

CHAPTER 40
STANDARDS FOR PROTECTION AGAINST RADIATION

GENERAL PROVISIONS

641—40.1(136C) Purpose and scope.

40.1(1) This chapter establishes standards for protection against ionizing radiation resulting from activities conducted pursuant to licenses or registrations issued by the agency. These rules are issued pursuant to the authority in Iowa Code section 136C.3 and 136C.4.

40.1(2) The requirements of this chapter 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 this chapter. However, nothing in this chapter shall be construed as limiting actions that may be necessary to protect health and safety.

40.1(3) In addition to complying with the requirements set forth in this chapter, every reasonable effort should be made to maintain radiation exposures and releases of radioactive material in effluents to unrestricted areas as low as is reasonably achievable (ALARA). The term “as low as is reasonably achievable” means as low as is reasonably achievable taking into account the state of technology and the economics of improvements in relation to benefits to the public health and safety, other societal and socioeconomic considerations, and in relation to the utilization of ionizing radiation in the public interest.

40.1(4) Except as specifically provided in other parts of these rules, this chapter applies to persons licensed or registered by the agency to receive, possess, use, transfer, or dispose of sources of radiation. The limits in this chapter do not apply to doses due to background radiation, to exposure of patients to radiation for the purpose of medical diagnosis or therapy, or to voluntary participation in medical research programs.

40.1(5) All references to Code of Federal Regulations (CFR) in this chapter are those in effect on or before May 4, 2005.

40.1(6) The provisions of Chapter 40 are in addition to, and not in substitution for, any other applicable portions of 641—Chapters 38 to 45.

641—40.2(136C) Definitions.

40.2(1) For the purposes of this chapter, the definitions of 641—Chapter 38 may also apply.

40.2(2) As used in this chapter, these terms have the definitions set forth below.

“*Annual limit on intake (ALI)*” means the derived limit for the amount of radioactive material taken into the body of an adult worker by inhalation or ingestion in a year. ALI is the smaller value of intake of a given radionuclide in a year by the reference person that would result in a committed effective dose equivalent of 5 rem (0.05 Sv) or a committed dose equivalent of 50 rem (0.5 Sv) to any individual organ or tissue. ALI values for intake by ingestion and by inhalation of selected radionuclides are given in Table I, Columns 1 and 2, of Appendix B.

“*Class (or lung class or inhalation class)*” means a classification scheme for inhaled material according to its rate of clearance from the pulmonary region of the lung. Materials are classified as D, W, or Y, which applies to a range of clearance half-times: for Class D, Days, of less than 10 days, for Class W, Weeks, from 10 to 100 days, and for Class Y, Years, of greater than 100 days.

“*Declared pregnant woman*” means a woman who has voluntarily informed her licensee or registrant, in writing, of her pregnancy and the estimated date of conception. The declaration remains in effect until the declared pregnant woman withdraws the declaration in writing or is no longer pregnant.

“Derived air concentration (DAC)” means the concentration of a given radionuclide in air which, if breathed by the reference person for a working year of 2,000 hours under conditions of light work (inhalation rate 1.2 cubic meters of air per hour) results in an intake of one ALI. DAC values are given in Table I, Column 3, of Appendix B.

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

“Dosimetry processor” means an individual or an organization that processes and evaluates individual monitoring devices in order to determine the radiation dose delivered to the monitoring devices.

“Inhalation class” (see “Class.”)

“Lung class” (see “Class.”)

“Nonstochastic effect” means a health effect, the severity of which varies with the dose and for which a threshold is believed to exist. Radiation-induced cataract formation is an example of a nonstochastic effect. For purposes of these rules, “deterministic effect” is an equivalent term.

“Planned special exposure” means an infrequent exposure to radiation, separate from and in addition to the annual occupational dose limits.

“Quarter” means a period of time equal to one-fourth of the year observed by the licensee, approximately 13 consecutive weeks, providing that the beginning of the first quarter in a year coincides with the starting date of the year and that no day is omitted or duplicated in consecutive quarters.

