DEPARTMENT OF HEALTH AND SOCIAL SERVICES

DIVISION OF PUBLIC HEALTH

AUTHORITY ON RADIATION PROTECTION

Statutory Authority: 16 Delaware Code, §7405 (16 **Del.C.** § 7405)
16 **DE Admin. Code** 4465

FINAL

ORDER

Delaware Radiation Control Regulations
4465 Part D Standards for Protection Against Radiation
4465 Part J Notices, Instructions and Reports to Workers, Inspections

NATURE OF THE PROCEEDINGS:

Delaware Health and Social Services ("DHSS") initiated proceedings to adopt the State of Delaware Radiation Control Regulations (4465 Parts D & J). The DHSS proceedings to adopt regulations were initiated pursuant to 29 **Delaware Code** Chapter 101 and authority as prescribed by 16 **Delaware Code**, §7405(a).

On May 1, 2015 (Volume 18, Issue 11), DHSS published in the Delaware *Register of Regulations* its notice of proposed regulations, pursuant to 29 **Delaware Code** Section 10115. It requested that written materials and suggestions from the public concerning the proposed regulations be delivered to DHSS by June 8, 2015, or be presented at a public hearing on May 27, 2015, after which time the DHSS would review information, factual evidence and public comment to the said proposed regulations.

No oral comments were made at the public hearing and no written comments were received during the public comment period. Therefore, no evaluation or summarization of comments is presented in the accompanying "Summary of Evidence."

SUMMARY OF EVIDENCE

In accordance with Delaware Law, public notices regarding proposed Department of Health and Social Services (DHSS) State of Delaware Radiation Control Regulations (4465 Parts D & J) were published in the *Delaware State News*, the *News Journal* and the Delaware *Register of Regulations*.

The public comment period was open from May 1, 2015 through June 8, 2015. No comments were received on the proposed regulations during the public comment period and no changes have been made to the proposed regulations.

Verifying documents are attached to the Hearing Officer's record. The regulation has been approved by the Delaware Attorney General's office and the Cabinet Secretary of DHSS.

FINDINGS OF FACT:

There were no public comments received. The Department finds that the proposed regulations, as set forth in the attached copy should be adopted in the best interest of the general public of the State of Delaware.

THEREFORE, IT IS ORDERED, that the proposed State of Delaware Radiation Control Regulations (4465 Parts D & J) is adopted and shall become effective August 11, 2015, after publication of the final regulation in the Delaware *Register of Regulations*.

Rita M. Landgraf, Secretary

4465 Delaware Radiation Control Regulations

~~**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): $H = w_R \cdot D$. 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.

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

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.

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).

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

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 [6/] 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[22] 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 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;[33] and

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

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2. [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.

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.

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;

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3. [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.

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.

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.

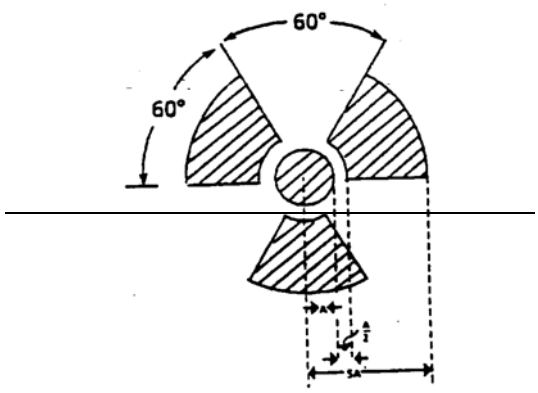
c. The registrant shall secure registered radiation machines from unauthorized removal.

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.

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

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,

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4. [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. [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. [6] See Footnote # 33

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.

Waste Disposal

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.

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

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7. [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.

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.~~

Part D

STANDARDS FOR PROTECTION AGAINST RADIATION

General Provisions

1.0 Purpose

1.1 Part D establishes standards for protection against ionizing radiation resulting from activities conducted pursuant to licenses or registrations issued by the Agency. These regulations are issued pursuant to the Title 16, **Delaware Code**, Chapter 74 Radiation Control.

1.2 The requirements of Part D are designed to control the receipt, possession, use, sale, 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.

2.0 Scope.

Except as specifically provided in other Parts of these regulations, Part D applies to persons licensed or registered by the Agency to receive, possess, use, sell, transfer, or dispose of sources of radiation. The 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, to exposure from individuals administered radioactive material and released in accordance with the providers ALARA license conditions, or to voluntary participation in medical research programs.

3.0 Definitions.

As used in Part D:

"**A1**" means the maximum activity of special form radioactive material permitted in a Type A package.

"**A2**" means the maximum activity of radioactive material, other than special form radioactive material, permitted in a Type A package.

These values are either listed in Appendix A of Part T of these regulations, Table I, or may be derived in accordance with the procedure prescribed in Appendix A of Part T of these regulations.

"**Absorbed dose**" means the energy imparted by ionizing radiation per unit mass of irradiated material. The units of absorbed dose are the gray (Gy) and the rad.

"**Accelerator**" means any machine capable of accelerating electrons, protons, deuterons, or other charged particles in a vacuum and of discharging the resultant particulate or other radiation into a medium at energies usually in excess of 1 MeV. For purposes of this definition, "**particle accelerator**" is an equivalent term.

"**Accelerator-produced material**" means any material made radioactive by a particle accelerator.

"**Activity**" means the rate of disintegration or transformation or decay of radioactive material. The units of activity are the becquerel (Bq) and the curie (Ci).

"**Address of use**" means the building or buildings that are identified on the permit (license) and where radioactive materials may be produced, prepared, received, used, or stored.

"**Adult**" means an individual 18 or more years of age.

"**Agency**" means the Division of Public Health, Delaware Department of Health and Social Services.

"**Agreement State**" means any State with which the Nuclear Regulatory Commission or the Atomic Energy Commission has entered into an effective agreement under subsection 274b. of the Atomic Energy Act of 1954, as amended (73 Stat. 689).

"**Airborne radioactive material**" means any radioactive material dispersed in the air in the form of dusts, fumes, particulates, mists, vapors, or gases.

"**Airborne radioactivity area**" means a room, enclosure, or area in which airborne radioactive materials exist in concentrations:

(1) In excess of the derived air concentrations (DAC's) specified in Appendix B, Table I of Part D of these regulations; or

(2) To such a degree that an individual present in the area without respiratory protective equipment could exceed, during the hours an individual is present in a week, an intake of 0.6 percent of the annual limit on intake (ALI) or 12 DAC-hours.

"**Airline respirator**" (see "**Supplied-air respirator (SAR)**").

"**Air-purifying respirator**" means a respirator with an air-purifying filter, cartridge, or canister that removes specific air contaminants by passing ambient air through the air-purifying element.

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

"**As low as is reasonably achievable**" (ALARA) means making every reasonable effort to maintain exposures to radiation as far below the dose limits in these regulations as is practical, consistent with the purpose for which the licensed or registered activity is undertaken, taking into account the state of technology, the economics of improvements in relation to 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 or registered sources of radiation in the public interest.

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

"**Atmosphere-supplying respirator**" means a respirator that supplies the respirator user with breathing air from a source independent of the ambient atmosphere, and includes supplied-air respirators (SAR's) and self-contained breathing apparatus (SCBA) units.

"**Authorized user**" means a practitioner of the healing arts who is identified as an authorized user on an Agency, Agreement State, Licensing State or the Nuclear Regulatory Commission license that authorizes the medical use of radioactive material.

"**Background radiation**" means radiation from cosmic sources, naturally occurring radioactive material, (which has not been technologically enhanced) including radon, except as a decay product of source or special nuclear material, and including global fallout as it exists in the environment from the testing of nuclear explosive devices, or from past nuclear accidents such as Chernobyl that contribute to background radiation and are not under the control of the licensee or registrant. "**Background radiation**" does not include sources of radiation from radioactive materials regulated by the Agency.

"**Becquerel**" (Bq) means the Standard Internationale (SI) unit of activity. One becquerel is equal to 1 disintegration or transformation per second (dps or tps).

"**Bioassay**" means the determination of kinds, quantities or concentrations, and, in some cases, the locations of radioactive material in the human body, whether by direct measurement, in vivo counting, or by analysis and evaluation of materials excreted or removed from the human body. For purposes of these regulations, "**radiobioassay**" is an equivalent term.

"**Brachytherapy**" means a method of radiation therapy in which radiation sources are utilized to deliver a radiation dose at a distance of up to a few centimeters, by surface, intracavitary, intraluminal, or interstitial application.

"**Byproduct material**" means:

(1) Any radioactive material (except special nuclear material) yielded in, or made radioactive by, exposure to the radiation incident to the process of producing or using special nuclear material;

(2) The tailings or wastes produced by the extraction or concentration of uranium or thorium from ore processed primarily for its source material content, including discrete surface wastes resulting from uranium solution extraction processes. Underground ore bodies depleted by these solution extraction operations do not constitute "**byproduct material**" within this definition;

(3) (i) Any discrete source of radium-226 that is produced, extracted, or converted after extraction, before, on, or after August 8, 2005, for use for a commercial, medical, or research activity; or

(ii) Any material that—

(A) Has been made radioactive by use of a particle accelerator; and

(B) Is produced, extracted, or converted after extraction, before, on, or after August 8, 2005, for use for a commercial, medical, or research activity; and

(4) Any discrete source of naturally occurring radioactive material, other than source material, that—

(i) The Commission, in consultation with the Administrator of the Environmental Protection Agency, the Secretary of Energy, the Secretary of Homeland Security, and the head of any other appropriate Federal agency, determines would pose a threat similar to the threat posed by a discrete source of radium-226 to the public health and safety or the common defense and security; and

(ii) Before, on, or after August 8, 2005, is extracted or converted after extraction for use in a commercial, medical, or research activity.

"**Calendar quarter**" means not less than 12 consecutive weeks nor more than 14 consecutive weeks. The first calendar quarter of each year shall begin in January and subsequent calendar quarters shall be so arranged such that no day is included in more than one calendar quarter and no day in any one year is omitted from inclusion within a calendar quarter. The method observed by the licensee or registrant for determining calendar quarters shall only be changed at the beginning of a year.

"**Calibration**" means the determination of (1) the response or reading of an instrument relative to a series of known radiation values over the range of the instrument, or (2) the strength of a source of radiation relative to a standard.

"**CFR**" means Code of Federal Regulations.

"**Chiropractic**" means a drugless system of health care based on the principle that interference with the transmission of nerve impulses may cause disease, per Title 24 Delaware Code, Chapter 7, Board of Chiropractic, as amended.

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

"**Collective dose**" means the sum of the individual doses received in a given period of time by a specified population from exposure to a specified source of radiation.

"**Committed dose equivalent**" (HT.50) means the dose equivalent to organs or tissues of reference (T) that will be received from an intake of radioactive material by an individual during the 50-year period following the intake.

"**Committed effective dose equivalent**" (HE.50) is the sum of the products of the weighting factors (wT) applicable to each of the body organs or tissues that are irradiated and the committed dose equivalent to each of these organs or tissues ($H_{E,50} = \Sigma\, w_T\ H_{T,50}$).

"**Constraint (dose constraint)**" means a value above which specified licensee actions are required.

"**Controlled area**" means an area, outside of a restricted but inside the site boundary, access to which can be limited by the licensee or registrant, for any reason.

"**Critical group**" means the group of individuals reasonably expected to receive the greatest exposure to residual radioactivity for any applicable set of circumstances.

