

**Department of State Health Services**  
**Council Agenda Memo for State Health Services Council**  
**June 25, 2009**

**Agenda Item Title:** Amendments to rules concerning general provisions for radioactive material; radiation notices, instructions, reports to workers, and inspection protocol; exemptions, general licenses, and general license acknowledgements; and licensing of radioactive material

**Agenda Number: 4f**

**Recommended Council Action:**

For Discussion Only

For Discussion and Action by the Council

**Background:** The Radiation Control Program (RCP) is in the Division for Regulatory Services and 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. The RCP regulates approximately 1,600 licensees and 16,000 registrants.

The RCP routinely monitors complaints received and resolved, numbers of new and renewed licenses, numbers of disciplinary actions taken, and violation trends. The number of complaints received, enforcement actions, inspections performed, and licensing actions are monitored on a quarterly basis.

The RCP is entirely fee funded from fees charged for licenses and registrations that it issues.

**Summary:** The purpose of the amendments is to ensure continued protection of the public, workers, and the environment from unnecessary exposure to radiation. The proposed amendments will revise the language to comply with the compatibility requirements of the United States Nuclear Regulatory Commission (NRC); clarify program policies and procedures; and update requirements for the notice of violation and Notice to Employees form. The rules comply with the four-year review of agency rules in Government Code, Section 2001.039.

Section 289.201 adds and revises definitions for terminology relating to radioactive materials. These definitions are items of compatibility with the NRC and as an agreement state, Texas must adopt them.

Section 289.203 clarifies requirements for posting of radiation notices, instructions, reports to workers, and inspection protocols for radiological working conditions. The revisions ensure that a radiation worker's exposure information is provided to the worker in a timely manner.

Section 289.251 clarifies exemptions of radioactive materials; adds general licenses for certain items; deletes the general license acknowledgement requirements for expiration and renewal since these acknowledgements will no longer have an expiration date, and modifies the termination requirements for general license acknowledgements.

Section 289.252 adds requirements for license applications; an applicant conducting business in the state; the radiation safety officer and the Radiation Safety Committee to have knowledge of federal and state security measures; license transfers; distribution of radioactive drugs for medical use; storage of radioactive material; and issuance of specific licenses for a medical facility or education institution. The amendment deletes references to rules that have been transferred to the Texas Commission on Environmental Quality (TCEQ) since TCEQ is the regulatory authority for licensing and inspection of low-level waste processing and uranium recovery and disposal.

Program will ensure appropriate licensing and enforcement actions are applied to prevent unnecessary radiation exposure to the public using existing mechanisms such as inspections, compliance verification, and enforcement tools, so continued protection to the public can be maintained.

**Summary of Input from Stakeholder Groups:** The draft rules were made available on the Radiation Control website ([www.dshs.state.tx.us/radiation/draft.shtm](http://www.dshs.state.tx.us/radiation/draft.shtm)). Notification of the availability of the amendments and the opportunity to comment was given to stakeholders and appropriate department staff using email/list servers and the United States Postal Service. No substantive comments were received. The proposed rules were presented to eight members of the Texas Radiation Advisory Board (TRAB) at their June 2009 meeting in Austin, Texas. A quorum was not present but none of the TRAB members present had any objection to the rules going forward to the State Health Services Council for consideration as proposed rules. Of the TRAB members not present, none have objected to the rules going forward.

**Proposed Motion:** Motion to recommend HHSC approval for publication of rules contained in agenda item #4f

**Approved by Assistant Commissioner/Director:** Kathryn C. Perkins, R.N., M.B.A. **Date:** 5/8/09

**Presenter:** Cindy Cardwell, **Program:** Policy/Standards/Quality **Phone No.:** 834-6770  
Manager, Radiation Assurance Unit, Environmental  
Group and Consumer Safety Section

**Approved by CPCPI:** Carolyn Bivens **Date:** 5/08/2009

TITLE 25. HEALTH SERVICES  
Part 1. DEPARTMENT OF STATE HEALTH SERVICES  
Chapter 289. Radiation Control  
Subchapter D. General  
Amendment §289.201  
Amendment §289.203  
Subchapter F. License Regulations  
Amendment §289.251  
Amendment §289.252

Proposed Preamble

The Executive Commissioner of the Health and Human Services Commission on behalf of the Department of State Health Services (department) proposes the amendments of §289.201 concerning general provisions for radioactive material, §289.203 concerning radiation notices, instructions, reports to workers, and inspection protocol, §289.251 concerning exemptions, general licenses, and general license acknowledgements, and §289.252 concerning licensing of radioactive material.

BACKGROUND AND PURPOSE

The amendments to §§289.201, 289.251, and 289.252 are necessary primarily 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 the revision of skin dose limits and requirements for the expanded definition of byproduct material. Other amendments are made to §§289.201, 289.251, and 289.252 to clarify program policies and procedures. The amendments to §289.203 are necessary to incorporate requirements for notice of violation documents that are related to increased control violations and to update the Notice to Employees Form.

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, 289.203, 289.251, and 289.252 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

Section 289.201(b) adds a definition for "consortium" as an association of medical use licensees and a PET radionuclide production facility, since the term is used in §289.252(kk) regarding new requirements for the issuance of specific licenses for a medical facility or educational institution to produce PET radioactive drugs for noncommercial transfer to licensees in its consortium. The definition of "shallow dose equivalent" is revised. These definitions are items of compatibility with the NRC and as an agreement state, Texas must adopt them. In addition, the definition of "residential location" is added to define a term that is used in §289.252(x) regarding specific terms and conditions of licenses.

The reference to the Texas Radiation Control Act is revised to state the complete legal citation in §289.203(a).

The title for the referenced §289.202 rule section is corrected in §289.203(b)(1)(A).

Section 289.203(b)(1)(D) restructures the sentence and adds the words "not been labeled "withhold from public disclosure under Government Code, §552.101," or equivalent phrase, in accordance with §289.252(ii) of this title." to clarify that notices of violation involving radiological working conditions or orders issued relating to increased security controls that have been labeled to withhold from public disclosure, shall not be posted.

The words "shall be posted by each licensee or registrant as required by this section" are deleted at the end of the sentence and subsequently the words, "Each licensee or registrant shall post" are added to the beginning of the first sentence in §289.203(b)(3) to be consistent with sentence structure used in this subsection. The term "Bureau of Radiation Control (BRC)" is deleted and replaced with "RC" to be consistent with the nomenclature for the applicable referenced form.

New language is added to §289.203(d)(2) in order to maintain compatibility with the NRC and to be consistent with language used in the related "Notice to Employees" form.

Section §289.203(i) adds "RC Form 203-1" after "The following form," to be consistent with language used throughout the chapter. In addition, to be consistent with language used throughout the chapter, the Notice to Employees form, referenced as a figure in this subsection, is revised with the following changes: form number now reads "RC Form 203-1;" corrects the department name and address, as applicable, throughout the form; replaces "radiation" with "registration" in item 2 of "YOUR EMPLOYER'S RESPONSIBILITY;" replaces "personnel monitoring" with "individual monitoring devices" in item 3 of "WHAT IS COVERED BY THESE RULES;" corrects the title of §289.202 in item 1 of "REPORTS ON YOUR RADIATION EXPOSURE HISTORY" and in item 2 replaces "personnel monitoring" with "individual monitoring devices" and deletes "is required by" and replaces it with "are provided in accordance with."

Throughout §289.251, references are revised to reflect the renumbering of subsequent subsections due to the deletion of §289.251(k) regarding renewal of general license acknowledgements. Change is reflected in new renumbered §289.251(k) concerning amendment of general license acknowledgements and §289.251(l) concerning appendices. Other typographical and minor grammatical corrections are made throughout the section.

New §289.251(e)(1)(C) adds language to clarify that manufacturers, processors, and producers must have an NRC license to introduce exempt concentrations of radioactive material into a product or material and then distribute it. This is an item of compatibility with the NRC.

Section 289.251(e)(2)(A) adds subparagraphs (D) and (F) to the list of references to state all applicable references for the exemption which is an item of compatibility with the NRC.

In §289.251(e)(2)(B), the words ", or owns" are added after "transfers" to maintain rules that are compatible with NRC.

New §289.251(e)(2)(F) adds the prohibition against combining exempt concentrations of radioactive material to increase the radiation level, except as specified. This is an item of compatibility with the NRC.

In §289.251(e)(3)(A)(i)(I)(-h-), the standard international units are added to be consistent with the format used for units of measure used throughout the chapter and the language is changed to clarify that the exemption applies to intact timepieces. This requirement is an item of compatibility with the NRC.

New §289.251(e)(3)(A)(i)(X) is added to include certain smoke detectors as specified. Smoke detectors were previously exempted under paragraph (3)(C) of this paragraph. Modern smoke detector design is very consistent and doses have been evaluated. Based on this, a product-specific exemption is being added. This is also an item of compatibility with the NRC.

New §289.251(e)(3)(C)(i)(III) is added to clarify that the exemption includes gas and aerosol detectors manufactured or distributed before November 30, 2007 in accordance with a specific license issued by the department with comparable provisions to Title 10, Code of Federal Regulations (CFR), §32.26 to maintain rules that are compatible with NRC and as an agreement state.

Current §289.251(e)(3)(D) is deleted to remove resins containing scandium-46 and designed for sand consolidation in oil wells from the listing of exempt items. The exemption is deleted because it is obsolete. No products are being distributed for use under the exemption. This is also an item of compatibility with the NRC.

Section 289.251(f)(4)(H)(iv)(IX) adds language to allow transfer or disposal of the device containing radioactive material by export in accordance with Title 10, CFR, Part 110. This is also an item of compatibility with NRC.

Concerning §289.251(f)(4)(H)(iv)(XI), language is added to clarify the ability of a specific licensee to transfer radioactive material for possession and use under its own specific license, under certain conditions, without prior approval. This is an item of compatibility with the NRC.

New §289.251(f)(4)(H)(iv)(XIX) adds a requirement to assure that the general license acknowledgement holder comply with information contained in the device safety evaluation.

New §289.251(f)(4)(K) adds requirements for a general license for certain items and self-luminous products containing radium-226 such as antiquities, intact and non-intact timepieces, and luminous items installed in air, marine or land vehicles. These requirements are compatibility items with NRC.

Concerning §289.251(g)(1), 3.7 megabecquerels of radium-226 is added to the list of radioactive material that, if possessed, requires filing an application for acknowledgement. This requirement is a compatibility item with NRC.

Section 289.251(g)(1)(B) adds ", and serial number of the source" after "label" to require that the serial number also be provided to the department.

Clarifying language is added to §289.251(g)(3) to specify that the General License Acknowledgement Form shall be completed in accordance with the instructions contained in the form and that the completed form shall be submitted to the department within 30 days of receipt.

In §289.251(i)(2), language is added to clarify that radioactive material shall not be used or stored in residential locations and that each person holding a GLA issued by the department shall obtain prior approval from the agency before storing or using radioactive material in an area not previously authorized in the GLA.

Concerning §289.251(j), the subsection is revised to delete the requirements for expiration and renewal of GLAs and only address requirements for the termination of GLAs. The department has determined that GLAs will no longer have an expiration date assigned to them and will not require renewal since GLAs are primarily a tracking system.

Current §289.251(k) deletes the requirements for renewal of GLAs as a result of the department's determination that GLAs will no longer have an expiration date and therefore there is no longer a need for GLA renewals. Subsequent subsections are renumbered as reflected in new §289.251(k) and (l).

New §289.251(l)(1) and (l)(2), revises the table of exempt concentrations to state the correct abbreviation of Tantalum (73), Ytterbium (70), and Yttrium (39) and to be compatible with the NRC.

Throughout §289.252, 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. These rules have been repealed as a result of Senate Bill 1604, 80th Legislative Session, 2007, that amended Health and Safety Code, §401.011, and transferred the regulatory authority for licensing and inspection of low-level waste processing and uranium recovery and disposal from the department to the Texas Commission on Environmental Quality (TCEQ). Other typographical, minor grammatical, and rule reference citation corrections are made throughout the section.

Concerning §289.252(d), ", abandoned" is added after "denied" to clarify that the agency has the option to abandon the specific license application in addition to denying or issuing the license.

New §289.252(d)(11) is added to specify that action on a specific license application will be considered abandoned if the applicant does not respond within 30 days from the date of a request for any information by the agency. In addition, the new paragraph clarifies that abandonment of

such actions does not provide an opportunity for a hearing but that the applicant retains the right to resubmit the application in accordance with paragraphs (1) through (7) of this subsection.

Concerning §289.252(e)(9) the department added "and/or used" after "stored" and deleted the word "storage" before "facility" to clarify that the requirement applies to facilities used for storage and/or use of radioactive material.

New §289.252(e)(11) adds a requirement that the applicant be listed on the Texas Secretary of State's website as authorized to conduct business in the state in order for the department to verify this information prior to issuing a license.

New §289.252(f)(3)(O) and (g)(11) respectively, add that a specific duty of the radiation safety officer and the Radiation Safety Committee is to have knowledge of and ensure compliance with federal and state security measures for radioactive material to enhance awareness.

New §289.252(i)(5) adds the prohibition of the introduction of exempt concentrations by all persons except for those authorized by a license issued by NRC. This is an item of compatibility with the NRC.

New §289.252(n)(2) adds a requirement for a dry wipe test on each source containing more than 0.1 microcurie of americium-241 or radium-226 before transferring the source to a general licensee. This is an item of compatibility with the NRC.

Section 289.252(o) adds a reference for calibration, transmission, or reference sources used in medical settings. This requirement is an item of compatibility with the NRC.

Concerning §289.252(p), the standard international units of measure are added to be compatible with the NRC.

Section 289.252(r)(1)(A)(i) is revised to clarify that the applicant provide evidence of being registered with the United States Food and Drug Administration as the owner or operator of a drug establishment that engages in the manufacture, preparation, propagation, compounding, or processing of a drug in accordance with Title 21, CFR, §207.20(a). This requirement is an item of compatibility with the NRC.

New §289.252(r)(1)(A)(iv) adds as an option for the information required for a license, that the applicant provide evidence of operating as a nuclear pharmacy within a federal medical institution. This requirement is an item of compatibility with the NRC.

New §289.252(r)(1)(A)(v) adds as an option for the information required for a license, that the applicant provide evidence that a PET drug production facility be registered with a state agency. This requirement is an item of compatibility with the NRC.

New §289.252(r)(3)(A) - (D) is added to recognize nuclear pharmacists, who prepared only accelerator-produced radioactive drugs, before the effective date of the rule, to work as

authorized nuclear pharmacists at a commercial nuclear pharmacy. This requirement is an item of compatibility with the NRC.

