

Department of State Health Services
Agenda Item for State Health Services Council
April 12—13, 2007

Agenda Item Title:

Amend 25 TAC §289.202, Rule Relating to Standards for Protection Against Radiation from Radioactive Materials

Repeal and new 25 TAC §289.255, Rule Relating to Radiation Safety Requirements and Licensing and Registration Procedures for Industrial Radiography

Repeal and new 25 TAC §289.256, Rule Relating to Medical and Veterinary Use of Radioactive Materials

Agenda Number: 5e

Recommended Council Action:

For Discussion Only

For Discussion and Action by the Council

Background: Radiation Control 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. Texas is an Agreement State, which means the state has an agreement with the United States Nuclear Regulatory Commission (NRC) under which the NRC has relinquished control over the majority of radioactive material uses in Texas. However, Texas must maintain certain rules compatible with the NRC.

Summary: Section 289.202 concerns standards for protection of the general public and workers from radiation from radioactive materials. The amendment is necessary because the revised requirements are items of immediate mandatory compatibility with the NRC and Texas must adopt them. The amendment adds a definition of nationally tracked source and renumbers subsequent definitions. A new subsection adds requirements for reports of transactions involving nationally tracked sources; provides the nationally tracked source thresholds; and incorporates the requirements for source manufacturers to assign a unique serial number to each nationally tracked source.

Section 289.255 concerns radiation safety requirements and licensing and registration procedures for industrial radiography. The current rule is being repealed and replaced with the new rule because the new rule is extensively reformatted and renumbered. The industrial radiographer examination fee is increased to \$120 and the certification fee is increased to \$110. This rule was last amended in 1999 and the increase in these fees will reflect 100 percent recovery of current program costs. Record retention requirements are changed to 3 years for several records required by this section for purposes of compatibility with the NRC rules.

Section 289.256 concerns standards for medical and veterinary use of radioactive materials. The current rule is being repealed and a new rule is being proposed. The proposal includes new training and qualification standards for individuals responsible for the uses of radioactive materials for medical and veterinary purposes. The proposed rule also provides standards for mobile nuclear medicine services. The training and qualification requirements are also items of compatibility with the NRC.

Summary of Stakeholder Input to Date (including advisory committees): The rules will be made available on the Radiation Control website (www.dshs.state.tx.us/radiation/draft.shtm) and Radiation Control stakeholders, staff, and the NRC were provided notification of the draft and proposed rules for their review and comment. The proposed rules were reviewed by the Texas Radiation Advisory Board (TRAB) at the January 6, 2007, meeting in Austin, Texas. TRAB recommended that the proposed §289.202 and §289.255 rules be forwarded to the Department of State Health Services advisory council for consideration as proposed rules. TRAB did not recommend that the proposed §289.256 rule be forwarded to the Department of State Health Services advisory council for consideration as a proposed rule because they disagreed with the NRC's training requirements. However, staff is presenting the §289.256 rule because it is an item of compatibility and for the State of Texas to remain compatible, it must be adopted.

Proposed Motion: Motion to recommend HHSC approval for publication of rules contained in agenda item #____.

Agenda Item Approved by: Kathryn C. Perkins, R.N., M.B.A.

Presented by: Cindy Cardwell 834-6770, ext. 2239 **Title:** Manager, Radiation Group

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Date Submitted

3/7/07

TITLE 25. HEALTH SERVICES
Part 1. DEPARTMENT OF STATE HEALTH SERVICES
Chapter 289. Radiation Control
Subchapter D. General
Amendment §289.202
Subchapter F. License Regulations
Repeal §289.255
New §289.255
Repeal §289.256
New §289.256

Proposed Preamble

The Executive Commissioner of the Health and Human Services Commission on behalf of the Department of State Health Services (department) proposes the amendment of §289.202, concerning standards for protection against radiation from radioactive materials, the repeal of §289.255 and new §289.255, concerning radiation safety requirements and licensing and registration procedures for industrial radiography, and the repeal of §289.256 and new §289.256, concerning medical and veterinary use of radioactive material.

BACKGROUND AND PURPOSE

The amendment of §289.202 adds requirements regarding the national radioactive source tracking system for certain sealed sources that are items of immediate mandatory compatibility with the United States Nuclear Regulatory Commission (NRC) and, as an agreement state with the NRC, Texas must adopt them.

The repeal and new §289.255 are necessary to modify radiation safety requirements and licensing and registration procedures for industrial radiography. Most of these requirements are items of compatibility with the NRC and, as an agreement state with the NRC, Texas must adopt them. In addition, the industrial radiography examination and certification fees are increased to recover 100 percent of current program costs. Several revisions were made to clarify existing requirements in the rule.

The repeal and new §289.256 are necessary to comply with compatibility requirements of the NRC. The repeal and new rule are the result of the NRC's adoption of training and education requirements for users of radioactive material for medical purposes. These include physicians, medical physicists, nuclear pharmacists, and radiation safety officers. Texas is an agreement state, which means the state has an agreement with the NRC under which the NRC has relinquished control over the majority of radioactive material uses in Texas. However, Texas must maintain certain rules compatible with the NRC.

Government Code, §2001.039, requires that each state agency review and consider for re-adoption each rule adopted by that agency pursuant to the Government Code, Chapter 2001 (Administrative Procedure Act). Sections 289.202, 289.255, and 289.256 have been reviewed

and the department has determined that reasons for adopting the sections continue to exist because rules on these subjects are needed.

SECTION-BY-SECTION SUMMARY

The revisions to §289.202 are necessary because these requirements are items of immediate mandatory compatibility with the NRC and Texas must adopt them. Section §289.202(c) adds a definition of nationally tracked source and renumbers subsequent definitions. New §289.202(hhh) adds requirements for reports of transactions involving nationally tracked sources; provides the nationally tracked source thresholds; and incorporates the requirements for source manufacturers to assign a unique serial number to each nationally tracked source.

Concerning §289.255, throughout the rule, reference to §289.231 relating to general provisions and standards for protection against machine-produced radiation is added to the specific parts of the rule that apply to industrial radiographic operations using machine-produced radiation.

In §289.255(b), the new rule addresses, in separate paragraphs, those sections that apply respectively to industrial radiographic operations using radioactive material and operations using machine-produced radiation. In addition, §289.255(b) includes reference to §289.228 relating to radiation safety requirements for analytical and other industrial radiation machines and §289.229 relating to radiation safety requirements for accelerators, therapeutic radiation machines, and simulators, to state the complete list of rules and requirements that apply to all industrial radiographic operations using machine-produced radiation.

Several definitions are revised in §289.255(c) to be compatible with NRC and the definition of “Conference of Radiation Control Program Directors, Inc. (CRCPD)” is added to define this term that is used in the rule text. The definition of “enclosed radiography” is deleted, as this term is included in the term “shielded room radiography.” As a result of deleting the definition of “enclosed radiography,” this term has been replaced with “shielded room” throughout the section to state the correct term. Section 289.255(d) includes language to clarify certain industrial radiographic operations that are exempt from this section.

The requirements for qualifications of radiographic personnel in §289.255(e) have been reformatted and renumbered for clarification of these requirements. Concerning §289.255(e)(1)(B), the number of days that a radiographer trainee may carry the copy of the completed BRC Form 255-E before receiving a trainee status card is changed from 60 days to 30 days because the agency has determined that the trainee status card is issued within 30 days after documentation has been submitted. In §289.255(f)(2), a statement is added to the additional radiographer and radiographer trainer requirements to clearly state that these individuals are responsible for ensuring that radiographic operations are conducted in accordance with the requirements of this section.

In §289.255(g)(1)(B), the industrial radiographer examination is now non-transferable as well as non-refundable in order to increase the efficiency of scheduling examinations. In addition, this subparagraph increases the examination fee from \$25 to \$120 to recover 100 percent of current program costs. A new subparagraph is added to §289.255(g)(1) to clarify that applicants who

fail to appear at a scheduled exam and do not reschedule 48 hours prior to their assigned exam session must reapply for a future exam session in an effort to decrease the relatively large number of applicants who fail to appear at a scheduled exam session and increase the efficiency of scheduling exams. Section 289.255(g)(2)(F) adds the words “government-issued” in front of the words “photo identification card” to specify the type of photo identification that is acceptable to the department.

Section 289.255(h)(1)(A) increases the radiographer certification fee to from \$100 to \$110 to recover 100 percent of current program costs. In addition, in §289.255(h)(4)(C), language is added to clarify that an individual whose radiographer certification has been suspended or revoked must comply with the conditions of the suspension or revocation orders before certification is reinstated, or the individual is permitted by the department to apply for a new certification. In §289.255(l)(1)(A), the words “make, model, and” are added in front of the words “serial number” because this revision is an item of compatibility with the NRC and Texas must adopt this. In §289.255(n)(1), the term “or” is replaced with the term “and” following the words “conspicuous visible” to clarify that both a conspicuous visible and audible alarm signal shall exist at permanent radiographic installations.

The term “personnel monitoring control” is changed to “individual monitoring” in §289.255(p) to be consistent with language used throughout this chapter. The word “operable” is added in front of the word “alarming” in §289.255(p)(2)(A)(iii) and the words “and the possibility of radiation exposure cannot be ruled out as the cause,” are added to §289.255(p)(2)(G) for clarification and because these requirements are items of compatibility with the NRC.

Section 289.255(q)(1) adds the word “continuous” in front of the word “visual” to clarify that radiographic personnel shall maintain continuous visual surveillance of the operation and to maintain rules compatible with the NRC.

Section §289.255(t)(4)(B) replaces “where the main business office is located” with “of an authorized use site listed on the certificate of registration” to clarify the location that must be prominently displayed on both sides of all vehicles used to transport radiation machines for temporary job site use. The requirements for radiation machines in shielded rooms and the requirements for certified and certifiable cabinet x-ray systems have been reformatted and renumbered in §289.255(t)(7) and (8) for clarification of these requirements.

Several revisions are made to §289.255(u)(1) concerning licensing requirements for industrial radiographic operations. The requirements are items of compatibility with the NRC and as an agreement state, Texas is required to adopt them. These revisions include addition of new language to §289.255(u)(1)(B)(x) concerning performance of leak testing of sealed sources or exposure devices containing depleted uranium shielding and addition of new language to §289.255(u)(2)(B)(xii) concerning performance of in-house calibrations of survey instruments. In addition these revisions add new language to the following: §289.255(u)(3) concerning locking of radiographic exposure devices, storage containers and source changers; §289.255(u)(5)(C)(ii) concerning modification of radiographic exposure devices, source changers, source assemblies, and associated equipment; and §289.255(u)(5)(D)(vii) concerning kinking and crushing tests for guide tubes. Section §289.255(u)(7)(D) replaces “where the main

business office is located” with “of an authorized use site listed on the license” to clarify the location that must be prominently displayed on both sides of all vehicles used to transport radioactive material for temporary job site use.

In §289.255(v)(1), the record keeping time requirements change from two years to three years for the following records because these requirements are items of compatibility with the NRC: survey instrument calibrations; quarterly inventory; utilization logs; inspection and maintenance; permanent radiographic installation tests; direct-reading pocket or electronic personal dosimeter readings; pocket dosimeter calibrations and yearly response checks; alarming ratemeter calibrations; internal audit program; annual refresher training; radiation surveys; leak tests; annual evaluation of enclosed sealed source systems; and test of sealed source interlocks. In addition, the department changes the record keeping time requirements in §289.255(v)(1) from two years to three years for the following records, to be consistent with other record keeping time requirements stated throughout the section: annual evaluation of enclosed x-ray systems; operating instructions in cabinet x-ray systems; tests of x-ray interlocks; and evaluation of certified cabinet x-ray systems.

The requirement that records of individual monitoring records be maintained at additional authorized use/storage sites is added to the list in §289.255(v)(2)(A)(xx) to state the complete list of records required at these sites. In addition, §289.255(v)(2)(A)(xix) and §289.255(v)(3)(H) add the words “NRC license,” in front of the words “agreement state license” and adds the word “state” in front of the word “certificate” to clarify the types of out-of-state licensees and registrants that may work in Texas under reciprocity.

The majority of the additional language in the new §289.256 is new training, education and use requirements for users of radioactive material for medical purposes. These users include physicians, medical physicists, nuclear pharmacists, and radiation safety officers. The other changes include the following; additional language is added to §289.256(q) concerning licensing information to allow for emerging technologies in medical uses of radioactive material, additional language is added to §289.256(u) to clarify suppliers of sealed sources and devices used in medicine, and additional language is added in §289.256(dd) to provide licensing and operating requirements for mobile nuclear medicine services. Due to the additions and realignment of §289.256, renumbering occurred.

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 §289.202 and §289.256 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. However, Ms. Tennyson has determined that for each calendar year of the first five years that §289.255 is in effect, there will be fiscal implications to the state as a result of enforcing or administering the section as proposed. The effect on state government will be an increase in revenue to the state of approximately \$64,950 for the first calendar year and \$77,940 each year for calendar years two through five due to the increase in examination and certification fees. The additional revenue will recover 100 percent

of current program costs. Implementation of the proposed sections will not result in any fiscal implications for local governments.

SMALL AND MICRO-BUSINESS IMPACT ANALYSIS

Ms. Tennyson has also determined that there will be no effect on small businesses or micro-businesses required to comply with §289.202 and §289.256 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 section. There are no anticipated economic costs to persons who are required to comply with §289.202 and §289.256 as proposed. However, Ms. Tennyson has determined that there are anticipated economic costs to small businesses or micro-businesses required to comply with §289.255 as proposed. There will be an increase in the examination fee of \$95 per exam and an increase in the certification fee of \$10. Each radiographer must take an exam and be certified. If the individual radiographer takes the exam given by the agency and is certified by the agency, the individual radiographer will have a total increase of \$105 to be certified. Small businesses or micro-businesses will only incur the additional cost if they choose to pay for an employee's exam and certification costs. Concerning §289.202, the reporting requirements allow reporting by common business resources such as computer, fax, mail, or telephone. Licensees are already required to keep records of source receipt, transfer, and disposal. 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 a result of enforcing or administering §289.202 is to ensure continued protection of the public, workers, and the environment from unnecessary exposure to radiation by ensuring security of sources by adequately tracking radioactive sources. The public benefit anticipated as a result of enforcing or administering §289.255 is to ensure continued provision of safe, properly operating industrial radiography operations for protection of the public, workers, and the environment from unnecessary exposure to radiation. The public benefit anticipated as a result of enforcing or administering §289.256 is to ensure adequate training and experience criteria for individuals responsible for medical and veterinary uses of radioactive materials.

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, 1100 West 49th Street, Austin, Texas 78756, 512/834-6770, extension 2239, or by email to 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). Please contact Cindy Cardwell at (512) 834-6770, extension 2239, or Cindy.Cardwell@dshs.state.tx.us if you have questions.

LEGAL CERTIFICATION

The Department of State Health Services, General Counsel, Cathy Campbell, 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 amendment, repeals, and new sections 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 proposed repeal and new §289.255 are also authorized by Health and Safety Code, §401.301, which allows the department to collect fees for radiation control licenses and registrations that it issues. The review of the rules implements Government Code, §2001.039.

The proposed amendment, repeals, and new sections affect the Health and Safety Code, Chapters 401 and 1001; and Government Code, Chapter 531.

Sections for Repeal

§289.255. Radiation Safety Requirements and Licensing and Registration Procedures for Industrial Radiography.

§289.256. Medical and Veterinary Use of Radioactive Material.

LEGEND: (Proposed Amendments)

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 designated subdivisions

§289.202. Standards for Protection Against Radiation from Radioactive Materials.

(a) - (b) (No change.)

(c) Definitions. The following words and terms when used in this section shall have the following meaning, unless the context clearly indicates otherwise.

(1) - (20) (No change.)

(21) Nationally tracked source -- A sealed source containing a quantity equal to or greater than Category 1 or Category 2 levels of any radioactive material listed in subsection (hhh)(2) of this section. In this context a sealed source is defined as radioactive material that is sealed in a capsule or closely bonded, in a solid form and which is not exempt from regulatory control. It does not mean material encapsulated solely for disposal, or nuclear material contained in any fuel assembly, subassembly, fuel rod, or fuel pellet. Category 1 nationally tracked sources are those containing radioactive material at a quantity equal to or greater than the Category 1 threshold. Category 2 nationally tracked sources are those containing radioactive material at a quantity equal to or greater than the Category 2 threshold but less than the Category 1 threshold.

(22) [(21)] Negative pressure respirator (tight fitting) -- A respirator in which the air pressure inside the facepiece is negative during inhalation with respect to the ambient air pressure outside the respirator.

(23) [(22)] Nonstochastic effect -- A health effect, the severity of which varies with the dose and for which a threshold is believed to exist. Radiation-induced cataract formation is an example of a nonstochastic effect. For purposes of this section, deterministic effect is an equivalent term.

(24) [(23)] Planned special exposure -- An infrequent exposure to radiation, separate from and in addition to the annual occupational dose limits.

(25) [(24)] Positive pressure respirator -- A respirator in which the pressure inside the respiratory inlet covering exceeds the ambient air pressure outside the respirator.

(26) [(25)] Powered air-purifying respirator -- An air-purifying respirator that uses a blower to force the ambient air through air-purifying elements to the inlet covering.

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(27) [(26)] Pressure demand respirator -- A positive pressure atmosphere-supplying respirator that admits breathing air to the facepiece when the positive pressure is reduced inside the facepiece by inhalation.

(28) [(27)] Qualitative fit test -- A pass/fail fit test to assess the adequacy of respirator fit that relies on the individual's response to the test agent.

(29) [(28)] Quantitative fit test -- An assessment of the adequacy of respirator fit by numerically measuring the amount of leakage into the respirator.

(30) [(29)] 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.

(31) [(30)] Reference man -- A hypothetical aggregation of human physical and physiological characteristics determined by international consensus. These characteristics may be used by researchers and public health employees to standardize results of experiments and to relate biological insult to a common base. A description of Reference Man is contained in the International Commission on Radiological Protection Report, ICRP Publication 23, "Report of the Task Group on Reference Man."

(32) [(31)] Respiratory protective equipment -- An apparatus, such as a respirator, used to reduce an individual's intake of airborne radioactive materials.

(33) [(32)] Sanitary sewerage -- A system of public sewers for carrying off waste water and refuse, but excluding sewage treatment facilities, septic tanks, and leach fields owned or operated by the licensee or registrant.

(34) [(33)] Self-contained breathing apparatus -- An atmosphere-supplying respirator for which the breathing air source is designed to be carried by the user.

(35) [(34)] Stochastic effect -- A health effect that occurs randomly and for which the probability of the effect occurring, rather than its severity, is assumed to be a linear function of dose without threshold. Hereditary effects and cancer incidence are examples of stochastic effects. For purposes of this section probabilistic effect is an equivalent term.

(36) [(35)] Supplied-air respirator or airline respirator -- An atmosphere-supplying respirator for which the source of breathing air is not designed to be carried by the user.

(37) [(36)] Tight-fitting facepiece -- A respiratory inlet covering that forms a complete seal with the face.

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(38) [(37)] User seal check (fit check) -- An action conducted by the respirator user to determine if the respirator is properly seated to the face. Examples include negative pressure check, positive pressure check, irritant smoke check, or isoamyl acetate check.

(39) [(38)] Weighting factor w_T for an organ or tissue (T) -- The proportion of the risk of stochastic effects resulting from irradiation of that organ or tissue to the total risk of stochastic effects when the whole body is irradiated uniformly. For calculating the effective dose equivalent, the values of w_T are:

Figure: 25 TAC §289.202(c)(39) [Figure: 25 TAC §289.202(c)(38)]

(d) - (ggg) (No change.)

(hhh) Requirements for nationally tracked sources.

(1) Reports of transactions involving nationally tracked sources. Each licensee who manufactures, transfers, receives, disassembles, or disposes of a nationally tracked source shall complete and submit to NRC a National Source Tracking Transaction Report as specified in the following subparagraphs for each type of transaction.

(A) Each licensee who manufactures a nationally tracked source shall complete and submit to NRC a National Source Tracking Transaction Report. The report shall include the following information:

(i) the name, address, and license number of the reporting licensee;

(ii) the name of the individual preparing the report;

(iii) the manufacturer, model, and serial number of the source;

(iv) the radioactive material in the source;

(v) the initial source strength in becquerels (curies) at the time of manufacture; and

(vi) the manufacture date of the source.

(B) Each licensee that transfers a nationally tracked source to another person shall complete and submit to NRC a National Source Tracking Transaction Report. The report shall include the following information:

(i) the name, address, and license number of the reporting licensee;

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- (ii) the name of the individual preparing the report;
- (iii) the name and license number of the recipient facility and the shipping address;
- (iv) the manufacturer, model, and serial number of the source or, if not available, other information to uniquely identify the source;
- (v) the radioactive material in the source;
- (vi) the initial or current source strength in becquerels (curies);
- (vii) the date for which the source strength is reported;
- (viii) the shipping date;
- (ix) the estimated arrival date; and
- (x) for nationally tracked sources transferred as waste under a Uniform Low-Level Radioactive Waste Manifest, the waste manifest number and the container identification of the container with the nationally tracked source.

(C) Each licensee that receives a nationally tracked source shall complete and submit to NRC a National Source Tracking Transaction Report. The report shall include the following information:

- (i) the name, address, and license number of the reporting licensee;
- (ii) the name of the individual preparing the report;
- (iii) the name, address, and license number of the person that provided the source;
- (iv) the manufacturer, model, and serial number of the source or, if not available, other information to uniquely identify the source;
- (v) the radioactive material in the source;
- (vi) the initial or current source strength in becquerels (curies);
- (vii) the date for which the source strength is reported;
- (viii) the date of receipt; and

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(ix) for material received under a Uniform Low-Level Radioactive Waste Manifest, the waste manifest number and the container identification with the nationally tracked source.

(D) Each licensee that disassembles a nationally tracked source shall complete and submit to NRC a National Source Tracking Transaction Report. The report shall include the following information:

(i) the name, address, and license number of the reporting licensee;

(ii) the name of the individual preparing the report;

(iii) the manufacturer, model, and serial number of the source or, if not available, other information to uniquely identify the source;

(iv) the radioactive material in the source;

(v) the initial or current source strength in becquerels (curies);

(vi) the date for which the source strength is reported; and

(vii) the disassemble date of the source.

(E) Each licensee who disposes of a nationally tracked source shall complete and submit to NRC a National Source Tracking Transaction Report. The report shall include the following information:

(i) the name, address, and license number of the reporting licensee;

(ii) the name of the individual preparing the report;

(iii) the waste manifest number;

(iv) the container identification with the nationally tracked source.

(v) the date of disposal; and

(vi) the method of disposal.

(F) The reports discussed in subparagraphs (A) through (E) of this paragraph shall be submitted to NRC by the close of the next business day after the transaction. A single report may be submitted for multiple sources and transactions. The reports shall be submitted to the National Source Tracking System by using the following:

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(i) the on-line National Source Tracking System;

(ii) electronically using a computer-readable format;

(iii) by facsimile;

(iv) by mail to the address on the National Source Tracking Transaction Report Form (NRC Form 748); or

(v) by telephone with follow-up by facsimile or mail.

(G) Each licensee shall correct any error in previously filed reports or file a new report for any missed transaction within 5 business days of the discovery of the error or missed transaction. Such errors may be detected by a variety of methods such as administrative reviews or by physical inventories required by regulation. In addition, each licensee shall reconcile the inventory of nationally tracked sources possessed by the licensee against that licensee's data in the National Source Tracking System. The reconciliation shall be conducted during the month of January in each year. The reconciliation process shall include resolving any discrepancies between the National Source Tracking System and the actual inventory by filing the reports identified by subparagraphs (A) through (E) of this paragraph. By January 31 of each year, each licensee shall submit to the National Source Tracking System confirmation that the data in the National Source Tracking System is correct.

(H) Each licensee that possesses Category 1 nationally tracked sources listed in paragraph (2) of this subsection shall report its initial inventory of Category 1 nationally tracked sources to the National Source Tracking System by November 15, 2007. Each licensee that possesses Category 2 nationally tracked sources listed in paragraph (2) of this subsection shall report its initial inventory of Category 2 nationally tracked sources to the National Source Tracking System by November 30, 2007. The information may be submitted to NRC by using any of the methods identified by subparagraph (F)(i) through (iv) of this paragraph. The initial inventory report shall include the following information:

(i) the name, address, and license number of the reporting licensee;

(ii) the name of the individual preparing the report;

(iii) the manufacturer, model, and serial number of each nationally tracked source or, if not available, other information to uniquely identify the source;

(iv) the radioactive material in the sealed source;

(v) the initial or current source strength in becquerels (curies); and

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(vi) the date for which the source strength is reported.

(2) Nationally tracked source thresholds. The Terabecquerel (TBq) values are the regulatory standards. The curie (Ci) values specified are obtained by converting from the TBq value. The curie values are provided for practical usefulness only and are rounded after conversion.

Figure: 25 TAC §289.202(hhh)(2)

(3) Serialization of nationally tracked sources. Each licensee who manufactures a nationally tracked source after February 6, 2007, shall assign a unique serial number to each nationally tracked source. Serial numbers shall be composed only of alpha-numeric characters.

Figure: 25 TAC §289.202(c)(39)

ORGAN DOSE WEIGHTING FACTORS

Organ or Tissue	w _T
Gonads	0.25
Breast	0.15
Red bone marrow	0.12
Lung	0.12
Thyroid	0.03
Bone surfaces	0.03
Remainder	0.30*
Whole Body	1.00**

* 0.30 results from 0.06 for each of five "remainder" organs, excluding the skin and the lens of the eye, that receive the highest doses.

** For the purpose of weighting the external whole body dose, for adding it to the internal dose, a single weighting factor, w_T = 1.0, has been specified. The use of other weighting factors for external exposure will be approved on a case-by-case basis until such time as specific guidance is issued.

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Figure: 25 TAC §289.202(hhh)(2)

Radioactive Material	Category 1 (TBq)	Category 1 (Ci)	Category 2 (TBq)	Category 2 (Ci)
Actinium-227	20	540	0.2	5.4
Americium-241	60	1,600	0.6	16.0
Americium-241/Be	60	1,600	0.6	16.0
Californium-252	20	540	0.2	5.4
Cobalt-60	30	810	0.3	8.1
Curium-244	50	1,400	0.5	14.0
Cesium-137	100	2,700	1.0	27.0
Gadolinium-153	1,000	27,000	10.0	270.0
Iridium-192	80	2,200	0.8	22.0
Plutonium-238	60	1,600	0.6	16.0
Plutonium-239/Be	60	1,600	0.6	16.0
Polonium-210	60	1,600	0.6	16.0
Promethium-147	40,000	1,100,000	400.0	11,100.0
Radium-226	40	1,100	0.4	11.0
Selenium-75	200	5,400	2.0	54.0
Strontium-90	1,000	27,000	10.0	270.0
Thorium-228	20	540	0.2	5.4
Thorium-229	20	540	0.2	5.4
Thulium-170	20,000	540,000	200.0	5,400.0
Ytterbium-169	300	8,100	3.0	81.0

LEGEND: (Proposed New Rules)
Regular Print = Proposed New Language

§289.255. Radiation Safety Requirements and Licensing and Registration Procedures for Industrial Radiography.

(a) Purpose.

(1) The requirements in this section establish radiation safety requirements and licensing and registration procedures for using sources of radiation for industrial radiography and for certification of industrial radiographers.

(2) The requirements in this section apply to licensees and registrants who possess sources of radiation for industrial radiography, including radiation machines, accelerators, and sealed radioactive sources.

(3) Each licensee and registrant is responsible for ensuring compliance with this chapter, license and registration conditions, and orders of the agency.

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(4) Each licensee and registrant is responsible for ensuring that radiographic personnel performing activities under a license or registration comply with this chapter, license and registration conditions, and orders of the agency.

(b) Scope.

(1) The requirements of this section are in addition to and not in substitution for other applicable requirements of this chapter.

(2) The requirements of the following sections of this chapter apply to all licensed industrial radiographic operations:

(A) §289.201 of this title (relating to General Provisions for Radioactive Material);

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

(C) §289.203 of this title (relating to Notices, Instructions, and Reports to Workers; Inspections);

(D) §289.204 of this title (relating to Fees for Certificates of Registration, Radioactive Material Licenses, Emergency Planning and Implementation, and Other Regulatory Services);

(E) §289.205 of this title (relating to Hearing and Enforcement Procedures);

(F) §289.251 of this title (relating to Exemptions, General Licenses, and General License Acknowledgements);

(G) §289.252 of this title (relating to Licensing of Radioactive Material);
and

(H) §289.257 of this title (relating to Packaging and Transportation of Radioactive Material).

(3) The requirements of the following sections of this chapter apply to all registered industrial radiographic operations:

(A) §289.203 of this title;

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(B) §289.204 of this title;

(C) §289.205 of this title;

(D) §289.226 of this title (relating to Registration of Radiation Machine Use and Services); and

(E) §289.231 of this title (relating to General Provisions and Standards for Protection Against Machine-Produced Radiation).

(4) The requirements of §289.228 of this title (relating to Radiation Safety Requirements for Analytical and Other Industrial Radiation Machines) apply to persons using analytical and other industrial radiation machines subject to this section.

(5) The requirements of §289.229 of this title (relating to Radiation Safety Requirements for Accelerators, Therapeutic Radiation Machines, and Simulators) apply to persons using accelerators subject to this section.

(c) Definitions. The following words and terms, when used in this section, shall have the following meaning, unless the context clearly indicates otherwise.

(1) Additional authorized use/storage site -- Authorized use/storage locations specifically named on a license or certificate of registration other than the main site specified on a license or certificate of registration or other than temporary job sites.

(2) ANSI -- American National Standards Institute.

(3) Annual refresher safety training -- A review conducted or provided by the licensee or registrant for its employees on radiation safety aspects of industrial radiography. The review may include, as appropriate, the results of internal audits, new procedures or equipment, new or revised regulations, accidents or errors that have been observed, and should also provide opportunities for employees to ask safety questions.

(4) Associated equipment -- Equipment that is used in conjunction with a radiographic exposure device to make radiographic exposures that drives, guides, or comes in contact with the source, (such as, guide tube, control tube, control cable (drive cable), removable source stop, "J" tube and collimator when it is used as an exposure head).

(5) Cabinet x-ray system -- An x-ray system with the x-ray tube installed in an enclosure independent of existing architectural structures except the floor on which it may be

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placed. An x-ray tube used within a shielded part of a building, or x-ray equipment that may temporarily or occasionally incorporate portable shielding, is not considered a cabinet x-ray system. The cabinet x-ray system is intended to:

- (A) contain at least that portion of a material being irradiated;
- (B) provide radiation attenuation; and
- (C) exclude personnel from its interior during generation of radiation.

(6) Certifiable cabinet x-ray system -- An existing uncertified x-ray system that has been modified to meet the certification requirements specified in Title 21, Code of Federal Regulations (CFR), §1020.40.

(7) Certification identification (ID) card -- The document issued by the agency to individuals who have completed the requirements stated in subsection (e)(2)(A) of this section.

(8) Certified cabinet x-ray system -- An x-ray system that has been certified in accordance with Title 21, CFR, §1010.2 as being manufactured and assembled on or after April 10, 1975, according to the provisions of Title 21, CFR, §1020.40.

(9) Certifying entity -- An entity that is:

- (A) an independent certifying organization;
- (B) an Agreement State whose industrial radiographer certification program meets the applicable parts of Title 10, CFR, Part 34, Appendix A, Parts II and III for radioactive material; or
- (C) a radiation control agency whose x-ray and/or combination certification requirements are found to be equivalent to criteria established by the Conference of Radiation Control Program Directions, Inc. (CRCPD).

(10) Collimator -- A radiation shield that is placed on the end of a guide tube or directly onto a radiographic exposure device to restrict the size of the radiation beam when the sealed source is cranked into position to make a radiographic exposure.

(11) Conference of Radiation Control Program Directors, Inc. (CRCPD) -- A 501(c)(3) nonprofit non-governmental professional organization dedicated to radiation protection to serve as a common forum for the many governmental radiation protection agencies to communicate with each other and to promote uniform radiation protection regulations and activities.

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(12) Control cable (drive cable) -- The cable that is connected to the source assembly and used to drive the source from and return it to the shielded position.

(13) Control mechanism (drive mechanism) -- A device that enables the source assembly to be moved from and returned to the shielded position. A drive mechanism is also known as a crank assembly.

(14) Control tube -- A protective sheath for guiding the control cable. The control tube connects the control drive mechanism to the radiographic exposure device.

(15) Crank-out device -- The control cable, control tube, and drive mechanism used to move the sealed source to and from the shielded position to make an industrial radiographic exposure.

(16) Exposure head -- A device that locates the gamma radiography sealed source in the selected working position. An exposure head is also known as a source stop.

(17) Fluoroscopic imaging assembly -- A subsystem in which x-ray photons produce a fluoroscopic image. It includes the image receptors such as the image intensifier and spot-film device, electrical interlocks, if any, and structural material providing linkage between the image receptor and source assembly.

(18) GED -- General educational development.

(19) Guide tube -- A flexible or rigid tube, such as a "J" tube, for guiding the source assembly and the attached control cable from the exposure device to the exposure head. The guide tube may also include the connections necessary for attachment to the exposure device and to the exposure head.

(20) Independent certifying organization -- An independent organization that meets all of the criteria of Title 10, CFR Part 34, Appendix A, for radioactive material, or comparable standards for x-ray machines.

(21) Industrial radiography (radiography) -- A nondestructive testing method using ionizing radiation, such as gamma rays or x rays, to make radiographic images for the purpose of detecting flaws in objects without destroying them.

(22) Lay-barge radiography -- Industrial radiography performed on any water vessel used for laying pipe.

(23) Lock-out survey -- A radiation survey performed to determine that a sealed source is in its fully shielded position before moving the radiographic exposure device or source

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changer to a different temporary job site or before securing the radiographic exposure device or source changer against unauthorized removal.

(24) Offshore -- Within the territorial waters of the state of Texas. The territorial waters of Texas extend to the three marine league line or nine nautical miles from the Texas coast.

(25) On-the-job training (hands-on experience) -- Experience in all of the areas considered to be directly involved in the radiography process. The hours of on-the-job training do not include safety meetings, classroom training, travel, darkroom activities, film development and interpretation, or use of a cabinet x-ray unit.

(26) Permanent radiographic installation -- A shielded room, cell, or vault, not located at a temporary jobsite, in which radiography is performed and meets the criteria of subsection (n) of this section.

(27) Permanent storage site -- Any location that is specifically named on a license or certificate of registration and that is used only for storage of sources of radiation.

(28) Personal supervision -- Guidance and instruction provided to a radiographer trainee by a radiographer trainer who is present at the site, in visual contact with the trainee while the trainee is using sources of radiation, associated equipment, and survey meters, and in such proximity that immediate assistance can be given if required.

(29) Pipeliners -- A directional beam radiographic exposure device.

(30) Platform radiography -- Industrial radiography performed on an offshore platform or other structure over a body of water.

(31) Practical examination -- A demonstration through practical application of the safety rules and principles in industrial radiography including use of all appropriate equipment and procedures.

(32) Radiation safety officer (RSO) -- An individual named by the licensee or registrant who has a knowledge of, responsibility for, and authority to enforce appropriate radiation protection rules, standards, and practices on behalf of the licensee or registrant and who meets the requirements of subsection (e)(4) of this section.

(33) Radiographer -- Any individual who has successfully completed the training, testing, and documentation requirements of subsection (e)(2)(A) of this section and who is responsible to the licensee or registrant for assuring compliance with the requirements of the agency's regulations and conditions of the license or certificate of registration. These individuals

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may be referred to as certified industrial radiographers or certified radiographers. The individual may also:

(A) perform industrial radiographic operations; or

(B) be in attendance at the site where the sources of radiation are being used.

(34) Radiographer certification -- Written approval received from a certifying entity stating that an individual has satisfactorily met certain established radiation safety, testing, and experience criteria.

(35) Radiographer trainee -- Any individual who has successfully completed the training and documentation requirements of subsection (e)(1)(A) of this section and who shall use sources of radiation and associated equipment or radiation survey instruments under the personal supervision of a radiographer trainer.

(36) Radiographer trainer -- A radiographer who instructs and supervises radiographer trainees during on-the-job training and who meets the requirements of subsection (e)(3) of this section.

(37) Radiographic exposure device -- Any instrument containing a sealed source fastened or contained therein, in which the sealed source or shielding thereof may be moved, or otherwise changed, from a shielded to unshielded position for purposes of making a radiographic exposure (e.g., camera).

(38) Radiographic operations -- All activities associated with the presence of x-ray machines or radioactive sources in a radiographic exposure device during the use of the machine or device or transport (except when being transported by a common or contract transport). Radiographic operations include surveys to confirm the adequacy of boundaries, setting up equipment, and any activity inside restricted area boundaries.

(39) Radiographic personnel -- Any radiographer, radiographer trainer, or radiographer trainee.

(40) Residential location -- Any area where 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.

(41) S-tube -- A tube through which the radioactive source travels when inside a radiographic exposure device.

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(42) Shielded position -- The location within the radiographic exposure device or source changer where the sealed source is secured and restricted from movement.

(43) Shielded-room radiography -- Industrial radiography conducted in a room shielded so radiation levels at every location on the exterior meet the limitations specified in §289.202(n) of this title or §289.231(o) of this title, as applicable. A shielded room is also known as a bay or bunker.

(44) Source assembly (pigtail) -- An assembly that consists of the sealed source and a connector that attaches the source to the control cable. The source assembly may also include a ball stop used to secure the source in the shielded position.

(45) Source changer -- A device designed and used to replace sealed sources in radiographic exposure devices, including those used to transport and store sealed sources.

(46) Storage area -- Any location, facility, or vehicle that is used to store and secure a radiation machine, radiographic exposure device, a storage container, or a sealed source when it is not used for radiographic operations. Storage areas are locked or have a physical barrier to prevent accidental exposure, tampering, or unauthorized removal of the machine, device, container, or source.

(47) Storage container -- A device in which the sealed source is secured and stored.

(48) Storage facility -- A structure designed to house one or more sources of radiation to provide security and shielding at a permanent storage site. A storage facility is also known as a vault.

(49) Temporary job site -- Any location where industrial radiography is performed other than the specific use location(s) listed on a license or certificate of registration. If use of sources of radiation is authorized at a temporary job site, storage incident to that use is also authorized.

(50) Trainee status card -- The document issued by the agency following completion of the requirements of subsection (e)(1)(A) of this section.

(51) Transport container -- A package that is designed to provide radiation safety and security when sealed sources are transported and meets all applicable requirements of the United States Department of Transportation (DOT).

(52) Underwater radiography -- Industrial radiography performed when the radiographic exposure device and/or related equipment are beneath the surface of the water.

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(d) Exemptions.

(1) Uses of certified and certifiable cabinet x-ray systems are exempt from the requirements of this section except for the requirements of subsections (a), (b)(3), (c), and (t)(8) of this section.

(2) Industrial uses of hand-held light intensified imaging devices are exempt from the requirements in this section if the exposure rate 18 inches from the source of radiation to any individual does not exceed 2 millirem per hour (mrem/hr) (0.02 millisievert per hour (mSv/hr)). Devices with exposure rates that exceed the 2 mrem/hr (0.02 mSv/hr) level shall meet the applicable requirements of this section and §289.252 of this title or §289.226 of this title, as applicable. This exemption will apply only to those radiation machines that do not allow a person or body part to be exposed to the radiation beam.

(3) Radiation machines determined by the agency to constitute a minimal threat to human health and safety in accordance with §289.231(II)(3) of this title, are exempt from the requirements in this section except for the requirements of paragraph (1) of this subsection.

(4) Facilities that utilize radiation machines for industrial radiography only at permanent radiographic installations are exempt from the requirements of this section except for the requirements of subsections (a), (b)(1), (b)(3)-(5), (c), (e)(1), (j), (n), (t)(1), and (t)(7).

(e) Requirements for qualifications of radiographic personnel.

(1) Radiographer trainee. No licensee or registrant shall permit any individual to act as a radiographer trainee until the individual possesses the original or a copy of an agency-issued trainee status card or certification ID card.

(A) To obtain an agency-issued trainee status card, the licensee, registrant, or the individual shall document to the agency on BRC Form 255-E or equivalent that such individual has successfully completed a course of at least 40 hours on the applicable subjects outlined in subsection (x)(1) of this section. The course shall be one accepted by the agency, another agreement state, or the United States Nuclear Regulatory Commission (NRC).

(B) The trainee shall carry a copy of the completed BRC Form 255-E, in the interim period after submitting documentation to the agency and before receiving a trainee status card. The copy of the completed BRC Form 255-E that was submitted to the agency may be used in lieu of the trainee status card for a period of 30 days from the date recorded by the trainee on the documentation.

(C) The individual shall notify the agency in writing of the need for a replacement trainee status card. The individual shall carry a copy of documentation of the

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request while performing industrial radiographic operations until a replacement trainee status card is received from the agency.

(D) Records required by subparagraph (A) of this paragraph shall be made and maintained in accordance with subsection (v)(1) of this section.

(E) Each licensee and registrant shall maintain for agency inspection clear and legible records that demonstrate that the applicable requirements of this paragraph are met. A copy of the trainee status card will satisfy the documentation requirements of this paragraph.

(2) Radiographer. No licensee or registrant shall permit any individual to act as a radiographer until the individual possesses a valid radiographer certification.

(A) To obtain a radiographer certification, an individual shall submit the fee as prescribed in subsection (h)(1) of this section and comply with the following:

(i) complete the requirements of paragraph (1)(A) of this subsection;

(ii) document to the Agency on BRC Form 255-R, completion of on-the-job training as a radiographer trainee supervised by one or more radiographer trainers authorized on a license or certificate of registration;

(I) The radiographer trainee shall carry a legible trainee status card in accordance with paragraph (1) of this subsection while obtaining the on-the-job training specified in subclauses (II)-(VII) of this clause.

(II) The on-the-job training shall include at least 200 hours of active participation in radioactive materials industrial radiographic operations or 120 hours of active participation in x-ray industrial radiographic operations, as applicable.

(III) Individuals performing industrial radiography utilizing radioactive materials and x-ray machines shall complete both segments (320 hours) of on-the-job training.

(IV) The hours of on-the-job training do not include safety meetings, classroom training, travel, darkroom activities, film development and interpretation, or use of a cabinet x-ray unit.

(V) One year of documented experience of on-the-job training as authorized by another agreement state or the NRC may be substituted for subclauses (II) or (III) of this clause. The documentation shall be submitted to the agency on BRC Form 255-OS or equivalent.

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(VI) The trainee shall be under the personal supervision of a radiographer trainer whenever a radiographer trainee:

(-a-) uses radiation machines, radiographic exposure devices, or associated equipment; or

(-b-) performs radiation surveys required by:

(-1-) subsection (t)(6) of this section to determine that the radiation machine has stopped producing radiation; or

(-2-) subsection (u)(9) of this section to determine that the sealed source has returned to the shielded position after an exposure.

(VII) The personal supervision shall include the following.

(-a-) The radiographer trainer's physical presence at the site where the sources of radiation are being used;

(-b-) The availability of the radiographer trainer to give immediate assistance if required; and

(-c-) The radiographer trainer's direct observation of the trainee's performance of the operations referred to in this section.

(iii) successfully complete within the last five years the appropriate agency-administered examination prescribed in subsection (g)(2) of this section or the appropriate examination of another certifying entity that affords the same or comparable certification standards as those afforded by this clause and clauses (i) and (ii) of this subparagraph; and

(iv) possesses a current certification ID card issued in accordance with subsection (h)(2) of this section or by another certifying entity that affords the same or comparable certification standards as those afforded by this clause or clauses (i)-(iii) of this subparagraph.

(B) Reciprocal recognition by the agency of an individual radiographer certification may be granted according to subsection (h)(5)(A) and (B) of this section.

(C) Once an individual has completed the requirements of paragraph (2)(A)(iv) of this subsection, the licensee or registrant is not required to submit the documentation referenced in paragraph (2)(A)(i) and (ii) of this subsection for renewal of a radiographer certification.

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(D) Records required by subparagraph (A) of this paragraph shall be made and maintained in accordance with subsection (v)(1) of this section.

(E) Each licensee and registrant shall maintain for agency inspection clear and legible records that demonstrate that the applicable requirements of this paragraph are met for all industrial radiographic personnel. A copy of the certification ID card will satisfy the documentation requirements of this paragraph.

(3) Radiographer trainer.

(A) No licensee or registrant shall permit any individual to act as a radiographer trainer until:

(i) it has been documented to the agency on BRC Form 255-T or equivalent that such individual has:

(I) met the radiographer certification requirements of paragraph (2)(A) of this subsection; and

(II) one year of documented experience as a certified radiographer.

(ii) such individual is named on the specific license or certificate of registration issued by the agency and under which the individual is acting as a radiographer trainer; and

(iii) determination is made by the agency that the individual is not currently under order from the agency prohibiting the individual from acting as a radiographer trainer.

(B) The specific duties of the radiographer trainer include, but are not limited to, the following:

(i) providing personal supervision to any radiographer trainee at the site where the sources of radiation are being used; and

(ii) preventing any unauthorized use of a source of radiation by a radiographer trainee.

(4) RSO for industrial radiography.

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(A) An RSO shall be designated on every industrial radiography license and certificate of registration issued by the agency. A single individual may be designated as RSO for more than one license or certificate of registration if authorized by the agency.

(B) The RSO's qualifications shall be submitted to the agency and shall include as a minimum:

(i) possession of a high school diploma or a certificate of high school equivalency based on the GED test;

(ii) completion of the training and testing requirements of paragraphs (1)(A) and (2)(A)(iii) of this subsection; and

(iii) two years of documented radiation protection experience, including knowledge of industrial radiographic operations with at least 40 hours of active participation in industrial radiographic operations.

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

(i) establishing and overseeing operating, safety, emergency, and as low as reasonably achievable (ALARA) procedures, and to review them regularly to ensure that the procedures are current and conform with the requirements of this chapter;

(ii) overseeing and approving all phases of the training program for radiographic personnel so that appropriate and effective radiation protection practices are taught;

(iii) ensuring that required radiation surveys and leak tests are performed and documented in accordance with this chapter, including any corrective measures when levels of radiation exceed established limits;

(iv) ensuring that personnel monitoring devices are calibrated and used properly by occupationally-exposed personnel;

(v) ensuring that timely notifications to employees are made as required by §289.203 of this title;

(vi) ensuring that timely notifications to the agency are made as required by this section and §289.202 of this title or §289.231 of this title, as applicable;

(vii) ensuring that any required interlock switches and warning signals are functioning and that radiation signs, ropes, and barriers are properly posted and positioned;

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(viii) investigating, determining the cause, taking steps to prevent the recurrence, and reporting to the agency each:

(I) known or suspected case of radiation exposure to an individual or radiation level detected in excess of limits established by this chapter; and

(II) theft or loss of a source(s) of radiation;

(ix) having a thorough knowledge of management policies and administrative procedures of the licensee or registrant;

(x) assuming control and having the authority to institute corrective actions including shutdown of operations when necessary in emergency situations or unsafe conditions;

(xi) maintaining records as required by this chapter in accordance with subsection (v)(1) of this section;

(xii) ensuring the proper storing, labeling, transport, and use of exposure devices and sources of radiation;

(xiii) ensuring that inventory and inspection and maintenance programs are performed in accordance with subsections (k) and (m) of this section;

(xiv) ensuring that personnel are complying with the requirements of this chapter and the conditions of the license or the certificate of registration; and

(xv) ensuring that the operating, safety, and emergency procedures of the licensee or registrant are met in accordance with subsections (t)(5)(A)-(C) and (G) and (u)(8)(A)-(C) and (I) of this section.

(f) Additional requirements.

(1) No licensee or registrant shall permit any individual to act as a radiographer trainee, radiographer, radiographer trainer, or RSO until such individual has met the certification requirements in accordance with subsection (e) of this section, as applicable, and has:

(A) received copies of and demonstrated an understanding of the following by successful completion of a written or oral examination administered by the licensee or registrant covering this material:

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(i) the requirements contained in this section and the applicable requirements of §289.201 of this title, §289.202 of this title, §289.203 of this title, §289.231 of this title, and §289.257 of this title;

(ii) the appropriate conditions of the license(s) and certificate(s) of registration;

(iii) the licensee's or registrant's operating, safety, and emergency procedures; and

(B) demonstrated competence in the use of sources of radiation, radiographic exposure devices, associated equipment, related handling tools, and radiation survey instruments, that may be employed in industrial radiographic assignments by successful completion of a practical examination administered by the licensee or registrant covering such use.

(2) A radiographer and radiographer trainer shall ensure that radiographic operations to which the individual is assigned are conducted in accordance with the requirements of this section.

(3) Records of the administration of and the examinations required by paragraph (1) of this subsection shall be made and maintained in accordance with subsection (v)(1) of this section. Records shall include the following:

(i) copies of written tests administered by the licensee or registrant;

(ii) dates of oral and practical examinations and names of individuals conducting and receiving the oral and practical examinations; and

(iii) a list of items tested and the results of the oral and practical examinations.

(g) Application and fee for radiographer certification examinations.

(1) Application.

(A) An application for taking the examination shall be on forms prescribed and furnished by the agency.

(B) The non-refundable and non-transferable application fee for examination shall be \$120.

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(C) The appropriate fee shall be submitted with the application for examination when filing with the agency.

(D) The application and the non-refundable and non-transferable fee shall be submitted to the agency on or before the dates specified by the agency.

(E) Applicants who fail to appear at a scheduled exam and do not reschedule 48 hours prior to their assigned exam session shall apply for a future exam session in accordance with subparagraphs (A)-(D) of this paragraph.

(2) Examination. The examination shall be given for the purpose of determining the qualifications of applicants.

(A) The scope of the examination and the methods of procedure, including determination of the passing score, shall be prescribed by the agency. The examination will assess the applicant's knowledge to safely use sources of radiation and related equipment and the applicant's knowledge of this section, and the applicable requirements of §289.201 of this title, §289.202 of this title, and §289.231 of this title.

(B) The examination will be administered by the agency or persons authorized by the agency.

(C) A candidate failing an examination may apply for re-examination in accordance with paragraph (1) of this subsection and will be re-examined. A candidate shall not retake the same version of the agency-administered examination.

(D) The examination shall normally be offered once each month. Times, dates, and locations of the examination will be furnished by the agency.

(E) The examination will be in the English language.

(F) To take the examination, an individual shall present a government-issued photo identification card, such as a driver's license, at the time of the examination.

(G) Calculators will be permitted during the examination. However, calculators or computers with preprogrammed data or formulas, including exposure calculators, will not be permitted during the examination.

(H) The examination will be a "closed-book" examination.

(I) Any individual observed by an agency proctor to be compromising the integrity of the examination shall be required to surrender the examination, the answer sheet, and all scratch paper. Such individual will not be allowed to complete the examination, will forfeit

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the examination fee, and will leave the examination site to avoid disturbing other examinees. Such individual shall wait 90 days before taking a new examination and shall resubmit a new application and a \$120 non-refundable and non-transferable examination fee.

(J) Examination material shall be returned to the agency at the end of the examination. No photographic or other copying of examination questions or materials shall be permitted. Disclosure by any individual of the contents of any examination prior to its administration is prohibited.

(K) The names and scores of individuals taking the examination shall be a public record.

(h) Radiographer certification.

(1) An application for radiographer certification shall be on BRC Form 255-R, BRC Form 255-OS, or equivalent.

(A) The non-refundable fee for radiographer certification shall be \$110.

(B) The appropriate fee shall be submitted with the application for radiographer certification when filing with the agency.

(2) A certification ID card shall be issued to each individual who successfully completes the requirements of subsection (e)(2)(A)(i)-(iii) of this section.

(A) Each individual's certification ID card shall contain the individual's photograph. The agency will take the photograph at the time the examination is administered.

(B) The certification ID card remains the property of the agency and may be revoked or suspended under the provisions of paragraph (4) of this subsection.

(C) Any individual who needs to replace a certification ID card shall submit to the agency a written request for a replacement certification ID card, stating the reason a replacement certification ID card is needed. A non-refundable fee of \$35 shall be paid to the agency for each replacement of a certification ID card. The prescribed fee shall be submitted with the written request for a replacement certification ID card. The individual shall carry a copy of the request while performing industrial radiographic operations until a replacement certification ID card is received from the agency.

(D) Each certification ID card is valid for a period of five years, unless revoked or suspended in accordance with paragraph (4) of this subsection. Each certification ID card expires at the end of the day, in the month and year stated on the certification ID card.

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(3) Renewal of a radiographer certification.

(A) Applications for examination to renew a radiographer certification shall be filed in accordance with subsection (g)(1) of this section.

(B) The examination for renewal of a radiographer certification shall be administered in accordance with subsection (g)(2) of this section.

(C) A renewal certification ID card shall be issued in accordance with paragraph (2) of this subsection.

(4) Suspension or revocation of a radiographer certification.

(A) Any radiographer who violates the requirements of this chapter, or provides any material false statement in the application or any statement of fact required in accordance with this chapter, may be required to show cause at a formal hearing why the radiographer certification should not be suspended or revoked in accordance with §289.205 of this title.

(B) When an agency order has been issued for an industrial radiographer to cease and desist from the use of sources of radiation or the agency suspends or revokes the individual's radiographer certification, the radiographer shall surrender the certification ID card to the agency until the order is changed or the suspension expires.

(C) An individual whose radiographer certification has been suspended or revoked by the agency or another certifying entity shall comply with the process and/or conditions of the suspension or revocation orders before certification is reinstated, or the individual is permitted by the agency to apply for a new certification.

(5) Reciprocity of a radiographer certification.

(A) Reciprocal recognition by the agency of an individual radiographer certification will be granted provided that:

(i) the individual holds a valid certification in the appropriate category and class issued by a certifying entity, as defined in subsection (c) of this section;

(ii) the requirements and procedures of the certifying entity issuing the certification afford the same or comparable certification standards as those afforded by subsection (e)(2)(A)(i)-(iii) of this section; and

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(iii) the individual submits a legible copy of the certification to the agency prior to entry into Texas.

(B) Enforcement actions with the agency, another agreement state, or the NRC or sanctions by an independent certifying entity may be considered when reviewing a request for reciprocal recognition from a licensee, registrant, or certified radiographer.

(C) Certified radiographers who are granted reciprocity by the agency shall maintain the certification upon which the reciprocal recognition was granted, or prior to the expiration of such certification, shall meet the requirements of paragraph (3) of this subsection.

(i) Receipt, transfer, and disposal of sources of radiation and devices using depleted uranium (DU) for shielding.

