25 TEXAS ADMINISTRATIVE CODE (TAC)

§289.202

Standards for Protection Against Radiation from Radioactive Materials

Texas Regulations for Control of Radiation

(revisions effective March 1, 2016, are shown as shaded text)

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

(a) Purpose.

(1) This section establishes standards for protection against ionizing radiation resulting from activities conducted in accordance with licenses issued by the agency.

(2) The requirements in this section are designed to control the receipt, possession, use, and transfer of sources of radiation by any licensee so the total dose to an individual, including doses resulting from all sources of radiation other than background radiation, does not exceed the standards for protection against radiation prescribed in this section. However, nothing in this section shall be construed as limiting actions that may be necessary to protect health and safety in an emergency.

(b) Scope.

(1) Except as specifically provided in other sections of this chapter, this section applies to persons who receive, possess, use, or transfer sources of radiation, unless otherwise exempted. No person may use, manufacture, produce, transport, transfer, receive, acquire, own, possess, process, or dispose of sources of radiation unless that person has a license or exemption from the agency. The dose limits in this section do not apply to doses due to background radiation, to exposure of patients to radiation for the purpose of medical diagnosis or therapy, to exposure from individuals administered radioactive material and released in accordance with this chapter, or to voluntary participation in medical research programs. However, no radiation may be deliberately applied to human beings except by or under the supervision of an individual authorized by and licensed in accordance with Texas' statutes to engage in the healing arts.

(2) Licensees who are also registered by the agency to receive, possess, use, and transfer radiation machines shall also comply with the requirements of §289.231 of this title (relating to General Provisions and Standards for Protection Against Machine-Produced Radiation).

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

(1) Air-purifying respirator--A respirator with an air-purifying filter, cartridge, or canister that removes specific air contaminants by passing ambient air through the air-purifying element.

(2) Annual limit on intake (ALI)--The derived limit for the amount of radioactive material taken into the body of an adult worker by inhalation or ingestion in a year. ALI is the smaller value of intake of a given radionuclide in a year by Reference Man that would result in a committed effective dose equivalent of 5 rems (0.05 sievert (Sv)) or a committed dose equivalent of 50 rems (0.5 Sv) to any individual organ or tissue. ALI values for intake by ingestion and by inhalation of selected radionuclides are given in Columns 1 and 2 of Table I of subsection (ggg)(2) of this section.

(3) Assigned protection factor (APF)--The expected workplace level of respiratory protection that would be provided by a properly functioning respirator or a class of respirators to properly fitted and trained users. Operationally, the inhaled concentration can be estimated by dividing the ambient airborne concentration by the APF.

(4) Atmosphere-supplying respirator--A respirator that supplies the respirator user with breathing air from a source independent of the ambient atmosphere and includes supplied-air respirators (SARs) and self-contained breathing apparatus (SCBA) units.

(5) Class--A classification scheme for inhaled material according to its rate of clearance from the pulmonary region of the lung. Materials are classified as D, W, or Y, which apply to a range of clearance half-times: for Class D, Days, of less than 10 days; for Class W, Weeks, from 10 to 100 days, and for Class Y, Years, of greater than 100 days. For purposes of this section, lung class and inhalation class are equivalent terms.

(6) Debris--The remains of something destroyed, disintegrated, or decayed. Debris does not include soils, sludges, liquids, gases, naturally occurring radioactive material regulated in accordance with §289.259 of this title (relating to Licensing of Naturally Occurring Radioactive Material (NORM)), or low-level radioactive waste (LLRW) received from other persons.

(7) Declared pregnant woman--A woman who has voluntarily informed the licensee, in writing, of her pregnancy and the estimated date of conception. The declaration remains in effect until the declared pregnant woman voluntarily withdraws the declaration in writing or is no longer pregnant.

(8) Demand respirator--An atmosphere-supplying respirator that admits breathing air to the facepiece only when a negative pressure is created inside the facepiece by inhalation.

(9) Derived air concentration (DAC)--The concentration of a given radionuclide in air that, if breathed by Reference Man for a working year of 2,000 hours under conditions of light work, results in an intake of 1 ALI. For purposes of this section, the condition of light work is an inhalation rate of 1.2 cubic meters of air per hour for 2,000 hours in a year. DAC values are given in Column 3 of Table I of subsection (ggg)(2) of this section.

(10) Derived air concentration-hour (DAC-hour)--The product of the concentration of radioactive material in air, expressed as a fraction or multiple of the derived air concentration for each radionuclide, and the time of exposure to that radionuclide, in hours. A licensee may take 2,000 DAC-hours to represent ALI, equivalent to a committed effective dose equivalent of 5 rems (0.05 Sv).

(11) Disposable respirator--A respirator for which maintenance is not intended and that is designed to be discarded after excessive breathing resistance, sorbent exhaustion, physical damage, or end-of-service-life renders it unsuitable for use. Examples of this type of respirator are a disposable half-mask respirator or a disposable escape-only self-contained breathing apparatus.

(12) Dosimetry processor--A person that processes and evaluates personnel monitoring devices in order to determine the radiation dose delivered to the monitoring devices.

(13) Filtering facepiece (dust mask)--A negative pressure particulate respirator with a filter as an integral part of the facepiece or with the entire facepiece composed of the filtering medium, not equipped with elastomeric sealing surfaces and adjustable straps.

(14) Fit factor--A quantitative estimate of the fit of a particular respirator to a specific individual, and typically estimates the ratio of the concentration of a substance in ambient air to its concentration inside the respirator when worn.

(15) Fit test--The use of a protocol to qualitatively or quantitatively evaluate the fit of a respirator on an individual.

(16) Helmet--A rigid respiratory inlet covering that also provides head protection against impact and penetration.

(17) Hood--A respiratory inlet covering that completely covers the head and neck and may also cover portions of the shoulders and torso.

(18) Inhalation class (see definition for Class).

(19) Loose-fitting facepiece--A respiratory inlet covering that is designed to form a partial seal with the face.

(20) Lung class (see definition for Class).

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

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

(26) 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.

(27) 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) 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) Quantitative fit test--An assessment of the adequacy of respirator fit by numerically measuring the amount of leakage into the respirator.

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

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

(35) 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) 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) Tight-fitting facepiece--A respiratory inlet covering that forms a complete seal with the face.

(38) 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) 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:

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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.

(d) Implementation.

(1) Any existing license condition that is more restrictive than this section remains in force until there is an amendment or renewal of the license that modifies or removes this condition.

(2) If a license condition exempts a licensee from a provision of this section in effect on or before January 1, 1994, it also exempts the licensee from the corresponding provision of this section.

(3) If a license condition cites provisions of this section in effect prior to January 1, 1994, that do not correspond to any provisions of this section, the license condition remains in force until there is an amendment or renewal of the license that modifies or removes this condition.

(e) Radiation protection programs.

(1) Each licensee shall develop, document, and implement a radiation protection program sufficient to ensure compliance with the provisions of this section. See subsection (mm) of this section for recordkeeping requirements relating to these programs. Documentation of the radiation protection program may be incorporated in the licensee's operating, safety, and emergency procedures.

(2) The licensee shall use, to the extent practicable, procedures and engineering controls based upon sound radiation protection principles to achieve occupational doses and public doses that are as low as is reasonably achievable (ALARA).

(3) The licensee shall, at intervals not to exceed 12 months, ensure the radiation protection program content and implementation is reviewed. The review shall include a reevaluation of the assessments made to determine monitoring is not required in accordance with subsection (q)(1) and (3) of this section in conjunction with the licensee's current operating conditions.

(4) To implement the ALARA requirement in paragraph (2) of this subsection and notwithstanding the requirements in subsection (n) of this section, a constraint on air emissions of radioactive material to the environment, excluding radon-222 and its daughters, shall be established by licensees such that the individual member of the public likely to receive the highest dose will not be expected to receive a total effective dose equivalent (TEDE) in excess of 10 millirems (mrem) (0.1 millisievert (mSv)) per year from these emissions. If a licensee subject to this requirement exceeds this dose constraint, the licensee shall report the exceedance as required in subsection (yy) of this section and promptly take appropriate corrective action to ensure against recurrence.

(5) If monitoring is not required in accordance with subsection (q)(1) and (3) of this section, the licensee shall document assessments made to determine the requirements of subsection (q)(1) and (3) of this section are not applicable. The licensee shall maintain the documentation in accordance with subsection (rr)(5) of this section.

(f) Occupational dose limits for adults.

(1) The licensee shall control the occupational dose to individuals, except for planned special exposures in accordance with subsection (k) of this section, to the following dose limits.

(A) An annual limit shall be the more limiting of:

(i) the total effective dose equivalent being equal to 5 rems (0.05 Sv); or

(ii) the sum of the deep dose equivalent and the committed dose equivalent to any individual organ or tissue other than the lens of the eye being equal to 50 rems (0.5 Sv).

(B) The annual limits to the lens of the eye, to the skin of the whole body, and to the skin of the extremities shall be:

(i) a lens dose equivalent of 15 rems (0.15 Sv); and

(ii) a shallow dose equivalent of 50 rems (0.5 Sv) to the skin of the whole body or to the skin of any extremity.

(2) Doses received in excess of the annual limits, including doses received during accidents, emergencies, and planned special exposures, shall be subtracted from the limits for planned special exposures that the individual may receive during the current year and during the individual's lifetime. See subsection (k)(6)(A) and (B) of this section.

(3) When the external exposure is determined by measurement with an external personal monitoring device, the deep-dose equivalent shall be used in place of the effective dose equivalent, unless the effective dose equivalent is determined by a dosimetry method approved by the agency. The assigned deep dose equivalent shall be for the portion of the body receiving the highest exposure. The assigned shallow-dose equivalent shall be the dose averaged over the contiguous 10 square centimeters (cm^2) of skin receiving the highest exposure.

(4) The deep dose equivalent, lens dose equivalent and shallow dose equivalent may be assessed from surveys, or other radiation measurements for the purpose of demonstrating compliance with the occupational dose limits, if the individual monitoring device was not in the region of highest potential exposure, or the results of individual monitoring are unavailable.

(5) Derived air concentration (DAC) and annual limit on intake (ALI) values are specified in Table I of subsection (ggg)(2) of this section and may be used to determine the individual's dose and to demonstrate compliance with the occupational dose limits. See subsection (rr) of this section.

(6) Notwithstanding the annual dose limits, the licensee shall limit the soluble uranium intake by an individual to 10 milligrams (mg) in a week in consideration of chemical toxicity. See footnote 3 of subsection (ggg)(2) of this section.

(7) The licensee shall reduce the dose that an individual may be allowed to receive in the current year by the amount of occupational dose received while employed by any other person. See subsection (j)(4) of this section.

(g) Compliance with requirements for summation of external and internal doses.

(1) If the licensee is required to monitor in accordance with both subsection (q)(1) and (3) of this section, the licensee shall demonstrate compliance with the dose limits by summing external and internal doses. If the licensee is required to monitor only in accordance with subsection (q)(1) of this section or only in accordance with subsection (q)(3) of this section, then summation is not required to demonstrate compliance with the dose limits. The licensee may demonstrate compliance with the requirements for summation of external and internal doses in accordance with paragraphs (2) - (4) of this subsection. The dose equivalents for the lens of the eye, the skin, and the extremities are not included in the summation, but are subject to separate limits.

(2) If the only intake of radionuclides is by inhalation, the total effective dose equivalent limit is not exceeded if the sum of the deep dose equivalent divided by the total effective dose equivalent limit, and one of the following, does not exceed unity:

(A) the sum of the fractions of the inhalation ALI for each radionuclide; or

(B) the total number of derived air concentration-hours (DAC-hours) for all radionuclides divided by 2,000; or

(C) the sum of the calculated committed effective dose equivalents to all significantly irradiated organs or tissues (T) calculated from bioassay data using appropriate biological models and expressed as a fraction of the annual limit. For purposes of this requirement, an organ or tissue is deemed to be significantly irradiated if, for that organ or tissue, the product of the weighting factors, w_T, and the committed dose equivalent, $H_{T,50}$, per unit intake is greater than 10% of the maximum weighted value of $H_{T,50}$, that is, $w_T H_{T,50}$, per unit intake for any organ or tissue.

(3) If the occupationally exposed individual receives an intake of radionuclides by oral ingestion greater than 10% of the applicable oral ALI, the licensee shall account for this intake and include it in demonstrating compliance with the limits.

(4) The licensee shall evaluate and, to the extent practical, account for intakes through wounds or skin absorption. The intake through intact skin has been included in the calculation of DAC for hydrogen-3 and does not need to be evaluated or accounted for in accordance with this paragraph.

(h) Determination of external dose from airborne radioactive material.

(1) Licensees shall, when determining the dose from airborne radioactive material, include the contribution to the deep dose equivalent, eye dose equivalent, and shallow dose equivalent from external exposure to the radioactive cloud. See footnotes 1 and 2 of subsection (ggg)(2) of this section.

(2) Airborne radioactivity measurements and DAC values shall not be used as the primary means to assess the deep dose equivalent when the airborne radioactive material includes radionuclides other than noble gases or if the cloud of airborne radioactive material is not relatively uniform. The determination of the deep dose equivalent to an individual shall be based upon measurements using instruments or individual monitoring devices.

(i) Determination of internal exposure.

(1) For purposes of assessing dose used to determine compliance with occupational dose equivalent limits, the licensee shall, when required in accordance with subsection (q) of this section, take suitable and timely measurements of:

(A) concentrations of radioactive materials in air in work areas;

(B) quantities of radionuclides in the body;

(C) quantities of radionuclides excreted from the body; or

(D) combinations of these measurements.

(2) Unless respiratory protective equipment is used, as provided in subsection (x) of this section, or the assessment of intake is based on bioassays, the licensee shall assume that an individual inhales radioactive material at the airborne concentration in which the individual is present.

(3) When specific information on the physical and biochemical properties of the radionuclides taken into the body or the behavior of the material in an individual is known, the licensee may:

(A) use that information to calculate the committed effective dose equivalent, and, if used, the licensee shall document that information in the individual's record;

(B) upon prior approval of the agency, adjust the DAC or ALI values to reflect the actual physical and chemical characteristics of airborne radioactive material, for example, aerosol size distribution or density; and

(C) separately assess the contribution of fractional intakes of Class D, W, or Y compounds of a given radionuclide to the committed effective dose equivalent. See subsection (ggg)(2) of this section.