"**Curie**" means the traditional unit of quantity of activity. One curie (Ci) is that quantity of radioactive material, which decays at the rate of 3.7E+10 disintegrations or transformations per second (dps or tps).

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

"**Deep dose equivalent**" (Hd), which applies to external whole body exposure, means the dose equivalent at a tissue depth of 1 centimeter (1000 mg/cm2).

"**Demand respirator**" means an atmosphere-supplying respirator that admits breathing air to the face piece only when a negative pressure is created inside the facepiece by inhalation

"**Dentist**" shall mean a person who is qualified to practice dentistry as prescribed in Title 24 **Delaware Code**, Chapter 11, Dentistry and Dental Hygiene, as amended.

"**Department of Energy**" means the Department of Energy established by Public Law 95-91, August 4, 1977, 91 Stat. 565, 42 U.S.C. Section 7101 as amended *et seq*., to the extent that the Department exercises functions formerly vested in the Atomic Energy Commission, its Chairman, members, officers and components and transferred to the Energy Research and Development Administration and to the Administrator thereof pursuant to sections 104(b), (c) and (d) of the Energy Reorganization Act of 1974 (Public Law 93-438, October 11, 1974, 88 Stat. 1233 at 1237, 42 U.S.C. 5814, effective January 19, 1975) and re-transferred to the Secretary of Energy pursuant to section 301(a) of the Department of Energy Organization Act (Public Law 95-91, August 4, 1977, 91 Stat. 565 at 577-578, 42 U.S.C. 7151, effective October 1, 1977 as amended.)

"**Depleted uranium**" means the source material uranium in which the isotope uranium-235 is less than 0.711 weight percent of the total uranium present. Depleted uranium does not include special nuclear material.

"**Derived air concentration (DAC)**" 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 (inhalation rate 1.2 cubic meters of air per hour), results in an intake of one ALI. DAC values are given in Appendix B of this regulation.

"**Discrete Source**" means a radionuclide that has been processed so that its concentration within a material has been purposely increased for use for commercial, medical, or research activities.

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

"**Distinguishable from background**" means that the detectable concentration of a radionuclide is statistically different from the background concentration of that radionuclide in the vicinity of the site or, in the case of structures, in similar materials using adequate measurement technology, survey, and statistical techniques.

"**Dose**" is a generic term that means absorbed dose, dose equivalent, effective dose equivalent, committed dose equivalent, committed effective dose equivalent, total organ dose equivalent, or total effective dose equivalent. For purposes of these regulations, "**radiation dose**" is an equivalent term.

"**Dose equivalent (HT)**" means the product of the absorbed dose in tissue, quality factor, and all other necessary modifying factors at the location of interest. The units of dose equivalent are the sievert (Sv) and rem.

"**Dose limits**" means the permissible upper bounds of radiation doses established in accordance with these regulations. For purposes of these regulations, "**limits**" is an equivalent term.

"**Effective dose equivalent (HE)**" means the sum of the products of the dose equivalent to the organ or tissue (HT) and the weighting factor (wT) applicable to each of the body organs or tissues that are irradiated ($H_E = \Sigma w_T H_T$).

"**Embryo/fetus**" means the developing human organism from conception until the time of birth.

"**Exposure**" generally means being exposed to ionizing radiation or to radioactive material;

"**Exposure Units**" specifically as used in these regulations, the SI unit of exposure is coulomb per kilogram (C/kg), see Section 9.1 of Part A for Units of Exposure and Dose.

"**Exposure rate**" means the exposure per unit of time, such as roentgen per minute or milliroentgen per hour.

"**External dose**" means that portion of the dose equivalent received from any source of radiation outside the body.

"**External Source**" means all ionizing radiation sources that could present exposure or external dose to an individual.

"**Extremity**" means hand, elbow, and arm below the elbow, foot, knee, and leg below the knee.

"**Facility**" means the location, building vehicle, or complex under one administrative control, at which one or more radiation sources are installed, located and/or used.

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

"**Fit factor**" means a quantitative estimate of the fit of a particular respirator to a specific individual, and typically estimates the ratio of the concentration of a substance in ambient air to its concentration inside the respirator when worn.

"**Fit Test**" means the use of a protocol to qualitatively evaluate the fit of a respirator on an individual.

"**Former Atomic Energy Commission or Nuclear Regulatory Commission licensed facilities**" means nuclear reactors, nuclear fuel reprocessing plants, uranium enrichment plants, or critical mass experimental facilities where Atomic Energy Commission or Nuclear Regulatory Commission licenses have been terminated.

"**Generally applicable environmental radiation standards**" means standards issued by the Environmental Protection Agency under the authority of the Atomic Energy Act of 1954, as amended, that impose limits on radiation exposures or levels, or concentrations or quantities of radioactive material, in the general environment outside the boundaries of locations under the control of persons possessing or using radioactive material.

"**Gray**" (Gy) means the Standard Internationale (SI) unit of absorbed dose. One gray is equal to an absorbed dose of 1 joule per kilogram (100 rad).

"**Hazardous waste**" means those wastes designated as hazardous by the Environmental Protection Agency regulations in 40 CFR Part 261, as amended.

"**Healing arts**" includes but is not limited to the practice of medicine, surgery, dentistry, registered pharmacy, podiatry, osteopathy, chiropractic, or veterinary medicine or nursing.

"**Healing arts screening**" means the testing of human beings using x-ray machines for the detection or evaluation of health indications when such tests are not specifically and individually ordered by a licensed practitioner of the healing arts legally authorized to prescribe such x-ray tests for the purpose of diagnosis or treatment.

"**Helmet**" means a rigid respiratory inlet covering that also provides head protection against impact and penetration.

"**High radiation area**" means an area, accessible to individuals, in which radiation levels from radiation sources external to the body could result in an individual receiving a dose equivalent in excess of 1 mSv (0.1 rem) in 1 hour at 30 centimeters from any source of radiation or 30 centimeters from any surface that the radiation penetrates.

"**Hood**" means a respiratory inlet covering that completely covers the head and neck and may also cover portions of the shoulders and torso.

"**Human use**" means the internal or external administration of radiation or radioactive material to human beings.

"**Individual**" means any human being.

"**Individual monitoring**" means the assessment of:

(1) Dose equivalent (a) by the use of individual monitoring devices or (b) by the use of survey data; or

(2) Committed effective dose equivalent (a) by bioassay or (b) by determination of the time-weighted air concentrations to which an individual has been exposed, that is, DAC-hours. [See the definition of DAC-hours in 4465 Part D of these regulations.]

(3) Dose equivalent by the use of survey data.

"**Individual monitoring devices**" means devices designed to be worn by a single individual for the assessment of dose equivalent. For purposes of these regulations, "**personnel dosimeter**" and "**dosimeter**" are equivalent terms. Examples of individual monitoring devices are film badges, thermoluminescence dosimeters (TLDs), pocket ionization chambers, optically stimulated luminescence (OSL) dosimeters and personal (lapel) air sampling devices.

"**Inspection**" means an official examination or observation including, but not limited to, tests, surveys, and monitoring to determine compliance with rules, regulations, orders, requirements, and conditions of the Agency.

"**Instrument traceability**" (for ionizing radiation measurements) means the ability to show that an instrument has been calibrated at specified time intervals using a national standard or a transfer standard. If a transfer standard is used, the calibration must be at a laboratory accredited by a program, which requires continuing participation in measurement quality assurance with the National Institute of Standards and Technology, or other equivalent national or international program.

"**Interlock**" means a device arranged or connected such that the occurrence of an event or condition is required before a second event or condition can occur or continue to occur.

"**Internal dose**" means that portion of the dose equivalent received from radioactive material taken into the body.

"**JRCECT**" means Joint Review Committee on Education in Cardiovascular Technology

"**JRCNMT**" means Joint Review Committee on Nuclear Medicine Technology

"**JRCERT**" means Joint Review Committee on Education in Radiologic Technology

"**Lens dose equivalent (LDE)**" means the external exposure to the lens of the eye as the dose equivalent at a tissue depth of 0.3 centimeter (300 mg/cm2).

"**License**" means a license issued by the US Nuclear Regulatory Commission, Agreement State, or the Agency, in accordance with applicable federal or state regulations, as amended.

"**Licensed Practitioner**" means an individual licensed to practice medicine, dentistry, podiatry, chiropractic, osteopathy, or veterinary medicine in this state.

"**Licensed [or registered] material**" means radioactive material received, possessed, used, transferred or disposed of under a general or specific license [or registration] issued by the Agency.

"**Licensee**" means the holder of a license.

"**Limits**" [See "**Dose limits**"].

"**Loose-fitting facepiece**" means a respiratory inlet covering that is designed to form a partial seal with the face.

"**Lost or missing source of radiation**" means licensed [or registered] source of radiation whose location is unknown. This definition includes, but is not limited to, radioactive material that has been shipped but has not reached its planned destination and whose location cannot be readily traced in the transportation system.

"**Major processor**" means a user processing, handling, or manufacturing radioactive material exceeding Type A quantities as unsealed sources or material, or exceeding 4 times Type B quantities as sealed sources, but

does not include nuclear medicine programs, universities, industrial radiographers, or small industrial programs. Type A and B quantities are defined in T.2 of these regulations.

"**Member of the public**" means any individual except when that individual is receiving an occupational dose.

"**Minor**" means an individual less than 18 years of age.

"**Misadministration**" means an event that meets the criteria in 4465 Part X, Therapeutic Radiation Machines, Section 5.2 of these regulations.

"**Monitoring**" means the measurement of radiation, radioactive material concentrations, surface area activities or quantities of radioactive material and the use of the results of these measurements to evaluate potential exposures and doses. For purposes of these regulations, "**radiation monitoring**" and "**radiation protection monitoring**" are equivalent terms.

"**Natural radioactivity**" means radioactivity of naturally occurring nuclides.

"**Negative pressure respirator (tight fitting)**" means a respirator in which the air pressure inside the facepiece is negative during inhalation with respect to the ambient air pressure outside the respirator.

"**NORM**" means any naturally occurring radioactive material. It does not include byproduct, source, or special nuclear material.

"**NRC**" means the US Nuclear Regulatory Commission or its duly authorized representatives.

"**Notice of Violation**" means a written statement of one or more alleged infringements of a legally binding requirement. The notice normally requires the licensee, registrant or other permit holder to provide a written statement describing the following:

Corrective steps taken by the licensee, registrant or other permit holder and the results achieved;

Corrective steps to be taken to prevent recurrence; and

The projected date for achieving full compliance. The Authority may require responses to notices of violation to be under oath.

"**Occupational dose**" means the dose received by an individual in the course of employment, education or training, in which the individual's assigned duties for the licensee or registrant involve exposure to sources of radiation, whether or not the sources of radiation are in the possession of the licensee, registrant, or other person. Occupational dose does not include doses received from background radiation, or from any medical administration the individual has received, from exposure to individuals administered radioactive material and released in accordance with U.S. Nuclear Regulatory Commission Regulations, from voluntary participation in medical research programs, or as a member of the public.

"**Office of Engineering**" means the office in the Delaware Division of Public Health that reviews radiation shielding plans and/or design plans and issues an Approval to Construct letter for new radiation source facilities or rooms.

"**Office of Radiation Control**" means the office in the Delaware Division of Public Health which carries out the Delaware Radiation Control Regulations, issues radiation source facility registration permits, and performs on-site inspections of new and existing radiation machine facilities to determine compliance.

"**Owner/Leasee**" means the person/individual who owns/leases the radiation source. An out-of-state owner shall authorize a manager to sign the application form.

"**Package**" means the packaging together with its radioactive contents as presented for transport.