(1) Each licensee and registrant shall make and maintain records in accordance with subsection (v)(1) of this section, showing the receipt, transfer, and disposal of sources of radiation and devices using DU for shielding.

(2) These records shall include the following, as appropriate:

(A) date of receipt, transfer, or disposal;

(B) name of the individual making the record;

(C) radionuclide;

(D) number of curies (becquerels) or mass (for DU);

(E) manufacturer, model, and serial number of each source of radiation and/or device;

(F) for the person transferring the source of radiation, the name of the transferee, the number of the transferee's radioactive material license authorizing possession of the material, and the regulatory agency issuing the license to the transferee; and

(G) for the person receiving the source of radiation, the name of the transferor, the number of the transferor's radioactive material license authorizing possession of the material, and the regulatory agency issuing the license to the transferor.

(j) Radiation survey instruments.

(1) Each licensee and registrant shall have a sufficient number of calibrated, appropriate, and operable radiation survey instruments at each location where sources of

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radiation are present to perform the radiation surveys required by this section and §289.202(p)(1) and (2) of this title and §289.231(s)(1) and (2) of this title, as applicable. These radiation survey instruments shall be capable of measuring a range from 2 mrem/hr (0.002 mSv/hr) through 1 rem per hour (rem/hr) (0.01 sievert per hour (Sv/hr)).

(2) Each radiation survey instrument shall be calibrated:

(A) by a person licensed or registered by the agency, another agreement state, or the NRC to perform such service;

(B) at energies appropriate for the licensee's or registrant's use;

(C) at intervals not to exceed six months and after each instrument servicing other than battery replacement;

(D) at two points located approximately one-third and two-thirds of full-scale on each scale for linear scale instruments; for logarithmic scale instruments, at mid-range of each decade, and at two points of at least one decade; and for digital instruments, at three points between 2 and 1,000 mrem/hr (0.02 and 10 mSv/hr); and

(E) to demonstrate an accuracy within plus or minus 20% of the true radiation level at each point checked.

(3) Each radiation survey instrument shall be checked with a radiation source at the beginning of each day of use and at the beginning of each work shift to ensure it is operating properly.

(4) Records of the calibrations required by paragraph (2) of this subsection shall be maintained in accordance with subsection (v)(1) of this section.

(k) Quarterly inventory.

(1) Each licensee and registrant shall perform a physical inventory at intervals not to exceed three months to account for all sources of radiation and for devices containing DU received or possessed.

(2) Records of the quarterly inventories required by paragraph (1) of this subsection shall be made and maintained in accordance with subsection (v)(1) of this section.

(3) The record shall include the following for each source of radiation, as appropriate:

(A) manufacturer, model, and serial number;

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- (B) radionuclide;
- (C) number of curies (except for depleted uranium);
- (D) location of each source of radiation;
- (E) date of the inventory; and
- (F) name of the individual making the inventory.

(l) Utilization logs.

(1) Each licensee and registrant shall make and maintain current logs of the use, removal, and return to storage of each source of radiation. The information shall be recorded in the log when the source is removed from and returned to storage. The logs shall include:

(A) a unique identification, for example, make, model and serial number, of the following:

- (i) each radiation machine;
- (ii) each radiographic exposure device containing a sealed source or transport and storage container in which the sealed source is located; and
- (iii) each sealed source;

(B) the name and signature of the radiographer using the source of radiation;

(C) the location(s) and date(s) where each source of radiation is used; and

(D) the date(s) each source of radiation is removed from storage and returned to storage.

(2) Utilization logs may be kept on clear legible records containing all the information required by paragraph (1) of this subsection.

(3) Records of utilization logs shall be made and maintained in accordance with subsection (v)(1) of this section.

(m) Inspection and maintenance of radiation machines, radiographic exposure devices, transport and storage containers, associated equipment, source changers, and survey instruments.

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(1) Each day before using equipment, the radiographer shall:

(A) perform visual and operational checks on radiation machines, survey instruments, radiographic exposure devices, transport and storage containers, associated equipment and source changers to ensure that:

(i) the equipment is in good working condition;

(ii) the sources are adequately shielded in radiographic exposure devices; and

(iii) required labeling is present and legible;

(B) determine the survey instrument is responding using check sources or other appropriate means; and

(C) remove the equipment from service until repaired if equipment problems are found.

(2) Each licensee and registrant shall perform and shall have written procedures for the following:

(A) inspection and routine maintenance of radiation machines, radiographic exposure devices, source changers, associated equipment, transport and storage containers, and survey instruments at intervals not to exceed three months to ensure the proper functioning of components important to safety. All appropriate components shall be maintained in accordance with manufacturers' specifications. Radiation machines, radiographic exposure devices, transport containers and source changers being stored are exempted from this requirement provided that each radiation machine, radiographic exposure device, transport container, or source changer is inspected and repaired prior to being returned to service. This inspection and maintenance program shall cover, as a minimum, the items listed in subsection (x)(2) of this section; and

(B) inspection and maintenance necessary to maintain the Type B packaging used to transport radioactive material. The inspection and maintenance program shall include procedures to assure that Type B packages are shipped and maintained in accordance with the certificate of compliance or other approval.

(3) Records of daily checks of equipment, equipment problems found in daily checks and quarterly inspections, and of any maintenance performed in accordance with paragraph (1) of this subsection shall be made and maintained in accordance with subsection (v)(1) of this section.

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(4) The record shall include the following:

- (A) date of check or inspection;
- (B) name of inspector;
- (C) equipment involved;
- (D) any problems found; and
- (E) what repairs or maintenance, if any, were done.

(n) Permanent radiographic installations.

(1) Permanent radiographic installations shall have high radiation area entrance controls (for example, a control device that energizes a conspicuous visible and audible alarm signal and/or continuous direct or electronic surveillance) as described in §289.202(s)(1)-(4) of this title or §289.231(t)(1)-(4) of this title, or if applicable, §289.229 of this title.

(2) The entrance controls shall be tested for proper operation at the beginning of each day of equipment use.

(3) The alarm system shall be tested for proper operation with a source of radiation each day before the installation is used for radiographic operations. The test shall include a check for the visible and audible signals.

(4) Entrance control devices that reduce the radiation level upon entry (designated in paragraph (1) of this subsection) shall be tested monthly.

(5) If an entrance control device or alarm is operating improperly, it shall be immediately labeled as defective and repaired within seven calendar days. The facility may continue to be used during this seven-day period, provided the licensee or registrant implements the continuous surveillance requirements of subsection (q) of this section, ensures that radiographic personnel use an alarming ratemeter, and complies with the requirements of subsection (u)(8)(G) of this section.

(6) Records of alarm systems and entrance control tests and repairs required by this subsection shall be made and maintained in accordance with subsection (v)(1) of this section.

(o) Notification of incidents.

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(1) The agency shall be notified of the loss or theft of sources of radiation, overexposures, and excessive levels in accordance with §289.202(ww)-(yy), and (bbb) of this title or §289.231(gg)-(jj) of this title, as applicable.

(2) In addition, each licensee or registrant shall submit a written report within 30 days to the agency whenever one of the following events occurs:

(A) a source assembly cannot be returned to the fully-shielded position and properly secured;

(B) the source assembly becomes unintentionally disconnected from the control cable;

(C) any component critical to safe operation of the radiographic exposure device fails to properly perform its intended function;

(D) an indicator on a radiation machine fails to show that radiation is being produced;

(E) an exposure switch on a radiation machine fails to terminate production of radiation when turned to the off position; or

(F) a safety interlock fails to terminate x-ray production.

(3) The licensee or registrant shall include the following information in each report submitted in accordance with paragraph (2) of this subsection:

(A) a description of the equipment problem;

(B) cause of each incident, if known;

(C) manufacturer and model and serial number of equipment involved in the incident;

(D) location, time, and date of the incident;

(E) actions taken to establish normal operations;

(F) corrective actions taken or planned to prevent recurrence; and

(G) names of personnel involved in the incident.

(p) Individual monitoring.

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(1) The individual monitoring program shall meet the applicable requirements of §289.202 of this title or §289.231 of this title.

(2) During industrial radiographic operations, the following shall apply:

(A) No licensee or registrant shall permit an individual to act as a radiographer, radiographer trainer, or radiographer trainee unless each individual wears, on the trunk of the body at all times during radiographic operations:

(i) an individual monitoring device that meets the applicable requirements of §289.202(p)(3) of this title or §289.231(s)(3) of this title;

(ii) direct-reading pocket dosimeter or an electronic personal dosimeter; and

(iii) an operable alarming ratemeter.

(B) For permanent radiographic installations where other appropriate alarming or warning devices are in routine use, the wearing of an alarming ratemeter is not required.

(C) Pocket dosimeters shall meet the criteria in ANSI 13.5-1972 at the time of manufacture and shall have a range of zero to 200 mrem (2 mSv). Electronic personal dosimeters may only be used in place of ion-chamber pocket dosimeters.

(D) Pocket dosimeters shall be recharged at the start of each work shift.

(E) As a minimum, direct reading pocket dosimeters shall be recharged and electronic personal dosimeters reset, and “start” readings recorded:

(i) immediately before checking out any source of radiation from an authorized storage location for the purposes of conducting industrial radiographic operations; and

(ii) before beginning radiographic operations on any subsequent calendar day (if the source of radiation has not been checked back into an authorized storage site).

(F) Whenever radiographic operations are concluded for the day, the “end” readings on pocket dosimeters or electronic personal dosimeters shall be recorded and the accumulated occupational doses for that day determined and recorded.

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(G) If an individual's pocket dosimeter is discharged beyond its range (for example, goes "off-scale"), or if an individual's electronic personal dosimeter reads greater than 200 mrem (2 mSv) and the possibility of radiation exposure cannot be ruled out as the cause, industrial radiographic operations by that individual shall cease and the individual's monitoring device shall be processed immediately. The individual shall not return to work with sources of radiation until a determination of the radiation exposure has been made. This determination shall be made by the RSO or the RSO's designee. The results of this determination shall be included in the records maintained in accordance with paragraphs (5) and (6) of this subsection and subsection (v)(1) of this section.

(H) Each individual monitoring device shall be assigned to and worn by only one individual.

(I) Individual monitoring devices shall be replaced at least monthly. After replacement, each individual monitoring device shall be returned to the supplier for processing within 14 calendar days of the exchange date specified by the personnel monitoring supplier or as soon as practicable. In circumstances that make it impossible to return each individual monitoring device within 14 calendar days, such circumstances shall be documented and available for review by the agency.

(J) If an individual monitoring device is lost or damaged, the worker shall cease work immediately until a replacement individual monitoring device is provided and the exposure is calculated for the time period from issuance to loss or damage of the individual monitoring device. The results of the calculated exposure and the time period for which the individual monitoring device was lost or damaged shall be included in the records maintained in accordance with paragraph (6) of this subsection and subsection (v)(1) of this section.

(3) Pocket dosimeters or electronic personal dosimeters shall be checked for correct response to radiation at periods not to exceed one year. Acceptable dosimeters shall read within plus or minus 20% of the true radiation exposure.

(4) Each alarming ratemeter shall:

(A) be checked without being exposed to radiation prior to use at the start of each work shift, to ensure that the audible alarm is functioning properly;

(B) be set to give an alarm signal at a preset dose rate of 500 mrem/hr (5 mSv/hr) or lower with an accuracy of plus or minus 20% of the true radiation dose rate;

(C) require special means to change the preset alarm function; and

(D) be calibrated for correct response to radiation at intervals not to exceed one year.

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(5) The following records required by this subsection shall be made and maintained by the licensee or registrant for inspection by the agency in accordance with the following time requirements and subsection (v)(1) of this section.

(A) Records of pocket dosimeter or electronic personal dosimeter readings and yearly operational response checks shall be maintained for three years. If the dosimeter readings were used to determine external radiation dose (for example, no individual monitoring device exposure records exist), the records shall be maintained for agency inspection until disposal is authorized by the agency.

(B) Records of pocket dosimeter and electronic personal dosimeter readings of personnel exposures shall be maintained for three years.

(C) Records of estimates of exposures as a result of off-scale personal direct-reading dosimeters, or lost or damaged individual monitoring devices shall be maintained until disposal is authorized by the agency.

(6) The following records required by this subsection shall be maintained in accordance with the following time requirements and subsection (v)(1) of this section.

(A) Records of alarming ratemeter calibrations shall be maintained for three years.

(B) Records of individual monitoring device results received from the device processor shall be maintained until disposal is authorized by the agency.

(q) Access control.

(1) During each industrial radiographic operation, radiographic personnel shall maintain continuous visual surveillance of the operation to protect against unauthorized entry into a radiation area or high radiation area, except at permanent radiographic installations where all entryways are locked and the requirements of subsection (n) of this section are met.

(2) Radiographic exposure devices shall not be left unattended except when in storage or physically secured against unauthorized removal or tampering.

(r) Posting. All areas in which industrial radiography is being performed shall be posted conspicuously in accordance with §289.202 of this title or §289.231 of this title, as applicable, including the following.

(1) Radiation areas. Each radiation area shall be posted conspicuously with a sign(s) displaying the radiation caution symbol and the words "CAUTION, RADIATION AREA" or "DANGER, RADIATION AREA."

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(2) High radiation area. Each high radiation area shall be posted conspicuously with a sign(s) displaying the radiation caution symbol and the words “CAUTION, HIGH RADIATION AREA” or “DANGER, HIGH RADIATION AREA.”

(3) Whenever practicable, ropes and/or barriers shall be used in addition to appropriate signs to designate areas in accordance with §289.202(n)(1) of this title or §289.231(o)(1) of this title, as applicable, and to help prevent unauthorized entry.

(4) During pipeline industrial radiographic operations, sufficient radiation signs and other barriers shall be posted to prevent unmonitored individuals from entering the area in accordance with §289.202(n)(1) of this title or §289.231(o)(1) of this title, as applicable.

(5) In lieu of the requirements of subsection (r)(1) and (2) of this section, a restricted area may be established in accordance with §289.202(n)(1) of this title or §289.231(o)(1) of this title, as applicable, and be posted in accordance with subsection (r)(1) and (2) of this section, for example, both signs may be posted at the same location at the boundary of the restricted area.

(6) Exceptions listed in §289.202(bb) of this title or §289.231(y) of this title, as applicable, do not apply to industrial radiographic operations.

(s) Specific requirements for radiographic personnel performing industrial radiography.

(1) At a job site, the following shall be supplied by the licensee or registrant:

(A) at least one operable, calibrated survey instrument for each exposure device or radiation machine in use;

(B) an individual monitoring device that meets the requirements of §289.202(p)(3) of this title or §289.231(s)(3) of this title, as applicable, for each worker;

(C) an operable, calibrated pocket dosimeter or electronic personal dosimeter with a range of zero to 200 mrem (2 mSv) for each worker;

(D) an operable, calibrated, alarming ratemeter for each worker; and

(E) the appropriate barrier ropes and signs.

(2) Each radiographer at a job site shall carry a valid certification ID card issued by the agency or another certifying entity whose certification offers the same or comparable certification standards.

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(3) Each radiographer trainee at a job site shall carry a trainee status card issued by the agency or equivalent documentation in accordance with subsection (e)(1) of this section.

(4) Radiographic personnel shall not perform radiographic operations if any of the items in paragraphs (1)-(3) of this subsection are not available at the job site or are inoperable. Radiographic personnel shall ensure that the items listed in paragraph (1) of this subsection, radiographic exposure devices, and radiation machines are used in accordance with the requirements of this section.

(5) During an inspection by the agency, an agency inspector may terminate an operation if any of the items in paragraphs (1)-(3) of this subsection are not available and operable or if the required number of radiographic personnel are not present. Operations shall not be resumed until all required conditions are met.

(t) Radiation safety and registration requirements for the use of radiation machines.

(1) Registration requirements for industrial radiographic operations.

(A) Radiation machines used in industrial radiographic operations shall be registered in accordance with §289.226 of this title.

(B) In addition to the registration requirements in §289.226(e) and (i) of this title, an application for a certificate of registration shall include the following information.

(i) A schedule or description of the program for training radiographic personnel that specifies:

(I) initial training;

(II) annual refresher training;

(III) on-the-job training;

(IV) procedures for administering the oral and written examination to determine the knowledge, understanding, and ability of radiographic personnel to comply with the requirements of this chapter, the conditions of the certificate of registration, and the registrant's operating, safety, and emergency procedures; and

(V) procedures for administering the practical examination to demonstrate competence in the use of sources of radiation and radiation survey instruments that may be employed in industrial radiographic assignments.

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(ii) Written operating, safety, and emergency procedures that are made available to each individual operating a radiation machine, including any restrictions of the operating technique required for the safe operation of the particular x-ray system;

(I) The registrant shall document that each individual operating a radiation machine has read the operating and safety procedures and shall maintain this documentation for inspection by the agency. The documentation shall include the following:

(-a-) name and signature of individual;

(-b-) date individual read the operating and safety procedures; and

(-c-) initials of the RSO;

(II) The operating and safety procedures shall include, but are not limited to, the items listed in subsection (x)(3) of this section;

(iii) A description of the internal audit program to ensure that radiographic personnel follow the requirements of this chapter, the conditions of the certificate of registration, and the registrant's operating, safety, and emergency procedures at intervals not to exceed six months;

(iv) A list of permanent radiographic installations, descriptions of permanent storage use sites, and the location(s) where all records required by this section and other sections of this chapter will be maintained. Radiographic equipment shall not be stored or used at a permanent site unless such site is specifically authorized by the certificate of registration. A storage site is permanent if radiation machines are stored at that location and if one or more of the following applies:

(I) the registrant establishes telephone service that is used for contracting or providing industrial radiographic services for the registrant;

(II) industrial radiographic services are advertised for or from the site;

(III) radiation machines stored at that location are used for industrial radiographic operations conducted at other sites; or

(IV) the registrant conducts radiographic operations or stores radiation machines at any location not listed on the certificate of registration for a period in excess of 90 days in a calendar year, in which case the registrant shall notify the agency prior to exceeding the 90 days;

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(v) A description of the organization of the industrial radiographic program, including delegations of authority and responsibility for operation of the radiation safety program; and

(vi) Procedures for verifying and documenting the certification status of radiographers and for ensuring that the certification of individuals acting as radiographers remains valid.

(C) A certificate of registration will be issued if the requirements of this paragraph of this subsection and §289.226(e) and (i) of this title are met.

(2) Locking of radiation machines. The control panel of each radiation machine shall be equipped with a locking device that will prevent the unauthorized use of an x-ray system or the accidental production of radiation. The radiation machine shall be kept locked and the key removed at all times except when under the direct visual surveillance of a radiographer.

(3) Permanent storage precautions for the use of radiation machines. Radiation machines shall be secured while in storage to prevent tampering or removal by unauthorized individuals.

(4) Requirements for radiation machines used in industrial radiographic operations.

(A) Equipment used in industrial radiographic operations involving radiation machines manufactured after October 1, 1987, shall be certified at the time of manufacture to meet the criteria set forth by ANSI N43.5 (relating to Radiological Safety Standards for the Design of Radiographic and Industrial X-Ray Equipment), except accelerators used in industrial radiography.

(B) The registrant's name and city or town of an authorized use site listed on the certificate of registration shall be prominently displayed with a durable, legible, clearly visible label(s) on both sides of all vehicles used to transport radiation machines for temporary job site use.

(5) Operating and internal audit requirements for the use of radiation machines.

(A) Each registrant shall conduct an internal audit program to ensure that the requirements of this chapter, the conditions of the certificate of registration, and the registrant's operating, safety, and emergency procedures are followed by radiographic personnel.

(B) Each radiographer's and radiographer trainee's performance during an actual radiographic operation shall be audited and documented at intervals not to exceed six months.

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(C) If a radiographer or a radiographer trainee has not participated in a radiographic operation during the six months since the last audit, the radiographer or the radiographer trainee shall demonstrate knowledge of the training requirements of subsection (f)(1) of this section by an oral or written and practical examination administered by the registrant before the individual can next participate in a radiographic operation.

(D) The agency may consider alternatives in those situations where the individual serves as both radiographer and RSO.

(E) In those operations where a single individual serves as both radiographer and RSO and performs all radiography operations, an audit program is not required.

(F) The registrant shall provide annual refresher safety training, as defined in subsection (c) of this section, for each radiographer trainee, radiographer, or radiographer trainer at intervals not to exceed 12 months.

(G) No individual, other than a radiographer or a radiographer trainee, who is under the personal supervision of a radiographer trainer, shall manipulate controls or operate radiation machines used in industrial radiographic operations. Only one radiographer is required to operate radiation machines during industrial radiography.

(H) Radiographic operations shall not be conducted at storage sites unless specifically authorized by the certificate of registration.

(I) Records of annual refresher training and audits of job performance specified in this subsection shall be made and maintained in accordance with subsection (v)(1) of this section.

(J) Records of annual refresher safety training and audits of job performance made in accordance with this subsection shall include the following:

(i) list of the topics discussed during the refresher safety training;

(ii) dates the annual refresher safety training was conducted;

(iii) names of the instructors and attendees; and

(iv) for audits of job performance, the records shall also include a list showing the items checked and any non-compliance observed by the RSO or designee.

(6) Radiation surveys for the use of radiation machines.

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(A) No industrial radiographic operation shall be conducted unless at least one calibrated and operable radiation survey instrument, as described in subsection (j) of this section, is used for each radiation machine energized.

(B) A physical radiation survey shall be made after each radiographic exposure using radiation machines to determine that the machine is “off.”

(C) All potential radiation areas where industrial radiographic operations are to be performed shall be posted in accordance with subsection (r) of this section, based on estimated dose rates, before industrial radiographic operations begin. An area survey shall be performed during the first radiographic exposure to confirm that subsection (r) of this section requirements have been met and that unrestricted areas do not have radiation levels in excess of the limits specified in §289.231(o)(1)(B) of this title.

(D) Records of the surveys required by subparagraph (C) of this paragraph shall be made and maintained in accordance with subsection (v)(1) of this section. If a survey was used to determine an individual’s exposure due to loss of personnel monitoring data, the records of the survey shall be maintained for agency inspection until disposal is authorized by the agency.

(7) Requirements for radiation machines in shielded rooms.

(A) Radiation machines in shielded rooms, shall comply with all applicable requirements of this section.

(B) Radiation machines in shielded rooms shall be evaluated at intervals not to exceed one year to ensure compliance with the applicable requirements of this section and §289.231(o)(1)-(3) of this title.

(C) Records of the annual evaluation of radiation machines in shielded rooms required by subparagraph (B) of this paragraph shall be made and maintained in accordance with subsection (v)(1) of this section.

(8) Requirements for certified and certifiable cabinet x-ray systems.

(A) Certified and certifiable cabinet x-ray systems, including those designed to allow admittance of individuals, are exempt from the requirements of this section except that:

(i) No registrant shall permit any individual to operate a cabinet x-ray system until the individual has received a copy of and instruction in the operating procedures for the unit.

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(ii) Tests for proper operation of interlocks shall be conducted and recorded at intervals not to exceed 12 months.

(iii) The registrant shall perform an evaluation to determine compliance with §289.231(o)(1)-(3) of this title and Title 21, CFR, §1020.40 at intervals not to exceed one year.

(B) Records of operating instructions in cabinet x-ray systems required by subparagraph (A)(i) of this paragraph and interlock tests required by subparagraph (A)(ii) of this paragraph shall be made and maintained in accordance with subsection (v)(1) of this section.

(C) Records of the evaluation of certified cabinet x-ray systems required by subparagraph (A)(iii) of this paragraph shall be made and maintained in accordance with subsection (v)(1) of this section.

(9) All reciprocal recognition of certificates of registration by the agency will be granted in accordance with §289.226(s) of this title.

(u) Radiation safety and licensing requirements for the use of sealed sources.

(1) Licensing requirements for industrial radiographic operations.

(A) Sealed sources used in industrial radiographic operations shall be licensed in accordance with §289.252 of this title.

(B) In addition to the licensing requirements in §289.252 of this title, an application for a license shall include the following information.

(i) A schedule or description of the program for training radiographic personnel that specifies:

(I) initial training;

(II) annual refresher training;

(III) on-the-job training;

(IV) procedures for administering the oral and written examinations to determine the knowledge, understanding, and ability of radiographic personnel to comply with the requirements of this chapter, the conditions of the license, and the licensee's operating, safety, and emergency procedures; and

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(V) procedures for administering the practical examination to demonstrate competence in the use of sources of radiation, radiographic exposure devices, related handling tools, and radiation survey instruments that may be employed in industrial radiographic assignments.

(ii) Written operating, safety, and emergency procedures that are made available to each individual operating a sealed source in radiographic operations, including any restrictions of the operating technique required for the safe operation of the particular sealed source.

(I) The licensee shall document that each individual operating a sealed source in radiographic operations has read the operating and safety procedures and shall maintain this documentation for inspection by the agency. The documentation shall include the following:

(-a-) name and signature of individual;

(-b-) date individual read the operating and safety procedures; and

(-c-) initials of the RSO;

(II) The operating and safety procedures shall include, but are not limited to, the items listed in subsection (x)(3) of this section;

(iii) A description of the internal audit program to ensure that radiographic personnel follow the requirements of this chapter, the conditions of the license, and the licensee's operating, safety, and emergency procedures at intervals not to exceed six months.

(iv) A list of permanent radiographic installations, descriptions of permanent storage and use sites, and the location(s) where all records required by this section and other sections of this chapter will be maintained. If records are to be maintained at a headquarters office in Texas and no use or storage is authorized for the site, this site will be designated as the main site. Radioactive material shall not be stored or used at a permanent use site unless such site is specifically authorized by the license. Any licensee conducting radiographic operations or storing radioactive material at any location not listed on the license for a period in excess of 90 days in a calendar year, shall notify the agency prior to exceeding the 90 days. A storage site is permanent if radioactive material is stored at that location and if any one or more of the following applies:

(I) the licensee establishes telephone service that is used for contracting or providing industrial radiographic services for the licensee;

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from the site;

(II) industrial radiographic services are advertised for or

(III) radioactive material stored at that location is used for industrial radiographic operations conducted at other sites; or

(IV) the licensee conducts radiographic operations or stores radioactive material at any location not listed on the license for a period in excess of 90 days in a calendar year.

(v) A description of the organization of the industrial radiographic program, including delegations of authority and responsibility for operation of the radiation safety program.

(vi) A description of the program for inspection and maintenance of radiographic exposure devices and transport and storage containers, including items in subsection (x)(2) of this section and the applicable items in subsection (m) of this section.

(vii) If a license application includes underwater radiography, as a minimum a description of:

(I) radiation safety procedures and radiographer responsibilities unique to the performance of underwater radiography;

(II) radiographic equipment and radiation safety equipment unique to underwater radiography; and

(III) methods for gas-tight encapsulation of equipment.

(viii) If a license application includes offshore platform and/or lay-barge radiography, as a minimum a description of:

(I) transport procedures for radioactive material to be used in industrial radiographic operations;

(II) storage facilities for radioactive material; and

(III) methods for restricting access to radiation areas;

(ix) Procedures for verifying and documenting the certification status of radiographers and for ensuring that the certification of individuals acting as radiographers remains valid.

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(x) If the applicant intends to perform leak testing of sealed sources or exposure devices containing DU shielding, the applicant shall describe the procedures for performing the leak test and the qualifications of the person authorized to do the leak test.

(xi) If the applicant intends to analyze its own wipe samples, the application shall include a description of the procedures to be followed. The description shall include at least the following:

(I) instruments to be used;

(II) methods of performing the analysis; and

(III) pertinent experience of the person(s) who will analyze the wipe samples; and

(xii) If the applicant intends to perform “in-house” calibrations of survey instruments, the applicant shall describe methods to be used and the relevant experience of the person(s) who will perform the calibrations. All calibrations shall be performed in accordance with subsection (j) of this section.

(C) A license will be issued if the requirements of this paragraph of this subsection and §289.252 of this title are met.

(2) Limits on external radiation levels from storage containers and source changers. The maximum exposure rate limits for storage containers and source changers are 200 mrem/hr (2 mSv/hr) at any exterior surface, and 10 mrem/hr (0.1 mSv/hr) at 1 meter from any exterior surface with the sealed source in the shielded position.

(3) Locking of radiographic exposure devices, storage containers and source changers.

(A) Each radiographic exposure device, storage container, and source changer shall have a lock or outer locked container designed to prevent unauthorized or accidental removal or exposure of a sealed source. Each exposure device and source changer shall be kept locked and, if a keyed lock, the key removed at all times except when under the direct visual surveillance of a radiographer or an individual specifically authorized by the agency, except at a permanent radiographic installation.

(B) Each radiographic exposure device, storage container, and source changer shall be locked and the key removed from any keyed lock prior to being transported from one location to another and also prior to being stored at a given location.

(4) Permanent storage precautions for the use of sealed sources.

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(A) Radiographic exposure devices, source changers, and transport containers that contain sealed sources shall be secured while in storage to prevent tampering or removal by unauthorized individuals.

(B) Radiographic exposure devices, source changers, or transport containers that contain radioactive material may not be stored in residential locations. This section does not apply to storage of radioactive material in a vehicle in transit for use at temporary job sites, if the licensee complies with paragraph (9)(G) of this subsection and if the vehicle does not constitute a permanent storage location as described in paragraph (1)(B)(iv) of this subsection.

(5) Performance requirements for industrial radiography equipment. Equipment used in industrial radiographic operations shall meet the following minimum criteria.

(A) Each radiographic exposure device, source assembly, sealed source, and associated equipment shall meet the criteria set forth by ANSI N432-1980.

(i) All newly manufactured radiographic exposure devices and associated equipment acquired by licensees after September 1, 1993, shall comply with the requirements of this section.

(ii) All radiographic exposure devices and associated equipment in use after January 1, 1996, shall comply with the requirements of this section.

(iii) In lieu of subparagraph (A) of this paragraph, equipment used in industrial radiographic operations need not comply with §8.9.2(c) of the Endurance Test in ANSI N432-1980, if the prototype equipment has been tested using a torque value representative of the torque that an individual using the radiography equipment can realistically exert on the lever or crankshaft of the drive mechanism.

(B) Engineering analysis may be submitted by a licensee to demonstrate the applicability of previously performed testing on similar individual radiography equipment components. Upon review, the agency may find this an acceptable alternative to actual testing of the component in accordance with subparagraph (A) of this paragraph.

(C) In addition to the requirements specified in subparagraph (A) of this paragraph the following requirements apply to radiographic exposure devices, source changers, source assemblies and sealed sources.

(i) Radiographic exposure devices intended for use as Type B transport containers shall meet the applicable requirements of §289.257 of this title.

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(ii) Modification of radiographic exposure devices, source changers, source assemblies, and associated equipment is prohibited, unless the design of any replacement component, including source holder, source assembly, controls or guide tubes would not compromise the design safety features of the system.

(D) In addition to the requirements specified in subparagraphs (A)-(C) of this paragraph, radiographic exposure devices, source assemblies, and associated equipment that allow the source to move outside the device shall meet the following criteria:

(i) The source assembly shall be designed so that the source will not become disconnected if cranked outside the guide tube. The source assembly shall be such that it cannot be unintentionally disconnected under normal and reasonably foreseeable abnormal conditions.

(ii) The control cable shall be positively connected to the source assembly before the source assembly can be driven out of the fully shielded position in a radiographic exposure device or source changer.

(iii) The radiographic exposure device shall automatically secure the source assembly when it is cranked back into the fully shielded position within the radiographic exposure device. This securing system shall only be released by means of a deliberate operation on the radiographic exposure device.

(iv) The outlet nipple and control cable fittings of each radiographic exposure device shall be equipped with safety plugs or covers that will protect the source assembly from damage and from other foreign matter, such as water, mud, or sand, during storage and transportation.

(v) Each sealed source or source assembly shall have attached to it or engraved on it, a durable, legible, visible label with the words "DANGER. RADIOACTIVE." The label may not interfere with the safe operation of the exposure device or associated equipment.

(vi) Guide tubes shall be used when moving the source out of the radiographic exposure device.

(vii) Guide tubes shall be able to withstand a crushing test that closely approximates the crushing forces that are likely to be encountered during use, and be able to withstand a kinking resistance test that closely approximates the kinking forces that are likely to be encountered during use.

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(viii) An exposure head, endcap, or similar device designed to prevent the source assembly from extending beyond the end of the guide tube shall be attached to the outermost end of the guide tube during radiographic operations.

(ix) The guide tube exposure head connection shall be able to withstand the tensile test for control units as specified in ANSI N432-1980.

(x) Source changers shall provide a system for ensuring that the source will not be accidentally withdrawn from the changer when connecting or disconnecting the control cable to or from a source assembly.

(6) Leak testing, repair, opening, and replacement of sealed sources and devices. Leak testing, repair, opening, and replacement of sealed sources and devices shall be performed according to the following criteria:

(A) Leak testing of sealed sources shall be done in accordance with §289.201(g) of this title, except records of leak tests shall be maintained in accordance with subsection (v)(1) of this section.

(B) The replacement, leak testing analysis, repair, opening, or any modification of a sealed source shall be performed only by persons specifically authorized to do so by the agency, the NRC, or another agreement state.

(C) Each exposure device using DU shielding and an “S” tube configuration shall be tested for DU contamination.

(i) Tests for DU contamination shall be performed at intervals not to exceed 12 months.

(ii) The analysis shall be capable of detecting the presence of 0.005 microcuries (185 Bq) of radioactive material on the test sample and shall be performed by a person specifically authorized by the agency, the NRC, or an agreement state to perform the analysis.

(iii) Should such testing reveal the presence of DU contamination, the exposure device shall be removed from use until an evaluation of the wear of the S-tube has been made.

(iv) Should the evaluation reveal that the S-tube is worn through, the device may not be used again.

(v) DU shielded devices do not have to be tested for DU contamination while in storage and not in use.

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(vi) The device shall be tested for DU contamination before using or transferring such a device, if the interval of storage exceeds 12 months.

(D) A record of the DU leak test shall be made and maintained in accordance with subsection (v)(1) of this section.

(7) Labeling and storage.

(A) Each transport container shall have permanently attached to it a durable, legible, clearly visible label(s) that has, as a minimum, the standard trefoil radiation caution symbol conventional colors, for example, magenta, purple or black on a yellow background, having a minimum diameter of 25 millimeters, and the following wording “CAUTION. RADIOACTIVE MATERIAL. NOTIFY CIVIL AUTHORITIES (OR NAME OF COMPANY)” or “DANGER. RADIOACTIVE MATERIAL. NOTIFY CIVIL AUTHORITIES (OR NAME OF COMPANY).” In addition, transport containers shall meet applicable requirements of the DOT.

(B) Radiographic exposure devices, source changers, and storage containers shall be physically secured to prevent tampering or removal by unauthorized personnel. The licensee shall store radioactive material in a manner that will minimize danger from explosion or fire.

(C) The licensee shall lock and physically secure the transport package containing radioactive material in the transporting vehicle to prevent accidental loss, tampering, or unauthorized removal.

(D) The licensee’s name and city or town of an authorized use site listed on the license shall be prominently displayed with a durable, clearly visible label(s) on both sides of all vehicles used to transport radioactive material for temporary job site use.

(E) The licensee shall ensure that each radiographic exposure device has attached to it a durable, legible, clearly visible label bearing the following:

(i) chemical symbol and mass number of the radionuclide in the device;

(ii) activity and the date on which this activity was last measured;

(iii) manufacturer, model and serial number of the sealed source;

(iv) licensee’s name, address, and telephone number; and

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(v) as a minimum, the standard radiation caution symbol as defined in §289.202 of this title, and the following wording “CAUTION. RADIOACTIVE MATERIAL--DO NOT HANDLE. NOTIFY CIVIL AUTHORITIES (OR NAME OF COMPANY)” or “DANGER. RADIOACTIVE MATERIAL--DO NOT HANDLE. NOTIFY CIVIL AUTHORITIES (OR NAME OF COMPANY).”

(F) Each radiographic exposure device shall have a permanently stamped, legible, and clearly visible unique serial number.

(8) Operating and internal audit requirements for the use of sealed sources of radiation.

(A) Each licensee shall conduct an internal audit program to ensure that the requirements of this chapter, the conditions of the license, and the licensee’s operating, safety, and emergency procedures are followed by radiographic personnel.

(B) Each radiographer’s and radiographer trainee’s performance during an actual radiographic operation shall be audited and documented at intervals not to exceed six months.

(C) If a radiographer or a radiographer trainee has not participated in a radiographic operation during the six months since the last audit, the radiographer or the radiographer trainee shall demonstrate knowledge of the training requirements of subsection (f)(1) of this section by an oral or written and practical examination administered by the licensee before these individuals can next participate in a radiographic operation.

(D) The agency may consider alternatives in those situations where the individual serves as both radiographer and RSO.

(E) In those operations where a single individual serves as both radiographer and RSO, and performs all radiography operations, an audit program is not required.

(F) Each licensee shall provide annual refresher safety training, as defined in subsection (c) of this section, for each radiographer and radiographer trainee at intervals not to exceed 12 months.

(G) Each licensee shall provide, as a minimum, two radiographic personnel for each exposure device in use for any industrial radiography conducted at a location other than at a permanent radiographic installation (shielded room, bay, or bunker) meeting the requirements of subsection (n)(1) of this section. If one of the personnel is a radiographer trainee, the other shall be a radiographer trainer authorized by the license.

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(H) Collimators shall be used in industrial radiographic operations that use crank-out devices except when physically impossible.

(I) No individual other than a radiographer or a radiographer trainee who is under the personal supervision of a radiographer trainer shall manipulate controls or operate radiographic exposure devices and associated equipment used in industrial radiographic operations.

(J) Radiographic operations shall not be conducted at storage sites unless specifically authorized by the license.

(K) Records of annual refresher training and audits of job performance specified in this subsection shall be made and maintained in accordance with subsection (v)(1) of this section.

(L) Records of annual refresher safety training and audits of job performance made in accordance with this subsection shall include the following:

- (i) list of the topics discussed during the refresher safety training;
- (ii) dates the annual refresher safety training was conducted;
- (iii) names of the instructors and attendees; and
- (iv) for audits of job performance, the records shall also include a list showing the items checked and any non-compliance observed by the RSO or designee.

(9) Radiation surveys for the use of sealed sources of radiation.

(A) No industrial radiographic operation shall be conducted unless at least one calibrated and operable radiation survey instrument, as described in subsection (j) of this section, is used at each site where radiographic exposures are made.

(B) A survey with a radiation survey instrument meeting the requirements of subsection (j)(1)-(3) of this section shall be made after each radiographic exposure to determine that the sealed source has been returned to its fully shielded position, and before exchanging films, repositioning the exposure head, or dismantling equipment. The entire circumference of the radiographic exposure device shall be surveyed. If the radiographic exposure device has a source guide tube, the survey shall also include the source guide tube and any collimator.

(C) All potential radiation areas where industrial radiographic operations are to be performed shall be posted in accordance with subsection (r) of this section, based on

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calculated dose rates, before industrial radiographic operations begin. An area survey shall be performed during the first radiographic exposure (for example, with the sealed source in the exposed position) to confirm that the requirements of subsection (r) of this section have been met.

(D) Each time re-establishment of the restricted area is required, the requirements of subparagraph (C) of this paragraph shall be met.

(E) The requirements of subparagraph (D) of this paragraph do not apply to pipeline industrial radiographic operations when the conditions of exposure including, but not limited to, the radiographic exposure device, duration of exposure, source strength, pipe size, and pipe thickness remain constant.

(F) A lock-out survey, in which all accessible surfaces of the radiographic exposure device or source changer are surveyed, shall be performed.

(G) Surveys shall be performed in the storage location to ensure that radiation levels do not exceed the limits specified in §289.202(n)(1) of this title. These surveys shall be performed initially with the maximum amount of radioactive material present in the storage location and thereafter at the time of the quarterly inventory and whenever storage conditions change.

(H) A survey meeting the requirements of subparagraph (B) of this paragraph shall be performed on the radiographic exposure device and the source changer after every sealed source exchange.

(I) Records of the surveys required by subparagraphs (C), (D), and (F)-(H) of this paragraph shall be made and maintained in accordance with subsection (v)(1) of this section. If a survey was used to determine an individual's exposure due to loss of personnel monitoring data, the records of the survey shall be maintained for agency inspection until disposal is authorized by the agency.

(10) Requirements for shielded rooms containing sealed sources.

(A) Shielded rooms containing sealed sources shall comply with all applicable requirements of this section.

(B) Shielded rooms containing sealed sources shall be evaluated at intervals not to exceed one year to ensure compliance with the applicable requirements of this section and §289.202(n)(1)-(3) of this title.

(C) Tests for proper operation of interlocks shall be conducted and recorded in accordance with subsection (n) of this section.

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(D) Records of evaluations required by subparagraph (B) of this paragraph shall be made and maintained in accordance with subsection (v)(1) of this section.

(E) Records of interlock tests required by subparagraph (C) of this paragraph shall be made and maintained in accordance with subsection (v)(1) of this section.

(11) Underwater, offshore platform, and lay-barge radiography.

(A) Underwater, offshore platform, and/or lay-barge radiography shall not be performed unless specifically authorized in a license issued by the agency in accordance with paragraph (1) of this subsection.

(B) In addition to the other requirements of this section, the following requirements apply to the performance of offshore platform or lay-barge radiography.

(i) Cobalt-60 sources with activities in excess of 20 curies (nominal) and iridium-192 sources with activities in excess of 100 curies (nominal) shall not be used in the performance of offshore platform or lay-barge radiography.

(ii) Collimators shall be used for all industrial radiographic operations performed on offshore platforms or lay-barges.

(12) Prohibitions.

(A) Industrial radiography performed with a sealed source that is not fastened to or contained in a radiographic exposure device (fishpole technique) is prohibited unless specifically authorized in a license issued by the agency.

(B) Retrieval of disconnected sources or sources that cannot be returned by normal means to a fully shielded position or automatically secured in the radiographic exposure device, shall not be performed unless specifically authorized by a license condition.

(13) All reciprocal recognition of licenses by the agency will be granted in accordance with §289.252(ee) of this title.

(v) Record/document requirements. Each licensee and registrant shall maintain the following records/documents at each site at the time intervals specified and make available to the agency for inspection.

(1) Time requirements for record keeping. The following are time requirements for record keeping.

Figure: 25 TAC §289.255(v)(1)

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(2) Records and documents required at additional authorized use/storage sites.

(A) Each licensee or registrant maintaining additional authorized use/storage sites where industrial radiography operations are performed shall maintain copies of the following records and documents specific to that site available at each site for inspection by the agency for a period of three years:

(i) a copy of the appropriate license or certificate of registration authorizing the use of licensed or registered sources of radiation;

(ii) operating, safety, and emergency procedures in accordance with subsection (x)(3) of this section;

(iii) applicable sections of this chapter as listed in the license or certificate of registration;

(iv) records of receipt, transfer, and disposal of sources of radiation and devices using DU for shielding at the additional site in accordance with subsection (i) of this section;

(v) records of the latest survey instrument calibrations in use at the site in accordance with subsection (j) of this section;

(vi) records of the latest calibrations of alarming ratemeters and operational checks of pocket dosimeters and/or electronic personal dosimeters in accordance with subsection (p) of this section;

(vii) inventories in accordance with subsection (k) of this section;

(viii) utilization records for each radiographic exposure device and radiation machine dispatched from that location in accordance with subsection (l) of this section;

(ix) records of equipment problems identified in daily checks of equipment in accordance with subsection (m) of this section, if applicable;

(x) records of alarm systems and entrance control checks in accordance with subsection (n) of this section;

(xi) training records in accordance with subsection (f) of this section;

(xii) records of direct-reading dosimeter readings in accordance with subsection (p) of this section;

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(xiii) audits in accordance with subsections (t)(5)(A)-(C) and (u)(8)(A)-(C) of this section;

(xiv) latest radiation survey records in accordance with subsections (t)(6)(D) and (u)(9)(I) of this section;

(xv) records of interlock testing in accordance with subsections (t)(8)(A)(ii) and (u)(10)(C) of this section;

(xvi) records of annual evaluation of cabinet x-ray systems in accordance with subsection (t)(7)(C) of this section;

(xvii) records of leak tests for specific devices and sources at the additional site in accordance with subsection (u)(6) of this section;

(xviii) shipping papers for the transportation of sources of radiation in accordance with §289.257 of this title;

(xix) a copy of the NRC license, agreement state license, or state certificate of registration authorizing the use of sources of radiation, when operating under reciprocity in accordance with §289.226 of this title and §289.252 of this title; and

(xx) individual monitoring records in accordance with subsection (p) of this section.

(B) The following records required for each additional authorized use site in accordance with this subsection shall also be maintained at the main authorized site:

(i) records of receipt, transfer, and disposal of sources of radiation and devices using DU for shielding at the additional site in accordance with subsection (i) of this section;

(ii) inventories in accordance with subsection (k) of this section;
and

(iii) individual monitoring records in accordance with subsection (p) of this section.

(3) Records required at temporary job sites. Each licensee and registrant conducting industrial radiography at a temporary job site shall have the following records available at that site for agency inspection:

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(A) a copy of the appropriate license or certificate of registration or equivalent document authorizing the use of sources of radiation;

(B) operating, safety, and emergency procedures in accordance with subsection (x)(3) of this section;

(C) applicable sections of this chapter as listed in the license or certificate of registration;

(D) latest radiation survey records required in accordance with subsections (t)(6)(D) and (u)(9)(I) of this section for the period of operation at the site;

(E) the daily pocket dosimeter records for the period of operation at the site;

(F) utilization records for each radiographic exposure device or radiation machine used at that location in accordance with subsection (l) of this section;

(G) the latest instrument calibration and leak test records for devices at the site. Acceptable records include tags or labels that are attached to the devices or survey instruments and decay charts for sources that have been manufactured within the last six months; and

(H) a copy of the NRC license, agreement state license, or state certificate of registration authorizing the use of sources of radiation, when operating under reciprocity in accordance with §289.226 of this title or §289.252 of this title.

(w) Form of records.

(1) Each record required by this section shall be legible throughout the specified retention period.

(2) The record shall be the original or a reproduced copy or a microform provided that the copy or microform is authenticated by authorized personnel and that the microform is capable of reproducing a clear copy throughout the required retention period.

(3) The record may also be stored in electronic media with the capability for producing legible, accurate, and complete records during the required retention period.

(4) Records, such as letters, drawings, and specifications, shall include all pertinent information, such as stamps, initials, and signatures.

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(5) The licensee or registrant shall maintain adequate safeguards against tampering with and loss of records.

(x) Appendices.

(1) Subjects to be included in training courses for radiographer trainees. Training provided to qualify individuals as radiographer trainees in compliance with subsection (e)(1)(A) of this section shall be presented on a formal basis. The training shall include the following subjects.

(A) Fundamentals of radiation safety to include the following:

- (i) characteristics of radiation;
- (ii) units of radiation dose in rems (sieverts) and quantity of radioactivity in curies (becquerels);
- (iii) significance of radiation dose to include:
 - (I) radiation protection standards;
 - (II) biological effects of radiation dose;
 - (III) hazards of exposure to radiation; and
 - (IV) case histories of radiography accidents;
- (iv) levels of radiation from sources of radiation; and
- (v) methods of controlling radiation dose to include:
 - (I) working time;
 - (II) working distances; and
 - (III) shielding.

(B) Radiation detection instrumentation to include the following:

- (i) use, operation, calibration and limitations of radiation survey instruments;
- (ii) survey techniques; and

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(iii) use of individual monitoring devices.

(C) Radiographic equipment to be used, including the following:

(i) remote handling equipment;

(ii) operation and control of radiographic exposure devices and sealed sources, including pictures or models of source assemblies (pigtailed);

(iii) storage and transport containers, source changers;

(iv) operation and control of x-ray equipment;

(v) collimators;

(vi) storage, control, and disposal of radioactive material; and

(vii) inspection and maintenance of equipment.

(D) Requirements of pertinent federal and state regulations.

(E) Generic written operating, safety, and emergency procedures (see subsection (x)(3) of this section).

(2) General requirements for inspection of industrial radiographic equipment.

(A) Radiographic exposure devices shall be inspected for:

(i) abnormal surface radiation levels anywhere on camera, collimator, or guide tube;

(ii) condition of safety plugs;

(iii) proper operation of locking mechanism;

(iv) condition of pigtail connector;

(v) condition of carrying device (straps, handle, etc.); and

(vi) proper and legible labeling.

(B) Guide tubes shall be inspected for:

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- (i) rust, dirt, or sludge buildup inside the guide tube;
- (ii) condition of guide tube connector;
- (iii) condition of source stop;
- (iv) kinks or damage that could prevent proper operation; and
- (v) presence of radioactive contamination.

(C) Control cables and drive mechanisms shall be inspected for:

- (i) proper drive mechanism with camera, as appropriate;
- (ii) changes in general operating characteristics;
- (iii) condition of connector on control cable;
- (iv) control cable flexibility, wear, and rust;
- (v) excessive wear or damage to crank-out devices;
- (vi) damage to control cable conduit that could prevent the cable from moving freely;
- (vii) proper connector mating between the control cable and the pigtail;
- (viii) proper operation of source position indicator, if applicable;
- (ix) presence of radioactive contamination.

from moving freely;

pigtail;

and

(D) Pipeliners shall be inspected for:

- (i) abnormal surface radiation;
- (ii) changes in the general operating characteristics of the unit;
- (iii) proper operation of shutter mechanism;
- (iv) chafing or binding of shutter mechanism;

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- (v) damage to the device that might impair its operation;
- (vi) proper operation of locking mechanism;
- (vii) proper drive mechanism with camera, as appropriate;
- (viii) condition of carrying device (strap, handle, etc.); and
- (ix) proper and legible labeling.

(E) X-ray equipment shall be inspected for:

- (i) change in the general operating characteristics of the unit;
- (ii) wear of electrical cables and connectors;
- (iii) proper and legible labeling of console;
- (iv) proper console with machine, as appropriate;
- (v) proper operation of locking mechanism;
- (vi) proper operation of timer run-down cutoff; and
- (vii) damage to tube head housing that might result in excessive

radiation levels.

(3) Operating, safety, and emergency procedures. The licensee's or registrant's operating, safety, and emergency procedures shall include instructions in at least the following:

(A) handling and use of sources of radiation for industrial radiography such that no individual is likely to be exposed to radiation doses that exceed the limits established in §289.202 of this title;

(B) methods and occasions for conducting radiation surveys, including lock-out survey requirements;

(C) methods for controlling access to industrial radiography areas;

(D) methods and occasions for locking and securing sources of radiation;

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(E) personnel monitoring and the use of personnel monitoring equipment, including steps to be taken immediately by industrial radiographic personnel in the event a pocket dosimeter is found to be off-scale (see subsection (p)(2)(G) of this section);

(F) methods of transporting equipment to field locations, including packing of sources of radiation in the vehicles, placarding of vehicles, and controlling of sources of radiation during transportation, including applicable DOT requirements;

(G) methods or procedures for minimizing exposure of individuals in the event of an accident, including procedures for a disconnect accident, a transportation accident, and loss of a sealed source;

(H) procedures for notifying proper personnel in the event of an accident;

(I) specific posting requirements;

(J) maintenance of records (see subsection (v)(1) of this section);

(K) inspection, maintenance, and operational checks of radiographic exposure devices, source changers, storage containers, transport containers, source guide tubes, crank-out devices, and radiation machines;

(L) method of testing and training in accordance with subsections (e) and (f) of this section; and

(M) source recovery procedures if the licensee is authorized to perform source recovery.

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Figure: 25 TAC §289.255(v)(1)

Specific Subsection	Name of Record	Time Interval Required for Record Keeping
(e)(1)(A) and (2)(A) and (f)(1)	Training and Certification Records	5 years
(i)	Receipt, Transfer, and Disposal of DU	3 years
(j)(2)	Survey Instrument Calibrations	3 years
(k)	Quarterly Inventory	3 years
(l)	Utilization Logs	3 years
(m)	Inspection and Maintenance	3 years
(n)	Permanent Radiographic Installation Tests	3 years
(p)	Individual Monitoring Devices	Until disposal is authorized by the agency
	Estimates of Exposure	Until disposal is authorized by the agency
	Direct-Reading Pocket or Electronic Personal Dosimeter Readings	3 years or until disposal is authorized by the agency if dosimeters were used to determine external radiation dose
	Pocket Dosimeter Calibrations and Yearly Response Checks	3 years
	Alarming Ratemeter Calibrations	3 years
(t)(5) and (u)(8)	Internal Audit Program	3 years

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Specific Subsection	Name of Record	Time Interval Required for Record Keeping
(t)(5)(F) and (u)(8)(F)	Annual Refresher Training	3 years
(t)(6) and (u)(9)	Radiation Surveys	3 years or until disposal is authorized by the agency if a survey was used to determine an individual's exposure
(t)(7)(C)	Annual Evaluation of Radiation Machines in Shielded Rooms	3 years
(t)(8)(A)(i)	Operating Instructions In Cabinet X-Ray Systems	3 years
(t)(8)(A)(ii)	Tests of X-Ray Interlocks	3 years
(t)(8)(A)(iii)	Evaluation of Certified Cabinet X-Ray Systems	3 years
(u)(6)	Leak Tests	3 years
(u)(10)(D)	Annual Evaluation of Shielded Rooms Containing Sealed Sources	3 years
(u)(10)(E)	Test of Sealed Source Interlocks	3 years
(v)(3)	Records at Temporary Job Sites	During temporary job site operations

§289.256 Medical and Veterinary Use of Radioactive Material.

(a) Purpose. This section establishes requirements for the medical and veterinary use of radioactive material and for the issuance of specific licenses authorizing the medical and veterinary use of radioactive material. Unless otherwise exempted, no person shall receive, possess, use, transfer, own, or acquire radioactive material for medical or veterinary use except as authorized in a license issued in accordance with this section. A person who receives, possesses, uses, transfers, owns, or acquires radioactive material prior to receiving a license is subject to the requirements of this chapter.

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(b) Scope.

(1) In addition to the requirements of this section, all licensees, unless otherwise specified, are subject to the requirements of §289.201 of this title (relating to General Provisions for Radioactive Material), §289.202 of this title (relating to Standards for Protection Against Radiation from Radioactive Materials), §289.203 of this title (relating to Notices, Instructions, and Reports to Workers; Inspections), §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), §289.252 of this title (relating to Licensing of Radioactive Material), and §289.257 of this title (relating to Packaging and Transportation of Radioactive Material).

(2) Veterinarians who receive, possess, use, transfer, own, or acquire radioactive material in the practice of veterinary medicine shall comply with the requirements of this section except for subsections (d), (dd) and (uuu) of this section.

