DRAFT 1 – 12/05/2012 -RQ

DEPARTMENT OF PUBLIC HEALTH AND ENVIRONMENT

Hazardous Materials and Waste Management Division

RADIATION CONTROL - STANDARDS FOR PROTECTION AGAINST RADIATION

6 CCR 1007-1 Part 04[JJ1]

[Editor's Notes follow the text of the rules at the end of this CCR Document.]

PART 4: STANDARDS FOR PROTECTION AGAINST RADIATION

STANDARDS FOR PROTECTION AGAINST RADIATION

4.1 Purpose and Scope

4.1.1 Authority.

4.1.1.1[JJ2] Rules and regulations set forth herein are adopted pursuant to the provisions of Sections 25-1-108, 25-1.5-101(1)(k) and (1)(l), and 25-11-104, CRS.

4.1.2 Basis and Purpose.

4.1.2.1 A statement of basis and purpose of these regulations is incorporated as part of these regulations; a copy may be obtained from the Department.

4.1.3 Scope.

4.1.3.1 This Part 4 establishes standards for protection against ionizing radiation resulting from activities conducted pursuant to licenses or registrations issued by the Department.

4.1.3.2 The requirements of Part 4 are designed to control the receipt, possession, use, transfer, and disposal of sources of radiation by any licensee or registrant 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 Part 4. However, nothing in Part 4 shall be construed as limiting actions that may be necessary to protect health and safety.

4.1.4 Applicability.

4.1.4.1 Except as specifically provided in other parts of these regulations, Part 4 applies to persons licensed or registered by the Department to receive, possess, use, transfer, or dispose of sources of radiation. The limits in Part 4 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 7.26, or to exposure from voluntary participation in medical research programs.

4.2 Definitions.

4.2.1 Reserved.

4.3 Implementation.

4.3.1 Any existing license or registration condition that is more restrictive than Part 4 remains in force until there is an amendment or renewal of the license or registration.

4.4 Reserved.

RADIATION PROTECTION PROGRAMS

4.5 Radiation Protection Programs.

4.5.1 Each licensee or registrant shall develop, document, and implement a radiation protection program sufficient to ensure compliance with the provisions of Part 4. See 4.41 for recordkeeping requirements relating to these programs.

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

4.5.3 The licensee or registrant shall, at intervals not to exceed 12 months, review the radiation protection program content and implementation.

4.5.4 To implement the ALARA requirements of 4.5.2 and notwithstanding the requirements in 4.14 of this part, a constraint on air emissions of radioactive material to the environment, excluding radon-222 and its decay products, 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 in excess of 0.1 millisievert (10 mrem) per year from these emissions. If a licensee subject to this requirement exceeds this dose constraint, the licensee shall report such event as provided in 4.53.2 and promptly take appropriate corrective action to ensure against recurrence.

OCCUPATIONAL DOSE LIMITS

4.6 Occupational Dose Limits for Adults.

4.6.1 The licensee or registrant shall control the occupational dose to individual adults, except for planned special exposures pursuant to 4.11, to the following dose limits:

4.6.1.1 An annual limit, which is the more limiting of:

(1) The total effective dose equivalent being equal to 0.05 Sv (5 rem); or

(2) 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 0.5 Sv (50 rem).

4.6.1.2 The annual limits to the lens of the eye, to the skin of the whole body, and to the skin of the extremities, which are:

(1) A lens dose equivalent of 0.15 Sv (15 rem), and

(2) A shallow dose equivalent of 0.5 Sv (50 rem) to the skin of the whole body or to the skin of any extremity.

4.6.2 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 4.11.5.1 and 4.11.5.2.

4.6.3 Assigned dose equivalent.

4.6.3.1 When the external exposure is determined by measurement with an external personal monitoring device, the deep-dose equivalent must be used in place of the effective dose equivalent, unless the effective dose equivalent is determined by a dosimetry method approved by the NRC[JJ3].

4.6.3.2~~1~~ The assigned deep dose equivalent must be for the part of the body receiving the highest exposure.

4.6.3.3~~2~~ The assigned shallow dose equivalent must be the dose averaged over the contiguous 10 square centimeters of skin receiving the highest exposure.

4.6.3.4~~3~~ 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.

4.6.3.5~~4~~ In the case of occupational exposures to x-rays with accelerating voltages of less than 145 kVp and where the worker utilizes lead garment protection, the registrant may calculate the assigned dose equivalent using ~~the following~~ methods discussed in NRC Regulatory Information Summary (RIS) 2002-06 [1], other methods as specifically approved by the Department, or by use of the following equation[JJ4]:

[1] NRC RIS 2002-06, Evaluating Occupational Dose For Individuals Exposed To NRC-licensed Material And Medical X-Rays, April 16, 2002 (http://www.nrc.gov/; ML021000613).

(1) Lead apron and no thyroid collar:

assigned deep dose equivalent = 0.06 x (collar dose – waist dose) + waist dose

(2) Lead apron and thyroid collar:

assigned deep dose equivalent = 0.02 x (collar dose – waist dose) + waist dose

4.6.4 Derived air concentration (DAC) and annual limit on intake (ALI) values are presented in Table 4B1 of Appendix 4B and may be used to determine the individual's dose and to demonstrate compliance with the occupational dose limits. See 4.46.

4.6.5 Notwithstanding the annual dose limits, the licensee shall limit the soluble uranium intake by an individual to 10 milligrams in a week in consideration of chemical toxicity. See footnote 3 of Appendix 4B.

4.6.6 The licensee or registrant 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 4.10.3.1 and 4.10.5.

4.7 Compliance with Requirements for Summation of External and Internal Doses.

4.7.1 If the licensee or registrant is required to monitor pursuant to both 4.18.1 and 4.18.2, the licensee or registrant shall demonstrate compliance with the dose limits by summing external and internal doses. If the licensee or registrant is required to monitor only pursuant to 4.18.1 or only pursuant to 4.18.2, then summation is not required to demonstrate compliance with the dose limits. The licensee or registrant may demonstrate compliance with the requirements for summation of external and internal doses pursuant to 4.7.2, 4.7.3 and 4.7.4. 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.

4.7.2 Intake by Inhalation.

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:

4.7.2.1 The sum of the fractions of the inhalation ALI for each radionuclide, or

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

4.7.2.3 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 percent of the maximum weighted value of H_{50}, that is, $W_T \times H_{T,50}$, per unit intake for any organ or tissue.

4.7.3 Intake by Oral Ingestion.

4.7.3.1 If the occupationally exposed individual also receives an intake of radionuclides by oral ingestion greater than 10 percent of the applicable oral ALI, the licensee or registrant shall account for this intake and include it in demonstrating compliance with the limits.

4.7.4 Intake through Wounds or Absorption through Skin.

4.7.4.1 The licensee or registrant 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 pursuant to 4.7.4.

4.8 Determination of External Dose from Airborne Radioactive Material.

4.8.1 Licensees or registrants shall, when determining the dose from airborne radioactive material, include the contribution to the deep dose equivalent, lens dose equivalent, and shallow dose equivalent from external exposure to the radioactive cloud. See Appendix 4B, footnotes 1 and 2.

4.8.2 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.

4.9 Determination of Internal Exposure.

4.9.1 For purposes of assessing dose used to determine compliance with occupational dose equivalent limits, the licensee or registrant shall, when required pursuant to 4.18, take suitable and timely measurements of:

4.9.1.1 Concentrations of radioactive materials in air in work areas; or

4.9.1.2 Quantities of radionuclides in the body; or

4.9.1.3 Quantities of radionuclides excreted from the body; or

4.9.1.4 Combinations of 4.9.1.1, 4.9.1.2 and 4.9.1.3.

4.9.2 Unless respiratory protective equipment is used, as provided in 4.24, or the assessment of intake is based on bioassays, the licensee or registrant shall assume that an individual inhales radioactive material at the airborne concentration in which the individual is present.

4.9.3 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 or registrant may:

4.9.3.1 Use that information to calculate the committed effective dose equivalent, and, if used, the licensee or registrant shall document that information in the individual's record; and

4.9.3.2 Upon prior approval of the Department, 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

4.9.3.3 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 Appendix 4B.

4.9.4 If the licensee or registrant chooses to assess intakes of Class Y material using the measurements given in 4.9.1.2 or 4.9.1.3, the licensee or registrant may delay the recording and reporting of the assessments for periods up to 7 months, unless otherwise required by 4.52 or 4.53. This delay permits the licensee or registrant to make additional measurements basic to the assessments.

4.9.5 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:

4.9.5.1 The sum of the ratios of the concentration to the appropriate DAC value, that is, D, W, or Y, from Appendix 4B for each radionuclide in the mixture; or

4.9.5.2 The ratio of the total concentration for all radionuclides in the mixture to the most restrictive DAC value for any radionuclide in the mixture.

4.9.6 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.

4.9.7 When a mixture of radionuclides in air exists, a licensee or registrant may disregard certain radionuclides in the mixture if:

4.9.7.1 The licensee or registrant uses the total activity of the mixture in demonstrating compliance with the dose limits in 4.6 and in complying with the monitoring requirements in 4.18.2; and

4.9.7.2 The concentration of any radionuclide disregarded is less than 10 percent of its DAC; and

4.9.7.3 The sum of these percentages for all of the radionuclides disregarded in the mixture does not exceed 30 percent.

4.9.8 When determining the committed effective dose equivalent, the following information may be considered:

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

4.9.8.2 For an ALI and the associated DAC determined by the nonstochastic organ dose limit of 0.5 Sv (50 rem), the intake of radionuclides that would result in a committed effective dose equivalent of 0.05 Sv (5 rem), that is, the stochastic ALI, is listed in parentheses in Table 4B1 of Appendix 4B. The licensee or registrant may, as a simplifying assumption, use the stochastic ALI to determine committed effective dose equivalent. However, if the licensee or registrant uses the stochastic ALI, the licensee or registrant shall also demonstrate that the limit in 4.6.1.1.2 is met.

4.10 Determination of Prior Occupational Dose.

4.10.1 For each individual who is likely to receive, in a year, an occupational dose requiring monitoring pursuant to 4.18, the licensee or registrant shall~~:~~

~~4.10.1.1 D~~ determine the occupational radiation dose received during the current year~~; and~~

~~4.10.1.2 Attempt to obtain the records of lifetime cumulative occupational radiation dose~~[JJ5].

4.10.2 Prior to permitting an individual to participate in a planned special exposure, the licensee or registrant shall determine:

4.10.2.1 The internal and external doses from all previous planned special exposures; and

4.10.2.2 All doses in excess of the limits, including doses received during accidents and emergencies, received during the lifetime of the individual; and

~~4.10.2.3 All lifetime cumulative occupational radiation dose~~[JJ6]~~.~~

4.10.3 In complying with the requirements of 4.10.1 or 4.10.2[JJ7], a licensee or registrant may:

4.10.3.1 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 most recent employer for work involving radiation exposure, that discloses the nature and the amount of any occupational dose that the individual received during the current year; and

4.10.3.2 Accept, as the record of ~~lifetime~~ cumulative radiation dose, an up-to-date Department Form R-16, Cumulative Occupational Exposure History, 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 or registrant; and

4.10.3.3 Obtain reports of the individual's dose equivalent from the most recent employer for work involving radiation exposure, or the individual's current employer, if the individual is not employed by the licensee or registrant, by telephone, telegram, facsimile, or letter. The licensee or registrant shall request a written verification of the dose data if the authenticity of the transmitted report cannot be established.

4.10.4 Record of Exposure History.

4.10.4.1 The licensee or registrant shall record the exposure history, as required by 4.10.1 or 4.10.2 [JJ8], on Department Form R-16, 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 or registrant obtains reports, the licensee or registrant shall use the dose shown in the report in preparing Department Form R-16 or equivalent. For any period in which the licensee or registrant does not obtain a report, the licensee or registrant shall place a notation on Department Form R-16 or equivalent indicating the periods of time for which data are not available.

4.10.4.2 Licensees or registrants are not required to reevaluate the separate external dose equivalents and internal committed dose equivalents or intakes of radionuclides assessed pursuant to the Regulations in Part 4 in effect before January 1, 1994. Further, occupational exposure histories obtained and recorded before January 1, 1994 on Department Form R-16 or equivalent, would not have included effective dose equivalent, but may be used in the absence of specific information on the intake of radionuclides by the individual.

4.10.5 If the licensee or registrant is unable to obtain a complete record of an individual's current and previously accumulated occupational dose, the licensee or registrant shall assume:

4.10.5.1 In establishing administrative controls pursuant to 4.6.6 for the current year, that the allowable dose limit for the individual is reduced by 12.5 mSv (1.25 rem) for each quarter for which records were unavailable and the individual was engaged in activities that could have resulted in occupational radiation exposure; and

4.10.5.2 That the individual is not available for planned special exposures.

4.10.6 The licensee or registrant shall retain the records on Department Form R-16 or equivalent until the Department terminates each pertinent license or registration requiring this record. The licensee or registrant shall retain records used in preparing Department Form R-16 or equivalent for 3 years after the record is made.

4.11 Planned Special Exposures.

A licensee or registrant may authorize an adult worker to receive doses in addition to and accounted for separately from the doses received under the limits specified in 4.6 provided that each of the following conditions in 4.11.1 through 4.11.7 is satisfied:

4.11.1 The licensee or registrant authorizes a planned special exposure only in an exceptional situation when alternatives that might avoid the dose estimated to result from the planned special exposure are unavailable or impractical.

4.11.2 The licensee or registrant, and employer if the employer is not the licensee or registrant, specifically authorizes the planned special exposure, in writing, before the exposure occurs.

4.11.3 Before a planned special exposure, the licensee or registrant ensures that each individual involved is:

4.11.3.1 Informed of the purpose of the planned operation; and

4.11.3.2 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

4.11.3.3 Instructed in the measures to be taken to keep the dose ALARA considering other risks that may be present.

4.11.4 Prior to permitting an individual to participate in a planned special exposure, the licensee or registrant ascertains prior doses as required by 4.10.2 during the lifetime of the individual for each individual involved.

4.11.5 Subject to 4.6.2, the licensee or registrant 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:

4.11.5.1 The numerical values of any of the dose limits in 4.6.1 in any year; and

4.11.5.2 Five times the annual dose limits in 4.6.1 during the individual's lifetime.

4.11.6 The licensee or registrant maintains records of the conduct of a planned special exposure in accordance with 4.45 and submits a written report in accordance with 4.54.

4.11.7 The licensee or registrant 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 pursuant to 4.6.1 but shall be included in evaluations required by 4.11.4 and 4.11.5.

4.12 Occupational Dose Limits for Minors.

The annual occupational dose limits for minors are 10 percent of the annual occupational dose limits specified for adult workers in 4.6.

4.13 Dose Equivalent to an Embryo/Fetus.

4.13.1 The licensee or registrant shall ensure that the dose equivalent to an embryo/fetus during the entire pregnancy, due to the occupational exposure of a declared pregnant woman, does not exceed 5 mSv (0.5 rem). See 4.46 for recordkeeping requirements.