"**Particle accelerator**" [See "**Accelerator**"].

"**Person**" means any individual, corporation, partnership, firm, association, trust, estate, public or private institution, group, agency, political subdivision of this State, any other State or political subdivision or agency thereof, and any legal successor, representative, agent, or agency of the foregoing, [but shall not include federal government agencies].

"**Personnel monitoring equipment**" [See "**Individual monitoring devices**"].

"**Physician**" means an allopathic doctor of medicine and surgery or a doctor of osteopathic medicine and surgery who is registered and certified to practice medicine pursuant to Title 24 **Delaware Code**, Chapter 17, Medical Practice Act, as amended.

"**Planned special exposure**" means an infrequent exposure to radiation, separate from and in addition to the annual dose limits.

"**Podiatrist**" means a person who is qualified to practice podiatry and is licensed under Title 24 **Delaware Code**, Chapter 5, Podiatry, as amended.

"**Positive pressure respirator**" means a respirator in which the pressure inside the respiratory inlet covering exceeds the ambient air pressure outside the respirator.

"**Powered air-purifying respirator (PAPR)**" means an air-purifying respirator that uses a blower to force the ambient air through air-purifying elements to the inlet covering.

"**Pressure demand respirator**" means a positive pressure atmosphere-supplying respirator that admits breathing air to the facepiece when the positive pressure is reduced inside the facepiece by inhalation.

"**Principal Supervisor**" means the State-Licensed Practitioner responsible for initiating use of x-ray equipment or other device generating ionizing radiation in the healing arts.

"**Protective apron**" means an apron made of radiation-attenuating materials used to reduce exposure to radiation.

"**Public dose**" means the dose received by a member of the public from exposure to sources of radiation released by the licensee or registrant, or to any other source of radiation under the control of the licensee or registrant. Public dose does not include occupational dose, or doses received from background radiation, from any medical administration the individual has received, from exposure to individuals administered radioactive material and released in accordance with U.S. Nuclear Regulatory Commission Regulations, or from voluntary participation in medical research programs.

"**Qualified expert**" means an individual who has satisfactorily fulfilled the training and experience requirements consistent with achieving a level of competency sufficient to function effectively in the position for which registration is sought. Such individuals must demonstrate to the satisfaction of the Agency their qualifications, for example, individuals certified in the appropriate field by the American Board of Radiology, or the American Board of Health Physics, or the American Board of Medical Physics, or those having equivalent qualifications. With reference to the calibration of radiation therapy equipment, an individual, in addition to the above qualifications, must be qualified in accordance with 4465 Part F and 4465 Part X of these regulations, as amended.

"**Qualified Medical Physicist**" means an individual qualified in accordance with Regulation 4465, Part X, Therapeutic Radiation Machines, Section 3.4, as amended.

"**Qualitative fit test (QLFT)**" means a pass/fail fit test to assess the adequacy of respirator fit that relies on the individual's response to the test agent.

"**Quality factor**" (Q) means the modifying factor, listed in Tables I and II of A.13, that is used to derive dose equivalent from absorbed dose.

"**Quantitative fit test (QNFT)**" means an assessment of the adequacy of respirator fit by numerically measuring the amount of leakage into the respirator.

"**Rad**" means the traditional unit of absorbed dose. One rad is equal to an absorbed dose of 100 erg per gram or 0.01 joule per kilogram (0.01 gray).

"**Radiation**" means alpha particles, beta particles, gamma rays, x rays, neutrons, high-speed electrons, high-speed protons, and other particles capable of producing ions. For purposes of these regulations, ionizing radiation is an equivalent term. Radiation, as used in these regulations, does not include non-ionizing radiation, such as radiowaves or microwaves, visible, infrared, or ultraviolet light.

"**Radiation area**" means any area, accessible to individuals, in which radiation levels could result in an individual receiving a dose equivalent in excess of 0.05 mSv (0.005 rem) in 1 hour at 30 centimeters from the source of radiation or from any surface that the radiation penetrates.

"**Radiation dose**" [See "**Dose**"].

"**Radiation machine**" means any device capable of producing ionizing radiation except those devices with radioactive material as the only source of radiation.

"**Radiation Safety Officer**" or RSO for a radiation machine facility means an individual assigned to perform RSO duties who has training and experience in the safe and effective use of radiation machines, their potential radiation hazards, and emergency precautions applicable to the type of activity or facility to which the RSO is assigned.

"**Radiation Technician**" means any individual who has not graduated from an approved program in radiation technology, but has passed an Authority approved examination.

"**Radiation Technologist**" means any individual who has successfully completed a JRCERT/JRCCVT approved program in radiation technology and has passed a national certification examination in his/her field of specialization.

"**Radiation Technology**" means the use of a radioactive substance or equipment emitting ionizing radiation on humans for diagnostic or therapeutic purposes.

"**Radioactive material**" means any solid, liquid or gas which emits radiation spontaneously.

"**Radioactivity**" means the transformation of unstable atomic nuclei by the emission of radiation.

"**Radiobioassay**" [See "**Bioassay**"].

"**Registrant**" means any person who is registered with the Agency and is legally obligated to register with the Agency pursuant to these regulations and the Act.

"**Registration**" means registration with the Agency in accordance with the regulations adopted by the Agency.

"**Regulations of the Department of Transportation**" means the regulations in 49 CFR Parts 100-189, as amended.

"**Rem**" means the traditional unit of any of the quantities expressed as dose equivalent. The dose equivalent in rem is equal to the absorbed dose in rad multiplied by the quality factor. (1 rem = 0.01 Sv)

"**Research and development**" means (1) theoretical analysis, exploration, or experimentation; or (2) the extension of investigative findings and theories of a scientific or technical nature into practical application for experimental and demonstration purposes, including the experimental production and testing of models, devices, equipment, materials, and processes. Research and development does not include the internal or external administration of radiation or radioactive material to human beings in the healing arts.

"**Residual radioactivity**" means radioactivity in structures, materials, soils, groundwater, and other media at a site resulting from activities under the licensee's control. This includes radioactivity from all licensed and unlicensed sources used by the licensee, but excludes background radiation. It also includes radioactive materials remaining at the site as a result of routine or accidental releases of radioactive materials at the site and previous burials at the site, even if those burials were made in accordance with the provisions of Part D of these regulations.

"**Restricted area**" means an area, access to which is limited by the licensee or registrant for the purpose of protecting individuals against undue risks from exposure to sources of radiation. Restricted area does not include areas used as residential quarters, but separate rooms in a residential building may be set apart as a restricted area.

"**Roentgen**" means the traditional unit of exposure. One roentgen (R) equals 2.58E-4 coulombs per kilogram of air (see "**Exposure**" and Part A.9.1 of this part.)

"**State Radiation Control Act**" or "**the Act**" means Title 16 **Delaware Code**, Chapter 74, Radiation Control, as amended.

"**Sealed source**" means any encapsulated radioactive material, which has been constructed in such a manner as to prevent the escape of any radioactive material.

"**Sealed Source and Device Registry (SSD)**" means the national registry that contains the registration certificates, maintained by the Nuclear Regulatory Commission (NRC), that summarize the radiation safety information for sealed sources and devices, and describe the licensing and use conditions approved for the product.

"**Self-contained breathing apparatus (SCBA)**" means an atmosphere-supplying respirator for which the breathing air source is designed to be carried by the user.

"**Shallow dose equivalent**" (Hs), which applies to the external exposure of the skin or an extremity, means the dose equivalent at a tissue depth of 0.007 centimeter (7 mg/cm2) averaged over the contiguous 10 square centimeters of skin receiving the highest exposure.

"**SI**" means the abbreviation for Standard Internationale, the International Metric System of Measurement.

"**Sievert**" means the Standard Internationale (SI) unit of any of the quantities expressed as dose equivalent. The dose equivalent in sievert is equal to the absorbed dose in gray multiplied by the quality factor. (1 Sv = 100 rem)

"**Source material**" means:

(1) Uranium or thorium, or any combination thereof, in any physical or chemical form; or

(2) Ores that contain by weight one-twentieth of 1 percent (0.05 percent) or more of uranium, thorium or any combination of uranium and thorium. Source material does not include special nuclear material.

"**Source material milling**" means any activity that results in the production of byproduct material as defined by definition (2) of byproduct material, of this part.

"**Source of radiation**" means any radioactive material or any device or equipment emitting, or capable of producing, radiation.

"**Source traceability**" means the ability to show that a radioactive source has been calibrated either by the national standards laboratory of the National Institute of Standards and Technology, or by a laboratory which participates in a continuing measurement quality assurance program with National Institute of Standards and Technology or other equivalent national or international program.

"**Special form radioactive material**" means radioactive material that satisfies the following conditions:

(1) It is either a single solid piece or is contained in a sealed capsule that can be opened only by destroying the capsule;

(2) The piece or capsule has at least one dimension not less than 5 millimeters (0.2 inch); and

(3) It satisfies the test requirements specified by the Nuclear Regulatory Commission. A special form encapsulation designed in accordance with the Nuclear Regulatory Commission requirements in effect on

June 30, 1983, and constructed prior to July 1, 1985, may continue to be used. A special form encapsulation either designed or constructed after June 30, 1985, must meet requirements of this definition applicable at the time of its design or construction.

"**Special nuclear material**" means:

(1) Plutonium, uranium-233, uranium enriched in the isotope 233 or in the isotope 235, and any other material that the Nuclear Regulatory Commission, pursuant to the provisions of section 51 of the Atomic Energy Act of 1954, as amended, determines to be special nuclear material, but does not include source material; or

(2) Any material artificially enriched by any of the foregoing but does not include source material.

"**Special nuclear material in quantities not sufficient to form a critical mass**" means uranium enriched in the isotope U-235 in quantities not exceeding 350 grams of contained U-235; uranium-233 in quantities not exceeding 200 grams; plutonium in quantities not exceeding 200 grams; or any combination of them in accordance with the following formula:

For each kind of special nuclear material, determine the ratio between the quantity of that special nuclear material and the quantity specified above for the same kind of special nuclear material.

The sum of such ratios for all of the kinds of special nuclear material in combination shall not exceed 1. For example, the following quantities in combination would not exceed the limitation and are within the formula:

$$\frac{175\ (\text{grams contained U-235})}{350} + \frac{50\ (\text{grams U-233})}{200} + \frac{50\ (\text{grams Pu})}{200} = 1$$

"**Standard Internationale (SI)**" means the international metric systems of measurement.

"**Supplied-air respirator (SAR)**" means an atmosphere-supplying respirator for which the source of breathing air is not designed to be carried by the user.

"**Survey**" means an evaluation of the radiological conditions and potential hazards incident to the production, use, transfer, release, disposal, or presence of sources of radiation. When appropriate, such evaluation includes, but is not limited to, tests, physical examinations, and measurements of levels of radiation or concentrations of radioactive material present.

"**Test**" means the process of verifying compliance with an applicable regulation.

"**These regulations**" means all parts of The Delaware Radiation Control Regulations 4465, as amended.

"**Tight-fitting facepiece**" means a respiratory inlet covering that forms a complete seal with the face.

"**Total effective dose equivalent**" (TEDE) means the sum of the deep dose equivalent for external exposures and the committed effective dose equivalent for internal exposures.

"**Total organ dose equivalent**" (TODE) means the sum of the deep dose equivalent and the committed dose equivalent to the organ receiving the highest dose as described in subsection 39.1.6 of these regulations.

"**Traceable to a National Standard**" [See "**Instrument traceability**" or "**Source traceability**"].