(4) If the licensee chooses to assess intakes of Class Y material using the measurements given in paragraph (1)(A) or (B) of this subsection, the licensee may delay the recording and reporting of the assessments for periods up to seven months, unless otherwise required by subsections (xx) or (yy) of this section. This delay permits the licensee to make additional measurements basic to the assessments.

(5) If the identity and concentration of each radionuclide in a mixture are known, the fraction of the DAC applicable to the mixture for use in calculating DAC-hours shall be either:

(A) the sum of the ratios of the concentration to the appropriate DAC value, that is, D, W, or Y, from subsection (ggg)(2) of this section for each radionuclide in the mixture; or

(B) the ratio of the total concentration for all radionuclides in the mixture to the most restrictive DAC value for any radionuclide in the mixture.

(6) If the identity of each radionuclide in a mixture is known, but the concentration of one or more of the radionuclides in the mixture is not known, the DAC for the mixture shall be the most restrictive DAC of any radionuclide in the mixture.

(7) When a mixture of radionuclides in air exists, a licensee may disregard certain radionuclides in the mixture if:

(A) the licensee uses the total activity of the mixture in demonstrating compliance with the dose limits in subsection (f) of this section and in complying with the monitoring requirements in subsection (q)(3) of this section;

(B) the concentration of any radionuclide disregarded is less than 10% of its DAC; and

(C) the sum of these percentages for all of the radionuclides disregarded in the mixture does not exceed 30%.

(8) When determining the committed effective dose equivalent, the following information may be considered.

(A) In order to calculate the committed effective dose equivalent, the licensee may assume that the inhalation of 1 ALI, or an exposure of 2,000 DAC-hours, results in a committed effective dose equivalent of 5 rems (0.05 Sv) for radionuclides that have their ALIs or DACs based on the committed effective dose equivalent.

(B) For an ALI and the associated DAC determined by the nonstochastic organ dose limit of 50 rems (0.5 Sv), the intake of radionuclides that would result in a committed effective dose equivalent of 5 rems (0.05 Sv), that is, the stochastic ALI, is listed in parentheses in Table I of subsection (ggg)(2) of this section. The licensee may, as a simplifying assumption, use the stochastic ALI to determine committed effective dose equivalent. However, if the licensee uses the stochastic ALI, the licensee shall also demonstrate that the limit in subsection (f)(1)(A)(ii) of this section is met.

(j) Determination of occupational dose for the current year.

(1) For each individual who is likely to receive, in a year, an occupational dose requiring monitoring in accordance with subsection (q) of this section, the licensee shall determine the occupational radiation dose received during the current year.

(2) In complying with the requirements of paragraph (1) of this subsection, a licensee may:

(A) accept, as a record of the occupational dose that the individual received during the current year, RC Form 202-2 from prior or other current employers, or other clear and legible record, of all information required on that form and indicating any periods of time for which data are not available; or

(B) accept, as a record of the occupational dose that the individual received during the current year, a written signed statement from the individual, or from the individual's prior or other current employer(s) for work involving radiation exposure, that discloses the nature and the amount of any occupational dose that the individual received during the current year; or

(C) obtain reports of the individual’s dose equivalent from prior or other current employer(s) for work involving radiation exposure, or the individual’s current employer, if the individual is not employed by the licensee, by telephone, facsimile, letter, or other electronic media transmission. The licensee shall request a written verification of the dose data if the authenticity of the transmitted report cannot be established.

(3) The licensee shall record the exposure data for the current year, as required by paragraph (1) of this subsection, on RC Form 202-3, or other clear and legible record, of all the information required on that form.

(4) If the licensee is unable to obtain a complete record of an individual’s current occupational dose while employed by any other licensee, the licensee shall assume in establishing administrative controls in accordance with subsection (f)(7) of this section for the current year, that the allowable dose limit for the individual is reduced by 1.25 rems (12.5 mSv) for each quarter; or 416 mrem (4.16 mSv) for each month for which records were unavailable and the individual was engaged in activities that could have resulted in occupational radiation exposure.

(5) If an individual has incomplete (e.g., a lost or damaged personnel monitoring device) current occupational dose data for the current year and that individual is employed solely by the licensee during the current year, the licensee shall:

(A) assume that the allowable dose limit for the individual is reduced by 1.25 rems (12.5 mSv) for each quarter;

(B) assume that the allowable dose limit for the individual is reduced by 416 mrem (4.16 mSv) for each month; or

(C) assess an occupational dose for the individual during the period of missing data using surveys, radiation measurements, or other comparable data for the purpose of demonstrating compliance with the occupational dose limits.

(6) Administrative controls established in accordance with paragraph (4) of this subsection shall be documented and maintained for inspection by the agency. Occupational dose assessments made in accordance with paragraph (5) of this subsection and records of data used to make the assessment shall be maintained for inspection by the agency. The licensee shall retain the records in accordance with subsection (rr) of this section.

(k) Planned special exposures. A licensee may authorize an adult worker to receive doses in addition to and accounted for separately from the doses received under the limits specified in subsection (f) of this section provided that each of the following conditions is satisfied.

(1) The licensee authorizes a planned special exposure only in an exceptional situation when alternatives that might avoid the doses estimated to result from the planned special exposure are unavailable or impractical.

(2) The licensee and employer, if the employer is not the licensee, specifically authorizes the planned special exposure, in writing, before the exposure occurs.

(3) Before a planned special exposure, the licensee ensures that each individual involved is:

(A) informed of the purpose of the planned operation;

(B) informed of the estimated doses and associated potential risks and specific radiation levels or other conditions that might be involved in performing the task; and

(C) instructed in the measures to be taken to keep the dose ALARA considering other risks that may be present.

(4) Prior to permitting an individual to participate in a planned special exposure, the licensee shall determine:

(A) the internal and external doses from all previous planned special exposures;

(B) all doses in excess of the limits, including doses received during accidents and emergencies, received during the lifetime of the individual; and

(C) all lifetime cumulative occupational radiation doses.

(5) In complying with the requirements of paragraph (4)(C) of this subsection, a licensee may:

(A) accept, as the record of lifetime cumulative radiation dose, an up-to-date RC Form 202-2 or equivalent, signed by the individual and countersigned by an appropriate official of the most recent employer for work involving radiation exposure, or the individual's current employer, if the individual is not employed by the licensee; and

(B) obtain reports of the individual's dose equivalent from prior employer(s) for work involving radiation exposure, or the individual's current employer, if the individual is not employed by the licensee, by telephone, facsimile, letter, or other electronic media transmission. The licensee shall request a written verification of the dose data if the authenticity of the transmitted report cannot be established.

(6) Subject to subsection (f)(2) of this section, the licensee shall not authorize a planned special exposure that would cause an individual to receive a dose from all planned special exposures and all doses in excess of the limits to exceed:

(A) the numerical values of any of the dose limits in subsection (f)(1) of this section in any year; and

(B) five times the annual dose limits in subsection (f)(1) of this section during the individual's lifetime.

(7) The licensee maintains records of the conduct of a planned special exposure in accordance with subsection (qq) of this section and submits a written report to the agency in accordance with subsection (zz) of this section.

(8) The licensee records the best estimate of the dose resulting from the planned special exposure in the individual's record and informs the individual, in writing, of the dose within 30 days from the date of the planned special exposure. The dose from planned special exposures shall not be considered in controlling future occupational dose of the individual in accordance with subsection (f)(1) of this section but shall be included in evaluations required by paragraphs (4) and (6) of this subsection.

(9) The licensee shall record the exposure history, as required by paragraph (4) of this subsection, on RC Form 202-2, or other clear and legible record, of all the information required on that form. The form or record shall show each period in which the individual received occupational exposure to radiation or radioactive material and shall be signed by the individual who received the exposure. For each period for which the licensee obtains reports, the licensee shall use the dose shown in the report in preparing RC Form 202-2 or equivalent.

(l) Occupational dose limits for minors. The annual occupational dose limits for minors are 10% of the annual occupational dose limits specified for adult workers in subsection (f) of this section.

(m) Dose equivalent to an embryo/fetus.

(1) If a woman declares her pregnancy, the licensee shall ensure that the dose equivalent to an embryo/fetus during the entire pregnancy, due to occupational exposure of a declared pregnant woman, does not exceed 0.5 rem (5 mSv). If a woman chooses not to declare pregnancy, the occupational dose limits specified in subsection (f)(1) of this section are applicable to the woman. See subsection (rr) of this section for recordkeeping requirements.

(2) The licensee shall make efforts to avoid substantial variation above a uniform monthly exposure rate to a declared pregnant woman so as to satisfy the limit in paragraph (1) of this subsection. The National Council on Radiation Protection and Measurements (NCRP) recommended in NCRP Report No. 91 "Recommendations on Limits for Exposure to Ionizing Radiation" (June 1, 1987) that no more than 0.05 rem (0.5 mSv) to the embryo/fetus be received in any one month.

(3) The dose equivalent to an embryo/fetus shall be taken as:

(A) the dose equivalent to the embryo/fetus from radionuclides in the embryo/fetus and radionuclides in the declared pregnant woman; and

(B) the dose equivalent that is most representative of the dose equivalent to the embryo/fetus from external radiation, that is, in the mother's lower torso region.

(i) If multiple measurements have not been made, assignment of the highest deep dose equivalent for the declared pregnant woman shall be the dose equivalent to the embryo/fetus.

(ii) If multiple measurements have been made, assignment of the deep dose equivalent for the declared pregnant woman from the individual monitoring device that is most representative of the dose equivalent to the embryo/fetus shall be the dose equivalent to the embryo/fetus. Assignment of the highest deep dose equivalent for the declared pregnant woman to the embryo/fetus is not required unless that dose equivalent is also the most representative deep dose equivalent for the region of the embryo/fetus.

(4) If by the time the woman declares pregnancy to the licensee, the dose equivalent to the embryo/fetus has exceeded 0.45 rem (4.5 mSv), the licensee shall be deemed to be in compliance with paragraph (1) of this subsection, if the additional dose equivalent to the embryo/fetus does not exceed 0.05 rem (0.5 mSv) during the remainder of the pregnancy.

(n) Dose limits for individual members of the public.

(1) Each licensee shall conduct operations so that:

(A) The total effective dose equivalent to individual members of the public from the licensed and/or registered operation does not exceed 0.1 rem (1 mSv) in a year, exclusive of the dose contribution from background radiation, from any medical administration the individual has received, from exposure to individuals administered radioactive material and released in accordance with §289.256 of this title (relating to Medical and Veterinary Use of Radioactive Material), from voluntary participation in medical research programs, and from the licensee's disposal of radioactive material into sanitary sewerage in accordance with subsection (gg) of this section; and

(B) the dose in any unrestricted area from licensed and/or registered external sources, exclusive of the dose contributions from patients administered radioactive material and released in accordance with §289.256 of this title, does not exceed 0.002 rem (0.02 mSv) in any one hour.

(2) If the licensee permits members of the public to have access to restricted areas, the limits for members of the public continue to apply to those individuals.

(3) A licensee or an applicant for a license may apply for prior agency authorization to operate up to an annual dose limit for an individual member of the public of 0.5 rem (5 mSv). This application shall include the following information:

(A) demonstration of the need for and the expected duration of operations in excess of the limit in paragraph (1) of this subsection;

(B) the licensee's program to assess and control dose within the 0.5 rem (5 mSv) annual limit; and

(C) the procedures to be followed to maintain the dose ALARA.

(4) In addition to the requirements of this section, a licensee subject to the provisions of the United States Environmental Protection Agency's (EPA) generally applicable environmental radiation standards in 40 Code of Federal Regulations (CFR), §190 shall comply with those requirements.

(5) The agency may impose additional restrictions on radiation levels in unrestricted areas and on the total quantity of radionuclides that a licensee may release in effluents in order to restrict the collective dose.

(6) Notwithstanding paragraph (1)(A) of this subsection, a licensee may permit visitors to an individual who cannot be released, in accordance with §289.256 of this title, to receive a radiation dose greater than 0.1 rem (1 mSv) if:

(A) the radiation dose received does not exceed 0.5 rem (5 mSv); and

(B) the authorized user, as defined in §289.256 of this title, has determined before the visit that it is appropriate.

(o) Compliance with dose limits for individual members of the public.

(1) The licensee shall make or cause to be made surveys of radiation levels in unrestricted areas and radioactive materials in effluents released to unrestricted areas to demonstrate compliance with the dose limits for individual members of the public as required in subsection (n) of this section.

(2) A licensee shall show compliance with the annual dose limit in subsection (n) of this section by:

(A) demonstrating by measurement or calculation that the total effective dose equivalent to the individual likely to receive the highest dose from the licensed or registered operation does not exceed the annual dose limit; or

(B) demonstrating that:

(i) the annual average concentrations of radioactive material released in gaseous and liquid effluents at the boundary of the unrestricted area do not exceed the values specified in Table II of subsection (ggg)(2) of this section; and

(ii) if an individual were continuously present in an unrestricted area, the dose from external sources of radiation would not exceed 0.002 rem (0.02 mSv) in an hour and 0.05 rem (0.5 mSv) in a year.

(3) Upon approval from the agency, the licensee may adjust the effluent concentration values in Table II, of subsection (ggg)(2) of this section, for members of the public, to take into account the actual physical and chemical characteristics of the effluents, such as, aerosol size distribution, solubility, density, radioactive decay equilibrium, and chemical form.

(p) General surveys and monitoring.

(1) Each licensee shall make, or cause to be made, surveys of areas, including the subsurface that:

(A) are necessary for the licensee to comply with this chapter; and

(B) are necessary under the circumstances to evaluate:

(i) the magnitude and extent of radiation levels;

(ii) concentrations or quantities of residual radioactivity; and

(iii) the potential radiological hazards of the radiation levels and residual radioactivity detected.

(2) In addition to subsection (nn) of this section, records from surveys describing the location and amount of subsurface residual radioactivity identified at the site shall be kept with records important for decommissioning, and such records shall be maintained and retained in accordance with §289.252(gg) of this title (relating to Licensing of Radioactive Material).

(3) The licensee shall ensure that instruments and equipment used for quantitative radiation measurements, for example, dose rate and effluent monitoring, are operable and calibrated:

(A) by a person licensed or registered by the agency, the United States Nuclear Regulatory Commission (NRC), or any agreement state to perform such service;

(B) at intervals not to exceed 12 months unless a different time interval is specified in another section of this chapter;

(C) after each instrument or equipment repair;

(D) for the types of radiation used and at energies appropriate for use; and

(E) at an accuracy within 20% of the true radiation level.