(c) Definitions. The following words and terms when used in this section shall have the following meaning unless the context clearly indicates otherwise.

(1) Address of use -- The building or buildings that are identified on the license and where radioactive material may be prepared, received, used, or stored.

(2) Area of use -- A portion of an address of use that has been set aside for the purpose of preparing, receiving, using, or storing radioactive material.

(3) Authorized medical physicist -- An individual who meets the following:

(A) the requirements in subsections (j) and (m) of this section; or

(B) is identified as an authorized medical physicist or teletherapy physicist on one of the following:

(i) a specific medical use license issued by the agency, the United States Nuclear Regulatory Commission (NRC), an agreement state, or licensing state;

(ii) a medical use permit issued by an NRC master material licensee;

(iii) a permit issued by an NRC, agreement state, or licensing state broad scope medical use licensee; or

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(iv) a permit issued by an NRC master material license broad scope medical use permittee; and

(C) holds a current Texas license under the Medical Physics Practice Act, Texas Occupations Code, Chapter 602, in therapeutic radiological physics for uses in subsections (rr) and (ddd) of this section.

(4) Authorized nuclear pharmacist -- A pharmacist who meets the following:

(A) the requirements in subsections (k) and (m) of this section or;

(B) is identified as an authorized nuclear pharmacist on one of the following;

(i) a specific license issued by the agency, the NRC, an agreement state, or licensing state that authorizes medical use or the practice of nuclear pharmacy;

(ii) a permit issued by an NRC master material licensee that authorizes medical use or the practice of nuclear pharmacy;

(iii) a permit issued by the agency, the NRC, an agreement state, or licensing state licensee with broad scope authorization that authorizes medical use or the practice of nuclear pharmacy; or

(iv) a permit issued by an NRC master material license broad scope medical use permittee that authorizes medical use or the practice of nuclear pharmacy;

(C) is identified as an authorized nuclear pharmacist by a commercial nuclear pharmacy that has been authorized to identify authorized nuclear pharmacists; or

(D) is designated as an authorized nuclear pharmacist in accordance with §289.252(r) of this title; and

(E) holds a current Texas license under the Texas Pharmacy Act, Chapters 551-566 and 568-569, Occupations Code, as amended, and who is certified as an authorized nuclear pharmacist by the Texas State Board of Pharmacy.

(5) Authorized user -- An authorized user is defined as follows:

(A) for human use, a physician licensed by the Texas Medical Board; or a dentist licensed by the Texas State Board of Dental Examiners; or a podiatrist licensed by the Texas State Board of Podiatric Medicine who:

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(i) meets the requirements in subsections (m), (gg)(1), (jj)(1), (nn)(1), (oo)(1), (pp)(1), (zz)(1), (ccc)(1) or (ttt)(1) of this section; or

(ii) is identified as an authorized user on any of the following:

(I) an agency, NRC, agreement state, or licensing state license that authorizes the medical use of radioactive material;

(II) a permit issued by an NRC master material licensee that is authorized to permit the medical use of radioactive material;

(III) a permit issued by a specific licensee with broad scope authorization issued by the agency, the NRC, an agreement state, or licensing state authorizing the medical use of radioactive material; or

(IV) a permit issued by an NRC master material licensee with broad scope authorization that is authorized to permit the medical use of radioactive material.

(B) for veterinary use, an individual who is, a veterinarian licensed by the Texas State Board of Veterinary Medical Examiners; and

(i) is certified by the American College of Veterinary Radiology for the use of radioactive materials in veterinary medicine; or

(ii) has received training in accordance with subsections (gg), (jj), (oo), (pp) and (ttt) of this section as applicable; or

(iii) is identified as an authorized user on any of the following:

(I) an agency, NRC, agreement state, or licensing state license that authorizes the veterinary use of radioactive material;

(II) a permit issued by an NRC master material licensee that is authorized to permit the medical use of radioactive material;

(III) a permit issued by a specific licensee with broad scope authorization issued by the agency, the NRC, an agreement state, or licensing state authorizing the medical or veterinary use of radioactive material; or

(IV) a permit issued by an NRC master material licensee with broad scope authorization that authorizes the medical use of radioactive material.

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(6) Brachytherapy -- A method of radiation therapy in which plated, embedded, activated, or sealed sources are utilized to deliver a radiation dose at a distance of up to a few centimeters, by surface, intracavitary, intraluminal, or interstitial application.

(7) Brachytherapy sealed source -- A sealed source or a manufacturer-assembled source train, or a combination of these sources that is designed to deliver a therapeutic dose within a distance of a few centimeters.

(8) High dose-rate remote afterloader -- A device that remotely delivers a dose rate in excess of 1200 rads (12 gray (Gy)) per hour at the point or surface where the dose is prescribed.

(9) Institutional Review Board (IRB) -- Any board, committee, or other group formally designated by an institution and approved by the United States Food and Drug Administration (FDA) to review, approve the initiation of, and conduct periodic review of biomedical research involving human subjects.

(10) Low dose-rate remote afterloader -- A device that remotely delivers a dose rate of less than or equal to 200 rads (2 Gy) per hour at the point or surface where the dose is prescribed.

(11) Management -- The chief executive officer or other individual delegated the authority to manage, direct, or administer the licensee's activities.

(12) Manual brachytherapy -- A type of brachytherapy in which the sealed sources, for example, seeds and ribbons, are manually inserted either into the body cavities that are in close proximity to a treatment site or directly in the tissue volume.

(13) Medical event -- An event that meets the criteria in subsection (uuu)(1) of this section.

(14) Medical institution -- An organization in which several medical disciplines are practiced.

(15) Medical use -- The intentional internal or external administration of radioactive material, or the radiation from radioactive material, to patients or human research subjects under the supervision of an authorized user.

(16) Medium dose-rate afterloader -- A device that remotely delivers a dose rate greater than 200 rads (2 Gy) and less than or equal to 1200 rads (12 Gy) per hour at the point or surface where the dose is prescribed.

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(17) Mobile nuclear medicine service -- A licensed service authorized to transport radioactive material to, and medical use of the material at, the client's address. Services transporting calibration sources only are not considered mobile nuclear medicine licensees.

(18) Output -- The exposure rate, dose rate, or a quantity related in a known manner to these rates from a teletherapy unit, a brachytherapy source, a remote afterloader unit, or a gamma stereotactic radiosurgery unit, for a specified set of exposure conditions.

(19) Patient -- A human or animal under medical care and treatment.

(20) Preceptor -- An individual who provides, directs, or verifies the training and experience required for an individual to become an authorized user, an authorized medical physicist, an authorized nuclear pharmacist, or a radiation safety officer.

(21) Permanent facility -- A building or buildings that are identified on the license within the state of Texas and where radioactive material may be prepared, received, used, or stored. This may also include an area or areas where administrative activities related to the license are performed.

(22) Prescribed dosage -- The specified activity or range of activity of a radiopharmaceutical as documented in a written directive or in accordance with the directions of the authorized user for procedures in subsections (ff) and (hh) of this section.

(23) Prescribed dose -- Prescribed dose means one of the following:

(A) for gamma stereotactic radiosurgery, the total dose as documented in the written directive;

(B) for teletherapy, the total dose and dose per fraction as documented in the written directive;

(C) for brachytherapy, either the total sealed source strength and exposure time, or the total dose, as documented in the written directive; or

(D) for remote afterloaders, the total dose and dose per fraction as documented in the written directive.

(24) Pulsed dose-rate remote afterloader -- A special type of remote afterloading device that uses a single sealed source capable of delivering dose rates greater than 1200 rads (12 Gy) per hour, but is approximately one-tenth of the activity of typical high dose-rate remote afterloader sealed sources and is used to simulate the radiobiology of a low dose rate remote afterloader treatment by inserting the sealed source for a given fraction of each hour.

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(25) Radiation safety officer (RSO) -- For purposes of this section, an individual who:

(A) meets the requirements in subsections (h) and (m) of this section or;

(B) is identified as an RSO on one of the following:

(i) a specific license issued by the agency, NRC, agreement state, or licensing state license that authorizes the medical or veterinary use of radioactive material; or

(ii) a permit issued by an NRC master material licensee that authorizes the medical or veterinary use of radioactive material.

(26) Sealed source and device registry -- The national registry that contains all the registration certificates, generated by both the NRC and the agreement states, that summarize the radiation safety information for sealed sources and devices and describe the licensing and use conditions approved for the product.

(27) Stereotactic radiosurgery -- The use of external radiation in conjunction with a guidance device to very precisely deliver a dose to a tissue volume by the use of three-dimensional coordinates.

(28) Technologist -- Technologist is defined as either of the following:

(A) in nuclear medicine, a person (nuclear medicine technologist) skilled in the performance of nuclear medicine procedures under the supervision of a physician; or

(B) in therapy, as described in subsections (rr) and (ddd) of this section, a person (radiation therapy technologist or radiation therapist) who delivers treatments of radiation therapy under the supervision of and as prescribed by an authorized user who meets the requirements of (zz) or (ttt).

(29) Teletherapy -- Therapeutic irradiation in which the sealed source is at a distance from the patient or human or animal research subject.

(30) Therapeutic dosage -- The specified activity or range of activity of radioactive material that is intended to deliver a radiation dose to a patient or human or animal research subject for palliative or curative treatment.

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(31) Therapeutic dose -- A radiation dose delivered from a sealed source containing radioactive material to a patient or human or animal research subject for palliative or curative treatment.

(32) Treatment site -- The anatomical description of the tissue intended to receive a radiation dose, as described in a written directive.

(33) Type of use -- Use of radioactive material as specified under the following subsections:

(A) uptake, and dilution and excretion studies in subsection (ff) of this section;

(B) imaging and localization studies in subsection (hh) of this section;

(C) therapy with unsealed radioactive material in subsection (kk) of this section;

(D) manual brachytherapy with sealed sources in subsection (rr) of this section;

(E) sealed sources for diagnosis in subsection (bbb) of this section; and

(F) sealed source in a remote afterloader unit, teletherapy unit, or gamma stereotactic radiosurgery unit in subsection (ddd) of this section.

(34) Unit dosage -- A dosage prepared for medical use for administration as a single dosage to a patient or human or animal research subject without any further modification of the dosage after it is initially prepared.

(35) Veterinary use -- The intentional internal or external administration of radioactive material, or the radiation from radioactive material, to patients under the supervision of an authorized user.

(36) Written directive -- An authorized user's written order for the administration of radioactive material or radiation from radioactive material to a specific patient or human research subject, as specified in subsection (t) of this section.

(d) Provisions for research involving human subjects.

(1) A licensee may conduct research involving human subjects only if it uses the radioactive materials specified on its license for the uses authorized on the license.

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(2) The licensee may conduct research specified in paragraph (1) of this subsection provided that:

(A) the research is conducted, funded, supported, or regulated by a federal agency that has implemented the Federal Policy for the Protection of Human Subjects as required by Title 10, Code of Federal Regulations (CFR), §35.6 (Federal Policy); or

(B) the licensee has applied for and received approval of a specific amendment to its license before conducting the research.

(3) Prior to conducting research as specified in paragraph (1) of this subsection, the licensee shall obtain the following:

(A) “informed consent,” as defined and described in the Federal Policy, from the human research subjects; and

(B) review and approval of the research from an IRB as required by Title 45, CFR, Part 46, and Title 21, CFR, Part 56, and in accordance with the Federal Policy.

(4) Nothing in this subsection relieves licensees from complying with the other requirements of this chapter.

(e) Implementation.

(1) If a license condition exempted a licensee from a provision of this section or §289.252 of this title on the effective date of this rule, then the license condition continues to exempt the licensee from the requirements in the corresponding provision until there is a license amendment or license renewal that modifies or removes the license condition.

(2) When a requirement in this section differs from the requirement in an existing license condition, the requirement in this section shall govern.

(3) Licensees shall continue to comply with any license condition that requires implementation of procedures required by subsections (ggg) and (mmm)-(ooo) of this section until there is a license amendment or renewal that modifies the license condition.

(f) Specific requirements for the issuance of licenses. In addition to the requirements in §289.252(e) of this title and subsections (n)-(q) of this section, as applicable, a license will be issued if the agency determines that:

(1) the applicant satisfies any applicable special requirement in this section;

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(2) qualifications of the designated radiation safety officer (RSO) as specified in subsection (h) of this section are adequate for the purpose requested in the application; and

(3) the following information submitted by the applicant is approved:

(A) an operating, safety, and emergency procedures manual to include specific information on the following:

(i) radiation safety precautions and instructions;

(ii) methodology for measurement of dosages or doses to be administered to patients or human or animal research subjects;

(iii) calibration, maintenance, and repair of instruments and equipment necessary for radiation safety; and

(iv) waste disposal procedures; and

(B) any additional information required by this chapter that is requested by the agency to assist in its review of the application; and

(C) qualifications of the following:

(i) RSO in accordance with subsection (h) of this section;

(ii) authorized user(s) in accordance with subsection (c)(5) of this section as applicable to the use(s) being requested;

(iii) authorized medical physicist in accordance with subsection (c)(3) of this section;

(iv) authorized nuclear pharmacist in accordance with subsection (c)(4) of this section, if applicable; and

(v) radiation safety committee (RSC), in accordance with subsection (i) of this section, if applicable; and

(4) the applicant's permanent facility is located in Texas; and

(5) 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 the owner's agent indicating such.

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(g) Radiation safety officer.

(1) Every licensee shall establish in writing the authority, duties, and responsibilities of the RSO and ensure that the RSO is provided sufficient authority, organizational freedom, time, resources, and management prerogative to perform the following duties:

(A) establish and oversee operating, safety, emergency, and as low as reasonably achievable (ALARA) procedures, and to review them at least annually to ensure that the procedures are current and conform with this chapter;

(B) ensure that required radiation surveys and leak tests are performed and documented in accordance with this chapter, including any corrective measures when levels of radiation exceed established limits;

(C) ensure that individual monitoring devices are used properly by occupationally-exposed personnel, that records are kept of the monitoring results, and that timely notifications are made in accordance with §289.203 of this title;

(D) investigate and cause a report to be submitted to the agency for each known or suspected case of radiation exposure to an individual or radiation level detected in excess of limits established by this chapter and each theft or loss of source(s) of radiation, to determine the cause(s), and to take steps to prevent a recurrence;

(E) investigate and cause a report to be submitted to the agency for each known or suspected case of release of radioactive material to the environment in excess of limits established by this chapter;

(F) have a thorough knowledge of management policies and administrative procedures of the licensee;

(G) identify radiation safety problems;

(H) assume control and initiate, recommend, or provide corrective actions, including shutdown of operations when necessary, in emergency situations or unsafe conditions;

(I) verify implementation of corrective actions;

(J) ensure that records are maintained as required by this chapter;

(K) ensure the proper storing, labeling, transport, use, and disposal of sources of radiation, storage, and/or transport containers;

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(L) ensure that inventories are performed in accordance with the activities for which the license application is submitted;

(M) 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) serve as the primary contact with the agency.

(2) The RSO shall ensure that the duties listed in paragraph (1)(A) through (N) of this subsection are performed.

(3) The RSO shall be on site periodically commensurate with the scope of licensed activities to satisfy the requirements of paragraphs (1) and (2) of this subsection.

(4) The RSO, or staff designated by the RSO, shall be capable of physically arriving at the licensee's authorized use site(s) within a reasonable time of being notified of an emergency situation or unsafe condition.

(5) For up to 60 days each calendar year, a licensee may permit an authorized user or an individual qualified to be an RSO to function as a temporary RSO and to perform the duties of an RSO in accordance with paragraph (1) of this subsection, provided the licensee takes the actions required in paragraph (1) of this subsection, and the RSO meets the qualifications in subsection (h) of this section. Records of qualifications and dates of service shall be maintained in accordance with subsection (www) of this section for inspection by the agency.

(h) Training for radiation safety officer. Except as provided in subsection (l) of this section, the licensee shall require the individual fulfilling the responsibilities of an RSO in accordance with subsection (g) of this section for licenses for medical or veterinary use of radioactive material to be an individual who:

(1) is certified by a specialty board whose certification process has been recognized by the agency, the NRC, or an agreement state and who meets the requirements in paragraphs (4) and (5) of this subsection. (The names of board certifications that have been recognized by the agency, the NRC, an agreement state, or licensing state will be posted on the agency's web page, www.dshs.state.tx.us/radiation).

(A) To have its certification process recognized, a specialty board shall require all candidates for certification to:

(i) hold a bachelor's or graduate degree from an accredited college or university in physical science or engineering or biological science with a minimum of 20 college credits in physical science;

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(ii) have five or more years of professional experience in health physics (graduate training may be substituted for no more than two years of the required experience) including at least three years in applied health physics; and

(iii) pass an examination, administered by diplomates of the specialty board, which evaluates knowledge and competence in radiation physics and instrumentation, radiation protection, mathematics pertaining to the use and measurement of radioactivity, radiation biology and radiation dosimetry; or

(B) To have its certification process recognized, a specialty board shall require all candidates for certification to:

(i) hold a master's or doctor's degree in physics, medical physics, other physical science, engineering, or applied mathematics from an accredited college or university;

(ii) have two years of full-time practical training and/or supervised experience in medical physics as follows;

(I) under the supervision of a medical physicist who is certified in medical physics by a specialty board recognized by the agency, the NRC, an agreement state; or a licensing state; or

(II) in clinical nuclear medicine facilities providing diagnostic and/or therapeutic services under the direction of physicians who meet the requirements for authorized users in subsection (jj) or (nn) of this section; and

(iii) pass an examination, administered by diplomates of the specialty board, that assesses knowledge and competence in clinical diagnostic radiological or nuclear medicine physics and in radiation safety; or

(2) meets the requirements of paragraphs (5) and (6) of this subsection and has completed a structured educational program consisting of the following:

(A) 200 hours of classroom and laboratory training in the following areas:

(i) radiation physics and instrumentation;

(ii) radiation protection;

(iii) mathematics pertaining to the use and measurement of radioactivity;

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(iv) radiation biology; and

(v) radiation dosimetry; and

(B) one year of full-time radiation safety experience under the supervision of the individual identified as the RSO on an agency, NRC, agreement state, or licensing state license or on a permit issued by an NRC master material licensee that authorizes similar type(s) of use(s) of radioactive material involving the following:

(i) shipping, receiving, and performing related radiation surveys;

(ii) using and performing checks for proper operation of dose calibrators, survey meters, and instruments used to measure radionuclides;

(iii) securing and controlling radioactive material;

(iv) using administrative controls to avoid mistakes in the administration of radioactive material;

(v) using procedures to prevent or minimize radioactive contamination and using proper decontamination procedures;

(vi) using emergency procedures to control radioactive material;

and

(vii) disposing of radioactive material; or

(3) is a medical physicist who has been certified by a specialty board whose certification process has been recognized by the agency, the NRC, an agreement state, or licensing state in accordance with subsection (j)(1) of this section and has experience in radiation safety for similar types of use of radioactive material for which the licensee is seeking the approval of the individual as RSO and who meets the requirements in paragraphs (5) and (6) of this subsection; or

(4) is an authorized user, authorized medical physicist, or authorized nuclear pharmacist identified on the licensee's license and has experience with the radiation safety aspects of similar types of use of radioactive material for which the individual has RSO responsibilities; and

(5) has obtained written attestation, signed by a preceptor RSO, that the individual has satisfactorily completed the requirements in paragraph (5) of this subsection and in paragraph (1)(A)(i) and (ii) or (1)(B)(i) and (ii), or (2) or (3) of this subsection, and has achieved

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a level of radiation safety knowledge sufficient to function independently as an RSO for a medical use licensee; and

(6) has training in the radiation safety, regulatory issues, and emergency procedures for the types of use for which a licensee seeks approval. This training requirement may be satisfied by completing training that is supervised by a RSO, authorized medical physicist, authorized nuclear pharmacist, or authorized user, as appropriate, who is authorized for the type(s) of use for which the licensee is seeking approval.

(i) Radiation safety committee. Licensees with broad scope authorization and licensees who are authorized for two or more different types of uses of radioactive material in accordance with subsections (kk), (rr), and (ddd) of this section, or two or more types of units under subsection (ddd) of this section shall establish an RSC to oversee all uses of radioactive material permitted by the license.

(1) The RSC for licenses for medical use with broad scope authorization shall be composed of the following individuals as approved by the agency:

(A) authorized users from each type of use of radioactive material authorized on the license;

(B) the RSO;

(C) a representative of nursing service;

(D) a representative of management who is neither an authorized user nor the RSO; and

(E) may include other members as the licensee deems appropriate.

(2) The RSC for licenses for medical and veterinary use authorized for two or more different types of uses of radioactive material in accordance with subsections (kk), (rr), and (ddd) of this section, or two or more types of units in accordance with subsection (ddd) of this section shall be composed of the following individuals as approved by the agency:

(A) an authorized user of each type of use permitted by the license;

(B) the RSO;

(C) a representative of nursing service, if applicable;

(D) a representative of management who is neither an authorized user nor the RSO; and

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(E) may include other members as the licensee deems appropriate.

(3) Duties and responsibilities of the RSC.

(A) For licensees without broad scope authorization, the duties and responsibilities of the RSC include, but are not limited to, the following:

(i) meeting as often as necessary to conduct business but no less than three times a year;

(ii) reviewing summaries of the following information presented by the RSO:

(I) over-exposures;

(II) significant incidents, including spills, contamination, or medical events; and

(III) items of non-compliance following an inspection;

(iii) reviewing the program for maintaining doses ALARA, and providing any necessary recommendations to ensure doses are ALARA; and

(iv) reviewing the audit of the radiation safety program and acting upon the findings.

(B) For licensees with broad scope authorization, the duties and responsibilities of the RSC include, but are not limited to, the items in subparagraph (A) of this paragraph and the following:

(i) reviewing the overall compliance status for authorized users;

(ii) sharing responsibility with the RSO to conduct periodic audits of the radiation safety program;

(iii) developing criteria to evaluate training and experience of new authorized user applicants;

(iv) evaluating and approving authorized user applicants who request authorization to use radioactive material at the facility; and

(v) reviewing and approving permitted program and procedural changes prior to implementation.

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(j) Training for an authorized medical physicist. Except as provided in subsection (l) of this section, the licensee shall require the authorized medical physicist to be an individual who:

(1) is certified by a specialty board whose certification process has been recognized by the agency, the NRC, an agreement state, or a licensing state and who meets the requirements in paragraphs (3) and (4) of this subsection. (The names of board certifications that have been recognized by the agency, the NRC, an agreement state, or licensing state will be posted on the agency's web page, www.dshs.state.tx.us/radiation). To have its certification process recognized, a specialty board shall require all candidates for certification to meet the following:

(A) hold a master's or doctor's degree in physics, medical physics, other physical science, engineering, or applied mathematics from an accredited college or university;

(B) complete two years of full-time practical training and/or supervised experience in medical physics as follows;

(i) under the supervision of a medical physicist who is certified in medical physics by a specialty board recognized by the agency, NRC, agreement state, or licensing state; or

(ii) in clinical radiation facilities providing high-energy, external beam therapy (photons and electrons with energies greater than or equal to 1 million electron volts) and brachytherapy services under the direction of physicians who meet the requirements for authorized users in subsection (zz) or (ttt) of this section; and

(C) pass an examination administered by diplomates of the specialty board that assesses knowledge and competence in clinical radiation therapy, radiation safety, calibration, quality assurance, and treatment planning for external beam therapy, brachytherapy, and stereotactic radiosurgery; or

(2) holds a post graduate degree and experience to include;

(A) a master's or doctor's degree in physics, medical physics, other physical science, engineering, or applied mathematics from an accredited college or university; and

(B) completion of one year of full-time training in medical physics and an additional year of full-time work experience under the supervision of an individual who meets the requirements for an authorized medical physicist for the type(s) of use for which the individual is seeking authorization. This training and work experience shall be conducted in clinical radiation facilities that provide high-energy, external beam therapy (photons and

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electrons with energies greater than or equal to 1 million electron volts) and brachytherapy services and shall include:

- (i) performing sealed source leak tests and inventories;
- (ii) performing decay corrections;
- (iii) performing full calibration and periodic spot checks of external beam treatment units, stereotactic radiosurgery units, and remote afterloading units as applicable; and
- (iv) conducting radiation surveys around external beam treatment units, stereotactic radiosurgery units, and remote afterloading units as applicable; and

(3) has obtained written attestation that the individual has satisfactorily completed the requirements in paragraphs (4) and (1)(A) and (1)(B) or (2)(A) and (2)(B) and (4) of this subsection, and has achieved a level of competency sufficient to function independently as an authorized medical physicist for each type of therapeutic medical unit for which the individual is requesting authorized medical physicist status. The written attestation shall be signed by a preceptor authorized medical physicist who meets the requirements in this subsection for each type of therapeutic medical unit for which the individual is requesting authorized medical physicist status; and

(4) has training for the type(s) of use for which authorization is sought that includes hands-on device operation, safety procedures, clinical use, and the operation of a treatment planning system. This training requirement may be satisfied by satisfactorily completing either a training program provided by the vendor or by training supervised by an authorized medical physicist authorized for the type(s) of use for which the individual is seeking authorization.

(k) Training for an authorized nuclear pharmacist. Except as provided in subsection (l) of this section, the licensee shall require the authorized nuclear pharmacist to be a pharmacist who:

(1) is certified by a specialty board whose certification process has been recognized by the agency, the NRC or an agreement state and who meets the requirements of subparagraph (C) of this paragraph. (The names of board certifications that have been recognized by the agency, the NRC, an agreement state, or licensing state will be posted on the agency's web page, www.dshs.state.tx.us/radiation). To have its certification process recognized, a specialty board shall require all candidates for certification to:

(A) have graduated from a pharmacy program accredited by the American Council on Pharmaceutical Education (ACPE) or have passed the Foreign Pharmacy Graduate Examination Committee (FPGEC) examination;

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(B) hold a current, active license to practice pharmacy in the state of Texas;

(C) provide evidence of having acquired at least 4000 hours of training/experience in nuclear pharmacy practice. Academic training may be substituted for no more than 2000 hours of the required training and experience; and

(D) pass an examination in nuclear pharmacy administered by diplomates of the specialty board, that assesses knowledge and competency in procurement, compounding, quality assurance, dispensing, distribution, health and safety, radiation safety, provision of information and consultation, monitoring patient outcomes, research and development; or

(2) has completed a 700 hour structured educational program including both:

(A) 200 hours of classroom and laboratory training in the following areas:

- (i) radiation physics and instrumentation;
- (ii) radiation protection;
- (iii) mathematics pertaining to the use and measurement of radioactivity;
- (iv) chemistry of radioactive material for medical use; and
- (v) radiation biology; and

(B) supervised practical experience in a nuclear pharmacy involving the following:

- (i) shipping, receiving, and performing related radiation surveys;
- (ii) using and performing checks for proper operation of instruments used to determine the activity of dosages, survey meters, and, if appropriate, instruments used to measure alpha- or beta-emitting radionuclides;
- (iii) calculating, assaying, and safely preparing dosages for patients or human research subjects;
- (iv) using administrative controls to avoid medical events in the administration of radioactive material; and

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(v) using procedures to prevent or minimize radioactive contamination and using proper decontamination procedures; and

(C) has obtained written attestation, signed by a preceptor authorized nuclear pharmacist, that the individual has satisfactorily completed the requirements in paragraphs (1)(A), (B) and (C) or (2) of this section and has achieved a level of competency sufficient to function independently as an authorized nuclear pharmacist.

(l) Training for experienced RSO, teletherapy or medical physicist, authorized medical physicist, authorized user, nuclear pharmacist, and authorized nuclear pharmacist.

(1) An individual identified as an RSO, a teletherapy or medical physicist, or a nuclear pharmacist on one of the following before the effective date of this rule need not comply with the training requirements of subsection (h), (j), or (k) of this section, respectively:

(A) an agency, NRC, agreement state, or licensing state license;

(B) a permit issued by an agency, NRC, agreement state, or licensing state licensee with broad scope authorization;

(C) an NRC master material license permit; or

(D) an NRC master material license permit with broad scope authorization.

(2) An individual identified as an RSO, an authorized medical physicist, or an authorized nuclear pharmacist on one of the following prior to the effective date of this rule need not comply with the training requirements of subsection (h), (j), or (k) of this section, respectively:

(A) an agency, NRC, agreement state, or licensing state license;

(B) a permit issued by an agency, NRC, agreement state, or licensing state licensee with broad scope authorization;

(C) an NRC master material license permit; or

(D) an NRC master material license permit with broad scope authorization.

(3) An individual identified as a physician, dentist, podiatrist or veterinarian authorized for the medical or veterinary use of radioactive material and who performs only those medical or veterinary uses for which they were authorized on one of the following before the

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effective date of this rule need not comply with the training requirements of subsections (ff)-(ttt) of this section:

(A) an agency, NRC, agreement state, or licensing state license;

(B) a permit issued by an agency, NRC, agreement state, or licensing state licensee with broad scope authorization;

(C) an NRC master material license permit; or

(D) an NRC master material license permit with broad scope authorization.

(4) An individual identified as a physician, dentist, podiatrist or veterinarian authorized for the medical or veterinary use of radioactive material and who performs only those medical or veterinary uses for which they were authorized on one of the following prior to the effective date of this rule need not comply with the training requirements of subsections (ff) - (ttt) of this section:

(A) an agency, NRC, agreement state, or licensing state license;

(B) a permit issued by an agency, NRC, agreement state, or licensing state licensee with broad scope authorization;

(C) an NRC master material license permit; or

(D) an NRC master material license permit with broad scope authorization.

(m) Recentness of training. The training and experience specified in subsections (j), (k), (l), (h), (ff)-(kk), (rr), (tt), (zz), (aaa), (bbb), and (ddd) of this section for medical and veterinary use shall have been obtained within the seven years preceding the date of application or the individual shall have had related continuing education and experience since the required training and experience was completed.

(n) Licenses for medical and veterinarian uses of radioactive material without broad scope authorization. In addition to the requirements of subsection (f) of this section, a license for medical and veterinarian use of radioactive material as described in the applicable subsections (ff), (hh), (kk), (rr), (bbb) and (ddd) of this section will be issued if the agency approves the following documentation submitted by the applicant:

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(1) that the physician(s) or veterinarian(s) designated on the application as the authorized user(s) is qualified in accordance with subsections (gg), (jj), (nn)-(qq), (zz), (aaa), (ccc) and (ttt) of this section, as applicable;

(2) that the radiation detection and measuring instrumentation is appropriate for performing surveys and procedures for the uses involved;

(3) that the radiation safety operating procedures are adequate for the handling and disposal of the radioactive material involved in the uses; and

(4) that an RSC has been established in accordance with subsection (i)(2) of this section, if applicable.

(o) License for medical and veterinary uses of radioactive material with broad scope authorization. In addition to the requirements of subsection (f) of this section, a license for medical use of radioactive material with broad scope authorization will be issued if the agency approves the following documentation submitted by the applicant:

(1) that the review of authorized user qualifications by the RSC is in accordance with subsections (gg), (jj), (nn)-(qq), (zz), (aaa), (ccc) and (ttt) of this section, as applicable;

(2) that the application is for a license authorizing unspecified forms and/or multiple types of radioactive material for medical research, diagnosis, and therapy;

(3) that the radiation detection and measuring instrumentation is appropriate for performing surveys and procedures for the uses involved;

(4) that the radiation safety operating procedures are adequate for the handling and disposal of the radioactive material involved in the uses;

(5) that staff has substantial experience in the use of a variety of radioactive material for a variety of human and animal uses;

(6) that the full-time RSO meets the requirements of subsection (h)(2) of this section; and

(7) that an RSC has been established in accordance with subsection (i)(1) of this section.

(p) License for the use of remote control brachytherapy units, teletherapy units, or gamma stereotactic radiosurgery units. In addition to the requirements of subsection (f) of this section, a license for the use of remote control brachytherapy (RCB) units, teletherapy units, or

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gamma stereotactic radiosurgery units will be issued if the agency approves the following documentation submitted by the applicant:

(1) that the physician(s) designated on the application as the authorized user(s) is qualified in accordance with subsection (ttt) of this section;

(2) that the radiation detection and measuring instrumentation is appropriate for performing surveys and procedures for the uses involved;

(3) that the radiation safety operating procedures are adequate for the handling and disposal of the radioactive material involved in the uses;

(4) of the radioactive isotopes to be possessed;

(5) of the sealed source manufacturer(s) name(s) and the model number(s) of the sealed source(s) to be installed;

(6) of the maximum number of sealed sources of each isotope to be possessed, including the activity of each sealed source;

(7) of the manufacturer and model name and/or number of the following units, as applicable:

(A) RCB unit;

(B) teletherapy unit; or

(C) gamma stereotactic radiosurgery unit;

(8) that the authorized medical physicist designated on the application is qualified in accordance with subsection (j) of this section;

(9) of the successful completion of unit-specific, manufacturer-provided training that includes standard clinical and emergency procedures for remote control brachytherapy and gamma stereotactic radiosurgery units for the following personnel:

(A) authorized medical physicist of this section;

(B) technologists; and

(C) authorized user;

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(10) of the safety procedures and instructions as required by subsection (ggg) of this section;

(11) of the spot check procedures as required by subsections (lll)-(nnn) of this section, as applicable; and

(12) that an RSC has been established in accordance with subsection (i)(1) or (2) of this section if applicable.

(q) License for other medical or veterinary uses of radioactive material or a radiation source approved for medical or veterinary use that is not specifically addressed in this section. A licensee may use radioactive material or a radiation source approved for medical use which is not specifically addressed in this section if the requirements of subsection (f) of this section have been met, the applicant or licensee has received written approval from the agency in a license or license amendment and the licensee uses the material in accordance with the regulations and specific conditions the agency considers necessary for the medical use of the material.

(r) Amendment of licenses at request of licensee.

(1) Requests for amendment of a license or deletion of an authorized use site shall be filed in accordance with §289.252(aa) of this title.

(2) A licensee without broad-scope authorization shall apply for and shall receive a license amendment prior to the following:

(A) receiving or using radioactive material for a type of use that is authorized in accordance with under this section, but is not authorized on their current license issued in accordance with this section;

(B) permitting anyone to work as an authorized user, authorized nuclear pharmacist or authorized medical physicist under the license;

(C) changing RSOs, except as provided in subsection (g)(5) of this section;

(D) receiving radioactive material in excess of the amount or in a different form, or receiving a different radionuclide than is authorized on the license;

(E) adding or changing the areas in which radioactive material is used or stored and are identified in the application or on the license;

(F) changing the address(es) of use identified in the application or on the license; and

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(G) changing operating, safety, and emergency procedures.

(3) A licensee with broad-scope authorization shall apply for and shall receive a license amendment prior to taking actions specified in paragraphs (2)(A), (C), (D), (F) and (G) of this subsection.

(s) Supervision. A licensee may permit the receipt, possession, use, or transfer of radioactive material by an individual under the supervision of an authorized user, unless prohibited by license condition.

(1) A licensee who permits the receipt, possession, use, or transfer of radioactive material by an individual under the supervision of an authorized user shall do the following:

(A) instruct the supervised individual in the licensee's written operating, safety, and emergency procedures, written directive procedures, requirements of this chapter, and license conditions with respect to the use of radioactive material; and

(B) require the supervised individual to follow the instructions of the supervising authorized user for medical uses of radioactive material, written operating, safety, and emergency procedures established by the licensee, written directive procedures, requirements of this chapter, and license conditions with respect to the medical use of radioactive material.

(2) A licensee who permits the preparation of radioactive material for medical use by an individual under the supervision of an authorized nuclear pharmacist or authorized user, shall do the following:

(A) instruct the supervised individual in the preparation of radioactive material for medical use, as appropriate to that individual's involvement with radioactive material; and

(B) require the supervised individual to follow the instructions of the supervising authorized user or authorized nuclear pharmacist regarding the preparation of radioactive material for medical use, the written operating, safety, and emergency procedures established by the licensee, the requirements of this chapter, and license conditions.

(3) A licensee who permits supervised activities in accordance with paragraphs (1) and (2) of this subsection is responsible for the acts and omissions of the supervised individual.

(4) Only an authorized user may authorize the medical use of radioactive material.

(t) Written directives.

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(1) A written directive shall be dated and signed by an authorized user prior to administration of sodium iodide I-131 greater than 30 microcuries (μCi) (1.11 megabecquerels (MBq)), any therapeutic dosage of unsealed radioactive material, or any therapeutic dose of radiation from radioactive material.

(A) A written revision to an existing written directive may be made provided that the revision is dated and signed by an authorized user prior to the administration of the dosage of unsealed radioactive material, the brachytherapy dose, the gamma stereotactic radiosurgery dose, the teletherapy dose, or the next fractional dose.

(B) If, because of the emergent nature of the patient's condition, a delay in order to provide a written directive or to revise a written directive would jeopardize the patient's health, an oral directive or an oral revision to an existing written directive is acceptable. The information contained in the oral directive or oral revision shall be documented in writing as soon as possible in the patient's record. A written directive or revised written directive shall be prepared and signed by the authorized user within 48 hours of the oral directive or oral revision.

(2) The written directive shall contain the patient or human research subject's name and the following information for each application.

(A) For any administration of quantities greater than 30 μCi (1.11 MBq) of sodium iodide I-131, the dosage.

(B) For an administration of a therapeutic dosage of a radiopharmaceutical other than sodium iodide I-131:

(i) the radiopharmaceutical;

(ii) the dosage; and

(iii) route of administration.

(C) For gamma stereotactic radiosurgery:

(i) the total dose;

(ii) the treatment site; and

(iii) the values for the target coordinate settings per treatment for each anatomically distinct treatment site.

(D) For teletherapy:

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- (i) the total dose;
- (ii) dose per fraction;
- (iii) number of fractions; and
- (iv) treatment site.

(E) For high-dose rate remote afterloading brachytherapy:

- (i) the radionuclide;
- (ii) treatment site;
- (iii) dose per fraction;
- (iv) number of fractions; and
- (v) total dose.

afterloaders:

(F) For all other brachytherapy, including low, medium, and pulsed rate

(i) prior to implantation:

- (I) treatment site;
- (II) the radionuclide; and
- (III) dose;

(ii) after implantation but prior to completion of the procedure:

- (I) the radionuclide;
- (II) treatment site;
- (III) number of sealed sources;
- (IV) total sealed source strength; and
- (V) exposure time or, the total dose.

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(3) The licensee shall retain the written directive in accordance with subsection (www) of this section for inspection by the agency.

(4) Procedures for administrations requiring a written directive.

(A) For any administration requiring a written directive, the licensee shall develop, implement, and maintain written procedures to ensure that:

(i) the patient's or human research subject's identity is verified before each administration; and

(ii) each administration is in accordance with the written directive.

(B) The procedures required by subparagraph (A) of this paragraph shall, at a minimum, address the following items that are applicable for the licensee's use of radioactive material:

(i) verifying the identity of the patient or human research subject;

(ii) verifying that the administration is in accordance with the treatment plan, if applicable, and the written directive;

(iii) checking both manual and computer-generated dose calculations; and

(iv) verifying that any computer-generated dose calculations are correctly transferred into the consoles of therapeutic medical units authorized by subsection (dd) of this section.

(C) A licensee shall maintain a copy of the procedures required by subparagraph (A) of this paragraph in accordance with subsection (www) of this section.

(u) Suppliers for sealed sources or devices for medical use. A licensee may only use the following for medical use:

(1) sealed sources or devices manufactured, labeled, packaged, and distributed in accordance with a license issued by the agency, NRC, an agreement state, or licensing state;

(2) sealed sources or devices non-commercially transferred from an NRC or agreement state medical use licensee; or

(3) teletherapy sources manufactured and distributed in accordance with a license issued by the agency, NRC, an agreement state, or licensing state.

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(v) Possession, use, and calibration of dose calibrators to measure the activity of unsealed radioactive material.

(1) For direct measurements performed in accordance with subsection (x) of this section, the licensee shall possess and use instrumentation to measure the activity of unsealed radioactive material before it is administered to each patient or human research subject.

(2) The licensee shall calibrate the instrumentation specified in paragraph (1) of this subsection in accordance with nationally recognized standards or the manufacturer's instructions.

(3) The calibration required by paragraph (2) of this subsection shall include tests for constancy, accuracy, linearity, and geometry dependence, as appropriate to demonstrate proper operation of the instrument. The tests for constancy, accuracy, linearity, and geometry dependence shall be conducted at the following intervals:

(A) constancy at least once each day prior to assay of patient dosages;

(B) linearity at installation, repair, relocation, and at least quarterly thereafter;

(C) geometry dependence at installation; and

(D) accuracy at installation and at least annually thereafter.

(4) The licensee shall maintain a record of each instrument calibration in accordance with subsection (www) of this section. The record shall include the following:

(A) model and serial number of the instrument and calibration sources;

(B) date of the calibration;

(C) results of the calibration; and

(D) name of the individual who performed the calibration.

(w) Calibration of survey instruments. A licensee shall calibrate the survey instruments used to show compliance with this subsection and with §289.202 of this title before first use, annually, and following a repair that affects the calibration. A licensee shall:

(1) calibrate all scales with readings up to 10 millisieverts (mSv) (1000 millirem (mrem)) per hour with a radiation source;

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(2) calibrate two separated readings on each scale or decade that will be used to show compliance;

(3) conspicuously note on the instrument the date of calibration;

(4) not use survey instruments if the difference between the indicated exposure rate and the calculated exposure rate is more than 20%; and

(5) maintain a record of each survey instrument calibration in accordance with subsection (www) of this section.

(x) Determination of dosages of radioactive material for medical use.

(1) Before medical use, the licensee shall perform the following:

(A) record the activity of each dosage; and

(B) determine the activity of each dosage using a dose calibrator, by direct measurement of radioactivity, or a decay correction, based on the activity or activity concentration determined by the following:

(i) a manufacturer or preparer licensed in accordance with §289.252(r) of this title, or under an equivalent NRC, agreement state, or licensing state license; or

(ii) an NRC or agreement state licensee for use in research in accordance with a Radioactive Drug Research Committee-approved protocol or an Investigational New Drug (IND) protocol accepted by the US Food and Drug Administration (FDA).

(2) For other than unit dosages, this determination shall be made by:

(A) direct measurement of radioactivity; or

(B) combination of direct measurement of radioactivity and mathematical calculations.

(3) Unless otherwise directed by the authorized user, a licensee shall not use a dosage if the dosage does not fall within the prescribed dosage range or if the dosage differs from the prescribed dosage by more than 20%.

(4) A licensee restricted to only unit doses prepared in accordance with §289.252(r) of this title need not comply with the requirements in paragraph (1)(B) of this

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subsection, unless the administration time of the unit dose deviates from the nuclear pharmacy's pre-calibrated time by 15 minutes or more.

(5) A licensee shall maintain a record of the dosage determination required by this subsection in accordance with subsection (www) of this section for inspection by the agency. The record shall contain the following:

(A) radionuclide, generic name, trade name, or abbreviation of the radiopharmaceutical;

(B) patient's or human research subject's name or identification number if one has been assigned;

(C) prescribed dosage;

(D) determined dosage or a notation that the total activity is less than 30 μCi (1.1 MBq);

(E) the date and time of the dosage determination; and

(F) the name of the individual who determined the dosage.

(y) Authorization for calibration and reference sources. Any licensee authorized by subsection (n), (o), (p) or (q) of this section for medical use of radioactive material may receive, possess, and use the following radioactive material for check, calibration, and reference use:

(1) sealed sources manufactured and distributed by a person licensed in accordance with §289.252 of this title that do not exceed 30 millicuries (mCi) (1.11 gigabecquerel (GBq)) each;

(2) sealed sources redistributed by a licensee authorized to redistribute the sealed sources manufactured and distributed by a person licensed in accordance with §289.252 of this title that do not exceed 30 mCi (1.11GBq) each, provided the redistributed sealed sources are in the original packaging and shielding and are accompanied by the manufacturer's approved instructions;

(3) any radioactive material with a half-life not longer than 120 days in individual amounts not to exceed 15 mCi (0.56 GBq);

(4) any radioactive material with a half-life longer than 120 days in individual amounts not to exceed the smaller of 200 μCi (7.4 MBq) or 1000 times the quantities in §289.202(qqq)(3) of this title; and

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(5) technetium-99m in amounts as needed.

(z) Requirements for possession of sealed sources and brachytherapy sealed sources. A licensee in possession of any sealed source or brachytherapy source shall:

(1) follow the radiation safety and handling instructions supplied by the manufacturer and the leakage test requirements in accordance with §289.201(g) of this title and reporting requirements in §289.202(bbb) of this title; and

(2) conduct a physical inventory at intervals not to exceed six months to account for all sealed sources in its possession. Records of the inventory shall be made and maintained for inspection by the agency in accordance with subsection (www) of this section and shall include the following:

(A) model number of each source and serial number if one has been assigned;

(B) identity of each source and its nominal activity;

(C) location of each source;

(D) date of the inventory; and

(E) identification of the individual who performed the inventory.

(aa) Labeling of vials and syringes. Each syringe and vial that contains a radiopharmaceutical shall be labeled to identify the radioactive drug. Each syringe shield and vial shield shall also be labeled unless the label on the syringe or vial is visible when shielded.

(bb) Surveys for ambient radiation exposure rate.

(1) In addition to the requirements of §289.202(p) of this title and except as provided in paragraph (2) of this subsection, a licensee shall survey with a radiation detection survey instrument at the end of each day of use all areas where radioactive material requiring a written directive was prepared for use or administered.

(2) A licensee does not need to perform the surveys required by paragraph (1) of this subsection in an area(s) where patients or human research subjects are confined when they cannot be released in accordance with subsection (cc) of this section or an animal that is confined. Once the patient or human or animal research subject is released from confinement, the licensee shall survey with a radiation survey instrument, the area in which the patient or human or animal research subject was confined.

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(3) A record of each survey shall be retained in accordance with subsection (www) of this section for inspection by the agency. The record shall include the following:

- (A) date of the survey;
- (B) results of the survey;
- (C) manufacturer's name, model, and serial number of the instrument used to make the survey; and
- (D) name of the individual who performed the survey.

(cc) Release of individuals containing radioactive drugs or implants containing radioactive material.

(1) The licensee may authorize the release from its control any individual who has been administered radioactive drugs or implants containing radioactive material if the total effective dose equivalent (TEDE) to any other individual from exposure to the released individual is not likely to exceed 0.5 rem (5 mSv). Patients treated with temporary eye plaques may be released from the hospital provided that the procedures ensure that the exposure rate from the patient is less than 5 mr per hour at a distance of 1 meter from the eye plaque location;

(2) The licensee shall provide the released individual, or the individual's parent or guardian, with written instructions on actions recommended to maintain doses to other individuals ALARA if the TEDE to any other individual is likely to exceed 0.1 rem (1 mSv). If the TEDE to a nursing infant or child could exceed 0.1 rem (1 mSv), assuming there was no interruption of breast-feeding, the instructions shall also include the following:

- (A) guidance on the interruption or discontinuation of breast-feeding; and
- (B) information on the potential consequences, if any, of failure to follow the guidance.

(3) The licensee shall maintain for inspection by the agency, a record in accordance with subsection (www) of this section of each patient released in accordance with paragraph (1) of this subsection. The record shall include the following:

- (A) the basis for authorizing the release of an individual; and
- (B) the instructions provided to a breast-feeding woman, if the radiation dose to the infant or child from continued breast-feeding could result in a TEDE exceeding 0.5 rem (5 mSv).

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(dd) Mobile nuclear medicine service. A license for a mobile nuclear medicine service for medical or veterinary use of radioactive material will be issued if the agency approves the documentation submitted by the applicant in accordance with the requirements of subsections (f) and (n) of this section. The clients of the mobile nuclear medicine service shall be licensed if the client receives or possesses radioactive material to be used by the mobile nuclear medicine service.

(1) A licensee providing mobile nuclear medicine service shall:

(A) obtain a letter signed by the management of each client for which services are rendered that permits the use of radioactive material at the client's address and clearly delineates the authority and responsibility of the licensee and the client;

(B) check instruments used to measure the activity of unsealed radioactive material for proper function before medical or veterinary use at each client's address or on each day of use, whichever is more frequent. At a minimum, the check for proper function required by this subparagraph shall include a constancy check;

(C) have at least one fixed facility where records may be maintained and radioactive material may be delivered by manufacturers or distributors each day prior to the mobile nuclear medicine licensee dispatching its vans to client sites;

(D) agree to have an authorized physician user directly supervise each technologist at a reasonable frequency;

(E) check survey instruments for proper operation with a dedicated check source before use at each client's address; and

(F) before leaving a client's address, survey all areas of use to ensure compliance with the requirements of §289.202 of this title.

(2) A mobile nuclear medicine service shall not have radioactive material delivered from the manufacturer or the distributor to the client unless the client has a license allowing possession of the radioactive material. Radioactive material delivered to the client shall be received and handled in conformance with the client's license.

(3) A licensee providing mobile nuclear medicine services shall maintain records, for inspection by the agency, in accordance with subsection (www) of this section including the letter required in paragraph (1)(A) of this subsection and the record of each survey required in paragraph (1)(F) of this subsection.

(ee) Decay-in-storage.

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(1) The licensee may hold radioactive material with a physical half-life of less than 65 days for decay-in-storage and dispose of it without regard to its radioactivity if the licensee does the following:

(A) monitors radioactive material at the surface before disposal and determines that its radioactivity cannot be distinguished from the background radiation level with an appropriate radiation detection survey meter set on its most sensitive scale and with no interposed shielding; and

(B) removes or obliterates all radiation labels, except for radiation labels on materials that are within containers and that will be handled as biomedical waste after it has been released from the licensee.

(2) The licensee shall retain a record of each disposal as required by paragraph (1) of this subsection in accordance with subsection (www) of this section for inspection by the agency. The record shall include the following:

(A) date of the disposal;

(B) manufacturer's name, model number and serial number of the survey instrument used;

(C) background radiation level;

(D) radiation level measured at the surface of each waste container; and

(E) name of the individual who performed the survey.

(ff) Use of unsealed radioactive material for uptake, dilution, and excretion studies that do not require a written directive. Except for quantities that require a written directive in accordance with subsection (t) of this section, a licensee may use any unsealed radioactive material prepared for medical or veterinary use for uptake, dilution, or excretion studies that meets the following:

(1) is obtained from a manufacturer or preparer licensed in accordance with §289.252 of this title or equivalent NRC, agreement state, or licensing state requirements; or

(2) is prepared by one of the following:

(A) an authorized nuclear pharmacist;

(B) a physician who is an authorized user and who meets the requirements specified in subsections (jj) or (nn) and (jj)(3)(B)(vii) of this section, or prior to the effective date

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of this rule, meets the requirements of subsection (1)(3) and (4) of this section for imaging and localization studies and unsealed radioactive material requiring a written directive;

(C) an individual under the supervision, as specified in subsection (s) of this section, of an authorized nuclear pharmacist or an authorized user in subparagraphs (A) and (B) of this paragraph; or

(3) is obtained from and prepared by an NRC, agreement state, or licensing state licensee for use in research in accordance with a Radioactive Drug Research Committee-approved protocol or an IND protocol accepted by the FDA; or

(4) is prepared by the licensee for use in research in accordance with a Radioactive Drug Research Committee-approved application or an IND protocol accepted by the FDA.

(gg) Training for uptake, dilution, and excretion studies. Except as provided in subsection (l) of this section, the licensee shall require an authorized user of unsealed radioactive material for the uses authorized in subsection (ff) of this section to be a physician who:

(1) is certified by a medical specialty board whose certification process has been recognized by the agency, the NRC or an agreement state and who meets the requirements in paragraph (4) of this subsection. (The names of board certifications that have been recognized by the agency, the NRC, an agreement state, or licensing state will be posted on the agency's web page, www.dshs.state.tx.us/radiation). To have its certification recognized, a specialty board shall require all candidates for certification to:

(A) complete 60 hours of training and experience in basic radionuclide handling techniques and radiation safety applicable to the medical use of unsealed radioactive material for uptake, dilution, and excretion studies that includes the topics listed in paragraph (3) of this subsection; and

(B) pass an examination, administered by diplomates of the specialty board, that assesses knowledge and competence in radiation safety, radionuclide handling, and quality control; or

(2) is an authorized user in accordance with subsection (jj) or (nn) of this section;
or

(3) has completed 60 hours of training and experience, including a minimum of eight hours of classroom and laboratory training, in basic radionuclide handling techniques applicable to the medical use of unsealed radioactive material for uptake, dilution, and excretion studies. The training and experience shall include the following.

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(A) Classroom and laboratory training in the following areas:

- (i) radiation physics and instrumentation;
- (ii) radiation protection;
- (iii) mathematics pertaining to the use and measurement of radioactivity;
- (iv) chemistry of radioactive material for medical use; and
- (v) radiation biology.

(B) Work experience, under the supervision of an authorized user who meets the requirements of this subsection, subsection (jj), or (nn) of this section involving the following:

- (i) ordering, receiving, and unpacking radioactive materials safely and performing the related radiation surveys;
- (ii) performing quality control procedures on instruments used to determine the activity of dosages and performing checks for proper operation of survey meters;
- (iii) calculating, measuring, and safely preparing patient or human research subject dosages;
- (iv) using administrative controls to prevent a medical event involving the use of unsealed radioactive material;
- (v) using procedures to contain spilled radioactive material safely and using proper decontamination procedures; and
- (vi) administering dosages of radioactive drugs to patients or human research subjects; and

(4) has obtained written attestation, signed by a preceptor authorized user who meets the requirements of this subsection, subsection (jj), or (nn) of this section that the individual has satisfactorily completed the requirements of paragraph (1)(A) or (3) of this subsection and has achieved a level of competency sufficient to function independently as an authorized user for the medical uses authorized in accordance with subsection (ff) of this section.

(hh) Use of unsealed radioactive material for imaging and localization studies that do not require a written directive. Except for quantities that require a written directive in accordance

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with subsection (t) of this section, a licensee may use any unsealed radioactive material prepared for medical or veterinary use for imaging and localization studies that meets the following:

(1) is obtained from a manufacturer or preparer licensed in accordance with §289.252 of this title or equivalent NRC, agreement state, or licensing state requirements; or

(2) is prepared by one of the following:

(A) an authorized nuclear pharmacist; or

(B) a physician who is an authorized user and who meets the requirements specified in subsections (jj) or (nn) and (jj)(3)(vii) of this section, or prior to the effective date of this rule, meets the requirements of subsection (1)(3) and (4) of this section for imaging and localization studies not requiring a written directive; or

(C) an individual under the supervision, as specified in subsection (s) of this section, of an authorized nuclear pharmacist or an authorized user in subparagraphs (A) and (B) of this paragraph; or

(D) is obtained from and prepared by an NRC, agreement state, or licensing state licensee for use in research in accordance with a Radioactive Drug Research Committee-approved protocol or an IND protocol accepted by the FDA; or

(E) is prepared by the licensee for use in research in accordance with a Radioactive Drug Research Committee-approved application or an IND protocol accepted by the FDA.