Concerning §289.252(x)(3), language is added to clarify that radioactive material shall not be used or stored in residential locations unless specifically authorized by the agency.

New §289.252(x)(9) is added to require licensees to measure strontium-82 and strontium-85 contamination before use of the first eluate when eluting strontium-82/rubidium-82 generators. This requirement is an item of compatibility with the NRC.

Section 289.252(y)(1) deletes the last sentence of the current paragraph because this statement is addressed in §289.252(y)(2).

New §289.252(ee)(1)(F) is added to specify the documents that out-of-state licensees shall have in their possession at all times when conducting work in Texas and make available for agency review upon request.

Concerning the table for §289.252(jj)(2), Calcium-45 is removed from the list of radionuclides for the 0.1 microcurie limit used for determining financial assurance for decommissioning to maintain compatibility with the NRC.

Concerning footnote 2 to the table for §289.252(jj)(9)(D), the words "with this Order" are deleted after "compliance" as they are not applicable to this statement.

New §289.252(kk) established requirements for issuing specific licenses for a medical facility or educational institution to produce PET drugs for noncommercial transfer within its consortium. Language is added to clarify that nothing in the authorization in accordance with this subsection relieves the licensee from complying with FDA, other federal, or state requirements for radioactive drugs, and includes requirements associated with the labeling and production of PET radioactive drugs by licensees authorized in accordance with this subsection to produce PET radioactive drugs for the noncommercial transfer to medical use licensees in their consortium. This new subsection also requires licensees to use the notification process in §289.252(r) of this title when permitting qualified authorized nuclear pharmacists to work as authorized nuclear pharmacists. These changes are made to maintain rules compatible with the NRC.

#### FISCAL NOTE

Susan E. Tennyson, Section Director, Environmental and Consumer Safety Section, has determined that for each year of the first five-year period that these sections are in effect, there will be no fiscal implications to the state or local government as a result of enforcing and administering the sections as proposed.

#### ECONOMIC IMPACT STATEMENT AND REGULATORY FLEXIBILITY ANALYSIS FOR SMALL AND MICRO-BUSINESSES

Ms. Tennyson has also determined that there will be no adverse economic impact on small businesses or micro-businesses required to comply with §§289.201, 289.203, 289.251, and 289.252 as proposed. This was 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 economic costs to persons who are required to comply with the sections as proposed because the amendments are clarifying in nature and do not impose additional actions on the part of those required to comply. 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 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 ensure continued protection of the public, workers, and the environment from unnecessary exposure to radiation by ensuring that rules are 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.

#### TAKINGS 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 Cindy Cardwell, Radiation Group, Policy/Standards/Quality Assurance Unit, Division of Regulatory Services, Environmental and Consumer Safety Section, Department of State Health Services, MC 1987, P. O. Box 149347, Austin, TX 78714-9347, 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 [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, Deputy 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 proposed amendments 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 rules implements Government Code, §2001.039.

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

Legend: (Proposed Amendment(s))

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 subdivision

§289.201. General Provisions for Radioactive Material.

(a) (No change.)

(b) Definitions. The following words and terms when used in this chapter shall have the following meanings, unless the context clearly indicates otherwise.

(1) - (21) (No change.)

(22) Consortium--An association of medical use licensees and a PET radionuclide production facility in the same geographical area that jointly own or share in the operation and maintenance costs of the PET radionuclide production facility that produces PET radionuclides for use in producing radioactive drugs within the consortium for noncommercial distributions among its associated members for medical use. The PET radionuclide production facility within the consortium shall be located at an educational institution or a medical facility.

(23) [(22)] Constraint (dose constraint)--A value above which specified licensee actions are required.

(24) [(23)] Critical group--The group of individuals reasonably expected to receive the greatest exposure to residual radioactivity for any applicable set of circumstances.

(25) [(24)] Curie (Ci)--A unit of measurement of radioactivity. One curie (Ci) is that quantity of radioactive material that decays at the rate of  $3.7 \times 10^{10}$  disintegrations per second (dps). Commonly used submultiples of the curie are the millicurie (mCi) and the microcurie ( $\mu$ Ci). One mCi =  $1 \times 10^{-3}$  Ci =  $3.7 \times 10^7$  dps. One  $\mu$ Ci =  $1 \times 10^{-6}$  Ci =  $3.7 \times 10^4$  dps. One nanocurie (nCi) =  $1 \times 10^{-9}$  Ci =  $3.7 \times 10^1$  dps. One picocurie (pCi) =  $1 \times 10^{-12}$  Ci =  $3.7 \times 10^{-2}$  dps.

(26) [(25)] Decommission--To remove a facility or site safely from service and reduce residual radioactivity to a level that permits the following:

(A) release of the property for unrestricted use and/or termination of license; or

(B) release of the property under alternate requirements for license termination.

(27) [(26)] Deep dose equivalent ( $H_d$ ), that applies to external whole body exposure--The dose equivalent at a tissue depth of 1 centimeter (cm) (1,000 milligrams per square centimeter ( $\text{mg}/\text{cm}^2$ )).

(28) [(27)] Depleted uranium--The source material uranium in which the isotope uranium-235 is less than 0.711 weight percent of the total uranium present. Depleted uranium does not include special nuclear material.

(29) [(28)] Discrete source--A radionuclide that has been processed so that its concentration within a material has been purposely increased for use for commercial, medical, or research activities.

(30) [(29)] Distinguishable from background--The detectable concentration of a radionuclide is statistically different from the background concentration of that radionuclide in the vicinity of the site, or, in the case of structures or equipment, in similar materials using adequate measurement technology, survey, and statistical techniques.

(31) [(30)] Distribution--The physical conveyance and authorized transfer of commodities from producers to consumers and any intermediate persons involved in that conveyance.

(32) [(31)] Dose--A generic term that means absorbed dose, dose equivalent, effective dose equivalent, committed dose equivalent, committed effective dose equivalent, total organ dose equivalent, or total effective dose equivalent. For purposes of this chapter, "radiation dose" is an equivalent term.

(33) [(32)] Dose equivalent ( $H_T$ )--The product of the absorbed dose in tissue, quality factor, and all other necessary modifying factors at the location of interest. The units of dose equivalent are the sievert (Sv) and rem.

(34) [(33)] Dose limits--The permissible upper bounds of radiation doses established in accordance with this chapter. For purposes of this chapter, "limits" is an equivalent term.

(35) [(34)] Effective dose equivalent ( $H_E$ )--The sum of the products of the dose equivalent to each organ or tissue ( $H_T$ ) and the weighting factor ( $w_T$ ) applicable to each of the body organs or tissues that are irradiated ( $H_E = \sum w_T H_T$ ).

(36) [(35)] Embryo/fetus--The developing human organism from conception until the time of birth.

(37) [(36)] Entrance or access point--Any opening through which an individual or extremity of an individual could gain access to radiation areas or to licensed sources of radiation. This includes portals of sufficient size to permit human access, irrespective of their intended use.

(38) [(37)] Exposure--The quotient of  $dQ$  by  $dm$  where " $dQ$ " is the absolute value of the total charge of the ions of one sign produced in air when all the electrons (negatrons and positrons) liberated by photons in a volume element of air having mass " $dm$ " are completely stopped in air. The SI unit of exposure is the coulomb per kilogram (C/kg). The roentgen is the special unit of exposure. For purposes of this chapter, this term is used as a noun.

(39) [(38)] Exposure rate--The exposure per unit of time.

(40) [(39)] External dose--That portion of the dose equivalent received from any source of radiation outside the body.

(41) [(40)] Extremity--Hand, elbow, arm below the elbow, foot, knee, and leg below the knee. The arm above the elbow and the leg above the knee are considered part of the whole body.

(42) [(41)] Generally applicable environmental radiation standards--Standards issued by the United States Environmental Protection Agency (EPA) under the authority of the Atomic Energy Act of 1954, as amended, that impose limits on radiation exposures or levels, or concentrations or quantities of radioactive material, in the general environment outside the boundaries of locations under the control of persons possessing or using radioactive material.

(43) [(42)] Gray (Gy)--The SI unit of absorbed dose. One gray is equal to an absorbed dose of 1 joule per kilogram (J/kg) or 100 rad.

(44) [(43)] High radiation area--An area, accessible to individuals, in which radiation levels from sources of radiation external to the body could result in an individual receiving a dose equivalent in excess of 0.1 rem (1 millisievert (mSv)) in one hour at 30 cm from any source of radiation or from any surface that the radiation penetrates.

(45) [(44)] Human use--The internal or external administration of radiation or radioactive material to human beings for healing arts purposes or research and/or development specifically authorized by the agency.

(46) [(45)] Individual--Any human being.

(47) [(46)] Individual monitoring--The assessment of:

(A) dose equivalent to an individual by the use of individual monitoring devices; or

(B) committed effective dose equivalent to an individual by bioassay or by determination of the time-weighted air concentrations to which an individual has been exposed, that is, DAC-hours. (See the definition for DAC-hours in §289.202(c) of this title); or

(C) dose equivalent to an individual by the use of survey data.

(48) [(47)] Individual monitoring devices--Devices designed to be worn by a single individual for the assessment of dose equivalent. For purposes of this chapter, "personnel dosimeter" and "dosimeter" are equivalent terms. Examples of individual monitoring devices include, but are not limited to, film badges, thermoluminescence dosimeters (TLDs), optically stimulated luminescence dosimeters (OSLs), pocket ionization chambers (pocket dosimeters), electronic personal dosimeters, and personal air sampling devices.

(49) [(48)] Inspection--An official examination and/or observation including, but not limited to, records, tests, surveys, and monitoring to determine compliance with the Act and rules, orders, requirements, and conditions of the agency.

(50) [(49)] Internal dose--That portion of the dose equivalent received from radioactive material taken into the body.

(51) [(50)] Ionizing radiation--Any electromagnetic or particulate radiation capable of producing ions, directly or indirectly, in its passage through matter. Ionizing radiation includes gamma rays and x rays, alpha and beta particles, high-speed electrons, neutrons, and other nuclear particles.

(52) [(51)] Land disposal facility--The land, buildings, and equipment that are intended to be used for the disposal of low-level radioactive waste (LLRW) into the subsurface of the land.

(53) [(52)] Lens dose equivalent--The external dose equivalent to the lens of the eye at a tissue depth of 0.3 cm (300 mg/cm<sup>2</sup>).

(54) [(53)] License--A form of permission given by the agency to an applicant who has met the requirements for licensing set out in the Act and this chapter.

(55) [(54)] Licensed material--Radioactive material received, possessed, used, or transferred under a general or specific license issued by the agency.

(56) [(55)] Licensee--Any person who is licensed by the agency in accordance with the Act and this chapter.

(57) [(56)] Licensing state--Any state with rules equivalent to the Suggested State Regulations for Control of Radiation relating to, and having an effective program for, the regulatory control of naturally occurring or accelerator-produced radioactive material (NARM) and has been designated as such by the Conference of Radiation Control Program Directors, Inc. For the purposes of evaluation and/or distribution of sealed sources, this includes Licensing State Status: Product Review Only.

(58) [(57)] Lost or missing radioactive material--Radioactive material whose location is unknown. This definition includes licensed material that has been shipped but has not reached its planned destination and whose location cannot be readily traced in the transportation system.

(59) [(58)] Low-level radioactive waste (LLRW)--Radioactive material that meets the following criteria:

(A) LLRW is radioactive material that is:

(i) discarded or unwanted and is not exempt by rule adopted under the Texas Radiation Control Act (Act), Health and Safety Code, §401.106;

(ii) waste, as that term is defined in Title 10, CFR, §61.2; and

(iii) subject to:

(I) concentration limits established in Title 10, CFR, §61.55, or compatible rules adopted by the agency or the Texas Commission on Environmental Quality (TCEQ), as applicable; and

(II) disposal criteria established in Title 10, CFR, or established by the agency or TCEQ, as applicable.

(B) LLRW does not include:

(i) high-level radioactive waste as defined by Title 10, CFR, §60.2;

(ii) spent nuclear fuel as defined by Title 10, CFR, §72.3;

(iii) byproduct material defined in the Act, Health and Safety Code, §401.003(3)(B);

(iv) naturally occurring radioactive material (NORM) waste that is not oil and gas NORM waste;

(v) oil and gas NORM waste; or

(vi) transuranics greater than 100 nanocuries per gram.

(60) [(59)] Manufacture--To fabricate or mechanically produce.

(61) [(60)] Member of the public--Any individual, except when that individual is receiving an occupational dose.

(62) [(61)] Minor--An individual less than 18 years of age.

(63) [(62)] Monitoring--The measurement of radiation, radioactive material concentrations, surface area activities, or quantities of radioactive material and the use of the

results of these measurements to evaluate potential exposures and doses. For purposes of this chapter, "radiation monitoring" and "radiation protection monitoring" are equivalent terms.

(64) [(63)] NARM--Any naturally occurring or accelerator-produced radioactive material except source material or special nuclear material.

(65) [(64)] Natural radioactivity--Radioactivity of naturally occurring nuclides whose location and chemical and physical form have not been altered by man.

(66) [(65)] NRC--The United States Nuclear Regulatory Commission or its duly authorized representatives.

(67) [(66)] Occupational dose--The dose received by an individual in the course of employment in which the individual's assigned duties involve exposure to sources of radiation from licensed/registered and unlicensed/unregistered sources of radiation, whether in the possession of the licensee/registrant or other person. Occupational dose does not include dose received from background radiation, from any medical administration the individual has received, from exposure to individuals administered radioactive material and released in accordance with this chapter, from voluntary participation in medical research programs, or as a member of the public.

(68) [(67)] Particle accelerator--Any machine capable of accelerating electrons, protons, deuterons, or other charged particles in a vacuum and designed to discharge the resultant particulate or other associated radiation at energies usually in excess of 1 MeV.

(69) [(68)] Person--Any individual, corporation, partnership, firm, association, trust, estate, public or private institution, group, agency, local government, any other state or political subdivision or agency thereof, or any other legal entity, and any legal successor, representative, agent, or agency of the foregoing, other than NRC, and other than federal government agencies licensed or exempted by NRC.

(70) [(69)] Personnel monitoring equipment (See definition for individual monitoring devices.)

(71) [(70)] Pharmacist--An individual licensed by the Texas State Board of Pharmacy to compound and dispense drugs, prescriptions, and poisons.

(72) [(71)] Physician--An individual licensed by the Texas Medical Board.

(73) [(72)] Principal activities--Activities authorized by the license that are essential to achieving the purpose(s) for which the license was issued or amended. Storage during which no licensed material is accessed for use or disposal and activities incidental to decontamination or decommissioning are not principal activities.

