PART D

STANDARDS FOR PROTECTION AGAINST RADIATION

General Provisions

Sec. D.1 Purpose

a. Part D establishes standards for protection against ionizing radiation resulting from activities conducted pursuant to licenses or registrations issued by the Agency. The regulations are issued pursuant to the Del. Code Title 16 Chapter 74.

b. The requirements of Part D 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 D. However, nothing in Part D shall be construed as limiting actions that may be necessary to protect health and safety in an emergency.

Sec. D.2 Scope. Except as specifically provided in other Parts of the regulations, Part D applies to persons licensed or registered by the Agency to receive, possess, use, transfer, or dispose of sources of radiation. The dose limits in Part D 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.

Sec. D.3 Definitions. As used in Part D:

“Absorbed dose (D)” means the energy deposited by ionizing radiation per unit mass (of any material). The conventional unit of absorbed dose is the rad. One rad is equal to 0.01 J/kg. The International Standard (SI) unit of absorbed dose is the gray (Gy) (1 Gy = 100 rad).

“Air Kerma (K)” means the kinetic energy released by ionizing radiation per unit mass of air. This unit is the gray. The air kerma in gray (mGy) is equivalent to exposure in roentgen (R) multiplied by 8.37 E+2.

“ALARA (as low as reasonably achievable)" means making every reasonable effort to maintain exposures to radiation as far below the dose limits in this part as is practical, consistent with the purpose for which the licensed activity is undertaken, taking into account the state of technology, the economics of improvements in relation to benefits to the public health and safety, and other societal and socioeconomic considerations, and in relation to utilization of nuclear energy and licensed materials in the public interest.

"ALI (Annual limit on intake)" 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 man that would result in a committed effective equivalent dose (H) of 0.05 Sv (5 rem) or a committed equivalent dose (H) of 0.5 Sv (50 rem) 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" 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. For purposes of the regulations, "lung class" and "inhalation class" are equivalent terms.

"Declared pregnant woman" means a woman who has voluntarily informed her employer, in writing, of her pregnancy and the estimated date of conception.

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

"DAC-hour (Derived air concentration-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 effective equivalent dose (H) of 0.05 Sv (5 rem).

"Direct supervision" means the physical presence of the supervisor and is used for purposes of instruction.

"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.

"Equivalent dose (H)" means the product of absorbed dose (D) and the radiation weighting factor (w_R), formerly called the quality factor (Q): $H = w_R H D$. The unit of equivalent dose is the Sievert (Sv). See Appendix C, Part F, for a table of radiation weighting factors (W_R).

"Exposure" means the amount of charge (i.e., the concentration of ions of one sign) produced by ionizing radiation per unit mass of air. The SI unit of exposure is coulombs per kilogram (C/kg). The traditional unit is the Roentgen (R), which corresponds to an exposure of $2.58 \cdot 10^{-4}$ c/kg of air. More recently, exposure has also been expressed in terms Air Kerma (K) given by the absorbed dose in air in units of Sieverts (Sv): $K(mGy) = 0.0873 \cdot X(R)$.

"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 the regulations, "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 man" means a hypothetical aggregation of human physical and physiological characteristics determined by international consensus. These characteristics may be used by researchers and public health employees to standardize results of experiments and to relate biological insult to a common base. A description of the reference man 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.

“Roentgen” means the special unit of exposure. One roentgen (R) equals 2.58E-4 coulombs per kilogram of air.

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

“Sievert (Sv) ” means the SI unit of any of the quantities expressed as equivalent dose. The equivalent dose in sieverts is equal to the absorbed dose in gray multiplied by the quality factor (1 Sv = 100 rem).

"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 the regulations, "probabilistic effect" is an equivalent term.

"Very high radiation area" means an area, accessible to individuals, in which radiation levels could result in an individual receiving an absorbed dose in excess of 5 Gy (500 rad) in 1 hour at 1 meter from a source of radiation or from any surface that the radiation penetrates.[1]

"Tissue Weighting factor w_T" means a weighting factor used in calculating effective dose intended to assign the proportion of risk of stochastic effects resulting from irradiation of a particular tissue compared to uniform whole body irradiation.

[1] At very high doses received at high dose rates, units of absorbed dose, gray and rad, are appropriate rather than units of equivalent dose (H), sievert and rem.

Tissue Weighting Factors (w_T) Assigned by the International Commission on Radiological Protection*

Tissue/Organ	w_T
Gonads	0.20
Stomach	0.12
Colon	0.12
Lung	0.12 (0.08) I
Red bone marrow	0.12
Breast	0.05
Esophagus	0.05
Bladder	0.05
Liver	0.05
Thyroid	0.05
Bone surfaces	0.01
Skin	0.01H
Remainder	0.05

*Adapted from 1990 Recommendations of the International Commission on Radiological Protection, ICRP Publication No. 60, Oxford: Pergamon 1991.
H Applied to the mean equivalent dose over the entire skin.
I Bronchial epithelium

Sec. D.4 Implementation

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

b. If a license or registration condition exempts a licensee or registrant from a provision of Part D in effect on or before July 10, 2002, it also exempts the licensee or registrant from the corresponding provision of Part D.

c. If a license or registration condition cites provisions of Part D in effect prior to effective date of the regulations, which do not correspond to any provisions of Part D, 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.

Radiation Protection Programs

Sec. D.101 Radiation Protection Programs

a. Each licensee or registrant shall develop, document, and implement a radiation protection program sufficient to ensure compliance with the provisions of Part D. See D.1102 for recordkeeping requirements relating to these programs.