(3) Any licensee who processes and prepares radiopharmaceuticals for human use shall do so 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 or the rules of the practice of pharmacy, as promulgated by the Texas State Board of Pharmacy.

(ii) Permissible molybdenum-99 concentration.

(1) The licensee may not administer to humans a radiopharmaceutical containing more than 0.15 μCi of molybdenum-99 per millicurie of technetium-99m (0.15 kilobecquerel of molybdenum-99 per megabecquerel of technetium-99m).

(2) The licensee who uses molybdenum-99/technetium-99m generators for preparing a technetium-99m radiopharmaceutical shall measure the molybdenum-99 concentration of the first eluate after receipt of a generator to demonstrate compliance with paragraph (1) of this subsection.

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(3) If the licensee is required to measure the molybdenum-99 concentration, the licensee shall retain a record of each measurement in accordance with subsection (www) of this section for inspection by the agency. The record shall include the following for each measured elution of technetium-99m:

(A) ratio of the measures expressed as microcuries of molybdenum-99 per millicurie of technetium-99m (kilobecquerel of molybdenum-99 per megabecquerel of technetium-99m);

(B) time and date of the measurement; and

(C) name of the individual who made the measurement.

(jj) Training for imaging and localization studies.

(1) Except as provided in subsection (l) of this section, the licensee shall require an authorized user of unsealed radioactive material for the uses authorized in subsection (hh) of this section to be a physician who:

(A) is certified by a medical specialty board whose certification process has been recognized by the agency, the NRC or an agreement state and who meets the requirements of subparagraph (D) of this paragraph. (The names of board certifications that have been recognized by the agency, the NRC, an agreement state, or licensing state will be posted on the agency's web page, www.dshs.state.tx.us/radiation). To have its certification recognized, a specialty board shall require all candidates for certification to:

(i) complete 700 hours of training and experience in basic radionuclide handling techniques and radiation safety applicable to the medical use of unsealed radioactive material for imaging and localization studies that includes the topics listed in subparagraph (C) of this paragraph; and

(ii) pass an examination, administered by diplomates of the specialty board, that assesses knowledge and competence in radiation safety, radionuclide handling, and quality control; or

(B) is an authorized user in accordance with subsection (nn) of this section; and meets the requirements of subparagraph (C)(ii)(VII) of this paragraph; or

(C) has completed 700 hours of training and experience, including a minimum of 80 hours of classroom and laboratory training, in basic radionuclide handling techniques applicable to the medical use of unsealed radioactive material for imaging and localization studies. The training and experience shall include the following.

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(i) Classroom and laboratory training in the following areas:

- (I) radiation physics and instrumentation;
- (II) radiation protection;
- (III) mathematics pertaining to the use and measurement of radioactivity;
- (IV) chemistry of radioactive material for medical use; and
- (V) radiation biology.

(ii) Work experience under the supervision of an authorized user who meets the requirements in this subsection, or subclause (VII) of this clause, and subsection (nn) of this section:, involving the following:

- (I) ordering, receiving, and unpacking radioactive materials safely and performing the related radiation surveys;
- (II) performing quality control procedures on instruments used to determine the activity of dosages and performing checks for proper operation of survey meters;
- (III) calculating, measuring, and safely preparing patient or human research subject dosages;
- (IV) using administrative controls to prevent a medical event involving the use of unsealed radioactive material;
- (V) using procedures to contain spilled radioactive material safely and using proper decontamination procedures;
- (VI) administering dosages of radioactive drugs to patients or human research subjects; and
- (VII) eluting generator systems appropriate for preparation of radioactive drugs for imaging and localization studies, measuring and testing the eluate for radionuclide purity, and processing the eluate with reagent kits to prepare labeled radioactive drugs; and

(D) has obtained written attestation, signed by a preceptor authorized user who meets the requirements of this subsection or subparagraph (C)(ii)(VII) of this paragraph and

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subsection (nn) of this section that the individual has satisfactorily completed the requirements of paragraphs (A)(i) or (C) of this subsection and has achieved a level of competency sufficient to function independently as an authorized user for the medical uses authorized in accordance with subsections (ff) and (hh) of this section.

(2) In addition to the training and experience requirements of paragraph (1) of this subsection, for the use of positron emission tomography (PET) radionuclides, the licensee shall require that the authorized user has:

(A) completed 24 hours of work experience specific to the use of PET radionuclides consistent with paragraph (1)(C)(ii)(I)-(VI) of this subsection; and

(B) a written attestation statement specific to the use of PET radionuclides for diagnostic imaging.

(kk) Use of unsealed radioactive material that requires a written directive. A licensee may use any unsealed radioactive material prepared for medical use that requires a written directive in accordance with subsection (t) of this section that meets the following:

(1) is obtained from a manufacturer or preparer licensed in accordance with §289.252 of this title or equivalent NRC, agreement state, or licensing state requirements;

(2) is prepared by one of the following:

(A) an authorized nuclear pharmacist;

(B) a physician who is an authorized user and who meets the requirements specified in subsection (jj) or (nn) of this section; or

(C) an individual under the supervision, as specified in subsection (s) of this section, of an authorized nuclear pharmacist or an authorized user in subparagraphs (A) and (B) of this paragraph;

(3) is obtained from and prepared by an NRC, agreement state, or licensing state licensee for use in research in accordance with an IND protocol accepted by the FDA; or

(4) is prepared by the licensee for use in research in accordance with an IND protocol accepted by the FDA.

(ll) Safety instruction to personnel.

(1) The licensee shall provide radiation safety instruction, initially and at least annually, to personnel caring for patients or human or animal research subjects who cannot be

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released in accordance with subsection (cc) of this section. The instruction shall be appropriate to the personnel's assigned duties and include the following:

(A) patient or human or animal research subject control; and

(B) visitor control to include the following:

(i) routine visitation to hospitalized individuals or animals in accordance with §289.202(n) of this title;

(ii) contamination control;

(iii) waste control; and

(iv) notification of the RSO, or his or her designee, and an authorized user if the patient or the human or animal research subject has a medical emergency or dies.

(2) The licensee shall maintain a record for inspection by the agency, in accordance with subsection (www) of this section, of individuals receiving instruction. The record shall include the following:

(A) list of the topics covered;

(B) date of the instruction or training;

(C) name(s) of the attendee(s); and

(D) name(s) of the individual(s) who provided the instruction.

(mm) Safety precautions. For each human patient or human research subject who cannot be released in accordance with subsection (cc) of this section, the licensee shall do the following:

(1) provide a private room with a private sanitary facility; or

(2) provide a room with a private sanitary facility with another individual who also has received therapy with an unsealed radioactive material and who also cannot be released in accordance with subsection (cc) of this section;

(3) post the patient's or the research subject's room with a "Radioactive Materials" sign and note on the door and in the patient's or research subject's chart where and how long visitors may stay in the patient's or the research subject's room; and

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(4) either monitor material and items removed from the patient's or the research subject's room to determine that their radioactivity cannot be distinguished from the natural background radiation level with a radiation detection survey instrument set on its most sensitive scale and with no interposed shielding, or handle such material and items as radioactive waste; and

(5) notify the RSO, or his or her designee, and the authorized user immediately if the patient or research subject has a medical emergency or dies.

(nn) Training for use of unsealed radioactive material that requires a written directive. Except as provided in subsection (l) of this section, the licensee shall require an authorized user of unsealed radioactive material for the uses authorized in subsection (kk) of this section to be a physician who:

(1) is certified by a medical specialty board whose certification process has been recognized by the agency, the NRC, an agreement state, or licensing state and who meets the requirements in paragraphs (2)(B)(vi) and (C) this subsection. (Specialty boards whose certification processes have been recognized by the agency, the NRC, an agreement state, or licensing state will be posted on the agency's webpage, www.dshs.state.tx.us/radiation). To be recognized, a specialty board shall require all candidates for certification to:

(A) successfully complete residency training in a radiation therapy or nuclear medicine training program or a program in a related medical specialty. These residency training programs shall include 700 hours of training and experience as described in paragraphs (2)(A)(i) through (2)(B)(v) of this subsection. Eligible training programs shall be approved by the Residency Review Committee of the Accreditation Council for Graduate Medical Education, the Royal College of Physicians and Surgeons of Canada, or the Committee on Post-Graduate Training of the American Osteopathic Association; and

(B) pass an examination, administered by diplomates of the specialty board, which tests knowledge and competence in radiation safety, radionuclide handling, quality assurance, and clinical use of unsealed radioactive material for which a written directive is required; or

(2) has completed 700 hours of training and experience, including a minimum of 200 hours of classroom and laboratory training, in basic radionuclide handling techniques applicable to the medical use of unsealed radioactive material requiring a written directive. The training and experience shall include the following.

(A) Classroom and laboratory training in the following areas:

(i) radiation physics and instrumentation;

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- (ii) radiation protection;
- radioactivity;
- (iii) mathematics pertaining to the use and measurement of
- (iv) chemistry of radioactive material for medical use; and
- (v) radiation biology.

(B) Work experience, under the supervision of an authorized user who meets the requirements of this subsection. A supervising authorized user, who meets the requirements of paragraph (2) of this subsection shall also have experience in administering dosages in the same dosage category or categories (for example, in accordance with clause (vi) of this subparagraph) as the individual requesting authorized user status. The work experience shall involve the following:

- (i) ordering, receiving, and unpacking radioactive materials safely and performing the related radiation surveys;
- (ii) performing quality control procedures on instruments used to determine the activity of dosages and performing checks for proper operation of survey meters;
- (iii) calculating, measuring, and safely preparing patient or human research subject dosages;
- (iv) using administrative controls to prevent a medical event involving the use of unsealed radioactive material;
- (v) using procedures to contain spilled radioactive material safely and using proper decontamination procedures; and
- (vi) administering dosages of radioactive drugs to patients or human research subjects involving a minimum of three cases in each of the following categories for which the individual is requesting authorized user status:
 - (I) oral administration of less than or equal to 33 mCi (1.22 GBq) of sodium iodide I-131, for which a written directive is required;
 - (II) oral administration of greater than 33 mCi (1.22 GBq) of sodium iodide I-131 (experience with at least three cases in this subclause also satisfies the requirement of subclause (I) of this clause;

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(III) parenteral administration of any beta emitter or a photon-emitting radionuclide with a photon energy less than 150 kiloelectron volts (keV) for which a written directive is required; and/or

(IV) parenteral administration of any other radionuclide for which a written directive is required; and

(C) written attestation that the individual has satisfactorily completed the requirements of paragraphs (1)(A) and (2)(B)(vi) or (2) of this subsection, and has achieved a level of competency sufficient to function independently as an authorized user for the medical uses authorized in accordance with subsection (kk) of this section. The written attestation shall be signed by a preceptor authorized user who meets the requirements of this subsection. The preceptor authorized user who meets the requirements in paragraph (2) of this subsection shall have experience in administering dosages in the same dosage category or categories (for example, in accordance with paragraph (2)(B)(vi) of this subsection) as the individual requesting authorized user status.

(oo) Training for the oral administration of sodium iodide I-131 requiring a written directive in quantities less than or equal to 33 mCi (1.22 GBq). Except as provided in subsection (l) of this section, the licensee shall require an authorized user for the oral administration of sodium iodide I-131 requiring a written directive in quantities less than or equal to 33 mCi (1.22 GBq) to be a physician who:

(1) is certified by a medical specialty board whose certification process includes all of the requirements of paragraphs (3) and (4) of this subsection and whose certification has been recognized by the agency, the NRC, an agreement state, or licensing state. (The names of board certifications which have been recognized by the agency, the NRC, agreement state or licensing state will be posted on the agency's web page, www.dshs.state.tx.us/radiation); or

(2) is an authorized user in accordance with subsection (nn) of this section for uses listed in subsection (nn)(2)(B)(vi)(I) or (II) of this section, or subsection (pp) of this section; or

(3) has successfully completed 80 hours of classroom and laboratory training and work experience applicable to the medical use of sodium iodide I131 for procedures requiring a written directive. The training and experience shall include the following.

(A) Classroom and laboratory training shall include the following:

(i) radiation physics and instrumentation;

(ii) radiation protection;

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(iii) mathematics pertaining to the use and measurement of radioactivity;

(iv) chemistry of radioactive material for medical use; and

(v) radiation biology.

(B) Work experience, under the supervision of an authorized user who meets the requirements of this subsection, subsection (nn) or subsection (pp) of this section. A supervising authorized user who meets the requirements in subsection (nn)(2) of this section, shall also have experience in administering dosages as specified in subsection (nn)(2)(B)(vi)(I) or (II) of this section. The work experience shall involve the following:

(i) ordering, receiving, and unpacking radioactive materials safely and performing the related radiation surveys;

(ii) performing quality control procedures on instruments used to determine the activity of dosages and performing checks for proper operation of survey meters;

(iii) calculating, measuring, and safely preparing patient or human research subject dosages;

(iv) using administrative controls to prevent a medical event involving the use of unsealed radioactive material;

(v) using procedures to contain spilled radioactive material safely and using proper decontamination procedures; and

(vi) administering dosages of radioactive drugs to patients or human research subjects that includes at least three cases involving the oral administration of less than or equal to 33mCi (1.22 GBq) of sodium iodide I-131; and

(4) has obtained written attestation that the individual has satisfactorily completed the requirements of paragraph (3) of this section, and has achieved a level of competency sufficient to function independently as an authorized user for the medical uses authorized in accordance with subsection (kk) of this section. The written attestation shall be signed by a preceptor authorized user who meets the requirements of this subsection, subsection (nn) or subsection (pp) of this section. A preceptor authorized user, who meets the requirements in subsection (nn)(2) of this section shall also have experience in administering dosages as specified in subsection (nn)(2)(B)(vi)(I) or (II) of this section.

(pp) Training for the oral administration of sodium iodide I-131 requiring a written directive in quantities greater than 33 mCi (1.22 GBq). Except as provided in subsection (l) of

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this section, the licensee shall require an authorized user for the oral administration of sodium iodide I-131 requiring a written directive in quantities greater than 33 mCi (1.22 GBq) to be a physician who:

(1) is certified by a medical specialty board whose certification process includes all of the requirements in paragraph (3) of this subsection and whose certification has been recognized by the agency, the NRC, an agreement state, or licensing state and who meets the requirements of paragraph (4) of this subsection). (The names of board certifications which have been recognized by the agency, the NRC, agreement state or licensing state will be posted on the agency's web page, www.dshs.state.tx.us/radiation);

(2) is an authorized user in accordance with subsection (nn) of this section for uses listed in subsection (nn)(2)(B)(vi)(II) of this section; or

(3) has training and experience including, having successfully completed 80 hours of classroom and laboratory training applicable to the medical use of sodium iodide I-131 for procedures requiring a written directive. The training and experience shall include the following.

(A) Classroom and laboratory training shall include the following:

- (i) radiation physics and instrumentation;
- (ii) radiation protection;
- (iii) mathematics pertaining to the use and measurement of radioactivity;
- (iv) chemistry of radioactive material for medical use;
- (v) radiation biology.

(B) Work experience, under the supervision of an authorized user who meets the requirements of subsection (nn) or (pp) of this section. A supervising authorized user who meets the requirements of subsection (nn)(2) of this section, shall also have experience in administering dosages as specified in subsection (nn)(2)(B)(vi)(II) of this section. The work experience shall involve the following:

- (i) ordering, receiving, and unpacking radioactive materials safely and performing the related radiation surveys;
- (ii) performing quality control procedures on instruments used to determine the activity of dosages and performing checks for proper operation of survey meters;

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(iii) calculating, measuring, and safely preparing patient or human research subject dosages;

(iv) using administrative controls to prevent a medical event involving the use of unsealed radioactive material;

(v) using procedures to contain spilled radioactive material safely and using proper decontamination procedures; and

(vi) administering dosages of radioactive drugs to patients or human research subjects that includes at least three cases involving the oral administration of greater than 33mCi (1.22 GBq) of sodium iodide I-131; and

(4) has obtained written attestation that the individual has satisfactorily completed the requirements of paragraph (3) of this subsection, and has achieved a level of competency sufficient to function independently as an authorized user for the medical uses authorized in accordance with subsection (kk) of this section. The written attestation shall be signed by a preceptor authorized user who meets the requirements in this subsection or subsection (nn) of this section. The preceptor authorized user, who meets the requirements in subsection (nn)(2) of this section, shall also have experience in administering dosages as specified in subsection (nn)(2)(B)(vi)(II) of this section.

(qq) Training for the parenteral administration of unsealed radioactive material requiring a written directive. Except as provided in subsection (l) of this section, the licensee shall require an authorized user for the parenteral administration requiring a written directive to be a physician who:

(1) is an authorized user in accordance with subsection (nn) of this section for uses listed in subsection (nn)(2)(B)(vi)(III) or (IV) of this section; or

(2) is an authorized user under subsection (zz) or (ttt) of this section and who meets the requirements of paragraph (4) of this subsection; or

(3) is certified by a medical specialty board whose certification process has been recognized by the agency, the NRC, an agreement state, or licensing state in accordance with subsection (zz) or (ttt) of this section, and who meets the requirements of paragraph (4) of this subsection. (The names of board certifications which have been recognized by the agency, the NRC, agreement state or licensing state will be posted on the agency's web page, www.dshs.state.tx.us/radiation); or

(4) has successfully completed training and experience including 80 hours of classroom and laboratory training applicable to parenteral administrations requiring a written directive, of any beta emitting radionuclide or any photon-emitting radionuclide with a photon

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energy less than 150 keV, and/or parenteral administration of any other radionuclide for which a written directive is required. The training and experience shall include the following.

(A) Classroom and laboratory training shall include the following:

- (i) radiation physics and instrumentation;
- (ii) radiation protection;
- (iii) mathematics pertaining to the use and measurement of radioactivity;
- (iv) chemistry of radioactive material for medical use; and
- (v) radiation biology.

(B) Work experience, under the supervision of an authorized user who meets the requirements of this subsection or subsection (nn) of this section in the parenteral administration, for which a written directive is required, of any beta emitter or any photon-emitting radionuclide with a photon energy less than 150 keV, and/or parenteral administration of any other radionuclide for which a written directive is required. A supervising authorized user who meets the requirements of subsection (nn) of this section, shall have experience in administering dosages as specified in subsections (nn)(2)(B)(vi)(III) and/or (IV) of this section. The work experience shall involve the following:

- (i) ordering, receiving, and unpacking radioactive materials safely and performing the related radiation surveys;
- (ii) performing quality control procedures on instruments used to determine the activity of dosages and performing checks for proper operation of survey meters;
- (iii) calculating, measuring, and safely preparing patient or human research subject dosages;
- (iv) using administrative controls to prevent a medical event involving the use of unsealed radioactive material;
- (v) using procedures to contain spilled radioactive material safely and using proper decontamination procedures; and
- (vi) administering dosages to patients or human research subjects that include at least three cases involving the parenteral administration, for which a written directive is required, of any beta emitter or any photon-emitting radionuclide with a photon

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energy less than 150 keV and /or at least three cases involving the parenteral administration of any other radionuclide, for which a written directive is required; and

(5) has obtained written attestation that the individual has satisfactorily completed the requirements of paragraphs (2) or (3) of this subsection, and has achieved a level of competency sufficient to function independently as an authorized user for the parenteral administration of unsealed radioactive materials requiring a written directive. The written attestation shall be signed by a preceptor authorized user who meets the requirements of this subsection or subsection (nn) of this section. A preceptor authorized user, who meets the requirements of subsection (nn) of this section shall have experience in administering dosages as specified in subsections (nn)(2)(B)(vi)(III) and/or (IV) of this section.

(rr) Use of sealed sources for manual brachytherapy. The licensee shall use only brachytherapy sealed sources for therapeutic medical uses as follows:

(1) as approved in the Sealed Source and Device Registry; or

(2) in research in accordance with an active Investigational Device Exemption application accepted by the FDA and as approved by the agency.

(ss) Surveys after sealed source implants and removal.

(1) Immediately after implanting sealed sources in a patient or a human or animal research subject, the licensee shall perform a survey to locate and account for all sealed sources that have not been implanted.

(2) Immediately after removing the last temporary implant sealed source from a patient or a human or animal research subject, the licensee shall perform a survey of the patient or the human or animal research subject with a radiation detection survey instrument to confirm that all sealed sources have been removed.

(3) A record of each survey shall be retained, for inspection by the agency, in accordance with subsection (www) of this section. The record shall include the following:

(A) date of the survey;

(B) results of the survey;

(C) manufacturer's name and model and serial number of the instrument used to make the survey; and

(D) name of the individual who performed the survey.

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(tt) Brachytherapy sealed sources accountability.

(1) The licensee shall maintain accountability at all times for all brachytherapy sealed sources in storage or use.

(2) Promptly after removing sealed sources from a patient or a human or animal research subject, the licensee shall return brachytherapy sealed sources to a secure storage area.

(3) The licensee shall maintain a record of the brachytherapy sealed source accountability in accordance with subsection (www) of this section for inspection by the agency.

(A) When removing temporary implants from storage, the licensee shall record the number and activity of sources, time and date the sources were removed, the name of the individual who removed the sources, and the location of use. When temporary implants are returned to storage, record the number and activity of sources, the time and date, and the name of the individual who returned them.

(B) When removing permanent implants from storage, the licensee shall record the number and activity of sources, date, the name of the individual who removed the sources, and the number and activity of sources permanently implanted in the patient or human research subject. Record the number and activity of sources not implanted and returned to storage, the date, and the name of the individual who returned them to storage.

(uu) Safety instruction to personnel. The licensee shall provide radiation safety instruction, initially and at least annually, to personnel caring for patients or human or animal research subjects who are receiving brachytherapy and who cannot be released in accordance with subsection (cc) of this section or animals that are confined.

(1) The instruction shall be appropriate to the personnel's assigned duties and include the following:

(A) size and appearance of brachytherapy sources;

(B) safe handling and shielding instructions;

(C) patient or human research subject control;

(D) visitor control to include visitation to hospitalized individuals in accordance with §289.202(n) of this title; and

(E) notification of the RSO, or his or her designee, and an authorized user if the patient or the human or animal research subject has a medical emergency or dies.

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(2) A licensee shall maintain a record, for inspection by the agency, in accordance with subsection (www) of this section, of individuals receiving instruction. The record shall include the following:

- (A) list of the topics covered;
- (B) date of the instruction or training;
- (C) name(s) of the attendee(s); and
- (D) name(s) of the individual(s) who provided the instruction.

(vv) Safety precautions for the use of brachytherapy

(1) For each patient or human research subject who is receiving brachytherapy and cannot be released in accordance with subsection (cc) of this section the licensee shall:

- (A) provide a private room with a private sanitary facility;
- (B) post the patient's or the research subject's room with a "Radioactive Materials" sign and note on the door or in the patient's or research subject's chart where and how long visitors may stay in the patient's or the research subject's room; and
- (C) have available near each treatment room applicable emergency response equipment to respond to a sealed source that is inadvertently dislodged from the patient or inadvertently lodged within the patient following removal of the sealed source applicators.

(2) The RSO, or his or her designee, and the authorized user shall be notified if the patient or research subject has a medical emergency and, immediately, if the patient dies.

(ww) Calibration measurements of brachytherapy sealed sources.

(1) Prior to the first medical use of a brachytherapy sealed source on or after October 1, 2000, the licensee shall do the following:

- (A) determine the sealed source output or activity using a dosimetry system that meets the requirements of subsection (iii)(1) of this section;
- (B) determine sealed source positioning accuracy within applicators; and
- (C) use published protocols accepted by nationally recognized bodies to meet the requirements of subparagraphs (A) and (B) of this paragraph.

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(2) Instead of the licensee making its own measurements as required in paragraph (1) of this subsection, the licensee may use measurements provided by the source manufacturer or by a calibration laboratory accredited by the American Association of Physicists in Medicine that are made in accordance with paragraph (1) of this subsection.

(3) The licensee shall mathematically correct the outputs or activities determined in paragraph (1) of this subsection for physical decay at intervals consistent with 1.0% physical decay.

(4) The licensee shall retain a record of each calibration in accordance with subsection (www) of this section for inspection by the agency. The record shall include the following:

(A) date of the calibration;

(B) manufacturer's name and model and serial number for the sealed source and instruments used to calibrate the sealed source;

(C) sealed source output or activity;

(D) sealed source positioning accuracy within applicators; and

(E) name of the individual, the source manufacturer, or the calibration laboratory that performed the calibration.

(xx) Decay of strontium-90 sources for ophthalmic treatments.

(1) Only an authorized medical physicist shall calculate the activity of each strontium-90 source that is used to determine the treatment times for ophthalmic treatments. The decay shall be based on the activity determined in accordance with subsection (ww) of this section.

(2) A licensee shall maintain a record of the strontium-90 source in accordance with subsection (www) of this section for inspection by the agency. The record shall include the following:

(A) date and initial activity of the source as determined in subsection (ww) of this section; and

(B) for each decay calculation, the date and the source activity as determined in subsection (ww) of this section.

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(yy) Therapy-related computer systems. The licensee shall perform acceptance testing on the treatment planning system in accordance with published protocols accepted by nationally recognized bodies. At a minimum, the acceptance testing shall include, as applicable, verification of the following:

(1) the sealed source-specific input parameters required by the dose calculation algorithm;

(2) the accuracy of dose, dwell time, and treatment time calculations at representative points;

(3) the accuracy of isodose plots and graphic displays; and

(4) the accuracy of the software used to determine radioactive sealed source positions from radiographic images.

(zz) Training for use of manual brachytherapy sealed sources. Except as provided in subsection (1) of this section, the licensee shall require an authorized user of a manual brachytherapy source for the uses authorized in subsection (rr) of this section to be a physician who:

(1) is certified by a medical specialty board whose certification process has been recognized by the agency, the NRC or an agreement state and who meets the requirements of subparagraph (2)(D) of this paragraph. (The names of board certifications that have been recognized by the agency, the NRC, an agreement state, or licensing state will be posted on the agency's web page, www.dshs.state.tx.us/radiation). To have its certification recognized, a specialty board shall require all candidates for certification to:

(A) successfully complete a minimum of three years of residency training in a radiation oncology program approved by the Residency Review Committee of the Accreditation Council for Graduate Medical Education, the Royal College of Physicians and Surgeons of Canada, or the Committee on Post-Graduate Training of the American Osteopathic Association; and

(B) pass an examination, administered by diplomates of the specialty board, that assesses knowledge and competence in radiation safety, radionuclide handling, treatment planning, quality assurance, and clinical use of manual brachytherapy; or

(2) has completed a structured educational program in basic radionuclide handling techniques applicable to the use of manual brachytherapy sources including the following:

(A) 200 hours of classroom and laboratory training in the following areas:

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- (i) radiation physics and instrumentation;
- (ii) radiation protection;
- (iii) mathematics pertaining to the use and measurement of radioactivity; and
- (iv) radiation biology.

(B) 500 hours of work experience, under the supervision of an authorized user who meets the requirements of this subsection at a medical institution, involving the following:

- (i) ordering, receiving, and unpacking radioactive materials safely and performing the related radiation surveys;
 - (ii) checking survey meters for proper operation;
 - (iii) preparing, implanting, and removing brachytherapy sources;
 - (iv) maintaining running inventories of material on hand;
 - (v) using administrative controls to prevent a medical event involving the use of radioactive material; and
 - (vi) using emergency procedures to control radioactive material;
- and

(C) has completed three years of supervised clinical experience in radiation oncology, under an authorized user who meets the requirements of this subsection as part of a formal training program approved by the Residency Review Committee for Radiation Oncology of the Accreditation Council for Graduate Medical Education, the Royal College of Physicians and Surgeons of Canada, or the Committee on Postdoctoral Training of the American Osteopathic Association. This experience may be obtained concurrently with the supervised work experience required by paragraph (2)(B) of this subsection; and

(D) has obtained written attestation, signed by a preceptor authorized user who meets the requirements of this subsection that the individual has satisfactorily completed the requirements of paragraph (1)(A) or (2)(A)-(C) of this subsection and has achieved a level of competency sufficient to function independently as an authorized user of manual brachytherapy for the medical uses authorized in accordance with subsection (rr) of this section.

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(aaa) Training for ophthalmic use of strontium-90. Except as provided in subsection (l) of this section, the licensee shall require an authorized user of strontium-90 for ophthalmic radiotherapy to be a physician who:

(1) is an authorized user under subsection (zz) of this section; or

(2) has completed 24 hours of classroom and laboratory training applicable to the medical use of strontium-90 for ophthalmic radiotherapy. The training shall include the following.

(A) Classroom training shall include the following:

- (i) radiation physics and instrumentation;
- (ii) radiation protection;
- (iii) mathematics pertaining to the use and measurement of radioactivity; and
- (iv) radiation biology.

(B) Supervised clinical training in ophthalmic radiotherapy under the supervision of an authorized user at a medical institution, clinic, or private practice that includes the use of strontium-90 for the ophthalmic treatment of five individuals. This supervised clinical training shall involve:

- (i) examination of each individual to be treated;
- (ii) calculation of the dose to be administered;
- (iii) administration of the dose; and
- (iv) follow-up and review of each individual's case history; and

(C) has obtained written attestation, signed by a preceptor authorized user who meets the requirements of this subsection or subsection (zz) of this section that the individual has satisfactorily completed the requirements of paragraphs (1) and (2) of this subsection and has achieved a level of competency sufficient to function independently as an authorized user of strontium-90 for ophthalmic use.

(bbb) Use of sealed sources for diagnosis. The licensee shall use only sealed sources for diagnostic medical uses as approved in the Sealed Source and Device Registry.

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(ccc) Training for use of sealed sources for diagnosis. Except as provided in subsection (1) of this section, the licensee shall require the authorized user of a diagnostic sealed source for use in a device authorized in accordance with subsection (bbb) of this section to be a physician, dentist, or podiatrist who:

(1) is certified by a specialty board whose certification process includes the requirements of paragraphs (2) and (3) of this subsection and whose certification has been recognized by the agency, the NRC, an agreement state, or licensing state. (The names of board certifications that have been recognized by the agency, the NRC, an agreement state, or licensing state will be posted on the agency's web page, www.dshs.state.tx.us/radiation); or

(2) has completed eight hours of classroom and laboratory training in basic radioisotope handling techniques specifically applicable to the use of the device. The training shall include:

(A) radiation physics and instrumentation;

(B) radiation protection;

(C) mathematics pertaining to the use and measurement of radioactivity; and

(D) radiation biology; and

(3) has completed training in the use of the device for the uses requested.

(ddd) Use of a sealed source in a remote afterloader unit, teletherapy unit, or gamma stereotactic radiosurgery unit. The licensee shall use sealed sources in photon-emitting remote afterloader units, teletherapy units, or gamma stereotactic units for therapeutic medical uses as follows:

(1) as approved in the Sealed Source and Device Registry; or

(2) in research in accordance with an active Investigational Device Exemption (IDE) application accepted by the FDA provided the requirements of subsection (u) of this section are met.

(eee) Surveys of patients and human research subjects treated with a remote afterloader unit.

(1) Before releasing a patient or a human research subject from licensee control, the licensee shall perform a survey of the patient or the human research subject and the remote afterloader unit with a portable radiation detection survey instrument to confirm that the sealed

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source(s) has been removed from the patient or human research subject and returned to the safe shielded position.

(2) The licensee shall maintain a record of the surveys in accordance with subsection (www) of this section for inspection by the agency. The record shall include the following:

(A) date of the survey;

(B) results of the survey;

(C) manufacturer's name, model, and serial number of the survey instrument used; and

(D) name of the individual who made the survey.

(fff) Installation, maintenance, adjustment, and repair.

(1) Only a person specifically licensed by the agency, the NRC, an agreement state, or licensing state shall install, maintain, adjust, or repair a remote afterloader unit, teletherapy unit, or gamma stereotactic radiosurgery unit that involves work on the sealed source(s) shielding, the sealed source(s) driving unit, or other electronic or mechanical component that could expose the sealed source(s), reduce the shielding around the sealed source(s), or compromise the radiation safety of the unit or the sealed source(s).

(2) Except for low dose-rate remote afterloader units, only a person specifically licensed by the agency, the NRC, an agreement state, or licensing state shall install, replace, relocate, or remove a sealed source or sealed source contained in other remote afterloader units, teletherapy units, or gamma stereotactic units.

(3) For a low dose-rate remote afterloader unit, only a person specifically licensed by the agency, the NRC, an agreement state, a licensing state, or an authorized medical physicist shall install, replace, relocate, or remove a sealed source(s) contained in the unit.

(4) The licensee shall maintain a record of the installation, maintenance, adjustment and repair done on remote afterloader units, teletherapy units, and gamma stereotactic radiosurgery units in accordance with subsection (www) of this section for inspection by the agency. For each installation, maintenance, adjustment and repair, the record shall include the date, description of the service, and name(s) of the individual(s) who performed the work.

(ggg) Safety procedures and instructions for remote afterloader units, teletherapy units, and gamma stereotactic radiosurgery units. A licensee shall do the following:

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(1) secure the unit, the console, the console keys, and the treatment room when not in use or unattended;

(2) permit only individuals approved by the authorized user, RSO, or authorized medical physicist to be present in the treatment room during treatment with the sealed source(s);

(3) prevent dual operation of more than one radiation producing device in a treatment room if applicable;

(4) develop, implement, and maintain written procedures for responding to an abnormal situation when the operator is unable to place the sealed source(s) in the shielded position, or remove the patient or human research subject from the radiation field with controls from outside the treatment room. The procedures shall include the following and shall be physically located at the unit console:

(A) instructions for responding to equipment failures and the names of the individuals responsible for implementing corrective actions;

(B) the process for restricting access to and posting of the treatment area to minimize the risk of inadvertent exposure; and

(C) the names and telephone numbers of the authorized users, the authorized medical physicist, and the RSO to be contacted if the unit or console operates abnormally;

(5) post instructions at the unit console to inform the operator of the following:

(A) the location of the procedures required by paragraph (4) of this subsection; and

(B) the names and telephone numbers of the authorized users, the authorized medical physicist, and the RSO to be contacted if the unit or console operates abnormally;

(6) provide instruction initially and at least annually, to all individuals who operate the unit, as appropriate to the individual's assigned duties, to include:

(A) procedures identified in paragraph (4) of this subsection; and

(B) operating procedures for the unit;

(7) ensure that operators, authorized medical physicists, and authorized users participate in drills of the emergency procedures, initially and at least annually; and

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(8) maintain records of individuals receiving instruction and participating in drills required by paragraphs (6) and (7) of this subsection in accordance with subsection (www) of this section for inspection by the agency. The record shall include the following:

- (A) a list of the topics covered;
- (B) date of the instruction or drill;
- (C) name(s) of the attendee(s); and
- (D) name(s) of the individual(s) who provided the instruction.

(hhh) Safety precautions for remote afterloader units, teletherapy units, and gamma stereotactic radiosurgery units. The licensee shall do the following:

- (1) control access to the treatment room by a door at each entrance;
- (2) equip each entrance to the treatment room with an electrical interlock system that will do the following:
 - (A) prevent the operator from initiating the treatment cycle unless each treatment room entrance door is closed;
 - (B) cause the sealed source(s) to be shielded promptly when an entrance door is opened; and
 - (C) prevent the sealed source(s) from being exposed following an interlock interruption until all treatment room entrance doors are closed and the sealed source(s) “on-off” control is reset at the console;
- (3) require any individual entering the treatment room to assure, through the use of appropriate radiation monitors, that radiation levels have returned to ambient levels;
- (4) except for low-dose remote afterloader units, construct or equip each treatment room with viewing and intercom systems to permit continuous observation of the patient or the human research subject from the treatment console during irradiation;
- (5) for licensed activities where sealed sources are placed within the patient’s or human research subject’s body, only conduct treatments that allow for expeditious removal of a decoupled or jammed sealed source;
- (6) in addition to the requirements specified in paragraphs (1)-(5) of this subsection, require the following:

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(A) for low dose-rate, medium dose-rate, and pulsed dose-rate remote afterloader units:

(i) an authorized medical physicist, and either an authorized user or a physician, under the supervision of an authorized user, who has been trained in the operation and emergency response for the unit, be physically present during the initiation of all patient treatments involving the unit; and

(ii) an authorized medical physicist, and either an authorized user or an individual, under the supervision of an authorized user, who has been trained to remove the sealed source applicator(s) in the event of an emergency involving the unit, be immediately available during continuation of all patient treatments involving the unit;

(B) for high dose-rate remote afterloader units:

(i) an authorized user and an authorized medical physicist be physically present during the initiation of all patient treatments involving the unit; and

(ii) an authorized medical physicist, and either an authorized user or a physician, under the supervision of an authorized user, who has been trained in the operation and emergency response for the unit, be physically present during continuation of all patient treatments involving the unit;

(C) for gamma stereotactic radiosurgery units, require that an authorized user and an authorized medical physicist be physically present throughout all patient treatments involving gamma stereotactic radiosurgery units; and

(D) notify the RSO, or his or her designee, and an authorized user as soon as possible, if the patient or human research subject has a medical emergency or dies; and

(7) have applicable emergency response equipment available near each treatment room to respond to a sealed source that remains in the unshielded position or lodges within the patient following completion of the treatment.

(iii) Dosimetry equipment.

(1) Except for low dose-rate remote afterloader sealed sources where the sealed source output or activity is determined by the manufacturer, the licensee shall have a calibrated dosimetry system available for use. To satisfy this requirement, one of the following two conditions shall be met.

(A) The system shall have been calibrated using a system or sealed source traceable to the National Institute of Standards and Technology (NIST) and published protocols

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accepted by nationally recognized bodies; or by a calibration laboratory accredited by the American Association of Physicists in Medicine (AAPM). The calibration shall have been performed within the previous two years and after any servicing that may have affected system calibration.

(B) The system shall have been calibrated within the previous four years. Eighteen to 30 months after that calibration, the system shall have been intercompared with another dosimetry system that was calibrated within the past 24 months by NIST or by a calibration laboratory accredited by the AAPM. The results of the intercomparison shall have indicated that the calibration factor of the licensee's system had not changed by more than 2.0%. The licensee may not use the intercomparison result to change the calibration factor. When intercomparing dosimetry systems to be used for calibrating sealed sources for therapeutic unit, the licensee shall use a comparable unit with beam attenuators or collimators, as applicable, and sealed sources of the same radionuclide as the sealed source used at the licensee's facility.

(2) The licensee shall have available for use a dosimetry system for spot check output measurements, if such measurements are required by this section. To satisfy this requirement, the system may be compared with a system that has been calibrated in accordance with paragraph (1) of this subsection. This comparison shall have been performed within the previous year and after each servicing that may have affected system calibration. The spot check system may be the same system used to meet the requirements of paragraph (1) of this subsection.

(3) The licensee shall retain a record of each calibration, intercomparison, and comparison of dosimetry equipment in accordance with subsection (www) of this section for inspection by the agency. The record shall include the following:

(A) date of the calibration;

(B) manufacturer's model and serial numbers of the instruments that were calibrated, intercompared, or compared;

(C) the correction factor that was determined from the calibration or comparison or the apparent correction factor that was determined from an intercomparison; and

(D) the names of the individuals who performed the calibration, intercomparison, or comparison.

(jjj) Full calibration measurements on teletherapy units.

(1) A licensee authorized to use a teletherapy unit for medical use shall perform full calibration measurements on each teletherapy unit as follows:

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(A) before the first medical use of the unit;

(B) before medical use under any of the following conditions:

(i) whenever spot check measurements indicate that the output differs by more than 5.0% from the output obtained at the last full calibration corrected mathematically for radioactive decay;

(ii) following replacement of the sealed source or following reinstallation of the teletherapy unit in a new location;

(iii) following any repair of the teletherapy unit that includes removal of the sealed source or major repair of the components associated with the sealed source exposure assembly; and

(C) at intervals not to exceed one year.

(2) Full calibration measurements shall include determination of the following:

(A) the output within plus or minus 3.0% for the range of field sizes and for the distance or range of distances used for medical use;

(B) the coincidence of the radiation field and the field indicated by the light beam localizing device;

(C) uniformity of the radiation field and its dependence on the orientation of the useful beam;

(D) timer accuracy and linearity over the range of use;

(E) “on-off” error; and

(F) the accuracy of all distance measuring and localization devices in medical use.

(3) The licensee shall use the dosimetry system described in subsection (iii)(1) of this section to measure the output for one set of exposure conditions. The remaining radiation measurements required in paragraph (2)(A) of this subsection may be made using a dosimetry system that indicates relative dose rates.

(4) The licensee shall make full calibration measurements required by paragraph (1) of this subsection in accordance with published protocols accepted by nationally recognized bodies.

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(5) The licensee shall mathematically correct the outputs determined in paragraph (2)(A) of this subsection for physical decay at intervals not to exceed one month for cobalt-60, six months for cesium-137, or at intervals consistent with 1.0% decay for all other nuclides.

(6) Full calibration measurements required by paragraph (1) of this subsection and physical decay corrections required by paragraph (5) of this subsection shall be performed by an authorized medical physicist.

(7) The licensee shall retain a record of each calibration in accordance with subsection (www) of this section for inspection by the agency. The record shall include the following:

(A) date of the calibration;

(B) manufacturer's name, model number and serial number of the teletherapy unit's sealed source and the instruments used to calibrate the unit;

(C) results and an assessment of the full calibrations; and

(D) signature of the authorized medical physicist who performed the full calibration.

(kkk) Full calibration measurements on remote afterloader units.

(1) A licensee authorized to use a remote afterloader for medical use shall perform full calibration measurements on each unit as follows:

(A) before the first medical use of the unit;

(B) before medical use under any of the following conditions:

(i) following replacement of the sealed source;

(ii) following reinstallation of the unit in a new location outside the facility;

(iii) following any repair of the unit that includes removal of the sealed source or major repair of the components associated with the sealed source exposure assembly;

(C) at intervals not to exceed three months for high dose-rate, medium dose-rate, and pulsed dose-rate remote afterloader units with sealed sources whose half-life exceeds 75 days; and

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(D) at intervals not to exceed one year for low dose-rate afterloader units.

(2) Full calibration measurements shall include, as applicable, determination of the following:

(A) the output within plus or minus 5.0%;

(B) sealed source positioning accuracy to within plus or minus 1 millimeter (mm);

(C) sealed source retraction with backup battery upon power failure;

(D) length of the sealed source transfer tubes;

(E) timer accuracy and linearity over the typical range of use;

(F) length of the applicators; and

(G) function of the sealed source transfer tubes, applicators, and transfer tube-applicator interfaces.

(3) A licensee shall use the dosimetry system described in subsection (iii)(1) of this section to measure the output.

(4) A licensee shall make full calibration measurements required by paragraph (1) of this subsection in accordance with published protocols accepted by nationally recognized bodies.

(5) In addition to the requirements for full calibrations for low dose-rate remote afterloader units in paragraph (2) of this subsection, a licensee shall perform an autoradiograph of the sealed source(s) to verify inventory and sealed source(s) arrangement at intervals not to exceed three months.

(6) For low dose-rate remote afterloader units, a licensee may use measurements provided by the sealed source manufacturer that are made in accordance with paragraphs (1)-(5) of this subsection.

(7) The licensee shall mathematically correct the outputs determined in paragraph (2)(A) of this subsection for physical decay at intervals consistent with 1.0% physical decay.

(8) Full calibration measurements required by paragraph (1) of this subsection and physical decay corrections required by paragraph (7) of this subsection shall be performed by an authorized medical physicist.

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(9) The licensee shall retain a record of each calibration in accordance with subsection (www) of this section for inspection by the agency. The record shall include the following:

(A) date of the calibration;

(B) manufacturer's name, model number and serial number of the remote afterloader unit's sealed source, and the instruments used to calibrate the unit;

(C) results and an assessment of the full calibrations;

(D) signature of the authorized medical physicist of this section; and

(E) results of the autoradiograph required for low dose-rate remote afterloader unit.

(III) Full calibration measurements on gamma stereotactic radiosurgery units.

(1) A licensee authorized to use a gamma stereotactic radiosurgery unit for medical use shall perform full calibration measurements on each gamma stereotactic radiosurgery unit as follows:

(A) before the first medical use of the unit;

(B) before medical use under the following conditions:

(i) whenever spot check measurements indicate that the output differs by more than 5.0% from the output obtained at the last full calibration corrected mathematically for radioactive decay;

(ii) following replacement of the sealed sources or following reinstallation of the gamma stereotactic radiosurgery unit in a new location; and

(iii) following any repair of the gamma stereotactic radiosurgery unit that includes removal of the sealed sources or major repair of the components associated with the sealed source exposure assembly; and

(C) at intervals not to exceed one year, with the exception that relative helmet factors need only be determined before the first medical use of a helmet and following any damage to a helmet.

(2) Full calibration measurements shall include determination of the following:

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- (A) the output within plus or minus 3.0%;
- (B) relative helmet factors;
- (C) isocenter coincidence;
- (D) timer accuracy and linearity over the range of use;
- (E) “on-off” error;
- (F) trunnion centricity;
- (G) treatment table retraction mechanism, using backup battery power or hydraulic backups with the unit “off”;
- (H) helmet microswitches;
- (I) emergency timing circuits; and
- (J) stereotactic frames and localizing devices (trunnions).

(3) The licensee shall use the dosimetry system described in subsection (iii)(1) of this section to measure the output for one set of exposure conditions. The remaining radiation measurements required in paragraph (2)(A) of this subsection may be made using a dosimetry system that indicates relative dose rates.

(4) The licensee shall make full calibration measurements required by paragraph (1) of this subsection in accordance with published protocols accepted by nationally recognized bodies.

(5) The licensee shall mathematically correct the outputs determined in paragraph (2)(A) of this subsection at intervals not to exceed one month for cobalt-60 and at intervals consistent with 1.0% physical decay for all other radionuclides.

(6) Full calibration measurements required by paragraph (1) of this subsection and physical decay corrections required by paragraph (5) of this subsection shall be performed by an authorized medical physicist.

(7) The licensee shall retain a record of each calibration in accordance with subsection (www) of this section for inspection by the agency. The record shall include the following:

- (A) date of the calibration;

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(B) manufacturer's name, model number, and serial number for the unit and the unit's sealed source and the instruments used to calibrate the unit;

(C) results and an assessment of the full calibration; and

(D) signature of the authorized medical physicist who performed the full calibration.

(mmm) Periodic spot checks for teletherapy units.

(1) A licensee authorized to use teletherapy units for medical use shall perform output spot checks on each teletherapy unit once in each calendar month that include determination of the following:

(A) timer constancy and linearity over the range of use;

(B) "on-off" error;

(C) the coincidence of the radiation field and the field indicated by the light beam localizing device;

(D) the accuracy of all distance measuring and localization devices used for medical use;

(E) the output for one typical set of operating conditions measured with the dosimetry system described in subsection (iii)(2) of this section; and

(F) the difference between the measurement made in paragraph (1)(E) of this subsection and the anticipated output, expressed as a percentage of the anticipated output, the value obtained at last full calibration corrected mathematically for physical decay.

(2) The licensee shall perform measurements required by paragraph (1) of this subsection in accordance with written procedures established by an authorized medical physicist. That authorized medical physicist need not actually perform the spot check measurements. The licensee shall maintain a copy of the written procedures in accordance with subsection (www) of this section for inspection by the agency.

(3) The licensee authorized to use a teletherapy unit for medical use shall perform safety spot checks of each teletherapy facility once in each calendar month and after each sealed source installation to assure proper operation of the following:

(A) electrical interlocks at each teletherapy room entrance;

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(B) electrical or mechanical stops installed for the purpose of limiting use of the primary beam of radiation (restriction of sealed source housing angulation or elevation, carriage or stand travel and operation of the beam “on-off” mechanism);

(C) sealed source exposure indicator lights on the teletherapy unit, on the control console, and in the facility;

(D) viewing and intercom systems;

(E) treatment room doors from inside and outside the treatment room; and

(F) electrically assisted treatment room doors with the teletherapy unit electrical power turned “off”.

(4) The licensee shall have an authorized medical physicist review the results of each spot check and submit a written report to the licensee within 15 days of the spot check.

(5) If the results of the checks required in paragraph (3) of this subsection indicate the malfunction of any system, the licensee shall lock the control console in the “off” position and not use the unit except as may be necessary to repair, replace, or check the malfunctioning system.

(6) The licensee shall retain a record of each spot check required by paragraphs (1) and (3) of this subsection, in accordance with subsection (www) of this section for inspection by the agency. The record shall include the following:

(A) date of the spot-check;

(B) manufacturer’s name and model and serial number for the teletherapy unit, and sealed source and instrument used to measure the output of the teletherapy unit;

(C) assessment of timer linearity and constancy;

(D) calculated “on-off” error;

(E) determination of the coincidence of the radiation field and the field indicated by the light beam localizing device;

(F) the determined accuracy of each distance measuring and localization device;

(G) the difference between the anticipated output and the measured output;

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(H) notations indicating the operability of each entrance door electrical interlock, each electrical or mechanical stop, each sealed source exposure indicator light, and the viewing and intercom system and doors;

(I) name of the individual who performed the periodic spot-check; and

(J) the signature of the authorized medical physicist who reviewed the record of the spot check.

(nnn) Periodic spot checks for remote afterloader units.

(1) A licensee authorized to use a remote afterloader unit for medical use shall perform spot checks of each remote afterloader facility and on each unit as follows:

(A) before the first use each day of use of a high dose-rate, medium dose-rate, or pulsed dose-rate remote afterloader unit;

(B) before each patient treatment with a low dose-rate remote afterloader unit; and

(C) after each sealed source installation.

(2) The licensee shall perform the measurements required by paragraph (1) of this subsection in accordance with written procedures established by an authorized medical physicist. That individual need not actually perform the spot check measurements. The licensee shall maintain a copy of the written procedures in accordance with subsection (www) of this section for inspection by the agency.

(3) The licensee shall have an authorized medical physicist review the results of each spot check and submit a written report to the licensee within 15 days of the spot check.

(4) To satisfy the requirements of paragraph (1) of this subsection, spot checks shall, at a minimum, assure proper operation of the following:

(A) electrical interlocks at each remote afterloader unit room entrance;

(B) sealed source exposure indicator lights on the remote afterloader unit, on the control console, and in the facility;

(C) viewing and intercom systems in each high dose-rate, medium dose-rate, and pulsed dose-rate remote afterloader facility;

(D) emergency response equipment;

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(E) radiation monitors used to indicate the sealed source position;

(F) timer accuracy;

(G) clock (date and time) in the unit's computer; and

(H) decayed sealed source(s) activity in the unit's computer.

(5) If the results of the checks required in paragraph (4) of this subsection indicate the malfunction of any system, the licensee shall lock the control console in the "off" position and not use the unit except as may be necessary to repair, replace, or check the malfunctioning system.

(6) The licensee shall maintain a record, in accordance with subsection (www) of this section for inspection by the agency, of each check required by paragraph (4) of this subsection. The record shall include the following, as applicable:

(A) date of the spot-check;

(B) manufacturer's name and model and serial number for the remote afterloader unit and sealed source;

(C) an assessment of timer accuracy;

(D) notations indicating the operability of each entrance door electrical interlock, radiation monitors, sealed source exposure indicator lights, viewing and intercom systems, clock, and decayed sealed source activity in the unit's computer;

(E) name of the individual who performed the periodic spot-check; and

(F) the signature of an authorized medical physicist who reviewed the record of the spot-check.

(ooo) Periodic spot checks for gamma stereotactic radiosurgery units.

(1) A licensee authorized to use a gamma stereotactic radiosurgery unit for medical use shall perform spot checks of each gamma stereotactic radiosurgery facility and on each unit as follows:

(A) monthly;

(B) before the first use of the unit on each day of use; and

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(C) after each source installation.

(2) The licensee shall perform the measurements required by paragraph (1) of this subsection in accordance with written procedures established by an authorized medical physicist with a specialty in therapeutic radiological physics. That individual need not actually perform the spot check measurements. The licensee shall maintain a copy of the written procedures in accordance with subsection (www) of this section for inspection by the agency.

(3) The licensee shall have an authorized medical physicist review the results of each spot check and submit a written report to the licensee within 15 days of the spot check.

(4) To satisfy the requirements of paragraph (1)(A) of this subsection, spot checks shall, at a minimum, achieve the following by:

(A) assurance of proper operation of these items:

(i) treatment table retraction mechanism, using backup battery power or hydraulic backups with the unit “off;”

(ii) helmet microswitches;

(iii) emergency timing circuits; and

(iv) stereotactic frames and localizing devices (trunnions); and

(B) determination of the following:

(i) the output for one typical set of operating conditions measured with the dosimetry system described in subsection (iii)(2) of this section;

(ii) the difference between the measurement made in clause (i) of this subparagraph and the anticipated output, expressed as a percentage of the anticipated output, (i.e., the value obtained at last full calibration corrected mathematically for physical decay);

(iii) sealed source output against computer calculation;

(iv) timer accuracy and linearity over the range of use;

(v) “on-off” error; and

(vi) trunnion centricity.

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(5) To satisfy the requirements of paragraphs (1)(B) and (C) of this subsection, spot checks shall assure proper operation of the following:

(A) electrical interlocks at each gamma stereotactic radiosurgery room entrance;

(B) sealed source exposure indicator lights on the gamma stereotactic radiosurgery unit, on the control console, and in the facility;

(C) viewing and intercom systems;

(D) timer termination;

(E) radiation monitors used to indicate room exposures; and

(F) emergency “off” buttons.

(6) The licensee shall arrange for prompt repair of any system identified in paragraph (4) of this subsection that is not operating properly.

(7) If the results of the checks required in paragraph (5) of this subsection indicate the malfunction of any system, the licensee shall lock the control console in the “off” position and not use the unit except as may be necessary to repair, replace, or check the malfunctioning system.