(74) [(73)] Public dose--The dose received by a member of the public from exposure to sources of radiation released by a licensee, or to any other source of radiation under

the control of a licensee/registrant. It does not include occupational dose or doses received from background radiation, from any medical administration the individual has received, from exposure to individuals administered radioactive material and released in accordance with this chapter, or from voluntary participation in medical research programs.

(75) [(74)] Quality factor (Q)--The modifying factor listed in subsection (n)(1) and (2) of this section that is used to derive dose equivalent from absorbed dose.

(76) [(75)] Quarter (calendar quarter)--A period of time equal to one-fourth of the year observed by the licensee, approximately 13 consecutive weeks, providing that the beginning of the first quarter in a year coincides with the starting date of the year and that no day is omitted or duplicated in consecutive quarters.

(77) [(76)] Rad--The special unit of absorbed dose. One rad is equal to an absorbed dose of 100 ergs per gram (erg/g) or 0.01 J/kg (0.01 gray).

(78) [(77)] Radiation--One or more of the following:

(A) gamma and x rays; alpha and beta particles and other atomic or nuclear particles or rays;

(B) emission of radiation from any electronic device to such energy density levels as to reasonably cause bodily harm; or

(C) sonic, ultrasonic, or infrasonic waves from any electronic device or resulting from the operation of an electronic circuit in an electronic device in the energy range to reasonably cause detectable bodily harm.

(79) [(78)] Radiation area--Any area, accessible to individuals, in which radiation levels could result in an individual receiving a dose equivalent in excess of 0.005 rem (0.05 mSv) in one hour at 30 cm from the source of radiation or from any surface that the radiation penetrates.

(80) [(79)] Radiation machine--Any device capable of producing ionizing radiation except those devices with radioactive material as the only source of radiation.

(81) [(80)] Radiation safety officer (RSO)--An individual who has a knowledge of and the authority and responsibility to apply appropriate radiation protection rules, standards, and practices, who must be specifically authorized on a radioactive material license, and who is the primary contact with the agency. Specific training and responsibilities for an RSO are listed in §289.252 of this title (relating to Licensing of Radioactive Material), §289.253 of this title (relating to Radiation Safety Requirements for Well Logging Service Operations and Tracer Studies), §289.255 of this title (relating to Radiation Safety Requirements and Licensing and Registration Procedures for Industrial Radiography), and §289.256 of this title (relating to Medical and Veterinary Use of Radioactive Material).

(82) [(81)] Radioactive material--Any material (solid, liquid, or gas) that emits radiation spontaneously.

(83) [(82)] Radioactive waste--As used in §289.254 of this title (relating to Licensing of Radioactive Waste Processing and Storage Facilities), this term is equivalent to LLRW.

(84) [(83)] Radioactivity--The disintegration of unstable atomic nuclei with the emission of radiation.

(85) [(84)] Radiobioassay (See definition for bioassay.)

(86) [(85)] Registrant--Any person issued a certificate of registration by the agency in accordance with the Act and this chapter.

(87) [(86)] Regulation (See definition for rule.)

(88) [(87)] Regulations of the United States Department of Transportation (DOT)--The requirements in Title 49, CFR, Parts 100 - 189.

(89) [(88)] Rem--The special unit of any of the quantities expressed as dose equivalent. The dose equivalent in rem is equal to the absorbed dose in rad multiplied by the quality factor (1 rem = 0.01 sievert (Sv)).

(90) [(89)] Research and development--Research and development is defined as:

(A) theoretical analysis, exploration, or experimentation; or

(B) the extension of investigative findings and theories of a scientific or technical nature into practical application for experimental and demonstration purposes, including the experimental production and testing of models, devices, equipment, materials, and processes.

(91) Residential location--Any area where a structure or structures are located in which people lodge or live, and the grounds on which these structures are located including, but not limited to, houses, apartments, condominiums, and garages.

(92) [(90)] Residual radioactivity--The radioactivity in structures, materials, soils, groundwater, and other media at a site resulting from activities under the licensee's control. This includes radioactivity from all licensed and unlicensed sources used by the licensee, but excludes background radiation. It also includes radioactive materials remaining at the site as a result of routine or accidental releases of radioactive material at the site and previous burials at the site, even if those burials were made in accordance with the provisions of Title 30, Texas Administrative Code, §336.334.

(93) [(91)] Restricted area--An area, access to which is limited by the licensee for the purpose of protecting individuals against undue risks from exposure to sources of radiation. Restricted area does not include areas used as residential quarters, but separate rooms in a residential building may be set apart as a restricted area.

(94) [(92)] Roentgen (R)--The special unit of exposure. One roentgen (R) equals  $2.58 \times 10^{-4}$  C/kg of air. (See definition for exposure.)

(95) [(93)] Rule (as defined in the Government Code, Chapters 2001 and 2002, as amended)--Any agency statement of general applicability that implements, interprets, or prescribes law or policy, or describes the procedure or practice requirements of an agency. The term includes the amendment or repeal of a prior section but does not include statements concerning only the internal management or organization of any agency and not affecting private rights or procedures. The word "rule" was formerly referred to as "regulation."

(96) [(94)] Sealed source--Radioactive material that is permanently bonded or fixed in a capsule or matrix designed to prevent release and dispersal of the radioactive material under the most severe conditions that are likely to be encountered in normal use and handling.

(97) [(95)] Shallow dose equivalent ( $H_s$ ) (that applies to the external exposure of the skin of the whole body or the skin of an extremity)--The dose equivalent at a tissue depth of 0.007 cm (7 mg/cm<sup>2</sup>) [**averaged over an area of 1 square centimeter (cm<sup>2</sup>)**].

(98) [(96)] SI--The abbreviation for the International System of Units.

(99) [(97)] Sievert--The SI unit of any of the quantities expressed as dose equivalent. The dose equivalent in sievert is equal to the absorbed dose in gray multiplied by the quality factor (1 Sv = 100 rem).

(100) [(98)] Site boundary--That line beyond which the land or property is not owned, leased, or otherwise controlled by the licensee.

(101) [(99)] Source material--Source material is defined as:

(A) uranium or thorium, or any combination thereof, in any physical or chemical form; or

(B) ores that contain by weight 0.05% or more of uranium, thorium, or any combination thereof; and

(C) does not include special nuclear material.

(102) [(100)] Source of radiation--Any radioactive material, or any device or equipment emitting or capable of producing radiation.

(103) [(101)] Special form radioactive material--Radioactive material that satisfies the following conditions.

(A) It is either a single solid piece or is contained in a sealed capsule that can be opened only by destroying the capsule;

(B) The piece or capsule has at least one dimension not less than 5 millimeters (mm) (0.2 inch); and

(C) It satisfies the requirements specified by NRC. A special form encapsulation designed in accordance with NRC requirements in effect on June 30, 1983, and constructed prior to July 1, 1985, may continue to be used. A special form encapsulation designed in accordance with NRC requirements in effect on March 31, 1996, and constructed prior to April 1, 1998, may continue to be used. A special form encapsulation either designed or constructed after April 1, 1998, must meet the requirements of this definition applicable at the time of its design or construction.

(104) [(102)] Special nuclear material--Special nuclear material is defined as:

(A) plutonium, uranium-233, uranium enriched in the isotope 233 or in the isotope 235, and any other material that NRC, in accordance with the provisions of the Atomic Energy Act of 1954, §51 as amended, determines to be special nuclear material, but does not include source material; or

(B) any material artificially enriched by any of the foregoing, but does not include source material.

(105) [(103)] Special nuclear material in quantities not sufficient to form a critical mass--Uranium enriched in the isotope 235 in quantities not exceeding 350 grams (g) of contained uranium-235; uranium-233 in quantities not exceeding 200 g; plutonium in quantities not exceeding 200 g; or any combination of them in accordance with the following formula.

(A) For each kind of special nuclear material, determine the ratio between the quantity of that special nuclear material and the quantity specified above for the same kind of special nuclear material. The sum of such ratios for all of the kinds of special nuclear material in combination shall not exceed "1" (i.e., unity).

(B) For example, the following quantities in combination would not exceed the limitation and are within the formula:

Figure: 25 TAC §289.201(b)(105)(B) [Figure: 25 TAC §289.201(b)(103)(B)]

(106) [(104)] Special units--The conventional units historically used by licensees, for example, curie (activity), rad (absorbed dose), and rem (dose equivalent).

(107) [(105)] Survey--An evaluation of the radiological conditions and potential hazards incident to the production, use, transfer, release, disposal, and/or presence of sources of radiation. When appropriate, such survey includes, but is not limited to, tests, physical examination of location of materials and equipment, measurements of levels of radiation or concentration of radioactive material present, and evaluation of administrative and/or engineered controls.

(108) [(106)] Termination--A release by the agency of the obligations and authorizations of the licensee under the terms of the license. It does not relieve a person of duties and responsibilities imposed by law.

(109) [(107)] Test--A method of determining the characteristics or condition of sources of radiation or components thereof.

(110) [(108)] Texas Regulations for Control of Radiation (TRCR)--All sections of Title 25 Texas Administrative Code (TAC), Chapter 289.

(111) [(109)] Total effective dose equivalent (TEDE)--The sum of the effective dose equivalent for external exposures and the committed effective dose equivalent for internal exposures.

(112) [(110)] Total organ dose equivalent (TODE)--The sum of the deep dose equivalent and the committed dose equivalent to the organ receiving the highest dose as described in §289.202(rr)(1)(F) of this title.

(113) [(111)] Transport index--The dimensionless number (rounded up to the next tenth) placed on the label of a package, to designate the degree of control to be exercised by the carrier during transportation. The transport index is determined as follows:

(A) For non-fissile material packages, the number determined by multiplying the maximum radiation level in millisievert per hour (mSv/hr) at 1 meter (m) (3.3 feet) from the external surface of the package by 100 (equivalent to the maximum radiation level in millirem per hour (mrem/hr) at 1 m (3.3 feet); or

(B) For fissile material packages, the number determined by multiplying the maximum radiation level in mSv/hr at 1 m (3.3 feet) from the external surface of the package by 100 (equivalent to the maximum radiation level in mrem/hr at 1 m (3.3 feet), or, for criticality control purposes, the number obtained as described in 10 CFR 71.59, whichever is larger.

(114) [(112)] Type A quantity--A quantity of radioactive material, the aggregate radioactivity of which does not exceed  $A_1$  for special form radioactive material or  $A_2$  for normal form radioactive material, where  $A_1$  and  $A_2$  are given in §289.257(ff) of this title (relating to Packaging and Transportation of Radioactive Material) or may be determined by procedures described in §289.257(ff) of this title.

(115) [(113)] Type B quantity--A quantity of radioactive material greater than a type A quantity.

(116) [(114)] Unrefined and unprocessed ore--Ore in its natural form prior to any processing, such as grinding, roasting, beneficiating, or refining.

(117) [(115)] Unrestricted area (uncontrolled area)--An area, or access to, which is neither limited nor controlled by the licensee. For purposes of this chapter, "uncontrolled area" is an equivalent term.

(118) [(116)] Very high radiation area--An area, accessible to individuals, in which radiation levels from sources of radiation external to the body could result in an individual receiving an absorbed dose in excess of 500 rads (5 grays) in one hour at 1 meter (m) from a source of radiation or from any surface that the radiation penetrates. At very high doses received at high dose rates, units of absorbed dose, gray and rad, are appropriate, rather than units of dose equivalent, Sv and rem.

(119) [(117)] Veterinarian--An individual licensed by the Texas State Board of Veterinary Medical Examiners.

(120) [(118)] Waste--Low-level radioactive wastes containing source, special nuclear, or byproduct material that are acceptable for disposal in a land disposal facility. For the purposes of this definition, low-level radioactive waste means radioactive waste not classified as high-level radioactive waste, transuranic waste, spent nuclear fuel, or byproduct material as defined in paragraph (15)(B) - (E) of this subsection.

(121) [(119)] Week--Seven consecutive days starting on Sunday.

(122) [(120)] Whole body--For purposes of external exposure, head, trunk including male gonads, arms above the elbow, or legs above the knee.

(123) [(121)] Worker--An individual engaged in work under a license or certificate of registration issued by the agency and controlled by a licensee or registrant, but does not include the licensee or registrant.

(124) [(122)] Working level (WL)--Any combination of short-lived radon daughters in 1 liter of air that will result in the ultimate emission of  $1.3 \times 10^5$  million electron volts (MeV) of potential alpha particle energy. The short-lived radon daughters are--for radon-222: polonium-218, lead-214, bismuth-214, and polonium-214; and for radon-220: polonium-216, lead-212, bismuth-212, and polonium-212.

(125) [(123)] Working level month (WLM)--An exposure to one working level for 170 hours--2,000 working hours per year divided by 12 months per year is approximately equal to 170 hours per month.

~~(126)~~ [(124)] Year--The period of time beginning in January used to determine compliance with the provisions of this chapter. The licensee may change the starting date of the year used to determine compliance by the licensee provided that the change is made at the beginning of the year and that no day is omitted or duplicated in consecutive years.

(c) - (o) (No change.)

Figure: 25 TAC §289.201(b)(105)(B)

$$\frac{175 \text{ (grams contained U - 235)}}{350} + \frac{50 \text{ (grams U - 233)}}{200} + \frac{50 \text{ (grams Pu)}}{200} = 1$$

§289.203. Notices, Instructions, and Reports to Workers; Inspections.

(a) Scope and purpose. This section establishes requirements for notices, instructions, and reports by licensees or registrants to individuals engaged in activities under a license or certificate of registration, and options available to such individuals in connection with agency inspections of licensees or registrants to ascertain compliance with the provisions of the Texas Radiation Control Act (Act), Health and Safety Code, Chapter 401, and rules, orders, licenses, and certificates of registration issued thereunder regarding radiological working conditions. The requirements in this section apply to all persons who receive, possess, use, or transfer sources of radiation licensed by or registered with the agency in accordance with this chapter.

(b) Posting of notices to workers.

(1) Each licensee or registrant shall post current copies of the following documents:

(A) the requirements in this section and in §289.202 of this title (relating to Standards for Protection Against Radiation from Radioactive Materials [**Material**]) or §289.231 of this title (relating to General Provisions and Standards for Protection Against Machine-Produced Radiation), as applicable;

(B) - (C) (No change.)

(D) any notice of violation involving radiological working conditions[,] or order that has:

(i) been issued in accordance with §289.201 of this title (relating to General Provisions for Radioactive Material), §289.205 of this title (relating to Hearing and Enforcement Procedures), and §289.231 of this title; and [.]

(ii) not been labeled "withhold from public disclosure under Government Code, §552.101," or equivalent phrase, in accordance with §289.252(ii) of this title (relating to Licensing of Radioactive Material).

(2) (No change.)