(4) All individual monitoring devices, except for direct and indirect reading pocket dosimeters, electronic personal dosimeters, and those individual monitoring devices used to measure the dose to any extremity, that require processing to determine the radiation dose and that are used by licensees to comply with subsection (f) of this section, with other applicable provisions of this chapter, or with conditions specified in a license, shall be processed and evaluated by a dosimetry processor:

(A) holding current personnel dosimetry accreditation from the National Voluntary Laboratory Accreditation Program (NVLAP) of the National Institute of Standards and Technology; and

(B) approved in this accreditation process for the type of radiation or radiations included in the NVLAP program that most closely approximates the type of radiation or radiations for which the individual wearing the dosimeter is monitored.

(5) All individual monitoring devices shall be appropriate for the environment in which they are used.

(q) Conditions requiring individual monitoring of external and internal occupational dose. Each licensee shall monitor exposures from sources of radiation at levels sufficient to demonstrate compliance with the occupational dose limits of this section. As a minimum:

(1) each licensee shall monitor occupational exposure to radiation and shall supply and require the use of individual monitoring devices by:

(A) adults likely to receive, in one year from sources external to the body, a dose in excess of 10% of the limits in subsection (f)(1) of this section;

(B) minors likely to receive, in one year from sources of radiation external to the body, a deep dose equivalent in excess of 0.1 rem (1 mSv), a lens dose equivalent in excess of 0.15 rem (1.5 mSv), or a shallow dose equivalent to the skin or to the extremities in excess of 0.5 rem (5 mSv);

(C) declared pregnant women likely to receive during the entire pregnancy, from sources of radiation external to the body, a deep dose equivalent in excess of 0.1 rem (1 mSv); and

(D) individuals entering a high or very high radiation area;

(2) notwithstanding paragraph (1)(C) of this subsection, a licensee is exempt from supplying individual monitoring devices to healthcare personnel who may enter a high radiation area while providing patient care if:

(A) the personnel are not likely to receive, in one year from sources external to the body, a dose in excess of 10% of the limits in subsection (f)(1) of this section; and

(B) the licensee complies with the requirements of subsection (e)(2) of this section; and

(3) each licensee shall monitor, to determine compliance with subsection (i) of this section, the occupational intake of radioactive material by and assess the committed effective dose equivalent to:

(A) adults likely to receive, in one year, an intake in excess of 10% of the applicable ALI in Columns 1 and 2 of Table I of subsection (ggg)(2) of this section;

(B) minors likely to receive, in one year, a committed effective dose equivalent in excess of 0.1 rem (1 mSv); and

(C) declared pregnant women likely to receive, during the entire pregnancy, a committed effective dose equivalent in excess of 0.1 rem (1 mSv).

(r) Location and use of individual monitoring devices.

(1) Each licensee shall ensure that individuals who are required to monitor occupational doses in accordance with subsection (q)(l) of this section wear and use individual monitoring devices as follows.

(A) An individual monitoring device used for monitoring the dose to the whole body shall be worn at the unshielded location of the whole body likely to receive the highest exposure. When a protective apron is worn, the location of the individual monitoring device is typically at the neck (collar).

(B) If an additional individual monitoring device is used for monitoring the dose to an embryo/fetus of a declared pregnant woman, in accordance with subsection (m)(1) of this section, it shall be located at the waist under any protective apron being worn by the woman.

(C) An individual monitoring device used for monitoring the lens dose equivalent, to demonstrate compliance with subsection (f)(1)(B)(i) of this section, shall be located at the neck (collar) or at a location closer to the eye, outside any protective apron being worn by the monitored individual.

(D) An individual monitoring device used for monitoring the dose to the skin of the extremities, to demonstrate compliance with subsection (f)(1)(B)(ii) of this section, shall be worn on the skin of the extremity likely to receive the highest exposure. Each individual monitoring device, to the extent practicable, shall be oriented to measure the highest dose to the skin of the extremity being monitored.

(E) An individual monitoring device shall be assigned to and worn by only one individual.

(F) An individual monitoring device shall be worn for the period of time authorized by the dosimetry processor's certificate of registration or for no longer than three months, whichever is more restrictive.

(2) Each licensee shall ensure that individual monitoring devices are returned to the dosimetry processor for proper processing.

(3) Each licensee shall ensure that adequate precautions are taken to prevent a deceptive exposure of an individual monitoring device.

(s) Control of access to high radiation areas.

(1) The licensee shall ensure that each entrance or access point to a high radiation area has one or more of the following features:

(A) a control device that, upon entry into the area, causes the level of radiation to be reduced below that level at which an individual might receive a deep dose equivalent of 0.1 rem (1 mSv) in one hour at 30 centimeters (cm) from the source of radiation from any surface that the radiation penetrates;

(B) a control device that energizes a conspicuous visible or audible alarm signal so that the individual entering the high radiation area and the supervisor of the activity are made aware of the entry; or

(C) entryways that are locked, except during periods when access to the areas is required, with positive control over each individual entry.

(2) In place of the controls required by paragraph (1) of this subsection for a high radiation area, the licensee may substitute continuous direct or electronic surveillance that is capable of preventing unauthorized entry.

(3) The licensee may apply to the agency for approval of alternative methods for controlling access to high radiation areas.

(4) The licensee shall establish the controls required by paragraphs (1) and (3) of this subsection in a way that does not prevent individuals from leaving a high radiation area.

(5) The licensee is not required to control each entrance or access point to a room or other area that is a high radiation area solely because of the presence of radioactive materials prepared for transport and packaged and labeled in accordance with the regulations of the United States Department of Transportation (DOT) provided that:

(A) the packages do not remain in the area longer than three days; and

(B) the dose rate at 1 meter (m) from the external surface of any package does not exceed 0.01 rem (0.1 mSv) per hour.

(6) The licensee is not required to control entrance or access to rooms or other areas in hospitals solely because of the presence of patients containing radioactive material, provided that there are personnel in attendance who are taking the necessary precautions to prevent the exposure of individuals to sources of radiation in excess of the established limits in this section and to operate within the ALARA provisions of the licensee's radiation protection program.

(t) Control of access to very high radiation areas. In addition to the requirements in subsection(s) of this section, the licensee shall institute measures to ensure that an individual is not able to gain unauthorized or inadvertent access to areas in which radiation levels could be encountered at 500 rads (5 grays) or more in one hour at 1 m from a source of radiation or any surface through which the radiation penetrates at this level.

(u) Control of access to very high radiation areas for irradiators.

(1) This subsection applies to licensees with sources of radiation in non-self-shielded irradiators. This subsection does not apply to sources of radiation that are used in teletherapy, in industrial radiography, or in completely self-shielded irradiators in which the source of radiation is both stored and operated within the same shielding radiation barrier and, in the designed configuration of the irradiator, is always physically inaccessible to any individual and cannot create high levels of radiation in an area that is accessible to any individual.

(2) Each area in which there may exist radiation levels in excess of 500 rads (5 grays) in one hour at 1 m from a source of radiation that is used to irradiate materials shall meet the following requirements.

(A) Each entrance or access point shall be equipped with entry control devices that:

(i) function automatically to prevent any individual from inadvertently entering a very high radiation area;

(ii) permit deliberate entry into the area only after a control device is actuated that causes the radiation level within the area, from the source of radiation, to be reduced below that at which it would be possible for an individual to receive a deep dose equivalent in excess of 0.1 rem (1 mSv) in one hour; and

(iii) prevent operation of the source of radiation if it would produce radiation levels in the area that could result in a deep dose equivalent to an individual in excess of 0.1 rem (1 mSv) in one hour.

(B) Additional control devices shall be provided so that, upon failure of the entry control devices to function as required by subparagraph (A) of this paragraph:

(i) the radiation level within the area, from the source of radiation, is reduced below that at which it would be possible for an individual to receive a deep dose equivalent in excess of 0.1 rem (1 mSv) in one hour; and

(ii) conspicuous visible and audible alarm signals are generated to make an individual attempting to enter the area aware of the hazard and at least one other authorized individual, who is physically present, familiar with the activity, and prepared to render or summon assistance, aware of the failure of the entry control devices.

(C) The licensee shall provide control devices so that, upon failure or removal of physical radiation barriers other than the sealed source's shielded storage container:

(i) the radiation level from the source of radiation is reduced below that at which it would be possible for an individual to receive a deep dose equivalent in excess of 0.1 rem (1 mSv) in one hour; and

(ii) conspicuous visible and audible alarm signals are generated to make potentially affected individuals aware of the hazard and the licensee or at least one other individual, who is familiar with the activity and prepared to render or summon assistance, aware of the failure or removal of the physical barrier.

(D) When the shield for stored sealed sources is a liquid, the licensee shall provide means to monitor the integrity of the shield and to signal, automatically, loss of adequate shielding.

(E) Physical radiation barriers that comprise permanent structural components, such as walls, that have no credible probability of failure or removal in ordinary circumstances, need not meet the requirements of subparagraphs (C) and (D) of this paragraph.

(F) Each area shall be equipped with devices that will automatically generate conspicuous visible and audible alarm signals to alert personnel in the area before the source of radiation can be put into operation and in time for any individual in the area to operate a clearly identified control device, which must be installed in the area and which can prevent the source of radiation from being put into operation.

(G) Each area shall be controlled by use of such administrative procedures and such devices as are necessary to ensure that the area is cleared of personnel prior to each use of the source of radiation.

(H) Each area shall be checked by a radiation measurement to ensure that, prior to the first individual's entry into the area after any use of the source of radiation, the radiation level from the source of radiation in the area is below that at which it would be possible for an individual to receive a deep dose equivalent in excess of 0.1 rem (1 mSv) in one hour.

(I) The entry control devices required in subparagraph (A) of this paragraph shall be tested for proper functioning. See subsection (uu) of this section for recordkeeping requirements.

(i) Testing shall be conducted prior to initial operation with the source of radiation on any day, unless operations were continued uninterrupted from the previous day.

(ii) Testing shall be conducted prior to resumption of operation of the source of radiation after any unintentional interruption.

(iii) The licensee shall submit and adhere to a schedule for periodic tests of the entry control and warning systems.

(J) The licensee shall not conduct operations, other than those necessary to place the source of radiation in safe condition or to effect repairs on controls, unless control devices are functioning properly.

(K) Entry and exit portals that are used in transporting materials to and from the irradiation area, and that are not intended for use by individuals, shall be controlled by such devices and administrative procedures as are necessary to physically protect and warn against inadvertent entry by any individual through these portals. Exit portals for irradiated materials shall be equipped to detect and signal the presence of any loose radioactive material that is carried toward such an exit and automatically to prevent loose radioactive material from being carried out of the area.

(3) Licensees or applicants for licenses for sources of radiation within the purview of paragraph (2) of this subsection that will be used in a variety of positions or in locations, such as open fields or forests, which make it impracticable to comply with certain requirements of paragraph (2) of this subsection, such as those for the automatic control of radiation levels, may apply to the agency for approval of alternative safety measures. Alternative safety measures shall provide personnel protection at least equivalent to those specified in paragraph (2) of this subsection. At least one of the alternative measures shall include an entry-preventing interlock control based on a measurement of the radiation that ensures the absence of high radiation levels before an individual can gain access to the area where such sources of radiation are used.

(4) The entry control devices required by paragraphs (2) and (3) of this subsection shall be established in such a way that no individual will be prevented from leaving the area.

(v) Use of process or other engineering controls. The licensee shall use, to the extent practicable, process or other engineering controls, such as containment, decontamination, or ventilation, to control the concentrations of radioactive material in air.

(w) Use of other controls.

(1) When it is not practicable to apply process or other engineering controls to control the concentrations of radioactive material in air to values below those that define an airborne radioactivity area, the licensee shall, consistent with maintaining the total effective dose equivalent ALARA, increase monitoring and limit intakes by one or more of the following means:

(A) control of access;

(B) limitation of exposure times;

(C) use of respiratory protection equipment; or

(D) other controls.

(2) If the licensee performs an ALARA analysis to determine whether respirators should be used, the licensee may consider safety factors other than radiological factors. The licensee shall also consider the impact of respirator use on workers' industrial health and safety.

(x) Use of individual respiratory protection equipment.

(1) If the licensee uses respiratory protection equipment to limit intakes of radioactive material in accordance with subsection (w) of this section, the licensee shall do the following.

(A) Except as provided in subparagraph (B) of this paragraph, the licensee shall use only respiratory protection equipment that is tested and certified by the National Institute for Occupational Safety and Health (NIOSH).

(B) If the licensee wishes to use equipment that has not been tested or certified by the NIOSH, or for which there is no schedule for testing or certification, the licensee shall submit an application to the agency for authorized use of that equipment, including a demonstration by testing, or a demonstration on the basis of test information, that the material and performance characteristics of the equipment are capable of providing the proposed degree of protection under anticipated conditions of use.

(C) The licensee shall implement and maintain a respiratory protection program that includes:

(i) air sampling sufficient to identify the potential hazard, permit proper equipment selection, and estimate doses;

(ii) surveys and bioassays, as appropriate, to evaluate actual intakes;

(iii) testing of respirators for operability (user seal check for face sealing devices and functional check for others) immediately prior to each use;

(iv) written procedures regarding the following:

(I) monitoring, including air sampling and bioassays;

(II) supervision and training of respirator users;

(III) fit testing;

(IV) respirator selection;

(V) breathing air quality;

(VI) inventory and control;

(VII) storage, issuance, maintenance, repair, testing, and quality assurance of respiratory protection equipment;

(VIII) recordkeeping; and

(IX) limitations on periods of respirator use and relief from respirator use;

(v) determination by a physician prior to initial fitting of a face sealing respirator and the first field use of non-face sealing respirators, and either every 12 months thereafter or periodically at a frequency determined by a physician, that the individual user is medically fit to use the respiratory protection equipment; and

(vi) fit testing, with fit factor > 10 times the APF for negative pressure devices, and a fit factor > 500 for any positive pressure, continuous flow, and presure-demand devices, before the first field use of tight fitting, face-sealing respirators and periodically thereafter at a frequency not to exceed 1 year. Fit testing shall be performed with the facepiece operating in the negative pressure mode.

(D) The licensee shall advise each respirator user that the user may leave the area at any time for relief from respirator use in the event of equipment malfunction, physical or psychological distress, procedural or communication failure, significant deterioration of operating conditions, or any other conditions that might require such relief.

(E) The licensee shall use respiratory protection equipment within the equipment manufacturer's expressed limitations for type and mode of use and shall provide for vision correction, adequate communication, low-temperature work environment, and the concurrent use of other safety or radiological protection equipment. The licensee shall use equipment in such a way as not to interfere with the proper operation of the respirator.