“Reference person” means a hypothetical aggregation of human physical and physiological characteristics determined by international consensus. These characteristics may be used by researchers and public health workers to standardize results of experiments and to relate biological insult to a common base. A description of the reference person is contained in the International Commission on Radiological Protection report, ICRP Publication 23, “Report of the Task Group on Reference Man.”

“Respiratory protective equipment” means an apparatus, such as a respirator, used to reduce an individual’s intake of airborne radioactive materials.

“Sanitary sewerage” means a system of public sewers for carrying off wastewater and refuse, but excluding sewage treatment facilities, septic tanks, and leach fields owned or operated by the licensee or registrant.

“Stochastic effect” means a health effect that occurs randomly and for which the probability of the effect occurring, rather than its severity, is assumed to be a linear function of dose without threshold. Hereditary effects and cancer incidence are examples of stochastic effects. For purposes of these rules, “probabilistic effect” is an equivalent term.

“*Weighting factor*” w_T for an organ or tissue (T) means the proportion of the risk of stochastic effects resulting from irradiation of that organ or tissue to the total risk of stochastic effects when the whole body is irradiated uniformly. For calculating the effective dose equivalent, the values of w_T are:

ORGAN DOSE WEIGHTING FACTORS	
Organ or Tissue	w_T
Gonads	0.25
Breast	0.15
Red bone marrow	0.12
Lung	0.12
Thyroid	0.03
Bone surfaces	0.03
Remainder	0.30 ^a
Whole Body	1.00 ^b

^a 0.30 results from 0.06 for each of 5 “remainder” organs, excluding the skin and the lens of the eye, that receive the highest doses.

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

641—40.3(136C) Implementation.

40.3(1) Any existing license or registration condition that is more restrictive than this chapter remains in force until there is an amendment or renewal of the license or registration.

40.3(2) If a license or registration condition exempts a licensee or registrant from a provision of this chapter in effect on or before January 1, 1994, it also exempts the licensee or registrant from the corresponding provision of this chapter.

40.3(3) If a license or registration condition cites provisions of this chapter in effect prior to January 1, 1994, which do not correspond to any provisions of this chapter, the license or registration condition remains in force until there is an amendment or renewal of the license or registration that modifies or removes this condition.

641—40.4 to 40.9 Reserved.

RADIATION PROTECTION PROGRAMS

641—40.10(136C) Radiation protection programs.

40.10(1) Each licensee or registrant shall develop, document, and implement a radiation protection program sufficient to ensure compliance with the provisions of this chapter. See 40.81(136C) for record-keeping requirements relating to these programs.

40.10(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 public doses that are as low as is reasonably achievable (ALARA).

40.10(3) The licensee or registrant shall, at intervals not to exceed 12 months, review the radiation protection program content and implementation.

40.10(4) To implement the ALARA requirements of 40.10(2), and notwithstanding the requirements in 641—40.26(136C), a constraint on air emissions of radioactive material to the environment, excluding radon-222 and its daughters, shall be established by licensees such that the individual member of the public likely to receive the highest dose will not be expected to receive a total effective dose equivalent in excess of 10 mrem (0.1 mSv) per year from these emissions. If a licensee subject to this requirement exceeds this dose constraint, the licensee shall report the exceedance as provided in 641—40.97(136C) and promptly take appropriate corrective action to ensure against recurrence.

641—40.11 to 40.14 Reserved.

OCCUPATIONAL DOSE LIMITS

641—40.15(136C) Occupational dose limits for adults.

40.15(1) The licensee or registrant shall control the occupational dose to individual adults, except for planned special exposures pursuant to 40.20(136C), to the following dose limits:

a. An annual limit, which is the more limiting of:

(1) The total effective dose equivalent being equal to 5 rem (0.05 Sv); 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 50 rem (0.5 Sv).

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

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

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

40.15(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 40.20(5) "a" and "b."

40.15(3) The assigned deep dose equivalent must be for the portion of the body receiving the highest exposure. The assigned shallow-dose equivalent must be the dose averaged over the contiguous 10 square centimeters of skin receiving the highest exposure.

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.