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

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

Occupational Dose Limits

Sec. D.201 Occupational Dose Limits for Adults

a. The licensee or registrant shall control the occupational dose to individual adults, except for planned special exposures pursuant to D.206, to the following dose limits:

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

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

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

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

(1) An eye equivalent dose (H) of 0.15 Sv (15 rem); and

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

b. 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 D.206e.i. and ii.

c. The assigned deep equivalent dose (H) and shallow equivalent dose (H) shall be for the portion of the body receiving the highest exposure:

i. The deep equivalent dose (H), eye equivalent dose (H) and shallow equivalent dose (H) 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; or

ii. When a protective apron is worn while working with medical radiation equipment and monitoring is conducted as specified in D.502a.iv., the effective equivalent dose (H) for external radiation shall be determined as follows:

(1) When only one individual monitoring device is used and it is located at the neck outside the protective apron, the reported deep equivalent dose (H) shall be the effective equivalent dose (H) for external radiation; or

(2) When only one individual monitoring device is used and it is located at the neck outside the protective apron, and the reported dose exceeds 25 percent of the limit specified in D.201a., the reported deep equivalent dose (H) value multiplied by 0.3 shall be the effective equivalent dose (H) for external radiation; or

(3) When individual monitoring devices are worn, both under the protective apron at the waist and outside the protective apron at the neck, the effective equivalent dose (H) for external radiation shall be assigned the value of the sum of the deep equivalent dose (H) reported for the individual monitoring device located at the waist under the protective apron multiplied by 1.5 and the deep equivalent dose (H) reported for the individual monitoring device located at the neck outside the protective apron multiplied by 0.04.

d. Derived air concentration (DAC) and annual limit on intake (ALI) values are specified 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 D.1107.

e. Notwithstanding the annual dose limits, the licensee or registrant shall limit the soluble uranium intake by an individual to 10 milligrams in a week in consideration of chemical toxicity. See footnote [c/] of Appendix B.

f. 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 during the current year. See D.205.

Sec. D.202 Compliance with Requirements for Summation of External and Internal Doses

a. If the licensee or registrant is required to monitor pursuant to both D.502a. and b., 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 D.502a. or only pursuant to D.502b., 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 D.202b., c. and d. The equivalent dose (H) for the lens of the eye, the skin, and the extremities are not included in the summation, but are subject to separate limits.

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

i. The sum of the fractions of the inhalation ALI for each radionuclide; or

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

iii. The sum of the calculated committed effective equivalent dose (H) 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 equivalent dose (H), $H_{T,50}$, per

unit intake is greater than 10 percent of the maximum weighted value of $H_{T,50}$, that is, $w_T H_{T,50}$, per unit intake for any organ or tissue.

c. Intake by Oral Ingestion. If the occupationally exposed individual 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.

d. Intake through Wounds or Absorption through Skin. 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 D.201.

Sec. D.203 - Determination of External Dose from Airborne Radioactive Material

a. Licensees or registrants shall, when determining the dose from airborne radioactive material, include the contribution to the deep equivalent dose (H), eye equivalent dose (H), and shallow equivalent dose (H) from external exposure to the radioactive cloud. See Appendix B, footnotes [a/] and [b/].

b. Airborne radioactivity measurements and DAC values shall not be used as the primary means to assess the deep equivalent dose (H) 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 equivalent dose (H) to an individual shall be based upon measurements using instruments or individual monitoring devices.

Sec. D.204 Determination of Internal Exposure

a. For purposes of assessing dose used to determine compliance with occupational equivalent dose (H) limits, the licensee or registrant shall, when required pursuant to D.502, take suitable and timely measurements of:

   i. Concentrations of radioactive materials in air in work areas; or

   ii. Quantities of radionuclides in the body; or

   iii. Quantities of radionuclides excreted from the body; or

   iv. Combinations of these measurements.

b. Unless respiratory protective equipment is used, as provided in D.703, 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.

c. 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:

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

ii. 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

iii. Separately assess the contribution of fractional intakes of Class D, W, or Y compounds of a given radionuclide to the committed effective equivalent dose (H). See Appendix B.

d. If the licensee or registrant chooses to assess intakes of Class Y material using the measurements given in D.204a.ii. or iii., the licensee or registrant may delay the recording and reporting of the assessments for periods up to 7 months, unless otherwise required by D.1202 or D.1203. This delay permits the licensee or registrant to make additional measurements basic to the assessments.

e. 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:

i. 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

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

f. 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.

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

i. The licensee or registrant uses the total activity of the mixture in demonstrating compliance with the dose limits in D.201 and in complying with the monitoring requirements in D.502b.; and

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

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

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

i. In order to calculate the committed effective equivalent dose (H), 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 equivalent dose (H) of 0.05 Sv (5 rem) for radionuclides that have their ALIs or DACs based on the committed effective equivalent dose (H);

ii. 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

equivalent dose (H) of 0.05 Sv (5 rem), 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 equivalent dose (H). However, if the licensee or registrant uses the stochastic ALI, the licensee or registrant shall also demonstrate that the limit in D.201a.i.(2) is met.

Sec. D.205 Determination of Prior Occupational Dose

a. For each individual who may enter the licensee's or registrant's restricted area and is likely to receive, in a year, an occupational dose requiring monitoring pursuant to D.502, the licensee or registrant shall:

   i. Determine the occupational radiation dose received during the current year; and

   ii. Attempt to obtain the records of lifetime cumulative occupational radiation dose.

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

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

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

c. In complying with the requirements of D.205a., a licensee or registrant may:

   i. 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

   ii. Accept, as the record of lifetime cumulative radiation dose, an up-to-date Agency Form Y 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

   iii. Obtain reports of the individual's equivalent dose (H) 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.

d. i. The licensee or registrant shall record the exposure history, as required by D.205a., on Agency Form Y, 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 Agency Form Y 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

Agency Form Y or equivalent indicating the periods of time for which data are not available.

ii. Licensees or registrants are not required to partition historical dose between external equivalent dose(s)(H) and internal committed equivalent dose(s)(H). Further, occupational exposure histories obtained and recorded on Agency Form Y or equivalent before July 10, 2002, might not have included effective equivalent dose (H), but may be used in the absence of specific information on the intake of radionuclides by the individual.

e. 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:

i. In establishing administrative controls pursuant to D.201f. 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

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

f. The licensee or registrant shall retain the records on Agency Form Y or equivalent until the Agency terminates each pertinent license or registration requiring this record. The licensee or registrant shall retain records used in preparing Agency Form Y or equivalent for 3 years after the record is made.