4.13.2 The licensee or registrant shall make efforts to avoid substantial variation [~~1~~2] above a uniform monthly exposure rate to a declared pregnant woman so as to satisfy the limit in 4.13.1.

[~~1~~2][JJ9] The National Council on Radiation Protection and Measurements recommended in NCRP Report No. 91 "Recommendations on Limits for Exposure to Ionizing Radiation" (June 1, 1987) that no more than 0.5 mSv (0.05 rem) to the embryo/fetus be received in any one month.

4.13.3 The dose equivalent to an embryo/fetus is the sum of:

4.13.3.1 The deep dose equivalent to the declared pregnant woman; and

4.13.3.2 The dose equivalent to the embryo/fetus resulting from radionuclides in the embryo/fetus and radionuclides in the declared pregnant woman.

4.13.4 If the dose equivalent to the embryo/fetus is found to have exceeded 5 mSv (0.5 rem), or is within 0.5 mSv (0.05 rem) of this dose, by the time the woman declares the pregnancy to the licensee or registrant, the licensee or registrant shall be deemed to be in compliance with 4.13.1 if the additional dose equivalent to the embryo/fetus does not exceed 0.5 mSv (0.05 rem) during the remainder of the pregnancy.

DRAFT 1 – 12/05/2012 -RQ

RADIATION DOSE LIMITS FOR INDIVIDUAL MEMBERS OF THE PUBLIC

4.14 Dose Limits for Individual Members of the Public.

4.14.1 Each licensee or registrant shall conduct operations so that:

4.14.1.1 The total effective dose equivalent to individual members of the public from the licensed or registered operation does not exceed 1 millisievert (0.1 rem) in a year, exclusive of the dose contributions from background radiation, from any medical administration the individual has received, from exposure to individuals administered radioactive material and released in accordance with 7.26, from voluntary participation in medical research programs, and from the dose contribution from the licensee's or registrant's disposal of radioactive material into sanitary sewerage in accordance with 4.35, and

4.14.1.2 The dose in any unrestricted area from external sources, exclusive of the dose contributions from patients administered radioactive material and released in accordance with 7.26, does not exceed 0.02 millisievert (0.002 rem) in any one hour.

4.14.2 A licensee may permit visitors to an individual who cannot be released under 7.26 to receive a radiation dose greater than 1 mSv (0.1 rem) if:

4.14.3.1 The radiation dose received does not exceed 5 mSv (0.5 rem); and

4.14.3.1 The authorized user, as defined in Part 7, has determined before the visit that it is appropriate.

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

4.14.3.1 Demonstration of the need for and the expected duration of operations in excess of the limit in 4.14.1; and

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

4.14.3.3 The procedures to be followed to maintain the dose ALARA.

4.14.4 In addition to the requirements of Part 4, a licensee or registrant subject to the provisions of the U.S. Environmental Protection Agency's generally applicable environmental radiation standards in 40 CFR 190 (July 1, 2004) shall comply with those standards.

4.14.5 The Department may impose additional restrictions on radiation levels in unrestricted areas and on the total quantity of radionuclides that a licensee or registrant may release in effluents in order to restrict the collective dose.

4.15 Compliance with Dose Limits for Individual Members of the Public.

4.15.1 The licensee or registrant 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 in 4.14.

4.15.2 A licensee or registrant shall show compliance with the annual dose limit in 4.14 by:

4.15.2.1 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

4.15.2.2 Demonstrating that:

(1) 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 4B2 of Appendix 4B; and

(2) If an individual were continually present in an unrestricted area, the dose from external sources would not exceed 0.02 mSv (0.002 rem) in an hour and 0.5 mSv (0.05 rem) in a year.

4.15.3 Upon approval from the Department, the licensee or registrant may adjust the effluent concentration values in Appendix 4B, Table 4B2, 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.

4.15.4 Rooms or areas in which diagnostic x-ray systems are the only source of radiation shall demonstrate compliance with 4.15.2.1 after construction of a new x-ray facility, after modification or renovation of an existing x-ray facility, or installation or a new x-ray machine in an existing x-ray facility when there is a change in primary beam orientation, or a change in primary shielding due to the modification or renovation of a facility, or where there is a projected increase in the x-ray workload from that which was used for a prior x-ray shielding design.

4.15.5 Rooms ~~Facilities~~ or areas in which~~using~~ only dental intraoral, ~~or~~dental panoramic, mini-c-arm x-ray, or bone densitometry systems~~machines in single occupancy rooms~~ are used, are exempt from the requirements of 4.15.2.1[JJ10].

TESTING FOR LEAKAGE OR CONTAMINATION OF SEALED SOURCES

4.16 Testing for Leakage or Contamination of Sealed Sources.

4.16.1 The licensee or registrant in possession of any sealed source shall assure that:

4.16.1.1 Each sealed source, except as specified in 4.16.2, is tested for leakage or contamination and the test results are received before the sealed source is put into use unless the licensee or registrant has a certificate from the transferor indicating that the sealed source was tested within 6 months before transfer to the licensee or registrant. Sources that indicate contamination in excess of 185 Bq (0.005 microcuries) shall not be put into use.

4.16.1.2 Each sealed source that is not designed to emit alpha particles is tested for leakage or contamination at intervals not to exceed 6 months or at alternative intervals approved by the Department, after evaluation of information specified by 3.12.12.2~~4~~[JJ11] and 3.12.12.3~~5~~ of these regulations, an Agreement State, a Licensing State, or the U.S. Nuclear Regulatory Commission.

4.16.1.3 Each sealed source that is designed to emit alpha particles is tested for leakage or contamination at intervals not to exceed 3 months or at alternative intervals approved by the Department, after evaluation of information specified by 3.12.12.2~~4~~ and 3.12.12.3~~5~~[JJ12] of these regulations, an Agreement State, a Licensing State, or the U.S. Nuclear Regulatory Commission.

4.16.1.4 For each sealed source that is required to be tested for leakage or contamination, at any other time there is reason to suspect that the sealed source might have been damaged or might be leaking, the licensee or registrant shall assure that the sealed source is tested for leakage or contamination before further use.

4.16.1.5 Tests, and evaluations of tests, for leakage for all sealed sources, except brachytherapy sources manufactured to contain radium, shall be capable of detecting the presence of 185 Bq (0.005 µCi) of radioactive material on a test sample. Test samples shall be taken[JJ13] from the sealed source or from the surfaces of the container in which the sealed source is stored or mounted on which one might expect contamination to accumulate. For a sealed source contained in a device, test samples are obtained when the source is in the "off" position.

4.16.1.6 The test for leakage for brachytherapy sources manufactured to contain radium shall be capable of detecting an absolute leakage rate of 37 Bq (0.001 µCi) of radon-222 in a 24-hour period when the collection efficiency for radon[JJ14]-222 and its decay products has been determined with respect to collection method, volume and time.

4.16.1.7 Tests for contamination from radium decay products shall be taken on the interior surface of brachytherapy source storage containers and shall be capable of detecting the presence of 185 Bq (0.005 µCi) of a radium decay product which has a half-life greater than 4 days.

4.16.2 A licensee or registrant need not perform test for leakage or contamination on the following sealed sources:

4.16.2.1 Sealed sources containing only radioactive material with a half-life of less than 30 days;

4.16.2.2 Sealed sources containing only radioactive material as a gas;

4.16.2.3 Sealed sources containing 3.7 MBq (100 µCi) or less of beta or photon-emitting material or 370 kBq (10 µCi) or less of alpha-emitting material;

4.16.2.4 Sealed sources containing only hydrogen-3;

4.16.2.5 Seeds of iridium-192 encased in nylon ribbon; and

4.16.2.6 Sealed sources, except teletherapy and brachytherapy sources, which are stored, not being used and identified as in storage. The licensee or registrant shall, however, test each such sealed source for leakage or contamination and receive the test results before any use or transfer unless it has been tested for leakage or contamination within 6 months before the date of use or transfer.

4.16.3 Tests for leakage or contamination from sealed sources shall be performed by persons specifically authorized by the Department, an Agreement State, a Licensing State, or the U.S. Nuclear Regulatory Commission to perform such services.

4.16.4 Test results shall be kept in units of becquerel (or microcurie) and maintained for inspection by the Department. Records of test results for sealed sources shall be made and retained as specified in[JJ15] 4.43.

4.16.5 The following shall be considered evidence that a sealed source is leaking:

4.16.5.1 T he presence of 185 Bq (0.005 µCi) or more of removable contamination on any test sample.

4.16.5.2 Leakage of 37 Bq (0.001 µCi) of radon-222 per 24 hours for brachytherapy sources manufactured to contain radium.

4.16.5.3 The presence of removable contaminat-ion resulting from the decay of 185 Bq (0.005 µCi) or more of radium.

4.16.6 The licensee or registrant shall immediately withdraw a leaking sealed source from use and shall take action to prevent the spread of contamination. The leaking sealed source shall be repaired or disposed of in accordance with this Part.

4.16.7 Reports of test results for leaking or contaminated sealed sources shall be made pursuant to 4.58.

SURVEYS AND MONITORING

4.17 General.

4.17.1 Each licensee or registrant shall make, or cause to be made, surveys of areas, including areas of subsurface residual radioactivity identified at the site[JJ16], that:

4.17.1.1 Are necessary for the licensee or registrant to comply with Part 4; and

4.17.1.2 Are necessary under the circumstances to evaluate:

(1) The magnitude and extent of radiation levels; and

(2) Concentrations or quantities of radioactive material; and

(3) The potential radiological hazards.

4.17.2 Notwithstanding 4.42.1, records from surveys describing the location and amount of subsurface residual radioactivity identified at the site must be kept with records important for decommissioning, and such records must be retained in accordance with 3.16.5, as applicable[JJ17].

4.17.3 The licensee or registrant shall ensure that instruments and equipment used for quantitative radiation measurements, for example, dose rate and effluent monitoring, are calibrated at intervals not to exceed 12 months for the radiation measured unless otherwise noted in these regulations.

4.17.43 All personnel dosimeters, except for direct and indirect reading pocket ionization chambers and those dosimeters used to measure the dose to any extremity, that require processing to determine the radiation dose and that are used by licensees and registrants to comply with 4.6, with other applicable provisions of these regulations, or with conditions specified in a license or registration shall be processed and evaluated by a dosimetry processor:

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

4.17.34.2 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.

4.17.54 The licensee or registrant shall ensure that adequate precautions are taken to prevent a deceptive exposure of an individual monitoring device.

4.18 Conditions Requiring Individual Monitoring of External and Internal Occupational Dose.

Each licensee or registrant shall monitor exposures from sources of radiation at levels sufficient to demonstrate compliance with the occupational dose limits of Part 4. As a minimum:

4.18.1 Each licensee or registrant shall monitor occupational exposure to radiation from licensed and unlicensed radiation sources under the control of the licensee and shall supply and require the use of individual monitoring devices by:

4.18.1.1 Adults likely to receive, in 1 year from sources external to the body, a dose in excess of 10 percent of the limits in 4.6.1;

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

4.18.1.3 Declared pregnant women likely to receive during the entire pregnancy, from radiation sources external to the body, a deep dose equivalent in excess of 1mSv (0.1 rem) [23] ; and

[23] All of the occupational doses in 4.6 continue to be applicable to the declared pregnant worker as long as the embryo/fetus dose limit is not exceeded.

4.18.1.4 Individuals entering a high radiation area or a very high radiation area.

4.18.2 Each licensee or registrant shall monitor, to determine compliance with 4.9, the occupational intake of radioactive material by and assess the committed effective dose equivalent to:

4.18.2.1 Adults likely to receive, in 1 year, an intake in excess of 10 percent of the applicable ALI(s) in Table 4B1, Columns 1 and 2, of Appendix 4B;

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

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

4.18.3 Upon approval of the Department, an acceptable alternative to the use of continuous individual monitoring devices in order to demonstrate compliance with 4.18.1 and 4.18.2 may be used.

4.18.3.1 Acceptable alternative demonstrations that doses will not exceed 10 percent of the annual limits in 4.6.1, 4.12 and 4.13 include submittal to the Department of:

(1) An acceptable application documenting six months of the use of continuous individual monitoring devices; or

(2) An acceptable assessment from a qualified expert, as defined in 1.24[JJ18], that takes into account design configuration, workload, radiation-producing machine output, and survey data.

4.18.3.2 To maintain approval of an acceptable alternative to the use of continuous individual monitoring devices:

(1) Reapplication under 4.18.3.1(1) or reassessment under 4.18.3.1(2) is required for any change in configuration, equipment or workload; and

(2) The licensee or registrant shall include assessment of individual monitoring in the review of the radiation protection program required annually by 4.5.

CONTROL OF EXPOSURE FROM EXTERNAL SOURCES IN RESTRICTED AREAS

4.19 Control of Access to High Radiation Areas.

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

4.19.1.1 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 1 mSv (0.1 rem) in 1 hour at 30 centimeters from the source of radiation from any surface that the radiation penetrates; or

4.19.1.2 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

4.19.1.3 Entryways that are locked, except during periods when access to the areas is required, with positive control over each individual entry.

4.19.2 In place of the controls required by 4.19.1 for a high radiation area, the licensee or registrant may substitute continuous direct or electronic surveillance that is capable of preventing unauthorized entry.

4.19.3 The licensee or registrant may apply to the Department for approval of alternative methods for controlling access to high radiation areas.

4.19.4 The licensee or registrant shall establish the controls required by 4.19.1 and 4.19.3 in a way that does not prevent individuals from leaving a high radiation area.

4.19.5 The licensee or registrant 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 U.S. Department of Transportation provided that:

4.19.5.1 The packages do not remain in the area longer than 3 days; and

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

4.19.6 The licensee or registrant 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 radiation or radioactive material in excess of the established limits in Part 4 and to operate within the ALARA provisions of the licensee's or registrant's radiation protection program.

4.19.7 The licensee or registrant is not required to control entrance or access to rooms or other areas containing sources of radiation capable of producing a high radiation area as described in 4.19 if the licensee or registrant has met all the specific requirements for access and control specified in other applicable parts of these regulations, such as, Part 5 for industrial radiography, Part 6 for x-rays in the healing arts, and Part 9 for particle accelerators not used in the healing arts[JJ19].

4.20 Control of Access to Very High Radiation Areas.

4.20.1 In addition to the requirements in 4.19, the licensee or registrant 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 5 Gy (500 rad) or more in 1 hour at 1 meter from a source of radiation or any surface through which the radiation penetrates. This requirement does not apply to rooms or areas in which diagnostic x-ray systems are the only source of radiation, or to non-self-shielded irradiators.

4.20.2 The registrant is not required to control entrance or access to rooms or other areas containing sources of radiation capable of producing a very high radiation area as described in 4.20.1 if the registrant has met all the specific requirements for access and control specified in other applicable parts of these regulations, such as, Part 5 for industrial radiography, Part 6 for x-rays in the healing arts, and Part 9 for particle accelerators not used in the healing arts[JJ20].