(F) Standby rescue persons are required whenever one-piece atmosphere-supplying suits, or any combination of supplied air respiratory protection device and personnel protective equipment are used from which an unaided individual may have difficulty extricating himself or herself. The standby persons shall be equipped with respiratory protection devices or other apparatus appropriate for the potential hazards. The standby rescue persons shall observe or otherwise maintain continuous communication with the workers (visual, voice, signal line, telephone, radio, or other suitable means), and be immediately available to assist them in case of a failure of the air supply or for any other reason that requires relief from distress. A sufficient number of standby rescue persons must be immediately available to assist all users of this type of equipment and to provide effective emergency rescue if needed.

(G) Atmosphere-supplying respirators shall be supplied with respirable air of grade D quality or better as defined by the Compressed Gas Association in publication G-7.1, "Commodity Specification for Air," 1997 and included in the regulations of the Occupational Safety and Health Administration (Title 29, CFR, §1910.134(i)(1)(ii)(A) through (E). Grade D quality air criteria include:

(i) oxygen content (volume/volume) of 19.5-23.5%;

(ii) hydrocarbon (condensed) content of 5 mg per cubic meter of air or less;

(iii) carbon monoxide (CO) content of 10 parts per million (ppm) or less;

(iv) carbon dioxide content of 1,000 ppm or less; and

(v) lack of noticeable odor.

(H) The licensee shall ensure that no objects, materials or substances, such as facial hair, or any conditions that interfere with the face-facepiece seal or valve function, and that are under the control of the respirator wearer, are present between the skin of the wearer's face and the sealing surface of a tight-fitting respirator facepiece.

(I) In estimating the dose to individuals from intake of airborne radioactive materials, the concentration of radioactive material in the air that is inhaled when respirators are worn is initially assumed to be the ambient concentration in air without respiratory protection, divided by the assigned protection factor. If the dose is later found to be greater than the estimated dose, the corrected value shall be used. If the dose is later found to be less than the estimated dose, the corrected value may be used.

(2) The agency may impose restrictions in addition to those in paragraph (1) of this subsection, subsection (w) of this section, and subsection (ggg)(1) of this section, in order to:

(A) ensure that the respiratory protection program of the licensee is adequate to limit doses to individuals from intakes of airborne radioactive materials consistent with maintaining total effective dose equivalent ALARA; and

(B) limit the extent to which a licensee may use respiratory protection equipment instead of process or other engineering controls.

(3) The licensee shall obtain authorization from the agency before assigning respiratory protection factors in excess of those specified in subsection (ggg)(1) of this section. The agency may authorize a licensee to use higher protection factors on receipt of an application that:

(A) describes the situation for which a need exists for higher protection factors; and

(B) demonstrates that the respiratory protection equipment provides these higher protection factors under the proposed conditions of use.

(y) Security and control of licensed sources of radiation.

(1) The licensee shall secure radioactive material from unauthorized removal or access.

(2) The licensee shall maintain constant surveillance, using devices and/or administrative procedures to prevent unauthorized access to use of radioactive material that is in an unrestricted area and that is not in storage.

(3) Each portable gauge licensee shall use a minimum of two independent physical controls that form tangible barriers to secure portable gauges from unauthorized removal, whenever portable gauges are not under the control and constant surveillance of the licensee.

(4) Utilization records shall be maintained for portable and mobile devices which contain radioactive material, and which are transported from a licensed site temporarily for use by the licensee and then returned to the licensed site of origin. The information required by subparagraphs (A) - (D) of this paragraph shall be recorded when a device is removed from the licensed site. The information in subparagraph (E) of this paragraph shall be recorded when a device is returned to the licensed site:

(A) the manufacturer, model, and serial number of the device;

(B) the name of the individual(s) transporting and using the device;

(C) the location(s) where each device is used;

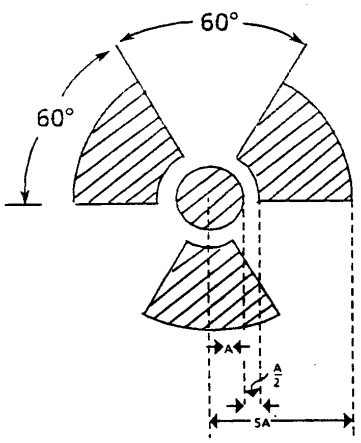
(D) the date each device is removed from storage; and

(E) the date each device is returned to storage.

(5) Utilization records shall be maintained at the licensed site where the devices are stored for inspection by the agency in accordance with subsection (ggg)(5) of this section.

(z) Caution signs.

(1) Unless otherwise authorized by the agency, the standard radiation symbol prescribed shall use the colors magenta, or purple, or black on yellow background. The standard radiation symbol prescribed is the three-bladed design as follows:



(A) the cross-hatched area of the symbol is to be magenta, or purple, or black; and

(B) the background of the symbol is to be yellow

(2) Notwithstanding the requirements of paragraph (1) of this subsection, licensees are authorized to label sources, source holders, or device components containing sources of radiation that are subjected to high temperatures, with conspicuously etched or stamped radiation caution symbols and without a color requirement.

(aa) Posting requirements.

(1) The licensee shall post each radiation area with a conspicuous sign or signs bearing the radiation symbol and the words "CAUTION, RADIATION AREA."

(2) The licensee shall post each high radiation area with a conspicuous sign or signs bearing the radiation symbol and the words "CAUTION, HIGH RADIATION AREA" or "DANGER, HIGH RADIATION AREA."

(3) The licensee shall post each very high radiation area with a conspicuous sign or signs bearing the radiation symbol and words "GRAVE DANGER, VERY HIGH RADIATION AREA." If the very high radiation area involves medical treatment of patients, the licensee may omit the word "GRAVE" from the sign or signs.

(4) The licensee shall post each airborne radioactivity area with a conspicuous sign or signs bearing the radiation symbol and the words "CAUTION, AIRBORNE RADIOACTIVITY AREA" or "DANGER, AIRBORNE RADIOACTIVITY AREA."

(5) The licensee shall post each area or room in which there is used or stored an amount of licensed material exceeding 10 times the quantity of such material specified in subsection (ggg)(3) of this section with a conspicuous sign or signs bearing the radiation symbol and the words "CAUTION, RADIOACTIVE MATERIAL(S)" or "DANGER, RADIOACTIVE MATERIAL(S)."

(bb) Exceptions to posting requirements.

(1) A licensee is not required to post caution signs in areas or rooms containing sources of radiation for periods of less than 8 hours, if each of the following conditions is met:

(A) the sources of radiation are constantly attended during these periods by an individual who takes the precautions necessary to prevent the exposure of individuals to sources of radiation in excess of the limits established in this section; and

(B) the area or room is subject to the licensee's control.

(2) Rooms or other areas in hospitals that are occupied by patients are not required to be posted with caution signs in accordance with subsection (aa) of this section provided that the patient could be released from licensee control in accordance with this chapter.

(3) A room or area is not required to be posted with a caution sign because of the presence of a sealed source(s) provided the radiation level at 30 cm from the surface of the sealed source container(s) or housing(s) does not exceed 0.005 rem (0.05 mSv) per hour.

(4) Rooms in medical facilities that are used for teletherapy are exempt from the requirement to post caution signs in accordance with subsection (aa) of this section provided the following conditions are met.

(A) Access to the room is controlled in accordance with this chapter; and

(B) Personnel in attendance take necessary precautions to prevent the inadvertent exposure of workers, other patients, and members of the public to radiation in excess of the limits established in this section.

(cc) Labeling containers.

(1) The licensee shall ensure that each container of licensed material bears a durable, clearly visible label bearing the radiation symbol and the words "CAUTION, RADIOACTIVE MATERIAL" or "DANGER, RADIOACTIVE MATERIAL." The label shall also provide information, such as the radionuclides present, an estimate of the quantity of radioactivity, the date for which the activity is estimated, radiation levels, kinds of materials, and mass enrichment, to permit individuals handling or using the containers, or working in the vicinity of the containers, to take precautions to avoid or minimize exposures.

(2) Each licensee shall, prior to removal or disposal of empty uncontaminated containers to unrestricted areas, remove or deface the radioactive material label or otherwise clearly indicate that the container no longer contains radioactive materials.

(dd) Exemptions to labeling requirements. A licensee is not required to label:

(1) containers holding licensed material in quantities less than the quantities listed in subsection (ggg)(3) of this section;

(2) containers holding licensed material in concentrations less than those specified in Table III of subsection (ggg)(2) of this section;

(3) containers attended by an individual who takes the precautions necessary to prevent the exposure of individuals in excess of the limits established by this section;

(4) containers when they are in transport and packaged and labeled in accordance with the rules of the DOT (labeling of packages containing radioactive materials is required by the DOT if the amount and type of radioactive material exceeds the limits for an excepted quantity or article as defined and limited by DOT regulations Title 49, CFR, §§173.403(m) and (w) and 173.424);

(5) containers that are accessible only to individuals authorized to handle or use them, or to work in the vicinity of the containers, if the contents are identified to these individuals by a readily available written record. Examples of containers of this type are containers in locations such as water-filled canals, storage vaults, or hot cells. The record shall be retained as long as the containers are in use for the purpose indicated on the record; or

(6) installed manufacturing or process equipment, such as piping and tanks.

(ee) Procedures for receiving and opening packages.

(1) Each licensee who expects to receive a package containing quantities of radioactive material in excess of a Type A quantity, as defined in §289.201(b) of this title (relating to General Provisions for Radioactive Material) and specified in §289.257(ee) of this title (relating to Packaging and Transportation of Radioactive Material), shall make arrangements to receive:

(A) the package when the carrier offers it for delivery; or

(B) the notification of the arrival of the package at the carrier's terminal and to take possession of the package expeditiously.

(2) Each licensee shall:

(A) monitor the external surfaces of a labeled package, labeled with a Radioactive White I, Yellow II, or Yellow III label as specified in DOT regulations Title 49, CFR, §§172.403 and 172.436-440, for radioactive contamination unless the package contains only radioactive material in the form of gas or in special form as defined in §289.201(b) of this title;

(B) monitor the external surfaces of a labeled package, labeled with a Radioactive White I, Yellow II, or Yellow III label as specified in DOT regulations Title 49, CFR, §§172.403 and 172.436-440, for radiation levels unless the package contains quantities of radioactive material that are less than or equal to the Type A quantity, as defined in §289.201(b) of this title and specified in §289.257(ee) of this title; and

(C) monitor all packages known to contain radioactive material for radioactive contamination and radiation levels if there is evidence of degradation of package integrity, such as packages that are crushed, wet, or damaged.

(3) The licensee shall perform the monitoring required by paragraph (2) of this subsection as soon as practicable after receipt of the package, but not later than three hours after the package is received at the licensee's facility if it is received during the licensee's normal working hours. If a package is received after working hours, the package shall be monitored no later than three hours from the beginning of the next working day. If the licensee discovers there is evidence of degradation of package integrity, such as a package that is crushed, wet, or damaged, the package shall be surveyed immediately.

(4) The licensee shall immediately notify the final delivery carrier and, by telephone, facsimile, or other electronic media transmission, the agency when removable radioactive surface contamination or external radiation levels exceed the limits established in subparagraphs (A) and (B) of this paragraph.

(A) Limits for removable radioactive surface contamination levels.

(i) The level of removable radioactive contamination on the external surfaces of each package offered for shipment shall be ALARA. The level of removable radioactive contamination may be determined by wiping an area of 300 square centimeters (cm^2) of the surface concerned with an absorbent material, using moderate pressure, and measuring the activity on the wiping material. Sufficient measurements shall be taken in the most appropriate locations to yield a representative assessment of the removable contamination levels. Except as provided in clause (iii) of this subparagraph, the amount of radioactivity measured on any single wiping material, when averaged over the surface wiped, shall not exceed the limits given in clause (ii) of this subparagraph at any time during transport. If other methods are used, the detection efficiency of the method used shall be taken into account and in no case may the removable contamination on the external surfaces of the package exceed 10 times the limits listed in clause (ii) of this subparagraph.

(ii) Removable external radioactive contamination wipe limits are as follows.

Contaminant	Maximum Permissible Limits pCi/cm^2 *	dpm/cm^2
Beta-gamma emitting radionuclides; all radionuclides with half-lives less than 10 days; natural uranium; natural thorium, uranium-235; uranium-238; thorium-232; thorium-228; and thorium-230 when contained in ores or physical concentrates….	100	220
All other alpha emitting radionuclides….	10	22

* To convert picocuries (pCi) to SI units of millibecquerels, multiply the values by 37.

(iii) In the case of packages transported as exclusive use shipments by rail or highway only, the removable radioactive contamination at any time during transport must not exceed 10 times the levels prescribed in clause (ii) of this subparagraph. The levels at the beginning of transport must not exceed the levels in clause (ii) of this subparagraph.

(B) Limits for external radiation levels.

(i) External radiation levels around the package and around the vehicle, if applicable, will not exceed 200 millirems per hour (mrem/hr) (2 millisieverts per hour (mSv/hr)) at any point on the external surface of the package at any time during transportation. The transport index shall not exceed 10.

(ii) For a package transported in exclusive use by rail, highway or water, radiation levels external to the package may exceed the limits specified in clause (i) of this subparagraph but shall not exceed any of the following:

(I) 200 mrem/hr (2 mSv/hr) on the accessible external surface of the package unless the following conditions are met, in which case the limit is 1,000 mrem/hr (10 mSv/hr):

(-a-) the shipment is made in a closed transport vehicle;

(-b-) provisions are made to secure the package so that its position within the vehicle remains fixed during transportation; and

(-c-) there are no loading or unloading operations between the beginning and end of the transportation;

(II) 200 mrem/hr (2 mSv/hr) at any point on the outer surface of the vehicle, including the upper and lower surfaces, or, in the case of a flat-bed style vehicle, with a personnel barrier, at any point on the vertical planes projected from the outer edges of the vehicle, on the upper surface of the load (or enclosure, if used), and on the lower external surface of the vehicle (a flat-bed style vehicle with a personnel barrier shall have radiation levels determined at vertical planes. If no personnel barrier, the package cannot exceed 200 mrem/hr (2 mSv/hr) at the surface.);

(III) 10 mrem/hr (0.1 mSv/hr) at any point 2 m from the vertical planes represented by the outer lateral surfaces of the vehicle, or, in the case of a flat-bed style vehicle, at any point 2 m from the vertical planes projected from the outer edges of the vehicle; and

(IV) 2 mrem/hr (0.02 mSv/hr) in any normally occupied positions of the vehicle, except that this provision does not apply to private motor carriers when persons occupying these positions are provided with special health supervision, personnel radiation exposure monitoring devices, and training in accordance with §289.203(c) of this title (relating to Notices, Instructions, and Reports to Workers; Inspections).