Sec. D.206 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 D.201 provided that each of the following conditions is satisfied:

a. The licensee or registrant authorizes a planned special exposure only in an exceptional situation when alternatives that might avoid the higher exposure are unavailable or impractical;

b. 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;

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

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

ii. 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

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

d. Prior to permitting an individual to participate in a planned special exposure, the licensee or registrant ascertains prior doses as required by D.205b. during the lifetime of the individual for each individual involved;

e. Subject to D.201b., 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:

i. The numerical values of any of the dose limits in D.201a. in any year; and

ii. Five times the annual dose limits in D.201a. during the individual's lifetime;

f. The licensee or registrant maintains records of the conduct of a planned special exposure in accordance with D.1106 and submits a written report in accordance with D.1204;

g. 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 D.201a. but shall be included in evaluations required by D.206d. and e.

Sec. D.207 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 D.201.

Sec. D.208 Dose to an Embryo/Fetus

a. The licensee or registrant shall ensure that the dose to an embryo/fetus during the entire pregnancy, due to occupational exposure of a declared pregnant woman, does not exceed 5 mSv (0.5 rem). See D.1107 for recordkeeping requirements.

b. The licensee or registrant shall make efforts to avoid substantial variation[2] above a uniform monthly exposure rate to a declared pregnant woman so as to satisfy the limit in D.208a.

c. The dose to an embryo/fetus shall be taken as the sum of:

i. The dose to the embryo/fetus from radionuclides in the embryo/fetus and radionuclides in the declared pregnant woman; and

ii. The dose that is most representative of the dose to the embryo/fetus from external radiation, that is, in the mother's lower torso region.

(1) If multiple measurements have not been made, assignment of the highest deep equivalent dose (H) for the declared pregnant woman shall be the dose to the embryo/fetus, in accordance with D.205c.; or

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

[2] 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.

also the most representative deep equivalent dose (H) for the region of the embryo/fetus.

d. If by the time the woman declares pregnancy to the licensee or registrant, the dose to the embryo/fetus has exceeded 4.5 mSv (0.45 rem), the licensee or registrant shall be deemed to be in compliance with D.208a. if the additional dose to the embryo/fetus does not exceed 0.5 mSv (0.05 rem) during the remainder of the pregnancy.

Radiation Dose Limits for Individual Members of the Public

Sec. D.301 Dose Limits for Individual Members of the Public

a. Each licensee or registrant shall conduct operations so that:

   i. The total effective equivalent dose (H) to individual members of the public from the licensed or registered operation does not exceed 1 mSv (0.1 rem) in a year, exclusive of the dose contribution from the licensee's or registrant's disposal of radioactive material into sanitary sewerage in accordance with D.1003;[3] and

   ii. The dose in any unrestricted area from external sources does not exceed 0.02 mSv (0.002 rem) in any one hour; and

b. If the licensee or registrant permits members of the public to have access to restricted areas, the limits for members of the public continue to apply to those individuals.

c. 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 5 mSv (0.5 rem). This application shall include the following information:

   i. Demonstration of the need for and the expected duration of operations in excess of the limit in D.301a.; and

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

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

d. In addition to the requirements of Part D, a licensee or registrant subject to the provisions of the Environmental Protection Agency's generally applicable environmental radiation standards in 40 CFR 190 shall comply with those standards.

e. 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.

[3] Retrofit shall not be required for locations within facilities where only radiation machines existed prior to [the effective date of the regulations] and met the previous requirements of 5 mSv (0.5 rem) in a year.

Sec. D.302 Compliance with Dose Limits for Individual Members of the Public.

a. 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 D.301.

b. A licensee or registrant shall show compliance with the annual dose limit in D.301 by:

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

   ii. 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 continuously 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.

c. 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.

Testing for Leakage or Contamination of Sealed Sources

Sec. D.401 Testing for Leakage or Contamination of Sealed Sources

a. The licensee or registrant in possession of any licensed or registered sealed source as defined by A.2 shall assure that:

   i. Each sealed source, except as specified in D.401b., 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;

   ii. 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 Agency, after evaluation of information specified by C.28 of the regulations, an Agreement State, a Licensing State, or the Nuclear Regulatory Commission;

   iii. 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 Agency, after evaluation of information specified by C.28 of the regulations, an Agreement State, a Licensing State, or the Nuclear Regulatory Commission;

   iv. 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;

   v. 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 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;

   vi. 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-222 and its daughters has been determined with respect to collection method, volume and time;

   vii. 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 185 Bq (0.005 μCi) of a radium daughter which has a half-life greater than 4 days.

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

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

   ii. Sealed sources containing only radioactive material as a gas;

iii. 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;

iv. Sealed sources containing only hydrogen-3;

v. Seeds of iridium-192 encased in nylon ribbon; and

vi. 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.

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

d. Test results shall be kept in units of becquerel or microcurie and maintained for inspection by the Agency. Records of test results for sealed sources shall be made pursuant to D.1104.

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

i. The presence of 185 Bq (0.005 μCi) or more of removable contamination on any test sample;

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

iii. The presence of removable contamination resulting from the decay of 185 Bq (0.005 μCi) or more of radium.

f. 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.

g. Reports of test results for leaking or contaminated sealed sources shall be made pursuant to D.1208.