4.21 Control of Access to Very High Radiation Areas - Irradiators.

4.21.1 Section 4.21 applies to licensees or registrants with sources of radiation in non-self-shielded irradiators. Section 4.21 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.

4.21.2 Each area in which there may exist radiation levels in excess of 5 Gy (500 rad) in 1 hour at 1 meter from a source of radiation that is used to irradiate materials shall meet the following requirements:

4.21.2.1 Each entrance or access point shall be equipped with entry control devices which:

(1) Function automatically to prevent any individual from inadvertently entering a very high radiation area; and

(2) 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 1 mSv (0.1 rem) in 1 hour; and

(3) 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 1 mSv (0.1 rem) in 1 hour.

4.21.2.2 Additional control devices shall be provided so that, upon failure of the entry control devices to function as required by 4.21.2.1:

(1) 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 1 mSv (0.1 rem) in 1 hour; and

(2) 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.

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

(1) 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 1 mSv (0.1 rem) in 1 hour; and

(2) Conspicuous visible and audible alarm signals are generated to make potentially affected individuals aware of the hazard and the licensee or registrant 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.

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

4.21.2.5 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 4.21.2.3 and 4.21.2.4.

4.21.2.6 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.

4.21.2.7 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.

4.21.2.8 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 1 mSv (0.1 rem) in 1 hour.

4.21.2.9 The entry control devices required in 4.21.2.1 shall be tested for proper functioning. See 4.49 for recordkeeping requirements.

(1) 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; and

(2) Testing shall be conducted prior to resumption of operation of the source of radiation after any unintentional interruption; and

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

4.21.2.10 The licensee or registrant 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.

4.21.2.11 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 to automatically prevent loose radioactive material from being carried out of the area.

4.21.3 Licensees, registrants, or applicants for licenses or registrations for sources of radiation within the purview of 4.21.2 which will be used in a variety of positions or in locations, such as open fields or forests, that make it impracticable to comply with certain requirements of 4.21.2, such as those for the automatic control of radiation levels, may apply to the Department for approval of alternative safety measures. Alternative safety measures shall provide personnel protection at least equivalent to those specified in 4.21.2. 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.

4.21.4 The entry control devices required by 4.21.2 and 4.21.3 shall be established in such a way that no individual will be prevented from leaving the area.

RESPIRATORY PROTECTION AND CONTROLS TO RESTRICT INTERNAL EXPOSURE IN RESTRICTED AREAS

4.22 Use of Process or Other Engineering Controls.

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

4.23 Use of Other Controls.

4.23.1 When it is not practical 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:

4.23.1.1 Control of access; or

4.23.1.2 Limitation of exposure times; or

4.23.1.3 Use of respiratory protection equipment; or

4.23.1.4 Other controls.

4.23.2 If the licensee performs an ALARA analysis to determine whether or not respirators should be used, the licensee may consider safety factors other than radiological factors. The licensee should also consider the impact of respirator use on workers' industrial health and safety.

4.24 Use of Individual Respiratory Protection Equipment.

4.24.1 If the licensee uses respiratory protection equipment to limit intakes pursuant to 4.23:

4.24.1.1 Except as provided in 4.24.1.2, the licensee shall use only respiratory protection equipment that is tested and certified or had certification extended by the National Institute for Occupational Safety and Health and the Mine Safety and Health Administration.

4.24.1.2 If the licensee wishes to use equipment that has not been tested or certified by the National Institute for Occupational Safety and Health and the Mine Safety and Health Administration, or has not had certification extended by the National Institute for Occupational Safety and Health and the Mine Safety and Health Administration, or for which there is no schedule for testing or certification, the licensee shall submit an application for authorized use of that equipment, including a demonstration by testing, or a demonstration on the basis of reliable 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.

4.24.1.3 The licensee shall implement and maintain a respiratory protection program that includes:

(1) Air sampling sufficient to identify the potential hazard, permit proper equipment selection, and estimate exposures; and

(2) Surveys and bioassays, as appropriate, to evaluate actual intakes; and

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

(4) Written procedures regarding selection, fitting, issuance, maintenance, repair, quality assurance, storage and testing of respirators, including testing for operability immediately prior to each use; supervision and training of personnel; limitations on periods of respirator use and relief from respirator use; breathing air quality; monitoring, including air sampling and bioassays; inventory, control and recordkeeping; and

(5) Determination by a physician, prior to initial fitting of respirators, before 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.

(6) Fit testing, with fit factor 10 times the assigned protection factor (APF) for negative pressure devices, and a fit factor greater than or equal to 500 for any positive pressure, continuous flow, and pressure 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 must be performed with the facepiece operating in the negative pressure mode.

4.24.1.4 The licensee shall:

(1) Issue a written policy statement on respirator usage covering:

(a) The use of process or other engineering controls, instead of respirators; and

(b) The routine, nonroutine, and emergency use of respirators; and

(c) The length of periods of respirator use and relief from respirator use; and

(2) 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.

4.24.1.5 The licensee shall also consider limitations appropriate to the type and mode of use. When selecting respiratory devices the licensee shall provide for vision correction, adequate communication, low temperature work environments, 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.

4.24.1.6 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 would have difficulty extricating himself or herself. The standby persons must 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.

4.24.1.7 Atmosphere-supplying respirators must 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," edition 5, published August 27, 2004, and included in the regulations of the Occupational Safety And Health Administration (29 CFR 1910.134(i)(1)(ii)(A) through (E), July 1, 2004).

Grade D quality air criteria include:

(1) Oxygen content (V/V) between 19.5 per cent and 23.5 per cent;

(2) Hydrocarbon (condensed) content of 5 milligrams per cubic meter of air or less;

(3) Carbon monoxide (CO) content of 10 parts per million or less;

(4) Carbon dioxide content of 1,000 parts per million or less; and

(5) Lack of noticeable odor.

4.24.1.8 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.

4.24.1.9 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 must be used. If the dose is later found to be less than the estimated dose, the corrected value may be used.

4.24.2 When estimating exposure of individuals to airborne radioactive materials, the licensee may make allowance for respiratory protection equipment used to limit intakes pursuant to 4.23, provided that the following conditions, in addition to those in 4.24.1, are satisfied:

4.24.2.1 The licensee selects respiratory protection equipment that provides a protection factor, specified in Appendix 4A, greater than the multiple by which peak concentrations of airborne radioactive materials in the working area are expected to exceed the values

specified in Appendix 4B, Table 4B1, Column 3. However, if the selection of respiratory protection equipment with a protection factor greater than the multiple defined in the preceding sentence is inconsistent with the goal specified in 4.23 of keeping the total effective dose equivalent ALARA, the licensee may select respiratory protection equipment with a lower protection factor provided that such a selection would result in a total effective dose equivalent that is ALARA. The concentration of radioactive material in the air that is inhaled when respirators are worn may be initially estimated by dividing the average concentration in air, during each period of uninterrupted use, by the protection factor. If the exposure is later found to be greater than initially estimated, the corrected value shall be used; if the exposure is later found to be less than initially estimated, the corrected value may be used.

4.24.2.2 The licensee shall obtain authorization from the Department before assigning respiratory protection factors in excess of those specified in Appendix 4A. The Department may authorize a licensee to use higher protection factors on receipt of an application that:

(1) Describes the situation for which a need exists for higher protection factors, and

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

4.24.3 In an emergency, the licensee shall use as emergency equipment only respiratory protection equipment that has been specifically certified or had certification extended for emergency use by the National Institute for Occupational Safety and Health and the Mine Safety and Health Administration.

4.24.4 The licensee shall notify the Department in writing at least 30 days before the date that respiratory protection equipment is first used pursuant to either 4.24.1 or 4.24.2.

4.24.5 The Department may impose restrictions in addition to the provisions of 4.23.2, 4.24.1, and Appendix 4A, in order to:

4.24.5.1 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

4.24.5.2 Limit the extent to which a licensee may use respiratory protection equipment instead of process or other engineering controls.

STORAGE AND CONTROL OF LICENSED OR REGISTERED SOURCES OF RADIATION

4.25 Security of Stored Sources of Radiation.

4.25.1 The licensee shall secure from unauthorized removal or access licensed or registered sources of radiation that are stored in unrestricted areas.

4.25.2 Security requirements for portable gauges.

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.

4.26 Control of Sources of Radiation not in Storage.

4.26.1 The licensee shall control and maintain constant surveillance of licensed or registered radioactive material that is in an unrestricted area and that is not in storage or in a patient.

4.26.2 The registrant shall maintain control of radiation machines that are in an unrestricted area and that are not in storage.

PRECAUTIONARY PROCEDURES

4.27 Caution Signs.

4.27.1 Standard Radiation Symbol. Unless otherwise authorized by the Department, the symbol prescribed by 4.27 shall use the colors magenta, or purple, or black on yellow background. The symbol prescribed is the three-bladed design as follows:

RADIATION SYMBOL

4.27.1.1. Cross-hatched area is to be magenta, or purple, or black, and

4.27.1.2. The background is to be yellow.

Radiation Symbol
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4.27.2 Exception to Color Requirements for Standard Radiation Symbol.

Notwithstanding the requirements of 4.27.1, licensees or registrants 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.

4.27.3 Additional Information on Signs and Labels.

In addition to the contents of signs and labels prescribed in Part 4, the licensee may~~shall~~[JJ22] provide, on or near the required signs and labels, additional information, as appropriate, to make individuals aware of potential radiation exposures and to minimize the exposures.

4.28 Posting Requirements.

4.28.1 Posting of Radiation Areas.

The licensee or registrant shall post each radiation area with a conspicuous sign or signs bearing the radiation symbol prescribed in 4.27 and the words “CAUTION, RADIATION AREA.”

4.28.2 Posting of High Radiation Areas.

The licensee or registrant shall post each high radiation area with a conspicuous sign or signs bearing the radiation symbol prescribed in 4.27 and the words “CAUTION, HIGH RADIATION AREA” or “DANGER, HIGH RADIATION AREA.”

4.28.3 Posting of Very High Radiation Areas.

The licensee or registrant shall post each very high radiation area with a conspicuous sign or signs bearing the radiation symbol prescribed in 4.27 and words “GRAVE DANGER, VERY HIGH RADIATION AREA.”

4.28.4 Posting of Airborne Radioactivity Areas.

The licensee or registrant shall post each airborne radioactivity area with a conspicuous sign or signs bearing the radiation symbol prescribed in 4.27 and the words “CAUTION, AIRBORNE RADIOACTIVITY AREA” or “DANGER, AIRBORNE RADIOACTIVITY AREA.”

4.28.5 Posting of Areas or Rooms in which Licensed or Registered Material is Used or Stored.

The licensee or registrant shall post each area or room in which there is used or stored an amount of licensed or registered material exceeding 10 times the quantity of such material specified in Appendix 4C with a conspicuous sign or signs bearing the radiation symbol prescribed in 4.27 and the words “CAUTION, RADIOACTIVE MATERIAL(S)” or “DANGER, RADIOACTIVE MATERIAL(S).”

4.29 Exceptions to Posting Requirements.

4.29.1 A licensee or registrant 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:

4.29.1.1 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 Part 4; and

4.29.1.2 The area or room is subject to the licensee's or registrant's control.

4.29.2 Rooms or other areas in hospitals that are occupied by patients are not required to be posted with caution signs pursuant to 4.28 provided that the total effective dose equivalent to individual members of the public from the patient does not exceed 1 millisievert (0.1 rem) in a year.

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

4.29.4 Rooms in hospitals or clinics that are used for teletherapy are exempt from the requirement to post caution signs under 4.28 if:

4.29.4.1 Access to the room is controlled pursuant to 7.52; and

4.29.4.2 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 part.

4.29.5 A room or area is not required to be posted with a caution sign because of the presence of radiation machines used solely for diagnosis in the healing arts.

4.30 Labeling Containers and Radiation Machines.

4.30.1 The licensee or registrant shall ensure that each container of licensed or registered material bears a durable, clearly visible label bearing the radiation symbol prescribed in 4.27 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.

4.30.2 Each licensee or registrant 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.

4.30.3 Each registrant shall ensure that each radiation machine is labeled in a conspicuous manner, which cautions individuals that radiation is produced when it is energized.

4.31 Exemptions to Labeling Requirements.

A licensee or registrant is not required to label:

4.31.1 Containers holding licensed or registered material in quantities less than the quantities listed in Appendix 4C; or

4.31.2 Containers holding licensed or registered material in concentrations less than those specified in Table 4B3 of Appendix 4B; or

4.31.3 Containers attended by an individual who takes the precautions necessary to prevent the exposure of individuals in excess of the limits established by Part 4; or

4.31.4 Containers when they are in transport and packaged and labeled in accordance with the regulations of the U.S. Department of Transportation [34] or

[34] Labeling of packages containing radioactive materials is required by the U.S. Department of Transportation if the amount and type of radioactive material exceeds the limits for an excepted quantity or article as defined and limited by U.S. Department of Transportation regulations 49 CFR 173.403(m) and (w) and 173.421-424, October 1, 2003.

4.31.5 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

4.31.6 Installed manufacturing or process equipment, such as piping and tanks.

4.32 Procedures for Receiving and Opening Packages.

4.32.1 Each licensee or registrant who expects to receive a package containing quantities of radioactive material in excess of a Type A quantity, as defined in 17.2 and Appendix 17A of Part 17 of these regulations, shall make arrangements to receive:

4.32.1.1 The package when the carrier offers it for delivery; or

4.32.1.2 The notification of the arrival of the package at the carrier's terminal and to take possession of the package expeditiously.

4.32.2 Each licensee or registrant shall:

4.32.2.1 Monitor the external surfaces of a labeled [45] package for radioactive contamination unless the package contains only radioactive material in the form of gas or in special form as defined in 1.24[JJ23] of these regulations; and

[45] Labeled with a Radioactive White I, Yellow II, or Yellow III label as specified in U.S. Department of Transportation regulations 49 CFR 172.403 and 172.436-440, October 1, 2003.

4.32.2.2 Monitor the external surfaces of a labeled [56] package 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 17.2 and Appendix 17A to Part 17 of these regulations; and

[56] Labeled with a Radioactive White I, Yellow II, or Yellow III label as specified in U.S. Department of Transportation regulations 49 CFR 172.403 and 172.436-440, October 1, 2003.

4.32.2.3 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.

4.32.3 The licensee or registrant shall perform the monitoring required by 4.32.2 as soon as practical after receipt of the package, but not later than 3 hours after the package is received at the licensee's or registrant's facility if it is received during the licensee's or registrant's normal working hours, or not later than 3 hours from the beginning of the next working day if it is received after working hours.

4.32.4 The licensee or registrant shall immediately notify the final delivery carrier and the Department by telephone, when:

4.32.4.1 Removable radioactive surface contamination exceeds the limits of 17.15.8 of these regulations; or

4.32.4.2 External radiation levels exceed the limits of 17.15.9 and 17.15.10 of these regulations.

4.32.5 Each licensee or registrant shall:

4.32.5.1 Establish, maintain, and retain written procedures for safely opening packages in which radioactive material is received; and

4.32.5.2 Ensure that the procedures are followed and that due consideration is given to special instructions for the type of package being opened.