(3) Each licensee or registrant shall post RC [Bureau of Radiation Control (BRC)] Form 203-1, "Notice to Employees," as contained in subsection (i) of this section, or an equivalent document containing at least the same wording as RC [BRC] Form 203-1 [, shall be posted by each licensee or registrant as required by this section].

(4) (No change.)

(c) (No change.)

(d) Notifications and reports to individuals.

(1) Radiation exposure data for an individual and the results of any measurements, analyses, and calculations of radioactive material deposited or retained in the body of an individual shall be made available [reported annually] to the individual as specified in this section. The information reported shall include data and results obtained in accordance with agency requirements, orders, license or certificate of registration conditions, as shown in records maintained by the licensee or registrant in accordance with §289.202 or §289.231 of this title, as applicable. Each notification and report shall:

(A) - (D) (No change.)

(2) Each licensee or registrant shall provide an annual written report to advise each worker [annually] of the worker's dose as shown in records maintained by the licensee or registrant in accordance with §289.202(rr) or §289.231(dd) of this title, as applicable, if the individual requests his or her annual dose report in writing.

(3) - (5) (No change.)

(e) - (h) (No change.)

(i) Notice to employees. The following form, RC Form 203-1, or an equivalent as stated in subsection (b)(3) of this section, shall be posted.

Figure: 25 TAC §289.203(i)      **[Figure: 25 TAC §289.203(i)]**

Department of State Health Services  
1100 West 49th Street  
P.O. Box 149347  
Austin, Texas 78714-9347

# NOTICE TO EMPLOYEES

## TEXAS REGULATIONS FOR CONTROL OF RADIATION

The Department of State Health Services has established standards for your protection against radiation hazards, in accordance with the Texas Radiation Control Act, Health and Safety Code, Chapter 401.

### YOUR EMPLOYER'S RESPONSIBILITY

Your employer is required to-

1. Apply these rules to work involving sources of radiation.
2. Post or otherwise make available to you a copy of the Department of State Health Services rules, licenses, certificates of registration, notices of violations, and operating procedures that apply to your work, and explain their provisions to you.

### YOUR RESPONSIBILITY AS A WORKER

You should familiarize yourself with those provisions of the rules and the operating procedures that apply to your work. You should observe the rules for your own protection and protection of your co-workers.

### WHAT IS COVERED BY THESE RULES

1. Limits on exposure to sources of radiation in restricted and unrestricted areas;
2. Measures to be taken after accidental exposure;
3. Individual monitoring devices, surveys and equipment;
4. Caution signs, labels, and safety interlock equipment;
5. Exposure records and reports;
6. Options for workers regarding agency inspections; and
7. Related matters.

### REPORTS ON YOUR RADIATION EXPOSURE HISTORY

1. The rules require that your employer give you a written report if you receive an exposure in excess of any applicable limit as stated in the rules, license, or certificate of registration. The basic limits for exposure to employees are stated in 25 Texas Administrative Code (TAC)

§289.202(f), (k), (l), and (m) (relating to Standards for Protection Against Radiation from Radioactive Materials) and 25 TAC §289.231(m) (relating to General Provisions and Standards for Protection Against Machine-Produced Radiation). These subsections specify limits on exposure to radiation and exposure to concentrations of radioactive material in air and water.

2. If you work where individual monitoring devices are provided in accordance with 25 TAC §289.202 or §289.231:

- (a) your employer must furnish to you, upon your written request, an annual written report of your exposure to radiation; and
- (b) your employer must give you a written report, upon termination of your employment, of your radiation exposures if you request the information on your radiation exposure in writing.

### INSPECTIONS

All licensed or registered activities are subject to inspection by representatives of the Department of State Health Services. In addition, any worker or representative of the workers who believe that there is a violation of the Texas Radiation Control Act, the rules issues thereunder, or the terms of the employer's license or registration with regard to radiological working conditions in which the worker is engaged, may request an inspection by sending a notice of the alleged violation to the Department of State Health Services. The request must state the specific grounds for the notice, and must be signed by the worker or the representative of the workers. During inspections, agency inspectors may confer privately with workers, and any worker may bring to the attention of the inspectors any past or present condition that the individual believes contributed to or caused any violation as described above.

### POSTING REQUIREMENT

Copies of this notice shall be posted in a sufficient number of places in every establishment where employees are employed in activities licensed or registered, in accordance with 25 TAC §289.252 (relating to Licensing of Radioactive Material) and 25 TAC §289.226 (relating to Registration of Radiation Machine Use and Services), to permit employees to observe a copy on the way to or from their place of employment.

Applicable sections of 25 TAC Chapter 289 may be reviewed online, at [www.dshs.state.tx.us/radiation/rules.shtm](http://www.dshs.state.tx.us/radiation/rules.shtm). Our license and/or certificate of registration and any associated documents, our operating procedures, and any "Notice of Violation" or order issued by the agency may be reviewed at the following location: \_\_\_\_\_

§289.251. Exemptions, General Licenses, and General License Acknowledgements.

(a) - (d) (No change.)

(e) Exemptions for radioactive material other than source material.

(1) Exempt concentrations.

(A) Except as provided in subparagraph (B) of this paragraph, any person is exempt from this section and §289.252 of this title if that person receives, possesses, uses, transfers, or acquires products or materials containing radioactive material in concentrations not in excess of those listed in subsection (l)(1) ~~[(m)(1)]~~ of this section.

(B) (No change.)

(C) A manufacturer, processor, or producer of a product or material is exempt from the requirements for a license, as specified in §289.252 of this title, if the manufacturer, processor, or producer transfers radioactive material contained in a product or material that does not exceed the concentrations specified in subsection (l)(1) of this section, and that has been introduced into the product or material by a licensee holding a specific license issued by the NRC that expressly authorizes such introduction. The exemption specified in this subparagraph does not apply to the transfer of radioactive material contained in any food, beverage, cosmetic, drug, or other commodity or product designed for ingestion or inhalation by, or application to, a human being.

(2) Exempt quantities.

(A) Except as provided in subparagraphs (C), (D), and (F) ~~[subparagraph (C)]~~ of this paragraph, any person is exempt from these rules if that person receives, possesses, uses, transfers, or acquires radioactive material in individual quantities, each of which does not exceed the applicable quantity set forth in subsection (l)(2) ~~[(m)(2)]~~ of this section.

(B) Any person who possesses radioactive material received or acquired, prior to September 25, 1971, in accordance with the general license provided in subsection (f)(4)(A) of this section is exempt from the requirements for a license set forth in §289.252 of this title if that person possesses, uses, ~~[or] transfers,~~ owns such radioactive material.

(C) (No change.)

(D) No person may, for purposes of commercial distribution, transfer radioactive material in quantities greater than the individual quantities set forth in subsection (l)(2) ~~[(m)(2)]~~ of this section, knowing or having reason to believe that such quantities of radioactive material will be transferred to persons exempt in accordance with this paragraph or equivalent regulations of the NRC, any agreement state, or any licensing state, except in accordance with a specific license issued by the NRC in accordance with Title 10, CFR, §32.18 or by the agency in accordance with §289.252(j) of this title, which states that the radioactive

material may be transferred by the licensee to persons exempt in accordance with this paragraph or the equivalent regulations of the NRC, any agreement state, or any licensing state.

(E) The schedule of quantities set forth in subsection (1)(2) ~~[(m)(2)]~~ of this section applies only to radioactive materials distributed as exempt quantities in accordance with a specific license issued by the agency, another licensing state, or the commission. Subsection (1)(2) ~~[(m)(2)]~~ of this section does not apply to radioactive materials that have decayed from quantities not originally exempt and does not make such material, or the sources or devices in which the material is contained except from the licensing requirements in this section or §289.252 of this title.

(F) No person may, for purposes of producing an increased radiation level, combine quantities of radioactive material covered by this exemption so that the aggregate quantity exceeds the limits set forth in subsection (1)(2) of this section, except for radioactive material combined within a device placed in use before May 3, 1999, or as otherwise permitted by the requirements in this title.

(3) Exempt items.

(A) Certain items containing radioactive material.

(i) Except for persons who apply radioactive material to, or persons who incorporate radioactive material into the following products, any person is exempt from this chapter if that person receives, possesses, uses, transfers, or acquires the following products:

(I) timepieces, hands, or dials containing not more than the following specified quantities of radioactive material and not exceeding the following specified levels of radiation:

(-a-) – (-g-) (No change.)

(-h-) 1 μCi (0.037 megabecquerel (MBq)) of radium-226 per timepiece in intact timepieces manufactured prior to January 1, 1986 **[1 μCi of radium-226 per timepiece in timepieces, hands, or dials manufactured or initially distributed prior to January 1, 1986];**

(II) - (VII) (No change.)

(VIII) ionizing radiation measuring instruments containing, for purposes of internal calibration or standardization, a source of radioactive material not exceeding the applicable quantity set forth in subsection (1)(2) ~~[(m)(2)]~~ of this section or 0.05 μCi of americium-241; **[or]**

(IX) spark gap irradiators containing not more than 1  $\mu\text{Ci}$  of cobalt-60 per spark gap irradiator for use in electrically ignited fuel oil burners having a firing rate of at least 3 gallons per hour; or [.]

(X) ionization chamber smoke detectors containing not more than 1 microcurie ( $\mu\text{Ci}$ ) of americium-241 per detector in the form of a foil and designed to protect life and property from fires.

(ii) (No change.)

(B) (No change.)

(C) Gas and aerosol detectors containing radioactive material.

(i) Except for persons who manufacture, process, **[or]** produce, or initially transfer gas and aerosol detectors containing radioactive material, any person is exempt from this chapter if that person receives, possesses, uses, transfers, owns, or acquires radioactive material in gas and aerosol detectors designed to protect life or property from fires and airborne hazards provided that:

(I) detectors containing radioactive material shall have been manufactured, imported, or transferred in accordance with a specific license issued by the NRC in accordance with Title 10, CFR, §32.26, or an agreement state or a licensing state in accordance with §289.252(k) of this title; **[and]**

(II) the specific license issued in accordance with §289.252 of this title authorizes the initial transfer of the detectors to persons who are exempt from regulatory requirements; and [.]

(III) this exemption also covers gas and aerosol detectors manufactured or distributed before November 30, 2007 in accordance with a specific license issued in accordance with §289.252 of this title or under comparable provisions to Title 10, CFR, §32.26 authorizing distribution to persons exempt from regulatory requirements.

(ii) - (iii) (No change.)

**[(D) Resins containing scandium-46 and designed for sand consolidation in oil wells. Any person is exempt from this chapter if that person receives, possesses, uses, transfers, or acquires synthetic plastic resins containing scandium-46, which are designed for sand consolidation in oil wells. Such resins shall have been manufactured or imported in accordance with a specific license issued by the NRC, or shall have been manufactured in accordance with the specifications contained in a specific license issued by the agency or any agreement state to the manufacturer of such resins in accordance with licensing requirements equivalent to those in Title 10, CFR, §§32.16 and 32.17. This exemption does not authorize the manufacture of any resins containing scandium-46.]**

(4) (No change.)

(f) General licenses. In addition to the requirements of this section, all general licenses, unless otherwise specified, are subject to the requirements of §289.201 of this title (relating to General Provisions for Radioactive Material), §289.202(ww) and (xx) of this title (relating to Standards for Protection Against Radiation from Radioactive Materials), §289.204 of this title (relating to Fees for Certificates of Registration, Radioactive Material Licenses, Emergency Planning and Implementation, and Other Regulatory Services), §289.205 of this title (relating to Hearing and Enforcement Procedures), and §289.257 of this title (relating to Packaging and Transportation of Radioactive Material).

(1) – (3) (No change.)

(4) General licenses for radioactive material other than source material.

(A) - (G) (No change.)

(H) General license for certain detecting, measuring, gauging, or controlling devices and certain devices for producing light or an ionized atmosphere.

(i) – (iii) (No change.)

(iv) Any person who receives, acquires, possesses, uses, or transfers radioactive material in a device in accordance with the general license in this subparagraph shall do the following:

(I) – (VI) (No change.)

(VII) immediately suspend operation of the device if there is a failure of, or damage to, or any indication of a possible failure of or damage to, the shielding of the radioactive material or the "on-off" mechanism, or indicator, or upon the detection of 185 becquerels (0.005  $\mu\text{Ci}$ ) or more of removable radioactive material. The device shall not be operated until it has been repaired by the manufacturer or other person holding a specific license from the agency, the NRC, an agreement state, or a licensing state to repair such devices. The device and any radioactive material from the device may only be disposed of by transfer to a person authorized by a specific license to receive the radioactive material in the device. A report, prepared in accordance with §289.202(xx) and (yy) of this title, containing a brief description of the event and the remedial action taken and in the case of detection of 185 becquerels (0.005  $\mu\text{Ci}$ ) or more removable radioactive material or failure of, or damage to a source likely to result in contamination of the premises or the environs, a plan for ensuring that the premises and environs are acceptable for unrestricted use shall be furnished to the agency within 30 days. Under these circumstances, the requirements in §289.202(ddd) of this title may be applicable, as determined by the agency on a case-by-case basis;

(VIII) (No change.)

(IX) transfer or dispose of the device containing radioactive material only by export in accordance with Title 10, CFR, Part 110, by transfer to another general licensee as authorized in subclauses (XII) and (XVI) of this clause or to a person authorized to receive the device by a specific license issued by the agency in accordance with §289.252(l) of this title, or an equivalent specific license issued by the NRC, an agreement state, or a licensing state, or as otherwise approved under subclause (XI) of this clause;

(X) (No change.)

(XI) obtain written agency approval before transferring the device to any other specific licensee not specifically identified in subclause (IX) of this clause; however, a holder of a specific license may transfer a device for possession and use under its own specific license without prior approval, if, the holder:

(-a-) verifies that the specific license authorizes the possession and use, or applies for and obtains an amendment to the license authorizing the possession and use;

(-b-) removes, alters, covers, or clearly and unambiguously augments the existing label (otherwise required by clause (iv)(I) of this subparagraph) so that the device is labeled in compliance with §289.202(cc) of this title; however the manufacturer, model number, and serial number must be retained;

(-c-) obtains the manufacturer's or initial transferor's information concerning maintenance that would be applicable under the specific license (such as leak testing procedures); and

(-d-) reports the transfer under subclause (X) of this subparagraph.

(XII) - (XIII) (No change.)

(XIV) report changes to the mailing address for the location of use (including change in name of general licensee) to the agency within 30 days of the effective date of the change. If it is a portable device, a report of address change is only required for a change in the device's primary place of storage; **[and]**

(XV) not hold devices that are not in use for longer than two years. If devices with shutters are not being used, the shutter shall be locked in the closed position. The testing required by clause (iv) of this subparagraph need not be performed during the period of storage only. However, when devices are put back into service or transferred to another person, and have not been tested within the required test interval, they shall be tested for leakage before use or transfer and the shutter tested before use. Devices kept in standby for future use are excluded from the two-year time limit if the general licensee performs quarterly physical inventories of these devices while they are in standby. The licensee shall make and

maintain, for intervals of five years, records of the quarterly physical inventories for inspection by the agency; [.]