Surveys and Monitoring

Sec. D.501 General

a. Each licensee or registrant shall make, or cause to be made, surveys that:

i. Are necessary for the licensee or registrant to comply with Part D; and

ii. Are necessary under the circumstances to evaluate:

(1) Radiation levels; and

(2) Concentrations or quantities of radioactive material; and

(3) The potential radiological hazards that could be present.

b. 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, except when a more frequent interval is specified in another applicable Part of the regulations or a license condition.

c. 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 D.201, with other applicable provisions of the regulations, or with conditions specified in a license or registration shall be processed and evaluated by a dosimetry processor:

i. Holding current personnel dosimetry accreditation from the National Voluntary Laboratory Accreditation Program of the National Institute of Standards and Technology; and

ii. Approved in this accreditation process for the type of radiation or radiations included in the National Voluntary Laboratory Accreditation Program that most closely approximates the type of radiation or radiations for which the individual wearing the dosimeter is monitored.

d. The licensee or registrant shall develop administrative controls over the use of personnel monitoring devices to ensure appropriate personnel monitoring.

Sec. D.502 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 D. As a minimum:

a. Each licensee or registrant shall monitor occupational exposure to radiation and shall supply and require the use of individual monitoring devices by:

i. Adults likely to receive, in 1 year from sources external to the body, a dose in excess of 10 percent of the limits in D.201a.; and

ii. Minors and declared pregnant women likely to receive, in 1 year from sources external to the body, a dose in excess of 10 percent of any of the applicable limits in D.207 or D.208; and

iii. Individuals entering a high or very high radiation area;

iv. Individuals working with medical fluoroscopic equipment.

(1) An individual monitoring device used for the dose to an embryo/fetus of a declared pregnant woman, pursuant to D.208a., shall be located under the protective apron at the waist.

(2) An individual monitoring device used for eye equivalent dose (H) shall be located at the neck, or an unshielded location closer to the eye, outside the protective apron.

(3) When only 1 individual monitoring device is used to determine the effective equivalent dose (H) for external radiation pursuant to D.201c.ii., it shall be located at the neck outside the protective apron. When a second individual monitoring device is used, for the same purpose, it shall be located under the protective apron at the waist. The second individual monitoring device is required for a declared pregnant woman.

b. Each licensee or registrant shall monitor, to determine compliance with D.204, the occupational intake of radioactive material by and assess the committed effective equivalent dose (H) to:

i. Adults likely to receive, in 1 year, an intake in excess of 10 percent of the applicable ALI in Table I, Columns 1 and 2, of Appendix B; and

ii. Minors and declared pregnant women likely to receive, in 1 year, a committed effective equivalent dose (H) in excess of 0.5 mSv (0.05 rem).

Sec. D.503 Location of Individual Monitoring Devices

Each licensee or registrant shall ensure that individuals who are required to monitor occupational doses in accordance with D.502a. wear individual monitoring devices as follows:

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

b. An individual monitoring device used for monitoring the dose to an embryo/fetus of a declared pregnant woman, pursuant to D.208a., shall be located at the waist under any protective apron being worn by the woman;

c. An individual monitoring device used for monitoring the eye equivalent dose (H), to demonstrate compliance with D.201a.ii.(1), shall be located at the neck (collar), outside any protective apron being worn by the monitored individual, or at an unshielded location closer to the eye;

d. An individual monitoring device used for monitoring the dose to the extremities, to demonstrate compliance with D.201a.ii.(2), shall be worn on the extremity likely to receive the highest exposure. Each individual monitoring device shall be oriented to measure the highest dose to the extremity being monitored.

Control of Exposure from External Sources in Restricted Areas

Sec. D.601 Control of Access to High Radiation Areas

a. 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:

   i. 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 equivalent dose (H) of 1 mSv (0.1 rem) in 1 hour at 30 centimeters from the source of radiation or from any surface that the radiation penetrates; or

   ii. 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

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

b. In place of the controls required by D.601a. for a high radiation area, the licensee or registrant may substitute continuous direct or electronic surveillance that is capable of preventing unauthorized entry.

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

d. The licensee or registrant shall establish the controls required by D.601a. and c. in a way that does not prevent individuals from leaving a high radiation area.

e. 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 Department of Transportation provided that:

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

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

f. 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 D and to operate within the ALARA provisions of the licensee's or registrant's radiation protection program.

g. The 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 D.601 if the

registrant has met all the specific requirements for access and control specified in other applicable Parts of the regulations, such as, Part E for industrial radiography, Part F for x-rays in the healing arts, and Part I for particle accelerators.

Sec. D.602 Control of Access to Very High Radiation Areas

a. In addition to the requirements in D.601, 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.

b. 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 D.602a. if the registrant has met all the specific requirements for access and control specified in other applicable Parts of the regulations, such as, Part E for industrial radiography, Part F for x- rays in the healing arts, and Part I for particle accelerators.

Sec. D.603 Control of Access to Very High Radiation Areas -- Irradiators

a. Section D.603 applies to licensees or registrants with sources of radiation in non-self-shielded irradiators. Section D.603 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.

b. 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:

    i. 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 equivalent dose (H) 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 equivalent dose (H) to an individual in excess of 1 mSv (0.1 rem) in 1 hour.

    ii. Additional control devices shall be provided so that, upon failure of the entry control devices to function as required by D.603b.i.:

(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 equivalent dose (H) 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.

iii. 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 equivalent dose (H) 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.

iv. 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.

v. 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 D.603b.iii. and iv.

vi. 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.

vii. 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.

viii. 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 equivalent dose (H) in excess of 1 mSv (0.1 rem) in 1 hour.

ix. The entry control devices required in D.603b.i. shall be tested for proper functioning. See D.1110 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.

x. 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.