40.15(4) Derived air concentration (DAC) and annual limit on intake (ALI) values are presented in Table I of Appendix B and may be used to determine the individual's dose and to demonstrate compliance with the occupational dose limits. See 40.86(136C).

40.15(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 B.

40.15(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 40.19(5).

641—40.16(136C) Compliance with requirements for summation of external and internal doses.

40.16(1) If the licensee or registrant is required to monitor pursuant to both 40.19(1) and 40.19(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 40.19(1), or only pursuant to 40.19(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 40.16(2), 40.16(3) and 40.16(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.

40.16(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:

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

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

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

40.16(3) Intake by oral ingestion. 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 shall account for this intake and include it in demonstrating compliance with the limits.

40.16(4) Intake through wounds or absorption through skin. The licensee shall evaluate and, to the extent practical, account for intakes through wounds or skin absorption. The intake through intact skin has been included in the calculation of DAC for hydrogen-3 and does not need to be evaluated or accounted for pursuant to this subrule.

641—40.17(136C) Determination of external dose from airborne radioactive material.

40.17(1) Licensees 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 B, footnotes 1 and 2.

40.17(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.

641—40.18(136C) Determination of internal exposure.

40.18(1) For purposes of assessing dose used to determine compliance with occupational dose equivalent limits, the licensee shall, when required pursuant to 40.37(136C), take suitable and timely measurements of:

- a. Concentrations of radioactive materials in air in work areas; or
- b. Quantities of radionuclides in the body; or
- c. Quantities of radionuclides excreted from the body; or
- d. Combinations of these measurements.

40.18(2) Unless respiratory protective equipment is used, as provided in 40.50(136C), or the assessment of intake is based on bioassays, the licensee shall assume that an individual inhales radioactive material at the airborne concentration in which the individual is present.

40.18(3) When specific information on the physical and biochemical properties of the radionuclides taken into the body or the behavior of the material in an individual is known, the licensee may:

- a. Use that information to calculate the committed effective dose equivalent, and, if used, the licensee shall document that information in the individual's record; and
- b. Upon prior approval of the agency, adjust the DAC or ALI values to reflect the actual physical and chemical characteristics of airborne radioactive material, for example, aerosol size distribution or density; and
- c. Separately assess the contribution of fractional intakes of Class D, W, or Y compounds of a given radionuclide to the committed effective dose equivalent. See Appendix B.

40.18(4) If the licensee chooses to assess intakes of Class Y material using the measurements given in 40.8(1)“b” or 40.8(1)“c,” the licensee may delay the recording and reporting of the assessments for periods up to seven months, unless otherwise required by 40.96(136C) or 40.97(136C). This delay permits the licensee to make additional measurements basic to the assessments.

40.18(5) If the identity and concentration of each radionuclide in a mixture are known, the fraction of the DAC applicable to the mixture for use in calculating DAC-hours shall be either:

- a. The sum of the ratios of the concentration to the appropriate DAC value, that is, D, W, or Y, from Appendix B for each radionuclide in the mixture; or
- b. The ratio of the total concentration for all radionuclides in the mixture to the most restrictive DAC value for any radionuclide in the mixture.

40.18(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.

40.18(7) When a mixture of radionuclides in air exists, a licensee may disregard certain radionuclides in the mixture if:

- a. The licensee uses the total activity of the mixture in demonstrating compliance with the dose limits in 40.15(136C) and in complying with the monitoring requirements in 40.37(136C), and
- b. The concentration of any radionuclide disregarded is less than 10 percent of its DAC, and
- c. The sum of these percentages for all of the radionuclides disregarded in the mixture does not exceed 30 percent.

40.18(8) When determining the committed effective dose equivalent, the following information may be considered:

- a. In order to calculate the committed effective dose equivalent, the licensee 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 5 rem (0.05 Sv) for radionuclides that have their ALIs or DACs based on the committed effective dose equivalent.
- b. For an ALI and the associated DAC determined by the nonstochastic organ dose limit of 50 rem (0.5 Sv), the intake of radionuclides that would result in a committed effective dose equivalent of 5 rem (0.05 Sv), that is, the stochastic ALI, is listed in parentheses in Table I of Appendix B. 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 40.15(1) "a"(2) is met.