(5) Each licensee shall:

(A) establish, maintain, and retain written procedures for safely opening packages in which radioactive material is received; and

(B) ensure that the procedures are followed and that due consideration is given to special instructions for the type of package being opened.

(6) Licensees transferring special form sources in vehicles owned or operated by the licensee to and from a work site are exempt from the contamination monitoring requirements of paragraph (2) of this subsection, but are not exempt from the monitoring requirement in paragraph (2) of this subsection for measuring radiation levels that ensures that the source is still properly lodged in its shield.

(ff) General requirements for waste management.

(1) Unless otherwise exempted, a licensee shall discharge, treat, or decay licensed material or transfer waste for disposal only:

(A) by transfer to an authorized recipient as provided in subsection (jj) of this section, §289.252 of this title, §289.257 of this title, §289.259 of this title, or to the United States Department of Energy (DOE);

(B) by decay in storage with prior approval from the agency, except as authorized in §289.256(ee) of this title;

(C) by release in effluents within the limits in subsection (n) of this section in accordance with the applicable requirements of the Texas Commission on Environmental Quality (TCEQ) or the Railroad Commission of Texas (RRC);

(D) as authorized in accordance with paragraph (2) of this subsection, and subsections (gg), (hh), and (fff) of this section; or

(E) by transfer of residual radiopharmaceutical waste for decay in storage only to persons who manufactured, compounded, and supplied the radiopharmaceutical and who otherwise meet the requirements for exemption under Title 30, Texas Administrative Code (TAC), §336.1209.

(2) Upon agency approval, emission control dust and other material from electric arc furnaces or foundries contaminated as a result of inadvertent melting of cesium-137 or americium-241 sources may be transferred for disposal to a hazardous waste disposal facility authorized by the TCEQ or its successor, another state's regulatory agency with jurisdiction to regulate hazardous waste as classified under Subtitle C of the Resource Conservation and Recovery Act (RCRA), or the EPA. The material may be transferred for disposal without regard to its radioactivity if the following conditions are met.

(A) Contaminated material described in paragraph (2) of this subsection, whether packaged or unpackaged (i.e., bulk), must be treated through stabilization to comply with all waste treatment requirements of the appropriate state or federal regulatory agency as listed in this paragraph. The treatment operations must be undertaken by either of the following:

(i) the owner/operator of the electric arc furnace or foundry licensed to possess, treat or transfer cesium-137 or americium-241 contaminated incident-related material; or

(ii) a service contractor licensed by the agency, NRC, or an agreement state to possess, treat, or transfer cesium-137 or americium-241 contaminated incident-related material.

(B) The emission control dust and other incident-related materials have been stored (if applicable) and transferred in accordance with operating and emergency procedures approved by the agency.

(C) The total cesium-137 or americium-241 activity contained in emission control dust and other incident-related materials to be transferred to a hazardous waste disposal facility has been specifically approved by NRC or the appropriate agreement state(s) and does not exceed the total activity associated with the inadvertent melting incident.

(D) The hazardous waste disposal facility operator has been notified in writing of the impending transfer of the incident-related materials and has agreed in writing to receive and dispose of the packaged or unpackaged materials. Copies of the notification and agreement shall be submitted to the agency.

(E) The licensee, as listed in subparagraph (A)(i) or (ii) of this paragraph, notifies the NRC or agreement state(s) in which the transferor and transferee are located, in writing, of the impending transfer, at least 30 days before the transfer.

(F) The packaged stabilized material has been packaged for transportation and disposal in non-bulk steel packaging as defined in DOT regulations at Title 49, CFR, §173.213.

(G) The emission control dust and other incident-related materials that have been stabilized and packaged as described in subparagraph (F) of this paragraph shall contain pretreatment average concentrations of cesium-137 that do not exceed 130 pCi/g of material, above background, or pretreatment average concentrations of americium-241 that do not exceed 3 pCi/g of material, above background.

(H) The dose rate at 3.28 feet (1 m) from the surface of any package containing stabilized waste shall not exceed 20 µrem per hour or 0.20 µSv per hour, above background.

(I) The unpackaged stabilized material shall contain pretreatment average concentrations of cesium-137 that do not exceed 100 pCi/g of material, above background, or pretreatment average concentrations of americium-241 that do not exceed 3 pCi/g of material, above background.

(J) The licensee transferring the cesium-137 or americium-241 contaminated incident-related material shall consult with the agency, the TCEQ or its successor, another state's regulatory agency with jurisdiction to regulate hazardous waste as classified under RCRA, or the EPA and other authorized parties, including state and local governments, and obtain all necessary approvals, in addition to those of the NRC and/or any agreement state, for the transfers described in paragraph (2) of this subsection.

(K) Nothing in this subsection shall be or is intended to be construed as a waiver of any RCRA permit condition or term, of any state or local statute or regulation, or of any federal RCRA regulation.

(L) The total incident-related cesium-137 activity described in paragraph (2) of this subsection received by a facility over its operating life shall not exceed 1 Ci (37 gigabequerels (GBq)). The total incident-related americium-241 activity described in paragraph (2) of this subsection received by a facility over its operating life shall not exceed 30 mCi (1.11 GBq). The agency will maintain a record of the total incident-related cesium-137 or americium-241 activity shipped by a person licensed by the agency. Upon consultation with the TCEQ, the agency will determine if the total incident-related activity received by a hazardous waste disposal facility over its operating life has reached 1 Ci (37 GBq) of cesium-137 or 30 mCi (1.11 GBq) of americium-241. The agency will not approve shipments of cesium-137 or americium-241 contaminated incident-related material that will cause this limit to be exceeded.

(3) Radioactive waste exempted by TCEQ for disposal in a hazardous waste disposal facility that holds a TCEQ permit issued under Subtitle C of the RCRA may be transferred for disposal as authorized by TCEQ.

(4) A person shall be specifically licensed to receive waste containing licensed material from other persons for:

(A) treatment prior to disposal;

(B) treatment by incineration;

(C) decay in storage;

(D) disposal at an authorized land disposal facility; or

(E) storage until transferred to a storage or disposal facility authorized to receive the waste.

(5) Byproduct material as defined in §289.201(b)(19)(C) - (E) of this title may be disposed of in accordance with Title 10, CFR, Part 61, even though it is not defined as low level radioactive waste. Therefore, any byproduct material being disposed of at a facility, or transferred for ultimate disposal at a facility licensed under Title 10, CFR, Part 61, shall meet the requirements of this chapter.

(6) A licensee may dispose of byproduct material, as defined in §289.201(b)(19)(C) - (E) of this title, at a disposal facility authorized to dispose of such material in accordance with any Federal or State solid or hazardous waste law.

(7) Any licensee shipping byproduct material as defined in §289.201(b)(19)(C) - (E) of this title intended for ultimate disposal at a land disposal facility licensed under Title 10, CFR, Part 61, shall document the information required on the NRC's Uniform Low-Level Radioactive Waste Manifest and transfer this recorded manifest information to the intended consignee in accordance with §289.257(gg) of this title.

(gg) Discharge by release into sanitary sewerage.

(1) A licensee may discharge licensed material into sanitary sewerage if each of the following conditions is satisfied:

(A) the material is readily soluble, or is readily dispersible biological material, in water;

(B) the quantity of licensed radioactive material that the licensee releases into the sewer in one month divided by the average monthly volume of water released into the sewer by the licensee does not exceed the concentration listed in Table III of subsection (ggg)(2) of this section; and

(C) if more than one radionuclide is released, the following additional conditions must also be satisfied:

(i) the fraction of the limit in Table III of subsection (ggg)(2) of this section represented by discharges into sanitary sewerage determined by dividing the actual monthly average concentration of each radionuclide released by the licensee into the sewer by the concentration of that radionuclide listed in Table III of subsection (ggg)(2) of this section; and

(ii) the sum of the fractions for each radionuclide required by clause (i) of this subparagraph does not exceed unity; and

(D) the total quantity of licensed radioactive material that the licensee releases into the sanitary sewerage in a year does not exceed 5 curies (Ci) (185 GBq) of hydrogen-3, 1 Ci (37 GBq) of carbon-14, and 1 Ci (37 GBq) of all other radioactive materials combined.

(2) Excreta from individuals undergoing medical diagnosis or therapy with radioactive material are not subject to the limitations contained in paragraph (1) of this subsection.

(hh) Treatment by incineration. A licensee may treat licensed material by incineration only in the form and concentration specified in subsection (fff)(1) of this section or as authorized by the agency.

(ii) Discharge by release into septic tanks. No licensee shall discharge radioactive material into a septic tank system except as specifically approved by the agency.

(jj) Transfer for disposal and manifests.

(1) The control of transfers of LLRW intended for disposal at a licensed low-level radioactive waste disposal facility, the establishment of a manifest tracking system, and additional requirements concerning transfers and recordkeeping for those wastes are found in §289.257(ff) of this title.

(2) Each person involved in the transfer of waste for disposal including the waste generator, waste collector, and waste processor, shall comply with the requirements specified in §289.257(ff) of this title.

(kk) Compliance with environmental and health protection regulations. Nothing in subsections (ff), (gg), (hh), or (jj) of this section relieves the licensee from complying with other applicable federal, state, and local regulations governing any other toxic or hazardous properties of materials that may be disposed of in accordance with subsections (ff), (gg), (hh), or (jj) of this section.

(ll) General provisions for records.

(1) Each licensee shall use the International System of Units (SI) units becquerel, gray, sievert, and coulomb per kilogram, or the special units curie, rad, rem, and roentgen, including multiples and subdivisions, and shall clearly indicate the units of all quantities on records required by this section. Disintegrations per minute may be indicated on records of surveys performed to determine compliance with subsections (ee)(4) and (ggg)(6) of this section. To ensure compatibility with international transportation standards, all limits in this section are given in terms of dual units: The SI units followed or preceded by United States (U.S.) standard or customary units. The U.S. customary units are not exact equivalents, but are rounded to a convenient value, providing a functionally equivalent unit. For the purpose of this section, either unit may be used.

(2) Notwithstanding the requirements of paragraph (1) of this subsection, when recording information on shipment manifests, as required in §289.257 of this title, information must be recorded in SI units or in SI and units as specified in paragraph (1) of this subsection.

(3) The licensee shall make a clear distinction among the quantities entered on the records required by this section, such as, total effective dose equivalent, total organ dose equivalent, shallow dose equivalent, lens dose equivalent, deep dose equivalent, or committed effective dose equivalent.

(4) Records required in accordance with §289.201(d) of this title, and subsections (mm) - (oo), and (ss) - (uu) of this section shall include the date and the identification of individual(s) making the record, and, as applicable, a unique identification of survey instrument(s) used, and an exact description of the location of the survey. Records of receipt, transfer, and disposal of sources of radiation shall uniquely identify the source of radiation.

(5) Copies of records required in accordance with §289.201(d) of this title, and subsections (mm) - (uu) of this section, and by license condition that are relevant to operations at an additional authorized use/storage site shall be maintained at that site in addition to the main site specified on a license.

(mm) Records of radiation protection programs.

(1) Each licensee shall maintain records of the radiation protection program, including:

(A) the provisions of the program; and

(B) audits and other reviews of program content and implementation.

(2) The licensee shall make, maintain, and retain the records required by paragraphs (1)(A) and (1)(B) of this subsection for inspection by the agency in accordance with subsection (ggg)(5) of this section.

(nn) Records of surveys.

(1) Each licensee shall make, maintain, and retain records documenting the results of surveys and calibrations required by subsections (p) and (ee)(2) of this section and include a unique identification of survey instrument(s). The licensee shall maintain these records for inspection by the agency in accordance with subsection (ggg)(5) of this section.

(2) Record of the calibration shall include:

(A) the manufacturer’s name, model and serial number of each calibrated source and/or device;

(B) the complete date of the calibration; and

(C) the name of the individual recording the information.

(3) The licensee shall make, maintain, and retain each of the following records for inspection by the agency in accordance with subsection (ggg)(5) of this section:

(A) the results of surveys to determine the dose from external sources of radiation used, in the absence of or in combination with individual monitoring data, in the assessment of individual dose equivalents; and

(B) the results of measurements and calculations used to determine individual intakes of radioactive material and used in the assessment of internal dose; and

(C) the results of air sampling, surveys, and bioassays required in accordance with subsection (x)(1)(C)(i) and (ii) of this section; and

(D) the results of measurements and calculations used to evaluate the release of radioactive effluents to the environment.

(oo) Records of tests for leakage or contamination of sealed sources. Records of tests for leakage or contamination of sealed sources required by §289.201(g) of this title shall be kept in units of becquerel or microcurie and maintained and retained for inspection by the agency in accordance with subsection (ggg)(5) of this section.

(pp) Records of lifetime cumulative occupational radiation dose. The licensee shall make, maintain, and retain the records of lifetime cumulative occupational radiation dose as specified in subsection (k) of this section on RC Form 202-2 or equivalent and the records used in preparing RC Form 202-2 or equivalent for inspection by the agency in accordance with subsection (ggg)(5) of this section.

(qq) Records of planned special exposures.

(1) For each use of the provisions of subsection (k) of this section for planned special exposures, the licensee shall maintain records that describe:

(A) the exceptional circumstances requiring the use of a planned special exposure;

(B) the name of the management official who authorized the planned special exposure and a copy of the signed authorization;

(C) what actions were necessary;

(D) why the actions were necessary;

(E) what precautions were taken to assure that doses were maintained ALARA;

(F) what individual and collective doses were expected to result; and

(G) the doses actually received in the planned special exposure.

(2) The licensee shall retain the records until the agency terminates each pertinent license requiring these records.

(rr) Records of individual monitoring results.

(1) Each licensee shall maintain records of doses received by all individuals for whom monitoring was required in accordance with subsection (q) of this section, and records of doses received during planned special exposures, accidents, and emergency conditions. Assessments of dose equivalent and records made using units in effect before January 1, 1994, need not be changed. These records shall include, when applicable:

(A) the deep dose equivalent to the whole body, lens dose equivalent, shallow dose equivalent to the skin, and shallow dose equivalent to the extremities;

(B) the estimated intake of radionuclides, see subsection (g) of this section;

(C) the committed effective dose equivalent assigned to the intake of radionuclides;

(D) the specific information used to calculate the committed effective dose equivalent in accordance with subsection (i)(1) and (3) of this section and when required by subsection (q)(1) of this section;

(E) the total effective dose equivalent when required by subsection (g) of this section;

(F) the total of the deep dose equivalent and the committed dose to the organ receiving the highest total dose; and

(G) the data used to make occupational dose assessments in accordance with subsection (j)(5) of this section.