(8) The licensee shall retain a record of each check required by paragraphs (4) and (5) of this subsection in accordance with subsection (www) of this section for inspection by the agency. The record shall include the following:

(A) date of the spot check;

(B) manufacturer’s name, and model and serial number for the gamma stereotactic radiosurgery unit and the instrument used to measure the output of the unit;

(C) an assessment of timer linearity and accuracy;

(D) the calculated “on-off” error;

(E) a determination of trunnion centricity;

(F) the difference between the anticipated output and the measured output;

(G) an assessment of sealed source output against computer calculations;

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(H) notations indicating the operability of radiation monitors, helmet microswitches, emergency timing circuits, emergency “off” buttons, electrical interlocks, sealed source exposure indicator lights, viewing and intercom systems, timer termination, treatment table retraction mechanism, and stereotactic frames and localizing devices (trunnions);

(I) the name of the individual who performed the periodic spot check; and

(J) the signature of an authorized medical physicist who reviewed the record of the spot check.

(ppp) Additional technical requirements for mobile remote afterloader units.

(1) A licensee providing mobile remote afterloader service shall do the following:

(A) check survey instruments before medical use at each address of use or on each day of use, whichever is more frequent; and

(B) account for all sealed sources before departure from a client’s address of use.

(2) In addition to the periodic spot checks required by subsection (nnn) of this section, a licensee authorized to use remote afterloaders for medical use shall perform checks on each remote afterloader unit before use at each address of use. At a minimum, checks shall be made to verify the operation of the following:

(A) electrical interlocks on treatment area access points;

(B) sealed source exposure indicator lights on the remote afterloader unit, on the control console, and in the facility;

(C) viewing and intercom systems;

(D) applicators, sealed source transfer tubes, and transfer tube-applicator interfaces;

(E) radiation monitors used to indicate room exposures;

(F) sealed source positioning (accuracy); and

(G) radiation monitors used to indicate whether the sealed source has returned to a safe shielded position.

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(3) In addition to the requirements for checks in paragraph (2) of this subsection, the licensee shall ensure overall proper operation of the remote afterloader unit by conducting a simulated cycle of treatment before use at each address of use.

(4) If the results of the checks required in paragraph (2) of this subsection indicate the malfunction of any system, the licensee shall lock the control console in the “off” position and not use the unit except as may be necessary to repair, replace, or check the malfunctioning system.

(5) The licensee shall maintain a record for inspection by the agency, in accordance with subsection (www) of this section, of each check required by subparagraph (B) of this paragraph. The record shall include the following:

(A) date of the check;

(B) manufacturer’s name, model number and serial number of the remote afterloader unit;

(C) notations accounting for all sealed sources before the licensee departs from a facility;

(D) notations indicating the operability of each entrance door electrical interlock, radiation monitors, sealed source exposure indicator lights, viewing and intercom system, applicators and sealed source transfer tubes, and sealed source positioning accuracy; and

(E) the signature of the individual who performed the check.

(qqq) Radiation surveys.

(1) In addition to the survey requirements of §289.202(p) of this title, a person licensed to use sealed sources in this section shall make surveys to ensure that the maximum radiation levels and average radiation levels, from the surface of the main sealed source safe with the sealed source(s) in the shielded position, do not exceed the levels stated in the Sealed Source and Device Registry.

(2) The licensee shall make the survey required by paragraph (1) of this subsection at installation of a new sealed source and following repairs to the sealed source(s) shielding, the sealed source(s) driving unit, or other electronic or mechanical component that could expose the sealed source, reduce the shielding around the sealed source(s), or compromise the radiation safety of the unit or the sealed source(s).

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(3) The licensee shall maintain a record for inspection by the agency, in accordance with subsection (www) of this section, of the radiation surveys required by paragraph (1) of this subsection. The record shall include:

(A) date of the measurements;

(B) manufacturer's name, model number and serial number of the treatment unit, sealed source, and instrument used to measure radiation levels;

(C) each dose rate measured around the sealed source while the unit is in the "off" position and the average of all measurements; and

(D) the signature of the individual who performed the test.

(rrr) Five-year inspection for teletherapy and gamma stereotactic radiosurgery units.

(1) The licensee shall have each teletherapy unit and gamma stereotactic radiosurgery unit fully inspected and serviced during sealed source replacement or at intervals not to exceed five years, whichever comes first, to assure proper functioning of the sealed source exposure mechanism.

(2) This inspection and servicing may only be performed by persons specifically licensed to do so by the agency, the NRC, an agreement state, or licensing state.

(3) The licensee shall maintain a record of the inspection and servicing in accordance with subsection (www) of this section for inspection by the agency. The record shall include the following:

(A) date of inspection;

(B) manufacturer's name and model and serial number of both the treatment unit and the sealed source;

(C) a list of components inspected and serviced, and the type of service; and

(D) the radioactive material license number and the signature of the individual performing the inspection.

(sss) Therapy-related computer systems. The licensee shall perform acceptance testing on the treatment planning system of therapy-related computer systems in accordance with published protocols accepted by nationally recognized bodies. At a minimum, the acceptance testing shall include, as applicable, verification of the following:

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(1) the sealed source-specific input parameters required by the dose calculation algorithm;

(2) the accuracy of dose, dwell time, and treatment time calculations at representative points;

(3) the accuracy of isodose plots and graphic displays;

(4) the accuracy of the software used to determine sealed source positions from radiographic images; and

(5) the accuracy of electronic transfer of the treatment delivery parameters to the treatment delivery unit from the treatment planning system.

(ttt) Training for use of remote afterloader units, teletherapy units, and gamma stereotactic radiosurgery units. Except as provided in subsection (l) of this section, the licensee shall require an authorized user of a sealed source for a use authorized in subsection (ddd) of this section to be a physician who:

(1) is certified by a medical specialty board whose certification process has been recognized by the agency, the NRC, an agreement state, or licensing state and who meets the requirements of paragraphs (2)(D) and (3) of this subsection. (The names of board certifications that have been recognized by the agency, the NRC, an agreement state, or licensing state will be posted on the agency's web page, www.dshs.state.tx.us/radiation). To have its certification recognized, a specialty board shall require all candidates for certification to:

(A) successfully complete a minimum of three years of residency training in a radiation therapy program approved by the Residency Review Committee of the Accreditation Council for Graduate Medical Education, the Royal College of Physicians and Surgeons of Canada, or the Committee on Post-Graduate Training of the American Osteopathic Association; and

(B) pass an examination, administered by diplomates of the specialty board, that assesses knowledge and competence in radiation safety, radionuclide handling, treatment planning, quality assurance, and clinical use of stereotactic radiosurgery, remote afterloaders and external beam therapy; or

(2) has completed a structured educational program in basic radionuclide handling techniques applicable to the use of a sealed source in a therapeutic medical unit including:

(A) 200 hours of classroom and laboratory training in the following areas:

(i) radiation physics and instrumentation;

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(ii) radiation protection;

(iii) mathematics pertaining to the use and measurement of radioactivity; and

(iv) radiation biology; and

(B) 500 hours of work experience, under the supervision of an authorized user who meets the requirements of this subsection at a medical institution involving the following:

(i) reviewing full calibration measurements and periodic spot checks;

(ii) preparing treatment plans and calculating treatment times;

(iii) using administrative controls to prevent a medical event involving the use of radioactive material;

(iv) implementing emergency procedures to be followed in the event of the abnormal operation of a medical unit or console;

(v) checking and using survey meters; and

(vi) selecting the proper dose and how it is to be administered; and

(C) has completed three years of supervised clinical experience in radiation therapy, under an authorized user who meets the requirements of this subsection as part of a formal training program approved by the Residency Review Committee for Radiation Oncology of the Accreditation Council for Graduate Medical Education, the Royal College of Physicians and Surgeons of Canada, or the Committee on Postdoctoral Training of the American Osteopathic Association. This experience may be obtained concurrently with the supervised work experience required by paragraph (2)(B) of this subsection: and

(D) has obtained written attestation that the individual has satisfactorily completed the requirements of paragraphs (1)(A) or (2), and (3) of this subsection, and has achieved a level of competency sufficient to function independently as an authorized user of each type of therapeutic medical unit for which the individual is requesting authorized user status. The written attestation shall be signed by a preceptor authorized user who meets the requirements in this subsection; and

(3) has received training in device operation, safety procedures, and clinical use for the type(s) of use for which authorization is sought. This training requirement may be

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satisfied by satisfactory completion of a training program provided by the vendor for new users or by receiving training supervised by an authorized user or authorized medical physicist, as appropriate, who is authorized for the type(s) of use for which the individual is seeking authorization.

(uuu) Report and notification of a medical event.

(1) The licensee shall report any event, except for events that result from intervention by a patient or human research subject, in which the administration of radioactive material, or radiation from radioactive material, results in the following:

(A) a dose that differs from the prescribed dose or dose that would have resulted from the prescribed dosage by more than 5 rem (0.05 Sievert (Sv)) effective dose equivalent, 50 rem (0.5 Sv) to an organ or tissue, or 50 rem (0.5 Sv) shallow dose equivalent to the skin and either:

(i) the total dose delivered differs from the prescribed dose by 20% or more;

(ii) the total dosage delivered differs from the prescribed dosage by 20% or more or falls outside the prescribed dosage range; or

(iii) the fractionated dose delivered differs from the prescribed dose, for a single fraction, by 50% or more;

(B) a dose that exceeds 5 rem (0.05 Sv) effective dose equivalent, 50 rem (0.5 Sv) to an organ or tissue, or 50 rem (0.5 Sv) shallow dose equivalent to the skin from any of the following:

(i) an administration of a wrong radioactive drug containing radioactive material;

(ii) an administration of a radioactive drug containing radioactive material by the wrong route of administration;

(iii) an administration of a dose or dosage to the wrong individual or human research subject;

(iv) an administration of a dose or dosage delivered by the wrong mode of treatment; or

(v) a leaking sealed source; or

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(C) a dose to the skin or an organ or tissue other than the treatment site that exceeds by 50 rem (0.5 Sv) to an organ or tissue and 50% or more of the dose expected from the administration defined in the written directive (excluding, for permanent implants, seeds that were implanted in the correct site but migrated outside the treatment site).

(2) The licensee shall report any event resulting from intervention of a patient or human research subject in which the administration of radioactive material, or radiation from radioactive material, results or will result in an unintended permanent functional damage to an organ or a physiological system, as determined by a physician.

(3) The licensee shall notify the agency by telephone no later than the next calendar day after discovery of the medical event.

(4) The licensee shall submit a written report to the agency within 15 calendar days after discovery of the medical event. The written report shall include the following, excluding the individual's name or any other information that could lead to identification of the individual:

(A) the licensee's name and radioactive material license number;

(B) the name of the prescribing physician;

(C) a brief description of the medical event;

(D) why the event occurred;

(E) the effect, if any, on the individual(s) who received the administration;

(F) actions, if any, that have been taken, or are planned, to prevent recurrence; and

(G) certification that the licensee notified the individual (or the individual's responsible relative or guardian), and if not, why not.

(5) The licensee shall notify the referring physician and also notify the individual who is the subject of the medical event no later than 24 hours after its discovery, unless the referring physician personally informs the licensee either that he or she will inform the individual or that, based on medical judgment, telling the individual would be harmful. The licensee is not required to notify the individual without first consulting the referring physician. If the referring physician or the affected individual cannot be reached within 24 hours, the licensee shall notify the individual as soon as possible thereafter. The licensee shall not delay any appropriate medical care for the individual, including any necessary remedial care as a result of the medical event, because of any delay in notification. To meet the requirements of this subsection, the

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notification of the individual who is the subject of the medical event may be made instead to that individual's responsible relative or guardian. If a verbal notification is made, the licensee shall inform the individual or appropriate responsible relative or guardian, that a written description of the event can be obtained from the licensee upon request. The licensee shall provide the written description if requested.

(6) Aside from the notification requirement, nothing in this section affects any rights or duties of licensees and physicians in relation to each other, to individuals affected by the medical event, or to that individual's responsible relatives or guardians.

(7) The licensee shall annotate a copy of the report provided to the agency with the following information:

(A) name of the individual who is the subject of the event; and

(B) social security number or other identification number, if one has been assigned, of the individual who is the subject of the event.

(8) The licensee shall provide a copy of the annotated report to the referring physician, if other than the licensee, no later than 15 calendar days after the discovery of the event.

(9) The licensee shall retain a copy of the annotated report of the medical event in accordance with subsection (www) of this section for inspection by the agency.

(vvv) Report and notification of a dose to an embryo/fetus or nursing child.

(1) The licensee shall report any dose to an embryo/fetus that is greater than 5 rem (50 mSv) dose equivalent that is a result of an administration of radioactive material or radiation from radioactive material to a pregnant individual, unless the dose to the embryo/fetus was specifically approved, in advance, by the authorized user.

(2) The licensee shall report any dose to a nursing child that is a result of an administration of radioactive material to a breast feeding individual that:

(A) is greater than 5 rem (50 mSv) TEDE; or

(B) has resulted in unintended permanent functional damage to an organ or a physiological system, as determined by a physician.

(3) The licensee shall notify the agency by telephone no later than the next calendar day after discovery of a dose to the embryo/fetus or nursing child that requires a report in accordance with paragraphs (1) or (2) of this subsection.

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(4) The licensee shall submit a written report to the agency no later than 15 calendar days after discovery of a dose to the embryo/fetus or nursing child that requires a report in accordance with paragraphs (1) or (2) of this subsection. The written report shall include the following, excluding the individual's or child's name or any other information that could lead to identification of the individual or child:

(A) the licensee's name and radioactive material license number;

(B) the name of the prescribing physician;

(C) a brief description of the event;

(D) why the event occurred;

(E) the effect, if any, on the embryo/fetus or the nursing child;

(F) actions, if any, that have been taken, or are planned, to prevent recurrence; and

(G) certification that the licensee notified the pregnant individual or mother (or the mother's or child's responsible relative or guardian), and if not, why not.

(5) The licensee shall notify the referring physician and also notify the pregnant individual or mother, both hereafter referred to as the mother, no later than 24 hours after discovery of an event that would require reporting in accordance with paragraphs (1) or (2) of this subsection, unless the referring physician personally informs the licensee either that he or she will inform the mother or that, based on medical judgment, telling the mother would be harmful. The licensee is not required to notify the mother without first consulting with the referring physician. If the referring physician or mother cannot be reached within 24 hours, the licensee shall make the appropriate notifications as soon as possible thereafter. The licensee may not delay any appropriate medical care for the embryo/fetus or for the nursing child, including any necessary remedial care as a result of the event, because of any delay in notification. To meet the requirements of this subsection, the notification may be made to the mother's or child's responsible relative or guardian instead of the mother, when appropriate. If a verbal notification is made, the licensee shall inform the mother, or the mother's or child's responsible relative or guardian, that a written description of the event can be obtained from the licensee upon request. The licensee shall provide such a written description if requested.

(6) The licensee shall annotate a copy of the report provided to the agency with the following information:

(A) name of the individual or the nursing child who is the subject of the event; and

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(B) social security number or other identification number, if one has been assigned, of the pregnant individual or the nursing child who is the subject of the event.

(7) The licensee shall provide a copy of the annotated report as described in paragraph (6) of this subsection to the referring physician, if other than the licensee, no later than 15 days after the discovery of the event.

(8) The licensee shall retain a copy of the annotated report as described in paragraph (6) of this subsection of a dose to an embryo/fetus or a nursing child in accordance with subsection (www) of this section for inspection by the agency.

(www) Records/documents for agency inspection. Each licensee shall maintain copies of the following records/documents at each authorized use site and make them available to the agency for inspection, upon reasonable notice.

Figure: 25 TAC §289.256(www)

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Rule Cross Reference	Name of Records/Documents	Time Interval for Keeping Records/Documents
§289.201(d)(1)	Records of receipt, transfer, and disposal of radioactive material	Until disposal is authorized by the agency
§289.201(g)(7), §289.202(bbb)	Records of leak tests for specific devices and sealed sources	3 years
§289.203(b)(1)(B)	Current applicable sections of this chapter as listed in the radioactive material license	Until termination of the radioactive material license
§289.203(b)(1)(B)	Copy of the current radioactive material license	Until termination of the radioactive material license
§289.203(b)(1)(C), §289.256(f)(3)(A)	Current operating, safety, and emergency procedures	Until termination of the radioactive material license
§289.256 (f)(3)(C)(i)	Qualifications of RSO	Duration of employment
§289.256(f)(3)(C)(ii)	Qualifications of authorized users	Duration of employment
§289.256(f)(3)(C)(iii)	Qualifications of authorized medical physicist	Duration of employment
§289.256(f)(3)(C)(iv)	Qualifications of authorized nuclear pharmacist, if applicable	Duration of employment
§289.256(g)(1)	Authority of RSO	Duration of employment
§289.256(g)(5)	Qualifications and dates of service for temporary RSO	3 years
§289.256(t)(3)	Written directives	3 years
§289.256(v)(4)	Calibration of instruments (dose calibrators)	3 years
§289.256(z)(2)	Sealed source/brachytherapy inventory	3 years
§289.256(bb)(3)	Surveys for ambient radiation exposure rate	3 years
§289.256(cc)(3) §289.256(eee)(2)	Patient release	3 years after date of release
§289.256(dd)(3)	Mobile nuclear medicine service client letters	Duration of licensee/client relationship
§289.256(dd)(3)	Mobile nuclear medicine service surveys	3 years
§289.256(ee)(2)	Decay in storage/disposal	3 years
§289.256(ii)(3)	Molybdenum-99 concentrations	3 years

Rule Cross Reference	Name of Records/Documents	Time Interval for Keeping Records/Documents
§289.256(ll)(2)	Safety instructions - unsealed radioactive materials	3 years
§289.256(ss)(3)	Surveys after sealed source implant and removal	3 years
§289.256(tt)(3)	Brachytherapy sealed sources accountability	3 years
§289.256(uu)(2)	Safety instructions - brachytherapy	3 years
§289.256(ww)(4)	Calibration measurements of brachytherapy sealed sources	3 years
§289.256(xx)(2)	Strontium 90 activity of source	Duration of life of source
§289.256(fff)(4)	Installation, maintenance, adjustment and repair-remote afterloader units, teletherapy units, and gamma stereotactic radiosurgery units	3 years
§289.256(iii)(3)	Dosimetry equipment calibration, intercomparison and comparison	Until termination of the radioactive material license
§289.256(jjj)(7)	Calibration – teletherapy units	3 years
§289.256(kkk)(9)	Calibration – remote afterleader units	3 years
§289.256(lll)(7)	Calibration – gamma stereotactic radiosurgery units	3 years
§289.256(mmm)(6)	Spot checks- teletherapy units	Until licensee no longer possesses unit
§289.256(nnn)(6)	Spot checks- remote afterloader	3 years
§289.256(ooo)(8)	Spot checks-gamma stereotactic radiosurgery units	3 years
§289.256(ppp)(5)	Technical requirements for mobile remote afterloader units	3 years
§289.256(qqq)(3)	Radiation surveys	Duration of the use of the unit
§289.256(rrr)(3)	Five-year inspection for teletherapy and gamma sterotactic radiosurgery units	Duration of the use of the unit
§289.256(uuu)(9)	Annotated report – medical event	Until termination of the radioactive material license
§289.256(vvv)(8)	Annotated report – dose to embryo/fetus or nursing child	Until termination of the radioactive material license

~~§289.255. Radiation Safety Requirements and Licensing and Registration Procedures For Industrial Radiography.~~

~~(a) Purpose.~~

~~—(1) The requirements in this section establish radiation safety requirements and licensing and registration procedures for using sources of radiation for industrial radiography and for certification of industrial radiographers.~~

~~—(2) The requirements in this section apply to licensees and registrants who possess sources of radiation for industrial radiography, including radiation machines, accelerators, and sealed radioactive sources.~~

~~—(3) Each licensee and registrant is responsible for ensuring compliance with this chapter, license and registration conditions, and orders of the agency.~~

~~—(4) Each licensee and registrant is also responsible for ensuring that radiographic personnel performing activities under a license or registration comply with this chapter, license and registration conditions, and orders of the agency.~~

~~(b) Scope.~~

~~—(1) The requirements of this section are in addition to and not in substitution for other applicable requirements of this chapter.~~

~~—(2) The requirements of §289.251 of this title (relating to Exemptions, General Licenses, and General License Acknowledgments), §289.252 of this title (relating to Licensing of Radioactive Material), and §289.257 of this title (relating to Packaging and Transportation of Radioactive Material) apply to licensees subject to this section.~~

~~—(3) The requirements of §289.226 of this title (relating to Registration of Radiation Machine Use and Services) apply to registrants subject to this section.~~

~~—(4) The requirements of §289.119 of this title (relating to Radiation Safety Requirements for Particle Accelerators) apply to certain persons using accelerators subject to this section.~~

~~—(5) The requirements of the following sections of this chapter apply to all licensed and registered industrial radiographic operations:~~

~~—(A) §289.201 of this title (relating to General Provisions);~~

~~—(B) §289.202 of this title (relating to Standards for Protection Against Radiation);~~

~~—(C) §289.203 of this title (relating to Notices, Instructions, and Reports to Workers; Inspections);~~

~~—(D) §289.204 of this title (relating to Fees for Certificates of Registration, Radioactive Material(s) Licenses, Emergency Planning and Implementation, and Other Regulatory Services); and~~

~~—(E) §289.205 of this title (relating to Hearing and Enforcement Procedures).~~

~~(c) Definitions. The following words and terms, when used in this section, shall have the following meaning unless the context clearly indicates otherwise.~~

~~—(1) Additional authorized use/storage site—Authorized use/storage locations specifically named on a license or certificate of registration other than the main site specified on a license or certificate of registration, or other than temporary job sites.~~

~~—(2) ANSI—American National Standards Institute.~~

~~—(3) Annual refresher safety training—A review conducted or provided by the licensee or registrant for its employees on radiation safety aspects of industrial radiography. The review may~~

include, as appropriate, the results of internal audits, new procedures or equipment, new or revised regulations, accidents or errors that have been observed, and should also provide opportunities for employees to ask safety questions.

~~–(4) Associated equipment—Equipment that is used in conjunction with a radiographic exposure device to make radiographic exposures that drives, guides, or comes in contact with the source, (such as, guide tube, control tube, control cable (drive cable), removable source stop, "J" tube and collimator when it is used as an exposure head).~~

~~–(5) Cabinet x-ray system—An x-ray system with the x-ray tube installed in an enclosure independent of existing architectural structures except the floor on which it may be placed. An x-ray tube used within a shielded part of a building, or x-ray equipment that may temporarily or occasionally incorporate portable shielding, is not considered a cabinet x-ray system. The cabinet x-ray system is intended to:~~

~~—(A) contain at least that portion of a material being irradiated;~~

~~—(B) provide radiation attenuation; and~~

~~—(C) exclude personnel from its interior during generation of radiation.~~

~~–(6) Certifiable cabinet x-ray system—An existing uncertified x-ray system that has been modified to meet the certification requirements specified in 21 Code of Federal Regulations (CFR) 1020.40.~~

~~–(7) Certification identification (ID) card—The document issued by the agency to individuals who have completed the requirements stated in subsection (m)(2)(A) of this section.~~

~~–(8) Certified cabinet x-ray system—An x-ray system that has been certified in accordance with 21 CFR 1010.2 as being manufactured and assembled on or after April 10, 1975, according to the provisions of 21 CFR 1020.40.~~

~~–(9) Certifying entity—An independent certifying organization meeting the requirements in Appendix A of 10 CFR Part 34 or an agreement state meeting the requirements in Appendix A, Parts II and III of 10 CFR Part 34.~~

~~–(10) Collimator—A small radiation shield that is placed on the end of a guide tube or directly onto a radiographic exposure device to restrict the size of the radiation beam when the sealed source is cranked into position to make a radiographic exposure.~~

~~–(11) Control cable (drive cable)—The cable that is connected to the source assembly and used to drive the source from and return it to the shielded position.~~

~~–(12) Control mechanism (drive mechanism)—A device that enables the source assembly to be moved from and returned to the shielded position. A drive mechanism is also known as a crank assembly.~~

~~–(13) Control tube—A protective sheath for guiding the drive cable. The control tube connects the drive mechanism to the radiographic exposure device.~~

~~–(14) Crank-out device—The drive cable, control tube, and drive mechanism used to move the sealed source to and from the shielded position to make an industrial radiographic exposure.~~

~~–(15) Enclosed radiography—Industrial radiography conducted in an enclosed cabinet or room. Enclosed radiography includes shielded room radiography.~~

~~–(16) Exposure head—A device that locates the gamma radiography sealed source in the selected working position. An exposure head is also known as a source stop.~~

~~–(17) Fluoroscopic imaging assembly—A subsystem in which x-ray photons produce a fluoroscopic image. It includes the image receptors such as the image intensifier and spot film~~

device, electrical interlocks, if any, and structural material providing linkage between the image receptor and source assembly.

~~-(18) GED—General educational development.~~

~~-(19) Guide tube—A flexible or rigid tube, such as a "J" tube, for guiding the source assembly and the attached drive cable from the exposure device to the exposure head. The guide tube may also include the connections necessary for attachment to the exposure device and to the exposure head.~~

~~-(20) Independent certifying organization—An independent organization that meets all of the criteria of Appendix A of 10 CFR Part 34.~~

~~-(21) Industrial radiography (radiography)—A nondestructive testing method using ionizing radiation, such as gamma rays or x rays, to make radiographic images for the purpose of detecting flaws in objects without destroying them.~~

~~-(22) Lay barge radiography—Industrial radiography performed on any water vessel used for laying pipe.~~

~~-(23) Lock out survey—A radiation survey performed to determine that a sealed source is in its fully shielded position before moving the radiographic exposure device or source changer to a different temporary job site or before securing the radiographic exposure device or source changer against unauthorized removal.~~

~~-(24) Offshore—Within the territorial waters of the state of Texas. The territorial waters of Texas extend to the three marine league line or nine nautical miles from the Texas coast.~~

~~-(25) On the job training—Experience in all of the areas considered to be directly involved in the radiography process. The hours of on the job training do not include safety meetings, classroom training, travel, darkroom activities, film development and interpretation, or use of a cabinet x-ray unit.~~

~~-(26) Permanent radiographic installation—An enclosed shielded room, cell, or vault, not located at a temporary jobsite, in which radiography is performed and meets the criteria of subsection (j) of this section.~~

~~-(27) Permanent storage site—Any location that is specifically named on a license or certificate of registration and that is used only for storage of sources of radiation.~~

~~-(28) Personal supervision—Guidance and instruction provided to a radiographer trainee by a radiographer trainer who is present at the site, in visual contact with the trainee while the trainee is using sources of radiation, associated equipment, and survey meters, and in such proximity that immediate assistance can be given if required.~~

~~-(29) Pipeliners—A directional beam radiographic exposure device.~~

~~-(30) Platform radiography—Industrial radiography performed on an offshore platform or other structure over a body of water.~~

~~-(31) Practical examination—A demonstration through practical application of the safety rules and principles in industrial radiography including use of all appropriate equipment and procedures.~~

~~-(32) Radiation safety officer (RSO)—An individual named by the licensee or registrant who has a knowledge of, responsibility for, and authority to enforce appropriate radiation protection rules, standards, and practices on behalf of the licensee or registrant and who meets the requirements of subsection (m)(4) of this section.~~

~~—(33) Radiographer—Any individual who has successfully completed the training, testing, and documentation requirements of subsection (m)(2)(A) of this section and who is responsible to the licensee or registrant for assuring compliance with the requirements of the agency's regulations and conditions of the license or certificate of registration. These individuals may be referred to as certified industrial radiographers or certified radiographers. The individual may also:~~

- ~~—(A) perform industrial radiographic operations; or~~
- ~~—(B) be in attendance at the site where the sources of radiation are being used.~~

~~—(34) Radiographer certification—Written approval received from a certifying entity stating that an individual has satisfactorily met certain established radiation safety, testing, and experience criteria.~~

~~—(35) Radiographer trainee—Any individual who has successfully completed the training and documentation requirements of subsection (m)(1)(A) of this section and who must use sources of radiation and related handling tools or radiation survey instruments under the personal supervision of a radiographer trainer.~~

~~—(36) Radiographer trainer—A radiographer who instructs and supervises radiographer trainees during on the job training and who meets the requirements of subsection (m)(3) of this section.~~

~~—(37) Radiographic exposure device—Any instrument containing a sealed source that is used to make a radiograph (e.g., camera).~~

~~—(38) Radiographic operations—All activities associated with the presence of x-ray machines or radioactive sources in a radiographic exposure device during the use of the machine or device or transport (except when being transported by a common or contract transport). Radiographic operations include surveys to confirm the adequacy of boundaries, setting up equipment, and any activity inside restricted area boundaries.~~

~~—(39) Radiographic personnel—Any radiographer, radiographer trainer, or radiographer trainee.~~

~~—(40) Residential location—Any area where 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.~~

~~—(41) S-tube—A tube through which the radioactive source travels when inside a radiographic exposure device.~~

~~—(42) Shielded position—The location within the radiographic exposure device or source changer where the sealed source is secured and restricted from movement.~~

~~—(43) Shielded room radiography—Industrial radiography conducted in a room shielded so radiation levels at every location on the exterior meet the limitations specified in §289.202(n) of this title. A shielded room is also known as a bay or bunker.~~

~~—(44) Source assembly (pigtail)—An assembly that consists of the sealed source and a connector that attaches the source to the control cable. The source assembly may also include a ball stop used to secure the source in the shielded position.~~

~~—(45) Source changer—A device designed and used to replace sealed sources in radiographic exposure devices, including those used to transport and store sealed sources.~~

~~—(46) Storage area—Any location, facility, or vehicle that is used to store and secure a radiation machine, radiographic exposure device, a storage container, or a sealed source when it is not used for radiographic operations. Storage areas are locked or have a physical barrier to prevent accidental exposure, tampering, or unauthorized removal of the machine, device, container, or source.~~

- ~~(47) Storage container—A device in which the sealed source is secured and stored.~~
- ~~(48) Storage facility—A structure designed to house one or more sources of radiation to provide security and shielding at a permanent storage site. A storage facility is also known as a vault.~~
- ~~(49) Temporary job site—Any location where industrial radiography is performed other than the specific use location(s) listed on a license or certificate of registration. If use of sources of radiation is authorized at a temporary job site, storage incident to that use is also authorized.~~
- ~~(50) Trainee status card—The document issued by the agency following completion of the requirements of subsection (m)(1)(A) of this section.~~
- ~~(51) Transport container—A package that is designed to provide radiation safety and security when sealed sources are transported and meets all applicable requirements of the United States Department of Transportation (DOT).~~
- ~~(52) Underwater radiography—Industrial radiography performed when the radiographic exposure device and/or related equipment are beneath the surface of the water.~~
- ~~(d) Exemptions:~~
- ~~(1) Uses of certified and certifiable cabinet x-ray systems are exempt from the requirements of this section except for the requirements of subsections (b)(3) and (5) and (u)(6)(C)–(E) of this section.~~
- ~~(2) Industrial uses of hand-held light intensified imaging devices are exempt from the requirements in this section if the exposure level 18 inches from the source of radiation to any individual does not exceed 2 millirem per hour (mrem/hr) (0.02 millisievert per hour (mSv/hr)). Devices with exposure levels that exceed the 2 mrem/hr (0.02 mSv/hr) level shall meet the applicable requirements of this section and §289.252 of this title or §289.226 of this title, as applicable.~~
- ~~(3) Radiation machines determined by the agency to constitute a minimal threat to human health and safety in accordance with §289.201(q)(2) of this title, are exempt from the requirements in this section except for the requirements of paragraph (1) of this subsection.~~
- ~~(4) Facilities that utilize radiation machines for industrial radiography at permanent radiographic installations only are exempt from the requirements of this section except for the requirements of subsections (b)(3) and (5), (j), (m)(1)(A) and (u)(6)(A), (B), and (E).~~
- ~~(e) Receipt, transfer, and disposal of sources of radiation and devices using depleted uranium (DU) for shielding. Each licensee and registrant shall make and maintain records in accordance with subsection (w)(1) of this section, showing the receipt, transfer, and disposal of sources of radiation and devices using DU for shielding.~~
- ~~(f) Radiation survey instruments:~~
- ~~(1) Each licensee and registrant shall have a sufficient number of calibrated, appropriate, and operable radiation survey instruments at each location where sources of radiation are present to perform the radiation surveys required by this section and §289.202(p)(1) and (2) of this title. These radiation survey instruments shall be capable of measuring a range from 2 mrem/hr (0.002 mSv/hr) through 1 rem per hour (rem/hr) (0.01 sievert per hour (Sv/hr)).~~
- ~~(2) Each radiation survey instrument shall be calibrated:~~
- ~~—(A) by a person licensed or registered by the agency, another agreement state, or the NRC to perform such service;~~
- ~~—(B) at energies appropriate for the licensee's or registrant's use;~~

~~—(C) at intervals not to exceed six months and after each instrument servicing other than battery replacement;~~

~~—(D) at two points located approximately one-third and two-thirds of full-scale on each scale for linear scale instruments; for logarithmic scale instruments, at mid-range of each decade, and at two points of at least one decade; and for digital instruments, at three points between 2 and 1,000 mrem/hr (0.02 and 10 mSv/hr); and~~

~~—(E) to demonstrate an accuracy within plus or minus 20% of the true radiation level at each point checked.~~

~~—(3) Each radiation survey instrument shall be checked with a radiation source at the beginning of each day of use and at the beginning of each work shift to ensure it is operating properly.~~

~~—(4) Records of the calibrations required by paragraph (2) of this subsection shall be maintained in accordance with subsection (w)(2) of this section.~~

~~(g) Quarterly inventory.~~

~~—(1) Each licensee and registrant shall perform a physical inventory at intervals not to exceed three months to account for all sources of radiation and for devices containing DU received or possessed.~~

~~—(2) Records of the quarterly inventories required by paragraph (1) of this subsection shall be made and maintained for agency inspection in accordance with subsection (w)(3) of this section.~~

~~(h) Utilization logs.~~

~~—(1) Each licensee and registrant shall make and maintain current logs of the use, removal, and return to storage of each source of radiation. The information shall be recorded in the log when the source is removed from and returned to storage. The logs shall include:~~

~~—(A) a unique identification, for example, the serial number, of the following:~~

~~—(i) each radiation machine;~~

~~—(ii) each radiographic exposure device containing a sealed source or transport and storage container in which the sealed source is located; and~~

~~—(iii) each sealed source;~~

~~—(B) the name and signature of the radiographer using the source of radiation;~~

~~—(C) the location(s) and date(s) where each source of radiation is used; and~~

~~—(D) the date(s) each source of radiation is removed from storage and returned to storage.~~

~~—(2) Utilization logs may be kept on BRC Form 255 U, Utilization Log, or on clear, legible records containing all the information required by paragraph (1) of this subsection.~~

~~—(3) Records of utilization logs shall be made and maintained for agency inspection in accordance with subsection (w)(15) of this section.~~

~~(i) Inspection and maintenance of radiation machines, radiographic exposure devices, transport and storage containers, associated equipment, source changers, and survey instruments.~~

~~—(1) Each day before using equipment, the radiographer shall:~~

~~—(A) perform visual and operational checks on radiation machines, survey instruments, radiographic exposure devices, transport and storage containers, associated equipment and source changers to ensure that:~~

~~—(i) the equipment is in good working condition;~~

~~—(ii) the sources are adequately shielded in radiographic exposure devices; and~~

~~—(iii) required labeling is present and legible.~~

- ~~—(B) determine the survey instrument is responding using check sources or other appropriate means; and~~
- ~~—(C) remove the equipment from service until repaired if equipment problems are found.~~
- ~~—(2) Each licensee and registrant shall have written procedures for the following:~~
 - ~~—(A) inspection and routine maintenance of radiation machines, radiographic exposure devices, source changers, associated equipment, transport and storage containers, and survey instruments at intervals not to exceed three months to ensure the proper functioning of components important to safety. All appropriate components shall be maintained in accordance with manufacturers' specifications. Radiation machines, radiographic exposure devices, transport containers and source changers being stored are exempted from this requirement provided that each radiation machine, radiographic exposure device, transport container, or source changer is inspected and repaired prior to being returned to service. This inspection and maintenance program shall cover, as a minimum, the items listed in subsection (y)(2) of this section; and~~
 - ~~—(B) inspection and maintenance necessary to maintain the Type B packaging used to transport radioactive material. The inspection and maintenance program must include procedures to assure that Type B packages are shipped and maintained in accordance with the certificate of compliance or other approval.~~
- ~~—(3) Records of equipment problems and of any maintenance performed in accordance with paragraph (1) of this subsection shall be made and maintained in accordance with subsection (w)(4) of this section.~~
- ~~(j) Permanent radiographic installations.~~
 - ~~—(1) Permanent radiographic installations shall have high radiation area entrance controls as described in §289.202(s)(1) (4) of this title or if applicable, the Texas Regulations for Control of Radiation (TRCR) Part 35, §§35.8 and 35.9, as adopted by reference in §289.119 of this title (relating to Radiation Safety Requirements for Particle Accelerators).~~
 - ~~—(2) The entrance controls shall be tested for proper operation at the beginning of each day of equipment use.~~
 - ~~—(3) The alarm system shall be tested for proper operation with a source of radiation each day before the installation is used for radiographic operations. The test shall include a check for the visible and/or audible signals.~~
 - ~~—(4) Entrance control devices that reduce the radiation level upon entry (designated in paragraph (1) of this subsection) shall be tested monthly.~~
 - ~~—(5) If an entrance control device or alarm is operating improperly, it shall be immediately labeled as defective and repaired within seven calendar days. The facility may continue to be used during this seven day period, provided the licensee or registrant implements the continuous surveillance requirements of subsection (r) of this section, ensures that radiographic personnel use an alarming ratemeter, and complies with the requirements of subsection (v)(7)(G) of this section.~~
 - ~~—(6) Records of the tests and repairs required by this subsection shall be made and maintained in accordance with subsection (w)(5) of this section.~~
- ~~(k) Notification of incidents.~~
 - ~~—(1) The agency shall be notified of the loss or theft of sources of radiation, overexposures, and excessive levels in accordance with §289.202(w)(yy), and (bbb) of this title.~~

~~(2) In addition, each licensee or registrant shall submit a written report within 30 days to the agency whenever one of the following events occurs:~~

- ~~—(A) a source assembly cannot be returned to the fully shielded position and properly secured;~~
- ~~—(B) the source assembly becomes unintentionally disconnected from the drive cable;~~
- ~~—(C) any component critical to safe operation of the radiographic exposure device fails to properly perform its intended function;~~
- ~~—(D) an indicator on a radiation machine fails to show that radiation is being produced;~~
- ~~—(E) an exposure switch on a radiation machine fails to terminate production of radiation when turned to the off position; or~~
- ~~—(F) a safety interlock fails to terminate x ray production.~~

~~(3) The licensee or registrant shall include the following information in each report submitted in accordance with paragraph (2) of this subsection:~~

- ~~—(A) a description of the equipment problem;~~
- ~~—(B) cause of each incident, if known;~~
- ~~—(C) manufacturer and model number of equipment involved in the incident;~~
- ~~—(D) manufacturer and model and serial number of equipment involved in the incident;~~
- ~~—(E) location, time, and date of the incident;~~
- ~~—(F) actions taken to establish normal operations;~~
- ~~—(G) corrective actions taken or planned to prevent recurrence; and~~
- ~~—(H) names of personnel involved in the incident.~~

~~(l) Reciprocity.~~

~~(1) All reciprocal recognition of licenses or certificates of registration by the agency will be granted in accordance with §289.226(r) of this title or §289.252(s) of this title.~~

~~(2) Reciprocal recognition by the agency of an individual radiographer certification will be granted provided that:~~

- ~~—(A) the individual holds a valid certification in the appropriate category and class issued by a certifying entity, as defined in subsection (e) of this section;~~
- ~~—(B) the requirements and procedures of the certifying entity issuing the certification afford the same or comparable certification standards as those afforded by subsection (m)(2)(A)(i)-(iv) of this section; and~~
- ~~—(C) the individual submits a legible copy of the certification to the agency prior to entry into Texas.~~

~~(3) Enforcement actions with the agency, another agreement state, or the NRC or sanctions by an independent certifying entity may be considered when reviewing a request for reciprocal recognition from a licensee, registrant, or certified radiographer.~~

~~(4) Certified radiographers who are granted reciprocity by the agency shall maintain the certification upon which the reciprocal recognition was granted, or prior to the expiration of such certification, shall meet the requirements of subsection (m)(2)(A) of this section.~~

~~(m) Requirements for qualifications of radiographic personnel.~~

~~(1) Radiographer trainee. No licensee or registrant shall permit any individual to act as a radiographer trainee until the individual possesses the original or a copy of an agency issued trainee status card or certification ID card.~~

~~(A) To obtain an agency issued trainee status card, the licensee, registrant, or the individual must document to the agency on BRC Form 255 E or equivalent that such individual has successfully~~

completed a course of at least 40 hours on the applicable subjects outlined in subsection (y)(1) of this section. The course must be one accepted by the agency, another agreement state, or the NRC.

—(B) The trainee must carry a copy of the completed BRC Form 255-E, in the interim period after submitting documentation to the agency and before receiving a trainee status card. The copy of the completed BRC Form 255-E that was submitted to the agency may be used in lieu of the trainee status card for a period of 60 days from the date recorded by the trainee on the documentation.

—(C) The individual shall notify the agency by telephone, telegram, telefacsimile, electronic media transmission, or in writing of the need for a replacement trainee status card. The individual shall carry a copy of documentation of the request while performing industrial radiographic operations until a replacement trainee status card is received from the agency.

—(2) Radiographer. No licensee or registrant shall permit any individual to act as a radiographer until the individual carries a valid radiographer certification. To obtain a radiographer certification, an individual must comply with subsection (p)(1) of this section and the following:

—(A) the licensee, registrant, or the individual must document to the agency on BRC Form 255-R or equivalent that such individual:

—(i) has completed the requirements of paragraph (1)(A) of this subsection;

—(ii) has completed on-the-job training as a radiographer trainee supervised by one or more radiographer trainers authorized on a license or certificate of registration;

—(I) The radiographer trainee must carry a legible trainee status card in accordance with paragraph (1) of this subsection while obtaining the on-the-job training specified in subclauses (H)-(VII) of this clause.

—(II) The on-the-job training shall include at least 200 hours of active participation in radioactive materials industrial radiographic operations or 120 hours of active participation in x-ray industrial radiographic operations.

—(III) Individuals performing industrial radiography utilizing radioactive materials and x-ray machines must complete both segments (320 hours) of on-the-job training.

—(IV) The hours of on-the-job training do not include safety meetings, classroom training, travel, darkroom activities, film development and interpretation, or use of a cabinet x-ray unit.

—(V) One year of documented experience or on-the-job training as authorized by another agreement state or the NRC may be substituted for subclauses (II) or (III) of this clause. The documentation must be submitted to the agency on BRC Form 255-OS or equivalent.

—(VI) The trainee shall be under the personal supervision of a radiographer trainer whenever a radiographer trainee:

—(a) uses radiation machines, radiographic exposure devices, or associated equipment; or

—(b) performs radiation surveys required by subsection (v)(8) of this section to determine that the sealed source has returned to the shielded position after an exposure or the radiation machine has stopped producing radiation.

—(VII) The personal supervision shall include the following.

—(a) The radiographer trainer's physical presence at the site where the sources of radiation are being used;

—(b) The availability of the radiographer trainer to give immediate assistance if required;

and

~~— (c) The radiographer trainer's direct observation of the trainee's performance of the operations referred to in this section.~~

~~— (iii) has successfully completed within the last five years the appropriate agency-administered examination prescribed in subsection (o)(2) of this section or the appropriate examination of another certifying entity that affords the same or comparable certification standards as those afforded by this clause and clauses (i), (ii) and (iv) of this subparagraph; and~~

~~— (iv) possesses a current certification ID card issued in accordance with subsection (p)(2) of this section or by another certifying entity that affords the same or comparable certification standards as those afforded by this clause and clauses (i)-(iii) of this subparagraph.~~

~~— (B) Reciprocal recognition by the agency of an individual radiographer certification may be granted according to subsection (1)(2) and (3) of this section:~~

~~— (C) Once an individual has completed the requirements of paragraph (2)(A)(iv) of this subsection, the licensee or registrant is not required to submit the documentation referenced in paragraph (2)(A)(i) and (ii) of this subsection.~~

~~— (3) Radiographer trainer.~~

~~— (A) No licensee or registrant shall permit any individual to act as a radiographer trainer until:~~

~~— (i) it has been documented to the agency on BRC Form 255 T or equivalent that such individual has:~~

~~— (I) met the radiographer certification requirements of paragraph (2)(A) of this subsection; and~~

~~— (II) one year of documented experience as a certified radiographer.~~

~~— (ii) such individual is named on the specific license or certificate of registration issued by the agency and under which the individual is acting as a radiographer trainer; and~~

~~— (iii) determination is made by the agency that the individual is not currently under order from the agency prohibiting the individual from acting as a radiographer trainer.~~

~~— (B) The specific duties of the radiographer trainer include, but are not limited to, the following:~~

~~— (i) providing personal supervision to any radiographer trainee at the site where the sources of radiation are being used; and~~

~~— (ii) preventing any unauthorized use of a source of radiation by a radiographer trainee.~~

~~— (4) RSO for industrial radiography.~~

~~— (A) An RSO shall be designated on every industrial radiography license and certificate of registration issued by the agency.~~

~~— (B) The RSO's qualifications shall be submitted to the agency and shall include as a minimum:~~

~~— (i) possession of a high school diploma or a certificate of high school equivalency based on the GED test;~~

~~— (ii) completion of the training and testing requirements of paragraph (1)(A) and (2)(A)(iii) of this subsection and subsection (n)(1)(B) of this section; and~~

~~— (iii) two years of documented radiation protection experience, including knowledge of industrial radiographic operations with at least 40 hours of active participation in industrial radiographic operations.~~

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

- (i) establishing and overseeing operating, safety, emergency, and as low as reasonably achievable (ALARA) procedures, and to review them regularly to ensure that the procedures are current and conform with the requirements of this chapter;
 - (ii) overseeing and approving all phases of the training program for radiographic personnel so that appropriate and effective radiation protection practices are taught;
 - (iii) ensuring that required radiation surveys and leak tests are performed and documented in accordance with this chapter, including any corrective measures when levels of radiation exceed established limits;
 - (iv) ensuring that personnel monitoring devices are calibrated and used properly by occupationally exposed personnel;
 - (v) ensuring that timely notifications to employees are made as required by §289.203 of this title;
 - (vi) ensuring that timely notifications to the agency are made as required by this section and §289.202 of this title;
 - (vii) ensuring that any required interlock switches and warning signals are functioning and that radiation signs, ropes, and barriers are properly posted and positioned;
 - (viii) investigating, determining the cause, taking steps to prevent the recurrence, and reporting to the agency each:
 - (I) known or suspected case of radiation exposure to an individual or radiation level detected in excess of limits established by this chapter; and
 - (II) theft or loss of a source(s) of radiation.
 - (ix) having a thorough knowledge of management policies and administrative procedures of the licensee or registrant;
 - (x) assuming control and having the authority to institute corrective actions including shutdown of operations when necessary in emergency situations or unsafe conditions;
 - (xi) maintaining records as required by this chapter in accordance with subsection (w) of this section;
 - (xii) ensuring the proper storing, labeling, transport, and use of exposure devices and sources of radiation;
 - (xiii) ensuring that inventory and inspection and maintenance programs are performed in accordance with subsections (g) and (i) of this section;
 - (xiv) ensuring that personnel are complying with the requirements of this chapter and the conditions of the license or the certificate of registration; and
 - (xv) ensuring that the operating, safety, and emergency procedures of the licensee or registrant are met in accordance with subsections (u)(4)(A) (C) and (G) and (v)(7)(A) (C) and (I) of this section.
- (n) Additional qualification requirements.
- (1) No licensee or registrant shall permit any individual to act as a radiographer trainee, radiographer, radiographer trainer, or RSO until such individual has:
 - (A) received copies of and demonstrated an understanding of the following by successful completion of a written or oral examination administered by the licensee or registrant covering this material:
 - (i) the requirements contained in this section and the applicable requirements of §289.201 of this title, §289.202 of this title, §289.203 of this title, and §289.257 of this title;

~~—(ii) the appropriate conditions of the license(s) and certificate(s) of registration;~~
~~—(iii) the licensee's or registrant's operating, safety, and emergency procedures; and~~
~~—(B) demonstrated competence in the use of sources of radiation, radiographic exposure devices, associated equipment, related handling tools, and radiation survey instruments, that may be employed in industrial radiographic assignments by successful completion of a practical examination administered by the licensee or registrant covering such use.~~
~~—(2) Records of the administration of and the examinations required by paragraph (1) of this subsection shall be made and maintained for agency inspection in accordance with subsection (w)(7) of this section.~~
~~(e) Application and fee for radiographer certification examinations.~~
~~—(1) Application.~~
~~—(A) An application for taking the examination shall be on forms prescribed and furnished by the agency.~~
~~—(B) The non-refundable application fee for examination shall be \$25.~~
~~—(C) The appropriate fee shall be submitted with the application for examination when filing with the agency.~~
~~—(D) The application and the non-refundable fee shall be submitted to the agency on or before the dates specified by the agency.~~
~~—(2) Examination. The examination shall be given for the purpose of determining the qualifications of applicants.~~
~~—(A) The scope of the examination and the methods of procedure, including determination of the passing score, shall be prescribed by the agency. The examination will assess the applicant's knowledge to safely use sources of radiation and related equipment and the applicant's knowledge of this section, §289.201 of this title, and §289.202 of this title.~~
~~—(B) The examination will be administered by the agency or persons authorized by the agency.~~
~~—(C) A candidate failing an examination may apply for re-examination in accordance with paragraph (1) of this subsection and will be re-examined. A candidate shall not retake the same version of the agency-administered examination.~~
~~—(D) The examination shall normally be offered once each month. Times, dates, and locations of the examination will be furnished by the agency.~~
~~—(E) The examination will be in the English language.~~
~~—(F) To take the examination, an individual shall present a photo-identification card, such as a driver's license, at the time of the examination.~~
~~—(G) Calculators will be permitted during the examination. However, calculators or computers with preprogrammed data or formulas, including exposure calculators, will not be permitted during the examination.~~
~~—(H) The examination will be a "closed-book" examination.~~
~~—(I) Any individual observed by an agency proctor to be compromising the integrity of the examination shall be required to surrender the examination, the answer sheet, and all scratch paper. Such individual will not be allowed to complete the examination, will forfeit the examination fee, and will leave the examination site to avoid disturbing other examinees. Such individual must wait 90 days before taking a new examination and must resubmit a new application and a \$25 non-refundable examination fee.~~

~~(J) Examination material shall be returned to the agency at the end of the examination. No photographic or other copying of examination questions or materials shall be permitted. Disclosure by any individual of the contents of any examination prior to its administration is prohibited.~~

~~—(K) The names and scores of individuals taking the examination shall be a public record.~~

~~(p) Radiographer certification.~~

~~—(1) An application for radiographer certification shall be on BRC Form 255 R, BRC Form 255 OS, or equivalent.~~

~~—(A) The non-refundable fee for radiographer certification shall be \$100.~~

~~—(B) The appropriate fee shall be submitted with the application for radiographer certification when filing with the agency.~~

~~—(2) A certification ID card shall be issued to each individual who successfully completes the requirements of subsection (m)(2)(A)(i)–(iii) of this section.~~

~~—(A) Each individual's certification ID card shall contain the individual's photograph. The agency will take the photograph at the time the examination is administered.~~

~~—(B) The certification ID card remains the property of the agency and may be revoked or suspended under the provisions of paragraph (4) of this subsection.~~

~~—(C) Any individual who needs to replace a certification ID card shall submit to the agency a written request for a replacement certification ID card, stating the reason a replacement certification ID card is needed. A non-refundable fee of \$35 shall be paid to the agency for each replacement of a certification ID card. The prescribed fee shall be submitted with the written request for a replacement certification ID card. The individual shall carry a copy of the request while performing industrial radiographic operations until a replacement certification ID card is received from the agency.~~

~~—(D) Each certification ID card is valid for a period of five years, unless revoked or suspended in accordance with paragraph (4) of this subsection. Each certification ID card expires at the end of the day, in the month and year stated on the certification ID card.~~

~~—(3) Renewal of a radiographer certification.~~

~~—(A) Applications for examination to renew a radiographer certification shall be filed in accordance with subsection (o)(1) of this section.~~

~~—(B) The examination for renewal of a radiographer certification shall be administered in accordance with subsection (o)(2) of this section.~~

~~—(C) A renewal certification ID card shall be issued in accordance with paragraph (2) of this subsection.~~

~~—(4) Suspension or revocation of a radiographer certification.~~

~~—(A) Any radiographer who violates the requirements of this chapter, or provides any material false statement in the application or any statement of fact required in accordance with this chapter, may be required to show cause at a formal hearing why the radiographer certification should not be suspended or revoked in accordance with §289.205 of this title.~~

~~—(B) When an agency order has been issued for an industrial radiographer to cease and desist from the use of sources of radiation or the agency suspends or revokes the individual's radiographer certification, the radiographer shall surrender the certification ID card to the agency until the order is changed or the suspension expires.~~

~~—(C) An individual whose radiographer certification has been suspended or revoked by the agency or another certifying entity shall obtain written approval from the agency to apply to take the examination.~~

~~(q) Personnel monitoring control:~~

~~—(1) The personnel monitoring program shall meet the applicable requirements of §289.202 of this title.~~

~~—(2) During industrial radiographic operations, the following shall apply:~~

~~—(A) No licensee or registrant shall permit an individual to act as a radiographer, radiographer trainer, or radiographer trainee unless each individual wears, on the trunk of the body at all times during radiographic operations:~~

~~—(i) an individual monitoring device that meets the requirements of §289.202(p)(3) of this title;~~

~~—(ii) direct reading pocket dosimeter or an electronic personal dosimeter; and~~

~~—(iii) an alarming ratemeter.~~

~~—(B) For permanent radiographic installations where other appropriate alarming or warning devices are in routine use, the wearing of an alarming ratemeter is not required.~~

~~—(C) Pocket dosimeters shall meet the criteria in ANSI 13.5-1972 at the time of manufacture and shall have a range of zero to 200 mrem (2 mSv). Electronic personal dosimeters may only be used in place of ion-chamber pocket dosimeters.~~

~~—(D) Pocket dosimeters shall be recharged at the start of each work shift.~~

~~—(E) As a minimum, direct reading pocket dosimeters shall be recharged and electronic personal dosimeters reset, and "start" readings recorded:~~

~~—(i) immediately before checking out any source of radiation from an authorized storage location for the purposes of conducting industrial radiographic operations; and~~

~~—(ii) before beginning radiographic operations on any subsequent calendar day (if the source of radiation has not been checked back into an authorized storage site).~~