641—40.19(136C) Determination of prior occupational dose.

40.19(1) For each individual who is likely to receive, in a year, an occupational dose requiring monitoring pursuant to this rule, the licensee or registrant shall:

- a. Determine the occupational radiation dose received during the current year; and
- b. Attempt to obtain the records of lifetime cumulative occupational radiation dose.

40.19(2) Prior to permitting an individual to participate in a planned special exposure, the licensee or registrant shall determine:

- a. The internal and external doses from all previous planned special exposures; and
- b. All doses in excess of the limits, including doses received during accidents and emergencies, received during the lifetime of the individual; and
- c. All lifetime cumulative occupational radiation dose.

40.19(3) In complying with the requirements of 40.19(1), a licensee or registrant may:

- a. 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

b. Accept, as the record of lifetime cumulative radiation dose, a form 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

c. 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.

40.19(4) *a.* The licensee or registrant shall record the exposure history, as required by 40.37(136C). 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 the exposure history. For any period in which the licensee or registrant does not obtain a report, the licensee or registrant shall place a notation on the report indicating the periods of time for which data are not available.

b. 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 rules in this chapter in effect on or before January 1, 1994. Further, occupational exposure histories obtained and recorded on or before January 1, 1994, 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.

40.19(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:

a. In establishing administrative controls pursuant to 40.15(6) for the current year, that the allowable dose limit for the individual is reduced by 1.25 rem (12.5 mSv) for each quarter for which records were unavailable and the individual was engaged in activities that could have resulted in occupational radiation exposure; and

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

40.19(6) The licensee or registrant shall retain the records in 641—40.19(136C) until the agency terminates each pertinent license or registration requiring this record. The licensee or registrant shall retain records used in preparing any record for this subrule for three years after the record is made.

641—40.20(136C) 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 40.15(136C) provided that each of the following conditions is satisfied:

40.20(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.

40.20(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.

40.20(3) Before a planned special exposure, the licensee or registrant ensures that each individual involved is:

a. Informed of the purpose of the planned operation; and

b. Informed of the estimated doses and associated potential risks and specific radiation levels or other conditions that might be involved in performing the task; and

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

40.20(4) Prior to permitting an individual to participate in a planned special exposure, the licensee or registrant ascertains prior doses as required by 40.19(2) during the lifetime of the individual for each individual involved.

40.20(5) Subject to 40.15(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:

- a. The numerical values of any of the dose limits in 40.15(1) in any year; and
- b. Five times the annual dose limits in 40.15(1) during the individual's lifetime.

40.20(6) The licensee or registrant maintains records of the conduct of a planned special exposure in accordance with 40.85(136C) and submits a written report in accordance with 40.98(136C).

40.20(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 40.15(1) but shall be included in evaluations required by 40.20(1) and 40.20(2).

641—40.21(136C) Occupational dose limits for minors. The annual occupational dose limits for minors are 10 percent of the annual dose limits specified for adult workers in 40.15(136C).

641—40.22(136C) Dose equivalent to an embryo/fetus.

40.22(1) The licensee or registrant shall ensure that the dose equivalent to an embryo/fetus during the entire pregnancy, due to occupational exposure of a declared pregnant woman, does not exceed 0.5 rem (5 mSv). See 40.86(136C) for record-keeping requirements.

40.22(2) The licensee or registrant shall make efforts to avoid substantial variation¹ above a uniform monthly exposure rate to a declared pregnant woman so as to satisfy the limit in 40.22(1).

40.22(3) The dose equivalent to an embryo/fetus shall be taken as the sum of:

- a. The deep dose equivalent to the declared pregnant woman; and
- b. The dose equivalent to the embryo/fetus from radionuclides in the embryo/fetus and radionuclides in the declared pregnant woman.

40.22(4) If by the time the woman declares pregnancy to the licensee or registrant, the dose equivalent to the embryo/fetus has exceeded 0.5 rem (5 mSv), or is within 0.05 rem (0.5 mSv) of this dose, the licensee or registrant shall be deemed to be in compliance with 40.22(1) if the additional dose equivalent to the embryo/fetus does not exceed 0.05 rem (0.5 mSv) during the remainder of the pregnancy.