(2) The licensee shall make entries of the records specified in paragraph (1) of this subsection at intervals not to exceed 1 year and by April 30 of the following year.

(3) The licensee shall maintain the records specified in paragraph (1) of this subsection on RC Form 202-3, in accordance with the instructions for RC Form 202-3, or in clear and legible records containing all the information required by RC Form 202-3.

(4) The licensee shall maintain the records of dose to an embryo/fetus with the records of dose to the declared pregnant woman. The declaration of pregnancy, including the estimated date of conception, shall also be kept on file, but may be maintained separately from the dose records.

(5) The licensee shall retain each required form or record until the agency terminates each pertinent license requiring the record. The licensee shall retain records used in preparing RC Form 202-3 or equivalent for three years after the record is made.

(ss) Records of dose to individual members of the public.

(1) Each licensee shall maintain records sufficient to demonstrate compliance with the dose limit for individual members of the public. See subsection (n) of this section.

(2) The licensee shall retain the records required by paragraph (1) of this subsection until the agency terminates each pertinent license requiring the record.

(tt) Records of discharge, treatment, or transfer for disposal.

(1) Each licensee shall maintain records of the discharge or treatment of licensed materials made in accordance with subsection (gg) and (hh) of this section and of transfers for disposal made in accordance with subsection (jj) of this section and §289.257 of this title.

(2) The licensee shall retain the records required by paragraph (1) of this subsection until the agency terminates each pertinent license requiring the record.

(uu) Records of testing entry control devices for very high radiation areas.

(1) Each licensee shall maintain records of tests made in accordance with subsection (u)(2)(I) of this section on entry control devices for very high radiation areas. These records must include the date, time, and results of each such test of function.

(2) The licensee shall retain the records required by paragraph (1) of this subsection for three years after the record is made.

(vv) Form of records. Each record required by this chapter shall be legible throughout the specified retention period. 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 producing a clear copy throughout the required retention period or the record may also be stored in electronic media with the capability for producing legible, accurate, and complete records during the required retention period. Records, such as letters, drawings, and specifications, shall include all pertinent information, such as stamps, initials, and signatures. The licensee shall maintain adequate safeguards against tampering with and loss of records.

(ww) Reports of stolen, lost, or missing licensed sources of radiation.

(1) Each licensee shall report to the agency by telephone as follows:

(A) immediately after its occurrence becomes known to the licensee, stolen, lost, or missing licensed radioactive material in an aggregate quantity equal to or greater than 1,000 times the quantity specified in subsection (ggg)(3) of this section, under such circumstances that it appears to the licensee that an exposure could result to individuals in unrestricted areas; or

(B) within 30 days after its occurrence becomes known to the licensee, lost, stolen, or missing licensed radioactive material in an aggregate quantity greater than 10 times the quantity specified in subsection (ggg)(3) of this section that is still missing.

(2) Each licensee required to make a report in accordance with paragraph (1) of this subsection shall, within 30 days after making the telephone report, make a written report to the agency setting forth the following information:

(A) a description of the licensed source of radiation involved, including, for radioactive material, the kind, quantity, chemical and physical form, source and/or device manufacturer, model number, and serial number;

(B) a description of the circumstances under which the loss or theft occurred;

(C) a statement of disposition, or probable disposition, of the licensed source of radiation involved;

(D) exposures of individuals to radiation, circumstances under which the exposures occurred, and the possible total effective dose equivalent to persons in unrestricted areas;

(E) actions that have been taken, or will be taken, to recover the source of radiation; and

(F) procedures or measures that have been, or will be, adopted to ensure against a recurrence of the loss or theft of licensed sources of radiation.

(3) Subsequent to filing the written report, the licensee shall also report additional substantive information on the loss or theft within 30 days after the licensee learns of such information.

(4) The licensee shall prepare any report filed with the agency in accordance with this subsection so that names of individuals who may have received exposure to radiation are stated in a separate and detachable portion of the report.

(xx) Notification of incidents.

(1) Notwithstanding other requirements for notification, each licensee shall immediately report each event involving a source of radiation possessed by the licensee that may have caused or threatens to cause:

(A) an individual, except a patient administered radiation for purposes of medical diagnosis or therapy, to receive:

(i) a total effective dose equivalent of 25 rems (0.25 Sv) or more;

(ii) a lens dose equivalent of 75 rems (0.75 Sv) or more; or

(iii) a shallow dose equivalent to the skin or extremities or a total organ dose equivalent of 250 rads (2.5 grays) or more; or

(B) the release of radioactive material, inside or outside of a restricted area, so that, had an individual been present for 24 hours, the individual could have received an intake five times the occupational ALI. This provision does not apply to locations where personnel are not normally stationed during routine operations, such as hot-cells or process enclosures.

(2) Each licensee shall, within 24 hours of discovery of the event, report to the agency each event involving loss of control of a licensed source of radiation possessed by the licensee that may have caused, or threatens to cause:

(A) an individual to receive, in a period of 24 hours:

(i) a total effective dose equivalent exceeding 5 rems (0.05 Sv);

(ii) a lens dose equivalent exceeding 15 rems (0.15 Sv); or

(iii) a shallow dose equivalent to the skin or extremities or a total organ dose equivalent exceeding 50 rems (0.5 Sv); or

(B) the release of radioactive material, inside or outside of a restricted area, so that, had an individual been present for 24 hours, the individual could have received an intake in excess of one occupational ALI. This provision does not apply to locations where personnel are not normally stationed during routine operations, such as hot-cells or process enclosures.

(3) Licensees shall make the initial notification reports required by paragraphs (1) and (2) of this subsection by telephone to the agency and shall confirm the initial notification report within 24 hours by facsimile or other electronic media transmission to the agency.

(4) The licensee shall prepare each report filed with the agency in accordance with this section so that names of individuals who have received exposure to sources of radiation are stated in a separate and detachable portion of the report.

(5) The provisions of this section do not apply to doses that result from planned special exposures, provided such doses are within the limits for planned special exposures and are reported in accordance with subsection (zz) of this section.

(6) Each licensee shall notify the agency as soon as possible but not later than four hours after the discovery of an event that prevents immediate protective actions necessary to avoid exposures to radioactive materials that could exceed regulatory limits or releases of radioactive materials that could exceed regulatory limits (events may include fires, explosions, toxic gas releases, etc.).

(7) Each licensee shall notify the agency within 24 hours after the discovery of any of the following events involving radioactive material:

(A) an unplanned contamination event that:

(i) requires access to the contaminated area, by workers or the public, to be restricted for more than 24 hours by imposing additional radiological controls or by prohibiting entry into the area;

(ii) involves a quantity of material greater than five times the lowest annual limit on intake specified in subsection (ggg)(2) of this section for the material; and

(iii) has access to the area restricted for a reason other than to allow isotopes with a half-life of less than 24 hours to decay prior to decontamination.

(B) an event in which equipment is disabled or fails to function as designed when:

(i) the equipment is required by rule or license condition to prevent releases exceeding regulatory limits, to prevent exposures to radioactive materials exceeding regulatory limits, or to mitigate the consequences of an accident;

(ii) the equipment is required to be available and operable when it is disabled or fails to function; and

(iii) no redundant equipment is available and operable to perform the required safety function;

(C) an event that requires unplanned medical treatment at a medical facility of an individual with spreadable radioactive contamination on the individual's clothing or body; or

(D) an unplanned fire or explosion damaging any radioactive material or any device, container, or equipment containing radioactive material when:

(i) the quantity of material involved is greater than five times the lowest annual limit on intake specified in subsection (ggg)(2) of this section for the material; and

(ii) the damage affects the integrity of the radioactive material or its container.

(8) Preparation and submission of reports. Reports made by licensees in response to the requirements of paragraphs (6) and (7) of this subsection shall be made as follows.

(A) Licensees shall make reports required by paragraphs (6) and (7) of this subsection by telephone to the agency. To the extent that the information is available at the time of notification, the information provided in these reports shall include:

(i) the caller's name and call back telephone number;

(ii) a description of the event, including date and time;

(iii) the exact location of the event;

(iv) the isotopes, quantities, and chemical and physical form of the radioactive material involved;

(v) any personnel radiation exposure data available; and

(vi) the source and/or device manufacturer, model, and serial number.

(B) Each licensee who makes a report required by paragraphs (6) and (7) of this subsection shall submit to the agency a written follow-up report within 30 days of the initial report. Written reports prepared in accordance with other requirements of this chapter may be submitted to fulfill this requirement if the reports contain all of the necessary information and the appropriate distribution is made. The reports must include the following:

(i) a description of the event, including the probable cause and the manufacturer and model number (if applicable) of any equipment that failed or malfunctioned;

(ii) the exact location of the event;

(iii) the isotopes, quantities, chemical and physical form of the radioactive material involved, and the source and/or device manufacturer, model number, and serial number;

(iv) date and time of the event;

(v) corrective actions taken or planned and the results of any evaluations or assessments; and

(vi) the extent of exposure of individuals to radioactive materials without identification of individuals by name.

(yy) Reports of exposures, radiation levels, and concentrations of radioactive material exceeding the limits.

(1) In addition to the notification required by subsection (xx) of this section, each licensee shall submit a written report within 30 days after learning of any of the following occurrences:

(A) incidents for which notification is required by subsection (xx) of this section;

(B) doses in excess of any of the following:

(i) the occupational dose limits for adults in subsection (f) of this section;

(ii) the occupational dose limits for a minor in subsection (l) of this section;

(iii) the limits for an embryo/fetus of a declared pregnant woman in subsection (m) of this section;

(iv) the limits for an individual member of the public in subsection (n) of this section;

(v) any applicable limit in the license; or

(vi) the ALARA constraints for air emissions as required by subsection (e)(4) of this section;

(C) levels of radiation or concentrations of radioactive material in:

(i) a restricted area in excess of applicable limits in the license; or

(ii) an unrestricted area in excess of 10 times the applicable limit set forth in this section or in the license, whether or not involving exposure of any individual in excess of the limits in subsection (n) of this section; or

(D) for licensees subject to the provisions of the EPA's generally applicable environmental radiation standards in Title 40, CFR, §190, levels of radiation or releases of radioactive material in excess of those standards, or of license conditions related to those requirements.

(2) Each report required by paragraph (1) of this subsection shall describe the extent of exposure of individuals to radiation and radioactive material, including, as appropriate:

(A) estimates of each individual's dose;

(B) the levels of radiation, dose limit exceeded, concentrations of radioactive material involved, and the source and/or device manufacturer, model number, and serial number;

(C) the cause of the elevated exposures, dose rates, or concentrations; and

(D) corrective steps taken or planned to ensure against a recurrence, including the schedule for achieving conformance with applicable limits, ALARA constraints, generally applicable environmental standards, and associated license conditions.

(3) Each report filed in accordance with paragraph (1) of this subsection shall include for each individual exposed: the name, identification number, and date of birth. With respect to the limit for the embryo/fetus in subsection (m) of this section, the identifiers should be those of the declared pregnant woman. The report shall be prepared so that this information is stated in a separate and detachable portion of the report.

(4) All licensees who make reports in accordance with paragraph (1) of this subsection shall submit the report in writing to the agency.

(zz) Reports of planned special exposures. The licensee shall submit a written report to the agency within 30 days following any planned special exposure conducted in accordance with subsection (k) of this section, informing the agency that a planned special exposure was conducted and indicating the date the planned special exposure occurred and the information required by subsection (qq) of this section.

(aaa) Notifications and reports to individuals.

(1) Requirements for notification and reports to individuals of exposure to sources of radiation are specified in §289.203 of this title.

(2) When a licensee is required in accordance with subsection (yy) or (zz) of this section to report to the agency any exposure of an identified occupationally exposed individual, or an identified member of the public, to sources of radiation, the licensee shall also notify the individual and provide a copy of the report submitted to the agency, to the individual. Such notice shall be transmitted at a time not later than the transmittal to the agency, and shall comply with the provisions of §289.203(d)(1) of this title.

(bbb) Reports of leaking or contaminated sealed sources. The licensee shall immediately notify the agency if the test for leakage or contamination required in accordance with §289.201(g) of this title indicates a sealed source is leaking or contaminated. A written report of a leaking or contaminated source shall be submitted to the agency within 5 days. The report shall include the equipment involved, including the device manufacturer, model and serial number; the test results; the date of the test; model and serial number; if assigned, of the leaking source, the radionuclide and its estimated activity; and the corrective action taken.

(ccc) Vacating premises.

(1) Each licensee or person possessing non-exempt sources of radiation shall, no less than 30 days before vacating and relinquishing possession or control of premises, notify the agency, in writing, of the intent to vacate.

(2) The licensee or person possessing non-exempt radioactive material shall decommission the premises to a degree consistent with subsequent use as an unrestricted area and in accordance with the requirements of subsection (ddd) of this section.

(ddd) Radiological requirements for license termination.

(1) General provisions and scope.

(A) The requirements in this section apply to the decommissioning of facilities licensed in accordance with §289.252 of this title, §289.253 of this title (relating to Radiation Safety Requirements for Well Logging Service Operations and Tracer Studies), §289.255 of this title (relating to Radiation Safety Requirements and Licensing and Registration Procedures for Industrial Radiography), §289.258 of this title (relating to Licensing and Radiation Safety Requirements for Irradiators), and §289.259 of this title (relating to Licensing of Naturally Occurring Radioactive Material).

(B) The requirements in this section do not apply to the following:

(i) sites that have been decommissioned prior to October 1, 2000, in accordance with requirements identified in this section and in §289.252 of this title; or

(ii) sites that have previously submitted and received approval on a decommissioning plan by October 1, 2000.

(C) After a site has been decommissioned and the license terminated in accordance with the requirements in the subsection, the agency will require additional cleanup if it determines that the requirements of the subsection were not met and residual radioactivity remaining at the site could result in significant threat to public health and safety.

(D) When calculating TEDE to the average member of the critical group, the licensee shall determine the peak annual TEDE dose expected within the first 1,000 years after decommissioning.