4.32.6 Licensees or registrants transferring special form sources in vehicles owned or operated by the licensee or registrant to and from a work site are exempt from the contamination monitoring requirements of 4.32.2, but are not exempt from the monitoring requirement in 4.32.2 for measuring radiation levels that ensures that the source is still properly lodged in its shield.

WASTE DISPOSAL

4.33 General Requirements.

4.33.1 A licensee or registrant shall dispose of licensed or registered material only:

4.33.1.1 By transfer to an authorized recipient as provided in 4.38 or in Parts 3, 14, or 18 of these regulations, or to the U.S. Department of Energy; or

4.33.1.2 By decay in storage; or

4.33.1.3 By release in effluents within the limits in 4.14; or

4.33.1.4 As authorized pursuant to 4.34, 4.35, 4.36, 4.37 or 4.39.27 [JJ24].

4.33.2 A person shall be specifically licensed or registered to receive waste containing licensed or registered material from other persons for:

4.33.2.1 Treatment prior to disposal; or

4.33.2.2 Treatment or disposal by incineration; or

4.33.2.3 Decay in storage; or

4.33.2.4 Disposal at a land disposal facility pursuant to Part 14 of these regulations or as authorized under Parts 3 or 18 of these regulations; or

4.33.2.5 Storage until transferred to a storage or disposal facility authorized to receive the waste.

4.34 Method for Obtaining Approval of Proposed Disposal Procedures.

A licensee or registrant or applicant for a license or registration may apply to the Department for approval of proposed procedures, not otherwise authorized in these regulations, to dispose of licensed or registered material generated in the licensee's or registrant's operations. Each application shall include:

4.34.1 A description of the waste containing licensed or registered material to be disposed of, including the physical and chemical properties that have an impact on risk evaluation, and the proposed manner and conditions of waste disposal; and

4.34.2 An analysis and evaluation of pertinent information on the nature of the environment; and

4.34.3 The nature and location of other potentially affected facilities; and

4.34.4 Analyses and procedures to ensure that doses are maintained ALARA and within the dose limits in Part 4.

4.35 Disposal by Release into Sanitary Sewerage.

4.35.1 A licensee or registrant may discharge licensed or registered material into sanitary sewerage if each of the following conditions is satisfied:

4.35.1.1 The material is “readily soluble,” or is “readily dispersible biological material,” in water; and

4.35.1.2 The quantity of licensed or registered radioactive material that the licensee or registrant releases into the sewer in 1 month divided by the average monthly volume of water released into the sewer by the licensee or registrant does not exceed the concentration listed in Table 4B3 of Appendix 4B; and

4.35.1.3 If more than one radionuclide is released, the following conditions must also be satisfied:

(1) The licensee or registrant shall determine the fraction of the limit in Table 4B3 of Appendix 4B represented by discharges into sanitary sewerage by dividing the actual monthly average concentration of each radionuclide released by the licensee or registrant into the sewer by the concentration of that radionuclide listed in Table 4B3 of Appendix 4B; and

(2) The sum of the fractions for each radionuclide required by 4.35.1.3.1 does not exceed unity; and

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

4.35.2 Excreta from individuals undergoing medical diagnosis or therapy with radioactive material are not subject to the limitations contained in 4.35.1.

4.36 Treatment or Disposal by Incineration.

4.36.1 A licensee or registrant may treat or dispose of licensed or registered material by incineration only in the amounts and forms specified in 4.37 or as specifically approved by the Department pursuant to 4.34.

4.37 Disposal of Specific Wastes.

4.37.1 A licensee or registrant may dispose of the following licensed or registered material as if it were not radioactive:

4.37.1.1 1.85 kBq (0.05 µCi), or less, of hydrogen-3 or carbon-14 per gr am of medium used for liquid scintillation counting; and

4.37.1.2 1.85 kBq (0.05 µCi), or less, of hydrogen-3 or carbon-14 per gram of animal tissue, averaged over the weight of the entire animal.

4.37.2 A licensee or registrant shall not dispose of tissue pursuant to 4.37.1.2 in a manner that would permit its use either as food for humans or as animal feed.

4.37.3 The licensee or registrant shall maintain records in accordance with 4.48.

4.38 Transfer for Disposal and Manifests.

4.38.1 The requirements of 4.38 and Appendix 4D are designed to control transfers of low-level radioactive waste by any waste generator, waste collector, or waste processor licensee, as defined in this part, who ships low-level waste either directly, or indirectly through a waste collector or waste processor, to a licensed low-level radioactive waste disposal facility, establish a manifest tracking system, and supplement existing requirements concerning transfers and recordkeeping for those wastes.

4.38.2 Any licensee shipping radioactive waste intended for ultimate disposal at a licensed land disposal facility shall document the information required on the uniform low-level radioactive waste manifest and transfer this recorded manifest information to the intended consignee in accordance with Appendix 4D.

4.38.3 Each shipment manifest shall include a certification by the waste generator as specified in Section II of Appendix 4D.

4.38.4 Each person involved in the transfer of waste for disposal or in the disposal of waste, including the waste generator, waste collector, waste processor, and disposal facility operator, shall comply with the requirements specified in Section III of Appendix 4D.

4.38.5 Any licensee shipping byproduct material as defined in paragraphs (3) and (4) of the definition of *Byproduct material* set forth in 1.2. intended for ultimate disposal at a land disposal facility licensed under 10 CFR Part 61, must 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 Appendix 4D[JJ25].

4.39 Additional Requirements[JJ26]

4.39.1 Compliance with Environmental and Health Protection Regulations.

4.39.1.1 Nothing in 4.33, 4.34, 4.35, 4.37, 4.38 or 4.39.2~~8~~ relieves the licensee or registrant from complying with other applicable Federal, State and local regulations governing any other toxic or hazardous properties of materials that may be disposed of pursuant to 4.33, 4.34, 4.35, 4.37, ~~or~~ 4.38, or 4.39.2.

4.39.2 Disposal of Certain Byproduct Material[JJ27]

4.39.2.1[JJ28] Licensed material as defined in paragraphs (3) and (4) of the definition of *Byproduct material* set forth in Part 1, Section 1.2 may be disposed of in accordance with Part 14 or equivalent regulations of NRC or an Agreement State, even though it is not defined as low-level radioactive waste. Therefore, any licensed material being disposed of at a facility, or transferred for ultimate disposal at a facility licensed under Part 14, or equivalent regulations of NRC or Agreement State, must meet the requirements of 4.38.

4.39.2.2 A licensee may dispose of byproduct material, as defined in paragraphs (3) and (4) of the definition of *Byproduct material* set forth in Part 1, Section 1.2, at a disposal facility authorized to dispose of such material in accordance with any Federal or State solid or hazardous waste law, including the Solid Waste Disposal Act, as authorized under the Energy Policy Act of 2005.

RECORDS

4.40 General Provisions.

4.40.1 Each licensee or registrant shall use the 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 Part 4.

4.40.2 The licensee or registrant shall make a clear distinction among the quantities entered on the records required by Part 4 (e.g., total effective dose equivalent, total organ dose equivalent, shallow dose equivalent, lens dose equivalent, deep dose equivalent, committed effective dose equivalent).

4.40.3 The licensee or registrant shall be consistent in their use of SI or special units. The licensee or registrant shall not change the units used on records required by Part 4 except at the beginning of the calendar year or with Department approval.

4.41 Records of Radiation Protection Programs.

4.41.1 Each licensee or registrant shall maintain records of the radiation protection program, including:

4.41.1.1 The provisions of the program; and

4.41.1.2 Audits and other reviews of program content and implementation.

4.41.2 The licensee or registrant shall retain the records required by 4.41.1.1 until the Department terminates each pertinent license or registration requiring the record. The licensee or registrant shall retain the records required by 4.41.1.2 for 3 years after the record is made.

4.42 Records of Surveys.

4.42.1 Each licensee or registrant shall maintain records showing the results of surveys and calibrations required by 4.17 and 4.32.2. The licensee or registrant shall retain these records for 3 years after the record is made.

4.42.2 The licensee or registrant shall retain each of the following records until the Department terminates each pertinent license or registration requiring the record:

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

4.42.2.2 Records of the results of measurements and calculations used to determine individual intakes of radioactive material and used in the assessment of internal dose; and

4.42.2.3 Records showing the results of air sampling, surveys, and bioassays required pursuant to 4.24.1.3(1) and 4.24.1.3(2); and

4.42.2.4 Records of the results of measurements and calculations used to evaluate the release of radioactive effluents to the environment.

4.42.3 Upon termination of the license or registration, the licensee or registrant shall permanently store records on Department Form R-16 or equivalent, or shall make provision with the Department for transfer to the Department.

4.43 Records of Tests for Leakage or Contamination of Sealed Sources.

Records of tests for leakage or contamination of sealed sources required by 4.16 shall be kept in units of becquerel (or microcurie) and maintained for inspection by the Department for 5 years after the records are made.

4.44 Records of Prior Occupational Dose.

4.44.1 The licensee or registrant shall retain the records of prior occupational dose and exposure history as specified in 4.10 on Department Form R-16 or equivalent until the Department terminates each pertinent license or registration requiring this record. The licensee or registrant shall retain records used in preparing Department Form R-16 or equivalent for 3 years after the record is made.

4.44.2 Upon termination of the license or registration, the licensee or registrant shall permanently store records on Department Form R-16 or equivalent, or shall make provision with the Department for transfer to the Department.

4.45 Records of Planned Special Exposures.

4.45.1 For each use of the provisions of 4.11 for planned special exposures, the licensee or registrant shall maintain records that describe:

4.45.1.1 The exceptional circumstances requiring the use of a planned special exposure; and

4.45.1.2 The name of the management official who authorized the planned special exposure and a copy of the signed authorization; and

4.45.1.3 What actions were necessary; and

4.45.1.4 Why the actions were necessary; and

4.45.1.5 What precautions were taken to assure that doses were maintained ALARA; and

4.45.1.6 What individual and collective doses were expected to result; and

4.45.1.7 The doses actually received in the planned special exposure.

4.45.2 The licensee or registrant shall retain the records until the Department terminates each pertinent license or registration requiring these records.

4.45.3 Upon termination of the license or registration, the licensee or registrant shall permanently store records on Department Form R-16 or equivalent, or shall make provision with the Department for transfer to the Department.

4.46 Records of Individual Monitoring Results.

4.46.1 Recordkeeping Requirement. Each licensee or registrant shall maintain records of doses received by all individuals for whom monitoring was required pursuant to 4.18, 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:

4.46.1.1 The deep dose equivalent to the whole body, lens dose equivalent, shallow dose equivalent to the skin, and shallow dose equivalent to the extremities;

4.46.1.2 The estimated intake of radionuclides (see 4.7);

4.46.1.3 The committed effective dose equivalent assigned to the intake of radionuclides;

4.46.1.4 The specific information used to assess and calculate the committed effective dose equivalent pursuant to 4.9.1 and 4.9.3, and when required by 4.18;

4.46.1.5 The total effective dose equivalent when required by 4.7; and

4.46.1.6 The total of the deep dose equivalent and the committed dose to the organ receiving the highest total dose.

4.46.2 Recordkeeping Frequency.

The licensee or registrant shall make entries of the records specified in 4.46.1 at intervals not to exceed 1 year.

4.46.3 Recordkeeping Format.

The licensee or registrant shall maintain the records specified in 4.46.1 on Department Form R-17, Occupational Exposure Record for a Monitoring Period, in accordance with the instructions for Department Form R-17, or in clear and legible records containing all the information required by Department Form R-17.

4.46.4 The licensee or registrant 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.

4.46.5 The licensee or registrant shall retain each required form or record until the Department terminates each pertinent license or registration requiring the record.

4.46.6 Upon termination of the license or registration, the licensee or registrant shall permanently store records on Department Form R-16 or equivalent, or shall make provision with the Department for transfer to the Department.

4.47 Records of Dose to Individual Members of the Public.

4.47.1 Each licensee or registrant shall maintain records sufficient to demonstrate compliance with the dose limit for individual members of the public. See 4.14.

4.47.2 The licensee or registrant shall retain the records required by 4.47.1 until the Department terminates each pertinent license or registration requiring the record.

4.48 Records of Waste Disposal.

4.48.1 Each licensee or registrant shall maintain records of the disposal of licensed or registered materials made pursuant to 4.34, 4.35, 4.36, 4.37, Part 14 of these regulations, and disposal by burial in soil, including burials authorized before December 30, 1985.

4.48.2 The licensee or registrant shall retain the records required by 4.48.1 in accordance with 3.15.4 until the Department terminates each pertinent license or registration requiring the record.

4.49 Records of Testing Entry Control Devices for Very High Radiation Areas.

4.49.1 Each licensee or registrant shall maintain records of tests made pursuant to 4.21.2.9 on entry control devices for very high radiation areas. These records must include the date, time, and results of each such test of function.

4.49.2 The licensee or registrant shall retain the records required by 4.49.1 for 3 years after the record is made.

4.50 Form of Records.

Each record required by Part 4 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 Department-approved 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.

REPORTS

4.51 Reports of Stolen, Lost, or Missing Licensed or Registered Sources of Radiation.

4.51.1 Telephone Reports.

Each licensee or registrant shall report to the Department by telephone as follows:

4.51.1.1 Immediately after its occurrence becomes known to the licensee or registrant, stolen[JJ29], lost, or missing licensed or registered radioactive material in an aggregate quantity equal to or greater than 1,000 times the quantity specified in Appendix 4C under

such circumstances that it appears to the licensee or registrant that an exposure could result to individuals in unrestricted areas; or

4.51.1.2 Within 30 days after its occurrence becomes known to the licensee or registrant, lost, stolen, or missing licensed or registered radioactive material in an aggregate quantity greater than 10 times the quantity specified in Appendix 4C that is still missing.

4.51.1.3 Immediately after its occurrence becomes known to the registrant, a stolen, lost, or missing radiation machine.

4.51.2 Written Reports.

Each licensee or registrant required to make a report pursuant to 4.51.1 shall, within 30 days after making the telephone report, make a written report to the Department setting forth the following information:

4.51.2.1 A description of the licensed or registered source of radiation involved, including, for radioactive material, the kind, quantity, and chemical and physical form; and, for radiation machines, the manufacturer, model and serial number, type and maximum energy of radiation emitted;

4.51.2.2 A description of the circumstances under which the loss or theft occurred; and

4.51.2.3 A statement of disposition, or probable disposition, of the licensed or registered source of radiation involved; and

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

4.51.2.5 Actions that have been taken, or will be taken, to recover the source of radiation; and

4.51.2.6 Procedures or measures that have been, or will be, adopted to ensure against a recurrence of the loss or theft of licensed or registered sources of radiation.