~~—(F) Whenever radiographic operations are concluded for the day, the "end" readings on pocket dosimeters or electronic personal dosimeters shall be recorded and the accumulated occupational doses for that day determined and recorded.~~

~~—(G) If an individual's pocket dosimeter is discharged beyond its range (for example, goes "off-scale"), or if an individual's electronic personal dosimeter reads greater than 200 mrem (2 mSv), industrial radiographic operations by that individual shall cease and the individual's monitoring device shall be processed immediately. The individual shall not return to work with sources of radiation until a determination of the radiation exposure has been made. This determination shall be made by the RSO or the RSO's designee. The results of this determination shall be included in the records maintained in accordance with subsection (w)(8) of this section.~~

~~—(H) Each individual monitoring device shall be assigned to and worn by only one individual.~~

~~—(I) Individual monitoring devices must be replaced at least monthly. After replacement, each individual monitoring device must be returned to the supplier for processing within 14 calendar days of the exchange date specified by the personnel monitoring supplier or as soon as practicable. In circumstances that make it impossible to return each individual monitoring device within 14 calendar days, such circumstances must be documented and available for review by the agency.~~

~~—(J) If an individual monitoring device is lost or damaged, the worker shall cease work immediately until a replacement individual monitoring device is provided and the exposure is calculated for the time period from issuance to loss or damage of the individual monitoring device. The results of the calculated exposure and the time period for which the individual monitoring device was lost or damaged shall be included in the records maintained in accordance with subsection (w)(8) of this section.~~

~~—(3) Pocket dosimeters or electronic personal dosimeters shall be checked for correct response to radiation at periods not to exceed one year. Acceptable dosimeters shall read within plus or minus 20% of the true radiation exposure.~~

~~—(4) Each alarming ratemeter shall:~~

~~—(A) be checked without being exposed to radiation prior to use at the start of each work shift, to ensure that the audible alarm is functioning properly;~~

~~—(B) be set to give an alarm signal at a preset dose rate of 500 mrem/hr (5 mSv/hr) or lower with an accuracy of plus or minus 20% of the true radiation dose rate;~~

~~—(C) require special means to change the preset alarm function; and~~

~~—(D) be calibrated for correct response to radiation at intervals not to exceed one year.~~

~~—(5) The following records required by this subsection shall be made and maintained in accordance with subsection (w)(8) of this section:~~

~~—(A) Records of pocket dosimeter response.~~

~~—(B) Records of pocket dosimeter and electronic personal dosimeter readings of personnel exposures.~~

~~—(6) The following records required by this subsection shall be maintained in accordance with subsection (w)(8) of this section:~~

~~—(A) Records of alarming ratemeter calibrations.~~

~~—(B) Records of individual monitoring device monitoring results received from the individual monitoring device processor.~~

~~(f) Access control:~~

~~—(1) During each industrial radiographic operation, radiographic personnel shall maintain visual surveillance of the operation to protect against unauthorized entry into a radiation area or high radiation area, except at permanent radiographic installations where all entryways are locked and the requirements of subsection (j) of this section are met.~~

~~—(2) Radiographic exposure devices shall not be left unattended except when in storage or physically secured against unauthorized removal or tampering.~~

~~(s) Posting. All areas in which industrial radiography is being performed shall be posted conspicuously in accordance with §289.202 of this title including the following.~~

~~—(1) Radiation areas. Each radiation area shall be posted conspicuously with a sign(s) displaying the radiation caution symbol and the words "CAUTION, RADIATION AREA" or "DANGER, RADIATION AREA."~~

~~—(2) High radiation area. Each high radiation area shall be posted conspicuously with a sign(s) displaying the radiation caution symbol and the words "CAUTION, HIGH RADIATION AREA" or "DANGER, HIGH RADIATION AREA."~~

~~—(3) Whenever practicable, ropes and/or barriers shall be used in addition to appropriate signs to designate areas in accordance with §289.202(n)(1) of this title and to help prevent unauthorized entry.~~

~~-(4) During pipeline industrial radiographic operations, sufficient radiation signs and other barriers shall be posted to prevent unmonitored individuals from entering the area in accordance with §289.202(n)(1) of this title.~~

~~-(5) In lieu of the requirements of subsection (s)(1) and (2) of this section, a restricted area may be established in accordance with §289.202(n)(1) of this title and be posted in accordance with subsection (s)(1) and (2) of this section, for example, both signs may be posted at the same location at the boundary of the restricted area.~~

~~-(6) Exceptions listed in §289.202(bb) of this title do not apply to industrial radiographic operations.~~

~~(t) Specific requirements for radiographic personnel performing industrial radiography.~~

~~-(1) At a job site, the following shall be supplied by the licensee or registrant:~~

~~—(A) at least one operable, calibrated survey instrument for each exposure device or radiation machine in use;~~

~~—(B) an individual monitoring device that meets the requirements of §289.202(p)(3) of this title for each worker;~~

~~—(C) an operable, calibrated pocket dosimeter or electronic personal dosimeter with a range of zero to 200 mrem (2 mSv) for each worker;~~

~~—(D) an operable, calibrated, alarming ratemeter for each worker; and~~

~~—(E) the appropriate barrier ropes and signs.~~

~~-(2) Each radiographer at a job site shall carry a valid certification ID card issued by the agency or another certifying entity whose certification offers the same or comparable certification standards.~~

~~-(3) Each radiographer trainee at a job site shall carry a trainee status card issued by the agency or equivalent documentation in accordance with subsection (m)(1) of this section.~~

~~-(4) Radiographic personnel shall not perform radiographic operations if any of the items in paragraphs (1) (3) of this subsection are not available at the job site or are inoperable.~~

~~Radiographic personnel shall ensure that the items listed in paragraph (1) of this subsection, radiographic exposure devices, and radiation machines are used in accordance with the requirements of this section.~~

~~-(5) During an inspection by the agency, an agency inspector may terminate an operation if any of the items in paragraphs (1) (3) of this subsection are not available and operable or if the required number of radiographic personnel are not present. Operations shall not be resumed until all required conditions are met.~~

~~(u) Radiation safety requirements for the use of radiation machines.~~

~~-(1) Locking of radiation machines. The control panel of each radiation machine shall be equipped with a locking device that will prevent the unauthorized use of an x ray system or the accidental production of radiation. The radiation machine shall be kept locked and the key removed at all times except when under the direct visual surveillance of a radiographer.~~

~~-(2) Permanent storage precautions for the use of radiation machines. Radiation machines shall be secured while in storage to prevent tampering or removal by unauthorized individuals.~~

~~-(3) Requirements for radiation machines used in industrial radiographic operations.~~

~~(A) Equipment used in industrial radiographic operations involving radiation machines manufactured after October 1, 1987, shall be certified at the time of manufacture to meet the criteria set forth by ANSI N537-1976, except accelerators used in industrial radiography.~~

~~—(B) The registrant's name and city or town where the main business office is located shall be prominently displayed with a durable, legible, clearly visible label(s) on both sides of all vehicles used to transport radiation machines for temporary job-site use.~~

~~—(4) Operating and internal audit requirements for the use of radiation machines:~~

~~—(A) Each registrant shall conduct an internal audit program to ensure that the requirements of this chapter, the conditions of the certificate of registration, and the registrant's operating, safety, and emergency procedures are followed by radiographic personnel.~~

~~—(B) Each radiographer's and radiographer trainee's performance during an actual radiographic operation shall be audited and documented at intervals not to exceed six months.~~

~~—(C) If a radiographer or a radiographer trainee has not participated in a radiographic operation during the six months since the last audit, the radiographer or the radiographer trainee shall demonstrate knowledge of the training requirements of subsection (n)(1) of this section by an oral or written and practical examination administered by the registrant before the individual can next participate in a radiographic operation.~~

~~—(D) The agency may consider alternatives in those situations where the individual serves as both radiographer and RSO.~~

~~—(E) In those operations where a single individual serves as both radiographer and RSO and performs all radiography operations, an audit program is not required.~~

~~—(F) The registrant shall provide annual refresher safety training, as defined in subsection (e) of this section, for each radiographer trainee, radiographer, or radiographer trainer at intervals not to exceed 12 months.~~

~~—(G) No individual, other than a radiographer or a radiographer trainee, who is under the personal supervision of a radiographer trainer, shall manipulate controls or operate radiation machines used in industrial radiographic operations. Only one radiographer is required to operate radiation machines during industrial radiography.~~

~~—(H) Radiographic operations shall not be conducted at storage sites unless specifically authorized by the certificate of registration.~~

~~—(I) Records of audits specified in this subsection shall be made and maintained in accordance with subsection (w)(6)(A) of this section.~~

~~—(J) Records of the annual refresher training required by subparagraph (F) of this paragraph shall be made and maintained in accordance with subsection (w)(7).~~

~~—(5) Radiation surveys for the use of radiation machines:~~

~~—(A) No industrial radiographic operation shall be conducted unless at least one calibrated and operable radiation survey instrument, as described in subsection (f) of this section, is used for each radiation machine energized.~~

~~—(B) A physical radiation survey shall be made after each radiographic exposure using radiation machines to determine that the machine is "off."~~

~~—(C) All potential radiation areas where industrial radiographic operations are to be performed shall be posted in accordance with subsection (s) of this section, based on estimated dose rates, before industrial radiographic operations begin. An area survey shall be performed during the first radiographic exposure to confirm that subsection (s) of this section requirements have been met and that unrestricted areas do not have radiation levels in excess of the limits specified in §289.202(n)(1)(B) and (C) of this title.~~

~~—(D) Records of the surveys required by subparagraph (C) of this paragraph shall be made and maintained in accordance with subsection (w)(12) of this section.~~

~~—(6) Requirements for radiation machines in enclosed radiography.~~

~~—(A) Systems for enclosed radiography, including shielded room radiography and cabinet x-ray systems not otherwise exempted, shall comply with all applicable requirements of this section.~~

~~—(B) Systems for enclosed radiography designed to allow admittance of individuals and systems not otherwise exempted shall be evaluated at intervals not to exceed one year to ensure compliance with the applicable requirements of this section and §289.202(n)(1)-(3) of this title.~~

~~—(C) Certified and certifiable cabinet x-ray systems, including those designed to allow admittance of individuals, are exempt from the requirements of this section except that:~~

~~—(i) No registrant shall permit any individual to operate a cabinet x-ray system until the individual has received a copy of and instruction in the operating procedures for the unit.~~

~~—(ii) Tests for proper operation of interlocks must be conducted and recorded at intervals not to exceed 12 months.~~

~~—(iii) The registrant shall perform an evaluation to determine compliance with §289.202(n)(1)-(3) of this title and 21 CFR 1020.40 at intervals not to exceed one year.~~

~~—(D) Certified cabinet x-ray systems shall be maintained in compliance with 21 CFR 1020.40 and no modification shall be made to the system unless prior agency approval has been granted in accordance with §289.201(e)(1) of this title.~~

~~—(E) Records required by this subsection shall be made and maintained in accordance with subsection (w)(13) of this section.~~

~~—(7) Registration requirements for industrial radiographic operations.~~

~~—(A) Radiation machines used in industrial radiographic operations shall be registered in accordance with §289.226 of this title.~~

~~—(B) In addition to the registration requirements in §289.226(c) and (h) of this title, an application for a certificate of registration shall include the following information:~~

~~—(i) a schedule or description of the program for training radiographic personnel that specifies:~~

~~—(I) initial training;~~

~~—(II) annual refresher training;~~

~~—(III) on the job training;~~

~~—(IV) procedures for administering the oral and written examination to determine the knowledge, understanding, and ability of radiographic personnel to comply with the requirements of this chapter, the conditions of the certificate of registration, and the registrant's operating, safety, and emergency procedures; and~~

~~—(V) procedures for administering the practical examination to demonstrate competence in the use of sources of radiation, radiographic exposure devices, related handling tools, and radiation survey instruments that may be employed in industrial radiographic assignments.~~

~~—(ii) written operating, safety, and emergency procedures, including all items listed in subsection (y)(4) of this section;~~

~~—(iii) a description of the internal audit program to ensure that radiographic personnel follow the requirements of this chapter, the conditions of the certificate of registration, and the registrant's operating, safety, and emergency procedures at intervals not to exceed six months;~~

~~—(iv) a list of permanent radiographic installations, descriptions of permanent storage use sites, and the location(s) where all records required by this section and other sections of this chapter~~

will be maintained. Radiographic equipment shall not be stored or used at a permanent site unless such site is specifically authorized by the certificate of registration. A storage site is permanent if radiation machines are stored at that location and if one or more of the following applies:

—(I) the registrant establishes telephone service that is used for contracting or providing industrial radiographic services for the registrant;

—(II) industrial radiographic services are advertised for or from the site;

—(III) radiation machines stored at that location are used for industrial radiographic operations conducted at other sites; or

—(IV) any registrant conducting radiographic operations or storing radiation machines at any location not listed on the certificate of registration for a period in excess of 90 days in a calendar year, shall notify the agency prior to exceeding the 90 days.

—(v) a description of the organization of the industrial radiographic program, including delegations of authority and responsibility for operation of the radiation safety program; and

—(vi) procedures for verifying and documenting the certification status of radiographers and for ensuring that the certification of individuals acting as radiographers remains valid.

—(C) A certificate of registration will be issued if the requirements of this paragraph of this subsection and §289.226(e) and (h) of this title are met.

(v) Radiation safety requirements for the use of sealed sources.

—(1) Limits on external radiation levels from storage containers and source changers. The maximum exposure rate limits for storage containers and source changers are 200 mrem/hr (2 mSv/hr) at any exterior surface, and 10 mrem/hr (0.1 mSv/hr) at 1 meter from any exterior surface with the sealed source in the shielded position.

—(2) Locking of radiographic exposure devices, storage containers and source changers.

—(A) Each radiographic exposure device, storage container, and source changer shall have a lock or outer locked container designed to prevent unauthorized or accidental removal or exposure of a sealed source. Each exposure device and source changer shall be kept locked and, if a keyed lock, the key removed at all times except when under the direct visual surveillance of a radiographer or an individual specifically authorized by the agency.

—(B) Each radiographic exposure device, storage container, and source changer shall be locked and the key removed from any keyed lock prior to being transported from one location to another and also prior to being stored at a given location.

—(3) Permanent storage precautions for the use of sealed sources.

—(A) Radiographic exposure devices, source changers, and transport containers that contain sealed sources shall be secured while in storage to prevent tampering or removal by unauthorized individuals.

—(B) Radiographic exposure devices, source changers, or transport containers that contain radioactive material may not be stored in residential locations. This section does not apply to storage of radioactive material in a vehicle in transit for use at temporary job sites, if the licensee complies with paragraph (8)(G) of this subsection and if the vehicle does not constitute a permanent storage location as described in paragraph (12)(B)(iv) of this subsection.

—(4) Performance requirements for industrial radiography equipment. Equipment used in industrial radiographic operations shall meet the following minimum criteria.

~~—(A) Each radiographic exposure device, source assembly, sealed source, and associated equipment shall meet the criteria set forth by ANSI N432-1980.~~

~~—(i) All newly manufactured radiographic exposure devices and associated equipment acquired by licensees after September 1, 1993, shall comply with the requirements of this section.~~

~~—(ii) All radiographic exposure devices and associated equipment in use after January 1, 1996, shall comply with the requirements of this section.~~

~~—(iii) In lieu of subparagraph (A) of this paragraph, equipment used in industrial radiographic operations need not comply with §8.9.2(c) of the Endurance Test in ANSI N432-1980, if the prototype equipment has been tested using a torque value representative of the torque that an individual using the radiography equipment can realistically exert on the lever or crankshaft of the drive mechanism.~~

~~—(B) Engineering analysis may be submitted by a licensee to demonstrate the applicability of previously performed testing on similar individual radiography equipment components. Upon review, the agency may find this an acceptable alternative to actual testing of the component in accordance with subparagraph (A) of this paragraph.~~

~~—(C) In addition to the requirements specified in subparagraph (A) of this paragraph the following requirements apply to radiographic exposure devices, source changers, source assemblies and sealed sources:~~

~~—(i) Radiographic exposure devices intended for use as Type B transport containers shall meet the applicable requirements of §289.257 of this title.~~

~~—(ii) Modification of radiographic exposure devices, source changers, source assemblies, and associated equipment is prohibited, unless specifically authorized on the license.~~

~~—(D) In addition to the requirements specified in subparagraphs (A)-(C) of this paragraph, radiographic exposure devices, source assemblies, and associated equipment that allow the source to move outside the device shall meet the following criteria:~~

~~—(i) The source assembly shall be designed so that the source will not become disconnected if cranked outside the guide tube. The source assembly must be such that it cannot be unintentionally disconnected under normal and reasonably foreseeable abnormal conditions.~~

~~—(ii) The drive cable must be positively connected to the source assembly before the source assembly can be driven out of the fully shielded position in a radiographic exposure device or source changer.~~

~~(iii) The radiographic exposure device shall automatically secure the source assembly when it is cranked back into the fully shielded position within the radiographic exposure device. This securing system shall only be released by means of a deliberate operation on the radiographic exposure device.~~

~~—(iv) The outlet nipple and drive cable fittings of each radiographic exposure device shall be equipped with safety plugs or covers that will protect the source assembly from damage and from other foreign matter, such as water, mud, or sand, during storage and transportation.~~

~~—(v) Each sealed source or source assembly shall have attached to it or engraved on it, a durable, legible, visible label with the words "DANGER. RADIOACTIVE." The label may not interfere with the safe operation of the exposure device or associated equipment.~~

~~—(vi) Guide tubes must be used when moving the source out of the radiographic exposure device.~~

~~—(vii) Guide tubes other than "J" tubes shall have passed the kinking and crushing tests for control units as specified in ANSI N432-1980.~~

~~—(viii) An exposure head, endcap, or similar device designed to prevent the source assembly from extending beyond the end of the guide tube shall be attached to the outermost end of the guide tube during radiographic operations.~~

~~—(ix) The guide tube exposure head connection must be able to withstand the tensile test for control units as specified in ANSI N432-1980.~~

~~—(x) Source changers shall provide a system for ensuring that the source will not be accidentally withdrawn from the changer when connecting or disconnecting the drive cable to or from a source assembly.~~

~~—(5) Leak testing, repair, opening, and replacement of sealed sources and devices. Leak testing, repair, opening, and replacement of sealed sources and devices shall be performed according to the following criteria:~~

~~—(A) Leak testing of sealed sources shall be done in accordance with §289.201(g) of this title, except records of leak tests shall be maintained in accordance with subsection (w)(11) of this section.~~

~~—(B) The replacement, leak testing analysis, repair, opening, or any modification of a sealed source shall be performed only by persons specifically authorized to do so by the agency, the NRC, or another agreement state.~~

~~—(C) Each exposure device using DU shielding and an "S" tube configuration shall be tested for DU contamination:~~

~~—(i) Tests for DU contamination shall be performed at intervals not to exceed 12 months.~~

~~—(ii) The analysis shall be capable of detecting the presence of 0.005 microcuries (185 Bq) of radioactive material on the test sample and shall be performed by a person specifically authorized by the agency, the NRC, or an agreement state to perform the analysis.~~

~~—(iii) Should such testing reveal the presence of DU contamination, the exposure device shall be removed from use until an evaluation of the wear of the S-tube has been made.~~

~~—(iv) Should the evaluation reveal that the S-tube is worn through, the device may not be used again.~~

~~—(v) DU shielded devices do not have to be tested for DU contamination while in storage and not in use.~~

~~—(vi) The device shall be tested for DU contamination before using or transferring such a device, if the interval of storage exceeds 12 months.~~

~~—(D) A record of the DU leak test shall be maintained in accordance with subsection (w)(11) of this section.~~

~~—(6) Labeling and storage.~~

~~—(A) Each transport container shall have permanently attached to it a durable, legible, clearly visible label(s) that has, as a minimum, the standard trefoil radiation caution symbol conventional colors, for example, magenta, purple or black on a yellow background, having a minimum diameter of 25 millimeters, and the following wording "CAUTION. RADIOACTIVE MATERIAL. NOTIFY CIVIL AUTHORITIES (OR NAME OF COMPANY)" or "DANGER. RADIOACTIVE MATERIAL. NOTIFY CIVIL AUTHORITIES (OR NAME OF COMPANY)." In addition, transport containers shall meet applicable requirements of the DOT.~~

~~—(B) Radiographic exposure devices, source changers, and storage containers shall be physically secured to prevent tampering or removal by unauthorized personnel. The licensee shall store radioactive material in a manner that will minimize danger from explosion or fire.~~

~~—(C) The licensee shall lock and physically secure the transport package containing radioactive material in the transporting vehicle to prevent accidental loss, tampering, or unauthorized removal.~~

~~—(D) The licensee's name and city or town where the main business office is located shall be prominently displayed with a durable, clearly visible label(s) on both sides of all vehicles used to transport radioactive material for temporary job-site use.~~

~~—(E) The licensee shall ensure that each radiographic exposure device has attached to it a durable, legible, clearly visible label bearing the following:~~

- ~~—(i) chemical symbol and mass number of the radionuclide in the device;~~
- ~~—(ii) activity and the date on which this activity was last measured;~~
- ~~—(iii) manufacturer, model and serial number of the sealed source;~~
- ~~—(iv) licensee's name, address, and telephone number; and~~
- ~~—(v) as a minimum, the standard radiation caution symbol as defined in §289.202 of this title, and the following wording "CAUTION. RADIOACTIVE MATERIAL—DO NOT HANDLE. NOTIFY CIVIL AUTHORITIES (OR NAME OF COMPANY)" or "DANGER. RADIOACTIVE MATERIAL—DO NOT HANDLE. NOTIFY CIVIL AUTHORITIES (OR NAME OF COMPANY)."~~

~~—(F) Each radiographic exposure device shall have a permanently stamped, legible, and clearly visible unique serial number.~~

~~—(7) Operating and internal audit requirements for the use of sealed sources of radiation.~~

~~—(A) Each licensee shall conduct an internal audit program to ensure that the requirements of this chapter, the conditions of the license, and the licensee's operating, safety, and emergency procedures are followed by radiographic personnel.~~

~~—(B) Each radiographer's and radiographer trainee's performance during an actual radiographic operation shall be audited and documented at intervals not to exceed six months.~~

~~—(C) If a radiographer or a radiographer trainee has not participated in a radiographic operation during the six months since the last audit, the radiographer or the radiographer trainee shall demonstrate knowledge of the training requirements of subsection (n)(1) of this section by an oral or written and practical examination administered by the licensee before these individuals can next participate in a radiographic operation.~~

~~—(D) The agency may consider alternatives in those situations where the individual serves as both radiographer and RSO.~~

~~—(E) In those operations where a single individual serves as both radiographer and RSO, and performs all radiography operations, an inspection program is not required.~~

~~—(F) Each licensee shall provide annual refresher safety training, as defined in subsection (e) of this section, for each radiographer and radiographer trainee at intervals not to exceed 12 months.~~

~~—(G) Each licensee shall provide, as a minimum, two radiographic personnel for each exposure device in use for any industrial radiography conducted at a location other than at a permanent radiographic installation (shielded room, bay, or bunker) meeting the requirements of subsection (j)(1) of this section. If one of the personnel is a radiographer trainee, the other shall be a radiographer trainer authorized by the license.~~

- ~~—(H) Collimators shall be used in industrial radiographic operations that use crank-out devices except when physically impossible.~~
- ~~—(I) No individual other than a radiographer or a radiographer trainee who is under the personal supervision of a radiographer trainer shall manipulate controls or operate radiographic exposure devices and associated equipment used in industrial radiographic operations.~~
- ~~—(J) Radiographic operations shall not be conducted at storage sites unless specifically authorized by the license.~~
- ~~—(K) Records of audits specified in this subsection shall be made and maintained by the licensee in accordance with subsection (w)(6)(B) of this section.~~
- ~~—(L) Records of the annual refresher training required by subparagraph (F) of this paragraph shall be made and maintained in accordance with subsection (w)(7) of this section.~~
- ~~—(8) Radiation surveys for the use of sealed sources of radiation.~~
- ~~—(A) No industrial radiographic operation shall be conducted unless at least one calibrated and operable radiation survey instrument, as described in subsection (f) of this section, is used at each site where radiographic exposures are made.~~
- ~~—(B) A survey with a radiation survey instrument meeting the requirements of subsection (f)(1)-(3) of this section shall be made after each radiographic exposure to determine that the sealed source has been returned to its fully shielded position, and before exchanging films, repositioning the exposure head, or dismantling equipment. The entire circumference of the radiographic exposure device shall be surveyed. If the radiographic exposure device has a source guide tube, the survey shall also include the source guide tube and any collimator.~~
- ~~—(C) All potential radiation areas where industrial radiographic operations are to be performed shall be posted in accordance with subsection (s) of this section, based on calculated dose rates, before industrial radiographic operations begin. An area survey shall be performed during the first radiographic exposure (for example, with the sealed source in the exposed position) to confirm that the requirements of subsection (s) of this section have been met.~~
- ~~—(D) Each time re-establishment of the restricted area is required, the requirements of subparagraph (C) of this paragraph shall be met.~~
- ~~—(E) The requirements of subparagraph (D) of this paragraph do not apply to pipeline industrial radiographic operations when the conditions of exposure including, but not limited to, the radiographic exposure device, duration of exposure, source strength, pipe size, and pipe thickness remain constant.~~
- ~~—(F) A lock-out survey, in which all accessible surfaces of the radiographic exposure device or source changer are surveyed, shall be performed.~~
- ~~—(G) Surveys shall be performed on storage containers to ensure that radiation levels do not exceed the limits specified in §289.202(n)(1) of this title. These surveys shall be performed initially with the maximum amount of radioactive material present in the storage location and thereafter at the time of the quarterly inventory and whenever storage conditions change.~~
- ~~—(H) A survey meeting the requirements of subparagraph (B) of this paragraph shall be performed on the radiographic exposure device and the source changer after every sealed source exchange.~~
- ~~—(I) Records of the surveys required by subparagraphs (C), (D), and (F)-(H) of this paragraph shall be made and maintained in accordance with subsection (w)(12) of this section.~~
- ~~—(9) Requirements for sealed sources in enclosed radiography.~~

~~—(A) Systems for enclosed radiography, including shielded room radiography not otherwise exempted, shall comply with all applicable requirements of this section.~~

~~—(B) Systems for enclosed radiography designed to allow admittance of individuals and systems not otherwise exempted shall be evaluated at intervals not to exceed one year to ensure compliance with the applicable requirements of this section and §289.202(n)(1)-(3) of this title.~~

~~—(C) Tests for proper operation of interlocks must be conducted and recorded in accordance with subsection (j) of this section.~~

~~—(D) Records required by this subsection shall be made and maintained in accordance with subsection (w)(14) of this section.~~

~~—(10) Underwater, offshore platform, and lay barge radiography.~~

~~—(A) Underwater, offshore platform, and/or lay barge radiography shall not be performed unless specifically authorized in a license issued by the agency in accordance with subsection (v)(12) of this section.~~

~~—(B) In addition to the other requirements of this section, the following requirements apply to the performance of offshore platform or lay barge radiography.~~

~~—(i) Cobalt 60 sources with activities in excess of 20 curies (nominal) and iridium 192 sources with activities in excess of 100 curies (nominal) shall not be used in the performance of offshore platform or lay barge radiography.~~

~~—(ii) Collimators shall be used for all industrial radiographic operations performed on offshore platforms or lay barges.~~

~~—(11) Prohibitions.~~

~~—(A) Industrial radiography performed with a sealed source that is not fastened to or contained in a radiographic exposure device (fishpole technique) is prohibited unless specifically authorized in a license issued by the agency.~~

~~—(B) Retrieval of disconnected sources or sources that cannot be returned by normal means to a fully shielded position or automatically secured in the radiographic exposure device, shall not be performed unless specifically authorized by a license condition.~~

~~—(12) Licensing requirements for industrial radiographic operations.~~

~~—(A) Sealed sources used in industrial radiographic operations shall be licensed in accordance with §289.252 of this title.~~

~~(B) In addition to the licensing requirements in §289.252 of this title, an application for a license shall include the following information:~~

~~—(i) A schedule or description of the program for training radiographic personnel that specifies:~~

~~—(I) initial training;~~

~~—(II) annual refresher training;~~

~~—(III) on-the-job training;~~

~~—(IV) procedures for administering the oral and written examinations to determine the knowledge, understanding, and ability of radiographic personnel to comply with the requirements of this chapter, the conditions of the license, and the licensee's operating, safety, and emergency procedures; and~~

~~—(V) procedures for administering the practical examination to demonstrate competence in the use of sources of radiation, radiographic exposure devices, related handling tools, and radiation survey instruments that may be employed in industrial radiographic assignments.~~

- ~~—(ii) Written operating, safety, and emergency procedures, including all items listed in subsection (y)(4) of this section.~~
- ~~—(iii) A description of the internal audit program to ensure that radiographic personnel follow the requirements of this chapter, the conditions of the license, and the licensee's operating, safety, and emergency procedures at intervals not to exceed six months.~~
- ~~—(iv) A list of permanent radiographic installations, descriptions of permanent storage and use sites, and the location(s) where all records required by this section and other sections of this chapter will be maintained. If records are to be maintained at a headquarters office in Texas and no use or storage is authorized for the site, this site will be designated as the main site. Radioactive material shall not be stored or used at a permanent use site unless such site is specifically authorized by the license. Any licensee conducting radiographic operations or storing radioactive material at any location not listed on the license for a period in excess of 90 days in a calendar year, shall notify the agency prior to exceeding the 90 days. A storage site is permanent if radioactive material is stored at that location and if any one or more of the following applies:
 - ~~—(I) the licensee establishes telephone service that is used for contracting or providing industrial radiographic services for the licensee;~~
 - ~~—(II) industrial radiographic services are advertised for or from the site;~~
 - ~~—(III) radioactive material stored at that location is used for industrial radiographic operations conducted at other sites; or~~
 - ~~—(IV) any licensee conducting radiographic operations or storing radioactive material at any location not listed on the license for a period in excess of 90 days in a calendar year.~~~~
- ~~—(v) A description of the organization of the industrial radiographic program, including delegations of authority and responsibility for operation of the radiation safety program.~~
- ~~—(vi) A description of the program for inspection and maintenance of radiographic exposure devices and transport and storage containers (including items in subsection (y)(2) of this section and the applicable items in subsection (i) of this section).~~
- ~~—(vii) If a license application includes underwater radiography, as a minimum a description of:
 - ~~—(I) radiation safety procedures and radiographer responsibilities unique to the performance of underwater radiography;~~
 - ~~—(II) radiographic equipment and radiation safety equipment unique to underwater radiography; and~~
 - ~~—(III) methods for gas-tight encapsulation of equipment.~~~~
- ~~—(viii) If a license application includes offshore platform and/or lay barge radiography, as a minimum a description of:
 - ~~—(I) transport procedures for radioactive material to be used in industrial radiographic operations;~~
 - ~~—(II) storage facilities for radioactive material; and~~
 - ~~—(III) methods for restricting access to radiation areas.~~~~
- ~~—(C) Procedures for verifying and documenting the certification status of radiographers and for ensuring that the certification of individuals acting as radiographers remains valid.~~
- ~~—(D) If a licensee intends to perform leak testing of sealed sources or exposure devices containing DU shielding, the licensee shall describe the procedures for performing the leak test.~~

~~—(E) If the licensee intends to analyze its own wipe samples, the application shall include a description of the procedures to be followed. The description shall include at least the following:~~

- ~~—(i) instruments to be used;~~
- ~~—(ii) methods of performing the analysis; and~~
- ~~—(iii) pertinent experience of the person who will analyze the wipe samples.~~

~~—(F) If the licensee intends to perform "in house" calibrations of survey instruments, the licensee shall describe methods to be used and the relevant experience of the person(s) who will perform the calibrations.~~

~~—(G) A license will be issued if the requirements of this paragraph of this subsection and §289.252 of this title are met.~~

~~(w) Record keeping requirements.~~

~~—(1) Records of receipt, transfer, and disposal of sources of radiation and devices using DU for shielding.~~

- ~~—(A) Each licensee and registrant shall maintain records showing the receipt, transfer, and disposal of sources of radiation and devices using DU for shielding as required by subsection (e) of this section for agency inspection until disposal is authorized by the agency.~~
- ~~—(B) These records shall include the following, as appropriate:~~

- ~~—(i) date of receipt, transfer, or disposal;~~
- ~~—(ii) name of the individual making the record;~~
- ~~—(iii) radionuclide;~~
- ~~—(iv) number of curies (becquerels) or mass (for DU); and~~
- ~~—(v) manufacturer, model, and serial number of each source of radiation and/or device.~~

~~—(2) Records of radiation survey instruments. Each licensee and registrant shall maintain records of the calibrations required by subsection (f)(2) of this section for agency inspection for two years after the calibration date.~~

~~—(3) Records of quarterly inventory.~~

- ~~—(A) Each licensee and registrant shall maintain records of the quarterly inventory of sources of radiation, including devices containing DU as required by subsection (g) of this section for agency inspection for two years from the date of the inventory.~~
- ~~—(B) The record shall include the following for each source of radiation, as appropriate:~~

- ~~—(i) manufacturer, model, and serial number;~~
- ~~—(ii) radionuclide;~~
- ~~—(iii) number of curies (except for depleted uranium);~~
- ~~—(iv) location of each source of radiation;~~
- ~~—(v) date of the inventory; and~~
- ~~—(vi) name of the individual making the inventory.~~

~~—(4) Records of inspection and maintenance of radiation machines, radiographic exposure devices, transport and storage containers, associated equipment, source changers, and survey instruments.~~

- ~~—(A) Each licensee and registrant shall maintain records specified in subsection (i)(3) of this section of equipment problems found in daily checks and quarterly inspections of:~~

- ~~—(i) radiographic exposure devices;~~
- ~~—(ii) transport and storage containers;~~
- ~~—(iii) associated equipment;~~

- (iv) source changers;
- (v) survey instruments; and
- (vi) radiation machines.
- (B) The record shall include the following:
 - (i) date of check or inspection;
 - (ii) name of inspector;
 - (iii) equipment involved;
 - (iv) any problems found; and
 - (v) what repairs or maintenance, if any, were done.
- (C) Each record shall be maintained for agency inspection for two years from the date of the inspection.
- (5) Records of alarm systems and entrance control tests at permanent radiographic installations. Each licensee and registrant shall maintain records of alarm system and entrance control device tests required by subsection (j) of this section for agency inspection for two years from the date of the test.
- (6) Records of operating and internal audit requirements.
 - (A) Records of operating and internal audit requirements for the use of radiation machines specified by subsection (u)(4) of this section shall be maintained by the registrant for agency inspection for two years from the date of the audit.
 - (B) Records of operating and internal audit requirements for the use of sealed sources specified by subsection (v)(7) of this section shall be maintained by the licensee for agency inspection for two years from the date of the audit.
- (7) Records of training and certification.
 - (A) Each licensee and registrant shall maintain for agency inspection the following clear and legible training and certification records that demonstrate that the applicable requirements of subsections (m)(1)(A) and (2)(A) and (n) of this section are met for all industrial radiographic personnel for agency inspection. A copy of the trainee status card will satisfy the documentation requirements of subsection (m)(1)(A) of this section. A copy of the certification ID card will satisfy the documentation requirements of subsection (m)(2)(A) of this section.
 - (i) Records of training shall include the following:
 - (I) radiographer certification documents and verification of certification status;
 - (II) copies of written tests administered by the licensee or registrant;
 - (III) dates of oral and practical examinations and names of individuals conducting and receiving the oral and practical examinations; and
 - (IV) a list of items tested and the results of the oral and practical examinations.
 - (ii) Records of annual refresher safety training and audits of job performance made in accordance with subsections (u)(4) and (v)(7) of this section shall include the following:
 - (I) list the topics discussed during the refresher safety training;
 - (II) dates the annual refresher safety training was conducted;
 - (III) names of the instructors and attendees; and
 - (IV) for audits of job performance, the records shall also include a list showing the items checked and any non-compliance observed by the RSO or designee.
 - (B) Records required by subsections (m)(1)(A) and (2)(A) and (n)(1) of this section shall be maintained for agency inspection for five years after the record is made.

- ~~—(C) Records of the annual refresher training required by subsections (u)(4)(F) and (v)(7)(F) of this section shall be maintained for agency inspection for two years after the record is made.~~
- ~~—(8) Records of personnel monitoring procedures. Each licensee and registrant shall maintain the following exposure records specified in subsection (q) of this section:~~
- ~~—(A) Direct reading pocket dosimeter or electronic personal dosimeter readings and yearly operational checks required by subsection (q) of this section shall be maintained for agency inspection for two years. If the dosimeter readings were used to determine external radiation dose (for example, no individual monitoring device exposure records exist), the records shall be maintained for agency inspection until disposal is authorized by the agency.~~
- ~~—(B) Records of alarming ratemeter calibrations shall be maintained for agency inspection for two years.~~
- ~~—(C) Reports received from the individual monitoring device processor shall be maintained for agency inspection until disposal is authorized by the agency.~~
- ~~—(D) Records of estimates of exposures as a result of off-scale personal direct-reading dosimeters, or lost or damaged individual monitoring devices, shall be maintained for agency inspection until disposal is authorized by the agency.~~
- ~~—(9) Records and documents required at additional authorized use/storage sites:~~
- ~~—(A) Each licensee or registrant maintaining additional authorized use/storage sites where industrial radiography operations are performed shall have copies of the following records and documents specific to that site available at each site for inspection by the agency:~~
- ~~—(i) a copy of the appropriate license or certificate of registration authorizing the use of licensed or registered sources of radiation;~~
- ~~—(ii) operating, safety, and emergency procedures in accordance with subsection (y)(4) of this section;~~
- ~~—(iii) applicable sections of this chapter as listed in the license or certificate of registration;~~
- ~~—(iv) records of receipt, transfer, and disposal of sources of radiation and devices using DU for shielding at the additional site in accordance with subsection (e) of this section;~~
- ~~—(v) records of the latest survey instrument calibrations in use at the site in accordance with subsection (f) of this section;~~
- ~~—(vi) records of the latest calibrations of alarming ratemeters and operational checks of pocket dosimeters and/or electronic personal dosimeters in accordance with subsection (q) of this section;~~
- ~~—(vii) inventories in accordance with subsection (g) of this section;~~
- ~~(viii) utilization records for each radiographic exposure device and radiation machine dispatched from that location in accordance with subsection (h) of this section;~~
- ~~—(ix) records of equipment problems identified in daily checks of equipment in accordance with subsection (i) of this section, if applicable;~~
- ~~—(x) records of alarm systems and entrance control checks in accordance with subsection (j) of this section;~~
- ~~—(xi) training records in accordance with subsection (n) of this section;~~
- ~~—(xii) records of direct reading dosimeter readings in accordance with subsection (q) of this section;~~
- ~~—(xiii) audits in accordance with subsections (u)(4)(A)-(C) and (v)(7)(A)-(C) of this section;~~

- ~~—(xiv) latest radiation survey records in accordance with subsections (u)(5)(D) and (v)(8)(J) of this section;~~
- ~~—(xv) records of interlock testing in accordance with subsections (u)(6)(C)(ii) and (v)(9)(C) of this section;~~
- ~~—(xvi) records of annual evaluation of cabinet x ray systems in accordance with subsection (u)(6)(C)(iii) of this section;~~
- ~~—(xvii) records of leak tests for specific devices and sources at the additional site in accordance with subsection (v)(5) of this section;~~
- ~~—(xviii) shipping papers for the transportation of sources of radiation in accordance with §289.257 of this title; and~~
- ~~—(xix) a copy of the agreement state license or certificate of registration authorizing the use of sources of radiation, when operating under reciprocity in accordance with §289.226 of this title and §289.252 of this title.~~
- ~~—(B) Records required in accordance with this subsection shall be maintained for agency inspection for a period of two years.~~
- ~~—(C) Records required in accordance with this subsection shall also be maintained at the main authorized site.~~
- ~~—(10) Records required at temporary job sites. Each licensee and registrant conducting industrial radiography at a temporary job site shall have the following records available at that site for agency inspection:~~
 - ~~—(A) a copy of the appropriate license or certificate of registration or equivalent document authorizing the use of sources of radiation;~~
 - ~~—(B) operating, safety, and emergency procedures in accordance with subsection (y)(4) of this section;~~
 - ~~—(C) applicable sections of this chapter as listed in the license or certificate of registration;~~
 - ~~—(D) latest radiation survey records required in accordance with subsections (u)(5)(D) and (v)(8)(I) of this section for the period of operation at the site;~~
 - ~~—(E) the daily pocket dosimeter records for the period of operation at the site;~~
 - ~~—(F) utilization records for each radiographic exposure device or radiation machine dispatched from that location in accordance with subsection (h) of this section; and~~
 - ~~—(G) the latest instrument calibration and leak test records for devices at the site. Acceptable records include tags or labels that are attached to the devices or survey instruments and decay charts for sources that have been manufactured within the last six months.~~
- ~~—(11) Records of leak testing of sealed sources and devices containing DU. Each licensee shall maintain records of leak testing of sealed sources and devices containing DU required by subsection (v)(5) of this section for agency inspection for two years from the date of the leak test.~~
- ~~—(12) Records of radiation surveys. Records of the surveys required by subsections (u)(5) and (v)(8) of this section shall be maintained for agency inspection for two years after completion of the survey. If a survey was used to determine an individual's exposure due to loss of personnel monitoring data, the records of the survey shall be maintained for agency inspection until disposal is authorized by the agency.~~
- ~~—(13) Records of requirements for radiation machines in enclosed radiography.~~
 - ~~—(A) Records of evaluations required by subsection (u)(6)(B) of this section shall be maintained for agency inspection for five years from the date of the evaluation.~~

~~—(B) Records of operating instructions in cabinet x ray systems required by subsection (u)(6)(C)(i) of this section and interlock tests required by subsection (u)(6)(C)(ii) of this section shall be maintained for agency inspection for five years from the date of the test.~~

~~—(C) Records of evaluation of certified cabinet x ray systems required by subsection (u)(6)(C)(iii) of this section shall be maintained for agency inspection for five years from the date of the evaluation.~~

~~—(14) Records of requirements for sealed sources in enclosed radiography.~~

~~—(A) Records of evaluations required by subsection (v)(9)(B) of this section shall be maintained for agency inspection for two years after the evaluation.~~

~~—(B) Records of interlock tests required by subsection (v)(9)(C) of this section shall be maintained for agency inspection for two years from the date of the test.~~

~~—(15) Records of utilization logs. Records of utilization logs shall be maintained for agency inspection for five years from the date the utilization log is made.~~

~~(x) Form of records.~~

~~—(1) Each record required by this section shall be legible throughout the specified retention period.~~

~~—(2) The record shall be the original or a reproduced copy or a microform provided that the copy or microform is authenticated by authorized personnel and that the microform is capable of reproducing a clear copy throughout the required retention period.~~

~~—(3) The record may also be stored in electronic media with the capability for producing legible, accurate, and complete records during the required retention period.~~

~~—(4) Records, such as letters, drawings, and specifications, shall include all pertinent information, such as stamps, initials, and signatures.~~

~~—(5) The licensee or registrant shall maintain adequate safeguards against tampering with and loss of records.~~

~~(y) Appendices.~~

~~—(1) Subjects to be included in training courses for radiographer trainees. Training provided to qualify individuals as radiographer trainees in compliance with subsection (m)(1)(A) of this section shall be presented on a formal basis. The training shall include the following subjects:~~

~~—(A) Fundamentals of radiation safety to include the following:~~

~~—(i) characteristics of radiation;~~

~~—(ii) units of radiation dose in rems (sieverts) and quantity of radioactivity in curies (becquerels);~~

~~—(iii) significance of radiation dose to include:~~

~~—(I) radiation protection standards;~~

~~—(II) biological effects of radiation dose;~~

~~—(III) hazards of exposure to radiation; and~~

~~—(IV) case histories of radiography accidents;~~

~~—(iv) levels of radiation from sources of radiation; and~~

~~—(v) methods of controlling radiation dose to include:~~

~~—(I) working time;~~

~~—(II) working distances; and~~

~~—(III) shielding.~~

~~—(B) Radiation detection instrumentation to include the following:~~

- (i) use, operation, calibration and limitations of radiation survey instruments;
 - (ii) survey techniques; and
 - (iii) use of individual monitoring devices to include as a minimum:
 - (I) film badges;
 - (II) TLDs;
 - (III) OSLs;
 - (IV) pocket dosimeters;
 - (V) alarming ratemeters; and
 - (VI) electronic personal dosimeters.
 - (C) Radiographic equipment to be used including the following:
 - (i) remote handling equipment;
 - (ii) operation and control of radiographic exposure devices and sealed sources, including pictures or models of source assemblies (pigtails);
 - (iii) storage and transport containers, source changers;
 - (iv) operation and control of x ray equipment;
 - (v) collimators;
 - (vi) storage, control, and disposal of radioactive material; and
 - (vii) inspection and maintenance of equipment.
 - (D) Requirements of pertinent federal and state regulations.
 - (E) Generic written operating, safety, and emergency procedures (see subsection (y)(4) of this section).
- (2) General requirements for inspection of industrial radiographic equipment.
- (A) Radiographic exposure devices shall be inspected for:
 - (i) abnormal surface radiation levels anywhere on camera, collimator, or guide tube;
 - (ii) condition of safety plugs;
 - (iii) proper operation of locking mechanism;
 - (iv) condition of pigtail connector;
 - (v) condition of carrying device (straps, handle, etc.); and
 - (vi) proper and legible labeling.
 - (B) Source tubes shall be inspected for:
 - (i) rust, dirt, or sludge buildup inside the source tube;
 - (ii) condition of source tube connector;
 - (iii) condition of source stop;
 - (iv) kinks or damage that could prevent proper operation; and
 - (v) presence of radioactive contamination.
 - (C) Control cables and drive mechanisms shall be inspected for:
 - (i) proper drive mechanism with camera, as appropriate;
 - (ii) changes in general operating characteristics;
 - (iii) condition of connector on drive cable;
 - (iv) drive cable flexibility, wear, and rust;
 - (v) excessive wear or damage to crank assembly parts;
 - (vi) damage to drive cable conduit that could prevent the cable from moving freely;
 - (vii) proper connector mating between the drive cable and the pigtail;
 - (viii) proper operation of source position indicator, if applicable; and

- (ix) presence of radioactive contamination.
- (D) Pipeliners shall be inspected for:
 - (i) abnormal surface radiation;
 - (ii) changes in the general operating characteristics of the unit;
 - (iii) proper operation of shutter mechanism;
 - (iv) chafing or binding of shutter mechanism;
 - (v) damage to the device that might impair its operation;
 - (vi) proper operation of locking mechanism;
 - (vii) proper drive mechanism with camera, as appropriate;
 - (viii) condition of carrying device (strap, handle, etc.); and
 - (ix) proper and legible labeling.
- (E) X ray equipment shall be inspected for:
 - (i) change in the general operating characteristics of the unit;
 - (ii) wear of electrical cables and connectors;
 - (iii) proper and legible labeling of console;
 - (iv) proper console with machine, as appropriate;
 - (v) proper operation of locking mechanism;
 - (vi) proper operation of timer run-down cutoff; and
 - (vii) damage to tube head housing that might result in excessive radiation levels.
- (3) Time requirements for record keeping. The following are time requirements for record keeping.

Attached Graphic

Figure: 25 TAC §289.255(y)(3)

Specific Subsection	Name of Record	Time Interval Required for Record Keeping
(e)	Receipt, Transfer, and Disposal	Until disposal is authorized by the agency
(f)(2)	Survey Instrument Calibrations	2 years
(g)	Quarterly Inventory	2 years
(h)	Utilization Logs	2 years
(i)	Inspection and Maintenance	2 years

(j)	Permanent Radiographic Installation Test	2 years
(m)(1)(A) and (2)(A) and (n)(1)	Training and Certification Records	5 years
(q)	Individual Monitoring Devices	Until disposal is authorized by the agency
	Estimates of Exposure	Until disposal is authorized by the agency
	Direct Reading Pocket or Electronic Personal Dosimeter Readings	2 years or until disposal is authorized by the agency if dosimeters were used to
	Pocket Dosimeter Calibrations	determine external radiation dose
	Alarming Ratemeter Calibrations	2 years
		2 years
(u)(4) and (v)(7)	Internal Audit Program	2 years
(u)(4)(F) and (v)(7)(F)	Annual Refresher Training	2 years
(u)(5) and (v)(8)	Radiation Surveys	2 years or until disposal is authorized by the agency if a survey was used to determine an individual's

		exposure
(u)(6)(B)	Annual Evaluation of Enclosed X-Ray Systems	5 years
(u)(6)(C)(i)	Operating Instructions In Cabinet X-Ray Systems	5 years
(u)(6)(C)(ii)	Tests of X-Ray Interlocks	5 years
(u)(6)(C)(iii)	Evaluation of Certified Cabinet X-Ray Systems	5 years
(v)(5)	Leak Tests	2 years
(v)(9)(B)	Annual Evaluation of Enclosed Sealed Source Systems	2 years
(v)(9)(C)	Test of Sealed Source Interlocks	2 years
(w)(10)	Records at Temporary Job Sites	During temporary job site operations

~~(4) Operating, safety, and emergency procedures. The licensee's or registrant's operating, safety, and emergency procedures shall include instructions in at least the following:~~

~~—(A) handling and use of sources of radiation for industrial radiography such that no individual is likely to be exposed to radiation doses that exceed the limits established in §289.202 of this title;~~

~~—(B) methods and occasions for conducting radiation surveys, including lock-out survey requirements;~~

~~—(C) methods for controlling access to industrial radiography areas;~~

~~—(D) methods and occasions for locking and securing sources of radiation;~~

~~—(E) personnel monitoring and the use of personnel monitoring equipment, including steps to be taken immediately by industrial radiographic personnel in the event a pocket dosimeter is found to be off scale (see subsection (q)(2)(F) of this section);~~

- (F) methods of transporting equipment to field locations, including packing of sources of radiation in the vehicles, placarding of vehicles, and controlling of sources of radiation during transportation (including applicable DOT requirements);
- (G) methods or procedures for minimizing exposure of individuals in the event of an accident, including procedures for a disconnect accident, a transportation accident, and loss of a sealed source;
- (H) procedures for notifying proper personnel in the event of an accident;
- (I) specific posting requirements;
- (J) maintenance of records (see subsection (y)(3) of this section);
- (K) inspection, maintenance, and operational checks of radiographic exposure devices, source changers, storage containers, transport containers, source guide tubes, crank-out devices, and radiation machines;
- (L) method of testing and training in accordance with subsections (m) and (n) of this section; and
- (M) source recovery procedures if the licensee is authorized to perform source recovery.