641—40.23 to 40.25 Reserved.

¹ 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 0.05 rem (0.5 mSv) to the embryo/fetus be received in any one month.

RADIATION DOSE LIMITS FOR INDIVIDUAL MEMBERS OF THE PUBLIC

641—40.26(136C) Dose limits for individual members of the public.

40.26(1) Each licensee or registrant shall conduct operations so that:

a. The total effective dose equivalent to individual members of the public from the licensed or registered operation does not exceed 0.1 rem (1 millisievert) 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 641—subrule 41.2(27), from voluntary participation in medical research programs, and from the licensee's or registrant's disposal of radioactive material into sanitary sewerage under 641—40.72(136C); and

b. The dose in any unrestricted area from external sources, exclusive of the dose contributions from patients administered radioactive material and released under 641—subrule 41.2(27), does not exceed 0.002 rem (0.02 millisievert) in any one hour.

40.26(2) If the licensee or registrant permits members of the public to have access to controlled areas, the limits for members of the public continue to apply to those individuals.

40.26(3) A licensee, registrant, or an applicant for a license or registration may apply for prior agency authorization to operate up to an annual dose limit for an individual member of the public of 0.5 rem (5 mSv). This application shall include the following information:

a. Demonstration of the need for and the expected duration of operations in excess of the limit in 40.26(1); and

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

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

40.26(4) In addition to the requirements of this chapter, 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 shall comply with those standards.

40.26(5) The agency 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.

40.26(6) Notwithstanding the requirements of 40.26(1) "a," a licensee may permit visitors to an individual who cannot be released under 641—subrule 41.2(27) to receive a radiation dose greater than 0.1 rem (1 mSv) if:

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

b. The authorized user, as defined in 641—subrule 41.2(2), has determined before the visit that it is appropriate.

641—40.27(136C) Compliance with dose limits for individual members of the public.

40.27(1) The licensee or registrant shall make or cause to be made, as appropriate, surveys of radiation levels in unrestricted and controlled areas and radioactive materials in effluents released to unrestricted and controlled areas to demonstrate compliance with the dose limits for individual members of the public in 40.26(136C).

40.27(2) A licensee or registrant shall show compliance with the annual dose limit in 40.26(136C) by:

a. Demonstrating by measurement or calculation that the total effective dose equivalent to the individual likely to receive the highest dose from the licensed or registered operation does not exceed the annual dose limit; or

b. Demonstrating that:

(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 II of Appendix B; and

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

40.27(3) Upon approval from the agency, the licensee or registrant may adjust the effluent concentration values in Appendix B, Table II, 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.

RADIOLOGICAL CRITERIA FOR LICENSE TERMINATION

641—40.28(136C) Radiological criteria for license termination.

40.28(1) The criteria in this rule apply to the decommissioning of facilities licensed under 641—Chapter 39, and to the release of part of a facility or site for unrestricted use, as well as other facilities subject to the agency's jurisdiction under Iowa Code chapter 136C.

40.28(2) The criteria in this rule do not apply to sites which:

a. Have been decommissioned prior to July 1, 1999, in accordance with criteria identified in 641—subrule 39.4(33).

b. Have previously submitted and received agency approval on a license termination plan (LTP) or decommissioning plan that is compatible with the United States Nuclear Regulatory Commission (NRC) Site Decommissioning Management Plan (SDMP) Action Plan criteria; or

c. Submit a sufficient LTP or decommissioning plan prior to July 1, 1999, and such LTP or decommissioning plan is approved by the agency prior to July 1, 1999, except that if an environmental impact statement is required in the submittal, there will be a provision for day-to-day extension.

40.28(3) After a site has been decommissioned and the license terminated in accordance with the criteria in this chapter, or after part of a facility or site has been released for unrestricted use in accordance with this chapter, the agency will require additional cleanup only if, based on new information, it determines that the criteria of this chapter were not met and residual radioactivity remaining at the site could result in significant threat to public health and safety.