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

c. Licensees, registrants, or applicants for licenses or registrations for sources of radiation within the purview of D.603b. 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 D.603b., such as those for the automatic control of radiation levels, may apply to the Agency for approval of alternative safety measures. Alternative safety measures shall provide personnel protection at least equivalent to those specified in D.603b. 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.

d. The entry control devices required by D.603b. and c. 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

Sec. D.701 Use of Process or Other Engineering Controls. The licensee or registrant shall use, to the extent practicable, process or other engineering controls, such as, containment or ventilation, to control the concentrations of radioactive material in air. (56 FR 23400, May 21, 1991 as amended at 60 Fr 20185, April 25, 1995)

Sec. D.702 Use of Other Controls. When it is not practicable to apply process or other engineering controls to restrict the concentrations of radioactive material in air to values below those that define an airborne radioactivity area, the licensee or registrant shall, consistent with maintaining the total effective equivalent dose (H) ALARA, increase monitoring and limit intakes by one or more of the following means:

a. Control of access; or

b. Limitation of exposure times; or

c. Use of respiratory protection equipment; or

d. Other controls. (56 FR 23400, May 21, 1991 as amended at 60 Fr 20185, April 25, 1995)

Sec. D.703 Use of Individual Respiratory Protection Equipment.

a. If the licensee or registrant uses respiratory protection equipment to limit intakes pursuant to D.702:

i. Except as provided in D.703a.ii., the licensee or registrant 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;

ii. The licensee or registrant may 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 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, provided the licensee or registrant has submitted to the Agency and the Agency has approved an application for authorized use of that equipment, including a demonstration by testing, or a demonstration on the basis of test information, that the material and performance characteristics of the equipment are capable of providing the proposed degree of protection under anticipated conditions of use;

iii. The licensee or registrant 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 immediately prior to each use; and

(4) Written procedures regarding selection, fitting, issuance, maintenance, and testing of respirators, including testing for operability immediately prior to each use; supervision and training of personnel; monitoring, including air sampling and bioassays; and recordkeeping; and

(5) Determination by a physician prior to initial fitting of respirators, and at least every 12 months thereafter, that the individual user is physically able to use the respiratory protection equipment;

iv. The licensee or registrant shall issue a written policy statement on respirator usage covering:

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

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

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

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

vi. The licensee or registrant shall use respiratory protection equipment within the equipment manufacturer's expressed limitations for type and mode of use and shall provide proper visual, communication, and other special capabilities, such as adequate skin protection, when needed.

b. When estimating exposure of individuals to airborne radioactive materials, the licensee or registrant may make allowance for respiratory protection equipment used to limit intakes pursuant to D.702, provided that the following conditions, in addition to those in D.703a., are satisfied:

i. The licensee or registrant selects respiratory protection equipment that provides a protection factor, specified in Appendix A, 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 B, Table I, Column 3. However, if the selection of respiratory protection equipment with a protection factor greater than the peak concentration is inconsistent with the goal specified in D.702 of keeping the total effective equivalent dose (H) ALARA, the licensee or registrant may select respiratory protection equipment with a lower protection factor provided that such a selection would result in a total effective equivalent dose (H) 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;

ii. The licensee or registrant shall obtain authorization from the Agency before assigning respiratory protection factors in excess of those specified in Appendix A. The Agency may authorize a licensee or registrant 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.

c. In an emergency, the licensee or registrant 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.

d. The licensee or registrant shall notify the Agency in writing at least 30 days before the date that respiratory protection equipment is first used pursuant to either D.703a. or b.

Storage and Control of Licensed or Registered Sources of Radiation

Sec. D.801 Security and Control of Licensed or Registered Sources of Radiation

a. The licensee or registrant shall secure licensed or registered radioactive material from unauthorized removal or access.

b. The licensee or registrant shall maintain constant surveillance, and use devices or administrative procedures to prevent unauthorized use of licensed or registered radioactive material that is in an unrestricted area and that is not in storage.

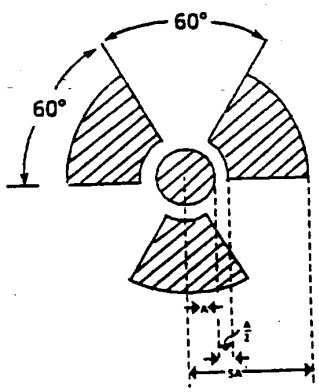
c. The registrant shall secure registered radiation machines from unauthorized removal.

d. The registrant shall use devices or administrative procedures to prevent unauthorized use of registered radiation machines.

Precautionary Procedures

Sec. D.901 Caution Signs

a. Standard Radiation Symbol. Unless otherwise authorized by the Agency, the symbol prescribed by D.901 shall use the colors magenta, or purple, or black on yellow background. The symbol prescribed is the three-bladed design as follows:



1. Cross-hatched area is to be magenta, or purple, or black, and
2. The background is to be yellow.

Figure 1. Radiation Symbol.

b. Exception to Color Requirements for Standard Radiation Symbol. Notwithstanding the requirements of D.901a., 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.

c. Additional Information on Signs and Labels. In addition to the contents of signs and labels prescribed in Part D, the licensee or registrant may 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.

Sec. D.902 Posting Requirements

a. Posting of Radiation Areas. The licensee or registrant shall post each radiation area with a conspicuous sign or signs bearing the radiation symbol and the words "CAUTION, RADIATION AREA."

b. 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 and the words "CAUTION, HIGH RADIATION AREA" or "DANGER, HIGH RADIATION AREA."

c. 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 and words "GRAVE DANGER, VERY HIGH RADIATION AREA."

d. 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 and the words "CAUTION, AIRBORNE RADIOACTIVITY AREA" or "DANGER, AIRBORNE RADIOACTIVITY AREA."

e. 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 C with a conspicuous sign or signs bearing the radiation symbol and the words "CAUTION, RADIOACTIVE MATERIAL(S)" or "DANGER, RADIOACTIVE MATERIAL(S)."

Sec. D.903 Exceptions to Posting Requirements

a. 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:

   i. 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 D; and

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

b. Rooms or other areas in hospitals that are occupied by patients are not required to be posted with caution signs pursuant to D.902 provided that the requirements of G.39a.ii. or G.45a.ii. of the regulations are met.

c. Rooms or other areas in hospitals that are occupied by patients are not required to be posted with caution signs, provided that:

i. A patient being treated with a permanent implant could be released from confinement pursuant to G.27 of the regulations; or

ii. A patient being treated with a therapeutic radiopharmaceutical could be released from confinement pursuant to G.39 of the regulations.

d. 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.

e. 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.