~~§289.256. Medical and Veterinary Use of Radioactive Material.~~

~~(a) Purpose. This section establishes requirements for the medical and veterinary use of radioactive material and for the issuance of specific licenses authorizing the medical and veterinary use of radioactive material. Unless otherwise exempted, no person shall receive, possess, use, transfer, own, or acquire radioactive material for medical or veterinary use except as authorized in a license issued in accordance with this section. A person who receives, possesses, uses, transfers, owns, or acquires radioactive material prior to receiving a license is subject to the requirements of this chapter.~~

~~(b) Scope.~~

~~—(1) In addition to the requirements of this section, all licensees, unless otherwise specified, are subject to the requirements of §289.201 of this title (relating to General Provisions for Radioactive Material), §289.202 of this title (relating to Standards for Protection Against Radiation from Radioactive Material), §289.203 of this title (relating to Notices, Instructions, and Reports to Workers; Inspections), §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), §289.252 of this title (relating to Licensing of Radioactive Material), and §289.257 of this title (relating to Packaging and Transportation of Radioactive Material).~~

~~—(2) Veterinarians who receive, possess, use, transfer, own, or acquire radioactive material in the practice of veterinary medicine shall do the following:~~

~~—(A) comply with the requirements in this subsection and subsections (a), (c), (e) (g), (h)(1), (i)(2), (j)(2) (4), (m) (o), (s), (t), (v), (x), (y)(1)(A), (z)(1)(A), (aa)(1)(A) and (2), (aa)(3)(A)(ii) and (iii) and (B), (bb)(1) (4), (bb)(5)(A)(ii) and (B), and (bb)(6) (7) of this section; and~~

~~—(B) verify that the training and experience specified in subsection (c)(3)(B) of this section has been obtained within the five years preceding the date of application or the individual shall have had related continuing education and experience since the required training and experience was completed.~~

- (c) Definitions. The following words and terms when used in this section shall have the following meaning unless the context clearly indicates otherwise.
- ~~–(1) Address of use—The building or buildings that are identified on the license and where radioactive material may be prepared, received, used, or stored.~~
 - ~~–(2) Area of use—A portion of an address of use that has been set aside for the purpose of preparing, receiving, using, or storing radioactive material.~~
 - ~~–(3) Authorized user—Authorized user is defined as either of the following:
 - ~~—(A) for medical use, a physician licensed by the Texas State Board of Medical Examiners who meets the applicable requirements in subsections (y) (dd) of this section; or~~
 - ~~—(B) for veterinary use, a veterinarian licensed by the Texas Board of Veterinary Medical Examiners and certified by the American College of Veterinary Radiology who is authorized for the use of radioactive materials in veterinary medicine.~~~~
 - ~~–(4) Brachytherapy—A method of radiation therapy in which plated, embedded, activated, or sealed sources are utilized to deliver a radiation dose at a distance of up to a few centimeters, by surface, intracavitary, intraluminal, or interstitial application.~~
 - ~~–(5) Brachytherapy sealed source—A sealed source or a manufacturer assembled source train, or a combination of these sources that is designed to deliver a therapeutic dose within a distance of a few centimeters.~~
 - ~~–(6) High dose rate remote afterloader—A device that remotely delivers a dose rate in excess of 1200 rads (12 gray (Gy)) per hour at the point or surface where the dose is prescribed.~~
 - ~~–(7) Institutional Review Board (IRB)—Any board, committee, or other group formally designated by an institution and approved by the United States Food and Drug Administration to review, approve the initiation of, and conduct periodic review of biomedical research involving human subjects.~~
 - ~~–(8) Low dose rate remote afterloader—A device that remotely delivers a dose rate of less than or equal to 200 rads (2 Gy) per hour at the point or surface where the dose is prescribed.~~
 - ~~–(9) Licensed medical physicist—An individual holding a current Texas license under the Medical Physics Practice Act, Texas Occupations Code, Chapter 602, in the appropriate specialty.~~
 - ~~–(10) Management—The chief executive officer or other individual delegated the authority to manage, direct, or administer the licensee's activities.~~
 - ~~–(11) Manual brachytherapy—A type of brachytherapy in which the sealed sources, for example, seeds and ribbons, are manually inserted either into the body cavities that are in close proximity to a treatment site or directly in the tissue volume.~~
 - ~~–(12) Medical institution—An organization in which several medical disciplines are practiced.~~
 - ~~–(13) Medical use—The intentional internal or external administration of radioactive material, or the radiation from radioactive material, to patients or human research subjects under the supervision of an authorized user.~~
 - ~~–(14) Medical event—An event that meets the criteria in subsection (ee)(1) of this section.~~
 - ~~–(15) Medium dose rate afterloader—A device that remotely delivers a dose rate greater than 200 rads (2 Gy) and less than or equal to 1200 rads (12 Gy) per hour at the point or surface where the dose is prescribed.~~

- ~~–(16) Output—The exposure rate, dose rate, or a quantity related in a known manner to these rates from a teletherapy unit, a brachytherapy source, a remote afterloader unit, or a gamma stereotactic radiosurgery unit, for a specified set of exposure conditions.~~
- ~~–(17) Patient—A human or animal under medical care and treatment.~~
- ~~–(18) Preceptor—An individual who provides or directs the training and experience requirements.~~
- ~~–(19) Permanent facility—A building or buildings that are identified on the license within the state of Texas and where radioactive material may be prepared, received, used, or stored. This may also include an area or areas where administrative activities related to the license are performed.~~
- ~~–(20) Prescribed dosage—The specified activity or range of activity of a radiopharmaceutical as documented in a written directive or in accordance with the directions of the authorized user for procedures in subsections (y) and (z) of this section.~~
- ~~–(21) Prescribed dose—Prescribed dose means one of the following:~~
- ~~—(A) for gamma stereotactic radiosurgery, the total dose as documented in the written directive;~~
 - ~~—(B) for teletherapy, the total dose and dose per fraction as documented in the written directive;~~
 - ~~—(C) for brachytherapy, either the total sealed source strength and exposure time, or the total dose, as documented in the written directive; or~~
 - ~~—(D) for remote afterloaders, the total dose and dose per fraction as documented in the written directive.~~
- ~~–(22) Pulsed dose rate remote afterloader—A special type of remote afterloading device that uses a single sealed source capable of delivering dose rates greater than 1200 rads (12 Gy) per hour, but is approximately one-tenth of the activity of typical high dose rate remote afterloader sealed sources and is used to simulate the radiobiology of a low dose rate remote afterloader treatment by inserting the sealed source for a given fraction of each hour.~~
- ~~–(23) Sealed source and device registry—The national registry that contains all the registration certificates, generated by both the NRC and the agreement states, that summarize the radiation safety information for sealed sources and devices and describe the licensing and use conditions approved for the product.~~
- ~~–(24) Stereotactic radiosurgery—The use of external radiation in conjunction with a guidance device to very precisely deliver a dose to a tissue volume by the use of three-dimensional coordinates.~~
- ~~–(25) Technologist—Technologist is defined as either of the following:~~
- ~~—(A) in nuclear medicine, a person (nuclear medicine technologist) skilled in the performance of nuclear medicine procedures under the supervision of a physician; and/or~~
 - ~~—(B) in therapy, as described in subsections (bb) and (dd) of this section, a person (radiation therapy technologist or radiation therapist) who delivers courses of radiation therapy as prescribed by a radiation oncologist.~~
- ~~–(26) Teletherapy—Therapeutic irradiation in which the sealed source is at a distance from the patient or human or animal research subject.~~
- ~~–(27) Therapeutic dosage—The specified activity or range of activity of radioactive material that is intended to deliver a radiation dose to a patient or human or animal research subject for palliative or curative treatment.~~
- ~~–(28) Therapeutic dose—A radiation dose delivered from a sealed source containing radioactive material to a patient or human or animal research subject for palliative or curative treatment.~~

- ~~—(29) Treatment site—The anatomical description of the tissue intended to receive a radiation dose, as described in a written directive.~~
- ~~—(30) Type of use—Use of radioactive material as specified under the following subsections:~~
- ~~—(A) training, uptake, and dilution studies in subsection (y) of this section;~~
 - ~~—(B) imaging and localization studies in subsection (z) of this section;~~
 - ~~—(C) therapy with unsealed radioactive material in subsection (aa) of this section;~~
 - ~~—(D) manual brachytherapy with sealed sources in subsection (bb) of this section;~~
 - ~~—(E) sealed sources for diagnosis in subsection (cc) of this section; and~~
 - ~~—(F) sealed source in a remote afterloader unit, teletherapy unit, or gamma stereotactic radiosurgery unit in subsection (dd) of this section.~~
- ~~—(31) Unit dosage—A dosage prepared for medical use for administration as a single dosage to a patient or human or animal research subject without any further modification of the dosage after it is initially prepared.~~
- ~~—(32) Veterinary use—The intentional internal or external administration of radioactive material, or the radiation from radioactive material, to patients under the supervision of an authorized user.~~
- ~~—(33) Written directive—An authorized user's written order for the administration of radioactive material or radiation from radioactive material to a specific patient or human research subject, as specified in subsection (p) of this section.~~
- ~~(d) Provisions for research involving human subjects.~~
- ~~—(1) A licensee may only conduct research involving human subjects if medical use of radioactive material for research is authorized on the license.~~
 - ~~—(2) The licensee may conduct research specified in paragraph (1) of this subsection provided that:~~
 - ~~—(A) the research is conducted, funded, supported, or regulated by a federal agency that has implemented the Federal Policy for the Protection of Human Subjects as required by Title 10, Code of Federal Regulations (CFR), §35.6 (Federal Policy); or~~
 - ~~—(B) the licensee has applied for and received approval of a specific amendment to its license before conducting the research.~~
 - ~~—(3) Prior to conducting research as specified in paragraph (1) of this subsection, the licensee shall obtain the following:~~
 - ~~—(A) "informed consent," as defined and described in the Federal Policy, from the human research subjects; and~~
 - ~~—(B) prior review and approval of the research activities from an IRB as required by Title 45, CFR, Part 46 and Title 21, CFR Part 56, and in accordance with the Federal Policy.~~
 - ~~—(4) Nothing in this subsection relieves licensees from complying with the other requirements of this chapter.~~
- ~~(e) Implementation.~~
- ~~—(1) If a license condition exempted a licensee from a provision of this section or §289.252 of this title on October 1, 2000, then the license condition continues to exempt the licensee from the requirements in the corresponding provision until there is a license amendment or license renewal that modifies or removes the license condition.~~
 - ~~—(2) When a requirement in this section differs from the requirement in an existing license condition, the requirement in this section shall govern.~~

~~—(3) Licensees shall continue to comply with any license condition that requires implementation of procedures required by subsection (dd)(4) and (10) (12) of this section until there is a license amendment or renewal that modifies the license condition.~~

~~(f) Specific requirements for the issuance of licenses. In addition to the requirements in §289.252(e) of this title and subsections (j) (l) of this section, as applicable, a license will be approved if the agency determines that:~~

~~—(1) the applicant satisfies any applicable special requirement in this section;~~

~~—(2) qualifications of the designated radiation safety officer (RSO) as specified in subsection (h) of this section are adequate for the purpose requested in the application; and~~

~~(3) the following submitted by the applicant is approved:~~

~~—(A) an operating, safety, and emergency procedures manual to include:~~

~~—(i) specific information on the following:~~

~~—(I) radiation safety precautions and instructions;~~

~~—(II) methodology for measurement of dosages or doses to be administered to patients or human or animal research subjects;~~

~~—(III) calibration, maintenance, and repair of instruments and equipment necessary for radiation safety; and~~

~~—(ii) any additional information required by this chapter that is requested by the agency to assist in its review of the application; and~~

~~—(B) qualifications of the following:~~

~~—(i) RSO in accordance with subsection (h) of this section;~~

~~—(ii) authorized user(s) in accordance with subsection (ff)(1) and (c)(3)(B) of this section as applicable to the use(s) being requested; and~~

~~—(iii) radiation safety committee (RSC), if applicable, in accordance with subsection (i) of this section;~~

~~—(4) the applicant's permanent facility is located in Texas; and~~

~~—(5) 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 indicating such.~~

~~(g) Radiation safety officer.~~

~~—(1) Every license issued by the agency shall have an RSO designated by the licensee's management. The licensee shall:~~

~~—(A) establish in writing the authority, duties, and responsibilities of the RSO;~~

~~—(B) provide the RSO sufficient authority, organizational freedom, time, resources, and management prerogative, to perform the following duties:~~

~~—(i) establish and oversee operating, safety, emergency, and as low as reasonably achievable (ALARA) procedures, and to review them at least annually to ensure that the procedures are current and conform with this chapter;~~

~~—(ii) ensure that required radiation surveys and leak tests are performed and documented in accordance with this chapter, including any corrective measures when levels of radiation exceed established limits;~~

- (iii) ensure that individual monitoring devices are used properly by occupationally exposed personnel, that records are kept of the monitoring results, and that timely notifications are made in accordance with §289.203 of this title;
 - (iv) investigate and cause a report to be submitted to the agency for each known or suspected case of radiation exposure to an individual or radiation level detected in excess of limits established by this chapter and each theft or loss of source(s) of radiation, to determine the cause(s), and to take steps to prevent a recurrence;
 - (v) investigate and cause a report to be submitted to the agency for each known or suspected case of release of radioactive material to the environment in excess of limits established by this chapter;
 - (vi) have a thorough knowledge of management policies and administrative procedures of the licensee;
 - (vii) assume control and institute corrective actions, including shutdown of operations when necessary, in emergency situations or unsafe conditions;
 - (viii) ensure that records are maintained as required by this chapter;
 - (ix) ensure the proper storing, labeling, transport, use, and disposal of sources of radiation, storage, and/or transport containers;
 - (x) ensure that inventories are performed in accordance with the activities for which the license application is submitted;
 - (xi) ensure that personnel are complying with this chapter, the conditions of the license, and the operating, safety, and emergency procedures of the licensee; and
 - (xii) serve as the primary contact with the agency; and
 - (C) have the RSO agree in writing to be responsible for implementing the radiation protection program.
- (2) The RSO's documented qualifications shall include training and experience in accordance with subsection (h) of this section.
- (3) For up to 60 days each calendar year, a licensee may permit an authorized user or an individual qualified to be an RSO to function as a temporary RSO and to perform the duties of an RSO in accordance with paragraph (1)(A) and (C) of this subsection, provided the licensee takes the actions required in paragraphs (1) and (2) of this subsection, and the RSO meets the qualifications in subsection (h) of this section. Records of qualifications and dates of service shall be maintained in accordance with subsection (ff)(2) of this section for inspection by the agency.
- (h) Qualifications for radiation safety officer.
- (1) The qualifications for RSOs for licenses for medical or veterinary use of radioactive material without broad scope authorization shall include the following:
 - (A) certification by a speciality board whose certification has been recognized by the agency;
 - or
 - (B) completion of a structured educational program consisting of the following:
 - (i) 200 hours of didactic training in the following areas:
 - (I) radiation physics and instrumentation;
 - (II) radiation protection;
 - (III) mathematics pertaining to the use and measurement of radioactivity;
 - (IV) radiation biology; and

~~—(V) radiation dosimetry; and~~
~~—(ii) one year of full-time radiation safety experience under the supervision of the individual identified as the RSO on an agency, NRC, agreement state, or licensing state license that authorizes similar type(s) of use(s) of radioactive material involving the following:~~
~~—(I) shipping, receiving, and performing related radiation surveys;~~
~~—(II) using and performing checks for proper operation of dose calibrators, survey meters, and instruments used to measure radionuclides;~~
~~—(III) securing and controlling radioactive material;~~
~~—(IV) using administrative controls to avoid mistakes in the administration of radioactive material;~~
~~—(V) using procedures to prevent or minimize radioactive contamination and using proper decontamination procedures; and~~
~~—(VI) disposing of radioactive material; and~~
~~—(iii) has obtained written documentation, signed by the supervising RSO, specified in clause (ii) of this subparagraph, that the individual has satisfactorily completed the requirements in clauses (i) and (ii) of this subparagraph and has achieved a level of radiation safety knowledge sufficient to independently function as an RSO for medical and veterinary uses of radioactive material; or~~
~~—(C) is an authorized user or licensed medical physicist identified on the licensee's radioactive material license and has experience with the radiation safety aspects of similar types of use of radioactive material for which the individual has RSO responsibilities.~~
~~—(2) The qualifications for RSOs for licenses for medical use of radioactive material with broad-scope authorization shall include the following:~~
~~—(A) a bachelor's degree in health physics, radiological health, physical science or a biological science with a physical science minor and four years of applied health physics experience in a program with radiation safety problems similar to those in the program to be managed;~~
~~—(B) a master's degree in health physics or radiological health and three years of applied health physics experience in a program with radiation safety problems similar to those in the program to be managed;~~
~~—(C) two years of applied health physics experience in a program with radiation safety issues similar to those in the program to be managed and one of the following:~~
~~—(i) doctorate degree in health physics or radiological health;~~
~~—(ii) comprehensive certification by the American Board of Health Physics;~~
~~—(iii) certification by the American Board of Radiology in Medical Nuclear Physics;~~
~~—(iv) certification by the American Board of Science in Nuclear Medicine in Radiation Protection;~~
~~—(v) certification by the American Board of Medical Physics in Medical Health Physics; or~~
~~—(D) equivalent qualifications as approved by the agency.~~
~~—(3) The qualifications in paragraphs (1)(A)–(C) and (2)(A)–(D) of this subsection do not apply to individuals who have been adequately trained and designated as RSOs on radioactive material licenses issued prior to October 1, 2000.~~
~~(i) Radiation safety committee. Licensees with broad-scope authorization and licensees who are authorized for two or more different types of uses of radioactive material under subsections (aa),~~

~~(bb), and (dd) of this section, or two or more types of units under subsection (dd) of this section shall establish an RSC to oversee all uses of radioactive material permitted by the license.~~

~~—(1) The RSC for licenses for medical use with broad scope authorization shall be composed of the following individuals as approved by the agency:~~

~~—(A) authorized users from each type of use of radioactive material authorized on the license;~~

~~—(B) the RSO;~~

~~—(C) a representative of nursing service;~~

~~—(D) a representative of management who is neither an authorized user nor the RSO; and~~

~~—(E) may include other members as the licensee deems appropriate.~~

~~—(2) The RSC for licenses for medical and veterinary use authorized for two or more different types of uses of radioactive material under subsections (aa), (bb), and (dd) of this section, or two or more types of units under subsection (dd) of this section shall be composed of the following individuals as approved by the agency:~~

~~—(A) an authorized user of each type of use permitted by the license;~~

~~—(B) the RSO;~~

~~—(C) a representative of nursing service, if applicable;~~

~~—(D) a representative of management who is neither an authorized user nor the RSO; and~~

~~—(E) may include other members as the licensee deems appropriate.~~

~~—(3) Duties and responsibilities of the RSC.~~

~~—(A) For licensees without broad scope authorization, the duties and responsibilities of the RSC include, but are not limited to, the following:~~

~~—(i) meeting as often as necessary to conduct business but no less than three times a year;~~

~~—(ii) reviewing summaries of the following information presented by the RSO:~~

~~—(I) over-exposures;~~

~~—(II) significant incidents, including spills, contamination, or medical events; and~~

~~—(III) items of non-compliance following an inspection;~~

~~—(iii) reviewing the program for maintaining doses ALARA, and providing any necessary recommendations to ensure doses are ALARA; and~~

~~—(iv) reviewing the audit of the radiation safety program and acting upon the findings.~~

~~—(B) For licensees with broad scope authorization, the duties and responsibilities of the RSC include, but are not limited to, the items in subparagraph (A) of this paragraph and the following:~~

~~—(i) reviewing the overall compliance status for authorized users;~~

~~—(ii) sharing responsibility with the RSO to conduct periodic audits of the radiation safety program;~~

~~—(iii) developing criteria to evaluate training and experience of new authorized user applicants;~~

~~—(iv) evaluating and approving authorized user applicants who request authorization to use radioactive material at the facility; and~~

~~—(v) reviewing and approving permitted program and procedural changes prior to implementation.~~

~~(j) Licenses for medical and veterinarian uses of radioactive material without broad scope authorization. In addition to the requirements of subsection (f) of this section, a license for medical and veterinarian use of radioactive material as described in the applicable subsections (y), (z), and (aa)-(cc) of this section will be issued if the agency approves the following documentation submitted by the applicant:~~

~~–(1) that the physician(s) designated on the application as the authorized user(s) is qualified in accordance with subsections (y), (z), and (aa) (cc) of this section as applicable;~~

~~–(2) that the radiation detection and measuring instrumentation is appropriate for performing surveys and procedures for the uses involved;~~

~~–(3) that the radiation safety operating procedures are adequate for the handling and disposal of the radioactive material involved in the uses; and~~

~~–(4) establishment of a RSC in accordance with subsection (i)(2) of this section, if applicable.~~

~~(k) License for medical uses of radioactive material with broad scope authorization. In addition to the requirements in subsection (f) of this section, a license for medical use of radioactive material with broad scope authorization will be issued if the agency approves the following documentation submitted by the applicant:~~

~~–(1) that the review of authorized user qualifications by the RSC is in accordance with subsections (y), (z), and (aa) (dd) of this section, as applicable;~~

~~–(2) that the application is for a license authorizing unspecified forms and/or multiple types of radioactive material for medical research, diagnosis, and therapy;~~

~~–(3) that the radiation detection and measuring instrumentation is appropriate for performing surveys and procedures for the uses involved;~~

~~–(4) that the radiation safety operating procedures are adequate for the handling and disposal of the radioactive material involved in the uses;~~

~~–(5) that staff has substantial experience in the use of a variety of radioactive material for a variety of human and animal uses;~~

~~–(6) a full-time RSO meeting the requirements of subsection (h)(2) of this section; and~~

~~–(7) establishment of a RSC in accordance with subsection (i)(1) of this section.~~

~~(l) License for the use of remote control brachytherapy units, teletherapy units, or gamma stereotactic radiosurgery units. In addition to the requirements in subsection (f) of this section, a license for the use of remote control brachytherapy (RCB) units, teletherapy units, or gamma stereotactic radiosurgery units will be issued if the agency approves the following documentation submitted by the applicant:~~

~~–(1) that the physician(s) designated on the application as the authorized user(s) is qualified in accordance with subsection (dd) of this section;~~

~~–(2) that the radiation detection and measuring instrumentation is appropriate for performing surveys and procedures for the uses involved;~~

~~–(3) that the radiation safety operating procedures are adequate for the handling and disposal of the radioactive material involved in the uses;~~

~~–(4) list of radioactive isotopes to be possessed;~~

~~–(5) the sealed source manufacturer(s) name(s) and the model number(s) of the sealed source(s) to be installed;~~

~~–(6) the maximum number of sealed sources of each isotope to be possessed, including the activity of each sealed source;~~

~~–(7) the manufacturer and model name and/or number of the following units, as applicable:~~

~~–(A) RCB unit;~~

~~–(B) teletherapy unit; or~~

~~–(C) gamma stereotactic radiosurgery unit;~~

- ~~—(8) the licensed medical physicist's current Texas license with a specialty in therapeutic radiological physics;~~
- ~~—(9) the successful completion of unit-specific, manufacturer-provided training that includes standard clinical and emergency procedures for remote control brachytherapy and gamma stereotactic radiosurgery units for the following personnel:

 - ~~—(A) licensed medical physicist with a specialty in therapeutic radiological physics;~~
 - ~~—(B) technologists; and~~
 - ~~—(C) authorized user;~~~~
- ~~—(10) safety procedures and instructions as required by subsection (dd)(4) of this section;~~
- ~~—(11) spot check procedures as required by subsection (dd)(10)–(12), as applicable; and~~
- ~~—(12) an established RSC in accordance with subsection (i)(1) or (2) of this section if applicable.~~
- ~~(m) Amendment of licenses at request of licensee.

 - ~~—(1) Requests for amendment of a license or deletion of a subsite shall be filed in accordance with §289.252(aa) of this title.~~
 - ~~—(2) A licensee without broad scope authorization shall apply for and shall receive a license amendment prior to the following:

 - ~~—(A) receiving or using radioactive material for a type of use that is permitted under this section, but that is not authorized on their current license issued in accordance with this section;~~
 - ~~—(B) permitting anyone to work as an authorized user or licensed medical physicist under the license;~~
 - ~~—(C) changing RSOs, except as provided in subsection (g)(3) of this section;~~
 - ~~—(D) receiving radioactive material in excess of the amount or in a different form, or receiving a different radionuclide than is authorized on the license;~~
 - ~~—(E) adding or changing the areas identified in the application or on the license;~~
 - ~~—(F) changing the address(es) of use identified in the application or on the license; and~~
 - ~~—(G) changing operating, safety, and emergency procedures.~~~~
 - ~~—(3) A licensee with broad scope authorization shall apply for and shall receive a license amendment prior to paragraph (2)(A), (C), (D), (F), and (G) of this subsection.~~~~
- ~~(n) Records/documents. Each licensee shall maintain copies of the records and documents specified in subsection (ff)(2) of this section at each authorized use site.~~
- ~~(o) Supervision. A licensee may permit the receipt, possession, use, or transfer of radioactive material by an individual under the supervision of an authorized user, unless prohibited by license condition.

 - ~~—(1) A licensee who permits the receipt, possession, use, or transfer of radioactive material by an individual under the supervision of an authorized user shall do the following:

 - ~~—(A) instruct the supervised individual in the licensee's written operating, safety, and emergency procedures, written directive procedures, requirements of this chapter, and license conditions with respect to the use of radioactive material; and~~
 - ~~—(B) require the supervised individual to follow the instructions of the supervising authorized user for medical uses of radioactive material, written operating, safety, and emergency procedures established by the licensee, requirements of this chapter, and license conditions with respect to the medical use of radioactive material.~~~~
 - ~~—(2) A licensee who permits the preparation of radioactive material for medical use by an individual under the supervision of an authorized user, shall do the following:~~~~

~~—(A) instruct the supervised individual in the preparation of radioactive material for medical use, as appropriate to that individual's involvement with radioactive material; and~~

~~—(B) require the supervised individual to follow the instructions of the supervising authorized user regarding the preparation of radioactive material for medical use, the written operating, safety, and emergency procedures established by the licensee, the requirements of this chapter, and license conditions.~~

~~—(3) A licensee who permits supervised activities under paragraphs (1) and (2) of this subsection is responsible for the acts and omissions of the supervised individual.~~

~~(p) Written directives.~~

~~—(1) A written directive shall be dated and signed by an authorized user prior to administration of sodium iodide I-131 greater than 30 microcuries (μCi)(1.11 MBq), any therapeutic dosage of unsealed radioactive material, or any therapeutic dose of radiation from radioactive material.~~

~~—(A) A written revision to an existing written directive may be made provided that the revision is dated and signed by an authorized user prior to the administration of the dosage of radioactive drug containing radioactive material, the brachytherapy dose, the gamma stereotactic radiosurgery dose, the teletherapy dose, or the next fractional dose.~~

~~—(B) If, because of the emergent nature of the patient's condition, a delay in order to provide a written directive or to revise a written directive would jeopardize the patient's health, an oral directive or an oral revision to an existing written directive is acceptable. The information contained in the oral directive or oral revision shall be documented as soon as possible in writing in the patient's record. A written directive shall be prepared and signed by the authorized user within 48 hours of the oral directive or oral revision.~~

~~—(2) The written directive shall contain the patient or human research subject's name and the following information:~~

~~—(A) for any administration of quantities greater than 30 μCi (1.11 MBq) of sodium iodide I-131: the dosage;~~

~~—(B) for an administration of a therapeutic dosage of a radiopharmaceutical other than sodium iodide I-131: the radiopharmaceutical, dosage, and route of administration;~~

~~—(C) for gamma stereotactic radiosurgery: the total dose, treatment site, and number of target coordinate settings per treatment for each anatomically distinct treatment site;~~

~~—(D) for teletherapy: the total dose, dose per fraction, number of fractions, and treatment site;~~

~~—(E) for high-dose rate remote afterloading brachytherapy: the radionuclide, treatment site, dose per fraction, number of fractions, and total dose; or~~

~~—(F) for all other brachytherapy:~~

~~—(i) prior to implantation: the treatment site, the radionuclide, number of sealed sources, and dose; and~~

~~—(ii) after implantation but prior to completion of the procedure: the radionuclide, treatment site, number of sealed sources, total sealed source strength and exposure time or, equivalently, the total dose.~~

~~—(3) The licensee shall maintain the written directive in accordance with subsection (ff)(2) of this section.~~

~~—(4) Procedures for administrations requiring a written directive.~~

~~—(A) For any administration requiring a written directive, the licensee shall develop, implement, and maintain written procedures to ensure that:~~

~~—(i) the patient's or human research subject's identity is verified before each administration; and~~

~~—(ii) each administration is in accordance with the written directive.~~

~~—(B) The procedures required by subparagraph (A) of this paragraph shall, at a minimum, address the following items that are applicable for the licensee's use of radioactive material:~~

~~—(i) verification of the identity of the patient or human research subject;~~

~~—(ii) verification that the specific details of the administration are in accordance with the treatment plan, if applicable, and the written directive;~~

~~—(iii) a check of both manual and computer-generated dose calculations; and~~

~~—(iv) verification that any computer-generated dose calculations are correctly transferred into the consoles of therapeutic medical units authorized by subsection (dd) of this section.~~

~~(q) Possession, use, and calibration of dose calibrators to measure the activity of unsealed radioactive material.~~

~~—(1) For direct measurements performed in accordance with subsection (r) of this section, the licensee shall possess and use instrumentation to measure the activity of unsealed radioactive material before it is administered to each patient or human research subject.~~

~~—(2) The licensee shall calibrate the instrumentation as specified in paragraph (1) of this subsection in accordance with nationally recognized standards or the manufacturer's instructions.~~

~~—(3) The calibration required by paragraph (2) of this subsection shall include tests for constancy, accuracy, linearity, and geometry dependence, as appropriate to demonstrate proper operation of the instrument. The tests for constancy, accuracy, linearity, and geometry dependence shall be conducted at the following intervals:~~

~~—(A) constancy at least once each day prior to assay of patient dosages;~~

~~—(B) linearity at installation, repair, relocation, and at least quarterly thereafter;~~

~~—(C) geometry dependence at installation; and~~

~~—(D) accuracy at installation and at least annually thereafter.~~

~~—(4) The licensee shall maintain a record of each instrument calibration in accordance with subsection (ff)(2) of this section. The record shall include the following:~~

~~—(A) model and serial number of the instrument and calibration sources;~~

~~—(B) dates of the calibration;~~

~~—(C) results of the calibration; and~~

~~—(D) name of the individual who performed the calibration.~~

~~(r) Determination of dosages of radioactive material for medical use.~~

~~—(1) Before medical use, the licensee shall perform the following:~~

~~—(A) record the activity of each dosage; and~~

~~—(B) determine the activity of each dosage using a dose calibrator, by direct measurement of radioactivity, or a decay correction, based on the activity or activity concentration determined by the following:~~

~~—(i) a manufacturer or preparer licensed in accordance with §289.252(r) of this title, or under an equivalent NRC, agreement state, or licensing state license; or~~

~~—(ii) an NRC or agreement state licensee for use in research in accordance with a Radioactive Drug Research Committee-approved protocol or an Investigational New Drug (IND) protocol accepted by the FDA.~~

~~—(2) For other than unit dosages, this determination shall be made by:~~

~~—(A) direct measurement of radioactivity; or~~

~~—(B) combination of direct measurement of radioactivity and mathematical calculations.~~

~~—(3) Unless otherwise directed by the authorized user, a licensee shall not use a dosage if the dosage does not fall within the prescribed dosage range or if the dosage differs from the prescribed dosage by more than 20%.~~

~~—(4) A licensee restricted to only unit doses prepared in accordance with §289.252(r) need not comply with the requirements in paragraph (1)(B) of this subsection, unless the administration time of the unit dose deviates from the nuclear pharmacy's pre-calibrated time by 15 minutes or more.~~

~~—(5) A licensee shall maintain a record of the dosage determination required by this subsection in accordance with subsection (ff)(2) of this section. The record shall contain the following:~~

~~—(A) radionuclide, generic name, trade name, or abbreviation of the radiopharmaceutical;~~

~~—(B) patient's or human research subject's name or identification number if one has been assigned;~~

~~—(C) prescribed dosage;~~

~~—(D) determined dosage or a notation that the total activity is less than 30 μCi (1.1 MBq);~~

~~—(E) the date and time of the dosage determination; and~~

~~—(F) the name of the individual who determined the dosage.~~

~~(s) Authorization for calibration and reference sources. Any licensee authorized by subsections (j) (1) of this section for medical use of radioactive material may receive, possess, and use the following radioactive material for check, calibration, and reference use:~~

~~—(1) sealed sources manufactured and distributed by a person licensed in accordance with §289.252 of this title and that do not exceed 30 millicurie (mCi) (1.1 GBq) each;~~

~~—(2) any radioactive material with a half life not longer than 120 days in individual amounts not to exceed 15 mCi (0.555 Gbq);~~

~~—(3) any radioactive material with a half life longer than 120 days in individual amounts not to exceed the smaller of 200 μCi (7.4 MBq) or 1000 times the quantities in §289.252(w)(6) of this title;~~

~~—(4) technetium 99m in amounts as needed; and~~

~~—(5) conduct a physical inventory at intervals not to exceed six months to account for all sealed sources received, possessed, and transferred. Records of the inventories shall be maintained for inspection by the agency in accordance with subsection (ff)(2) of this section and shall include the quantities and kinds of radioactive material, sealed source identification numbers, location of sealed sources, the dates of the inventory, and the identification of the individual(s) making the record.~~

~~(t) Requirements for possession of sealed sources and brachytherapy sealed sources. A licensee in possession of any sealed source or brachytherapy source shall:~~

~~—(1) follow the radiation safety and handling instructions supplied by the manufacturer and the leakage test requirements in accordance with §289.201(g) of this title.~~

~~—(2) conduct a physical inventory at intervals not to exceed six months to account for all sealed sources received, possessed, and transferred. Records of the inventories shall be maintained for inspection by the agency in accordance with subsection (ff)(2) of this section and shall include the quantities and kinds of radioactive material, sealed source identification numbers, location of~~

sealed sources, the dates of the inventory, and the identification of the individual(s) making the record.

~~(u) Labeling of vials and syringes. Each syringe and vial that contains a radiopharmaceutical shall be labeled to identify the radioactive drug. Each syringe shield and vial shield shall also be labeled unless the label on the syringe or vial is visible when shielded.~~

~~(v) Surveys for ambient radiation exposure rate.~~

~~—(1) Except as provided in paragraph (2) of this subsection, a licensee shall survey with a radiation detection survey instrument at the end of each day of use all areas where radioactive material requiring a written directive was prepared for use or administered.~~

~~—(2) A licensee does not need to perform the surveys required by paragraph (1) of this subsection in an area(s) where patients or human research subjects are confined when they cannot be released in accordance with subsection (w) of this section or an animal that is confined. Once the patient or human or animal research subject is released from confinement, the licensee shall survey with a radiation survey instrument, the area in which the patient or human or animal research subject was confined.~~

~~—(3) A record of each survey shall be maintained in accordance with subsection (ff)(2) of this section. The record shall include the following:~~

~~—(A) dates of the survey;~~

~~—(B) results of the survey;~~

~~—(C) manufacturer's name and model and serial number of the instrument used to make the survey; and~~

~~—(D) name of the individual who performed the survey.~~

~~(w) Release of individuals containing radioactive drugs or implants containing radioactive material.~~

~~—(1) The licensee may authorize the release from its control any individual who has been administered radioactive drugs or implants containing radioactive material in accordance with a written directive specified in subsection (p) of this section if the total effective dose equivalent (TEDE) to any other individual from exposure to the released individual is not likely to exceed 0.5 rem (5 mSv). Patients treated with temporary eye plaques may be released from the hospital provided that the procedures ensure that the exposure rate from the patient is less than 5 milliroentgens per hour at a distance of 1 meter from the eye plaque location;~~

~~—(2) The licensee shall provide the released individual, or the individual's parent or guardian, with written instructions on actions recommended to maintain doses to other individuals ALARA if the TEDE to any other individual is likely to exceed 0.1 rem (1 mSv). If the TEDE to a breast-feeding infant or child could exceed 0.1 rem (1 mSv), assuming there was no interruption of breast feeding, the instructions shall also include the following:~~

~~—(A) guidance on the interruption or discontinuation of breast feeding; and~~

~~—(B) information on the potential consequences, if any, of failure to follow the guidance.~~

~~—(3) The licensee shall maintain a record in accordance with subsection (ff)(2) of this section of each patient released in accordance with paragraph (1) of this subsection. The record shall include the following:~~

~~—(A) the basis for authorizing the release of an individual; and~~

~~—(B) the instructions provided to a breast-feeding woman if the radiation dose to the infant or child from continued breast feeding could result in a TEDE exceeding 0.5 rem (5 mSv).~~

~~(x) Decay in storage.~~

~~—(1) The licensee may hold radioactive material with a physical half life of less than 65 days for decay in storage and dispose of it without regard to its radioactivity if the licensee does the following:~~

~~—(A) monitors radioactive material at the surface before disposal and determines that its radioactivity cannot be distinguished from the background radiation level with an appropriate radiation detection survey meter set on its most sensitive scale and with no interposed shielding; and~~

~~—(B) removes or obliterates all radiation labels, except for material that will be handled as biomedical waste after it has been released.~~

~~—(2) The licensee shall maintain a record of each disposal permitted under paragraph (1) of this subsection in accordance with subsection (ff)(2) of this section. The record shall include the following:~~

~~—(A) dates of the disposal;~~

~~—(B) manufacturer's name and model and serial number of the survey instrument used;~~

~~—(C) background dose rate;~~

~~—(D) dose rate measured at the surface of each waste container; and~~

~~—(E) name of the individual who performed the disposal.~~

~~(y) Use of and training for radioactive material for uptake, dilution, and excretion studies that do not require a written directive.~~

~~—(1) Use of radioactive material for uptake, dilution, and excretion studies. Except for quantities that require a written directive in accordance with subsection (p) of this section, the licensee may use any unsealed radioactive material prepared for medical use for uptake, dilution, or excretion studies that meets the following:~~

~~—(A) is obtained from a manufacturer or preparer licensed in accordance with §289.252 of this title or equivalent NRC, agreement state, or licensing state requirements;~~

~~—(B) is prepared by a physician who is an authorized user and who meets the requirements specified in paragraph (2) of this subsection, or an individual under the supervision of an authorized user as specified in subsection (o) of this section;~~

~~—(C) is obtained from an NRC, agreement state, or licensing state licensee for use in research in accordance with a Radioactive Drug Research Committee approved protocol or an IND protocol accepted by the FDA; or~~

~~—(D) is prepared by the licensee for use in research in accordance with a Radioactive Drug Research Committee approved application or an IND protocol accepted by the FDA.~~

~~—(2) Training for uptake, dilution, and excretion studies. An authorized user of radiopharmaceuticals for the uses authorized in paragraph (1) of this subsection shall be a physician who meets the requirements of subsection (ff)(1)(A) and (I) or (ff)(1)(H) and (I) of this section.~~

~~(z) Use of and training for radioactive material for imaging and localization studies that do not require a written directive.~~

~~—(1) Use of radioactive material for imaging and localization studies. Except for quantities that require a written directive in accordance with subsection (p) of this section, the licensee may use any unsealed radioactive material prepared for medical use for imaging and localization studies that meets the following:~~

~~—(A) is obtained from a manufacturer or preparer licensed in accordance with §289.252 of this title or equivalent NRC, agreement state, or licensing state requirements;~~

~~—(B) is prepared by a physician who is an authorized user and who meets the requirements specified in paragraph (4) of this subsection, or an individual under the supervision of an authorized user as specified in subsection (o) of this section;~~

~~—(C) is obtained from an NRC, agreement state, or licensing state licensee for use in research in accordance with a Radioactive Drug Research Committee approved protocol or an Investigational New Drug (IND) protocol accepted by the FDA; or~~

~~—(D) is prepared by the licensee for use in research in accordance with a Radioactive Drug Research Committee approved application or an IND protocol accepted by FDA.~~

~~—(2) Any licensee who processes and prepares radiopharmaceuticals for human use shall do so 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 or the rules of the practice of pharmacy, as promulgated by the Texas State Board of Pharmacy.~~

~~—(3) Permissible molybdenum-99 concentration.~~

~~—(A) The licensee may not administer to humans a radiopharmaceutical containing more than 0.15 μ Ci of molybdenum-99 per millicurie of technetium-99m (0.15 kilobecquerel of molybdenum-99 per megabecquerel of technetium-99m).~~

~~—(B) The licensee who uses molybdenum-99/technetium-99m generators for preparing a technetium-99m radiopharmaceutical shall measure the molybdenum-99 concentration of the first eluate after receipt of a generator to demonstrate compliance with paragraph (1) of this subsection.~~

~~—(C) If the licensee is required to measure the molybdenum-99 concentration, the licensee shall maintain a record of each measurement in accordance with subsection (ff)(2) of this section. The record shall include the following for each measured elution of technetium-99m:~~

~~—(i) ratio of the measures expressed as microcuries of molybdenum-99 per millicurie of technetium-99m (kilobecquerel of molybdenum-99 per megabecquerel of technetium-99m);~~

~~—(ii) times and dates of the measurement; and~~

~~—(iii) name of the individual who made the measurement.~~

~~—(4) Training for imaging and localization studies. An authorized user of radiopharmaceuticals for the uses authorized in paragraph (1) of this subsection shall be a physician who meets the requirements of subsection (ff)(1)(B) and (I) or (ff)(1)(H) and (I) of this section.~~

~~(aa) Use of and training for unsealed radioactive material for human therapy that requires a written directive or veterinary therapeutic use.~~

~~—(1) Use of unsealed radioactive material for therapy. A licensee may use any unsealed radioactive material prepared for medical use that requires a written directive in accordance with subsection (p) of this section or veterinary therapeutic use that meets the following:~~

~~—(A) is obtained from a manufacturer or preparer licensed in accordance with §289.252 of this title or equivalent NRC, agreement state, or licensing state requirements;~~

~~(B) is prepared by a physician who is an authorized user and who meets the requirements specified in paragraph (4) of this subsection, or an individual under the supervision of an authorized user as specified in subsection (o) of this section;~~

~~—(C) is obtained from an NRC, agreement state, or licensing state licensee for use in research in accordance with an IND application accepted by the FDA; or~~

~~—(D) is prepared by the licensee for use in research in accordance with an IND protocol accepted by FDA.~~

~~—(2) Safety instruction to personnel.~~

~~—(A) The licensee shall provide radiation safety instruction, initially and at least annually, to personnel caring for patients or human or animal research subjects who have received therapy with a drug containing radioactive material and cannot be released in accordance with subsection (w) of this section or an animal that is confined. The instruction shall be appropriate to the personnel's assigned duties and include the following:~~

~~—(i) patient or human or animal research subject control; and~~

~~—(ii) visitor control to include the following:~~

~~—(I) routine visitation to hospitalized individuals or animals in accordance with §289.202(n) of this title;~~

~~—(II) contamination control;~~

~~—(III) waste control; and~~

~~—(IV) notification of the RSO, or his or her designee, and the authorized user if the patient or the human or animal research subject dies or has a medical emergency.~~

~~—(B) The licensee shall maintain a record, in accordance with subsection (ff)(2) of this section, of individuals receiving instruction. The record shall include the following:~~

~~—(i) list of the topics covered;~~

~~—(ii) date of the instruction or training;~~

~~—(iii) name(s) of the attendee(s); and~~

~~—(iv) name(s) of the individual(s) who provided the instruction.~~

~~—(3) Safety precautions for patients or human or animal research subjects receiving radiopharmaceutical therapy.~~

~~—(A) For each patient or human or animal research subject receiving radiopharmaceutical therapy and hospitalized in accordance with subsection (w) of this section or animal that is confined, the licensee shall do the following:~~

~~—(i) provide a private room with a private sanitary facility;~~

~~—(ii) post the patient's or the human or animal research subject's room with a "Radioactive Materials" sign and note on the door and in the patient's or human research subject's chart where and how long visitors may stay in the patient's or the human research subject's room; and~~

~~—(iii) either monitor material and items removed from the patient's or the human or animal research subject's room to determine that their radioactivity cannot be distinguished from the natural background radiation level with a radiation detection survey instrument set on its most sensitive scale and with no interposed shielding, or handle such material and items as radioactive waste.~~

~~—(B) The RSO, or his or her designee, and the authorized user shall be notified immediately if the patient or human or animal research subject has a medical emergency or if the patient dies.~~

~~—(4) Training for use of radioactive material for therapy that requires a written directive. An authorized user of radiopharmaceuticals for the uses authorized in paragraph (1) of this subsection shall be a physician who meets the requirements of subsection (ff)(1)(C) and (I) or (ff)(1)(H) and (I) of this section.~~

~~(bb) Use of and training for sealed sources for manual brachytherapy.~~

~~—(1) Use of sealed sources for manual brachytherapy. The licensee shall use only brachytherapy sealed sources for therapeutic medical uses as follows:~~

~~—(A) as approved in the Sealed Source and Device Registry; or~~

~~—(B) in research in accordance with an effective Investigational Device Exemption (IDE) application accepted by the FDA and as approved by the agency.~~

~~—(2) Surveys after sealed source implants and removal.~~

~~—(A) Immediately after implanting sealed sources in a patient or a human or animal research subject, the licensee shall perform a survey to locate and account for all sealed sources that have not been implanted.~~

~~—(B) Immediately after removing the last temporary implant sealed source from a patient or a human or animal research subject, the licensee shall make a survey of the patient or the human or animal research subject with a radiation detection survey instrument to confirm that all sealed sources have been removed.~~

~~—(C) A record of each survey shall be maintained in accordance with subsection (ff)(2) of this section. The record shall include the following:~~

~~—(i) dates of the survey;~~

~~—(ii) results of the survey;~~

~~—(iii) manufacturer's name and model and serial number of the instrument used to make the survey; and~~

~~—(iv) name of the individual who performed the survey.~~

~~—(3) Brachytherapy sealed sources inventory.~~

~~—(A) The licensee shall maintain accountability at all times for all brachytherapy sealed sources in storage or use.~~

~~—(B) Promptly after removing sealed sources from a patient or a human or animal research subject, the licensee shall return brachytherapy sealed sources to a secure storage area.~~

~~—(C) The licensee shall maintain a record of the brachytherapy sealed source accountability in accordance with subsection (ff)(2) of this section.~~

~~—(i) The following information shall be recorded when temporary implants are removed from storage:~~

~~—(I) number and activity of sealed sources;~~

~~—(II) times and dates;~~

~~—(III) name of the individual who removed them from storage;~~

~~—(IV) location of use; and~~

~~—(V) when returned to storage, the name of the individual who returned them and the information in subclauses (I) and (II) of this clause.~~

~~—(ii) The following information shall be recorded when permanent implants are removed from storage:~~

~~—(I) number and activity of sealed sources;~~

~~—(II) dates;~~

~~—(III) name of the individual who removed them from storage;~~

~~—(IV) the information in subclauses (I)–(III) of this clause for all sealed sources not implanted; and~~

~~—(V) the number and activity of sealed sources permanently implanted in the patient or human research subject.~~

~~-(4) Safety instruction to personnel. The licensee shall provide radiation safety instruction, initially and at least annually, to personnel caring for patients or human or animal research subjects who are undergoing implant therapy and who cannot be released in accordance with subsection (w) of this section or animals that are confined.~~

~~—(A) The instruction shall be appropriate to the personnel's assigned duties and include the following:~~

~~—(i) size and appearance of brachytherapy sealed sources;~~

~~—(ii) safe handling and shielding instructions;~~

~~—(iii) patient or human research subject control;~~

~~—(iv) visitor control to include visitation to hospitalized individuals in accordance with §289.202(n) of this title; and~~

~~—(v) notification of the RSO, or his or her designee, and an authorized user if the patient or the human or animal research subject dies or has a medical emergency.~~

~~—(B) A licensee shall maintain a record, in accordance with subsection (ff)(2) of this section, of individuals receiving instruction. The record shall include the following:~~

~~—(i) list of the topics covered;~~

~~—(ii) date of the instruction or training;~~

~~—(iii) name(s) of the attendee(s); and~~

~~—(iv) name(s) of the individual(s) who provided the instruction.~~

~~-(5) Safety precautions for the use of brachytherapy.~~

~~—(A) For each patient or human or animal research subject who is receiving brachytherapy and cannot be released in accordance with subsection (w) of this section or animals that are confined, the licensee shall:~~

~~—(i) provide a private room with a private sanitary facility;~~

~~—(ii) post the patient's or the human or animal research subject's room with a "Radioactive Materials" sign and note on the door or in the patient's or human or animal research subject's chart where and how long visitors may stay in the patient's or the human or animal research subject's room; and~~

~~—(iii) have available near each treatment room emergency response equipment to respond to a sealed source that is inadvertently dislodged from the patient or inadvertently lodged within the patient following removal of the sealed source applicators.~~

~~—(B) The RSO, or his or her designee, and the authorized user shall be notified if the patient or human research subject has a medical emergency and, immediately, if the patient dies.~~

~~-(6) Calibration measurements of brachytherapy sealed sources.~~

~~—(A) Prior to the first medical use of a brachytherapy sealed source on or after October 1, 2000, the licensee shall do the following:~~

~~—(i) determine the sealed source output or activity using a dosimetry system that meets the requirements of subsection (dd)(6) of this section;~~

~~—(ii) determine sealed source positioning accuracy within applicators; and~~

~~—(iii) use published protocols accepted by nationally recognized bodies to meet the requirements of clauses (i) and (ii) of this subparagraph.~~

- ~~—(B) The licensee may use measurements provided by the sealed source manufacturer that are made in accordance with subparagraph (A) of this paragraph.~~
- ~~—(C) The licensee shall mathematically correct the outputs or activities determined in subparagraph (A) of this paragraph for physical decay at intervals consistent with 1.0% physical decay.~~
- ~~—(D) The licensee shall maintain a record of each calibration in accordance with subsection (ff)(2) of this section. The record shall include the following:

 - ~~—(i) dates of the calibration;~~
 - ~~—(ii) manufacturer's name and model and serial number for the sealed source and instruments used to calibrate the sealed source;~~
 - ~~—(iii) sealed source output or activity;~~
 - ~~—(iv) sealed source positioning accuracy within applicators; and~~
 - ~~—(v) signature of a licensed medical physicist.~~~~
- ~~—(7) Therapy related computer systems. The licensee shall perform acceptance testing on the treatment planning system in accordance with published protocols accepted by nationally recognized bodies. At a minimum, the acceptance testing shall include, as applicable, verification of the following:

 - ~~—(A) the sealed source specific input parameters required by the dose calculation algorithm;~~
 - ~~—(B) the accuracy of dose, dwell time, and treatment time calculations at representative points;~~
 - ~~—(C) the accuracy of isodose plots and graphic displays; and~~
 - ~~—(D) the accuracy of the software used to determine radioactive sealed source positions from radiographic images.~~~~
- ~~—(8) Training for use of manual brachytherapy sealed sources.

 - ~~—(A) An authorized user of sealed sources for the uses authorized in paragraph (1) of this subsection shall be a physician who meets the requirements of subsection (ff)(1)(D), (E), and (I) or (ff)(1)(H) and (I) of this section.~~
 - ~~—(B) An authorized user who is limited to the use of eye applicators shall be a physician who meets the requirements of subsection (ff)(1)(E) and (I) or (ff)(1)(H) and (I) of this section.~~~~
- ~~(cc) Use of and training for sealed sources for diagnosis.

 - ~~—(1) Use of sealed sources for diagnosis. The licensee shall use only sealed sources for diagnostic medical uses as approved in the Sealed Source and Device Registry.~~
 - ~~—(2) Training for use of sealed sources for diagnosis. An authorized user of radiopharmaceuticals for the uses authorized in paragraph (1) of this subsection shall be a physician who meets the requirements of subsection (ff)(1)(F) and (I) or (ff)(1)(H) and (I) of this section.~~~~
- ~~(dd) Use of and training for a sealed source in a remote afterloader unit, teletherapy unit, or gamma stereotactic radiosurgery unit.

 - ~~—(1) Use of a sealed source in a remote afterloader unit, teletherapy unit, or gamma stereotactic radiosurgery unit. The licensee shall use sealed sources in photon emitting remote afterloader units, teletherapy units, or gamma stereotactic units for therapeutic medical uses as follows:

 - ~~—(A) as approved in the Sealed Source and Device Registry; or~~
 - ~~—(B) in research in accordance with an effective Investigational Device Exemption (IDE) application accepted by the FDA.~~~~
 - ~~—(2) Surveys of patients and human research subjects treated with a remote afterloader unit.~~~~

~~—(A) Before releasing a patient or a human research subject from licensee control, the licensee shall perform a survey of the patient or the human research subject and the remote afterloader unit with a portable radiation detection survey instrument to confirm that the sealed source(s) has been removed from the patient or human research subject and returned to the safe shielded position.~~

~~—(B) The licensee shall maintain a record of the surveys in accordance with subsection (ff)(2) of this section. The record shall include the following:~~

~~—(i) dates of the survey;~~

~~—(ii) results of the survey;~~

~~—(iii) manufacturer's name and model and serial number of the survey instrument used; and~~

~~—(iv) name of the individual who made the survey.~~

~~—(3) Installation, maintenance, adjustment, and repair.~~

~~—(A) Only a person specifically licensed by the agency, the NRC, an agreement state, or licensing state shall install, maintain, adjust, or repair a remote afterloader unit, teletherapy unit, or gamma stereotactic radiosurgery unit that involves work on the sealed source(s) shielding, the sealed source(s) driving unit, or other electronic or mechanical component that could expose the sealed source(s), reduce the shielding around the sealed source(s), or compromise the radiation safety of the unit or the sealed source(s).~~

~~—(B) Except for low dose rate remote afterloader units, only a person specifically licensed by the agency, the NRC, an agreement state, or licensing state shall install, replace, relocate, or remove a sealed source or sealed source contained in other remote afterloader units, teletherapy units, or gamma stereotactic units.~~

~~—(C) For a low dose rate remote afterloader unit, only a person specifically licensed by the agency, the NRC, an agreement state, a licensing state, or a licensed medical physicist shall install, replace, relocate, or remove a sealed source(s) contained in the unit.~~

~~—(D) The licensee shall maintain a record of the installation, maintenance, adjustment and repair done on remote afterloader units, teletherapy units, and gamma stereotactic radiosurgery units in accordance with subsection (ff)(2) of this section. For each installation, maintenance, adjustment and repair, the record shall include the dates, description of the service, and name(s) of the individual(s) who performed the work.~~

~~—(4) Safety procedures and instructions for remote afterloader units, teletherapy units, and gamma stereotactic radiosurgery units. A licensee shall do the following:~~

~~—(A) secure the unit, the console, the console keys, and the treatment room when not in use or unattended;~~

~~—(B) permit only individuals approved by the authorized user, RSO, or licensed medical physicist with a specialty in therapeutic radiological physics to be present in the treatment room during treatment with the sealed source(s);~~

~~—(C) prevent dual operation of more than one radiation producing device in a treatment room if applicable;~~

~~—(D) develop, implement, and maintain written procedures for responding to an abnormal situation when the operator is unable to place the sealed source(s) in the shielded position, or remove the patient or human research subject from the radiation field with controls from outside the treatment room;~~

~~—(i) The procedure required by this paragraph shall include the following:~~

- ~~—(I) instructions for responding to equipment failures and the names of the individuals responsible for implementing corrective actions;~~
- ~~—(II) the process for restricting access to and posting of the treatment area to minimize the risk of inadvertent exposure; and~~
- ~~—(III) the names and telephone numbers of the authorized users, the licensed medical physicist with a specialty in therapeutic radiological physics, and the RSO to be contacted if the unit or console operates abnormally.~~
- ~~—(ii) A copy of the procedures required by this paragraph shall be physically located at the unit console.~~
- ~~—(E) post instructions at the unit console to inform the operator of the following:~~
 - ~~—(i) the location of the procedures required by subparagraph (D) of this paragraph; and~~
 - ~~—(ii) the names and telephone numbers of the authorized users, the licensed medical physicist with a specialty in therapeutic radiological physics, and the RSO to be contacted if the unit or console operates abnormally;~~
- ~~—(F) provide instruction initially and at least annually, to all individuals who operate the unit, as appropriate to the individual's assigned duties, in the following:~~
 - ~~—(i) procedures identified in subparagraph (D) of this paragraph; and~~
 - ~~—(ii) operating procedures for the unit;~~
- ~~—(G) ensure that operators, licensed medical physicists with a specialty in therapeutic radiological physics, and authorized users participate in drills of the emergency procedures, initially and at least annually; and~~
- ~~—(H) maintain a record, in accordance with subsection (ff)(2) of this section, of individuals receiving instruction and participating in drills required by subparagraphs (F) and (G) of this paragraph. The record shall include the following:~~
 - ~~—(i) a list of the topics covered;~~
 - ~~—(ii) date of the instruction or drill;~~
 - ~~—(iii) name(s) of the attendee(s); and~~
 - ~~—(iv) name(s) of the individual(s) who provided the instruction.~~
- ~~—(5) Safety precautions for remote afterloader units, teletherapy units, and gamma stereotactic radiosurgery units. The licensee shall do the following:~~
 - ~~—(A) control access to the treatment room by a door at each entrance;~~
 - ~~—(B) equip each entrance to the treatment room with an electrical interlock system that will do the following:~~
 - ~~—(i) prevent the operator from initiating the treatment cycle unless each treatment room entrance door is closed;~~
 - ~~—(ii) cause the sealed source(s) to be shielded promptly when an entrance door is opened; and~~
 - ~~—(iii) prevent the sealed source(s) from being exposed following an interlock interruption until all treatment room entrance doors are closed and the sealed source(s) "on-off" control is reset at the console;~~
 - ~~—(C) require any individual entering the treatment room to assure, through the use of appropriate radiation monitors, that radiation levels have returned to ambient levels;~~
 - ~~—(D) except for low-dose remote afterloader units, construct or equip each treatment room with viewing and intercom systems to permit continuous observation of the patient or the human research subject from the treatment console during irradiation;~~

~~—(E) for licensed activities where sealed sources are placed within the patient's or human research subject's body, only conduct treatments that allow for expeditious removal of a decoupled or jammed sealed source;~~

~~—(F) in addition to the requirements specified in subparagraph (B) of this paragraph, require the following for low dose rate, medium dose rate, and pulsed dose rate remote afterloader units:~~

~~—(i) a licensed medical physicist with a specialty in therapeutic radiological physics, and either an authorized user or a physician, under the supervision of an authorized user, who has been trained in the operation and emergency response for the unit, be physically present during the initiation of all patient treatments involving the unit; and~~

~~—(ii) a licensed medical physicist with a specialty in therapeutic radiological physics, and either an authorized user or an individual, under the supervision of an authorized user, who has been trained to remove the sealed source applicator(s) in the event of an emergency involving the unit, be immediately available during continuation of all patient treatments involving the unit;~~

~~—(G) in addition to the requirements specified in subparagraphs (A) and (B) of this paragraph, require the following for high dose rate remote afterloader units:~~

~~—(i) an authorized user and a licensed medical physicist with a specialty in therapeutic radiological physics be physically present during the initiation of all patient treatments involving the unit; and~~

~~—(ii) a licensed medical physicist with a specialty in therapeutic radiological physics, and either an authorized user or a physician, under the supervision of an authorized user, who has been trained in the operation and emergency response for the unit, be physically present during continuation of all patient treatments involving the unit;~~

~~—(H) in addition to the requirements specified in subparagraphs (A) and (B) of this paragraph, require that an authorized user and a licensed medical physicist with a specialty in therapeutic radiological physics be physically present throughout all patient treatments involving gamma stereotactic radiosurgery units;~~

~~—(I) notify the RSO, or his or her designee, and an authorized user as soon as possible, if the patient or human research subject has a medical emergency and, immediately, if the patient dies; and~~

~~—(J) have applicable emergency response equipment available near each treatment room to respond to a sealed source that inadvertently remains in the unshielded position or inadvertently lodges within the patient following completion of the treatment.~~

~~—(6) Dosimetry equipment.~~

~~—(A) Except for low dose rate remote afterloader sealed sources where the sealed source output or activity is determined by the manufacturer, the licensee shall have a calibrated dosimetry system available for use. To satisfy this requirement, one of the following two conditions shall be met:~~

~~—(i) The system shall have been calibrated using a system or sealed source traceable to the National Institute of Standards and Technology (NIST) and published protocols accepted by nationally recognized bodies; or by a calibration laboratory accredited by the American Association of Physicists in Medicine (AAPM). The calibration shall have been performed within the previous two years and after any servicing that may have affected system calibration.~~

~~—(ii) The system shall have been calibrated within the previous four years. Eighteen to 30 months after that calibration, the system shall have been intercompared with another dosimetry~~

system that was calibrated within the past 24 months by NIST or by a calibration laboratory accredited by the AAPM. The results of the intercomparison shall have indicated that the calibration factor of the licensee's system had not changed by more than 2.0%. The licensee may not use the intercomparison result to change the calibration factor. When intercomparing dosimetry systems to be used for calibrating sealed sources for therapeutic unit, the licensee shall use a comparable unit with beam attenuators or collimators, as applicable, and sealed sources of the same radionuclide as the sealed source used at the licensee's facility.