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

4.51.4 The licensee or registrant shall prepare any report filed with the Department pursuant to 4.51 so that names of individuals who may have received exposure to radiation are stated in a separate and detachable portion of the report.

4.52 Notification of Incidents.

4.52.1 Immediate Notification.

Notwithstanding other requirements for notification, each licensee or registrant shall notify the Department as soon as possible but not later than 4 hours after the discovery of an event:

4.52.1.1 Involving a source of radiation possessed by the licensee or registrant that may have caused or threatens to cause any of the following conditions:

(1) An individual to receive:

(a) A total effective dose equivalent of 0.25 Sv (25 rem) or more; or

(b) A lens dose equivalent of 0.75 Sv (75 rem) or more; or

(c) A shallow dose equivalent to the skin or extremities or a total organ dose equivalent of 2.5 Gy (250 rad) or more; or

(2) 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.

4.52.1.2 That prevents immediate protective actions necessary to avoid exposures to radiation and/or radioactive materials that could exceed regulatory limits, or releases of licensed material that could exceed regulatory limits (events may include fires, explosions, toxic gas releases, etc.).

4.52.2 Twenty-Four Hour Notification.

Each licensee or registrant shall, within 24 hours of discovery of the event, report to the Department:

4.52.2.1 Each event involving loss of control of a licensed or registered source of radiation possessed by the licensee or registrant that may have caused, or threatens to cause, any of the following conditions:

(1) An individual to receive, in a period of 24 hours:

(a) A total effective dose equivalent exceeding 0.05 Sv (5 rem); or

(b) A lens dose equivalent exceeding 0.15 Sv (15 rem); or

(c) A shallow dose equivalent to the skin or extremities or a total organ dose equivalent exceeding 0.5 Sv (50 rem); or

(2) 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.

4.52.2.2 An unplanned contamination event that:

(1) 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;

(2) Involves a quantity of material greater than five times the lowest annual limit on intake specified in Appendix 4B for the material; and

(3) 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.

4.52.2.3 An event in which equipment is disabled or fails to function as designed when:

(1) The equipment is required by regulation or license condition to prevent releases exceeding regulatory limits, to prevent exposures to radiation and/or radioactive materials exceeding regulatory limits, or to mitigate the consequences of an accident; and

(2) The equipment is required to be available and operable when it is disabled or fails to function during the event; and

(3) No redundant equipment is available and operable to perform the required safety function.

4.52.2.4 An event that requires unplanned medical treatment at a medical facility of an individual whose body or clothing is contaminated with spreadable radioactive material.

4.52.2.5 An unplanned fire or explosion damaging any licensed material or any device, container, or equipment containing licensed material when:

(1) The quantity of material involved is greater than five times the lowest annual limit on intake specified in Appendix 4B for the material; and

(2) The damage affects the integrity of the licensed material or its container.

4.53 Preparation and Submission of Reports.

4.53.1 Reports made by licensees or registrants in response to the requirements of 4.52, must be made as follows:

4.53.1.1 Licensees or registrants shall make the reports required by 4.52.1 and 4.52.2 to the Department by telephone. To the extent that the information is available at the time of notification, the information provided in these reports must include:

(1) The caller's name and call back telephone number;

(2) A description of the event including date and time;

(3) The exact location of the event;

(4) The isotopes, quantities, and chemical and physical form of the licensed material involved; and

(5) Any personnel radiation exposure data available.

4.53.1.2 Each licensee or registrant who makes a report required by 4.52.1 or 4.52.2 shall submit a written follow-up report to the Department pursuant to 4.53.3 within 30 days of the initial report. Written reports prepared pursuant to other regulations may be submitted to fulfill this requirement if the reports contain all of the necessary information and the appropriate distribution is made.

4.53.1.3 The provisions of 4.52 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 pursuant to 4.54.

4.53.2 Reports of Exposures, Radiation Levels, and Concentrations of Radioactive Material Exceeding the Constraints or Limits.

In addition to the notification required by 4.52, each licensee or registrant shall submit a written report to the Department within 30 days after learning of any of the following occurrences:

4.53.2.1 Incidents for which notification is required by 4.52; or

4.53.2.2 Doses in excess of any of the following:

(1) The occupational dose limits for adults in 4.6; or

(2) The occupational dose limits for a minor in 4.12; or

(3) The limits for an embryo/fetus of a declared pregnant woman in 4.13; or

(4) The limits for an individual member of the public in 4.14; or

(5) Any applicable limit in the license or registration; or

(6) The ALARA constraints for air emissions established under 4.5.4.

4.53.2.3 Levels of radiation or concentrations of radioactive material in:

(1) A restricted area in excess of applicable limits in the license or registration; or

(2) An unrestricted area in excess of 10 times the applicable limit set forth in Part 4 or in the license or registration, whether or not involving exposure of any individual in excess of the limits in 4.14; or

4.53.2.4 For licensees subject to the provisions of U.S. Environmental Protection Agency's generally applicable environmental radiation standards in 40 CFR 190, July 1, 2004, levels of radiation or releases of radioactive material in excess of those standards, or of license conditions related to those standards.

4.53.3 Contents of Written Reports.

4.53.3.1 Each report required by 4.53.1.2 or 4.53.2 shall include the following, as appropriate:

(1) A description of the event, including the possible cause and the manufacturer and model number (if applicable) of any equipment that failed or malfunctioned;

(2) The exact location of the event;

(3) The isotopes, quantities, and chemical and physical form of the licensed material involved;

(4) Date and time of the event;

(5) The results of any evaluations or assessments, including:

(a) Estimates of each individual's dose;

(b) The levels of radiation and concentrations of radioactive material involved;

(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 or registration conditions.

4.53.3.2 Each report filed pursuant to 4.53 shall include for each occupationally overexposed individual exposed: the name, Social Security account number, and date of birth. With respect to the limit for the embryo/fetus in 4.13, 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 and must be clearly labeled "Privacy Act Information: Not for Public Disclosure" .

4.54 Reports of Planned Special Exposures.

4.54.1[JJ30] The licensee or registrant shall submit a written report to the Department within 30 days following any planned special exposure conducted in accordance with 4.11, informing the Department that a planned special exposure was conducted and indicating the date the planned special exposure occurred and the information required by 4.45.

4.55 ~~Reserved~~Reports of Transactions Involving Nationally T**rac**ked S**ources**[JJ31]**.**

4.55.1 Each licensee who manufactures, transfers, receives, disassembles, or disposes of a nationally tracked source shall complete and submit a National Source Tracking Transaction Report as specified in 4.55.1.1 through 4.55.1.5 for each type of transaction.

4.55.1.1 Each licensee who manufactures a nationally tracked source shall complete and submit a National Source Tracking Report. The report must include the following information:

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

(2) The name of the individual preparing the report;

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

(4) The radioactive material in the source;

(5) The initial source strength in becquerels (curies) at the time of manufacture;

and

(6) The manufacture date of the source.

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

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

(2) The name of the individual preparing the report;

(3) The name and license number of the recipient facility and the shipping address;

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

(5) The radioactive material in the source;

(6) The initial or current source strength in becquerels (curies);

(7) The date for which the source strength is reported;

(8) The shipping date;

(9) The estimated arrival date;

and

(10) For nationally tracked sources transferred as waste under a Uniform Low-Level Radioactive Waste Manifest, the waste manifest number and the container identification of the container with the nationally tracked source.

4.55.1.3 Each licensee that receives a nationally tracked source shall complete and submit a National Source Tracking Transaction Report. The report must include the following information:

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

(2) The name of the individual preparing the report;

(3) The name, address, and license number of the person that provided the source;

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

(5) The radioactive material in the source;

(6) The initial or current source strength in becquerels (curies);

(7) The date for which the source strength is reported;

(8) The date of receipt;

and

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

4.55.1.4 Each licensee that disassembles a nationally tracked source shall complete and submit a National Source Tracking Transaction Report. The report must include the following information:

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

(2) The name of the individual preparing the report;

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

(4) The radioactive material in the source;

(5) The initial or current source strength in becquerels (curies);

(6) The date for which the source strength is reported;

(7) The disassemble date of the source.

4.55.1.5 Each licensee who disposes of a nationally tracked source shall complete and submit a National Source Tracking Transaction Report. The report must include the following information:

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

(2) The name of the individual preparing the report;

(3) The waste manifest number;

(4) The container identification with the nationally tracked source.

(5) The date of disposal;

and

(6) The method of disposal.

4.55.1.6 The reports discussed in 4.55.1.1 through 4.55.1.5 must be submitted by the close of the next business day after the transaction. A single report may be submitted for multiple sources and transactions. The reports must be submitted to the National Source Tracking System by using:

(1) The on-line National Source Tracking System;

(2) Electronically using a computer readable format;

(3) By facsimile;

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

(5) By telephone with followup by facsimile or mail.

4.55.2 Each licensee shall correct any error in previously filed reports or file a new report for any missed transaction within 5 business days of the discovery of the error or missed transaction. Such errors may be detected by a variety of methods such as administrative reviews or by physical inventories required by regulation. In addition, each licensee shall reconcile the inventory of nationally tracked sources possessed by the licensee against that licensee's data in the National Source Tracking System. The reconciliation must be conducted during the month of January in each year. The reconciliation process must include resolving any discrepancies between the National Source Tracking System and the actual inventory by filing the reports identified by 4.55.1.1 through 4.55.1.5. By January 31 of each year, each licensee must submit to the National

Source Tracking System confirmation that the data in the National Source Tracking System is correct.

4.56 Reports of Individual Monitoring.

4.56.1 This section applies to each person licensed or registered by the Department to:

4.56.1.1 Possess or use sources of radiation for purposes of industrial radiography pursuant to Parts 3 and 5 of these regulations; or

4.56.1.2 Receive radioactive waste from other persons for disposal pursuant to Part 14 of these regulations; or

4.56.1.3 Possess or use at any time, for processing or manufacturing for distribution pursuant to Part 3 or 7 of these regulations, radioactive material in quantities exceeding any one of the following quantities:

Radionuclide	Activity [67] Ci	Activity [67] GBq
Cesium-137	1	37
Cobalt-60	1	37
Gold-198	100	3,700
Iodine-131	1	37
Iridium-192	10	370
Krypton-85	1,000	37,000
Promethium-147	10	370
Technetium- 99m	1,000	37,000

~~67~~ The Department may require as a license condition, or by rule, regulation, or order pursuant to 1.9, reports from licensees or registrants who are licensed or registered to use radionuclides not on this list, in quantities sufficient to cause comparable radiation levels.

4.56.2 Each licensee or registrant in a category listed in 4.56.1 shall submit an annual report to the Department of the results of individual monitoring carried out by the licensee or registrant for each individual for whom monitoring was required by 4.18 during that year. The licensee or registrant may include additional data for individuals for whom monitoring was provided but not required. The licensee or registrant shall use Department Form R-17 or equivalent or Department-approved electronic media containing all the information required by Department Form R-17.

4.56.3 The licensee or registrant shall file the report required by 4.56.2, covering the preceding year, on or before April 30 of each year.

4.57 Notifications and Reports to Individuals.

4.57.1 Requirements for notification and reports to individuals of exposure to radiation or radioactive material are specified in 10.4 of these regulations.

4.57.2 When a licensee or registrant is required pursuant to 4.53.2 or 4.54 to report to the Department any exposure of an identified occupationally exposed individual or an identified member of the public, to radiation or radioactive material, the licensee or registrant shall also provide~~notify~~ the individual a report on his or her exposure data included in the report to the Department. Such report~~notice~~[JJ32] shall be transmitted at a time not later than the transmittal to the Department, and shall comply with the provisions of 10.4.1 of these regulations.

4.58 Reports of Leaking or Contaminated Sealed Sources.

4.58.1 The licensee or registrant shall file a report within 5 days with the Department if the test for leakage or contamination indicates a sealed source is leaking or contaminated. The report shall include the equipment involved, the test results and the corrective action taken.

ADDITIONAL REQUIREMENTS

4.59 Vacating Premises.

4.59.1 Each specific licensee or registrant shall, no less than 30 days before vacating or relinquishing possession or control of premises which may have been contaminated with radioactive material as a result of the licensee's or registrant's activities, notify the Department in writing of intent to vacate. When deemed necessary by the Department, the licensee shall decontaminate the premises in such a manner as the Department may specify.

4.60 Permissible Levels of Radioactive Material in Uncontrolled Areas.

4.60.1 Plutonium. Contamination of the soil in excess of 2.0 disintegrations per minute (0.03 Bq) of plutonium per gram of dry soil or square centimeter of surface area (0.01 microcurie [370 Bq] per square meter) presents a sufficient hazard to the public health to require the utilization of special techniques of construction upon property so contaminated. Evaluation of proposed control techniques shall be available from the Department upon request.

4.61 Radiological Criteria For License Termination.

4.61.1 The criteria in this section apply to the decommissioning of facilities licensed under Parts 3, 5, 7, 14, 16, and 19 of these regulations. For low-level waste disposal facilities licensed under Part 14, the criteria apply only to the ancillary surface facilities that support radioactive waste disposal activities.

4.61.1.1 The criteria in this section do not apply to uranium and thorium recovery facilities already subject to Appendix 18A of Part 18; uranium solution extraction facilities; sites which have been decommissioned and the license terminated prior to July 1, 1999; or sites which submitted a decommissioning plan prior to July 1, 2000 and received Department approval of that decommissioning plan prior to July 1, 2001.

4.61.1.2 When calculating the TEDE to the average member of the critical group, the licensee shall determine the peak annual TEDE expected within the first 1000 years after decommissioning. In accordance with 1.5.1, the Department may authorize the licensee to exclude dose contributions from the inhalation of radon and its decay products when calculating TEDE.

4.61.1.3 Determination of dose and residual radioactivity levels which are as low as reasonably achievable (ALARA) must take into account consideration of any detriments, such as deaths from transportation accidents, expected to potentially result from decontamination and waste disposal.

4.61.2 Radiological Criteria For Unrestricted Use.

A site will be considered acceptable for license termination under conditions of 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 0.25 mSv per year (25 mrem/y), including that from groundwater sources of drinking water, and the residual radioactivity has been reduced to levels that are ALARA.

4.61.3 Radiological Criteria For Restricted Use.

A site will be considered acceptable for license termination under restricted conditions if:

4.61.3.1 The licensee can demonstrate that further reductions in residual radioactivity necessary to comply with the provisions of 4.61.2 would result in net public or environmental harm or were not being made because the residual levels of contamination associated with restricted conditions are ALARA. Determination of the levels which are ALARA must take into consideration any detriments, such as traffic accidents, expected to potentially result from decontamination and waste disposal[JJ33];

4.61.3.2 The licensee has made provisions for durable, legally enforceable institutional controls which provide reasonable assurance that the TEDE from residual radioactivity distinguishable from background to the average member of the critical group will not exceed 0.25 mSv per year (25 mrem/y). ~~; and~~

4.61.3.3 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[JJ34] ~~.~~ :

(1) Funds placed into an account segregated from the licensee's assets and outside the licensee's administrative control as described in Part 3, Section 3.9.5.4(2)(a);

(2) In the case of Federal, State, or local Government licensees, a statement of intent containing a cost estimate for decommissioning and indicating that funds for decommissioning will be obtained when necessary; or

(3) When a governmental entity is assuming custody and ownership of a site, an arrangement that is deemed acceptable by such governmental entity; and

4.61.3.4[JJ35] 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:

(1) 1 mSv per year (100 mrem/y); or

(2) 5 mSv per year (500 mrem/y), provided the licensee:

(a) demonstrates that further reductions in residual radioactivity necessary to comply with the 1-mSv-per-year (100 mrem/y) value of this paragraph are not technically achievable, would be prohibitively expensive, or would result in net public or environmental harm.