40.28(4) When calculating TEDE to the average member of the critical group the licensee shall determine the peak annual TEDE dose expected within the first 1000 years after decommissioning.

40.28(5) Public notification and public participation. Upon the receipt of an LTP or decommissioning plan from the licensee or a proposal by the licensee for release of a site pursuant to 40.30(136C) or 40.31(136C) or whenever the agency deems such notice to be in the public interest, the agency shall:

a. Notify and solicit comments from:

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

(2) The Environmental Protection Agency for cases where the licensee proposes to release a site pursuant to 40.31(136C).

b. Publish a notice in the Iowa Administrative Bulletin and in a forum, such as local newspapers, letters to state or local organizations, or other appropriate forum, that is readily accessible to individuals in the vicinity of the site, and solicit comments from affected parties.

40.28(6) Minimization of contamination. Applicants for licenses, other than renewals, after July 1, 1999, shall describe in the application how facility design and procedures for operation will minimize, to the extent practicable, contamination of the facility and the environment, facilitate eventual decommissioning, and minimize, to the extent practicable, the generation of radioactive waste.

641—40.29(136C) Radiological criteria for unrestricted use. A site will be considered acceptable for unrestricted use if the residual radioactivity that is distinguishable from background radiation results in a TEDE to an average member of the critical group that does not exceed 25 mrem (0.25 mSv) per year, including that from groundwater sources of drinking water, and the residual radioactivity has been reduced to levels that are ALARA. Determination of the levels which are ALARA must take into account consideration of any detriments, such as deaths from transportation accidents, expected to potentially result from decontamination and waste disposal.

641—40.30(136C) Criteria for license termination under restricted conditions. A site will be considered acceptable for license termination under restricted conditions if:

40.30(1) The licensee can demonstrate that reductions in residual radioactivity necessary to comply with the provisions of 40.29(136C) would result in net public or environmental harm or were not being made because the residual levels associated with restricted conditions are ALARA. Determination of the levels which are ALARA must take into account consideration of any detriments, such as traffic accidents, expected to potentially result from decontamination and waste disposal;

40.30(2) The licensee has made provisions for legally enforceable institutional controls that provide reasonable assurance that the TEDE from residual radioactivity distinguishable from background to the average member of the critical group will not exceed 25 mrem (0.25 mSv) per year;

40.30(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:

a. Funds placed into an account segregated from the licensee's assets and outside the licensee's administrative control as described in 641—subparagraph 39.4(26)“*f*”(1);

b. Surety method, insurance or other guarantee method as described in 641—subparagraph 39.4(26)“*f*”(2);

c. A statement of intent in the case of federal, state, or local government licensees, as described in 641—subparagraph 39.4(26)“*f*”(4); or

d. When a governmental entity is assuming custody and ownership of a site, an arrangement that is deemed acceptable by such governmental entity.

40.30(4) The licensee has submitted a decommissioning plan or license termination plan (LTP) to the agency indicating the licensee's intent to decommission in accordance with 641—paragraph 39.4(33)“*d*” and specifying that the licensee intends to decommission by restricting use of the site. The licensee shall document in the LTP or decommissioning plan how the advice of individuals and institutions in the community, who may be affected by the decommissioning, has been sought and incorporated, as appropriate, following analysis of that advice. Licensees proposing to decommission by restricting use of the site shall seek advice from such affected parties regarding the following matters concerning the proposed decommissioning:

a. Whether provisions for institutional controls proposed by the licensee:

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

(2) Will be enforceable; and

(3) Will not impose undue burdens on the local community or other affected parties.

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

c. In seeking advice on the issues identified in 40.30(4)“*a*,” the licensee shall provide for:

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

(2) An opportunity for a comprehensive, collective discussion of the issues by the participants represented; and

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

40.30(5) 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 as low as reasonably achievable and would not exceed either:

- a. 100 mrem (1 mSv) per year; or
- b. 500 mrem (5 mSv) per year provided the licensee:

(1) Demonstrates that further reductions in residual radioactivity necessary to comply with the 100 mrem/yr (1 mSv/yr) value of 40.30(5)“a” are not technically achievable, would be prohibitively expensive, or would result in net public or environmental harm;

(2) Makes provisions for durable institutional controls; and

(3) Provides sufficient financial assurance to enable a responsible government entity or independent third party, including a governmental custodian of a site, both to carry out periodic rechecks of the site no less frequently than every five years to ensure that the institutional controls remain in place as necessary to meet the criteria of 40.30(2) and to assume and carry out responsibilities for any necessary controls and maintenance of those controls. Acceptable financial assurance mechanisms are those in subrule 40.30(3).