(XVI) not export the device containing radioactive material except in accordance with Title 10, CFR, Part 110; [.]

(XVII) comply with the provisions of §289.202(ww) and (xx) of this title for reporting radiation incidents, theft or loss of licensed material, but shall be exempt from the other requirements of §289.202 and §289.203 of this title; [.]

(XVIII) respond to written requests from the agency to provide information relating to the general license within 30 calendar days of the date of the request, or other time specified in the request. If the general licensee cannot provide the requested information within the allotted time, it shall, within that same time period, request a longer period to supply the information by providing the agency a written justification for the request; and [.]

(XIX) assure that the device is used in accordance with information contained in the device safety evaluation.

(I) – (J) (No change.)

(K) General license for certain items and self-luminous products containing radium-226.

(i) A general license is hereby issued to any person to acquire, receive, possess, use, or transfer radium-226 contained in the following products.

(I) Antiquities originally intended for use by the general public. For purposes of this subclause, antiquities are products distributed for use by the general public in the late 19th and early 20th centuries; such as radium emanator jars, revigators, radium water jars, radon generators, refrigerator cards, radium bath salts, and healing pads.

(II) Intact timepieces containing greater than 1  $\mu$ Ci (0.037 MBq), nonintact timepieces, and timepiece hands and dials no longer installed in timepieces.

(III) Luminous items installed in air, marine, or land vehicles.

(IV) All other luminous products, provided that no more than 100 items are used or stored at the same location at any one time.

(V) Small radium sources containing no more than 1  $\mu$ Ci (0.037 MBq) of radium 226.

(ii) Any person who acquires, receives, possesses, uses, or transfers radioactive material in accordance with this subparagraph shall do the following.

(I) Provide to the agency within 30 days of any indication of possible damage to the product that could result in a loss of the radioactive material. The report should include a brief description of the event, and the remedial action taken.

(II) Not abandon products containing radium-226.

(-a-) The product, and any radioactive material from the product, may only be disposed of according to §289.202 of this title or as otherwise approved by the agency.

(-b-) The product, and any radioactive material from the product, may be transferred to a person authorized by a specific license to receive the radium-226 or as otherwise approved by the agency.

(III) The general license in this subparagraph does not authorize the manufacture, assembly, disassembly, repair, or import of products containing radium-226, except that timepieces may be disassembled and repaired provided that paint containing radium-226 is not applied or removed.

(g) General license acknowledgements for radioactive material other than source material. In addition to the requirements of this section, all general license acknowledgement holders, unless otherwise specified, are subject to the requirements of §§289.201, 289.202(ww) and (xx), 289.204, 289.205, and 289.257 of this title.

(1) Persons possessing a general license for devices in accordance with subsection (f)(4)(H) of this section and being in the possession of radioactive material in devices containing at least 370 MBq (10 mCi) of cesium-137, 3.7 MBq (0.1 mCi) of strontium-90, 37 MBq (1 mCi) of cobalt-60, 3.7 MBq (0.1 mCi) of radium-226, 37 MBq (1 mCi) of americium-241, or any transuranic (for example, element with atomic number greater than uranium (92)), based on the activity indicated on the label on the device, shall file an application for acknowledgement within 30 days of receipt, acquisition, or possession of such a device. The application shall be on a form prescribed by the agency to include the following information and any other information specifically requested by the agency:

(A) (No change.)

(B) information about each device to include the manufacturer (or initial transferor), model number, and serial number of the device, and the radioisotope and activity (as indicated on the label), and serial number of the source;

(C) - (G) (No change.)

(2) (No change.)

(3) Persons possessing [in possession of] a device meeting the criteria of paragraph (1) of this subsection shall respond annually to the General License Acknowledgement Self Evaluation Form provided by the agency. The form shall be completed in accordance with the instructions contained in the form. The completed form shall be submitted to the agency within 30 days of receipt. **[Response should be in accordance with the instructions on the form.]**

(h) Issuance of general license acknowledgements.

(1) - (2) (No change.)

(3) The agency may request, and the licensee shall provide, additional information after the general license acknowledgement has been issued to enable the agency to determine whether the general license acknowledgement should be modified in accordance with subsection (k) [(1)] of this section.

(i) Specific terms and conditions.

(1) (No change.)

(2) Each person holding a general license acknowledgement issued by the agency in accordance with this section shall confine use and possession of the devices and radioactive material identified in the general license acknowledgement to the locations specified in the general license acknowledgement. Radioactive material shall not be used or stored in residential locations unless authorized by the agency. Each person holding a general license acknowledgement issued by the agency shall obtain prior approval from the agency before storing or using radioactive material in an area not previously authorized in the general license acknowledgement.

(3) - (5) (No change.)

(j) Termination [Expiration and termination] of general license acknowledgements [acknowledgement].

**[(1) Each general license acknowledgement expires at the end of the day, in the month and year stated in the general license acknowledgement.]**

**[(2) Expiration of the general license acknowledgement does not relieve the holder of the general license acknowledgement of the requirements of this chapter.]**

(1) [(3)] Each holder of a general license acknowledgement shall notify the agency immediately, in writing, and request termination of the general license acknowledgement when the holder of the general license acknowledgement decides to terminate all activities involving materials specified in the general license acknowledgement.

**[(4) No less than 30 days before the expiration date specified in a general license acknowledgement, the holder of the general license acknowledgement shall submit an application for general license acknowledgement renewal in accordance with subsection (k) of this section.]**

**(2) [(5)]** Each holder of a general license acknowledgement shall, no less than 30 days before vacating or relinquishing possession of control of premises that have been used as a place of storage or use of radioactive material as a result of general licensed activities, notify the agency in writing of intent to vacate and do the following: [.]

(A) terminate use of radioactive material;

(B) dispose of radioactive material in accordance with this section and/or §289.202(ff) of this title; and

(C) pay any outstanding fees in accordance with §289.204 of this title.

**[(6) If a holder of a general license acknowledgement does not submit an application for renewal in accordance with subsection (k) of this section, such person shall on or before the expiration date specified in the general license acknowledgement:]**

**[(A) terminate use of radioactive material; and]**

**[(B) dispose of radioactive material in accordance with this section and/or §289.202(ff).]**

**[(k) Renewal of general license acknowledgements.]**

**[(1) Applications for renewal of general license acknowledgements shall be filed in accordance with subsection (g)(1) or (f)(4)(G)(iv) of this section, as applicable.]**

**[(2) If a holder of a general license acknowledgement has properly filed a renewal application for the same activities at least 30 days before the expiration of the existing general license acknowledgement in accordance with this section, such existing general license acknowledgement shall not expire until the application has been finally determined by the agency.]**

**(k) [(I)]** Amendment of general license acknowledgements.

(1) The holder of the general license acknowledgement required by subsection (g)(1) of this section shall report in writing to the agency any changes in information furnished by the holder of the general license acknowledgement. The report shall be submitted within 30 days after the effective date of such change.

(2) Applications for amendments of a general license acknowledgement shall be filed in accordance with subsection (g)(1)(A)-(F) of this section, as applicable, and shall specify

the respects in which the holder of a general license acknowledgement desires a general license acknowledgement to be amended.

(1) [(m)] Appendices.

(1) Exempt concentrations.

Figure: 25 TAC §289.251(1)(1) [Figure: 25 TAC §289.251(m)(1)]

(2) Exempt quantities.

Figure: 25 TAC §289.251(1)(2) [Figure: 25 TAC §289.251(m)(2)]

Figure: 25 TAC §289.251(l)(1)

		Column I	Column II
Element (atomic number)	Isotope	Gas Concentration Ci/ml*	Liquid and Solid Concentration μCi/ml**
Antimony (51)	Sb-122		$3 \times 10^{-4}$
	Sb-124		$2 \times 10^{-4}$
	Sb-125		$1 \times 10^{-3}$
Argon (18)	Ar-37	$1 \times 10^{-3}$	
	Ar-41	$1 \times 10^{-7}$	
Arsenic (33)	As-73		$5 \times 10^{-3}$
	As-74		$5 \times 10^{-4}$
	As-76		$2 \times 10^{-4}$
	As-77		$8 \times 10^{-4}$
Barium (56)	Ba-131		$2 \times 10^{-3}$
	Ba-140		$3 \times 10^{-4}$
Beryllium (4)	Be-7		$2 \times 10^{-2}$
Bismuth (83)	Bi-206		$4 \times 10^{-4}$
Bromine (35)	Br-82	$4 \times 10^{-7}$	$3 \times 10^{-3}$
Cadmium (48)	Cd-109		$2 \times 10^{-3}$
	Cd-115m		$3 \times 10^{-4}$
	Cd-115		$3 \times 10^{-4}$
Calcium (20)	Ca-45		$9 \times 10^{-5}$
	Ca-47		$5 \times 10^{-4}$
Carbon (6)	C-14	$1 \times 10^{-6}$	$8 \times 10^{-3}$
Cerium (58)	Ce-141		$9 \times 10^{-4}$
	Ce-143		$4 \times 10^{-4}$
	Ce-144		$1 \times 10^{-4}$
Cesium (55)	Cs-131		$2 \times 10^{-2}$
	Cs-134m		$6 \times 10^{-2}$
	Cs-134		$9 \times 10^{-5}$
Chlorine (17)	Cl-138	$9 \times 10^{-7}$	$4 \times 10^{-3}$
Chromium (24)	Cr-51		$2 \times 10^{-2}$
Cobalt (27)	Co-57		$5 \times 10^{-3}$
	Co-58		$1 \times 10^{-3}$
	Co-60		$5 \times 10^{-4}$
Copper (29)	Cu-64		$3 \times 10^{-3}$

\* Values are given in Column I only for those materials normally used in gases.

\*\* μCi/gm for solids

Figure: 25 TAC §289.251(l)(1)

		Column I	Column II
Element (atomic number)	Isotope	Gas Concentration $\mu\text{Ci/ml}^*$	Liquid and Solid Concentration $\mu\text{Ci/ml}^{**}$
Dysprosium (66)	Dy-165		$4 \times 10^{-3}$
	Dy-166		$4 \times 10^{-4}$
Erbium (68)	Er-169		$9 \times 10^{-4}$
	Er-171		$1 \times 10^{-3}$
Europium (63)	Eu-152 (T/2=9.2 h)		$6 \times 10^{-4}$
	Eu-155		$2 \times 10^{-3}$
Fluorine (9)	F-18	$2 \times 10^{-6}$	$8 \times 10^{-3}$
Gadolinium (64)	Gd-153		$2 \times 10^{-3}$
	Gd-159		$8 \times 10^{-4}$
Gallium (31)	Ga-72		$4 \times 10^{-4}$
Germanium (32)	Ge-71		$2 \times 10^{-2}$
Gold (79)	Au-196		$2 \times 10^{-3}$
	Au-198		$5 \times 10^{-4}$
	Au-199		$2 \times 10^{-3}$
Hafnium (72)	Hf-181		$7 \times 10^{-4}$
Hydrogen (1)	H-3	$5 \times 10^{-6}$	$3 \times 10^{-2}$
Indium (49)	In-113m		$1 \times 10^{-2}$
	In-114m		$2 \times 10^{-4}$
Iodine (53)	I-126	$3 \times 10^{-9}$	$2 \times 10^{-5}$
	I-131	$3 \times 10^{-9}$	$2 \times 10^{-5}$
	I-132	$8 \times 10^{-8}$	$6 \times 10^{-4}$
	I-133	$1 \times 10^{-8}$	$7 \times 10^{-5}$
	I-134	$2 \times 10^{-7}$	$1 \times 10^{-3}$
Iridium (77)	Ir-190		$2 \times 10^{-3}$
	Ir-192		$4 \times 10^{-4}$
	Ir-194		$3 \times 10^{-4}$
Iron (26)	Fe-55		$8 \times 10^{-3}$
	Fe-59		$6 \times 10^{-4}$
Krypton (36)	Kr-85m	$1 \times 10^{-6}$	
	Kr-85	$3 \times 10^{-6}$	
Lanthanum (57)	La-140		$2 \times 10^{-4}$
Lead (82)	Pb-203		$4 \times 10^{-3}$

\* Values are given in Column I only for those materials normally used in gases.

\*\*  $\mu\text{Ci/gm}$  for solids

Figure: 25 TAC §289.251(l)(1)

		Column I	Column II
Element (atomic number)	Isotope	Gas Concentration $\mu\text{Ci/ml}^*$	Liquid and Solid Concentration $\mu\text{Ci/ml}^{**}$
Lutetium (71)	Lu-177		$1 \times 10^{-3}$
Manganese (25)	Mn-52		$3 \times 10^{-4}$
	Mn-54		$1 \times 10^{-3}$
	Mn-56		$1 \times 10^{-3}$
Mercury (80)	Hg-197m		$2 \times 10^{-3}$
	Hg-197		$3 \times 10^{-3}$
	Hg-203		$2 \times 10^{-4}$
Molybdenum (42)	Mo-99		$2 \times 10^{-3}$
Neodymium (60)	Nd-147		$6 \times 10^{-4}$
	Nd-149		$3 \times 10^{-3}$
Nickel (28)	Ni-65		$1 \times 10^{-3}$
Niobium (Columbium) (41)	Nb-95		$1 \times 10^{-3}$
	Nb-97		$9 \times 10^{-3}$
Osmium (76)	Os-185		$7 \times 10^{-4}$
	Os-191m		$3 \times 10^{-2}$
	Os-191		$2 \times 10^{-3}$
	Os-193		$6 \times 10^{-4}$
Palladium (46)	Pd-103		$3 \times 10^{-3}$
	Pd-109		$9 \times 10^{-4}$
Phosphorus (15)	P-32		$2 \times 10^{-4}$
Platinum (78)	Pt-191		$1 \times 10^{-3}$
	Pt-193m		$1 \times 10^{-2}$
	Pt-197m		$1 \times 10^{-2}$
	Pt-197		$1 \times 10^{-3}$
Polonium (84)	Po-210		$7 \times 10^{-6}$
Potassium (19)	K-42		$3 \times 10^{-3}$
Praseodymium	Pr-142		$3 \times 10^{-4}$
	Pr-143		$5 \times 10^{-4}$
Promethium (61)	Pm-147		$2 \times 10^{-3}$
	Pm-149		$4 \times 10^{-4}$
Radium (88)	Ra-226		$1 \times 10^{-7}$
	Ra-228		$3 \times 10^{-7}$

\* Values are given in Column I only for those materials normally used in gases.