(2) Radiological requirements for unrestricted use. A site will be considered acceptable for unrestricted use if the residual radioactivity that is distinguishable from background radiation results in a TEDE to an average member of the critical group that does not exceed 25 mrem (0.25 mSv) per year, including that from groundwater sources of drinking water, and the residual radioactivity has been reduced to levels that are ALARA. Determination of the levels that are ALARA shall take into account consideration of any detriments, such as deaths from transportation accidents, expected to potentially result from decontamination and waste disposal.

(3) Criteria for license termination under restricted conditions. A site will be considered acceptable for license termination under restricted conditions if:

(A) the licensee can demonstrate that further reductions in residual radioactivity necessary to comply with the requirements of paragraph (2) of this subsection would result in net public or environmental harm or were not being made because the residual levels associated with restricted conditions are ALARA. Determination of the levels which are ALARA shall take into account consideration of any detriments, such as traffic accidents, expected to potentially result from decontamination and waste disposal;

(B) the licensee has made provisions for legally enforceable institutional controls that provide reasonable assurance that the TEDE from residual radioactivity distinguishable from background to the average member of the critical group will not exceed 25 mrem (0.25 mSv) per year;

(C) the licensee has provided sufficient financial assurance to enable an independent third party, including a governmental custodian of a site, to assume and carry out responsibilities for any necessary control and maintenance of the site. Acceptable financial assurance mechanisms are:

(i) funds placed into a trust segregated from the licensee's assets and outside the licensee's administrative control, and in which the adequacy of the trust funds is to be assessed based on an assumed annual 1% real rate of return on investment;

(ii) a statement of intent in the case of federal, state, or local government licensees, as described in §289.252(gg) of this title; or

(iii) when a governmental entity is assuming custody and ownership of a site, an arrangement that is deemed acceptable by such governmental entity.

(D) the licensee has submitted a decommissioning plan or License Termination Plan (LTP) to the agency indicating the licensee's intent to decommission in accordance with §289.252(y) of this title, and specifying that the licensee intends to decommission by restricting use of the site. The licensee shall document in the LTP or decommissioning plan how the advice of individuals and institutions in the community who may be affected by the decommissioning has been sought and incorporated, as appropriate, following analysis of that advice.

(i) Licensees proposing to decommission by restricting use of the site shall seek advice from such affected parties regarding the following matters concerning the proposed decommissioning:

(I) whether provisions for institutional controls proposed by the licensee;

(-a-) will provide reasonable assurance that the TEDE from residual radioactivity distinguishable from background to the average member of the critical group will not exceed 25 mrem (0.25 mSv) TEDE per year;

(-b-) will be enforceable; and

(-c-) will not impose undue burdens on the local community or other affected parties; and

(II) whether the licensee has provided sufficient financial assurance to enable an independent third party, including a governmental custodian of a site, to assume and carry out responsibilities for any necessary control and maintenance of the site.

(ii) In seeking advice on the issues identified in clause (i) of this subparagraph, the licensee shall provide for:

(I) participation by representatives of a broad cross section of community interests who may be affected by the decommissioning;

(II) an opportunity for a comprehensive, collective discussion on the issues by the participants represented; and

(III) a publicly available summary of the results of all such discussions, including a description of the individual viewpoints of the participants on the issues and the extent of agreement and disagreement among the participants on the issues; and

(E) residual radioactivity at the site has been reduced so that if the institutional controls were no longer in effect, there is reasonable assurance that the TEDE from residual radioactivity distinguishable from background to the average member of the critical group is ALARA and would not exceed either:

(i) 100 mrem (1 mSv) per year; or

(ii) 500 mrem (5 mSv) per year provided the licensee:

(I) demonstrates that further reductions in residual radioactivity necessary to comply with the 100 mrem/y (1 mSv/y) value of clause (i) of this subparagraph are not technically achievable, would be prohibitively expensive, or would result in net public or environmental harm;

(II) makes provisions for durable institutional controls; and

(III) provides sufficient financial assurance to enable a responsible government entity or independent third party, including a governmental custodian of a site, both to carry out periodic rechecks of the site no less frequently than every 5 years to assure that the institutional controls remain in place as necessary to meet the criteria of paragraph (2) of this subsection and to assume and carry out responsibilities for any necessary control and maintenance of those controls. Acceptable financial assurance mechanisms are those in subparagraph (C) of this paragraph.

(4) Alternate requirements for license termination.

(A) The agency may terminate a license using alternate requirements greater than the dose requirements specified in paragraph (2) of this subsection if the licensee does the following:

(i) provides assurance that public health and safety would continue to be protected, and that it is unlikely that the dose from all man-made sources combined, other than medical, would be more than the 1 mSv per year (100 mrem per year) limit specified in subsection (o) of this section, by submitting an analysis of possible sources of exposure;

(ii) reduces doses to ALARA levels, taking into consideration any detriments such as traffic accidents expected to potentially result from decontamination and waste disposal;

(iii) has submitted a decommissioning plan to the agency indicating the licensee's intent to decommission in accordance with the requirements in §289.252(y) of this title, and specifying that the licensee proposes to decommission by use of alternate requirements. The licensee shall document in the decommissioning plan how the advice of individuals and institutions in the community who may be affected by the decommissioning has been sought and addressed, as appropriate, following analysis of that advice. In seeking such advice, the licensee shall provide for the following:

(I) participation by representatives of a broad cross section of community interests who may be affected by the decommissioning;

(II) an opportunity for a comprehensive, collective discussion on the issues by the participants represented; and

(III) a publicly available summary of the results of all such discussions, including a description of the individual viewpoints of the participants on the issues and the extent of agreement and disagreement among the participants on the issues; and

(iv) has provided sufficient financial assurance in the form of a trust fund to enable an independent third party, including a governmental custodian of a site, to assume and carry out responsibilities for any necessary control and maintenance of the site.

(B) The use of alternate requirements to terminate a license requires the approval of the agency after consideration of the agency's recommendations that will address any comments provided by the EPA and any public comments submitted in accordance with paragraph (5) of this subsection.

(5) Public notification and public participation. Upon receipt of a decommissioning plan from the licensee, or a proposal from the licensee for release of a site pursuant to paragraphs (3) and (4) of this subsection, or whenever the agency deems such notice to be in the public interest, the agency will do the following:

(A) notify and solicit comments from the following:

(i) local and state governments in the vicinity of the site and any Indian Nation or other indigenous people that have treaty or statutory rights that could be affected by the decommissioning; and

(ii) the EPA for cases where the licensee proposes to release a site in accordance with paragraph (4) of this subsection; and

(B) publish a notice in the *Texas Register* and a forum, such as local newspapers, letters to state or local organizations, or other appropriate forum, that is readily accessible to individuals in the vicinity of the site, and solicit comments from affected parties.

(6) Minimization of contamination.

(A) Applicants for licenses, other than renewals, after October 1, 2000, shall describe in the application how facility design and procedures for operation will minimize, to the extent practical, contamination of the facility and the environment, facilitate eventual decommissioning, and minimize, to the extent practical, the generation of LLRW.

(B) Licensees shall, to the extent practical, conduct operations to minimize the introduction of residual radioactivity into the site, including the subsurface, in accordance with the existing radiation protection requirements and radiological criteria for license termination in this subsection.

(eee) Limits for contamination of soil, surfaces of facilities and equipment, and vegetation.

(1) No licensee shall possess, receive, use, or transfer radioactive material in such a manner as to cause contamination of surfaces of facilities or equipment in unrestricted areas to the extent that the contamination exceeds the limits specified in subsection (ggg)(6) of this section.

(2) No licensee shall possess, receive, use, or transfer radioactive material in such a manner as to cause contamination of soil in unrestricted areas, to the extent that the contamination exceeds, on a dry weight basis, the concentration limits specified in:

(A) subsection (ddd) of this section; or

(B) the effluent concentrations in Table II, Column 2 of subsection (ggg)(2)(F) of this section, with the units changed from microcuries per milliliter to microcuries per gram, for radionuclides not specified in paragraph (4) of this subsection.

(3) Where combinations of radionuclides are involved, the sum of the ratios between the concentrations present and the limits specified in paragraph (2) of this subsection shall not exceed one.

(4) Notwithstanding the limits specified in paragraph (2) of this subsection, no licensee shall cause the concentration of radium-226 or radium-228 in soil in unrestricted areas, averaged over any 100 square meters (m^2), to exceed the background level by more than:

(A) 5 picocuries per gram (pCi/g) (0.185 becquerel per gram (Bq/g)), averaged over the first 15 cm of soil below the surface; and

(B) 15 pCi/g (0.555 Bq/g), averaged over 15 cm thick layers of soil more than 15 cm below the surface.

(5) No licensee shall possess, receive, use, or transfer radioactive material in such a manner as to cause contamination of vegetation in unrestricted areas to exceed 5 pCi/g (0.185 Bq/g), based on dry weight, for radium-226 or radium-228.

(6) Notwithstanding the limits specified in paragraph (2) of this subsection, no licensee shall cause the concentration of natural uranium with no daughters present, based on dry weight and averaged over any 100 m^2 of area, to exceed the following limits:

(A) 30 pCi/g (1.11 Bq/g), averaged over the top 15 cm of soil below the surface; and

(B) 150 pCi/g (5.55 Bq/g), average concentration at depths greater than 15 centimeters below the surface so that no individual member of the public will receive an effective dose equivalent in excess of 100 mrem (1 mSv) per year.

(fff) Exemption of specific wastes.

(1) A licensee may discard the following licensed material without regard to its radioactivity:

(A) 0.05 microcurie (µCi) (1.85 kilobecquerels (kBq)), or less, of hydrogen-3, carbon-14, or iodine-125 per gram of medium used for liquid scintillation counting or in vitro clinical or in vitro laboratory testing; and

(B) 0.05 µCi (1.85 kBq), or less, of hydrogen-3, carbon-14, or iodine-125, per gram of animal tissue, averaged over the weight of the entire animal.

(2) A licensee shall not discard tissue in accordance with paragraph (1)(B) of this subsection in a manner that would permit its use either as food for humans or as animal feed.

(3) The licensee shall maintain records in accordance with subsection (tt) of this section.

(4) Any licensee may, upon agency approval of procedures required in paragraph (6) of this subsection, discard licensed material included in subsection (ggg)(7) of this section, provided that it does not exceed the concentration and total curie limits contained therein, in a Type I municipal solid waste site as defined in the Municipal Solid Waste Regulations of the authorized regulatory agency (Title 30, Texas Administrative Code, Chapter 330), unless such licensed material also contains hazardous waste, as defined in §361.003(15) of the Solid Waste Disposal Act, Health and Safety Code, Chapter 361. Any licensed material included in subsection (ggg)(7) of this section and which is a hazardous waste as defined in the Solid Waste Disposal Act may be discarded at a facility authorized to manage hazardous waste by the authorized regulatory agency.

(5) Each licensee who discards material described in paragraphs (1) or (4) of this subsection shall:

(A) make surveys adequate to assure that the limits of paragraphs (1) or (4) of this subsection are not exceeded; and

(B) remove or otherwise obliterate or obscure all labels, tags, or other markings that would indicate that the material or its contents is radioactive.

(6) Prior to authorizations in accordance with paragraph (4) of this subsection, a licensee shall submit procedures to the agency for:

(A) the physical delivery of the material to the disposal site;

(B) surveys to be performed for compliance with paragraph (5)(A) of this subsection;

(C) maintaining secure packaging during transportation to the site; and

(D) maintaining records of any discards made under paragraph (4) of this subsection.

(7) Nothing in this section relieves the licensee of maintaining records showing the receipt, transfer, and discard of such radioactive material as specified in §289.201(d) of this title.

(8) Nothing in this section relieves the licensee from complying with other applicable federal, state, and local regulations governing any other toxic or hazardous property of these materials.

(9) Licensed material discarded under this section is exempt from the requirements of §289.252(ff) of this title.

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(ggg) Appendices.

(1) Assigned protection factors for respirators. The following table contains assigned protection factors for respirators[a]:

	Operating Mode	Assigned Protection Factors
I. Air Purifying Respirators (Particulate[b] only)[c]:		
Filtering faceplate disposable[d]	Negative Pressure	([d])
Facepiece, half[e]	Negative Pressure	10
Facepiece, full	Negative Pressure	100
Facepiece, half	Powered air-purifying respirators	50
Facepiece, full	Powered air-purifying respirators	1000
Helmet/hood	Powered air-purifying respirators	1000
Facepiece, loose-fitting	Powered air-purifying respirators	25
II. Atmosphere Supplying Respirators (particulate, gases and vapors[f]):		
1. Air-line respirator		
Facepiece, half	Demand	10
Facepiece, half	Continuous Flow	50
Facepiece, half	Pressure Demand	50
Facepiece, full	Demand	100
Facepiece, full	Continuous Flow	1000
Facepiece, full	Pressure Demand	1000
Helmet/hood	Continuous Flow	1000
Facepiece, loose-fitting	Continuous Flow	25
Suit	Continuous Flow	([g])
2. Self-contained breathing apparatus (SCBA):		
Facepiece, full	Demand	100
Facepiece, full	Pressure Demand	[i]10,000
Facepiece, full	Demand, Recirculating	[h]100
Facepiece, full	Positive Pressure Recirculating	[i]10,000
III. Combination Respirators		
Any combination of air-purifying atmosphere-supplying respirators	Assigned protection factor for type and mode of operation as listed above	

[a]These assigned protection factors apply only in a respiratory protection program that meets the requirements of this section. They are applicable only to airborne radiological hazards and may not be appropriate to circumstances when chemical or other respiratory hazards exist instead of, or in addition to, radioactive hazards. Selection and use of respirators for such circumstances shall also comply with Department of Labor regulations.

Radioactive contaminants for which the concentration values in Table 1, Column 3 of subsection (ggg)(2)(F) of this section are based on internal dose due to inhalation may, in addition, present external exposure hazards at higher concentrations. Under these circumstances, limitations on occupancy may have to be governed by external dose limits.

[b]Air purifying respirators with APF < 100 must be equipped with particulate filters that are at least 95% efficient. Air purifying respirators with APF = 100 shall be equipped with particulate filters that are at least 99% efficient. Air purifying respirators with APFs > 100 shall be equipped with particulate filters that are at least 99.97% efficient.

[c]The licensee may apply to the agency for the use of an APF greater than 1 for sorbent cartridges as protection against airborne radioactive gases and vapors (e.g., radioiodine).

