A)(iv), (aaa)(2)(A)(iv), and (ttt)(2)(A). The revisions do not create additional training requirements for licensees but clarify existing requirements.

Concerning §289.256(pp)(1) the word "or" is added to clarify the requirements for the training of physicians regarding the oral administration of sodium iodide I-131 in quantities greater than 33 millicuries requiring a written directive because, as an agreement state, Texas must adopt rules compatible with the NRC rules.

To maintain rules that are compatible with the NRC's, the word "and" is added to §289.256 (jjj)(1)(A) to clarify the requirements for full calibration measurements on teletherapy units for medical use.

Changes to the figure in §289.256(www) add a record keeping requirement to keep procedures for administrations requiring a written directive until termination of the license and a 3-year record keeping requirement for the calibration of survey instruments that were previously omitted; correct a rule cross reference; and delete the record name "Physical inventory for all sealed sources received, possessed, and transferred" because the rule does not require a record to be made and maintained; and change the record name "Sealed source/brachytherapy inventory" to "Physical inventory for all sealed source/ brachytherapy inventory" to accurately reflect the name of the record to be made and maintained.

Concerning new §289.257(d)(22) and (40), the definitions for "Indian tribe" and "Tribal official" are added to maintain rules that are compatible with the NRC's. Subsequent definitions are renumbered.

New §289.257(d)(30) revises the definition of "NRC Forms 540, 540A, 541, 541A, 542, and 542A" to allow licensees the option to include additional information deemed relevant to the licensees shipment of LLRW.

Concerning new §289.257(q)(2), a requirement is added for advance notification to Native American tribes of the transportation of certain types of radioactive waste within or across the boundary of the Tribe's reservation. This requirement is added to maintain rules that are compatible with the NRC's. The subsection is subsequently renumbered.

To maintain rules that are compatible with the NRC rules, new §289.257(q)(3) deletes the words "Advance notification is required in accordance with this section for shipment of irradiated reactor fuel in quantities less than that subject to advance notification requirements of Title 10, CFR, §73.37."

New §289.257(q)(4)(A)(ii) and (iii) are added to specify that the office of each appropriate Tribal official or Tribal official's designee and the Director, Division of Security Policy, Office of Nuclear Security and Incident Response shall be provided advanced written notification of the transport of irradiated reactor fuel and certain radioactive wastes to maintain rules that are compatible with the NRC rules.

As an item of compatibility with the NRC, new §289.257(q)(4)(C) and (q)(6) add the words "or the Tribal official or Tribal official's designee" to the delivery notification timeframe requirements and the telephone notification requirements of any changes to the scheduling of the transport.

The words "of governor's designees and Tribal official's designees of participating Tribes" are added to new §289.257(q)(4)(C)(ii) for clarification regarding the list of persons to be notified that is published annually in the Federal Register to maintain rules that are compatible with the NRC's.

To maintain rules that are compatible with the NRC rules, wording is added to new §289.257(q)(4)(C)(iii) to include the names and mailing addresses of the Tribal official's designees of participating Tribes along with the governor's designees and to specify the appropriate contact office information for obtaining the listing.

New §289.257(q)(5)(D) adds the words "or Tribal reservation" to clarify the information to be provided for each advance notification of shipment of irradiated reactor fuel or radioactive waste to maintain rules that are compatible with the NRC's.

Wording is added to new §289.257(q)(7)(A) to include "each Tribal official or Tribal official's designee previously notified, and to the Director, Division of Security Policy, Office of Nuclear Security and Incident Response" to the notification requirements of any cancellations of an irradiated reactor fuel or radioactive waste shipment as an item of compatibility with the NRC.

To comply with SB 347, which includes amendments to Health and Safety Code, §401.052 and a new provision, Health and Safety Code, §401.307, the language in §289.257(dd) regarding LLRW shippers' fees has been changed in several respects. First, §289.257(dd)(1)(C) is amended to clarify that money deposited in the PCA shall also be used for first responder training in counties through which transportation of LLRW occurs.

Second, new §289.257(dd)(1)(D) is added to specify that fees for LLRW shipments shall not be collected on waste disposed of at a federal waste disposal facility in compliance with Health and Safety Code, §401.052(d)(5).

Third, to comply with new Health and Safety Code, §401.307(a), revisions to §289.257(dd)(2) change the PCA cap from \$500,000 to \$100 million and change the PCA balance from \$350,000 to \$50 million or less.

Fourth, new §289.257(dd)(3) is added to allow the suspension of LLRW shippers' fee assessments from imposition against a party state compact waste generator when the amount of such fees in the PCA reaches \$500,000 and reinstates those fees when the amount of such fees in the PCA is reduced to \$350,000 or less, in order to comply with Health and Safety Code, §401.307(d). The subsection is subsequently renumbered.

Fifth, in order to comply with Health and Safety Code, §401.307(e), new §289.257(dd)(6) is added to clarify that this subsection does not relieve a generator from liability for a transportation accident involving LLRW.

The figure in §289.257(ee)(6) is revised to correctly reflect the specific activity for Tellurium-132 in terabecquerels per gram. The related footnote "b" for the table is also revised to change the rule reference from "(ff)(1)" to "(ee)(1)."

Sections 289.201 - 289.202, 289.251 - 289.253, and 289.255 - 289.257, also are revised to include changes which update and/or correct: rule citation references; terminology; form names; and minor grammatical, typographical, formatting, language consistency, and unit of measure errors.

FISCAL NOTE

Jon Huss, Section Director, Environmental and Consumer Safety Section, has determined that for each year of the first five years that §§289.201 - 289.202, 289.251 - 289.253, and 289.255 - 289.257 are in effect, there will be no fiscal implications to state or local governments as a result of enforcing and administering the sections as proposed.

SMALL AND MICRO-BUSINESS IMPACT ANALYSIS

Mr. Huss also has determined that there will be no adverse economic impact on small businesses or micro-businesses required to comply with §§289.201 - 289.202, 289.251 - 289.253, and 289.255 - 289.257 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 §§289.201 - 289.202, 289.251 - 289.253, and 289.255 - 289.257 as proposed. There is no anticipated negative impact on local employment.

PUBLIC BENEFIT

In addition, Mr. Huss 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 proposed amendments 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 Chuck Flynn, 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 2821, or by email to Chuck.Flynn@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 Chuck Flynn at (512) 834-6770, extension 2821, or Chuck.Flynn@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 amendments are authorized by Health and Safety Code, §401.052, which allows the department to collect fees from shippers for shipments of low-level radioactive waste originating in Texas or out-of-state to a Texas low-level radioactive waste disposal facility; Health and Safety Code, §401.051, which provides the required 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 rules implements Government Code, §2001.039.

The amendments affect Health and Safety Code, Chapters 401 and 1001; and Government Code, Chapter 531.