\*\*  $\mu\text{Ci/gm}$  for solids

Figure: 25 TAC §289.251(l)(1)

		Column I	Column II
Element (atomic number)	Isotope	Gas Concentration $\mu\text{Ci/ml}^*$	Liquid and Solid Concentration $\mu\text{Ci/ml}^{**}$
Rhenium (75)	Re-183		$6 \times 10^{-3}$
	Re-186		$9 \times 10^{-4}$
	Re-188		$6 \times 10^{-4}$
Rhodium (45)	Rh-103m		$1 \times 10^{-1}$
	Rh-105		$1 \times 10^{-3}$
Rubidium (37)	Rb-86		$7 \times 10^{-4}$
Ruthenium (44)	Ru-97		$4 \times 10^{-3}$
	Ru-103		$8 \times 10^{-4}$
	Ru-105		$1 \times 10^{-3}$
	Ru-106		$1 \times 10^{-4}$
Samarium (62)	Sm-153		$8 \times 10^{-4}$
Scandium (21)	Sc-46		$4 \times 10^{-4}$
	Sc-47		$9 \times 10^{-4}$
	Sc-48		$3 \times 10^{-4}$
Selenium (34)	Se-75		$3 \times 10^{-3}$
Silicon (14)	Si-131		$9 \times 10^{-3}$
Silver (47)	Ag-105		$1 \times 10^{-3}$
	Ag-110m		$3 \times 10^{-4}$
	Ag-111		$4 \times 10^{-4}$
Sodium (11)	Na-24		$2 \times 10^{-3}$
Strontium (38)	Sr-85		$1 \times 10^{-3}$
	Sr-89		$1 \times 10^{-4}$
	Sr-91		$7 \times 10^{-4}$
	Sr-92		$7 \times 10^{-4}$
Sulfur (16)	S-35	$9 \times 10^{-8}$	$6 \times 10^{-4}$
Tantalum (73)	Ta-182		$4 \times 10^{-4}$
Technetium (43)	Tc-96m		$1 \times 10^{-1}$
	Tc-96		$1 \times 10^{-3}$

\* Values are given in Column I only for those materials normally used in gases.

\*\*  $\mu\text{Ci/gm}$  for solids

Figure: 25 TAC §289.251(l)(1)

		Column I	Column II
Element (atomic number)	Isotope	Gas Concentration $\mu\text{Ci/ml}^*$	Liquid and Solid Concentration $\mu\text{Ci/ml}^{**}$
Tellurium (52)	Te-125m		$2 \times 10^{-3}$
	Te-127m		$6 \times 10^{-4}$
	Te-127		$3 \times 10^{-3}$
	Te-129m		$3 \times 10^{-4}$
	Te-131m		$6 \times 10^{-4}$
	Te-132		$3 \times 10^{-4}$
Terbium (65)	Tb-160		$4 \times 10^{-4}$
Thallium (81)	Tl-200		$4 \times 10^{-3}$
	Tl-201		$3 \times 10^{-3}$
	Tl-202		$1 \times 10^{-3}$
	Tl-204		$1 \times 10^{-3}$
Thulium (69)	Tm-170		$5 \times 10^{-4}$
	Tm-171		$5 \times 10^{-3}$
Tin (50)	Sn-113		$9 \times 10^{-4}$
	Sn-125		$2 \times 10^{-4}$
Tungsten (Wolfram ) (74)	W-181		$4 \times 10^{-3}$
	W-187		$7 \times 10^{-4}$
Vanadium (23)	V-48		$3 \times 10^{-4}$
Xenon (54)	Xe-131m	$4 \times 10^{-6}$	
	Xe-133	$3 \times 10^{-6}$	
	Xe-135	$1 \times 10^{-6}$	
Ytterbium (70)	Yb-175		$1 \times 10^{-3}$
Yttrium (39)	Y-90		$2 \times 10^{-4}$
	Y-91m		$3 \times 10^{-2}$
	Y-91		$3 \times 10^{-4}$
	Y-92		$6 \times 10^{-4}$
	Y-93		$3 \times 10^{-4}$
Zinc (30)	Zn-65		$1 \times 10^{-3}$
	Zn-69m		$7 \times 10^{-4}$
	Zn-69		$2 \times 10^{-2}$

\* Values are given in Column I only for those materials normally used in gases.

\*\*  $\mu\text{Ci/gm}$  for solids

Figure: 25 TAC §289.251(l)(1)

		Column I	Column II
Element (atomic number)	Isotope	Gas Concentration μCi/ml*	Liquid and Solid Concentration μCi/ml**
Zirconium (40)	Zr-95		$6 \times 10^{-4}$
	Zr-97		$2 \times 10^{-4}$
Beta and/or gamma emitting radioactive material not listed above with half-life less than 3 years		$1 \times 10^{-10}$	$1 \times 10^{-6}$

NOTE 1: Many radioisotopes disintegrate into isotopes that are also radioactive. In expressing the concentrations in this paragraph, the activity stated is that of the parent isotope and takes into account the daughters.

NOTE 2: For purposes of subsection (d) of this section where a combination of isotopes is involved, the limit for the combination should be derived as follows: Determine for each isotope in the product the ratio between the concentration present in the product and the exempt concentration established in this paragraph for the specific isotope when not in combination. The sum of such ratios may not exceed "1" (for example, unity).

EXAMPLE:

$$\frac{\text{Concentration of Isotope A in Product}}{\text{Exempt Concentration of Isotope A}} + \frac{\text{Concentration of Isotope B in Product}}{\text{Exempt Concentration of Isotope B}} \leq 1$$

\* Values are given in Column I only for those materials normally used in gases.

\*\* μCi/gm for solids

Figure: 25 §289.251(1)(2)

<u>Radioactive Material</u>	<u>Microcuries</u>
Antimony-122 (Sb-122)	100
Antimony-124 (Sb-124)	10
Antimony-125 (Sb-125)	10
Arsenic-73 (As-73)	100
Arsenic-74 (As-74)	10
Arsenic-76 (As-76)	10
Arsenic-77 (As-77)	100
Barium-131 (Ba-131)	10
Barium-133 (Ba-133)	10
Barium-140 (Ba-140)	10
Beryllium-7 (Be-7)	100
Bismuth-210 (Bi-210)	1
Bromine-82 (Br-82)	10
Cadmium-109 (Cd-109)	10
Cadmium-115m (Cd-115m)	10
Cadmium-115 (Cd-115)	100
Calcium-45 (Ca-45)	10
Calcium-47 (Ca-47)	10
Carbon-14 (C-14)	100
Cerium-141 (Ce-141)	100
Cerium-143 (Ce-143)	100
Cerium-144 (Ce-144)	1
Cesium-129 (Cs-129)	100
Cesium-131 (Cs-131)	1,000
Cesium-134m (Cs-134m)	100
Cesium-134 (Cs-134)	1
Cesium-135 (Cs-135)	10
Cesium-136 (Cs-136)	10
Cesium-137 (Cs-137)	10
Chlorine-36 (Cl-36)	10
Chlorine-38 (Cl-38)	10
Chromium-51 (Cr-51)	1,000
Cobalt-57 (Co-57)	100
Cobalt-58m (Co-58m)	10
Cobalt-58 (Co-58)	10
Cobalt-60 (Co-60)	1
Copper-64 (Cu-64)	100
Dysprosium-165 (Dy-165)	10
Dysprosium-166 (Dy-166)	100

Figure: 25 §289.251(1)(2)

<u>Radioactive Material</u>	<u>Microcuries</u>
Erbium-169 (Er-169)	100
Erbium-171 (Er-171)	100
Europium-152 (Eu-152) 9.2h	100
Europium-152 (Eu-152) 13 yr	1
Europium-154 (Eu-154)	1
Europium-155 (Eu-155)	10
Fluorine-18 (F-18)	1,000
Gadolinium-153 (Gd-153)	10
Gadolinium-159 (Gd-159)	100
Gallium-67 (Ga-67)	100
Gallium-72 (Ga-72)	10
Germanium-68 (Ge-68)	10
Germanium-71 (Ge-71)	100
Gold-195 (Au-195)	10
Gold-198 (Au-198)	100
Gold-199 (Au-199)	100
Hafnium-181 (Hf-181)	10
Holmium-166 (Ho-166)	100
Hydrogen-3 (H-3)	1,000
Indium-111 (In-111)	100
Indium-113m (In-113m)	100
Indium-114m (In-114m)	10
Indium-115m (In-115m)	100
Indium-115 (In-115)	10
Iodine-123 (I-123)	100
Iodine-125 (I-125)	1
Iodine-126 (I-126)	1
Iodine-129 (I-129)	0.1
Iodine-131 (I-131)	1
Iodine-132 (I-132)	10
Iodine-133 (I-133)	1
Iodine-134 (I-134)	10
Iodine-135 (I-135)	10
Iridium-192 (Ir-192)	10
Iridium-194 (Ir-194)	100
Iron-52 (Fe-52)	10
Iron-55 (Fe-55)	100
Iron-59 (Fe-59)	10
Krypton-85 (Kr-85)	100

Figure: 25 §289.251(1)(2)

<u>Radioactive Material</u>	<u>Microcuries</u>
Krypton-87 (Kr-87)	10
Lanthanum-140 (La-140)	10
Lutetium-177 (Lu-177)	100
Manganese-52 (Mn-52)	10
Manganese-54 (Mn-54)	10
Manganese-56 (Mn-56)	10
Mercury-197m (Hg-197m)	100
Mercury-197 (Hg-197)	100
Mercury-203 (Hg-203)	10
Molybdenum-99 (Mo-99)	100
Neodymium-147 (Nd-147)	100
Neodymium-149 (Nd-149)	100
Nickel-59 (Ni-59)	100
Nickel-63 (Ni-63)	10
Nickel-65 (Ni-65)	100
Niobium-93m (Nb-93m)	10
Niobium-95 (Nb-95)	10
Niobium-97 (Nb-97)	10
Osmium-185 (Os-185)	10
Osmium-191m (Os-191m)	100
Osmium-191 (Os-191)	100
Osmium-193 (Os-193)	100
Palladium-103 (Pd-103)	100
Palladium-109 (Pd-109)	100
Phosphorus-32 (P-32)	10
Platinum-191 (Pt-191)	100
Platinum-193m (Pt-193m)	100
Platinum-193 (Pt-193)	100
Platinum-197m (Pt-197m)	100
Platinum-197 (Pt-197)	100
Polonium-210 (Po-210)	0.1
Potassium-42 (K-42)	10
Potassium-43 (K-43)	10
Praseodymium-142 (Pr-142)	100
Praseodymium-143 (Pr-143)	100
Promethium-147 (Pm-147)	10
Promethium-149 (Pm-149)	10
Radon-222 (Rn-222)	100
Rhenium-186 (Re-186)	100
Rhenium-188 (Re-188)	100

Figure: 25 §289.251(1)(2)

<u>Radioactive Material</u>	<u>Microcuries</u>
Rhodium-103m (Rh-103m)	100
Rhodium-105 (Rh-105)	100
Rubidium-81 (Rb-81)	10
Rubidium-86 (Rb-86)	10
Rubidium-87 (Rb-87)	10
Ruthenium-97 (Ru-97)	100
Ruthenium-103 (Ru-103)	10
Ruthenium-105 (Ru-105)	10
Ruthenium-106 (Ru-106)	1
Samarium-151 (Sm-151)	10
Samarium-153 (Sm-153)	100
Scandium-46 (Sc-46)	10
Scandium-47 (Sc-47)	100
Scandium-48 (Sc-48)	10
Selenium-75 (Se-75)	10
Silicon-31 (Si-31)	100
Silver-105 (Ag-105)	10
Silver-110m (Ag-110m)	1
Silver-111 (Ag-111)	100
Sodium-22 (Na-22)	10
Sodium-24 (Na-24)	10
Strontium-85 (Sr-85)	10
Strontium-87m (Sr-87m)	10
Strontium-89 (Sr-89)	1
Strontium-90 (Sr-90)	0.1
Strontium-91 (Sr-91)	10
Strontium-92 (Sr-92)	10
Sulphur-35 (S-35)	100
Tantalum-182 (Ta-182)	10
Technetium-96 (Tc-96)	10
Technetium-97m (Tc-97m)	100
Technetium-97 (Tc-97)	100
Technetium-99m (Tc-99m)	100
Technetium-99 (Tc-99)	10
Tellurium-125m (Te-125m)	10
Tellurium-127m (Te-127m)	10
Tellurium-127 (Te-127)	100
Tellurium-129m (Te-129m)	10
Tellurium-129 (Te-129)	100
Tellurium-131m (Te-131m)	10

Figure: 25 §289.251(1)(2)

<u>Radioactive Material</u>	<u>Microcuries</u>
Tellurium-132 (Te-132)	10
Terbium-160 (Tb-160)	10
Thallium-200 (Tl-200)	100
Thallium-201 (Tl-201)	100
Thallium-202 (Tl-202)	100
Thallium-204 (Tl-204)	10
Thulium-170 (Tm-170)	10
Thulium-171 (Tm-171)	10
Tin-113 (Sn-113)	10
Tin-125 (Sn-125)	10
Tungsten-181 (W-181)	10
Tungsten-185 (W-185)	10
Tungsten-187 (W-187)	100
Vanadium-48 (V-48)	10
Xenon-131m (Xe-131m)	1,000
Xenon-133 (Xe-133)	100
Xenon-135 (Xe-135)	100
Ytterbium-175 (Yb-175)	100
Yttrium-87 (Y-87)	10
Yttrium-88 (Y-88)	10
Yttrium-90 (Y-90)	10
Yttrium-91 (Y-91)	10
Yttrium-92 (Y-92)	100
Yttrium-93 (Y-93)	100
Zinc-65 (Zn-65)	10
Zinc-69m (Zn-69m)	100
Zinc-69 (Zn-69)	1,000
Zirconium-93 (Zr-93)	10
Zirconium-95 (Zr-95)	10
Zirconium-97 (Zr-97)	10
Any radioactive material not listed above other than alpha emitting radioactive material	0.1

§289.252. Licensing of Radioactive Material.

(a) Purpose. The intent of this section is as follows.

(1) (No change.)

(2) Unless otherwise exempted, no person shall receive, possess, use, transfer, own, or acquire radioactive material except as authorized by the following:

(A) a specific license issued in accordance with this section and/or any of the following sections:

**[(i) §289.254 of this title (relating to Licensing of Radioactive Waste Processing and Storage Facilities);]**

**[(i) [(ii)] §289.255 of this title (relating to Radiation Safety, Requirements and Licensing and Registration Procedures for Industrial Radiography);**

**[(ii) [(iii)] §289.256 of this title (relating to Medical and Veterinary Use of Radioactive Material);**

**[(iii) [(iv)] §289.258 of this title (relating to Licensing and Radiation Safety Requirements for Irradiators);**

**[(iv) [(v)] §289.259 of this title (relating to Licensing of Naturally Occurring Radioactive Material (NORM)); or**

**[(vi) §289.260 of this title (relating to Licensing of Uranium Recovery and Byproduct Material Disposal Facilities); or]**

(B) (No change.)