"**Unrefined and unprocessed ore**" means ore in its natural form prior to any processing such as grinding, roasting, beneficiating, or refining.

"**Unrestricted area**" means an area, access to which is neither limited nor controlled by the licensee or registrant. For purposes of these regulations, "**uncontrolled area**" is an equivalent term.

"**User seal check (fit check)**" means an action conducted by the respirator user to determine if the respirator is properly seated to the face. Examples include negative pressure check, positive pressure check, irritant smoke check, or isoamyl acetate check.

"**Very high radiation area**" means an area, accessible to individuals, in which radiation levels from radiation sources external to the body could result in an individual receiving an absorbed dose in excess of 500 rads (5 grays) in 1 hour at 1 meter from a source of radiation or 1 meter from any surface that the radiation penetrates.[8] 82/

"**Veterinarian**" shall mean a person who has received a degree in veterinary medicine from a school of veterinary medicine, per Title 24 **Delaware Code**, Chapter 33, Veterinarians, as amended.

"**Waste**" means those low-level radioactive wastes that are acceptable for disposal in a land disposal facility. For the purposes of this definition, low-level waste has the same meaning as in the Low-Level Radioactive Waste Policy Act, P.L. 96-573, as amended by P.L. 99-240, effective January 15, 1986; that is, radioactive waste (a)

8. ***2/*** At very high doses received at high dose rates, units of absorbed dose, gray and rad, are appropriate, rather than units of dose equivalent, sievert and rem.

not classified as high-level radioactive waste, spent nuclear fuel, or byproduct material as defined in Section 11e.(2) of the Atomic Energy Act, as amended (uranium or thorium tailings and waste) and (b) classified as low-level radioactive waste consistent with existing law and in accordance with (a) by the Nuclear Regulatory Commission.

"**Waste handling licensees**" mean persons licensed to receive and store radioactive wastes prior to disposal and/ or persons licensed to dispose of radioactive waste.

"**Week**" means 7 consecutive days starting on Sunday.

"**Whole body**" means, for purposes of external exposure, head, trunk including male gonads, arms above the elbow, or legs above the knee.

"**Worker**" means an individual engaged in activities under a license or registration issued by the Agency and controlled by a licensee or registrant, including but not limited to employees, but does not include the licensee or registrant.

"**Working level**" (WL) means any combination of short-lived radon daughters in 1 liter of air that will result in the ultimate emission of 1.3E+5 MeV of potential alpha particle energy. The short-lived radon daughters of radon-222 are polonium-218, lead-214, bismuth-214, and polonium-214; and those of radon-220 are polonium-216, lead-212, bismuth-212, and polonium-212.

"**Working level month**" (WLM) means an exposure to 1 working level for 170 hours. 2,000 working hours per year divided by 12 months per year is approximately equal to 170 hours per month.

"**Year**" means the period of time beginning in January used to determine compliance with the provisions of these regulations. The licensee or registrant may change the starting date of the year used to determine compliance by the licensee or registrant provided that the change is made at the beginning of the year. If a licensee or registrant changes in a year, the licensee or registrant shall assure that no day is omitted or duplicated in consecutive years.

4.0 Implementation.

4.1 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.

4.2 If a license or registration condition exempts a licensee or registrant from a provision of Part D in effect on or before the effective date of these regulations, it also exempts the licensee or registrant from the corresponding provision of Part D.

4.3 If a license or registration condition cites provisions of Part D in effect prior to the effective date of these 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.

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

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

Radiation Protection Programs

5.0 Radiation Protection Programs.

5.1 Each licensee or registrant shall develop, document, and implement a radiation protection program sufficient to ensure compliance with the provisions of Section 35.0 for recordkeeping requirements relating to these programs.

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

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

5.4 To implement the ALARA requirements of subsection 5.2, and notwithstanding the requirements in Section 13.0, a constraint on air emissions of radioactive material to the environment, excluding Radon-222 and its daughters, shall be established by licensees other than those subject to 10 CFR Part 50.34a of the USNRC regulations, such that the individual member of the public likely to receive the highest dose will not be expected to receive a total effective dose equivalent in excess of 0.1 millisievert (10 mrem) per year from these

emissions. If a licensee subject to this requirement exceeds this dose constraint, the licensee shall report the exceedance as provided in Section 47.0 and promptly take appropriate corrective action to ensure against recurrence.

Occupational Dose Limits

6.0 Occupational Dose Limits for Adults.

6.1 The licensee or registrant shall control the occupational dose to individual adults, except for planned special exposures pursuant to Section 10.0, to the following dose limits:

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

6.1.1.1 The total effective dose equivalent being equal to 0.05 Sievert (5 rem, or 5000 millirem); or

6.1.1.2 The sum of the deep dose equivalent and the committed dose equivalent to any individual organ or tissue other than the lens of the eye being equal to 0.5 Sievert (50 rem, or 50,000 millirem).

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

6.1.2.1 A lens dose equivalent of 0.15 Sievert (15 rem, or 15,000 millirem); and

6.1.2.2 A shallow dose equivalent of 0.5 Sievert (50 rem, or 50,000 millirem) to the skin or to any extremity.

6.2 Doses received in excess of the annual limits, including doses received during accidents, emergencies, and planned special exposures, shall be subtracted from the limits for planned special exposures that the individual may receive during the current year and during the individual's lifetime. See subsections 10.1.5.1 and 10.1.5.2.

6.3 The assigned deep dose equivalent and shallow dose equivalent shall be for the portion of the body receiving the highest exposure:

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

6.3.2 When a protective apron is worn while working with medical fluoroscopic equipment and monitoring is conducted as specified in subsection 17.1.1.5, the effective dose equivalent for external radiation shall be determined as follows:

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

6.3.2.2 When only one individual monitoring device is used and it is located at the neck (collar) outside the protective apron, and the reported dose exceeds 25 percent of the limit specified in subsection 6.1 the reported deep dose equivalent value multiplied by 0.30 shall be the effective dose equivalent for external radiation; or

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

6.4 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 Section 39.0.

6.5 In addition to 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.

6.6 The licensee or registrant shall reduce the dose that an individual may be allowed to receive in the current year by the amount of occupational dose received while employed by any other person during the current year. See Section 37.0.

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

7.1 If the licensee or registrant is required to monitor pursuant to both subsections 17.1.1 and 17.1.2 the licensee or registrant shall demonstrate compliance with the dose limits by summing external and internal doses. If the licensee or registrant is required to monitor only pursuant to subsection 17.1.1 or only pursuant to subsection 17.1.2, then summation is not required to demonstrate compliance with the dose limits. The licensee or

registrant may demonstrate compliance with the requirements for summation of external and internal doses pursuant to subsections 7.2, 7.3 and 7.4. The dose equivalents for the lens of the eye, the skin, and the extremities are not included in the summation, but are subject to separate limits.

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

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

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

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

7.3 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.

7.4 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.

8.0 Determination of External Dose from Airborne Radioactive Material.

8.1 Licensees or registrants shall, when determining the dose from airborne radioactive material, include the contribution to the deep dose equivalent, lense dose equivalent, and shallow dose equivalent from external exposure to the radioactive cloud. See Appendix B, footnotes a/ and b/.

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

9.0 Determination of Internal Exposure.

9.1 For purposes of assessing dose used to determine compliance with occupational dose equivalent limits, the licensee or registrant shall, when required pursuant to Section 17.0, take suitable and timely measurements of:

9.1.1 Concentrations of radioactive materials in air in work areas;

9.1.2 Quantities of radionuclides in the body;

9.1.3 Quantities of radionuclides excreted from the body; or

9.1.4 Combinations of these measurements.

9.2 Unless respiratory protective equipment is used, as provided in Section 24.0, 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.

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

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

9.3.2 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

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

9.4 If the licensee or registrant chooses to assess intakes of Class Y material using the measurements given in 9.1.2 or 9.1.3, the licensee or registrant may delay the recording and reporting of the assessments for periods up to 7 months, unless otherwise required by Sections 46.0 or 47.0. This delay permits the licensee or registrant to make additional measurements basic to the assessments.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:

9.4.1 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

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

9.5 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.

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

9.6.1 The licensee or registrant uses the total activity of the mixture in demonstrating compliance with the dose limits in Section 6.0 and in complying with the monitoring requirements in subsection 7.2;

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

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

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

9.7.1 In order to calculate the committed effective dose equivalent, the licensee or registrant may assume that the inhalation of one ALI, or an exposure of 2,000 DAC- hours, results in a committed effective dose equivalent of 0.05 Sievert (5 rem, or 5000 millirem) for radionuclides that have their ALIs or DACs based on the committed effective dose equivalent;

9.7.2 For an ALI and the associated DAC determined by the nonstochastic organ dose limit of 0.5 Sievert (50 rem, or 50,000 millirem), the intake of radionuclides that would result in a committed effective dose equivalent of 0.05 Sievert (5 rem, or 5000 millirem), that is, the stochastic ALI, is listed in parentheses in Table I of Appendix B. The licensee or registrant may, as a simplifying assumption, use the stochastic ALI to determine committed effective dose equivalent. However, if the licensee or registrant uses the stochastic ALI, the licensee or registrant shall also demonstrate that the limit in subsection 6.1.1.2 is met.

10.0 Planned Special Exposures.

10.1 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 Section 6.0 provided that each of the following conditions is satisfied:

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

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

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

10.1.3.1 Informed of the purpose of the planned operation;

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

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

10.1.4 Prior to permitting an individual to participate in a planned special exposure, the licensee or registrant ascertains prior doses as required by subsection 37.2 during the lifetime of the individual for each individual involved;

10.1.5 Subject to subsection 6.2, the licensee or registrant shall not authorize a planned special exposure that would cause an individual to receive a dose from all planned special exposures and all doses in excess of the limits to exceed:

10.1.5.1 The numerical values of any of the dose limits in subsection 6.1 in any year; and

10.1.5.2 Five times the annual dose limits in subsection 6.1 during the individual's lifetime;

10.1.6 The licensee or registrant maintains records of the conduct of a planned special exposure in accordance with Section 38.0 and submits a written report in accordance with Section 48.0;

10.1.7 The licensee or registrant records the best estimate of the dose resulting from the planned special exposure in the individual's record and informs the individual, in writing, of the dose within 30 days from the date of the planned special exposure. The dose from planned special exposures shall not be considered in

controlling future occupational dose of the individual pursuant to subsection 6.1 but shall be included in evaluations required by subsections 10.1.4 and 10.1.5.

11.0 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 Section 6.0.

12.0 Dose Equivalent to an Embryo/Fetus.

12.1 The licensee or registrant shall ensure that the dose equivalent to an embryo/fetus during the entire pregnancy, due to occupational exposure of a declared pregnant woman, does not exceed 5 millisievert (0.5 rem, or 500 millirem). See subsection 39.4 for recordkeeping requirements. See Appendix D for "Sample Letter for Declaring Pregnancy - Confidential, Protected Health Information".

12.2 The licensee or registrant shall make efforts to avoid substantial variation*/ above a uniform monthly exposure rate to a declared pregnant woman so as to satisfy the limit in subsection 12.1.

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

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

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

12.4 If the dose equivalent to the embryo/fetus is found to have exceeded 5 millisieverts (0.5 rem, or 500 millirem), or is within 0.5 millisieverts (0.05 rem, or 50 millirem) of this dose, by the time the woman declares the pregnancy to the licensee or registrant, the licensee or registrant shall be deemed to be in compliance with subsection 12.1. if the additional dose to the embryo/fetus does not exceed 0.5 millisievert (0.05 rem, or 50 millirem) during the remainder of the pregnancy.