—(B) The licensee shall have available for use a dosimetry system for spot check output measurements, if applicable. To satisfy this requirement, the system may be compared with a system that has been calibrated in accordance with subparagraph (A) of this paragraph. This comparison shall have been performed within the previous year and after each servicing that may have affected system calibration. The spot check system may be the same system used to meet the requirement in subparagraph (A) of this paragraph.

—(C) The licensee shall maintain a record of each calibration, intercomparison, and comparison of dosimetry equipment in accordance with subsection (ff)(2) of this section. The record shall include the following:

—(i) dates of the calibration;

—(ii) model and serial numbers of the instruments that were calibrated, intercompared, or compared;

—(iii) the correction factor that was determined from the calibration or comparison or the apparent correction factor that was determined from an intercomparison; and

—(iv) the names of the individuals who performed the calibration, intercomparison, or comparison.

—(7) Full calibration measurements on teletherapy units.

—(A) The licensee shall perform full calibration measurements on each teletherapy unit as follows:

—(i) before the first medical use of the unit; and

—(ii) before medical use under the following conditions:

—(I) whenever spot check measurements indicate that the output differs by more than 5.0% from the output obtained at the last full calibration corrected mathematically for radioactive decay;

—(II) following replacement of the sealed source or following reinstallation of the teletherapy unit in a new location;

—(III) following any repair of the teletherapy unit that includes removal of the sealed source or major repair of the components associated with the sealed source exposure assembly; and

—(iii) at intervals not to exceed one year.

—(B) Full calibration measurements shall include determination of the following:

—(i) output within plus or minus 3.0% for the range of field sizes and for the distance or range of distances used for medical use;

—(ii) the coincidence of the radiation field and the field indicated by the light beam localizing device;

—(iii) uniformity of the radiation field and its dependence on the orientation of the useful beam;

—(iv) timer constancy and linearity over the range of use;

—(v) "on off" error; and

~~—(vi) the accuracy of all distance measuring and localization devices in medical use.~~

~~—(C) The licensee shall use the dosimetry system described in paragraph (6)(A) of this subsection to measure the output for one set of exposure conditions. The remaining radiation measurements required in subparagraph (B)(i) of this paragraph may be made using a dosimetry system that indicates relative dose rates.~~

~~—(D) The licensee shall make full calibration measurements required by subparagraph (A) of this paragraph in accordance with published protocols accepted by nationally recognized bodies.~~

~~—(E) The licensee shall mathematically correct the outputs determined in subparagraph (B)(i) of this paragraph for physical decay at intervals not to exceed one month for cobalt-60, six months for cesium-137, or at intervals consistent with 1.0% decay for all other nuclides.~~

~~—(F) Full calibration measurements required by subparagraph (A) of this paragraph and physical decay corrections required by subparagraph (E) of this paragraph shall be performed by a licensed medical physicist with a specialty in therapeutic radiological physics.~~

~~—(G) The licensee shall maintain a record of each calibration in accordance with subsection (ff)(2) of this section. The record shall include the following:~~

- ~~—(i) dates of the calibration;~~
- ~~—(ii) manufacturer's name and model and serial number for the unit's sealed source;~~
- ~~—(iii) instruments used to calibrate the unit;~~
- ~~—(iv) results and an assessment of the full calibration; and~~
- ~~—(v) signature of the licensed medical physicist with a specialty in therapeutic radiological physics who performed the full calibration.~~

~~—(8) Full calibration measurements on remote afterloader units.~~

~~—(A) The licensee shall perform full calibration measurements on each remote afterloader unit as follows:~~

- ~~—(i) before the first medical use of the unit; and~~
- ~~—(ii) before medical use under the following conditions:~~
 - ~~—(I) following replacement of the sealed source;~~
 - ~~—(II) following reinstallation of the unit in a new location outside the facility;~~
 - ~~—(III) following any repair of the unit that includes removal of the sealed source or major repair of the components associated with the sealed source exposure assembly;~~
- ~~—(iii) at intervals not to exceed three months for high dose rate, medium dose rate, and pulsed dose rate remote afterloader units with sealed sources whose half-life exceeds 75 days; and~~
- ~~—(iv) at intervals not to exceed one year for low dose rate afterloader units.~~

~~—(B) Full calibration measurements shall include, as applicable, determination of the following:~~

- ~~—(i) the output within plus or minus 5.0%;~~
- ~~—(ii) sealed source positioning accuracy to within plus or minus 1 mm;~~
- ~~—(iii) sealed source retraction with backup battery upon power failure;~~
- ~~—(iv) length of the sealed source transfer tubes;~~
- ~~—(v) timer accuracy and linearity over the typical range of use;~~
- ~~—(vi) length of the applicators; and~~
- ~~—(vii) function of the sealed source transfer tubes, applicators, and transfer tube applicator interfaces.~~

~~—(C) A licensee shall use the dosimetry system described in paragraph (6)(A) of this subsection to measure the output.~~

~~—(D) A licensee shall make full calibration measurements required by subparagraph (A) of this paragraph in accordance with published protocols accepted by nationally recognized bodies.~~

~~—(E) In addition to the requirements for full calibrations for low dose rate remote afterloader units in subparagraph (B) of this paragraph, a licensee shall perform an autoradiograph of the sealed source(s) to verify inventory and sealed source(s) arrangement at intervals not to exceed three months.~~

~~—(F) For low dose rate remote afterloader units, a licensee may use measurements provided by the sealed source manufacturer that are made in accordance with subparagraphs (A) (E) of this paragraph.~~

~~—(G) The licensee shall mathematically correct the outputs determined in subparagraph (B)(i) of this paragraph for physical decay at intervals consistent with 1.0% physical decay.~~

~~—(H) Full calibration measurements required by subparagraph (A) of this paragraph and physical decay corrections required by subparagraph (G) of this paragraph shall be performed by a licensed medical physicist with a specialty in therapeutic radiological physics.~~

~~—(I) The licensee shall maintain a record of each calibration in accordance with subsection (ff)(2) of this section. In addition to the items in paragraph (7)(G) of this subsection, the record shall also include results of the autoradiograph required for low dose rate remote afterloader units.~~

~~—(9) Full calibration measurements on gamma stereotactic radiosurgery units.~~

~~—(A) The licensee shall perform full calibration measurements on each gamma stereotactic radiosurgery unit as follows:~~

~~—(i) before the first medical use of the unit;~~

~~—(ii) before medical use under the following conditions:~~

~~—(I) whenever spot check measurements indicate that the output differs by more than 5.0% from the output obtained at the last full calibration corrected mathematically for radioactive decay;~~

~~—(II) following replacement of the sealed sources or following reinstallation of the gamma stereotactic radiosurgery unit in a new location;~~

~~—(III) following any repair of the gamma stereotactic radiosurgery unit that includes removal of the sealed sources or major repair of the components associated with the sealed source exposure assembly; and~~

~~—(iii) at intervals not to exceed one year.~~

~~—(B) Full calibration measurements shall include determination of the following:~~

~~—(i) the output within plus or minus 3.0%;~~

~~—(ii) relative helmet factors;~~

~~—(iii) isocenter coincidence;~~

~~—(iv) timer accuracy and linearity over the range of use;~~

~~—(v) "on-off" error;~~

~~—(vi) trunnion centricity;~~

~~—(vii) treatment table retraction mechanism, using backup battery power or hydraulic backups with the unit "off";~~

~~—(viii) helmet microswitches;~~

~~—(ix) emergency timing circuits; and~~

~~—(x) stereotactic frames and localizing devices (trunnions).~~

~~—(C) The licensee shall use the dosimetry system described in paragraph (6)(A) of this subsection to measure the output for one set of exposure conditions. The remaining radiation measurements required in subparagraph (B)(i) of this paragraph may be made using a dosimetry system that indicates relative dose rates.~~

~~—(D) The licensee shall make full calibration measurements required by subparagraph (A) of this paragraph in accordance with published protocols accepted by nationally recognized bodies.~~

~~—(E) The licensee shall mathematically correct the outputs determined in subparagraph (B)(i) of this paragraph at intervals not to exceed one month for cobalt-60 and at intervals consistent with 1.0% physical decay for all other radionuclides.~~

~~—(F) Full calibration measurements required by subparagraph (A) of this paragraph and physical decay corrections required by subparagraph (E) of this paragraph shall be performed by a licensed medical physicist with a specialty in therapeutic radiological physics.~~

~~—(G) The licensee shall maintain a record of each calibration in accordance with subsection (ff)(2) of this section. The record shall include the following:~~

~~—(i) dates of the calibration;~~

~~—(ii) manufacturer's name and model and serial number for the unit's sealed source;~~

~~—(iii) instruments used to calibrate the unit;~~

~~—(iv) results and an assessment of the full calibration; and~~

~~—(v) signature of the licensed medical physicist with a specialty in therapeutic radiological physics who performed the full calibration.~~

~~—(10) Periodic spot checks for teletherapy units.~~

~~—(A) The licensee authorized to use teletherapy units for medical use shall perform output spot checks on each teletherapy unit once in each calendar month that include determination of the following:~~

~~—(i) timer constancy and linearity over the range of use;~~

~~—(ii) "on-off" error;~~

~~—(iii) the coincidence of the radiation field and the field indicated by the light beam localizing device;~~

~~—(iv) the accuracy of all distance measuring and localization devices used for medical use;~~

~~—(v) the output for one typical set of operating conditions measured with the dosimetry system described in paragraph (6)(A) of this subsection; and~~

~~—(vi) the difference between the measurement made in subparagraph (A)(v) of this section and the anticipated output, expressed as a percentage of the anticipated output, the value obtained at last full calibration corrected mathematically for physical decay.~~

~~—(B) The licensee shall perform measurements required by subparagraph (A) of this paragraph in accordance with procedures established by a licensed medical physicist with a specialty in therapeutic radiological physics. That individual need not actually perform the spot check measurements.~~

~~—(C) The licensee authorized to use a teletherapy unit for medical use shall perform safety spot checks of each teletherapy facility once in each calendar month and after each sealed source installation to assure proper operation of the following:~~

~~—(i) electrical interlocks at each teletherapy room entrance;~~

~~—(ii) electrical or mechanical stops installed for the purpose of limiting use of the primary beam of radiation (restriction of sealed source housing angulation or elevation, carriage or stand travel and operation of the beam "on-off" mechanism);~~

~~—(iii) sealed source exposure indicator lights on the teletherapy unit, on the control console, and in the facility;~~

~~—(iv) viewing and intercom systems;~~

~~—(v) treatment room doors from inside and outside the treatment room; and~~

~~—(vi) electrically assisted treatment room doors with the teletherapy unit electrical power turned "off".~~

~~—(D) The licensee shall have a licensed medical physicist with a specialty in therapeutic radiological physics review the results of each spot check and submit a written report to the licensee within 15 days of the spot check.~~

~~—(E) If the results of the checks required in subparagraph (C) of this paragraph indicate the malfunction of any system, the licensed medical physicist with a specialty in therapeutic radiological physics shall immediately notify the licensee and the licensee shall lock the control console in the "off" position and not use the unit except as may be necessary to repair, replace, or check the malfunctioning system.~~

~~—(F) The licensee shall maintain a record of each spot check required by subparagraphs (A) and (D) of this paragraph, in accordance with subsection (ff)(2) of this section. The record shall include the following:~~

~~—(i) dates of the spot check;~~

~~—(ii) manufacturer's name and model and serial number for the teletherapy unit, and sealed source and instrument used to measure the output of the teletherapy unit;~~

~~—(iii) assessment of timer linearity and constancy;~~

~~—(iv) calculated "on-off" error;~~

~~—(v) determination of the coincidence of the radiation field and the field indicated by the light beam localizing device;~~

~~—(vi) the determined accuracy of each distance measuring and localization device;~~

~~—(vii) the difference between the anticipated output and the measured output;~~

~~—(viii) notations indicating the operability of each entrance door electrical interlock, each electrical or mechanical stop, each sealed source exposure indicator light, and the viewing and intercom system and doors;~~

~~—(ix) name of the individual who performed the periodic spot check; and~~

~~—(x) the signature of the licensed medical physicist with a specialty in therapeutic radiological physics who reviewed the record of the spot check.~~

~~—(11) Periodic spot checks for remote afterloader units.~~

~~—(A) The licensee shall perform spot checks of each remote afterloader facility and on each unit as follows:~~

~~—(i) at the beginning of each day of use of a high dose rate, medium dose rate, or pulsed dose rate remote afterloader unit;~~

~~—(ii) before each patient treatment with a low dose rate remote afterloader unit; and~~

~~—(iii) after each sealed source installation.~~

~~—(B) The licensee shall perform the measurements required by subparagraph (A) of this paragraph in accordance with written procedures established by a licensed medical physicist with~~

a specialty in therapeutic radiological physics. That individual need not actually perform the spot check measurements.

~~—(C) The licensee shall have a licensed medical physicist with a specialty in therapeutic radiological physics review the results of each spot check and submit a written report to the licensee within 15 days of the spot check.~~

~~—(D) To satisfy the requirements of subparagraph (A) of this paragraph, spot checks shall, at a minimum, assure proper operation of the following:~~

~~—(i) electrical interlocks at each remote afterloader unit room entrance;~~

~~—(ii) sealed source exposure indicator lights on the remote afterloader unit, on the control console, and in the facility;~~

~~—(iii) viewing and intercom systems in each high dose rate, medium dose rate, and pulsed dose rate remote afterloader facility;~~

~~—(iv) emergency response equipment;~~

~~—(v) radiation monitors used to indicate the sealed source position;~~

~~—(vi) timer accuracy;~~

~~—(vii) clock (date and time) in the unit's computer; and~~

~~—(viii) decayed sealed source(s) activity in the unit's computer.~~

~~—(E) If the results of the checks required in subparagraph (D) of this paragraph indicate the malfunction of any system, the licensee shall lock the control console in the "off" position and not use the unit except as may be necessary to repair, replace, or check the malfunctioning system.~~

~~—(F) The licensee shall maintain a record, in accordance with subsection (ff)(2) of this section, of each check required by subparagraph (A) of this paragraph. The record shall include the following, as applicable:~~

~~—(i) dates of the spot check;~~

~~—(ii) manufacturer's name and model and serial number for the remote afterloader unit and sealed source;~~

~~—(iii) an assessment of timer accuracy;~~

~~—(iv) notations indicating the operability of each entrance door electrical interlock, radiation monitors, sealed source exposure indicator lights, viewing and intercom systems, clock, and decayed sealed source activity in the unit's computer;~~

~~—(v) name of the individual who performed the periodic spot check; and~~

~~—(vi) the signature of the licensed medical physicist with a specialty in therapeutic radiological physics who reviewed the record of the spot check.~~

~~—(12) Periodic spot checks for gamma stereotactic radiosurgery units.~~

~~—(A) The licensee shall perform spot checks of each gamma stereotactic radiosurgery facility and on each unit as follows:~~

~~—(i) monthly;~~

~~—(ii) at the beginning of each day of use; and~~

~~—(iii) after each source installation.~~

~~—(B) The licensee shall perform the measurements required by subparagraph (A) of this paragraph in accordance with written procedures established by a licensed medical physicist with a specialty in therapeutic radiological physics. That individual need not actually perform the spot check measurements.~~

- ~~—(C) The licensee shall have a licensed medical physicist with a specialty in therapeutic radiological physics review the results of each spot check and submit a written report to the licensee within 15 days of the spot check.~~
- ~~—(D) To satisfy the requirements of subparagraph (A)(i) of this paragraph, spot checks shall, at a minimum, achieve the following by:

 - ~~—(i) assurance of proper operation of these items:

 - ~~—(I) treatment table retraction mechanism, using backup battery power or hydraulic backups with the unit "off;"~~
 - ~~—(II) helmet microswitches;~~
 - ~~—(III) emergency timing circuits; and~~
 - ~~—(IV) stereotactic frames and localizing devices (trunnions); and~~~~
 - ~~—(ii) determination of the following:

 - ~~—(I) the output for one typical set of operating conditions measured with the dosimetry system described in paragraph (6)(A) of this subsection;~~
 - ~~—(II) the difference between the measurement made in subclause (I) of this clause and the anticipated output, expressed as a percentage of the anticipated output, the value obtained at last full calibration corrected mathematically for physical decay;~~
 - ~~—(III) sealed source output against computer calculation;~~
 - ~~—(IV) timer accuracy and linearity over the range of use;~~
 - ~~—(V) "on off" error; and~~
 - ~~—(VI) trunnion centricity.~~~~~~
- ~~—(E) To satisfy the requirements of subparagraph (A)(ii) and (iii) of this paragraph, spot checks shall assure proper operation of the following:

 - ~~—(i) electrical interlocks at each gamma stereotactic radiosurgery room entrance;~~
 - ~~—(ii) sealed source exposure indicator lights on the gamma stereotactic radiosurgery unit, on the control console, and in the facility;~~
 - ~~—(iii) viewing and intercom systems;~~
 - ~~—(iv) timer termination;~~
 - ~~—(v) radiation monitors used to indicate room exposures; and~~
 - ~~—(vi) emergency "off" buttons.~~~~
- ~~—(F) The licensee shall arrange for prompt repair of any system identified in subparagraph (D) of this paragraph that is not operating properly.~~
- ~~—(G) If the results of the checks required in subparagraph (D) of this paragraph indicate the malfunction of any system, the licensee shall lock the control console in the "off" position and not use the unit except as may be necessary to repair, replace, or check the malfunctioning system.~~
- ~~—(H) The licensee shall retain a record of each check required by subparagraphs (D) and (E) of this paragraph in accordance with subsection (ff)(2) of this section. The record shall include the following:

 - ~~—(i) dates of the spot check;~~
 - ~~—(ii) manufacturer's name and model and serial number for the gamma stereotactic radiosurgery unit and the instrument used to measure the output of the unit;~~
 - ~~—(iii) an assessment of timer linearity and accuracy;~~
 - ~~—(iv) the calculated "on off" error;~~~~

- (v) a determination of trunnion centricity;
 - (vi) the difference between the anticipated output and the measured output;
 - (vii) an assessment of sealed source output against computer calculations;
 - (viii) notations indicating the operability of radiation monitors, helmet microswitches, emergency timing circuits, emergency "off" buttons, electrical interlocks, sealed source exposure indicator lights, viewing and intercom systems, timer termination, treatment table retraction mechanism, and stereotactic frames and localizing devices (trunnions);
 - (ix) the name of the individual who performed the periodic spot check; and
 - (x) the signature of the licensed medical physicist with a specialty in therapeutic radiological physics who reviewed the record of the spot check.
- (13) Additional technical requirements for mobile remote afterloader units.
- (A) The licensee providing mobile remote afterloader service shall do the following:
- (i) check survey instruments before medical use at each address of use or on each day of use, whichever is more frequent; and
 - (ii) account for all sealed sources before departure from a client's address of use.
- (B) In addition to the periodic spot checks required by paragraph (11) of this subsection, the licensee shall perform checks on each remote afterloader unit before medical use at each address of use. At a minimum, checks shall be made to verify the operation of the following:
- (i) electrical interlocks on treatment area access points;
 - (ii) sealed source exposure indicator lights on the remote afterloader unit, on the control console, and in the facility;
 - (iii) viewing and intercom systems;
 - (iv) applicators, sealed source transfer tubes, and transfer tube applicator interfaces;
 - (v) radiation monitors used to indicate room exposures;
 - (vi) sealed source positioning (accuracy); and
 - (vii) radiation monitors used to indicate whether the sealed source has returned to a safe shielded position.
- (C) In addition to the requirements for checks in subparagraph (B) of this paragraph, the licensee shall ensure overall proper operation of the remote afterloader unit by conducting a simulated cycle of treatment before use at each address of use.
- (D) If the results of the checks required in subparagraph (B) of this paragraph indicate the malfunction of any system, the licensee shall lock the control console in the "off" position and not use the unit except as may be necessary to repair, replace, or check the malfunctioning system.
- (E) The licensee shall retain a record, in accordance with subsection (ff)(2) of this section, of each check required by subparagraph (B) of this paragraph. The record shall include the following:
- (i) dates of the check;
 - (ii) manufacturer's name and model and serial number of the remote afterloader unit;
 - (iii) notations accounting for all sealed sources before the licensee departs from a facility;
 - (iv) notations indicating the operability of each entrance door electrical interlock, radiation monitors, sealed source exposure indicator lights, viewing and intercom system, applicators and sealed source transfer tubes, and sealed source positioning accuracy; and
 - (v) the signature of the individual who performed the check.

~~-(14) Radiation surveys.~~

~~—(A) In addition to the survey requirement in §289.202(p) of this title, a person licensed to use sealed sources in this subsection shall make surveys as defined in the Sealed Source and Device Registry to assure that the maximum radiation levels and average radiation levels from the surface of the main sealed source safe with the sealed source(s) in the shielded position do not exceed the levels stated in the Registry.~~

~~—(B) The licensee shall make the survey required by paragraph (A) of this section at installation of a new sealed source and following repairs to the sealed source(s) shielding, the sealed source(s) driving unit, or other electronic or mechanical component that could expose the sealed source, reduce the shielding around the sealed source(s), or compromise the radiation safety of the unit or the sealed source(s).~~

~~—(C) The licensee shall retain a record, in accordance with subsection (ff)(2) of this section, of the radiation surveys required by subparagraph (A) of this paragraph. The record shall include:~~

~~—(i) dates of the measurements;~~

~~—(ii) manufacturer's name and model and serial number of the treatment unit, sealed source, and instrument used to measure radiation levels;~~

~~—(iii) each dose rate measured around the sealed source while the unit is in the "off" position and the average of all measurements; and~~

~~—(iv) the signature of the individual who performed the test.~~

~~-(15) Five year inspection for teletherapy and gamma stereotactic radiosurgery units.~~

~~—(A) The licensee shall have each teletherapy unit and gamma stereotactic radiosurgery unit fully inspected and serviced during sealed source replacement or at intervals not to exceed five years, whichever comes first, to assure proper functioning of the sealed source exposure mechanism.~~

~~—(B) This inspection and servicing may only be performed by persons specifically licensed to do so by the agency, the NRC, an agreement state, or licensing state.~~

~~—(C) The licensee shall keep a record of the inspection and servicing in accordance with subsection (ff)(2) of this section. The record shall include the following:~~

~~—(i) dates of inspection;~~

~~—(ii) manufacturer's name and model and serial number of both the treatment unit and the sealed source;~~

~~—(iii) a list of components inspected and serviced, and the type of service; and~~

~~—(iv) the radioactive material license number and the signature of the individual performing the inspection.~~

~~-(16) Therapy related computer systems. The licensee shall perform acceptance testing on the treatment planning system in accordance with published protocols accepted by nationally recognized bodies. At a minimum, the acceptance testing shall include, as applicable, verification of the following:~~

~~—(A) the sealed source specific input parameters required by the dose calculation algorithm;~~

~~—(B) the accuracy of dose, dwell time, and treatment time calculations at representative points;~~

~~—(C) the accuracy of isodose plots and graphic displays;~~

~~—(D) the accuracy of the software used to determine sealed source positions from radiographic images; and~~

~~(E) the accuracy of electronic transfer of the treatment delivery parameters to the treatment delivery unit from the treatment planning system.~~

~~—(17) Training for use of remote afterloader units, teletherapy units, and gamma stereotactic radiosurgery units. An authorized user of radiopharmaceuticals for the uses authorized in paragraph (1) of this subsection shall be a physician who meets the requirements of subsection (ff)(1)(G) and (I) or (ff)(1)(H) and (I) of this section.~~

~~(ee) Report and notification of a medical event.~~

~~—(1) The licensee shall report any event, except for events that result from intervention by a patient or human research subject, in which the administration of radioactive material, or radiation from radioactive material, results in the following:~~

~~—(A) a dose that differs from the prescribed dose by more than 5 rem (0.05 Sv) effective dose equivalent, 50 rem (0.5 Sv) to an organ or tissue, or 50 rem (0.5 Sv) shallow dose equivalent to the skin and either:~~

~~—(i) the total dose delivered differs from the prescribed dose by 20% or more;~~

~~—(ii) the total dosage delivered differs from the prescribed dosage by 20% or more or falls outside the prescribed dosage range; or~~

~~—(iii) the fractionated dose delivered differs from the prescribed dose, for a single fraction, by 50% or more.~~

~~—(B) a dose that exceeds 5 rem (0.05 Sv) effective dose equivalent, 50 rem (0.5 Sv) to an organ or tissue, or 50 rem (0.5 Sv) shallow dose equivalent to the skin from any of the following:~~

~~—(i) an administration of a wrong radioactive drug containing radioactive material;~~

~~—(ii) an administration of a radioactive drug containing radioactive material by the wrong route of administration;~~

~~—(iii) an administration of a dose or dosage to the wrong individual or human research subject;~~

~~—(iv) an administration of a dose or dosage delivered by the wrong mode of treatment; or~~

~~—(v) a leaking sealed source.~~

~~—(C) a dose to the skin or an organ or tissue other than the treatment site that exceeds by 50 rem (0.5 Sv) to an organ or tissue and 50% of the dose expected from the administration defined in the written directive (excluding, for permanent implants, seeds that were implanted in the correct site but migrated outside the treatment site).~~

~~—(2) The licensee shall report any event resulting from intervention of a patient or human research subject in which the administration of radioactive material, or radiation from radioactive material, results or will result in an unintended permanent functional damage to an organ or a physiological system, as determined by a physician.~~

~~—(3) The licensee shall notify the agency by telephone no later than the next calendar day after discovery of the medical event.~~

~~—(4) The licensee shall submit a written report to the agency within 15 days after discovery of the medical event. The written report shall include the following, excluding the individual's name or any other information that could lead to identification of the individual:~~

~~—(A) the licensee's name and radioactive material license number;~~

~~—(B) the name of the prescribing physician;~~

~~—(C) a brief description of the medical event;~~

~~—(D) why the event occurred;~~

~~—(E) the effect, if any, on the individual(s) who received the administration;~~

- ~~—(F) actions, if any, that have been taken, or are planned, to prevent recurrence;~~
- ~~—(G) whether the licensee notified the individual (or the individual's responsible relative or guardian), and if not, why not; and~~
- ~~—(H) if there was notification, what information was provided.~~
- ~~—(5) The licensee shall notify the referring physician and also notify the individual who is the subject of the medical event no later than 24 hours after its discovery, unless the referring physician personally informs the licensee either that he or she will inform the individual or that, based on medical judgement, telling the individual would be harmful. The licensee is not required to notify the individual without first consulting the referring physician. If the referring physician or the affected individual cannot be reached within 24 hours, the licensee shall notify the individual as soon as possible thereafter. The licensee shall not delay any appropriate medical care for the individual, including any necessary remedial care as a result of the medical event, because of any delay in notification. To meet the requirements of this subsection, the notification of the individual who is the subject of the medical event may be made instead to that individual's responsible relative or guardian. If a verbal notification is made, the licensee shall inform the individual or appropriate responsible relative or guardian, that a written description of the event can be obtained from the licensee upon request. The licensee shall provide the written description if requested.~~
- ~~—(6) Aside from the notification requirement, nothing in this section affects any rights or duties of licensees and physicians in relation to each other, to individuals affected by the medical event, or to that individual's responsible relatives or guardians.~~
- ~~—(7) The licensee shall maintain a record of the medical event in accordance with subsection (ff)(2) of this section. A copy of the record shall be provided to the referring physician if other than the licensee. The record shall contain the following:
 - ~~—(A) licensee's name and radioactive material license number;~~
 - ~~—(B) names of the individuals involved;~~
 - ~~—(C) the identification number of the individual who is the subject of the medical event;~~
 - ~~—(D) brief description of the event and why it occurred;~~
 - ~~—(E) the effect, if any, on the individual; and~~
 - ~~—(F) the actions, if any, taken, or planned, to prevent recurrence; and~~
 - ~~—(G) whether the licensee notified the individual or the individual's responsible relative or guardian, and if not, whether the failure to notify was based on guidance from the referring physician.~~~~
- ~~—(8) The licensee shall report any dose to an embryo/fetus that is greater than 5 rem (50 mSv) dose equivalent that is a result of an administration of radioactive material or radiation from radioactive material to a pregnant individual, unless the dose to the embryo/fetus was specifically approved, in advance, by the authorized user.~~
- ~~—(9) The licensee shall report any dose to a nursing child that is a result of an administration of radioactive material to a breast feeding individual that:
 - ~~—(A) is greater than 5 rem (50 mSv) TEDE; or~~
 - ~~—(B) has resulted in unintended permanent functional damage to an organ or a physiological system, as determined by a physician.~~~~

~~—(10) The licensee shall notify the agency by telephone no later than the next calendar day after discovery of a dose to the embryo/fetus or nursing child that requires a report in accordance with paragraph (8) or (9) of this subsection.~~

~~—(11) The licensee shall submit a written report to the agency no later than 15 days after discovery of a dose to the embryo/fetus or nursing child that requires a report in accordance with paragraph (8) or (9) of this subsection. The written report shall include the items in paragraph (4)(A) (F) of this subsection, excluding the individual's or child's name or any other information that could lead to identification of the individual or child.~~

~~—(12) The licensee shall notify the referring physician and also notify the pregnant individual or mother, both hereafter referred to as the mother, no later than 24 hours after discovery of an event that would require reporting in accordance with paragraph (8) or (9) of this subsection, unless the referring physician personally informs the licensee either that he or she will inform the mother or that, based on medical judgement, telling the mother would be harmful.~~

~~—(13) To meet the requirements of this subsection, the notification may be made to the mother's or child's responsible relative or guardian instead of the mother, when appropriate.~~

~~—(14) The licensee is not required to notify the mother without first consulting with the referring physician. If the referring physician or mother cannot be reached within 24 hours, the licensee shall make the appropriate notifications as soon as possible thereafter. The licensee may not delay any appropriate medical care for the embryo/fetus or for the nursing child, including any necessary remedial care as a result of the event, because of any delay in notification.~~

~~—(15) If notification was made in accordance with paragraphs (12) and (13) of this subsection, the licensee shall also furnish, within 15 days after discovery of the event, a written report to the mother or responsible relative or guardian, by sending either of the following:~~

~~—(A) a copy of the report that was submitted to the agency; or~~

~~—(B) a brief description of both the event and the consequences as they may affect the embryo/fetus or nursing child.~~

~~—(16) The licensee shall retain a record of a dose to an embryo/fetus or a nursing child in accordance with subsection (ff)(2) of this section. The record shall contain items in paragraph (7)(A) of this subsection.~~

~~(ff) Appendices.~~

~~—(1) Acceptable training and experience for medical uses of radioactive material.~~

~~—(A) Training for uptake, dilution, and excretion studies:~~

~~—(i) The licensee shall require the authorized user of radiopharmaceuticals for uptake, dilution, and excretion studies to be a physician who:~~

~~—(I) is certified in:~~

~~—(a) nuclear medicine by the American Board of Nuclear Medicine (ABNM);~~

~~—(b) diagnostic radiology or radiology by the American Board of Radiology (ABR);~~

~~—(c) diagnostic radiology or radiology by the American Osteopathic Board of Radiology (AOBR);~~

~~—(d) nuclear medicine by the Royal College of Physicians and Surgeons of Canada (RCPSC); or~~

~~—(e) nuclear medicine by the American Osteopathic Board of Nuclear Medicine (AOBNM); or~~

~~—(II) has successfully completed classroom and laboratory training in basic radioisotope handling techniques applicable to the use of prepared radiopharmaceuticals and supervised clinical experience as follows:~~

~~—(a) 40 hours of classroom and laboratory training that includes:~~

~~—(1) radiation physics and instrumentation;~~

~~—(2) radiation protection;~~

~~—(3) mathematics pertaining to the use and measurement of radioactivity;~~

~~—(4) radiation biology; and~~

~~—(5) radiopharmaceutical chemistry; and~~

~~—(b) 20 hours of supervised clinical experience under the supervision of an authorized user and that includes:~~

~~—(1) examining patients and reviewing their case histories to determine their suitability for radioisotope diagnosis, limitations, or contraindications;~~

~~—(2) selecting the suitable radiopharmaceuticals and calculating and measuring the dosages;~~

~~—(3) administering dosages to patients and using syringe radiation shields;~~

~~—(4) collaborating with the authorized user in the interpretation of radioisotope test results; and~~

~~—(5) patient follow-up; or~~

~~—(c) has successfully completed a six-month training program in nuclear medicine as part of a residency program that has been accredited by the Accreditation Council for Graduate Medical Education (ACGME) or the Council on Postdoctoral Training of the American Osteopathic Association (COPT-AOA) and that included classroom and laboratory training, work experience, and supervised clinical experience in all the topics identified in this subclause.~~

~~—(ii) Training in all the topics identified in clause (i)(II)(a) of this subparagraph, which is not a part of a residency program as in clause (i)(II)(c) of this subparagraph, shall be obtained in an ACGME or COPT-AOA-accredited medical teaching institution. The 40 hours of classroom and laboratory training in clause (i)(II)(a) of this subparagraph shall have been initiated prior to completion of the clinical experience in clause (i)(II)(b) of this subparagraph. The clinical experience described in clause (i)(II)(b) of this subparagraph shall be supervised by a physician licensed for the full scope of diagnostic nuclear medicine procedures or by an authorized physician in an ACGME or COPT-AOA-accredited medical teaching institution.~~

~~—(iii) Notwithstanding the requirements of clauses (i) and (ii) of this subparagraph, proof of alternative training that includes the topics and hours listed in subparagraph (B)(i)(II) of this paragraph may be accepted on a case-by-case basis if the agency, after providing the Medical Committee of the Texas Radiation Advisory Board with the opportunity to review and comment, determines that the alternative training would give an equal or greater level of training to the standards in clauses (i) and (ii) of this subparagraph.~~

~~—(B) Training for imaging and localization studies.~~

~~(i) The licensee shall require the authorized user of radiopharmaceuticals for imaging and localization studies to be a physician who:~~

~~—(I) is certified in:~~

~~—(a) nuclear medicine by the ABNM;~~

~~—(b) diagnostic radiology or radiology by the ABR;~~

~~— (c) diagnostic radiology or radiology by the AOBRR;~~
~~— (d) nuclear medicine by the RCPSC; or~~
~~— (e) nuclear medicine by the AOBNM; or~~
~~— (II) has successfully completed classroom and laboratory training in basic radioisotope handling techniques applicable to the use of prepared radiopharmaceuticals, generators, and reagent kits, supervised work experience, and supervised clinical experience as follows:~~
~~— (a) 200 hours of classroom and laboratory training that includes:~~
~~— (1) radiation physics and instrumentation;~~
~~— (2) radiation protection;~~
~~— (3) mathematics pertaining to the use and measurement of radioactivity;~~
~~— (4) radiopharmaceutical chemistry; and~~
~~— (5) radiation biology; and~~
~~— (b) 500 hours of supervised work experience under the supervision of an authorized user that includes:~~
~~— (1) ordering, receiving, and unpacking radioactive materials safely and performing the related radiation surveys;~~
~~— (2) calibrating dose calibrators and diagnostic instruments and performing checks for proper operation of survey meters;~~
~~— (3) calculating and safely preparing patient dosages;~~
~~— (4) using administrative controls to prevent the misadministration of byproduct material;~~
~~— (5) using procedures to contain spilled byproduct material safely and using proper decontamination procedures; and~~
~~— (6) eluting technetium 99m from generator systems, measuring and testing the eluate for molybdenum 99 and alumina contamination, and processing the eluate with reagent kits to prepare technetium 99m labeled radiopharmaceuticals; and~~
~~— (c) 500 hours of supervised clinical experience under the supervision of an authorized user that includes:~~
~~— (1) examining patients and reviewing their case histories to determine their suitability for radioisotope diagnosis, limitations, or contraindications;~~
~~— (2) selecting the suitable radiopharmaceuticals and calculating and measuring the dosages;~~
~~— (3) administering dosages to patients and using syringe radiation shields;~~
~~— (4) collaborating with the authorized user in the interpretation of radioisotope test results; and~~
~~— (5) patient follow up; or~~
~~— (d) has successfully completed a six-month training program in nuclear medicine as part of a residency program that has been accredited by the ACGME or the COPT-AOA and that included classroom and laboratory training, work experience, and supervised clinical experience in all the topics identified in this subclause.~~
~~— (ii) Training in all the topics identified in clause (i)(II)(a) of this subparagraph, which is not a part of a residency program as in clause (i)(II)(d) of this subparagraph, shall be obtained in a medical teaching institution that provides appropriate training programs that have been accredited by the ACGME or the COPT-AOA. The 200 hours of classroom and laboratory~~

training in clause (i)(II)(a) of this subparagraph shall have been initiated prior to completion of the work and clinical experience in clauses (i)(II)(b) and (c) of this subparagraph. The work and clinical experience described in clause (i)(II)(b) and (c) of this subparagraph shall be supervised by a physician licensed for the full scope of diagnostic nuclear medicine procedures or by a licensed authorized physician in a medical teaching institution that also provides appropriate training programs that have been accredited by the ACGME or the COPT AOA. The experience in clause (i)(II)(b) and (c) of this subparagraph may be obtained concurrently.

—(iii) Classroom and laboratory training identified in clause (i)(II)(a) of this subparagraph that was initiated before October 1, 1995, and completed by October 1, 1997, will be accepted if it is obtained in an accredited medical school, a federal teaching hospital, or a training program for medical use of radioactive material that has been accepted by the agency, NRC, or another agreement state.

—(iv) Notwithstanding the requirements of clauses (i) and (ii) of this subparagraph, proof of alternative training that includes the topics and hours listed in clause (i)(II) of this subparagraph may be accepted on a case-by-case basis if the agency, after providing the Medical Committee of the Texas Radiation Advisory Board with the opportunity to review and comment, determines that the alternative training would give an equal or greater level of training to the standards in clauses (i) and (ii) of this subparagraph.

—(C) Training for the therapeutic use of radiopharmaceuticals.

—(i) The licensee shall require the authorized user of radiopharmaceuticals for therapeutic use to be a physician who:

—(I) is certified in:

—(a) nuclear medicine by the ABNM;

—(b) radiology or therapeutic radiology by the ABR;

—(c) therapeutic radiology or radiology by the AOBR;

—(d) nuclear medicine by the RCPSC; or

—(e) nuclear medicine by the AOBNM; or

—(II) has classroom and laboratory training in basic radioisotope handling techniques applicable to the use of therapeutic radiopharmaceuticals and supervised clinical experience as follows:

—(a) 80 hours of classroom and laboratory training that includes:

—(1) radiation physics and instrumentation;

—(2) radiation protection;

—(3) mathematics pertaining to the use and measurement of radioactivity; and

—(4) radiation biology; and

—(b) supervised clinical experience under the supervision of an authorized physician user for the type of therapy authorization requested from the following list:

—(1) use of iodine-131 for diagnosis of thyroid function and the treatment of hyperthyroidism in 10 individuals;

—(2) use of iodine-131 for treatment of thyroid carcinoma in three individuals;

—(3) use of colloidal phosphorus-32 for intracavitary treatment in three individuals;

—(4) use of phosphorus-32 for treatment of polycythemia vera, leukemia and/or bone metastasis in three individuals;

—(5) use of colloidal gold-198 for intracavitary treatment in three individuals; or

~~(6) use of radiopharmaceuticals not listed in subitems (1) through (5) of this item for therapeutic treatment in three individuals; or
 (7) has successfully completed a six-month training program in nuclear medicine as part of a residency program that has been accredited by the ACGME or the COPT AOA and that included classroom and laboratory training, work experience and supervised clinical experience in all the topics identified in this subclause.
 (ii) Training in all the topics identified in clause (i)(II) of this subparagraph, which is not a part of a residency program as in clause (i)(II)(b) of this subparagraph, shall be obtained in a medical teaching institution accredited by the ACGME or the COPT AOA.
 (D) Training for use of brachytherapy sealed sources (except for beta applicators—See subparagraph (E) of this paragraph).
 (i) The licensee shall require the authorized user of a brachytherapy sealed source to be a physician who:
 (I) is certified in:
 (a) therapeutic radiology, radiation oncology, or radiology by the ABR; or
 (b) therapeutic radiology, radiation oncology, or radiology by the AOBR; or
 (c) radiology with specialization in radiotherapy, as a British "Fellow of the Faculty of Radiology" or "Fellow of the Royal College of Radiology"; or
 (d) therapeutic radiology by the Canadian Royal College of Physicians and Surgeons; or
 (II) is in the active practice of therapeutic radiology, has had classroom training in radioisotope handling techniques applicable to the therapeutic use of brachytherapy sealed sources, and supervised clinical experience as follows:
 (a) 200 hours of classroom and laboratory training that includes:
 (1) radiation physics and instrumentation;
 (2) radiation protection;
 (3) mathematics pertaining to the use and measurement of radioactivity; and
 (4) radiation biology; and
 (b) 500 hours of supervised work experience under the supervision of an authorized user at a medical institution that includes:
 (1) ordering, receiving, and unpacking radioactive materials safely and performing the related radiation surveys;
 (2) checking survey meters for proper operation;
 (3) preparing, implanting, and removing sealed sources;
 (4) maintaining running inventories of material on hand;
 (5) using administrative controls to prevent the misadministration of byproduct material; and
 (6) using emergency procedures to control byproduct material; and
 (c) three years of supervised clinical experience that includes one year in a formal training program approved by the Residency Review Committee for Radiology of the ACGME or the COPT AOA, and an additional two years of clinical experience in therapeutic radiology under the supervision of an authorized user at a medical institution that includes:
 (1) examining individuals and reviewing their case histories to determine their suitability for brachytherapy treatment, and any limitations or contraindications;~~

- (2) selecting the proper brachytherapy sealed sources and dose and method of administration;
- (3) calculating the dose; and
- (4) post-administration follow-up and review of case histories in collaboration with the authorized user.
- (ii) Training in all the topics identified in clause (i)(II)(a) of this subparagraph shall be accredited by the ACGME or the COPT AOA. The clinical experience described in clause (i)(II)(b) and (c) of this subparagraph should be supervised by a physician licensed to use brachytherapy sealed sources. The experience in clause (i)(II)(b) and (c) of this subparagraph may be obtained concurrently.
- (E) Training for ophthalmic use of strontium 90.
 - (i) The licensee shall require the authorized user of only strontium 90 for ophthalmic radiotherapy to be a physician who:
 - (I) is certified in:
 - (a) therapeutic radiology, radiation oncology, or radiology by the ABR;
 - (b) therapeutic radiology, radiation oncology, or radiology by the AOBR;
 - (c) radiology with specialization in radiotherapy, as a British "Fellow of the Faculty of Radiology" or "Fellow of the Royal College of Radiology"; or
 - (d) therapeutic radiology by the Canadian Royal College of Physicians and Surgeons; or
 - (II) is in the active practice of therapeutic radiology or ophthalmology, and has had classroom and laboratory training in basic radioisotope handling techniques applicable to the use of strontium 90 for ophthalmic radiotherapy, and a period of supervised clinical training in ophthalmic radiotherapy as follows:
 - (a) 24 hours of classroom and laboratory training that includes:
 - (1) radiation physics and instrumentation;
 - (2) radiation protection;
 - (3) mathematics pertaining to the use and measurement of radioactivity; and
 - (4) radiation biology; and
 - (b) supervised clinical training in ophthalmic radiotherapy under the supervision of an authorized user at a medical institution that includes the use of strontium 90 for the ophthalmic treatment of five individuals that includes:
 - (1) examination of each individual to be treated;
 - (2) calculation of the dose to be administered;
 - (3) administration of the dose; and
 - (4) follow up and review of each individual's case history.
 - (ii) Training in all the topics identified in clause (i)(II)(a) of this subparagraph shall be obtained in a medical teaching institution or shall be accredited by the ACGME or the COPT AOA. The clinical experience described in clause (i)(II)(b) of this subparagraph shall be supervised by a physician licensed for the use of sealed sources in therapy.
- (F) Training for use of sealed sources for diagnosis.
 - (i) The licensee shall require the authorized user of a sealed source in the devices listed in clause (ii) of this subparagraph, to be a physician, dentist, or podiatrist who:
 - (I) is certified in:

- ~~— (a) therapeutic radiology, diagnostic radiology, radiation oncology, or radiology by the ABR;~~
- ~~— (b) nuclear medicine by the ABNM;~~
- ~~— (c) diagnostic radiology or radiology by the AOBR; or~~
- ~~— (d) nuclear medicine by the RCPSC; or~~
- ~~— (e) nuclear medicine by the AOBNM; or~~
- ~~— (H) has had eight hours of classroom and laboratory training in radioisotope handling techniques specifically applicable to the use of the device that includes:~~
 - ~~— (a) radiation physics, mathematics pertaining to the use and measurement of radioactivity, and instrumentation;~~
 - ~~— (b) radiation biology;~~
 - ~~— (c) radiation protection; and~~
 - ~~— (d) training in the use of the device for the uses requested.~~
- ~~— (ii) The following sealed sources shall be used in accordance with the manufacturer's radiation safety and handling instructions:~~
 - ~~— (I) iodine 125, americium 241, or gadolinium 153 as a sealed source in a device for bone mineral analysis; and~~
 - ~~— (II) iodine 125 as a sealed source in a portable imaging device.~~
- ~~— (iii) Training in all the topics identified in clause (i)(H) of this subparagraph shall be obtained in a medical teaching institution or shall be accredited by the ACGME or the COPT AOA. The clinical experience shall be supervised by a physician, dentist, or podiatrist licensed to use the devices.~~
- ~~— (G) Training for teletherapy, remote afterloader units, and gamma stereotactic radiosurgery.~~
 - ~~— (i) The licensee shall require the authorized user of a sealed source in a teletherapy unit to be a physician who:~~
 - ~~— (I) is certified in:~~
 - ~~— (a) therapeutic radiology, radiation oncology, or radiology by the ABR;~~
 - ~~— (b) therapeutic radiology, radiation oncology, or radiology by the AOBR;~~
 - ~~— (c) radiology with specialization in radiotherapy, as a British "Fellow of the Faculty of Radiology" or "Fellow of the Royal College of Radiology"; or~~
 - ~~— (d) therapeutic radiology by the Canadian Royal College of Physicians and Surgeons; or~~
 - ~~— (II) is in the active practice of therapeutic radiology, and has had classroom and laboratory training in basic radioisotope techniques applicable to the use of a sealed source in a teletherapy unit, supervised work experience, and supervised clinical experience as follows:~~
 - ~~— (a) 200 hours of classroom and laboratory training that includes:~~
 - ~~— (1) radiation physics and instrumentation;~~
 - ~~— (2) radiation protection;~~
 - ~~— (3) mathematics pertaining to the use and measurement of radioactivity; and~~
 - ~~— (4) radiation biology; and~~
 - ~~— (b) 500 hours of supervised work experience under the supervision of an authorized user at a medical institution that includes:~~
 - ~~— (1) review of the full calibration measurements and periodic spot checks;~~
 - ~~— (2) preparing treatment plans and calculating treatment times;~~
 - ~~— (3) using administrative controls to prevent misadministration;~~

- ~~— (4) implementing emergency procedures to be followed in the event of the abnormal operation of a teletherapy unit or console; and~~
- ~~— (5) checking and using survey meters; and~~
- ~~— (c) three years of supervised clinical experience that includes one year in a formal training program accredited by the ACGME or the COPT AOA and an additional two years of clinical experience in therapeutic radiology under the supervision of an authorized user at a medical institution that includes:~~
 - ~~— (1) examining individuals and reviewing their case histories to determine their suitability for teletherapy treatment; and any limitations or contraindications;~~
 - ~~— (2) selecting the proper dose and how it is to be administered;~~
 - ~~— (3) calculating the therapy doses and collaborating with the authorized user in the review of patients' progress and consideration of the need to modify originally prescribed doses as warranted by patients' reaction to radiation; and~~
 - ~~— (4) post-administration follow-up and review of case histories.~~
- ~~—(ii) Training in all the topics identified in clause (i)(II)(a) of this subparagraph shall be accredited by the ACGME or the COPT AOA. The clinical experience described in clause (i)(II)(b) and (c) of this subparagraph shall be supervised by a physician licensed for teletherapy procedures. The experience in clause (i)(II)(b) and (c) of this subparagraph may be obtained concurrently.~~
- ~~—(H) Training for experienced authorized users. Physicians, dentists, or podiatrists identified as authorized users for the medical, dental, or podiatric use of radioactive material on a NRC or agreement state license issued before September 1, 1993, and those issued by the agency before October 1, 1995, who perform only those methods of use for which they were authorized on that date need not comply with the training requirements in this paragraph.~~
- ~~—(I) Recentness of training. The training and experience specified in this paragraph for medical use shall have been obtained within the five years preceding the date of application or the individual must have had related continuing education and experience since the required training and experience was completed.~~
- ~~—(2) Records/documents for agency inspection. Each licensee shall make the following records/documents available to the agency for inspection, upon reasonable notice.~~

Attached Graphic

Figure: 25 TAC §289.256(ff)(2)

Rule Cross Reference	Name of Records/Documents	Time Interval for Keeping Records/Documents
(g)(3)	Qualifications and dates of service for temporary RSO	3 years
(n)	Copy of the current radioactive	Until termination of the

	material license	radioactive material license
	Current operating, safety, and emergency procedures	Until termination of the radioactive material license
	Current applicable sections of this chapter as listed in the radioactive material license	Until termination of the radioactive material license
	Records of receipt, transfer, and disposal of radioactive material	Until disposal is authorized by the agency
	Records of leak tests for specific devices and sealed sources	3 years
	Shipping papers	3 years
(p)(3)	Written directives	3 years
(q)(4)	Calibration of instruments (dose calibrators)	3 years
(r)(5)	Determination of dosage of radioactive material for medical use	3 years
(s)(5)	Calibration/reference source inventory	3 years
(t)(2)	Sealed source/brachytherapy inventory	3 years
(v)(3)	Surveys for ambient radiation exposure rate	Duration of use of units
(w)(3)	Patient release	3 years after date of release
(x)(2)	Decay in storage/disposal	3 years
(z)(3)(C)	Molybdenum-99 concentrations	3 years
(aa)(2)(B)	Safety instructions—unsealed radioactive materials therapy	3 years

(bb)(2)(C)	Surveys—after sealed source implant and removal	3 years
(bb)(3)(C)	Brachytherapy sealed source inventory	3 years
(bb)(4)(B)	Safety instructions—manual brachytherapy	3 years
(bb)(6)(D)	Calibration measurements of brachytherapy sealed sources	3 years
(dd)(2)(B)	Surveys—patients treated with remote afterloaders	Duration of use of units
(dd)(3)(D)	Installation, maintenance and repair of remote afterloaders, teletherapy units and gamma stereotactic radiotherapy units	3 years
(dd)(4)(H)	Safety instructions and drills—remote afterloader, teletherapy, gamma stereotactic units	3 years
(dd)(6)(C)	Calibration, intercomparison, comparison of dosimetry equipment	3 years
(dd)(7)(G)	Calibration/teletherapy units	3 years
(dd)(8)(I)	Calibration/remote afterloader units	3 years
(dd)(9)(G)	Calibration/gamma stereotactic radiotherapy units	3 years
(dd)(10)(F)	Periodic spot checks for teletherapy units	3 years
(dd)(11)(F)	Periodic spot checks for remote afterloader units	3 years
(dd)(12)(H)	Periodic spot checks for gamma stereotactic radiotherapy units	3 years

(dd)(13)(E)	Periodic spot checks for mobile remote afterloader units	3 years
(dd)(14)(C)	Surveys—gamma stereotactic radiosurgery units	Duration of use of units
(dd)(15)(C)	5-yr inspection for teletherapy gamma stereotactic radiotherapy	Duration of use of units
(ee)(7)(16)	Medical events, dose to embryo/fetus or nursing child	3 years