(3) (No change.)

(b) Scope. In addition to the requirements of this section, the following additional requirements are applicable.

(1) All licensees, unless otherwise specified, are subject to the requirements in the following sections:

(A) (No change.)

(B) §289.202 of this title (relating to Standards for Protection Against Radiation from Radioactive Materials [**Material**]);

(C) - (F) (No change.)

(2) (No change.)

**[(3) Licensees engaged in radioactive waste processing and/or storage are subject to the requirements of §289.254 of this title.]**

~~(3)~~ [(4)] Licensees engaged in industrial radiographic operations are subject to the requirements of §289.255 of this title.

~~(4)~~ [(5)] Licensees using radioactive material for medical or veterinary use are subject to the requirements of §289.256 of this title.

~~(5)~~ [(6)] Licensees using sealed sources in irradiators are subject to the requirements of §289.258 of this title.

~~(6)~~ [(7)] Licensees possessing or using naturally occurring radioactive material are subject to the requirements of §289.259 of this title.

**[(8) Licensees engaged in uranium recovery and byproduct material disposal are subject to the requirements of §289.260 of this title.]**

(c) (No change.)

(d) Filing application for specific licenses. The agency may, at any time after the filing of the original application, require further statements in order to enable the agency to determine whether the application should be denied, abandoned or the license should be issued.

(1) - (10) (No change.)

(11) Action on a specific license application will be considered abandoned if the applicant does not respond within 30 days from the date of a request for any information by the agency. Abandonment of such actions does not provide an opportunity for a hearing; however, the applicant retains the right to resubmit the application in accordance with paragraphs (1) - (7) of this subsection.

(e) General requirements for the issuance of specific licenses. A license application will be approved if the agency determines that:

(1) - (3) (No change.)

(4) the applicant satisfied [**satisfies**] any applicable special requirement in this section and other sections as specified in subsection (a)(2)(A) of this section;

(5) - (6) (No change.)

(7) the applicant submitted [**submits an**] adequate operating, safety, and emergency procedures [**manual**];

(8) the applicant's permanent facility is located in Texas (if the applicant's permanent facility is not located in Texas, reciprocal recognition shall be sought as required by subsection (ee) of this section); [**and**]

(9) the owner of the property is aware that radioactive material is stored and/or used on the property, if the proposed [**storage**] facility is not owned by the applicant. The applicant shall provide a written statement from the owner, or from the owner's agent, indicating such. This paragraph does not apply to property owned or held by a government entity or to property on which radioactive material is used under an authorization for temporary job site use; [.]

(10) there is no reason to deny the license as specified in subsections (d)(10) or (x)(8) [**subsection (d)(10) or (x)(7)**] of this section; and [.]

(11) the applicant is listed on the Texas Secretary of State's website as authorized to conduct business in the state, unless the applicant is exempt. All applicants using an assumed name in their application shall file an assumed name certificate with the Secretary of State and/or the office of the county clerk as required under the Business and Commerce Code Chapter 71.

(f) Radiation safety officer.

(1) - (2) (No change.)

(3) The specific duties of the RSO include, but are not limited to, the following:

(A) - (L) (No change.)

(M) to ensure that personnel are complying with this chapter, the conditions of the license, and the operating, safety, and emergency procedures of the licensee; [**and**]

(N) to serve as the primary contact with the agency; and [.]

(O) to have knowledge of and ensure compliance with federal and state security measures for radioactive material.

(4) - (5) (No change.)

(g) The duties and responsibilities of the Radiation Safety Committee (RSC) include but are not limited to the following:

(1) - (8) (No change.)

(9) evaluating new uses of radioactive material; **[and]**

(10) reviewing and approving permitted program and procedural changes prior to implementation; and [.]

(11) having knowledge of and ensuring compliance with federal and state security measures for radioactive material.

(h) Specific licenses for broad scope authorization for multiple quantities or types of radioactive material for use in research and development.

(1) - (2) (No change.)

(3) Unless specifically authorized, in accordance with a separate license, persons licensed according to paragraph (1) of this subsection shall not:

(A) receive, acquire, own, possess, use, or transfer devices containing 100,000 curies (Ci) or more of radioactive material in sealed sources used for irradiation of materials;

(B) conduct activities for which a specific license issued by the agency in accordance with subsections (i)-(u) of this section and §289.255, §289.256, and §289.259 [~~§§289.254, 289.255, 289.256, and §289.259~~] of this title is required;

(C) - (D) (No change.)

(i) Specific licenses for introduction of radioactive material into products in exempt concentrations.

(1) - (4) (No change.)

(5) No person may introduce radioactive material into a product or material knowing or having reason to believe that it will be transferred to persons exempt in accordance with §289.251 of this title (relating to Exemptions, General Licenses, and General License Acknowledgements) except as specified with a license issued by the NRC.

(j) Specific licenses for commercial distribution of radioactive material in exempt quantities.

(1) Authority to transfer possession or control by the manufacturer, processor, or producer of any equipment, device, commodity, or other product containing source material or byproduct material whose subsequent possession, use, transfer, and disposal by all other persons are exempted from regulatory requirements may be obtained only from the United States Nuclear Regulatory Commission (NRC), Washington, DC 20555.

(2) (No change.)

(3) The license issued in accordance with paragraph (2) of this subsection is subject to the following conditions.

(A) - (C) (No change.)

(D) In addition to the labeling information required by subparagraph (C) of this paragraph, the label affixed to the immediate container, or an accompanying brochure, shall:

(i) state that the contents are exempt from the NRC [United States Nuclear Regulatory Commission (NRC)], agreement state, or licensing state requirements;

(ii) - (iii) (No change.)

(4) - (5) (No change.)

(k) - (m) (No change.)

(n) Specific licenses for the manufacture of calibration sources containing americium-241, plutonium, or radium-226 for commercial distribution to persons generally licensed in accordance with §289.251(f)(4)(D) of this title.

(1) In addition to the requirements in subsection (e) of this section, a specific license to manufacture calibration sources containing americium-241, plutonium, or radium-226 to persons generally licensed in accordance with §289.251(f)(4)(D) of this title will be issued if the agency approves the information submitted by the applicant. The information shall satisfy the requirements of Title 10, CFR, §§32.57, 32.58, 32.59, and 32.102, and Title 10, CFR, §70.39 [10 CFR 70.39] or their equivalent.

(2) Each person licensed in accordance with this section shall perform a dry wipe test on each source containing more than 0.1 µCi (3.7 kilobecquerels) of americium-241 or radium-226 before transferring the source to a general licensee in accordance with §289.251(f)(4)(D) of this title. This test shall be performed by wiping the entire radioactive surface of the source with a filter paper with the application of moderate pressure. The radioactivity on the paper shall be measured by using radiation detection instrumentation capable of detecting 0.005 µCi (0.185 kilobecquerel) of americium-241 or radium-226. If removable contamination from any source wipe test exceeds 0.005 µCi (0.185 kilobecquerels) of americium-241 or radium-226, the source is deemed to be leaking and it shall not be transferred to a general licensee.

(o) Specific licenses for the manufacture and commercial distribution of sealed sources or devices containing radioactive material for medical use. In addition to the requirements in subsection (e) of this section, a specific license to manufacture and commercially distribute sealed sources and devices containing radioactive material to persons licensed in accordance with §289.256 of this title for use as a calibration, transmission, or reference source or for use of

sealed sources listed in §289.256(rr), (bbb), and (ddd) [**§289.256(bb), §289.256(cc), and §289.256(dd)**] of this title will be issued if the agency approves the following information submitted by the applicant:

(1) - (4) (No change.)

(p) Specific licenses for the manufacture and commercial distribution of radioactive material for certain *in vitro* clinical or laboratory testing in accordance with the general license. In addition to the requirements in subsection (e) of this section, a specific license to manufacture or commercially distribute radioactive material for use in accordance with the general license in §289.251(f)(4)(G) of this title will be issued if the agency approves the following information submitted by the applicant:

(1) documentation that the radioactive material will be prepared for distribution in prepackaged units of:

(A) iodine-125 in units not exceeding 10 microcuries ( $\mu\text{Ci}$ ) (0.37 megabecquerel) each;

(B) iodine-131 in units not exceeding 10  $\mu\text{Ci}$  (0.37 megabecquerel) each;

(C) carbon-14 in units not exceeding 10  $\mu\text{Ci}$  (0.37 megabecquerel) each;

(D) hydrogen-3 (tritium) in units not exceeding 50  $\mu\text{Ci}$  (1.85 megabecquerels) each;

(E) iron-59 in units not exceeding 20  $\mu\text{Ci}$  (0.74 megabecquerel) each;

(F) cobalt-57 in units not exceeding 10  $\mu\text{Ci}$  (0.37 megabecquerel) each;

(G) selenium-75 in units not exceeding 10  $\mu\text{Ci}$  (0.37 megabecquerel) each;

or

(H) mock iodine-125 in units not exceeding 0.05  $\mu\text{Ci}$  (1.85 kilobecquerels) of iodine-129 and 0.005  $\mu\text{Ci}$  (0.185 kilobecquerel) of americium-241 each;

(2) evidence that each prepackaged unit will bear [**bears**] a durable, clearly visible label:

(A) identifying the radioactive contents as to chemical form and radionuclide, and indicating that the amount of radioactivity does not exceed 10  $\mu\text{Ci}$  (0.37 megabecquerel) of iodine-125, iodine-131, carbon-14, cobalt-57, or selenium-75; 50  $\mu\text{Ci}$  (1.85 megabecquerels) of hydrogen-3 (tritium); 20  $\mu\text{Ci}$  (0.74 megabecquerel) of iron-59; or mock iodine-125 in units not exceeding 0.05  $\mu\text{Ci}$  (1.85 kilobecquerels) of iodine-129 and 0.005  $\mu\text{Ci}$  (0.185 kilobecquerel) of americium-241; and

(B) (No change.)

(3) - (4) (No change.)

(q) (No change.)

(r) Specific licenses for the manufacture, preparation, or transfer for commercial distribution of radioactive drugs containing radioactive materials for medical use.

(1) In addition to the requirements in subsection (e) of this section, a specific license to manufacture, prepare, or transfer for commercial distribution, radioactive drugs containing radioactive material for use by persons authorized in accordance with §289.256 of this title will be issued if the agency approves the following information submitted by the applicant:

(A) evidence that the applicant is at least one of the following:

(i) registered [**or licensed**] with the United States Food and Drug Administration (FDA) as the owner or operator of a drug establishment that engages in the manufacture, preparation, propagation, compounding, or processing of a drug in accordance with Title 21, CFR, §207.20(a) [manufacturer];

(ii) registered or licensed with a state agency as a drug manufacturer; [**or**]

(iii) (No change.)

(iv) operating as a nuclear pharmacy within a federal medical institution; or

(v) a positron emission tomography (PET) drug production facility registered with a state agency.

(B) – (C) (No change.)

(2) A licensee shall possess and use instrumentation to measure the radioactivity of radioactive drugs and shall have procedures for the use of the instrumentation. The licensee shall measure, by direct measurement or by a combination of measurements and calculations, the amount of radioactivity in dosages of alpha, beta, or photon-emitting radioactive drugs prior to transfer for commercial distribution. In addition, the licensee shall:

(A) - (C) (No change.)

(3) A licensee described in paragraph (1)(A)(iii) or (iv) of this subsection shall prepare radioactive drugs for medical use as defined [described] in §289.256 of this title with the following provisions. [:]

(A) Radioactive drugs shall be prepared by either an authorized nuclear pharmacist, as specified in subparagraphs (B) and (C) of this paragraph, or an individual under the supervision of an authorized nuclear pharmacist as specified in §289.256(s) of this title.

**[(A) radioactive drugs shall be prepared by a nuclear pharmacist(s) designated in the application as the individual user(s) who has completed the training and experience requirements specified in §289.256 of this title;]**

(B) A pharmacist shall be allowed to work as an authorized nuclear pharmacist if:

(i) the individual qualifies as an authorized nuclear pharmacist as defined in §289.256 of this title;

(ii) the individual meets the requirements specified in §289.256(k)(2) and (m) of this title, and the licensee has received from the agency, an approved license amendment identifying this individual as an authorized nuclear pharmacist; or

(iii) the individual is designated as an authorized nuclear pharmacist in accordance with subparagraph (C) of this paragraph.

(C) May designate a pharmacist, as defined in §289.256 of this title, as an authorized nuclear pharmacist if:

(i) the individual was a nuclear pharmacist preparing only radioactive drugs containing accelerator-produced radioactive material, and

(ii) the individual practiced at a pharmacy at a government agency or federally recognized Indian Tribe or at all other pharmacies prior to the effective date of this rule as noticed by the NRC or the agency.

(D) Provide the following to the agency:

(i) a copy of each individual's certification by a specialty board whose certification process has been recognized by the NRC, agency, or an agreement state as specified in §289.256(k)(1) of this title with the written attestation signed by a preceptor as required by §289.256(k)(2)(C) of this title ; or

(ii) the agency, NRC, or another agreement state license, or

(iii) the permit issued by a broad scope licensee or the authorization from a commercial nuclear pharmacy authorized to list its own authorized nuclear pharmacist, or

(iv) documentation that only accelerator-produced radioactive materials were used in the practice of nuclear pharmacy at a government agency or federally recognized Indian Tribe or at all other locations of use prior to the effective date of this rule as noticed by the NRC or the agency; and

(v) a copy of the Texas State Board of Pharmacy licensure or registration, no later than 30 days after the date that the licensee allows, in accordance with subparagraph (B)(i) and (iii) of this paragraph, the individual to work as an authorized nuclear pharmacist.

**(E) [(B)] The [the] radiopharmaceuticals for human use shall be processed and prepared according to instructions that are furnished by the manufacturer on the label attached to or in the FDA-accepted instructions in the leaflet or brochure that accompanies the generator or reagent kit. [;]**

**(F) [(C)] If [if] the authorized nuclear pharmacist elutes generators or processes radioactive material with the reagent kit in a manner that deviates from instructions furnished by the manufacturer on the label attached to or in the leaflet or brochure that accompanies the generator or reagent kit or in the accompanying leaflet or brochure, a complete description of the deviation shall be made and maintained for inspection by the agency for a period of three years. [; and]**

**[(D) provide to the agency a copy of each individual's certification by the Texas State Board of Pharmacy or the permit issued by a licensee of broad scope, and a copy of the state pharmacy license. If the licensee adds a nuclear pharmacist(s) to the license, this shall be completed no later than 30 days after the date that the licensee allows the individual(s) to work as a nuclear pharmacist.]**

(4) Nothing in this subsection relieves the licensee from complying with applicable FDA, or other federal[,] and state requirements governing radioactive drugs.