Radiation Dose Limits for Individual Members of the Public

13.0 Dose Limits for Individual Members of the Public.

13.1 Each licensee or registrant shall conduct operations so that:

13.1.1 The total effective dose equivalent to individual members of the public from the licensed or registered operation does not exceed 1 millisievert (0.1 rem, or 100 millirem) in a year, exclusive of the dose contribution from background radiation, from any medical administration the individual has received, from exposure to individuals administered radioactive material and released in accordance with their health care providers ALARA license conditions, from voluntary participation in medical research programs, and from the licensee's or registrant's disposal of radioactive material into sanitary sewerage in accordance with **D.2003;****/ and

13.1.2 The dose in any unrestricted area from external sources exclusive of the dose contributions from patients administered radioactive material and released in accordance with their health care providers ALARA license conditions, does not exceed 0.02 millisievert (0.002 rem, or 2 millirem) in any one hour; and

*/ 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 millisievert (0.05 rem) to the embryo/fetus be received in any one month.

**/ Retrofit shall not be required for locations within facilities where only radiation machines existed prior to the effective date of these regulations and met the previous requirements of 5 millisievert (0.5 rem) in a year

13.2 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.

13.3 A licensee, registrant, or an applicant for a license or registration may apply for prior Agency authorization to operate up to an annual dose limit for an individual member of the public of 5 millisievert (0.5 rem, or 500 millirem). This application shall include the following information:

13.3.1 Demonstration of the need for and the expected duration of operations in excess of the limit in subsection 13.1;

13.3.2 The licensee's or registrant's program to assess and control dose within the 5 millisieverts (0.5 rem or 500 millirem) annual limit; and

13.3.3 The procedures to be followed to maintain the dose as low as is reasonably achievable (ALARA).

13.4 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.

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

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

14.1 The licensee or registrant shall make or cause to be made surveys of radiation levels in unrestricted areas and radioactive materials in effluents released to unrestricted areas to demonstrate compliance with the dose limits for individual members of the public in Section 13.0

14.2 A licensee or registrant shall show compliance with the annual dose limit in Section 13.0 by:

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

14.2.2 Demonstrating that:

14.2.2.1 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

14.2.2.2 If an individual were continuously present in an unrestricted area, the dose from external sources would not exceed 0.02 millisievert (0.002 rem, or 2 millirem) in an hour and 0.5 millisievert (0.05 rem, or 50 millirem) in a year.

14.3 Upon approval from the Agency, the licensee or registrant may adjust the effluent concentration values in Appendix B, Table II, for members of the public, to take into account the actual physical and chemical characteristics of the effluents, such as aerosol size distribution, solubility, density, radioactive decay equilibrium, and chemical form.

Testing for Leakage or Contamination of Sealed Sources

15.0 Testing for Leakage or Contamination of Sealed Sources.

The licensee or registrant in possession of any sealed source shall perform leak testing of sealed sources in accordance with their radioactive material license conditions.

Surveys and Monitoring

16.0 General.

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

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

16.1.2 Are necessary under the circumstances to evaluate:

16.1.2.1 The magnitude and extent of radiation levels;

16.1.2.2 Concentrations or quantities of radioactive material; and

16.1.2.3 The potential radiological hazards.

16.2 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 these regulations or a license condition.

16.3 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 Section 6.0, with other applicable provisions of these regulations, or with conditions specified in a license or registration shall be processed and evaluated by a dosimetry processor:

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

16.3.2 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.

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

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

17.1 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:

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

17.1.1.1 Adults likely to receive, in 1 year from sources external to the body, a dose in excess of 10 percent of the limits in subsection 6.1;

17.1.1.2 Minors likely to receive, in 1 year from sources external to the body, a deep dose equivalent in excess of 1 millisievert (0.1 rem, or 100 millirem), a lens dose equivalent in excess of 1.5 millisievert (0.15 rem, or 150 millirem), or a shallow dose equivalent to the skin or to the extremities in excess of 5 millisievert (0.5 rem, or 500 millirem);

17.1.1.3 Declared pregnant women likely to receive during the entire pregnancy, from radiation sources external to the body, a deep dose equivalent in excess of 1 millisievert (0.1 rem, or 100 millirem);

17.1.1.4 Individuals entering a high or very high radiation area; and

17.1.1.5 Individuals working with medical fluoroscopic equipment.

17.1.1.5.1 An individual monitoring device used for the dose to an embryo/fetus of a declared pregnant woman, pursuant to subsection 12.1, shall be located under the protective apron at the waist.

17.1.1.5.2 An individual monitoring device used for lense dose equivalent shall be for external radiation pursuant to subsection 6.3.2, it shall be located at the neck (collar) 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.

17.1.2 Each licensee or registrant shall monitor, to determine compliance with Section 9.0, the occupational intake of radioactive material by and assess the committed effective dose equivalent to:

17.1.2.1 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;

17.1.2.2 Minors likely to receive, in 1 year, a committed effective dose equivalent in excess of 0.1 millisievert (0.01 rem, or 100 millirem); and

17.1.2.3 Declared pregnant women likely to receive, during the entire pregnancy, a committed dose equivalent in excess of 1 millisievert (0.1 rem, or 100 millirem).

18.0 Location of Individual Monitoring Devices.

18.1 Each licensee or registrant shall ensure that individuals who are required to monitor occupational doses in accordance with subsection 17.1.1 wear individual monitoring devices as follows:

18.1.1 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);

18.1.2 An individual monitoring device used for monitoring the dose to an embryo/fetus of a declared pregnant woman, pursuant to subsection 12.1, shall be located at the waist under any protective apron being worn by the woman;

18.1.3 An individual monitoring device used for monitoring the lens dose equivalent, to demonstrate compliance with subsection 6.1.2.1, 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;

18.1.4 An individual monitoring device used for monitoring the dose to the extremities, to demonstrate compliance with subsection 6.1.2.2, 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

19.0 Control of Access to High Radiation Areas.

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

19.1.1 A control device that, upon entry into the area, causes the level of radiation to be reduced below that level at which an individual might receive a deep dose equivalent of 1 millisievert (0.1 rem, or 100 millirem) in 1 hour at 30 centimeters from the source of radiation or from any surface that the radiation penetrates;

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

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

19.2 In place of the controls required by subsection 19.1 for a high radiation area, the licensee or registrant may substitute continuous direct or electronic surveillance that is capable of preventing unauthorized entry.

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

19.4 The licensee or registrant shall establish the controls required by subsections 19.1 and 19.3 in a way that does not prevent individuals from leaving a high radiation area.

19.5 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.

19.6 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 Section 19.0 if the registrant has met all the specific requirements for access and control specified in other applicable Parts of these regulations, such as, Part E for industrial radiography, Part F for X-rays in the healing arts, and Part I for particle accelerators.

20.0 Control of Access to Very High Radiation Areas.

20.1 In addition to the requirements in Section 19.0, 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 gray (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.

20.2 The registrant is not required to control entrance or access to rooms or other areas containing sources of radiation capable of producing a very high radiation area as described in subsection 20.1. if the registrant has met all the specific requirements for access and control specified in other applicable Parts of these regulations, such as, Part E for industrial radiography, Part F for X-rays in the healing arts, and Part I for particle accelerators.

21.0 Control of Access to Very High Radiation Areas – Irradiators.

21.1 Section 21.0 applies to licensees or registrants with sources of radiation in non-self- shielded irradiators. Section 21.0 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.

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

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

21.2.1.1 Function automatically to prevent any individual from inadvertently entering a very high radiation area;

21.2.1.2 Permit deliberate entry into the area only after a control device is actuated that causes the radiation level within the area, from the source of radiation, to be reduced below that at which it would be possible for an individual to receive a deep dose equivalent in excess of 1 millisievert (0.1 rem, or 100 millirem) in 1 hour; and

21.2.1.3 Prevent operation of the source of radiation if it would produce radiation levels in the area that could result in a deep dose equivalent to an individual in excess of 1 millisievert (0.1 rem, or 100 millirem) in 1 hour.

21.2.2 Additional control devices shall be provided so that, upon failure of the entry control devices to function as required by subsection 21.2.1:

21.2.2.1 The radiation level within the area, from the source of radiation, is reduced below that at which it would be possible for an individual to receive a deep dose equivalent in excess of 1 millisievert (0.1 rem, or 100 millirem) in 1 hour; and

21.2.2.2 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.

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

21.2.3.1 The radiation level from the source of radiation is reduced below that at which it would be possible for an individual to receive a deep dose equivalent in excess of 1 millisievert (0.1 rem, or 100 millirem) in 1 hour; and

21.2.3.2 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.

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

21.2.5 Physical radiation barriers that comprise permanent structural components, such as walls, that have no credible probability of failure or removal in ordinary circumstances need not meet the requirements of subsections 21.2.3 and 21.2.4.

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

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

21.2.8 Each area shall be checked by a radiation measurement to ensure that, prior to the first individual's entry into the area after any use of the source of radiation, the radiation level from the source of radiation in the area is below that at which it would be possible for an individual to receive a deep dose equivalent in excess of 1 millisievert (0.1 rem or 100 millirem) in 1 hour.

21.2.9 The entry control devices required in subsection 21.2.1 shall be tested for proper functioning. See Section 42.0 for recordkeeping requirements.

21.2.9.1 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;

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

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

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

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

21.3 Licensees, registrants, or applicants for licenses or registrations for sources of radiation within the purview of subsection 21.2 which will be used in a variety of positions or in locations, such as open fields or forests, that make it impracticable to comply with certain requirements of subsection 21.2, 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 subsection 21.2. At least one of the alternative measures shall include an entry-preventing interlock control based on a measurement of the radiation that ensures the absence of high radiation levels before an individual can gain access to the area where such sources of radiation are used.

21.4 The entry control devices required by subsections 21.2 and 21.3 shall be established in such a way that no individual will be prevented from leaving the area.

Respiratory Protection and Controls to Restrict Internal Exposure in Restricted Areas

22.0 Use of Process or Other Engineering Controls.

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

23.0 Use of Other Controls.

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

23.1.1 Control of access;

23.1.2 Limitation of exposure times;

23.1.3 Use of respiratory protection equipment; or

23.1.4 Other controls.

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

24.0 Use of Individual Respiratory Protection Equipment.

24.1 If the licensee or registrant uses respiratory protection equipment to limit intakes pursuant to Section 23.0:

24.1.1 Except as provided in subsection 24.1.2, the licensee or registrant shall use only respiratory protection equipment that is tested and certified by the National Institute for Occupational Safety and Health;

24.1.2 If the licensee or registrant wishes to use equipment that has not been tested or certified by the National Institute for Occupational Safety and Health, or for which there is no schedule for testing or certification, the licensee shall submit an application to the Agency for authorized use of this equipment, except as otherwise noted in this Part. The application must include evidence that the material and performance characteristics of the equipment are capable of providing the proposed degree of protection under anticipated conditions of use. This must be demonstrated either by the licensee's or registrant's testing or on the basis of reliable test information;

24.1.3 The licensee or registrant shall implement and maintain a respiratory protection program that includes:

24.1.3.1 Air sampling sufficient to identify the potential hazard, permit proper equipment selection, and estimate doses;

24.1.3.2 Surveys and bioassays, as necessary, to evaluate actual intakes;

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

24.1.3.4 Written procedures regarding:

24.1.3.4.1 Monitoring, including air sampling and bioassays;

24.1.3.4.2 Supervision and training or respirator users;

24.1.3.4.3 Fit testing;

24.1.3.4.4 Respirator selection;

24.1.3.4.5 Breathing air quality;

24.1.3.4.6 Inventory and control;

24.1.3.4.7 Storage, issuance, maintenance, repair, testing, and quality assurance of respiratory protection equipment;

24.1.3.4.8 Recordkeeping; and

24.1.3.4.9 Limitations on periods of respirator use and relief from respirator use.

24.1.3.5 Determination by a physician that the individual user is medically fit to use the respiratory protection equipment before:

24.1.3.5.1 The initial fitting of a face sealing respirator;

24.1.3.5.2 Before the first field use of non- face sealing respirators, and

24.1.3.5.3 Either every 12 months thereafter, or periodically at a frequency determined by a physician.

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

24.1.4 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.