Sec. D.904 Labeling Containers and Radiation Machines

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

b. 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.

c. 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/unshielded.

Sec. D.905 Exemptions to Labeling Requirements. A licensee or registrant is not required to label:

a. Containers holding licensed or registered material in quantities less than the quantities listed in Appendix C; or

b. Containers holding licensed or registered material in concentrations less than those specified in Table III of Appendix B; or

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

d. Containers when they are in transport and packaged and labeled in accordance with the regulations of the Department of Transportation;[4] or

e. 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

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

Sec. D.906 Procedures for Receiving and Opening Packages

a. 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 the regulations, shall make arrangements to receive:

   i. The package when the carrier offers it for delivery; or

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

b. Each licensee or registrant shall:

   i. Monitor the external surfaces of a labeled[5] package for radioactive contamination unless the package contains only radioactive material in the form of gas or in special form as defined in A.2 of the regulations; and

   ii. Monitor the external surfaces of a labeled[6] 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 the regulations; and

[4] Labeling of packages containing radioactive materials is required by the Department of Transportation if the amount and type of radioactive material exceeds the limits for an accepted quantity or article as defined and limited by Department of Transportation regulations 49 CFR 173.403(m) and (w) and 173.421-424.
[5] Labeled means labeled with a Radioactive White I, Yellow II, or Yellow III label as specified in Department of Transportation regulations 49 CFR 172.436-440.
[6] See Footnote # 33

iii. 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.

c. The licensee or registrant shall perform the monitoring required by D.906b. as soon as practicable 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 if there is evidence of degradation of package integrity, such as a package that is crushed, wet, or damaged. If a package is received after working hours, and has no evidence of degradation of package integrity, the package shall be monitored no later than 3 hours from the beginning of the next working day.

d. The licensee or registrant shall immediately notify the final delivery carrier and, by telephone and either telegram, mailgram, or facsimile, the Agency when:

i. Removable radioactive surface contamination exceeds the limits of the U.S. Department of Transportation; or

ii. External radiation levels exceed the limits of the U.S. Department of Transportation.

e. Each licensee or registrant shall:

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

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

f. 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 D.906b., but are not exempt from the monitoring requirement in D.906b. for measuring radiation levels that ensures that the source is still properly lodged in its shield.

Sec. D.1001 General Requirements

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

   i. By transfer to an authorized recipient as provided in D.1006 or in Parts C of the regulations, or to the Department of Energy; or

   ii. By decay in storage; or

   iii. By release in effluents within the limits in D.301; or

   iv. As authorized pursuant to D.1002, D.1003, D.1004, or D.1005.

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

   i. Treatment prior to disposal; or

   ii. Treatment or disposal by incineration; or

   iii. Decay in storage; or

   iv. Disposal at a land disposal facility licensed pursuant to the regulations; or

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

Sec. D.1002 Method for Obtaining Approval of Proposed Disposal Procedures. A licensee or registrant or applicant for a license or registration may apply to the Agency for approval of proposed procedures, not otherwise authorized in the regulations, to dispose of licensed or registered material generated in the licensee's or registrant's operations. Each application shall include:

a. 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

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

c. The nature and location of other potentially affected facilities; and

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

Sec. D.1003 Disposal by Release into Sanitary Sewerage.

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

   i. The material is readily soluble, or is readily dispersible biological material, in water; and

ii. 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 III of Appendix B; and

iii. 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 III of Appendix B 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 III of Appendix B; and

(2) The sum of the fractions for each radionuclide required by D.1003a.iii.(1) does not exceed unity; and

iv. 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.

b. Excreta from individuals undergoing medical diagnosis or therapy with radioactive material are not subject to the limitations contained in D.1003a.

Sec. D.1004 Treatment or Disposal by Incineration. A licensee or registrant may treat or dispose of licensed or registered material by incineration only in the form and concentration specified in D.1005 or as specifically approved by the Agency pursuant to D.1002.

Sec. D.1005 Disposal of Specific Wastes

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

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

ii. 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.

b. A licensee or registrant shall not dispose of tissue pursuant to D.1005a.ii. in a manner that would permit its use either as food for humans or as animal feed.

c. The licensee or registrant shall maintain records in accordance with D.1109.

Sec. D.1006 Transfer for Disposal and Manifests.

a. The requirements of D.1006 and Appendix D are designed to control transfers of low-level radioactive waste intended for disposal at a licensed low-level radioactive waste disposal facility, establish a manifest tracking system, and supplement existing requirements concerning transfers and recordkeeping for those wastes.

b. Each shipment of radioactive waste designated for disposal at a licensed low-level radioactive waste disposal facility shall be accompanied by a shipment manifest as specified in Appendix D.Section I.

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

d. 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 Appendix D. Section III.

Sec. D.1007 Compliance with Environmental and Health Protection Regulations. Nothing in D.1001, D.1002, D.1003, D.1004, D.1005, or D.1006 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 to D.1001, D.1002, D.1003, D.1004, D.1005, or D.1006.

Records

Sec. D.1101 General Provisions

a. 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 D.

b. The licensee or registrant shall make a clear distinction among the quantities entered on the records required by Part D, such as, total effective equivalent dose (H), total organ equivalent dose (H), shallow equivalent dose (H), eye equivalent dose (H), deep equivalent dose (H), or committed effective equivalent dose (H).

Sec. D.1102 Records of Radiation Protection Programs

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

   i. The provisions of the program; and

   ii. Audits and other reviews of program content and implementation.

b. The licensee or registrant shall retain the records required by D.1102a.i. until the Agency terminates each pertinent license or registration requiring the record. The licensee or registrant shall retain the records required by D.1102a.ii. for 3 years after the record is made.