[d]Licensees may permit individuals to use this type of respirator who have not been medically screened or fit tested on the device provided that no credit be taken for their use in estimating intake or dose. It is also recognized that it is difficult to perform an effective positive or negative pressure pre-use seal check on this type of device. All other respiratory protection program requirements listed in subsection (x) of this section apply. An assigned protection factor has not been assigned for these devices. However, an APF equal to 10 may be used if the licensee can demonstrate a fit factor of at least 100 by use of a validated or evaluated, qualitative or quantitative fit test.

[e]Under-chin type only. No distinction is made in this paragraph between elastomeric half-masks with replaceable cartridges and those designed with the filter medium as an integral part of the facepiece (e.g., disposable or reusable disposable). Both types are acceptable so long as the seal area of the latter contains some substantial type of seal-enhancing material such as rubber or plastic, the two or more suspension straps are adjustable, the filter medium is at least 95% efficient and all other requirements of this section are met.

[f]The assigned protection factors for gases and vapors are not applicable to radioactive contaminants that present an absorption or submersion hazard. For tritium oxide vapor, approximately one-third of the intake occurs by absorption through the skin so that an overall protection factor of 3 is appropriate when atmosphere-supplying respirators are used to protect against tritium oxide. Exposure to radioactive noble gases is not considered a significant respiratory hazard, and protective actions for these contaminants should be based on external (submersion) dose considerations.

[g]No NIOSH approval schedule is currently available for atmosphere supplying suits. This equipment may be used in an acceptable respiratory protection program as long as all the other minimum program requirements, with the exception of fit testing, are met, for example, subsection (x) of this section.

[h]The licensee should implement institutional controls to assure that these devices are not used in areas immediately dangerous to life or health (IDLH).

[i]This type of respirator may be used as an emergency device in unknown concentrations for protection against inhalation hazards. External radiation hazards and other limitations to permitted exposure such as skin absorption shall be taken into account in these circumstances. This device may not be used by any individual who experiences perceptible outward leakage of breathing gas while wearing the device.

(2) Annual limits on intake (ALI) and derived air concentrations (DAC) of radionuclides for occupational exposure; effluent concentrations; concentrations for release to sanitary sewerage.

(A) Introduction.

(i) For each radionuclide, Table I of subparagraph (F) of this paragraph indicates the chemical form that is to be used for selecting the appropriate ALI or DAC value. The ALIs and DACs for inhalation are given for an aerosol with an activity median aerodynamic diameter (AMAD) of 1 micron, and for three classes (D, W, Y) of radioactive material, which refer to their retention (approximately days, weeks, or years) in the pulmonary region of the lung. This classification applies to a range of clearance half-times for D if less than 10 days, for W from 10 to 100 days, and for Y greater than 100 days. Table II of subparagraph (F) of this paragraph provides concentration limits for airborne and liquid effluents released to the general environment. Table III of subparagraph (F) of this paragraph provides concentration limits for discharges to sanitary sewerage.

(ii) The values in Tables I, II, and III of subparagraph (F) of this paragraph are presented in the computer "E" notation. In this notation a value of 6E-02 represents a value of 6×10^{-2} or 0.06, 6E+2 represents 6×10^{2} or 600, and 6E+0 represents 6×10^{0} or 6.

(B) Occupational values.

(i) Note that the columns in Table I of subparagraph (F) of this paragraph captioned "Oral Ingestion ALI," "Inhalation ALI," and "DAC," are applicable to occupational exposure to radioactive material.

(ii) The ALIs in subparagraph (F) of this paragraph are the annual intakes of given radionuclide by "Reference Man" that would result in either a committed effective dose equivalent of 5 rems (0.05 Sv), stochastic ALI, or a committed dose equivalent of 50 rems (0.5 Sv) to an organ or tissue, non-stochastic ALI. The stochastic ALIs were derived to result in a risk, due to irradiation of organs and tissues, comparable to the risk associated with deep dose equivalent to the whole body of 5 rems (0.05 Sv). The derivation includes multiplying the committed dose equivalent to an organ or tissue by a weighting factor, w_T. This weighting factor is the proportion of the risk of stochastic effects resulting from irradiation of the organ or tissue, T, to the total risk of stochastic effects when the whole body is irradiated uniformly. The values of w_T are listed under the definition of "weighting factor" in subsection (c) of this section. The non-stochastic ALIs were derived to avoid non-stochastic effects, such as prompt damage to tissue or reduction in organ function.

(iii) A value of $w_T = 0.06$ is applicable to each of the five organs or tissues in the "remainder" category receiving the highest dose equivalents, and the dose equivalents of all other remaining tissues may be disregarded. The following portions of the GI tract; stomach, small intestine, upper large intestine, and lower large intestine, are to be treated as four separate organs.

(iv) The dose equivalents for an extremity, skin, and lens of the eye are not considered in computing the committed effective dose equivalent, but are subject to limits that shall be met separately.

(v) When an ALI is defined by the stochastic dose limit, this value alone is given. When an ALI is determined by the non-stochastic dose limit to an organ, the organ or tissue to which the limit applies is shown, and the ALI for the stochastic limit is shown in parentheses. Abbreviated organ or tissue designations are used as follows:

(I) LLI wall = lower large intestine wall;

(II) St. wall = stomach wall;

(III) Blad wall = bladder wall; and

(IV) Bone surf = bone surface.

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(vi) The use of the ALIs listed first, the more limiting of the stochastic and non-stochastic ALIs, will ensure that non-stochastic effects are avoided and that the risk of stochastic effects is limited to an acceptably low value. If, in a particular situation involving a radionuclide for which the non-stochastic ALI is limiting, use of that non-stochastic ALI is considered unduly conservative, the licensee may use the stochastic ALI to determine the committed effective dose equivalent. However, the licensee shall also ensure that the 50 rems (0.5 sievert) dose equivalent limit for any organ or tissue is not exceeded by the sum of the external deep dose equivalent plus the internal committed dose equivalent to that organ, not the effective dose. For the case where there is no external dose contribution, this would be demonstrated if the sum of the fractions of the nonstochastic ALIs (ALI_{ns}) that contribute to the committed dose equivalent to the organ receiving the highest dose does not exceed unity, that is, $\sum$ (intake (in μCi) of each radionuclide/ALI_{ns}) ≤ 1.0. If there is an external deep dose equivalent contribution of H_d, then this sum must be less than $1 - (H_d/50)$, instead of ≤ 1.0.

(vii) The dose equivalents for an extremity, skin, and lens of the eye are not considered in computing the committed effective dose equivalent, but are subject to limits that must be met separately.

(viii) The DAC values are derived limits intended to control chronic occupational exposures. The relationship between the DAC and the ALI is given by:

DAC = ALI(in μCi)/(2000 hours per working year x 60 minutes/hour x 2×10^4 ml per minute) = [ALI/2.4×10^9] μCi/ml,

where 2×10^4 milliliter is the volume of air breathed per minute at work by Reference Man under working conditions of light work.

(ix) The DAC values relate to one of two modes of exposure: either external submersion or the internal committed dose equivalents resulting from inhalation of radioactive materials. DACs based upon submersion are for immersion in a semi-infinite cloud of uniform concentration and apply to each radionuclide separately.

(x) The ALI and DAC values include contributions to exposure by the single radionuclide named and any in-growth of daughter radionuclides produced in the body by decay of the parent. However, intakes that include both the parent and daughter radionuclides should be treated by the general method appropriate for mixtures.

(xi) The values of ALI and DAC do not apply directly when the individual both ingests and inhales a radionuclide, when the individual is exposed to a mixture of radionuclides by either inhalation or ingestion or both, or when the individual is exposed to both internal and external irradiation. See subsection (g) of this section. When an individual is exposed to radioactive materials which fall under several of the translocation classifications of the same radionuclide, such as, Class D, Class W, or Class Y, the exposure may be evaluated as if it were a mixture of different radionuclides.

(xii) It should be noted that the classification of a compound as Class D, W, or Y is based on the chemical form of the compound and does not take into account the radiological half-life of different radionuclides. For this reason, values are given for Class D, W, and Y compounds, even for very short-lived radionuclides.

(C) Effluent concentrations.

(i) The columns in Table II of subparagraph (F) of this paragraph captioned "Effluents," "Air," and "Water" are applicable to the assessment and control of dose to the public, particularly in the implementation of the provisions of subsection (o) of this section. The concentration values given in Columns 1 and 2 of Table II of subparagraph (F) of this paragraph are equivalent to the radionuclide concentrations which, if inhaled or ingested continuously over the course of a year, would produce a total effective dose equivalent of 0.05 rem (0.5 mSv).

(ii) Consideration of non-stochastic limits has not been included in deriving the air and water effluent concentration limits because non-stochastic effects are presumed not to occur at or below the dose levels established for individual members of the public. For radionuclides, where the non-stochastic limit was governing in deriving the occupational DAC, the stochastic ALI was used in deriving the corresponding airborne effluent limit in Table II of subparagraph (F) of this paragraph. For this reason, the DAC and airborne effluent limits are not always proportional as they were in the previous radiation protection standards.

(iii) The air concentration values listed in Column I of Table II of subparagraph (F) of this paragraph were derived by one of two methods. For those radionuclides for which the stochastic limit is governing, the occupational stochastic inhalation ALI was divided by 2.4×10^9, relating the inhalation ALI to the DAC, as explained in subparagraph (B)(viii) of this paragraph, and then divided by a factor of 300. The factor of 300 includes the following components:

(I) a factor of 50 to relate the 5 rems (0.05 Sv) annual occupational dose limit to the 0.1 rem limit for members of the public;

(II) a factor of 3 to adjust for the difference in exposure time and the inhalation rate for a worker and that for members of the public; and

(III) a factor of 2 to adjust the occupational values, derived for adults, so that they are applicable to other age groups.

(iv) For those radionuclides for which submersion, that is external dose, is limiting, the occupational DAC in Column 3 of Table I of subparagraph (F) of this paragraph was divided by 219. The factor of 219 is composed of a factor of 50, as described in clause (iii) of this subparagraph, and a factor of 4.38 relating occupational exposure for 2,000 hours per year to full-time exposure (8,760 hours per year). Note that an additional factor of 2 for age considerations is not warranted in the submersion case.

(v) The water concentrations were derived by taking the most restrictive occupational stochastic oral ingestion ALI and dividing by 7.3×10^7. The factor of 7.3×10^7 milliliters (ml) includes the following components:

(I) the factors of 50 and 2 described in clause (iii) of this subparagraph; and

(II) a factor of 7.3×10^5 ml which is the annual water intake of "Reference Man."

(vi) Note 2 of subparagraph (F) of this paragraph provides groupings of radionuclides that are applicable to unknown mixtures of radionuclides. These groupings, including occupational inhalation ALIs and DACs, air and water effluent concentrations, and releases to sewer, require demonstrating that the most limiting radionuclides in successive classes are absent. The limit for the unknown mixture is defined when the presence of one of the listed radionuclides cannot be definitely excluded as being present either from knowledge of the radionuclide composition of the source or from actual measurements.

(D) Releases to sewers. The monthly average concentrations for release to sanitary sewerage are applicable to the provisions in subsection (gg) of this section. The concentration values were derived by taking the most restrictive occupational stochastic oral ingestion ALI and dividing by 7.3×10^6 ml. The factor of 7.3×10^6 ml is composed of a factor of 7.3×10^5 ml, the annual water intake by "Reference Man," and a factor of 10, such that the concentrations, if the sewage released by the licensee were the only source of water ingested by a "Reference Man" during a year, would result in a committed effective dose equivalent of 0.5 rem.

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(E) List of elements.

Name	Symbol	Atomic Number	Name	Symbol	Atomic Number
Actinium	Ac	89	Iodine	I	53
Aluminum	Al	13	Iridium	Ir	77
Americium	Am	95	Iron	Fe	26
Antimony	Sb	51	Krypton	Kr	36
Argon	Ar	18	Lanthanum	La	57
Arsenic	As	33	Lead	Pb	82
Astatine	At	85	Lutetium	Lu	71
Barium	Ba	56	Magnesium	Mg	12
Berkelium	Bk	97	Manganese	Mn	25
Beryllium	Be	4	Mendelevium	Md	101
Bismuth	Bi	83	Mercury	Hg	80
Bromine	Br	35	Molybdenum	Mo	42
Cadmium	Cd	48	Neodynium	Nd	60
Calcium	Ca	20	Neptunium	Np	93
Californium	Cf	98	Nickel	Ni	28
Carbon	C	6	Niobium	Nb	41
Cerium	Ce	58	Nitrogen	N	7
Cesium	Cs	55	Osmium	Os	76
Chlorine	Cl	17	Oxygen	O	8
Chromium	Cr	24	Palladium	Pd	46
Cobalt	Co	27	Phosphorus	P	15
Copper	Cu	29	Platinum	Pt	78
Curium	Cm	96	Plutonium	Pu	94
Dysprosium	Dy	66	Polonium	Po	84
Einsteinium	Es	99	Potassium	K	19
Erbium	Er	68	Praseodymium	Pr	59
Europium	Eu	63	Promethium	Pm	61
Fermium	Fm	100	Protactinium	Pa	91
Fluorine	F	9	Radium	Ra	88
Francium	Fr	87	Radon	Rn	86
Gadolinium	Gd	64	Rhodium	Rh	45
Gallium	Ga	31	Rubidium	Rb	37
Germanium	Ge	32	Ruthenium	Ru	44
Gold	Au	79	Samarium	Sm	62
Hafnium	Hf	72	Scandium	Sc	21
Holmium	Ho	67	Selenium	Se	34
Hydrogen	H	1	Silicon	Si	14
Indium	In	49	Silver	Ag	47

Name	Symbol	Atomic Number	Name	Symbol	Atomic Number
Sodium	Na	11			
Strontium	Sr	38			
Sulfur	S	16			
Tantalum	Ta	73			
Technetium	Tc	43			
Tellurium	Te	52			
Terbium	Tb	65			
Thallium	Tl	81			
Thorium	Th	90			
Thulium	Tm	69			
Tin	Sn	50			
Titanium	Ti	22			
Tungsten	W	74			
Uranium	U	92			
Vanadium	V	23			
Xenon	Xe	54			
Ytterbium	Yb	70			
Yttrium	Y	39			
Zinc	Zn	30			
Zirconium	Zr	40			

(F) Tables--Values for annual limits. The following tables contain values for annual limits on intake (ALI) and derived air concentrations (DAC) of radionuclides for occupational exposure; effluent concentrations; concentrations for release to sanitary sewerage:

Notes (<u>not</u> in rule text):

1) see separate file §289.202(ggg)(2)(F) - DAC and ALI Table)
2) see separate files §289.202(ggg)(3) - (9) and §289.202(hhh) for remainder of text for §289.202

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