24.1.5 The licensee or registrant shall also consider limitations appropriate to the type and mode of use. When selecting respiratory devices the licensee or registrant shall provide for vision correction, adequate communication, low temperature work environments and the concurrent use of other safety or radiological protection equipment. The licensee or registrant shall use equipment in such a way as not to interfere with the proper operation of the respirator.

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

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

24.1.7.1 Oxygen content (v/v) of 19.5-23.5%;

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

24.1.7.3 Carbon Monoxide (CO) content of 10 ppm or less;

24.1.7.4 Carbon Dioxide content of 1,000 ppm or less; and

24.1.7.5 Lack of noticeable odor.

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

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

25.0 Further Restrictions on the Use of Respiratory Protection Equipment.

25.1 The Agency may impose restrictions in addition to the provisions of Sections 23.0 and 24.0, and Appendix A of this Part, in order to:

25.1.1 Ensure that the respiratory protection program of the licensee is adequate to limit doses to individuals from intakes of radioactive materials consistent with maintaining total effective dose equivalent ALARA; and

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

26.0 Application for use of Higher Assigned Protection Factors.

26.1 The licensee or registrant shall obtain authorization from the Agency before using assigned 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:

26.1.1 Describes the situation for which a need exists for higher protection factors; and

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

Storage and Control of Licensed or Registered Sources of Radiation

27.0 Security and Control of Licensed or Registered Sources of Radiation.

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

27.2 The licensee or registrant shall maintain constant surveillance, and use engineering controls or 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.

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

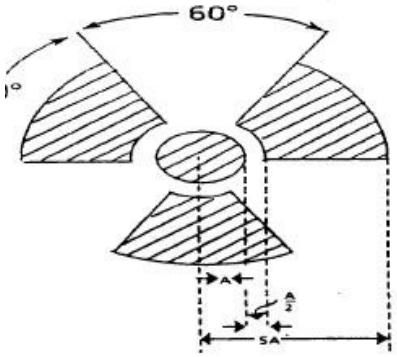
27.4 The registrant shall use devices or administrative procedures to prevent unauthorized use of registered radiation machines.

Precautionary Procedures

28.0 Caution Signs.

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

Figure 1. Radiation Symbol.



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

28.2 Exception to Color Requirements for Standard Radiation Symbol. Notwithstanding the requirements of subsection 28.1, licensees or registrants are authorized to label sources, source holders, or device components containing sources of radiation that are subjected to high temperatures, with conspicuously etched or stamped radiation caution symbols and without a color requirement.

28.3 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.

29.0 Posting Requirements.

29.1 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."

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

29.3 Posting of Very High Radiation Areas. The licensee or registrant shall post each very high radiation area with a conspicuous sign or signs bearing the radiation symbol and words " DANGER, VERY HIGH RADIATION AREA."

29.4 Posting of Airborne Radioactivity Areas. The licensee or registrant shall post each airborne radioactivity area with a conspicuous sign or signs bearing the radiation symbol and the words "CAUTION, AIRBORNE RADIOACTIVITY AREA" or "DANGER, AIRBORNE RADIOACTIVITY AREA."

29.5 Posting of Areas or Rooms in which Licensed or Registered Material is Used or Stored. The licensee or registrant shall post each area or room in which there is used or stored an amount of licensed or registered material exceeding 10 times the quantity of such material specified in Appendix C with a conspicuous sign or signs bearing the radiation symbol and the words "CAUTION, RADIOACTIVE MATERIAL(S)" or "DANGER, RADIOACTIVE MATERIAL(S)."

30.0 Exceptions to Posting Requirements.

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

30.1.1 The sources of radiation are constantly attended during these periods by an individual who takes the precautions necessary to prevent the exposure of individuals to sources of radiation in excess of the limits established in Part D; and

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

30.2 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 millisievert (0.005 rem or 5 millirem) per hour.

30.3 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.

30.4 Rooms in hospitals or clinics that are used for teletherapy are exempt from the requirement to post caution signs under Section 29.0 if:

30.4.1 Access to the room is controlled pursuant to the providers ALARA license conditions; and

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

31.0 Labeling of Radiation Machines.

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.

32.0 Exemptions to Labeling Requirements for Radiation Machines.

32.1 A licensee or registrant is not required to label radiation machines if:

32.1.1 The area or room is subject to the licensee's or registrant's control and precautions are taken to prevent the exposure of individuals to sources of radiation in excess of the limits established in Part D.

Waste Disposal

33.0 General Requirements.

Compliance with Environmental and Health Protection Regulations. Nothing in these regulations relieves the licensee or registrant from complying with other applicable Federal, State and local regulations governing any other toxic or hazardous properties of materials disposed of by the licensee or registrant.

Records

34.0 General Provisions.

34.1 Each licensee or registrant shall use the Standard Internationale (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.

34.2 The licensee or registrant shall make a clear distinction among the quantities entered on the records required by Part D, such as, total effective dose equivalent shallow dose equivalent, lens dose equivalent, deep dose equivalent, or committed effective dose equivalent.

35.0 Records of Radiation Protection Programs.

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

35.1.1 The provisions of the program; and

35.1.2 Audits and other reviews of program content and implementation.

35.2 The licensee or registrant shall retain the records required by subsection 35.1.1 until the Agency terminates each pertinent license or registration requiring the record. The licensee or registrant shall retain the records required by subsection 35.1.2 for 3 years after the record is made.

36.0 Records of Surveys.

36.1 Each licensee or registrant shall maintain records showing the results of surveys and calibrations required by Section 16.0. The licensee or registrant shall retain these records for 3 years after the record is made.

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

36.2.1 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 dose equivalents;

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

36.2.3 Records showing the results of air sampling, surveys, and bioassays required pursuant to subsections 24.1.3.1 and 24.1.3.2; and

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

37.0 Determination and Records of Prior Occupational Dose.

37.1 For each individual who is likely to receive, in a year, an occupational dose requiring monitoring pursuant to Section 17.0, the licensee or registrant shall:

37.1.1 Determine the occupational radiation dose received during the current year; and

37.1.2 Attempt to obtain the records of cumulative occupational radiation dose.

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

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

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

37.3 In complying with the requirements of subsection 37.1, a licensee or registrant may:

37.3.1 Accept, as a record of the occupational dose that the individual received during the current year, a written signed statement from the individual, or from the individual's most recent employer for work involving radiation exposure, that discloses the nature and the amount of any occupational dose that the individual received during the current year; and

37.3.2 Accept, as the record of cumulative radiation dose, an up-to-date Agency Form Y (Part J, Appendix B) 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.

37.3.3 Obtain reports of the individual's dose equivalent(s) 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, email, facsimile, other electronic media 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.

37.4 The licensee or registrant shall record the exposure history, as required by subsection 37.1, on Agency Form Y, (Part J, Appendix B) or other clear and legible record, of all the information required on that form.

37.4.1 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 (Part J, Appendix B) 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.

37.4.2 For the purposes of complying with this requirement, licensees or registrants are not required to partition historical dose between external dose equivalent(s) and internal committed dose equivalent(s). Further,

occupational exposure histories obtained and recorded on Agency Form Y (Part J, Appendix B) or equivalent before July 10, 2002, would not have included effective dose equivalent, but may be used in the absence of specific information on the intake of radionuclides by the individual.

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

37.5.1 In establishing administrative controls pursuant to subsection 6.6 for the current year, that the allowable dose limit for the individual is reduced by 12.5 millisievert (1.25 rem, or 1250 millirem) for each quarter for which records were unavailable and the individual was engaged in activities that could have resulted in occupational radiation exposure; and

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

37.6 The licensee or registrant shall retain the records on Agency Form Y (Part J, Appendix B) 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 (Part J, Appendix B) or equivalent for 3 years after the record is made.

37.7 Upon termination of the license or registration, the licensee or registrant shall permanently store records on Agency Form Y (Part J, Appendix B) or equivalent, or shall make provision with the Agency for transfer to the Agency.

38.0 Records of Planned Special Exposures.

38.1 For each use of the provisions of Section 10.0 for planned special exposures, the licensee or registrant shall maintain records that describe:

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

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

38.1.3 What actions were necessary;

38.1.4 Why the actions were necessary;

38.1.5 What precautions were taken to assure that doses were maintained ALARA;

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

38.1.7 The doses actually received in the planned special exposure.

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

38.3 Upon termination of the license or registration, the licensee or registrant shall permanently store records on Agency Form Y (Part J, Appendix B) or equivalent, or shall make provision with the Agency for transfer to the Agency.

39.0 Records of Individual Monitoring Results.

39.1 Recordkeeping Requirement. Each licensee or registrant shall maintain records of doses received by all individuals for whom monitoring was required pursuant to Section 17.0, and records of doses received during planned special exposures, accidents, and emergency conditions. Assessments of dose equivalent and records made using units in effect before need not be changed. These records shall include, when applicable:

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

39.1.2 The estimated intake of radionuclides, see Section 7.0;

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

39.1.4 The specific information used to calculate the committed effective dose equivalent pursuant to subsections 9.1 and 9.3 and when required by Section 17.0;

39.1.5 The total effective dose equivalent when required by Section 7.0; and

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

39.2 Recordkeeping Frequency. The licensee or registrant shall make entries of the records specified in subsection 39.1 at intervals not to exceed 1 year.

39.3 Recordkeeping Format. The licensee or registrant shall maintain the records specified in subsection 39.1 on Agency Form Z (Part J, Appendix C), in accordance with the instructions for Agency Form Z (Part J, Appendix C), or in clear and legible records containing all the information required by Agency Form Z (Part J, Appendix C).

39.4 The licensee or registrant shall maintain the records of dose to an embryo/fetus with the records of dose to the declared pregnant woman. The declaration of pregnancy, including the estimated date of conception, shall also be kept on file, but must be maintained as confidential records, accessible only to the registrant or licensee Radiation Safety Officer, the declared pregnant woman, and medical personnel authorized to access her confidential health records.

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

39.6 Upon termination of the license or registration, the licensee or registrant shall permanently store records on Agency Form Y (Part J, Appendix B) or equivalent, or shall make provision with the Agency for transfer to the Agency.

40.0 Records of Dose to Individual Members of the Public.

40.1 Each licensee or registrant shall maintain records sufficient to demonstrate compliance with the dose limit for individual members of the public. See Section 13.0.

40.2 The licensee or registrant shall retain the records required by subsection 40.1 until the Agency terminates each pertinent license or registration requiring the record.

41.0 Records of Waste Disposal.

Compliance with Environmental and Health Protection Regulations. Nothing in these regulations 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 by the licensee or registrant.

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

42.1 Each licensee or registrant shall maintain records of tests made pursuant to subsection 21.2.9 on entry control devices for very high radiation areas. These records must include the date, time, and results of each such test of function.

42.2 The licensee or registrant shall retain the records required by subsection 42.1 for 3 years after the record is made.