Sec. D.1103 Records of Surveys

a. Each licensee or registrant shall maintain records showing the results of surveys and calibrations required by D.501 and D.906b. The licensee or registrant shall retain these records for 3 years after the record is made.

b. The licensee or registrant shall retain each of the following records until the Agency terminates each pertinent license or registration requiring the record:

   i. Records of the results of surveys to determine the dose from external sources of radiation used, in the absence of or in combination with individual monitoring data, in the assessment of individual equivalent dose (H); and

   ii. 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

   iii. Records showing the results of air sampling, surveys, and bioassays required pursuant to D.703a.iii.(1) and (2); and

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

c. Upon termination of the license or registration, the licensee or registrant shall permanently store records on Agency Form Y or equivalent. The licensee or registrant shall make available to all employees who have been exposed to radiation their appropriate Form Y or equivalent records.

Sec. D.1104 Records of Tests for Leakage or Contamination of Sealed Sources. Records of tests for leakage or contamination of sealed sources required by D.401 shall be kept in units of becquerel or microcurie and maintained for inspection by the Agency for 5 years after the records are made.

Sec. D.1105 Records of Prior Occupational Dose

a. The licensee or registrant shall retain the records of prior occupational dose and exposure history as specified in D.205 on Agency Form Y or equivalent until the Agency terminates each pertinent license or registration requiring this record. The licensee or registrant shall retain records used in preparing Agency Form Y or equivalent for 3 years after the record is made. The licensee or registrant shall make available to all employees who have been exposed to radiation their appropriate Form Y or equivalent records.

b. Upon termination of the license or registration, the licensee or registrant shall permanently store records on Agency Form Y or equivalent, or shall make provision with the Agency for transfer to the Agency.

Sec. D.1106 Records of Planned Special Exposures

a. For each use of the provisions of D.206 for planned special exposures, the licensee or registrant shall maintain records that describe:

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

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

iii. What actions were necessary; and

iv. Why the actions were necessary; and

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

vi. What individual and collective doses were expected to result; and

vii. The doses actually received in the planned special exposure.

b. The licensee or registrant shall retain the records until the Agency terminates each pertinent license or registration requiring these records. The licensee or registrant shall make available to all employees who have been exposed to radiation their appropriate Form Y or equivalent records.

c. Upon termination of the license or registration, the licensee or registrant shall permanently store records on Agency Form Y or equivalent, or shall make provision with the Agency for transfer to the Agency.

Sec. D.1107 Records of Individual Monitoring Results

a. Recordkeeping Requirement. Each licensee or registrant shall maintain records of doses received by all individuals for whom monitoring was required pursuant to D.502, and records of doses received during planned special exposures, accidents, and emergency conditions. Assessments of equivalent dose (H) and records made using units in effect before the effective date of Part D need not be changed. The licensee or registrant shall make available to all employees who have been exposed to radiation their appropriate Form Y or equivalent records. These records shall include, when applicable:

i. The deep equivalent dose (H) to the whole body, eye equivalent dose (H), shallow equivalent dose (H) to the skin, and shallow equivalent dose (H) to the extremities; and

ii. The estimated intake of radionuclides, see D.202; and

iii. The committed effective equivalent dose (H) assigned to the intake of radionuclides; and

iv. The specific information used to calculate the committed effective equivalent dose (H) pursuant to D.204c.; and

v. The total effective equivalent dose (H) when required by D.202; and

vi. The total of the deep equivalent dose (H) and the committed dose to the organ receiving the highest total dose.

b. Recordkeeping Frequency. The licensee or registrant shall make entries of the records specified in D.1107a. at intervals not to exceed 1 year.

c. Recordkeeping Format. The licensee or registrant shall maintain the records specified in D.1107a. on Agency Form Z, in accordance with the instructions for Agency Form Z, or in clear and legible records containing all the information required by Agency Form Z.

d. 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.

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

f. Upon termination of the license or registration, the licensee or registrant shall permanently store records on Agency Form Y or equivalent, or shall make provision with the Agency for transfer to the Agency.

Sec. D.1108 Records of Dose to Individual Members of the Public

a. Each licensee or registrant shall maintain records sufficient to demonstrate compliance with the dose limit for individual members of the public. See D.301.

b. The licensee or registrant shall retain the records required by D.1108a. until the Agency terminates each pertinent license or registration requiring the record.

Sec. D.1109 Records of Waste Disposal

a. Each licensee or registrant shall maintain records of the disposal of licensed or registered materials made pursuant to D.1002, D.1003, D.1004, D.1005, the regulations, and disposal by burial in soil, including burials authorized before the effective date of rule that removed the authorization.[7]

b. The licensee or registrant shall retain the records required by D.1109a. until the Agency terminates each pertinent license or registration requiring the record.

Sec. D.1110 Records of Testing Entry Control Devices for Very High Radiation Areas

a. Each licensee or registrant shall maintain records of tests made pursuant to D.603b.ix. on entry control devices for very high radiation areas. These records must include the date, time, and results of each such test of function.

b. The licensee or registrant shall retain the records required by D.1110a. for 3 years after the record is made.

[7] A previous D.394 permitted burial of small quantities of licensed materials in soil before [date of rule that removed authorization], without specific Agency authorization.

Sec. D.1111 Form of Records. Each record required by Part D shall be legible throughout the specified retention period. The record shall be the original or a reproduced copy or a microform, provided that the copy or microform is authenticated by authorized personnel and that the microform is capable of producing a clear copy throughout the required retention period or the record may also be stored in electronic media with the capability for producing legible, accurate, and complete records during the required retention period. Records, such as letters, drawings, and specifications, shall include all pertinent information, such as stamps, initials, and signatures. The licensee shall maintain adequate safeguards against tampering with and loss of records.