4.61.4 Alternate Criteria For License Termination.

4.61.4.1 The Department may terminate a license using alternate criteria greater than the dose criterion of 4.61.2 or 4.61.3.2, if:

(1) The licensee has performed an analysis for possible sources of exposure to radiation which provides assurance that public health and safety would continue to be protected, and that it is unlikely the TEDE to an average member of the critical group from all radiation that is distinguishable from background radiation, other than medical, would be more than 1 mSv per year (100 mrem/y);

(2) The licensee has employed, to the extent practical, restrictions on site use which minimize exposures at the site in accordance with the provisions of 4.61.3; ~~and~~

(3) The licensee has reduced doses to levels which are ALARA;~~,~~ and

(4) 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[JJ36].

PART 4, APPENDIX 4A: ASSIGNED PROTECTION FACTORS FOR RESPIRATORS

ASSIGNED PROTECTION FACTORS FOR RESPIRATORS [a]

.	Operating Mode	Assigned Protection Factors
I. Air purifying respirators [particulate only] [b] [c] :	.	.
Filtering facepiece disposable	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	[h] 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 and 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 part. 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 must also comply with department of labor regulations.

Radioactive contaminants for which the concentration values in Table 4B1, Column 3 of Appendix 4B 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 percent efficient. Air-purifying respirators with APF = 100 must be equipped with particulate filters that are at least 99 percent efficient. Air-purifying respirators with APFs > 100 must be equipped with particulate filters that are at least 99.97 percent efficient.

c The licensee may apply to the commission 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 user seal check on this type of device. All other respiratory protection program requirements listed in 4.24.1 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 appendix 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 percent efficient and all other requirements of this part 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 National Institute of Occupational Safety and Health (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 (that is, 4.24.1).

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.

PART 4, APPENDIX 4B: ANNUAL LIMITS ON INTAKE (ALI) AND DERIVED AIR CONCENTRATIONS (DAC) OF RADIONUCLIDES FOR OCCUPATIONAL EXPOSURE; EFFLUENT CONCENTRATIONS; CONCENTRATIONS FOR RELEASE TO SANITARY SEWERAGE

ANNUAL LIMITS ON INTAKE (ALI) AND DERIVED AIR CONCENTRATIONS (DAC) OF RADIONUCLIDES FOR OCCUPATIONAL EXPOSURE; EFFLUENT CONCENTRATIONS; CONCENTRATIONS FOR RELEASE TO SANITARY SEWERAGE

DRAFT 1 – 12/05/2012 -RQ

Introduction

For each radionuclide, Table 4B1 indicates the chemical form which is to be used for selecting the appro priate ALI or DAC value. The ALIs and DACs for inhalation are given for an aerosol with an activity median aerodynamic diameter (AMAD) of 1 µm, micron, and for three classes (D, W, Y) of radioactive material, which refer to their retention (approximately d ays, 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 4B2 provides concentration limits for airborne and liquid effluents released to the general environment. Table 4B3 provides concentration limits for discharges to sanitary sewerage.

Note:

The values in Table 4B1, Table 4B2, and Table 4B3 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.

Table 4B1[JJ37] "Occupational Values"

Note that the columns in Table 4B1 of this appendix captioned "Oral Ingestion ALI," "Inhalation ALI," and "DAC," are applicable to occupational exposure to radioactive material.

The ALIs in this appendix are the annual intakes of given radionuclide by "reference man" which would result in either (1) a committed effective dose equivalent of 0.05 Sv (5 rem), stochastic ALI, or (2) a committed dose equivalent of 0.5 Sv (50 rem) 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 0.05 Sv (5 rem). 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 4.3. The non-stochastic ALIs were derived to avoid non-stochastic effects, such as prompt damage to tissue or reduction in organ function.

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.

Note that 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.

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:

LLI wall = lower large intestine wall;

St. wall = stomach wall;

Blad wall = bladder wall; and

Bone surf = bone surface.

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 0.5 Sv (50 rem) 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 t he organ receiving the highest dose does not exceed unity, that is, ∑ (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.

Note that 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.

The derived air concentration (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 x 10^4 ml per minute) = (ALI/2.4 x 10^9) µCi/ml, where 2 x 10^4 ml is the volume of air breathed per minute at work by reference man under working conditions of light work.

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.

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

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 4.7. 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.

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.

Table 4B2[JJ38] "Effluent Concentrations"

The columns in Table 4B2 of this appendix 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 4.15. The concentration values given in Columns 1 and 2 of Table 4B2 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 0.5 mSv (0.05 rem).

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 4B2. For this reason, the DAC and airborne effluent limits are not always proportional as they were in Appendix A of Part D of the Eighth Edition of Volume I of the Suggested State Regulations for Control of Radiation, April 2004.

The air concentration values listed in Table 4B2, Column 1, 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 above, and then divided by a factor of 300. The factor of 300 includes the following components: a factor of 50 to relate the 0.05 Sv (5 rem) annual occupational dose limit to the 0.1 rem limit for members of the public, 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 a factor of 2 to adjust the occupational values, derived for adults, so that they are applicable to other age groups.

For those radionuclides for which submersion, that is external dose, is limiting, the occupational DAC in Table 4B1, Column 3 was divided by 219. The factor of 219 is composed of a factor of 50, as described above, 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.

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} (ml) includes the following components: the factors of 50 and 2 described above and a factor of 7.3×10^{5} (ml) which is the annual water intake of reference man.

Note 2 of this appendix provides groupings of radionuclides which 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.

Table 4B3[JJ39] "Releases to Sewerage"

The monthly average concentrations for release to sanitary sewerage are applicable to the provisions in 4.35. 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.

Table 4B1, Table 4B2, and Table 4B3 are found at

~~http://www.cdphe.state.co.us/op/regs/radiationcontrol/10070104app.pdf~~[JJ40]http://www.colorado.gov/cs/Satellite/CDPHE-Main/CBON/1251595089423

LIST OF ELEMENTS

Name	Atomic Symbol	Atomic Number
Actinium	Ac	89
Aluminum	Al	13
Americium	Am	95
Antimony	Sb	51
Argon	Ar	18

DRAFT 1 – 12/05/2012 -RQ

Arsenic	As	33
Astatine	At	85
Barium	Ba	56
Berkelium	Bk	97
Beryllium	Be	4
Bismuth	Bi	83
Bromine	Br	35
Cadmium	Cd	48
Calcium	Ca	20
Californium	Cf	98
Carbon	C	6
Cerium	Ce	58
Cesium	Cs	55
Chlorine	Cl	17
Chromium	Cr	24
Cobalt	Co	27
Copper	Cu	29
Curium	Cm	96
Dysprosium	Dy	66
Einsteinium	Es	99
Erbium	Er	68
Europium	Eu	63
Fermium	Fm	100
Fluorine	F	9
Francium	Fr	87
Gadolinium	Gd	64
Gallium	Ga	31
Germanium	Ge	32
Gold	Au	79
Hafnium	Hf	72
Holmium	Ho	67
Hydrogen	H	1
Indium	In	49
Iodine	I	53
Iridium	Ir	77
Iron	Fe	26
Krypton	Kr	36
Lanthanum	La	57
Lead	Pb	82
Lutetium	Lu	71
Magnesium	Mg	12
Manganese	Mn	25
Mendelevium	Md	101
Mercury	Hg	80
Molybdenum	Mo	42
Neodymium	Nd	60

DRAFT 1 – 12/05/2012 -RQ

Neptunium	Np	93
Nickel	Ni	28
Niobium	Nb	41
Nitrogen	N	7[JJ41]
Osmium	Os	76
Oxygen	O	8
Palladium	Pd	46
Phosphorus	P	15
Platinum	Pt	78
Plutonium	Pu	94
Polonium	Po	84
Potassium	K	19
Praseodymium	Pr	59
Promethium	Pm	61
Protactinium	Pa	91
Radium	Ra	88
Radon	Rn	86
Rhenium	Re	75
Rhodium	Rh	45
Rubidium	Rb	37
Ruthenium	Ru	44
Samarium	Sm	62
Scandium	Sc	21
Selenium	Se	34
Silicon	Si	14
Silver	Ag	47
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

PART 4, APPENDIX 4C: QUANTITIES OF LICENSED OR REGISTERED MATERIAL REQUIRING LABELING

QUANTITIES [j] OF LICENSED OR REGISTERED MATERIAL REQUIRING LABELING

* To convert µCi to kBq, multiply the µCi value by 37.

Licensed or registered mat'l req labels C1
1007_1_Part4C1.jpg[JJ42]
Licensed or registered mat'l req labels C2
1007_1_Part4C2.jpg
Licensed or registered mat'l req labels C3
1007_1_Part4C3.jpg
Licensed or registered mat'l req labels C4
1007_1_Part4C4.jpg
Licensed or registered mat'l req labels C5
1007_1_Part4C5.jpg
Licensed or registered mat'l req labels C6
1007_1_Part4C6.jpg
Licensed or registered mat'l req labels C7
1007_1_Part4C7.jpg
Licensed or registered mat'l req labels C8
1007_1_Part4C8.jpg
Licensed or registered mat'l req labels C9
1007_1_Part4C9.jpg
Licensed or registered mat'l req labels C10
1007_1_Part4C10.jpg
Licensed or registered mat'l req labels C11
1007_1_Part4C11.jpg
Licensed or registered mat'l req labels C12
1007_1_Part4C12.jpg
Licensed or registered mat'l req labels C13
1007_1_Part4C13.jpg
Licensed or registered mat'l req labels C14
1007_1_Part4C14.jpg
Licensed or registered mat'l req labels C15
1007_1_Part4C15.jpg

Note: For purposes of 4.28.5, 4.31.1, and 4.51.1, where there is involved a combination of radionuclides in known amounts, the limit for the combination shall be derived as follows: determine, for each radionuclide in the combination, the ratio between the quantity present in the combination and the limit otherwise established for the specific radionuclide when not in combination. The sum of such ratios for all radionuclides in the combination may not exceed "1" - that is, unity.

j The quantities listed above were derived by taking 1/10th of the most restrictive ALI listed in Table 4B1, Columns 1 and 2, of Appendix 4B, rounding to the nearest factor of 10, and constraining the values listed between 37 Bq and 37 MBq (0.001 and 1,000 µCi). Values of 3.7 MBq (100 µCi) have been assigned for radionuclides having a radioactive half-life in excess of E+9 years, except Rhenium, 37 MBq (1,000 µCi), to take into account their low specific activity.

PART 4, APPENDIX 4D: REQUIREMENTS FOR TRANSFERS OF LOW-LEVEL RADIOACTIVE WASTE FOR DISPOSAL AT LAND DISPOSAL FACILITIES AND MANIFESTS

REQUIREMENTS FOR TRANSFERS OF LOW-LEVEL RADIOACTIVE WASTE FOR DISPOSAL AT LAND DISPOSAL FACILITIES AND MANIFESTS

I. Manifest

A. A waste generator, collector, or processor who transports, or offers for transportation, low-level radioactive waste intended for ultimate disposal at a licensed low-level radioactive waste land disposal facility must prepare a manifest reflecting information requested on applicable forms 540, uniform low-level radioactive waste manifest (shipping paper), and 541, Uniform Low-Level Radioactive Waste Manifest (container and waste description), and, if necessary, on an applicable Form 542, Uniform Low-Level Radioactive Waste Manifest (manifest index and regional compact tabulation). Forms 540 and 540a must be completed and must physically accompany the pertinent low-level waste shipment. Upon agreement between the shipper and consignee, Forms 541 and 541a and 542 and 542a may be completed, transmitted, and stored in electronic media with the capability for producing legible, accurate and complete records on the respective forms.

B. Licensees are not required by this department to comply with manifesting requirements of this part when they ship:

1. Low-level radioactive waste for processing and expect its return (that is, for storage under their license) prior to disposal at a licensed land disposal facility;

2. Low-level radioactive waste that is being returned to the licensee who is the “waste generator” or “generator” as defined in this appendix; or

3. Radioactively contaminated material to a “waste processor” that becomes the processor's “residual waste” .

C. For guidance in completing these forms, refer to the instructions that accompany the forms. Copies of manifests required by this appendix may be legible carbon copies, photocopies, or computer printouts that reproduce the data in the format of the uniform manifest.

D. As used in this appendix, the following definitions apply:

“Chelating agent” means amine polycarboxylic acids, hydroxy-carboxylic acids, and polycarboxylic acids.

“Chemical description” means a description of the principal chemical characteristics of the low-level radioactive waste.

“Consignee” means the designated receiver of the shipment of low-level radioactive waste.

“Decontamination facility” means a facility operating under a U.S. Nuclear Regulatory Commission or Agreement State license whose principal purpose is decontamination of equipment or materials to accomplish recycle, reuse, or other waste management objectives, and, for the purposes of this Part, is not considered to be a consignee for low-level radioactive waste shipments.

“Disposal container” means a container principally used to confine low-level radioactive waste during disposal operations at a land disposal facility (also see “high integrity container”). Note that for some shipments, the disposal container may be the transport package.

“EPA identification number” means the number received by a transporter following application to the administrator of the U.S. Environmental Protection Agency as required by 40 CFR Part 263, July 1, 2004.

Forms 540, 540a, 541, 541a, 542, and 542a are official forms referenced in this appendix. Licensees need not use originals of these forms so long as any substitute forms are equivalent to the original documentation in respect to content, clarity, size, and location of information. Upon agreement between the shipper and consignee, Form 541 (and 541a) and Form 542 (and 542a) may be completed, transmitted and stored in electronic media. The electronic media must have the capability for producing legible, accurate, and complete records in the format of the uniform manifest.

"Generator" means a licensee operating under a Nuclear Regulatory Commission or Agreement State license who (1) is a waste generator as defined in this appendix or (2) is a licensee to whom waste can be attributed (for example, waste generated as a result of decontamination or recycle activities).

"High integrity container" (HIC) means a container commonly designed to meet the applicable Nuclear Regulatory Commission structural stability requirements and to meet U.S. Department of Transportation requirements for a Type A package.

"Land disposal facility" means the same as in Part 14 of these regulations.

"Physical description" means the items called for on Form 541 to describe a low-level radioactive waste.