(s) - (w) (No change.)

(x) Specific terms and conditions of licenses.

(1) – (2) (No change.)

(3) Each person licensed by the agency in accordance with this section shall confine use and possession of the radioactive material licensed to the locations and purposes authorized in the license. Radioactive material shall not be used or stored in residential locations unless specifically authorized by the agency.

(4) (No change.)

(5) Each licensee shall notify the agency's Radiation Safety Licensing Branch [**agency**], in writing, immediately following the filing of a voluntary or involuntary petition for bankruptcy by the licensee or its parent company, if the parent company is involved in the bankruptcy.

(6) The notification in paragraph (5) [(**4**)] of this subsection shall include:

(A) - (B) (No change.)

(7) - (8) (No change.)

(9) Each licensee preparing technetium-99m radiopharmaceuticals from molybdenum-99/technetium-99m generators or rubidium-82 from strontium-82/rubidium-82 generators shall test the generator eluates for molybdenum-99 breakthrough or strontium-82 and strontium-85 contamination, respectively, in accordance with §289.256 of this title. The licensee shall record the results of each test and retain each record for 3 years after the record is made for inspection by the agency.

(y) Expiration and termination of licenses and decommissioning of sites and separate buildings or outdoor areas.

(1) Except as provided in paragraph (2) of this subsection and subsection (z)(2) of this section, each specific license expires at the end of the day, in the month and year stated in the license. [**Expiration of the specific license does not relieve the licensee of the requirements of this chapter.**]

(2) - (17) (No change.)

(z) - (dd) (No change.)

(ee) Reciprocal recognition of licenses.

(1) Subject to this section, any person who holds a specific license from NRC, any agreement state, or any licensing state, and issued by the agency having jurisdiction where the licensee maintains an office for directing the licensed activity and at which radiation safety records are normally maintained, is granted a general license to conduct the activities authorized in such licensing document within the State of Texas provided that:

(A) - (C) (No change.)

(D) the out-of-state licensee supplies such other information as the agency may request; [**and**]

(E) the out-of-state licensee shall not transfer or dispose of radioactive material possessed or used in accordance with the general license provided in this subsection except by transfer to a person:

(i) (No change.)

(ii) exempt from the requirements for a license for such material in accordance with §289.251(e)(1) of this title; and [.]

(F) The out-of-state licensee shall have the following documents in their possession at all times when conducting work in Texas, and make them available for agency review upon request:

(i) a copy of the agency letter granting the licensee reciprocal recognition of their out-of-state license;

(ii) a copy of the licensee's operating and emergency procedures;

(iii) a copy of the licensee's radioactive material license;

(iv) a copy of all applicable sections of 25 TAC §289; and

(v) a copy of the completed BRC Form 252-3 notifying the agency of the licensee's intent to work in Texas.

(2) - (3) (No change.)

(ff) - (hh) (No change.)

(ii) Increased controls (ICs). Licensees possessing sources containing radioactive material, at any given time, in quantities greater than or equal to the quantities of concern listed in subsection (jj)(9) of this section shall:

(1) (No change.)

(2) limit access to such radioactive material and devices to only approved individuals who require access to perform their duties.

(A) The licensee shall allow only trustworthy and reliable individuals, approved in writing by the licensee, to have unescorted access to radioactive material quantities of concern (RAM QC) and devices.

(B) - (C) (No change.)

(D) Service providers shall be escorted unless determined to be trustworthy and reliable by an NRC [**U.S. Nuclear Regulatory Commission (NRC)**] required

background investigation as an employee of a manufacturing and distribution (M&D) licensee. Written verification attesting to or certifying the person's trustworthiness and reliability shall be obtained from the M&D [manufacturing and distribution] licensee providing the service.

(E) The licensee shall document the basis for concluding that there is reasonable assurance that an individual granted unescorted access is trustworthy and reliable, and does not constitute an unreasonable risk for unauthorized use of RAM QC [radioactive material quantities of concern]. The licensee shall maintain a list of persons approved for unescorted access to such radioactive material and devices by the licensee.

(3) Each licensee shall have a documented program to monitor and immediately detect, assess, and respond to unauthorized access to RAM QC [radioactive material quantities of concern] and devices in use or in storage. Enhanced monitoring shall be provided during periods of source delivery or shipment, where the delivery or shipment exceeds 100 times the values listed in subsection (jj)(9) of this section.

(A) - (E) (No change.)

(4) (No change.)

(5) For domestic highway and rail shipments, prior to shipping licensed radioactive material that exceeds 100 times the quantities in subsection (jj)(9) of this section per consignment, the licensee shall:

(A) Notify the NRC Director, Office of Nuclear Material Safety and Safeguards U.S. Nuclear Regulatory Commission, Washington, DC 20555, in writing, at least 90 days prior to the anticipated date of shipment. The NRC will issue the Order to implement the Additional Security Measures (ASMs) for the transportation of RAM QC [Radioactive Material Quantities of Concern (RAM QC)]. The licensee shall not ship this material until the ASMs for the transportation of RAM QC are implemented or the licensee is notified otherwise, in writing, by the NRC.

(B) (No change.)

(6) - (8) (No change.)

(9) The licensee shall retain documentation required by these ICs [increased controls] for inspection by the agency for three years after they are no longer effective.

(A) - (D) (No change.)

(E) After the license is terminated or amended to reduce possession limits below the quantities of concern, the licensee shall retain all documentation required by these ICs [increased controls] for three years.

(10) Detailed information generated by the licensee that describes the physical protection of RAM QC [radioactive material quantities of concern], is sensitive information and shall be protected from unauthorized disclosure.

(A) - (B) (No change.)

(jj) Appendices.

(1) (No change.)

(2) Isotope quantities (for use in subsection (gg) of this section).

Figure: 25 TAC §289.252(jj)(2) [**Figure: 25 TAC §289.252(jj)(2)**]

(3) - (8) (No change.)

(9) Radionuclide quantities of concern. The following methods shall be used to determine which sources of radioactive material require ICs [increased controls (ICs)]:

(A) - (C) (No change.)

(D) quantities of radioactive materials used to determine quantities of concern. The following table contains quantities of radioactive materials to be used in determining a quantity of concern.

Figure: 25 TAC §289.252(jj)(9)(D) [**Figure: 25 TAC §289.252(jj)(9)(D)**]

(kk) Requirements for the issuance of specific licenses for a medical facility or educational institution to produce Positron Emission Tomography (PET) radioactive drugs for noncommercial transfer to licensees in its consortium.

(1) A license application will be approved if the agency determines that an application from a medical facility or educational institution to produce PET radioactive drugs for noncommercial transfer to licensees in its consortium authorized for medical use in accordance with §289.256 of this title includes:

(A) a request for authorization for the production of PET radionuclides or evidence of an existing license issued in accordance with this section, the NRC, or another agreement states requirements for a PET radionuclide production facility within its consortium from which it receives PET radionuclides;

(B) evidence that the applicant is qualified to produce radioactive drugs for medical use by meeting one of the criteria in subsection (r)(1)(A) of this section;

(C) identification of individual(s) authorized to prepare the PET radioactive drugs if the applicant is a pharmacy, and documentation that each individual meets

the requirements of an authorized nuclear pharmacist as specified in subsection (r)(3)(B) of this section; and

(D) information identified in subsection (r)(1)(B) of this section on the PET drugs to be noncommercially transferred to members of its consortium.

(2) Authorization in accordance with paragraph (1) of this subsection to produce PET radioactive drugs for noncommercial transfer to medical use licensees in its consortium does not relieve the licensee from complying with applicable FDA, other federal, and state requirements governing radioactive drugs.

(3) Each licensee authorized in accordance with paragraph (1) of this subsection to produce PET radioactive drugs for noncommercial transfer to medical use licensees in its consortium shall:

(A) satisfy the labeling requirements in subsection (r)(1)(C) of this subsection for each PET radioactive drug transport radiation shield and each syringe, vial, or other container used to hold a PET radioactive drug intended for noncommercial distribution to members of its consortium; and

(B) possess and use instrumentation meeting the requirements of §289.202(p)(2)(D) of this title to measure the radioactivity of the PET radioactive drugs intended for noncommercial distribution to members of its consortium and meet the procedural, radioactivity measurement, instrument test, instrument check, and instrument adjustment requirements in subsection (r)(2) of this section.

(4) A licensee that is a pharmacy authorized in accordance with paragraph (1) of this subsection to produce PET radioactive drugs for noncommercial transfer to medical use licensees in its consortium shall require that any individual that prepares PET radioactive drugs shall be:

(A) an authorized nuclear pharmacist that meets the requirements in subsection (r)(3)(B) of this section; or

(B) an individual under the supervision of an authorized nuclear pharmacist as specified in §289.256(s) of this title.

(5) A pharmacy, authorized in accordance with paragraph (1) of this subsection to produce PET radioactive drugs for noncommercial transfer to medical use licensees in its consortium that allows an individual to work as an authorized nuclear pharmacist, shall meet the requirements of subsection (r)(3)(D) of this section.

Figure: 25 TAC §289.252(jj)(2)

RADIONUCLIDES							Limit	Unsealed Sources			Sealed Sources					
								10 <sup>3</sup>	10 <sup>4</sup>	10 <sup>5</sup>	10 <sup>10</sup>					
Pr-141	Gd-152	Bi-209m	U-232	Pu-240	Cm-245	Cf-252	0.01 µCi	0.01 mCi	0.1 mCi	1.0 mCi	100 Ci					
Ce-142	Dy-154	Po-208	U-233	Pu-241	Cm-246	Es-254										
Nd-144	Dy-156	Po-209	U-234	Pu-242	Cm-247											
Nd-145	Tb-159	Po-210	U-235	Pu-244	Cm-248											
Sm-146	Ho-165	Ra-226	U-236	Am-241	Bk-247											
Sm-147	Hf-174	Ac-227	Np-235	Am-242m	Bk-249											
Sm-148	W-180	Th-228	Np-237	Am-243	Cf-248											
Gd-148	Pt-190	Th-229	Pu-236	Cm-242	Cf-249											
Gd-150	Pb-210	Th-230	Pu-238	Cm-243	Cf-250											
Gd-151	Bi-209	Pa-231	Pu-239	Cm-244	Cf-251											
and any alpha-emitting radionuclide not listed above or mixtures of unknown alpha emitters of unknown composition.																
Be-10	Fe-60	Rh-102	Te-123	Sm-145	Lu-175	Ir-199m	0.1 µCi	0.1 mCi	1.0 mCi	10 mCi	1.0 kCi					
Al-26	Zn-70	Pd-107	Te-130	Nd-150	Lu-176	Pt-192										
Si-32	Ge-68	Ag-108m	I-129	Eu-150	Lu-177m	Pt-198										
Ar-39	Ge-76	Cd-113m	La-137	Tb-157	Hf-172	Hg-194										
K-40	Kr-81	Cd-116	La-138	Tb-158	Hf-182	Pb-202										
Ar-42	Sr-90	Sn-121m	Ce-139	Dy-159	Ta-179	Pb-205										
Ca-48	Zr-96	Sn-123	Pm-143	Ho-166m	Re-184m	Bi-208										
Ti-44	Mo-100	Sn-124	Pm-144	Lu-173	Re-187	Ra-228										
V-49	Tc-98	Sn-126	Pm-145	Lu-174	Re-189	Np-236										
V-50	Rh-101	Te-121m	Pm-146	Lu-174m	Os-194	Bk-248										
and any other alpha-emitting radionuclides not listed above or mixtures of beta emitters of unknown composition.																
Na-22	Ru-106	Cs-134	Eu-152	Bi-210								1.0 µCi	1.0 mCi	10 mCi	100 mCi	10 kCi
Co-60	Ag-110m	Ce-144	Eu-154													
Cl-36	Ni-63	Rb-87	Cd-109	Ba-133	Gd-153	Tm-171	10 µCi	10 mCi	100 mCi	1.0 Ci	100 kCi					
Ca-45	Zn-65	Zr-93	In-115	Ba-135	Eu-155	W-181										
Mn-54	Se-75	Nb-93m	Sb-125	Cs-137	Tm-170	Tl-204										
C-14,	Co-57	Kr-85	Tc-99	Ir-194	U (natural)	U-238	100 µCi	100 mCi	1.0 Ci	10 Ci	1.0MCi					
Fe-55	Ni-59	Tc-97	Pt-193,	Th-232	Th (natural)											
H-3							1.0 mCi	1 Ci	10 Ci	100 Ci	10 MCi					

Figure: 25 TAC §289.252(jj)(9)(D)

<u>Radionuclide</u>	<u>Quantity of Concern<sup>1</sup> (TBq)</u>	<u>Quantity of Concern<sup>2</sup> (Ci)</u>
Am-241	0.6	16
Am-241/Be	0.6	16
Cf-252	0.2	5.4
Cm-244	0.5	14
Co-60	0.3	8.1
Cs-137	1	27
Gd-153	10	270
Ir-192	0.8	22
Pm-147	400	11,000
Pu-238	0.6	16
Pu-239/Be	0.6	16
Ra-226	0.4	11
Se-75	2	54
Sr-90 (Y-90)	10	270
Tm-170	200	5,400
Yb-169	3	81
Combinations of radioactive materials listed above <sup>3</sup>	See footnote below <sup>4</sup>	

<sup>1</sup> The aggregate activity of multiple, collocated sources of the same radionuclide should be included when the total activity equals or exceeds the quantity of concern.

<sup>2</sup> The primary values used for compliance are TBq. The curie (Ci) values are rounded to 2 significant figures for informational purposes only.

<sup>3</sup> Radioactive materials are to be considered aggregated or collocated if breaching a common physical security barrier (e.g., a locked door at the entrance to a storage room) would allow access to the radioactive material or devices containing the radioactive material. When transporting or storing sources on vehicles and/or trailers, the sources are automatically considered co-located.

<sup>4</sup> If several radionuclides are aggregated, the sum of the ratios of the activity of each source,  $i$  of radionuclide,  $n$ ,  $A(i,n)$ , to the quantity of concern for radionuclide  $n$ ,  $Q(n)$ , listed for that radionuclide equals or exceeds 1. [(aggregated source activity for radionuclide A) ÷ (quantity of concern for radionuclide A)] + [(aggregated source activity for radionuclide B) ÷ (quantity of concern for radionuclide B)] + etc..... >1