43.0 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.

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

Records of tests for leakage or contamination of sealed sources required by Section 15.0 shall be kept on file in accordance with the facility radioactive material license.

Reports

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

45.1 Telephone Reports. Each licensee or registrant shall report to the Agency by telephone immediately after its occurrence becomes known to the registrant, any stolen, lost, or missing radiation machine.

45.2 Written Reports. Each licensee or registrant required to make a report pursuant to subsection 45.1 shall, within 30 days after making the telephone report, make a written report to the Agency setting forth the following information:

45.2.1 A description of the licensed or registered source of radiation involved, including, for radiation machines, the manufacturer, model and serial number, type and maximum energy of radiation emitted;

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

45.2.3 A statement of disposition, or probable disposition, of the registered source of radiation involved;

45.2.4 Exposures of individuals to radiation, and circumstances under which the exposures occurred;

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

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

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

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

46.0 Notification of Incidents.

46.1 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:

46.1.1 An individual to receive:

46.1.1.1 A total effective dose equivalent of 0.25 sievert (25 rem, or 25,000 millirem) or more;

46.1.1.2 A lense dose equivalent of 0.75 sievert (75 rem, or 75,000 millirem) or more; or

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

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

46.2 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:

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

46.2.1.1 A total effective dose equivalent exceeding 0.05 sievert (5 rem, or 5000 millirem);

46.2.1.2 A lense dose equivalent exceeding 0.15 sievert (15 rem, or 15,000 millirem);

46.2.1.3 A shallow dose equivalent to the skin or extremities or a total organ dose equivalent exceeding 0.5 sievert (50 rem, or 50,000 millirem); or

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

46.3 Licensees or registrants shall make the reports required by subsections 46.1 and 46.2 by initial contact by telephone to the Agency and shall confirm the initial contact immediately by email, express mail or facsimile to the Agency. The Agency shall reply to the written notification within 24 hours to discuss timing of follow-up action by the Agency.

46.4 The licensee or registrant shall prepare each report filed with the Agency pursuant to Section 46.0 so that names of individuals who have received exposure to sources of radiation are stated in a separate and detachable portion of the report.

46.5 The provisions of Section 46.0 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 Section 48.0.

47.0 Reports of Exposures, Radiation Levels, and Concentrations of Radioactive Material Exceeding the Limits.

47.1 Reportable Events. In addition to the notification required by Section 46.0, each licensee or registrant shall submit a written report within 30 days after learning of any of the following occurrences:

47.1.1 Incidents for which notification is required by Section 46.0; or

47.1.2 Doses in excess of any of the following:

47.1.2.1 The occupational dose limits for adults in Section 6.0;

47.1.2.2 The occupational dose limits for a minor in Section 11.0;

47.1.2.3 The limits for an embryo/fetus of a declared pregnant woman in Section 12.0;

47.1.2.4 The limits for an individual member of the public in Section 13.0;

47.1.2.5 Any applicable limit in the license or registration; or

47.1.2.6 The ALARA constraints for air emissions established under subsection 5.4

47.1.3 Level of radiation or concentrations of radioactive material in:

47.1.3.1 A restricted area in excess of applicable limits in the license or registration; or

47.1.3.2 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 Section 13.0; or

47.1.4 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.

47.2 Contents of Reports.

47.2.1 Each report required by subsection 47.1 shall describe the extent of exposure of individuals to radiation and radioactive material, including, as appropriate:

47.2.1.1 Estimates of each individual's dose;

47.2.1.2 The levels of radiation and concentrations of radioactive material involved;

47.2.1.3 The cause of the elevated exposures, dose rates, or concentrations; and

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

47.2.2 Each report filed pursuant to subsection 47.1 shall include for each occupationally overexposeda/ individual: the name, unique identification number such as employee or Social Security number, and date of birth. With respect to the limit for the embryo/fetus in Section 12.0, 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.

47.3 All licensees or registrants who make reports pursuant to subsection 47.1 shall submit the report in writing to the Agency.

48.0 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 Section 10.0, informing the Agency that a planned special exposure was conducted and indicating the date the planned special exposure occurred and the information required by Section 38.0.

49.0 Reports to Individuals of Exceeding Dose Limits.

When a licensee or registrant is required, pursuant to Sections 47.0, 48.0, or D.2206 to report to the Agency any exposure of an identified occupationally exposed individual, or an identified member of the public, to radiation or radioactive material, the licensee shall also provide a copy of the report submitted to the Agency to the individual. This report must be transmitted at a time no later than the transmittal to the Agency.

50.0 Notifications and Reports to Individuals.

50.1 Requirements for notification and reports to individuals of exposure to radiation or radioactive material are specified in Part J, Section 4.0 of these regulations.

50.2 When a licensee or registrant is required pursuant to Section 47.0 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 Part J, Subsection 4.1 of these regulations.

Additional Requirements

51.0 Vacating Premises.

Each specific licensee or registrant in possession of a radiation source 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.

a/ The Agency may require as a license condition, or by rule, regulation, or order pursuant to Section A.6.0 of these 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 level

A PDF version of Appendices A-F for Part D is available here:
http://regulations.delaware.gov/register/august2015/final/4465 PART D APPENDICES A-F.pdf

Part J

NOTICES, INSTRUCTIONS, AND REPORTS TO WORKERS; INSPECTIONS

Sec. J.1 Purpose and Scope. This Part establishes requirements for notices, instructions and reports by licensees or registrants to individuals engaged in activities under a license or registration and options available to such individuals in connection with Agency inspections of licensees or registrants to ascertain compliance with the provisions of the Act and regulations, orders, and licenses issued thereunder regarding radiological working conditions. The regulations in this Part apply to all persons who receive, possess, use, own, or transfer sources of radiation registered with or licensed by the Agency pursuant to Parts B and C of the regulations.

General Regulatory Provisions and Specific Requirements

Sec. J.11 Posting of Notices to Workers

a. Each licensee or registrant shall post current copies of the following documents:

i. The regulations in this Part and in Part D of the regulations;

ii. The license, certificate of registration, conditions or documents incorporated into the license by reference and amendments thereto;

iii. The operating procedures applicable to activities under the license or registration; and

iv. Any notice of violation involving radiological working conditions, proposed imposition of civil penalty, or order issued pursuant to Part A and K of the regulations, and any response from the licensee or registrant.

b. If posting of a document specified in J.11a.i., ii., or iii. is not practicable, the licensee or registrant may post a notice which describes the document and states where it may be examined.

c. Agency Form X "Notice to Employees" shall be posted by each licensee or registrant as required by the regulations.

d. Agency documents posted pursuant to J.11a.iv. shall be posted within five working days after receipt of the documents from the Agency; the licensee's or registrant's response, if any, shall be posted within five working days after dispatch from the licensee or registrant. Such documents shall remain posted conspicuously until the violation has been completed.

e. Documents, notices, or forms posted pursuant to J.11 shall appear in a sufficient number of places to permit individuals engaged in work under the license or registration to observe them on the way to or from any particular work location to which the document applies, shall be conspicuous, and shall be replaced if defaced or altered.

Sec. J.12 Instructions to Workers

a. All individuals likely to receive an occupational dose:

i. Shall be kept informed of the storage, transfer, or use of sources of radiation in the licensee's or registrant's workplace;

ii. Shall be instructed in the health protection problems associated with exposure to radiation or radioactive material to the individual and potential offspring, in precautions or procedures to minimize exposure, and in the purposes and functions of protective devices employed;

iii. Shall be instructed in, and instructed to observe, to the extent within the worker's control, the applicable provisions of the regulations and licenses for the protection of personnel from exposures to radiation or radioactive material;

iv. Shall be instructed of their responsibility to report promptly to the licensee or registrant any condition which may constitute, lead to, or cause a violation of the Act, the regulations, or license condition, or any unnecessary exposure to radiation or radioactive material;

v. Shall be instructed in the appropriate response to warnings made in the event of any unusual occurrence or malfunction that may involve exposure to radiation or radioactive material; and

vi. Shall be advised as to the radiation exposure reports which workers shall be furnished pursuant to J.13.

b. The extent of these instructions shall be commensurate with potential radiological health protection problems present in the workplace.

Sec. J.13 Notifications and Reports to Individuals

a. Radiation exposure data for an individual and the results of any measurements, analyses, and calculations of radioactive material deposited or retained in the body of an individual shall be reported to the individual as specified in J.13. The information reported shall include data and results obtained pursuant to the regulations, orders, or license conditions,

as shown in records maintained by the licensee or registrant pursuant to D.1107 of the regulations. Each notification and report shall:

i. Be in writing;

ii. Include appropriate identifying data such as the name of the licensee or registrant, the name of the individual, and the individual's identification number, preferably social security number;

iii. Include the individual's exposure information; and

iv. Contain the following statement:

"This report is furnished to you under the provisions of the Delaware Radiation Control Regulations, Part J. You should preserve this report for further reference."

b. Each licensee or registrant shall furnish to each worker annually a written report of the worker's dose as shown in records maintained by the licensee or registrant pursuant to D.1107 of the regulations.

c. Each licensee or registrant shall furnish a written report of the worker's exposure to sources of radiation at the request of a worker formerly engaged in activities controlled by the licensee or registrant. The report shall include the dose record for each year the worker was required to be monitored pursuant to D.502 of the regulations. Such report shall be furnished within 30 days from the date of the request, or within 30 days after the dose of the individual has been determined by the licensee or registrant, whichever is later. The report shall cover the period of time that the worker's activities involved exposure to sources of radiation and shall include the dates and locations of work under the license or registration in which the worker participated during this period.

d. When a licensee or registrant is required pursuant to D.1202, D.1203, or D.1204 of the regulations to report to the Agency any exposure of an individual to sources of radiation, the licensee or the registrant shall also provide the individual a written report on the exposure data included therein. Such reports shall be transmitted at a time not later than the transmittal to the Agency.

e. At the request of a worker who is terminating employment with the licensee or registrant in work involving exposure to radiation or radioactive material, during the current year, each licensee or registrant shall provide at termination to each such worker, or to the worker's designee, a written report regarding the radiation dose received by that worker from operations of the licensee or registrant during the current year or fraction thereof. If the most recent individual monitoring results are not available at that time, a written estimate of the dose shall be provided together with a clear indication that this is an estimate. The worker shall be provided a copy of the results within 30 days of receipt by the company.

Sec. J.14 Presence of Representatives of Licensees or Registrants and Workers During Inspection

a. Each licensee or registrant shall afford to the Agency at all reasonable times opportunity to inspect materials, machines, activities, facilities, premises, and records pursuant to the regulations.

b. During an inspection, Agency inspectors may consult privately with workers as specified in J.15. The licensee or registrant may accompany Agency inspectors during other phases of an inspection.

c. If, at the time of inspection, an individual has been authorized by the workers to represent them during Agency inspections, the licensee or registrant shall notify the inspectors of such authorization and shall give the workers' representative an opportunity to accompany the inspectors during the inspection of physical working conditions.

d. Each workers' representative shall be routinely engaged in work under control of the licensee or registrant and shall have received instructions as specified in J.12.

e. Different representatives of licensees or registrants and workers may accompany the inspectors during different phases of an inspection if there is no resulting interference with the conduct of the inspection. However, only one workers' representative at a time may accompany the inspectors.

f. With the approval of the licensee or registrant and the workers' representative, an individual who is not routinely engaged in work under control of the licensee or registrant, for example, a consultant to the licensee or registrant or to the workers' representative, shall be afforded the opportunity to accompany Agency inspectors during the inspection of physical working conditions.

g. Notwithstanding the other provisions of J.14, Agency inspectors are authorized to refuse to permit accompaniment by any individual who deliberately interferes with a fair and orderly inspection. With regard to areas containing information classified by an Agency of the U.S. Government in the interest of national security, an individual who accompanies an inspector may have access to such information only if authorized to do so. With regard to any area containing proprietary information, the workers' representative for that area shall be an individual previously authorized by the licensee or registrant to enter that area.