"Residual waste" means low-level radioactive waste resulting from processing or decontamination activities that cannot be easily separated into distinct batches attributable to specific waste generators. This waste is attributable to the processor or decontamination facility, as applicable.

"Shipper" means the licensed entity (that is, the waste generator, waste collector, or waste processor) who offers low-level radioactive waste for transportation, typically consigning this type of waste to a licensed waste collector, waste processor, or land disposal facility operator.

"Shipping paper" means Form 540 and, if required, Form 540a which includes the information required by the U.S. Department of Transportation in 49 CFR Part 172, October 1, 2003.

"Uniform low-level radioactive waste manifest" or "uniform manifest" means the combination of Nuclear Regulatory Commission Forms 540, 541, and, if necessary, 542, and their respective continuation sheets as needed, or equivalent.

"Waste collector" means an entity, operating under a Nuclear Regulatory Commission or Agreement State license, whose principal purpose is to collect and consolidate waste generated by others, and to transfer this waste, without processing or repackaging the collected waste, to another licensed waste collector, licensed waste processor, or licensed land disposal facility.

"Waste description" means the physical, chemical and radiological description of a low-level radioactive waste as called for in Form 541.

"Waste generator" means an entity, operating under a Nuclear Regulatory Commission or Agreement State license, who (1) possesses any material or component that contains radioactivity or is radioactively contaminated for which the licensee foresees no further use, and (2) transfers this material or component to a licensed land disposal facility or to a licensed waste collector or processor for handling or treatment prior to disposal. A

licensee performing processing or decontamination services may be a “waste generator” if the transfer low-level radioactive waste from the facility is defined as “residual waste” .

“Waste processor” means an entity, operating under a Nuclear Regulatory Commission or Agreement State license, whose principal purpose is to process, repackage, or otherwise treat low-level radioactive material or waste generated by others prior to eventual transfer of waste to a licensed low-level radioactive waste land disposal facility.

“Waste type” means a waste within a disposal container having a unique physical description (that is, a specific waste descriptor code or description, or a waste sorbed on or solidified in a specifically defined media).

II. Information requirements

A. General information. The shipper of the radioactive waste shall provide the following information on the uniform manifest:

1. The name, facility address, and telephone number of the licensee shipping the waste;

2. An explicit declaration indicating whether the shipper is acting as a waste generator, collector, processor, or a combination of these identifiers for purposes of the manifested shipment; and

3. The name, address, and telephone number or the name and U.S. Environmental Protection Agency hazardous waste identification number for the carrier transporting the waste.

B. Shipment information. The shipper of the radioactive waste shall provide the following information regarding the waste shipment on the uniform manifest:

1. The date of the waste shipment;

2. The total number of packages/disposal containers;

3. The total disposal volume and disposal weight of the shipment;

4. The total radionuclide activity in the shipment;

5. The activity of each of the radionuclides H-3, C-14, Tc-99, and I-129 contained in the shipment; and

6. The total masses of U-233, U-235, and plutonium in special nuclear material, and the total mass of uranium and thorium in source material.

C. Disposal container and waste information. The shipper of the radioactive waste shall provide the following information on the uniform manifest regarding the waste and each disposal container of waste in the shipment:

1. An alphabetic or numeric identification that uniquely identifies each disposal container in the shipment;

2. A physical description of the disposal container, including the manufacturer and model of any high integrity container;

3. The volume displaced by the disposal container;

4. The gross weight of the disposal container, including the waste;

5. For waste consigned to a disposal facility, the maximum radiation level at the surface of each disposal container;

6. A physical and chemical description of the waste;

7. The total weight percentage of chelating agent for any waste containing more than 0.1 % chelating agents by weight, plus the identity of the principal chelating agent;

8. The approximate volume of waste within the container;

9. The sorbing or solidification media, if any, and the identity of the solidification media vendor and brand name;

10. The identities and activities of individual radionuclides contained in each container, the masses of U-233, U-235, and plutonium in special nuclear material, and the masses of uranium and thorium in source material. For discrete waste types (that is, activated materials, contaminated equipment, mechanical filters, sealed source/devices, and wastes in solidification/stabilization media), the identities and activities of individual radionuclides associated with or contained in these waste types within a disposal container shall be reported;

11. The total radioactivity within each container; and

12. For wastes consigned to a disposal facility, the classification as Class A, Class B, or Class C pursuant to Section I of Appendix 4E. Waste not meeting the structural stability requirements of Appendix 4E shall be identified.

D. Uncontainerized waste information

The shipper of the radioactive waste shall provide the following information on the uniform manifest regarding a waste shipment delivered without a disposal container:

1. The approximate volume and weight of the waste;

2. A physical and chemical description of the waste;

3. The total weight percentage of chelating agent if the chelating agent exceeds 0.1 % by weight, plus the identity of the principal chelating agent;

4. For wastes consigned to a disposal facility, the classification as Class A, Class B, or Class C pursuant to Section I of Appendix 4E; Waste not meeting the structural stability requirements of Appendix 4E shall be identified;

5. The identities and activities of individual radionuclides contained in each container, the masses of U-233, U-235, and plutonium in special nuclear material, and the masses of uranium and thorium in source material;

6. For wastes consigned to a disposal facility, the maximum radiation levels at the surface of the waste.

E. Multi-generator disposal container information

This section applies to disposal containers enclosing mixtures of waste originating from different generators. The origin of the low-level radioactive waste resulting from a processor's activities may be attributable to one or more “generators,” including “waste generators,” as defined in this Part. This section also applies to mixtures of wastes shipped in an uncontainerized form, for which portions of the mixture within the shipment originate from different generators.

1. For homogeneous mixtures of waste, such as incinerator ash, provide the waste description applicable to the mixture and the volume of the waste attributed to each generator.

2. For heterogenous mixtures of waste, such as the combined products from a large compactor, identify each generator contributing waste to the disposal container, and, for discrete waste types (that is, activated materials, contaminated equipment, mechanical filters, sealed source/devices, and wastes in solidification stabilization media), the identities and activities of individual radionuclides associated with or contained on these waste types within a disposal container.

For each generator, provide the following:

1. The volume of waste within the container

2. A physical and chemical description of the waste, including the solidification agent, if any;

3. The total weight percentage of chelating agent for any disposal container containing more than 0.1% chelating agents by weight, plus the identity of the principal chelating agent;

4. The sorbing or solidification media, if any, and the identity of the solidification media vendor and brand name if the media is claimed to meet stability requirements in Appendix 4E;

5. Radionuclide identities and activities contained in the waste, the masses of U 233, U-235, and plutonium in special nuclear material, and the masses of uranium and thorium in source material if contained in the waste.

III. Certification

An authorized representative of the waste generator, collector or processor shall certify by signing and dating the shipment manifest that the transported materials are properly classified, described, packaged, marked, and labeled and are in proper condition for transportation according to the applicable regulations of the Department of Transportation and the Department. A collector in signing the certification is certifying that nothing has been done to the collected waste which would invalidate the waste generator's certification.

IV. Control and tracking

A. Any license who transfers radioactive waste to a land disposal facility or a licensed waste collector shall comply with the requirements in IV.A.1. through IV.A.9. of this section. Any licensee who transfers waste to a licensed waste processor for waste treatment or repackaging shall comply with the requirements of IV.A.4. through IV.A.9. of this section.

A licensee shall:

1. Prepare all wastes so that the waste is classified according to Section I of Appendix 4E and meets the waste characteristics requirements in Section II of Appendix 4E;

2. Label each disposal container (or transport package if potential radiation hazards preclude labeling of the individual disposal container) of waste to identify whether it is Class A waste, Class B waste, or Class C waste, in accordance with Section I of Appendix 4E;

3. Conduct a quality assurance program to ensure compliance with Sections I and II of Appendix 4E; the program shall include management evaluation of audits;

4. Prepare the uniform manifest as required by this appendix;

5. Forward a copy or electronically transfer the uniform manifest to the intended consignee so that either:

   a. Receipt of the manifest precedes the low-level radioactive waste shipment or

   b. The manifest is delivered to the consignee with the waste at the time the waste is transferred to the consignee. Using both (a) and (b) is also acceptable;

6. Include Form 540 (and Form 540a, if required) with the shipment regardless of the option chosen in Section IV.A.5.;

7. Receive acknowledgement of the receipt of the shipment in the form of a signed copy of Form 540;

8. Retain a copy of or electronically store the uniform manifest and documentation of acknowledgment of receipt as the record of transfer of licensed material as required by 3.22 of these regulations; and

9. For any shipments or any portion of a shipment for which acknowledgment of receipt has not been received within the times set forth in this appendix, conduct an investigation in accordance with Section V.

B. Any waste collector licensee who handles only prepackaged waste shall:

1. Acknowledge receipt of the waste from the shipper within 1 week of receipt by returning a signed copy of Form 540;

2. Prepare a new manifest to reflect consolidated shipments that meet the requirements of this appendix. The waste collector shall ensure that, for each container of waste in the shipment, the manifest identifies the generator of that container of waste;

3. Forward a copy or electronically transfer the uniform manifest to the intended consignee so that either: (i) receipt of the manifest precedes the low-level radioactive waste shipment or (ii) the manifest is delivered to the consignee with the waste at the time the waste is transferred to the consignee. Using both (i) and (ii) is also acceptable;

4. Include Form 540 (and Form 540a, if required) with the shipment regardless of the option chosen in Section IV.B.3.;

5. Receive acknowledgement of the receipt of the shipment in the form of a signed copy of Form 540;

6. Retain a copy of or electronically store the uniform manifest and documentation of acknowledgment of receipt as the record of transfer of licensed material as required by 3.22 of these regulations; and

7. For any shipments or any portion of a shipment for which acknowledgment of receipt has not been received within the times set forth in this appendix, conduct an investigation in accordance with Section V.

8. Notify the shipper and the department when any shipment, or part of a shipment, has not arrived within 60 days after receipt of an advance manifest, unless notified by the shipper that the shipment has been cancelled.

C. Any licensed waste processor who treats or repackages wastes shall:

1. Acknowledge receipt of the waste from the shipper within 1 week of receipt by returning a signed copy of Form 540;

2. Prepare a new manifest that meet the requirements of this appendix. Preparation of the new manifest reflects that the processor is responsible for meeting these requirements. For each container of waste in the shipment, the manifest shall identify the waste generators, the preprocessed waste volume, and the other information required in Section II.E of this appendix;

3. Prepare all wastes so that the waste is classified according to Appendix 4E and meets the waste characteristics requirements in Section I of Appendix 4E;

4. Label each package of waste to identify whether is Class A waste, Class B waste, or Class C waste in accordance with Appendix 4E;

5. Conduct a quality assurance program to ensure compliance with Sections I and II of Appendix 4E; the program shall include management evaluation of audits;

6. Forward a copy or electronically transfer the uniform manifest to the intended consignee so that either:

   a. Receipt of the manifest precedes the low-level radioactive waste shipment or

   b. The manifest is delivered to the consignee with the waste at the time the waste is transferred to the consignee. Using both (a) and (b) is also acceptable;

7. Include Form 540 (and Form 540a, if required) with the shipment regardless of the option chosen in IV.C.6;

8. Receive acknowledgement of the receipt of the shipment in the form of a signed copy of Form 540;

9. Retain a copy of or electronically store the uniform manifest and documentation of acknowledgment of receipt as the record of transfer of licensed material as required by 3.22 of these regulations; and

10. For any shipments or any portion of a shipment for which acknowledgment of receipt has not been received within the times set forth in this appendix, conduct an investigation in accordance with Section V.

11. Notify the shipper and the Department when any shipment, or part of a shipment, has not arrived within 60 days after receipt of an advance manifest, unless notified by the shipper that the shipment has been cancelled.

D. The land disposal facility operator shall:

1. Acknowledge receipt of the waste within 1 week of receipt by returning, as a minimum, a signed copy of Form 540 to the shipper. The shipper to be notified is the licensee who last possessed the waste and transferred the waste to the operator. If any discrepancy exists between materials listed on the uniform manifest and materials received, copies or electronic transfer of the affected forms must be returned indicating the discrepancy;

2. Maintain copies of all completed manifests and electronically store the information required by Part 14 of these Regulations until license termination;

3. Notify the shipper and the Department when any shipment, or part of a shipment, has not arrived within 60 days after receipt of an advance manifest, unless notified by the shipper that the shipment has been cancelled.

V. Any shipment or part of a shipment for which acknowledgement is not received within the times set forth in this section shall:

A. Be investigated by the shipper if the shipper has not received notification or receipt within 20 days after transfer; and

B. Be traced and reported. The investigation shall include tracing the shipment and filing a report with the Department. Each licensee who conducts a trace investigation shall file a written report with the Department within 2 weeks of completion of the investigation.

C. Notify the shipper and the Department when any shipment, or part of a shipment, has not arrived within 60 days after receipt of an advance manifest, unless notified by the shipper that the shipment has been cancelled.

PART 4 APPENDIX 4E[JJ43]: CLASSIFICATION AND CHARACTERISTICS OF LOW-LEVEL RADIOACTIVE WASTE

CLASSIFICATION AND CHARACTERISTICS OF LOW-LEVEL RADIOACTIVE WASTE

I. Classification of Radioactive Waste for Land Disposal

A. Considerations. Determination of the classification of radioactive waste involves two considerations. First, consideration must be given to the concentration of long-lived radionuclides (and their shorter-lived precursors) whose potential hazard will persist long after such precautions as institutional controls, improved waste form, and deeper disposal have ceased to be effective. These precautions delay the time when long-lived radionuclides could cause exposures. In addition, the magnitude of the potential dose is limited by the concentration and availability of the radionuclide at the time of exposure. Second, consideration must be given to the concentration of shorter-lived radionuclides for which requirements on institutional controls, waste form, and disposal methods are effective.

B. Classes of waste.

1. Class A waste is waste that is usually segregated from other waste classes at the disposal site. The physical form and characteristics of Class A waste must meet the minimum requirements set forth in Section II.A. If Class A waste also meets the stability requirements set forth in Section II.B. It is not necessary to segregate the waste for disposal.

2. Class B waste is waste that must meet more rigorous requirements on waste form to ensure stability after disposal. The physical form and characteristics of Class B waste must meet both the minimum and stability requirements set forth in Section II.

3. Class C waste is waste that not only must meet more rigorous requirements on waste form to ensure stability but also requires additional measures at the disposal facility to protect against inadvertent intrusion. The physical form and characteristics of Class C waste must meet both the minimum and stability requirements set forth in Section II.

C. Classification determined by long-lived radionuclides. If the radioactive waste contains only radionuclides listed in Table 4EB1[JJ44], classification shall be determined as follows:

1. If the concentration does not exceed 0.1 times the value in Table 4EB1, the waste is Class A.

2. If the concentration exceeds 0.1 times the value in Table 4EB1, but does not exceed the value in Table 4EB1, the waste is Class C.

3. If the concentration exceeds the value in Table 4EB1, the waste is not generally acceptable for land disposal.

4. For wastes containing mixtures of radionuclides listed in Table 4EB1, the total concentration shall be determined by the sum of fractions rule described in Section I.G. of this appendix.