Reports

Sec. D.1201 Reports of Stolen, Lost, or Missing Licensed or Registered Sources of Radiation

a. Telephone Reports. Each licensee or registrant shall report to the Agency by telephone as follows:

   i. Immediately after its occurrence becomes known to the licensee or registrant, stolen, 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 C under such circumstances that it appears to the licensee or registrant that an exposure could result to individuals in unrestricted areas; or

   ii. 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 C that is still missing;

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

b. Written Reports. Each licensee or registrant required to make a report pursuant to D.1201a. shall, within 30 days after making the telephone report, make a written report to the Agency setting forth the following information:

   i. A description of the licensed or registered source of radiation involved, including, for radioactive material, dimensions and weight, 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;

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

   iii. A statement of disposition, or probable disposition, of the licensed or registered radioactive material or radiation producing device involved; and

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

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

vi. 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.

c. 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.

d. The licensee or registrant shall prepare any report filed with the Agency pursuant to D.1201 so that names of individuals who may have received exposure to radiation are stated in a separate and detachable portion of the report.

e. The licensee or registrant shall make available to all employees who have been exposed to radiation their appropriate Form Y or equivalent records.

f. Upon termination of the license or registration, the licensee or registrant shall permanently store records on Agency Form Y or equivalent, or shall make provision with the Agency for transfer to the Agency.

Sec. D.1202 Notification of Incidents

a. Immediate Notification. Notwithstanding other requirements for notification, each licensee or registrant shall immediately report each event involving a source of radiation possessed by the licensee or registrant that may have caused or threatens to cause any of the following conditions:

i. An individual to receive:

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

(2) An eye equivalent dose (H) of 0.75 Sv (75 rem) or more; or

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

ii. 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.

b. Twenty-Four Hour Notification. Each licensee or registrant shall, within 24 hours of discovery of the event, report to the Agency 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:

i. An individual to receive, in a period of 24 hours:

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

(2) An eye equivalent dose (H) exceeding 0.15 Sv (15 rem); or

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

ii. 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.

c. Licensees or registrants shall make the reports required by D.1202a. and b. by initial contact by telephone to the Agency and shall confirm the initial contact by telegram, mailgram, or facsimile to the Agency.

d. The licensee or registrant shall prepare each report filed with the Agency pursuant to D.1202 so that names of individuals who have received exposure to sources of radiation are stated in a separate and detachable portion of the report.

e. The provisions of D.1202 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 D.1204.

Sec. D.1203 Reports of Exposures, Radiation Levels, and Concentrations of Radioactive Material Exceeding the Limits

a. Reportable Events. In addition to the notification required by D.1202, each licensee or registrant shall submit a written report within 30 days after learning of any of the following occurrences:

i. Incidents for which notification is required by D.1202; or

ii. Doses in excess of any of the following:

(1) The occupational dose limits for adults in D.201; or

(2) The occupational dose limits for a minor in D.207; or

(3) The limits for an embryo/fetus of a declared pregnant woman in D.208; or

(4) The limits for an individual member of the public in D.301; or

(5) The dose to a patient of one (1) gray (100 rads) or more; or

(6) Any applicable limit in the license or registration.

iii. 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 D or in the license or registration, whether or not involving exposure of any individual in excess of the limits in D.301; or

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

b. Contents of Reports

i. Each report required by D.1203a. shall describe the extent of exposure of individuals to radiation and radioactive material, including, as appropriate:

(1) Estimates of each individual's dose; and

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

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

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

ii. Each report filed pursuant to D.1203a. shall include for each individual exposed: the name, Social Security account number, and date of birth. With respect to the limit for the embryo/fetus in D.208, 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.

c. All licensees or registrants who make reports pursuant to D.1203a. shall submit the report in writing to the Agency.

Sec. D.1204 Reports of Planned Special Exposures. The licensee or registrant shall submit a written report to the Agency within 30 days following any planned special exposure conducted in accordance with D.206, informing the Agency that a planned special exposure was conducted and indicating the date the planned special exposure occurred and the information required by Sec. D.1106.

Sec. D.1205 Reserved

Sec. D.1206 Reports of Individual Monitoring

a. This section applies to each person licensed or registered by the Agency to:

i. Possess or use sources of radiation for purposes of industrial radiography pursuant to Parts C and E of the regulations; or

ii. Receive radioactive waste from other persons for disposal pursuant to the regulations; or

iii. Possess or use at any time, for processing or manufacturing for distribution pursuant to Part C or G of the regulations, radioactive material in quantities exceeding any one of the following quantities:

Radionuclide	Activity[a]	
	Ci	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

[a/] *The Agency may require as a license condition, or by rule, regulation, or order pursuant to A.7 of the regulations, 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.*

b. Each licensee or registrant in a category listed in D.1206a. shall submit an annual report of the results of individual monitoring carried out by the licensee or registrant for each individual for whom monitoring was required by D.502 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 Agency Form Z or equivalent or electronic media containing all the information required by Agency Form Z.

c. The licensee or registrant shall file the report required by D.1206b., covering the preceding year, on or before April 30 of each year. The licensee or registrant shall submit the report to the Agency.

Sec D.1207 Notifications and Reports to Individuals

a. Requirements for notification and reports to individuals of exposure to radiation or radioactive material are specified in J.13 of the regulations.

b. When a licensee or registrant is required pursuant to D.1203 to report to the Agency any exposure of an individual to radiation or radioactive material, the licensee or registrant shall also notify the individual. Such notice shall be transmitted at a time not later than the transmittal to the Agency, and shall comply with the provisions of J.13a. of the regulations.

Sec. D.1208 Reports of Leaking or Contaminated Sealed Sources. The licensee or registrant shall file a report within 5 days with the Agency if the test for leakage or contamination [required pursuant to D.401] 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

Sec. D.1301 Vacating Premises. Each specific licensee or registrant shall, no less than 30 days before vacating or relinquishing possession or control of premises notify the Agency in writing of intent to vacate. When deemed necessary by the Agency, the licensee shall decontaminate the premises in such a manner as the Agency may specify.