641—40.31(136C) Alternate criteria for license termination.

40.31(1) The agency may terminate a license using alternate criteria greater than the dose criterion of 641—40.29(136C), 40.30(2) and 40.30(4)“a”(1) if the licensee:

a. Provides assurance that public health and safety would continue to be protected and that it is unlikely that the dose from all man-made sources combined, other than medical, would be more than the 100 mrem/yr (1 mSv/yr) by submitting an analysis of possible sources of exposure;

b. Has employed, to the extent practical, restrictions on site use according to the provisions of 641—40.30(136C) in minimizing exposures at the site;

c. Reduces doses to ALARA levels taking into consideration any detriments such as traffic accidents expected to potentially result from decontamination and waste disposal; and

d. Has submitted a decommissioning plan or license termination plan (LTP) to the agency indicating the licensee’s intent to decommission in accordance with 641—paragraph 39.4(33)“d,” and specifying that the licensee proposes to decommission by use of alternate criteria. The licensee shall document in the decommissioning plan or LTP how the advice of individuals and institutions in the community, who may be affected by the decommissioning, has been sought and addressed, as appropriate, following analysis of that advice. In seeking such advice, the licensee shall provide for:

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

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

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

40.31(2) The use of alternate criteria to terminate a license requires the approval of the agency after consideration of the staff’s recommendations that will address any comments provided by the Environmental Protection Agency and any public comments submitted pursuant to 40.32(136C).

TESTING FOR LEAKAGE OR CONTAMINATION OF SEALED SOURCES

641—40.32(136C) Testing for leakage or contamination of sealed sources.

40.32(1) The licensee in possession of any sealed source shall ensure that:

a. Each sealed source, except as specified in 40.32(2), is tested for leakage or contamination and the test results are received before the sealed source is put into use unless the licensee has a certificate from the transferor indicating that the sealed source was tested within six months before transfer to the licensee.

b. Each sealed source that is not designed to emit alpha particles is tested for leakage or contamination at intervals not to exceed six months or at alternative intervals approved by the Agency, after evaluation of information specified by 641—subparagraphs 39.4(29)“l”(4) and 39.4(29)“l”(5) of these rules, an Agreement State, a Licensing State, or the U.S. Nuclear Regulatory Commission.

c. Each sealed source that is designed to emit alpha particles is tested for leakage or contamination at intervals not to exceed three months or at alternative intervals approved by the Agency, after evaluation of information specified by 641—subparagraphs 39.4(29)“l”(4) and 39.4(29)“l”(5) of these rules, an Agreement State, a Licensing State, or the Nuclear Regulatory Commission.

d. 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 ensure that the sealed source is tested for leakage or contamination before further use.

e. Tests for leakage for all sealed sources, except brachytherapy sources manufactured to contain radium, shall be capable of detecting the presence of 0.005 μCi (185 Bq) of radioactive material on a test sample. Test samples shall be taken 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.

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

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

40.32(2) A licensee need not perform tests for leakage or contamination on the following sealed sources:

- a.* Sealed sources containing only radioactive material with a half-life of less than 30 days;
- b.* Sealed sources containing only radioactive material as a gas;
- c.* Sealed sources containing 100 μCi (3.7 MBq) or less of beta- or photon-emitting material or 10 μCi (370 kBq) or less of alpha-emitting material;
- d.* Sealed sources containing only hydrogen-3;
- e.* Seeds of iridium-192 encased in nylon ribbon; and
- f.* Sealed sources, except those used in teletherapy and brachytherapy and those containing radium, which are stored, not being used and identified as in storage. The licensee 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 six months before the date of use or transfer.