TABLE 4E1

.	**Concentration**	**Concentration**
Radionuclide	**curie/cubic meter [k] (Ci/m ^{3})**	**nanocurie/gram [l] (nCi/g)**
C-14 in activated metal	80	.
C-14	8	.
Ni-59 in activated metal	220	.
Nb-94 in activated metal	0.2	.
I-129	0.08	.
Tc-99	3	.
Alpha-emitting transuranic radionuclides with half-life greater than five years	.	100
Cm-242	.	20,000
Ra-226	100	.

Pu-241	3,500	.

k To convert the Ci/m3 values to gigabecquerel (GBq) per cubic meter, multiply the Ci/m3 value by 37.

l To convert the nCi/g values to becquerel (Bq) per gram, multiply the nCi/g value by 37.

D. Classification determined by short-lived radionuclides.

If the waste does not contain any of the radionuclides listed in Table 4EB1, classification shall be determined based on the concentrations shown in Table 4EB2. However, as specified in Section I.F. of this appendix, if radioactive waste does not contain any nuclides listed in either Table 4EB1 or Table 4EB2, it is Class A.

1. If the concentration does not exceed the value in Column 1, the waste is Class A.

2. If the concentration exceeds the value in Column 1 but does not exceed the value in Column 2, the waste is Class B.

3. If the concentration exceeds the value in Column 2 but does not exceed the value in Column 3, the waste is Class C.

4. If the concentration exceeds the value in Column 3, the waste is not generally acceptable for near-surface disposal.

5. For wastes containing mixtures of the radionuclides listed in Table 4EB2, the total concentration shall be determined by the sum of fractions rule described in Section I.G.

TABLE 4E2

Radionuclide	Concentration,	curie/cubic meter*	curie/cubic meter*
.	Column 1	Column 2	Column 3
Total of all radionuclides with less than 5-year half-life	700	*	*
Co-60	700	*	*
Cs-137	1	44	4600
H-3	40	*	*
Ni-63	3.5	70	700
Ni-63 in activated metal	35	700	7000
Sr-90	0.04	150	7000

*Department Note: To convert the Ci/m3 value to gigabecquerel (GBq) per cubic meter, multiply the Ci/m3 value by 37. There are no limits established for these radionuclides in Class B or C wastes. Practical considerations such as the effects of external radiation and internal heat generation on transportation, handling, and disposal will limit the concentrations for these wastes. These wastes shall be Class B unless the concentrations of other radionuclides in Table 4EB2 determine the waste to be Class C independent of these radionuclides.

E. Classification determined by both long- and short-lived radionuclides. If the radioactive waste contains a mixture of radionuclides, some of which are listed in Table 4EB1 and some of which are listed in Table 4EB2, classification shall be determined as follows:

1. If the concentration of a radionuclide listed in Table 4EB1 is less than 0.1 times the value listed in Table 4EB1, the class shall be that determined by the concentration of radionuclides listed in Table 4EB2.

2. If the concentration of a radionuclide listed in Table 4EB1 exceeds 0.1 times the value listed in Table 4EB1, but does not exceed the value in Table 4EB1, the waste shall be Class C, provided the concentration of radionuclides listed in Table 4EB2 does not exceed the value shown in Column 3 of Table 4EB2.

F. Classification of wastes with radionuclides other than those listed in Table 4EB1 and Table 4EB2. If the waste does not contain any radionuclides listed in either Table 4EB1 or Table 4EB2, it is Class A.

G. The sum of the fractions rule for mixtures of radionuclides. For determining classification for waste that contains a mixture of radionuclides, it is necessary to determine the sum of fractions by dividing each radionuclide's concentration by the appropriate limit and adding the resulting values. The appropriate limits must all be taken from the same column of the same table. The sum of the fractions for the column must be less than 1.0 if the waste class is to be determined by that column. Example: A waste contains Sr-90 in a concentration of 1.85 TBq/m^3 (50 Ci/m^3) and Cs-137 in a concentration of 814 GBq/m^3 (22 Ci/m^3). Since the concentrations both exceed the values in Column 1, Table 4EB2, they must be compared to Column 2 values. For Sr-90 fraction, 50/150 = 0.33, for Cs-137 fraction, 22/44 = 0.5; the sum of the fractions = 0.83. Since the sum is less than 1.0, the waste is Class B.

H. Determination of concentrations in wastes. The concentration of a radionuclide may be determined by indirect methods such as use of scaling factors which relate the inferred concentration of one radionuclide to another that is measured, or radionuclide material accountability, if there is reasonable assurance that the indirect methods can be correlated with actual measurements. The concentration of a radionuclide may be averaged over the volume of the waste, or weight of the waste if the units are expressed as becquerel (microcurie) per gram.

II. Radioactive Waste Characteristics

A. The following are minimum requirements for all classes of waste and are intended to facilitate handling and provide protection of health and safety of personnel at the disposal site.

1. Wastes shall be packaged in conformance with the conditions of the license issued to the site operator to which the waste will be shipped. Where the conditions of the site license are more restrictive than the provisions of Part 4, the site license conditions shall govern.

2. Wastes shall not be packaged for disposal in cardboard or fiberboard boxes.

3. Liquid waste shall be packaged in sufficient absorbent material to absorb twice the volume of the liquid.

4. Solid waste containing liquid shall contain as little free-standing and non-corrosive liquid as is reasonably achievable, but in no case shall the liquid exceed 1 % of the volume.

5. Waste shall not be readily capable of detonation or of explosive decomposition or reaction at normal pressures and temperatures, or of explosive reaction with water.

6. Waste shall not contain, or be capable of generating, quantities of toxic gases, vapors, or fumes harmful to persons transporting, handling, or disposing of the waste. This does not apply to radioactive gaseous waste packaged in accordance with Section II.A.8.

7. Waste must not be pyrophoric. Pyrophoric materials contained in wastes shall be treated, prepared, and packaged to be nonflammable.

8. Wastes in a gaseous form shall be packaged at an absolute pressure that does not exceed 1.5 atmospheres at 20° C. Total activity shall not exceed 3.7 TBq (100 Ci) per container.

9. Wastes containing hazardous, biological, pathogenic, or infectious material shall be treated to reduce to the maximum extent practicable the potential hazard from the non-radiological materials.

B. The following requirements are intended to provide stability of the waste. Stability is intended to ensure that the waste does not degrade and affect overall stability of the site through slumping, collapse, or other failure of the disposal unit and thereby lead to water infiltration. Stability is also a factor in limiting exposure to an inadvertent intruder, since it provides a recognizable and nondispersible waste.

1. Waste shall have structural stability. A structurally stable waste form will generally maintain its physical dimensions and its form, under the expected disposal conditions such as weight of overburden and compaction equipment, the presence of moisture, and microbial activity, and internal factors such as radiation effects and chemical changes. Structural stability can be provided by the waste form itself, processing the waste to a stable form, or placing the waste in a disposal container or structure that provides stability after disposal.

2. Notwithstanding the provisions in Section II.A.3. and II.A.4., liquid wastes, or wastes containing liquid, shall be converted into a form that contains as little free-standing and non-corrosive liquid as is reasonably achievable, but in no case shall the liquid exceed 1 % of the volume of the waste when the waste is in a disposal container designed to ensure stability, or 0.5% of the volume of the waste for waste processed to a stable form.

3. Void spaces within the waste and between the waste and its package shall be reduced to the extent practicable.

III. Labeling.

Each package of waste shall be clearly labeled to identify whether it is Class A, Class B, or Class C waste, in accordance with Section I.

PART 4, APPENDIX 4F: QUANTITIES FOR USE WITH DECOMMISSIONING

QUANTITIES FOR USE WITH DECOMMISSIONING

Material	Microcurie*
Americium-241	0.01
Antimony-122	100

DRAFT 1 – 12/05/2012 -RQ

Antimony-124	10
Antimony-125	10
Arsenic-73	100
Arsenic-74	10
Arsenic-76	10
Arsenic-77	100
Barium-131	10
Barium-133	10
Barium-140	10
Bismuth-210	1
Bromine-82	10
Cadmium-109	10
Cadmium-115	100
Cadmium-115m	10
Calcium-45	10
Calcium-47	10
Carbon-14	100
Cerium-141	100
Cerium-143	100
Cerium-144	1
Cesium-131	1,000
Cesium-134	1
Cesium-134m	100
Cesium-135	10
Cesium-136	10
Cesium-137	10
Chlorine-36	10
Chlorine-38	10
Chromium-51	1,000
Cobalt-58	10
Cobalt-58m	10
Cobalt-60	1
Copper-64	100
Dysprosium-165	10
Dysprosium-166	100
Erbium-169	100
Erbium-171	100
Europium-152 (13 yr)	1
Europium-152 (9.2 h)	100
Europium-154	1
Europium-155	10
Florine-18	1,000
Gadolinium-153	10
Gadolinium-159	100
Gallium-72	10
Germanium-71	100

DRAFT 1 – 12/05/2012 -RQ

Gold-198	100
Gold-199	100
Hafnium-181	10
Holmium-166	100
Hydrogen-3	1,000
Indium-113m	100
Indium-114m	10
Indium-115	10
Indium-115m	100
Iodine-125	1
Iodine-126	1
Iodine-129	0.1
Iodine-131	1
Iodine-132	10
Iodine-133	1
Iodine-134	10
Iodine-135	10
Iridium-192	10
Iridium-194	100
Iron-55	100
Iron-59	10
Krypton-85	100
Krypton-87	10
Lanthanum-140	10
Lutetium-177	100
Manganese-52	10
Manganese-54	10
Manganese-56	10
Mercury-197	100
Mercury-197m	100
Mercury-203	10
Molybdenum-99	100
Neodymium-147	100
Neodymium-149	100
Nickel-59	100
Nickel-63	10
Nickel-65	100
Niobium-93m	10
Niobium-95	10
Niobium-97	10
Osmium-185	10
Osmium-191	100
Osmium-191m	100
Osmium-193	100
Palladium-103	100
Palladium-109	100

DRAFT 1 – 12/05/2012 -RQ

Phosphorus-32	10
Platinum-191	100
Platinum-193	100
Platinum-193m	100
Platinum-197	100
Platinum-197m	100
Plutonium-239	0.01
Polonium-210	0.1
Potassium-42	10
Praseodymium-142	100
Praseodymium-143	100
Promethium-147	10
Promethium-149	10
Radium-226	0.01
Rhenium-186	100
Rhenium-188	100
Rhodium-103m	100
Rhodium-105	100
Rubidium-86	10
Rubidium-87	10
Ruthenium-103	10
Ruthenium-105	10
Ruthenium-106	1
Ruthenium-97	100
Samarium-151	10
Samarium-153	100
Scandium-46	10
Scandium-47	100
Scandium-48	10
Selenium-75	10
Silicon-31	100
Silver-105	10
Silver-111	100
Silver-110m	1
Sodium-22	1
Sodium-24	10
Strontium-85	10
Strontium-89	1
Strontium-90	0.1
Strontium-91	10
Strontium-92	10
Sulfur -35	100
Tantalum-182	10
Technetium-96	10
Technetium-97	100
Technetium-97m	100

DRAFT 1 – 12/05/2012 -RQ

Technetium-99	10
Technetium-99m	100
Tellurium-125m	10
Tellurium-127	100
Tellurium-127m	10
Tellurium-129	100
Tellurium-129m	10
Tellurium-131m	10
Tellurium-132	10
Terbium-160	10
Thallium-200	100
Thallium-201	100
Thallium-202	100
Thallium-204	10
Thorium (natural)**	100
Thulium-170	10
Thulium-171	10
Tin-113	10
Tin-125	10
Tungsten-181	10
Tungsten-185	10
Tungsten-187	100
Uranium (natural)***	100
Uranium-233	0.01
Uranium-234	0.01
Uranium-235	0.01
Vanadium-48	10
Xenon-131m	1,000
Xenon-133	100
Xenon-135	100
Ytterbium-175	100
Yttrium-90	10
Yttrium-91	10
Yttrium-92	100
Yttrium-93	100
Zinc-65	10
Zinc-69	1,000
Zinc-69m	100
Zirconium-93	10
Zirconium-95	10
Zirconium-97	10
Any alpha emitting radionuclide not listed above or mixtures of alpha emitters of unknown composition	0.01

Any radionuclide other than alpha emitting radionuclides, not listed above or mixtures of beta emitters of unknown composition	0.1
* To convert µCi to kBq, multiply the µCi value by 37.	.
** Based on alpha disintegration rate of Th-232, Th-230 and their decay products.	.
*** Based on alpha disintegration rate of U-238, U-234, and U-235.	.

Note: Where there is involved a combination of isotopes in known amounts, the limit for the combination should be derived as follows: Determine, for each isotope in the combination, the ratio between the quantity present in the combination and the limit otherwise established for the specific isotope when not in combination. The sum of such ratios for all the isotopes in the combination may not exceed "1" — that is, unity.

PART 4, APPENDIX 4G: NATIONALLY TRACKED SOURCE THRESHOLDS [JJ45]

The Terabecquerel (TBq) values are the regulatory standard. The curie (Ci) values specified are obtained by converting the TBq value. The Curie (Ci) values are provided for practical usefulness only and are rounded after conversion.

Radioactive material	Category 1 (TBq)	Category 1 (Ci)	Category 2 (TBq)	Category 2 (Ci)
Actinium-227	20	540	0.2	5.4
Americium-241	60	1,600	0.6	16
Americium-241/Be	60	1,600	0.6	16
Californium-252	20	540	0.2	5.4
Cobalt-60	30	810	0.3	8.1
Curium-244	50	1,400	0.5	14
Cesium-137	100	2,700	1	27
Gadolinium-153	1,000	27,000	10	270
Iridium-192	80	2,200	0.8	22

Plutonium-238	60	1,600	0.6	16
Plutonium-239/Be	60	1,600	0.6	16
Polonium-210	60	1,600	0.6	16
Promethium-147	40,000	1,100,000	400	11,000
Radium-226	40	1,100	0.4	11
Selenium-75	200	5,400	2	54
Strontium-90	1,000	27,000	10	270
Thorium-228	20	540	0.2	5.4
Thorium-229	20	540	0.2	5.4
Thulium-170	20,000	540,000	200	5,400
Ytterbium-169	300	8,100	3	81

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2224 **EDITOR'S NOTES**

2225 6 CCR 1007-1 has been divided into smaller sections for ease of use. Versions prior to 4/1/07 and rule
2226 history are located in the first section, 6 CCR 1007-1. Prior versions can be accessed from the History link
2227 that appears above the text in 6 CCR 1007-1. To view versions effective on or after 4/1/07, Select the
2228 desired part of the rule, for example 6 CCR 1007-1 Part 1 or 6 CCR 1007-1 Parts 8 - 10.

2229 **History**

2230 *[For history of this section, see Editor's Notes in the first section, 6 CCR 1007-1]*