Sec. J.15 Consultation with Workers During Inspections

a. Agency inspectors may consult privately with workers concerning matters of occupational radiation protection and other matters related to applicable provisions of the regulations and licenses to the extent the inspectors deem necessary for the conduct of an effective and thorough inspection.

b. During the course of an inspection, any worker may bring privately to the attention of the inspectors, either orally or in writing, any past or present condition which the worker has reason to believe may have contributed to or caused any violation of the Act, the regulations, or license condition, or any unnecessary exposure of an individual to sources of

~~radiation under the licensee's or registrant's control. Any such notice in writing shall comply with the requirements of J.16a.~~

~~c. The provisions of J.15.b. shall not be interpreted as authorization to disregard instructions pursuant to J.12.~~

~~Sec. J.16 Requests by Workers for Inspections~~

~~a. Any worker or representative of workers believing that a violation of the Act, the regulations, or license conditions exists or has occurred in work under a license or registration with regard to radiological working conditions in which the worker is engaged may request an inspection by giving notice of the alleged violation to the Office of Radiation Control. Any such notice shall be in writing, shall set forth the specific grounds for the notice, and shall be signed by the worker or representative of the workers. A copy shall be provided to the licensee or registrant by the Office of Radiation Control no later than at the time of inspection except that, upon the request of the worker giving such notice, such worker's name and the name of individuals referred to therein shall not appear in such copy or on any record published, released, or made available by the Agency, except for good cause shown.~~

~~b. If, upon receipt of such notice, the Office of Radiation Control determines that the complaint meets the requirements set forth in J.16.a., and that there are reasonable grounds to believe that the alleged violation exists or has occurred, an inspection shall be made as soon as practicable to determine if such alleged violation exists or has occurred. Inspections pursuant to J.16 need not be limited to matters referred to in the complaint.~~

~~c. No licensee, registrant, or contractor or subcontractor of a licensee or registrant shall discharge or in any manner discriminate against any worker because such worker has filed any complaint or instituted or caused to be instituted any proceeding under the regulations or has testified or is about to testify in any such proceeding or because of the exercise by such worker on behalf of such worker or others of any option afforded by this Part.~~

~~Sec. J.17 Inspections Not Warranted; Informal Review.~~

~~a. i. If the Office of Radiation Control determines, with respect to a complaint under J.16, that an inspection is not warranted because there are no reasonable grounds to believe that a violation exists or has occurred, the Office of Radiation Control shall notify the complainant in writing of such determination. The complainant may obtain review of such determination by submitting a written statement of position with the Authority on Radiation Protection. The Agency will provide the licensee or registrant with a copy of such statement by certified mail, excluding, at the request of the complainant, the name of the complainant. The licensee or registrant may submit an opposing written statement of position with the Authority on Radiation Protection. The agency will provide the complainant with a copy of such statement by certified mail.~~

~~ii. Upon the request of the complainant, the Authority on Radiation Protection may hold an informal conference in which the complainant and the licensee or registrant may orally present their views. An informal conference may also be held at the request of the licensee or registrant, but disclosure of the identity of the complainant will be made only following receipt of written authorization from the complainant. After considering all written and oral views presented, the Authority on Radiation Protection shall affirm, modify, or reverse the determination of the Office of Radiation Control and furnish the complainant and the licensee or registrant a written notification of the decision and the reason therefore.~~

~~b. If the Office of Radiation Control determines that an inspection is not warranted because the requirements of J.16.a. have not been met, the complainant shall be notified in writing of such determination. Such determination shall be without prejudice to the filing of a new complaint meeting the requirements of J.16.a.~~

NOTICES, INSTRUCTIONS AND REPORTS TO WORKERS; INSPECTIONS

1.0 Purpose and Scope.

This Part establishes requirements for notices, instructions and reports by licensees or registrants to individuals engaged in activities under a license or registration including but not limited to employees, and options available to such individuals in connection with Agency inspections of licensees or registrants to ascertain compliance with the provisions of the Act and regulations, orders, and licenses issued thereunder regarding radiological working conditions. The regulations in this Part apply to all persons who receive, possess, use, own, sell or transfer sources of radiation registered with or licensed by the Agency pursuant to Parts B and C of these regulations.

General Regulatory Provisions and Specific Requirements

2.0 Posting of Notices to Workers.

2.1 Each licensee or registrant shall post current copies of the following documents:

2.1.1 The regulations in this Part and in Part D of these regulations;

2.1.2 The license or certificate of registration,

2.1.3 The operating safety procedures applicable to activities under the license or registration; and

2.1.4 Any notice of violation involving radiological working conditions, proposed imposition of administrative penalty, or order issued pursuant to Part A of these regulations, and any response from the licensee or registrant.

2.2 If posting of a document specified in subsections 2.1.1, or 2.1.3 is not practicable, the licensee or registrant may post a notice which describes the document and states where it may be examined.

2.3 Agency Form **X** "Notice to Workers" shall be posted conspicuously by each licensee or registrant as required by these regulations, see Appendix A.

2.4 Agency documents posted pursuant to subsection 2.1.4 shall be posted conspicuously within 5 working days after receipt of the documents from the Agency; the licensee's or registrant's response, if any, shall be posted within five working days after dispatch from the licensee or registrant. Such documents shall remain posted for a minimum of five working days or until action correcting the violation has been completed, whichever is later.

2.5 Documents, notices, or forms posted pursuant to Section 2.0 shall appear in a sufficient number of places to permit individuals engaged in work under the license or registration to observe them on the way to or from any particular work location to which the document applies, shall be conspicuous, and shall be replaced if defaced or altered.

3.0 Instructions to Workers.

3.1 All individuals who in the course of employment, education, or training are likely to receive in a year an occupational dose in excess of 1 millisievert (100 mrem):

3.1.1 Shall be kept informed of the storage, transfer, or use of sources of radiation in the licensee's or registrant's workplace;

3.1.2 Shall be instructed in the health protection problems associated with exposure to radiation or radioactive material to the individual and potential offspring, in precautions or procedures to minimize exposure, and in the purposes and functions of protective devices employed;

3.1.3 Shall be instructed in, and instructed to observe, to the extent within the worker's control, the applicable provisions of these regulations and licenses for the protection of personnel from exposures to radiation or radioactive material;

3.1.4 Shall be instructed of their responsibility to report promptly to the licensee or registrant any condition which may constitute, lead to, or cause a violation of the Act, these regulations, or license condition, or any unnecessary exposure to radiation or radioactive material;

3.1.5 Shall be instructed in the appropriate response to warnings made in the event of any unusual occurrence or malfunction that may involve exposure to radiation or radioactive material; and

3.1.6 Shall be advised as to the radiation exposure reports which workers shall be furnished pursuant to Section 4.0.

3.2 In determining those individuals subject to the requirements of subsection 3.1, licensees or registrant must take into consideration assigned activities during normal and abnormal situations involving exposure to radiation and/or radioactive material which can reasonably be expected to occur during the life of a licensed facility. The extent of these instructions shall be commensurate with potential radiological health protection problems present in the workplace.

4.0 Notifications and Reports to Individuals.

4.1 Radiation exposure data for an individual and the results of any measurements, analyses, and calculations of radioactive material deposited or retained in the body of an individual shall be reported to the individual as specified in this section. The information reported shall include data and results obtained pursuant to these regulations, orders, or license conditions, as shown in records maintained by the licensee or registrant pursuant to Part D, Section 39.0 of these regulations. Each notification and report shall:

4.1.1 Be in writing;

4.1.2 Include appropriate identifying data such as: the name of the licensee or registrant, the name of the individual, and the individual's unique identification number, such as employee number or Social Security Number;

4.1.3 Include the individual's exposure information; and

4.1.4 Contain the following statement:

> "This report is furnished to you under the provisions of the Delaware Radiation Control Regulations, Part J. You should preserve this report for further reference."

4.2 The licensee shall provide an annual report to each individual required to be monitored under these regulations of the dose received in that monitoring year if their occupational dose is in excess of 1 millisievert (100 mrem).

4.3 Each licensee or registrant shall furnish a written report of the worker's exposure to sources of radiation at the request of a worker currently or formerly engaged in activities controlled by the licensee or registrant. The report shall include the dose record for each year the worker was required to be monitored pursuant to Part D, Section 17.0 of these regulations such report shall be furnished within 30 days from the date of the request, or within 30 days after the dose of the individual has been determined by the licensee or registrant, whichever is later. The report shall cover the period of time that the worker's activities involved exposure to sources of radiation and shall include the dates and locations of work under the license or registration in which the worker participated during this period.

4.4 When a licensee or registrant is required pursuant to Sections 46.0, 47.0, 48.0, or 49.0 of these regulations to report to the Agency any exposure of an individual to sources of radiation, the licensee or the registrant shall also provide the individual a written report on the exposure data included therein. Such reports shall be transmitted at a time not later than the transmittal to the Agency.

4.5 At the request of a worker who is terminating employment with the licensee or registrant in work involving exposure to radiation or radioactive material, during the current year, each licensee or registrant shall provide at termination to each such worker, or to the worker's designee, a written report regarding the radiation dose received by that worker from operations of the licensee or registrant during the current year or fraction thereof. If the most recent individual monitoring results are not available at that time, a written estimate of the dose shall be provided together with a clear indication that this is an estimate.

5.0 Presence of Representatives of Licensees or Registrants and Workers During Inspection.

5.1 Each licensee or registrant shall afford to the Agency at all reasonable times opportunity to inspect materials, machines, activities, facilities, premises, and records pursuant to these regulations.

5.2 During an inspection, Agency inspectors may consult privately with workers as specified in Section 6.0. The licensee or registrant may accompany Agency inspectors during other phases of an inspection.

5.3 If, at the time of inspection, an individual has been authorized by the workers to represent them during Agency inspections, the licensee or registrant shall notify the inspectors of such authorization and shall give the workers' representative an opportunity to accompany the inspectors during the inspection of physical working conditions.

5.4 Each worker's representative shall be routinely engaged in work under control of the licensee or registrant and shall have received instructions as specified in Section 3.0.

5.5 Different representatives of licensees or registrants and workers may accompany the inspectors during different phases of an inspection if there is no resulting interference with the conduct of the inspection. However, only one workers' representative at a time may accompany the inspectors.

5.6 With the approval of the licensee or registrant and the workers' representative, an individual who is not routinely engaged in work under control of the licensee or registrant, for example, a consultant to the licensee or registrant or to the workers' representative, shall be afforded the opportunity to accompany Agency inspectors during the inspection of physical working conditions.

5.7 Notwithstanding the other provisions of Section 5.0, Agency inspectors are authorized to refuse to permit accompaniment by any individual who deliberately interferes with a fair and orderly inspection. With regard to areas containing information classified by an Agency of the US Government in the interest of national security, an individual who accompanies an inspector may have access to such information only if authorized to do so. With regard to any area containing proprietary information, the workers' representative for that area shall be an individual previously authorized by the licensee or registrant to enter that area.

6.0 Consultation with Workers During Inspections.

6.1 Agency inspectors may consult privately with workers concerning matters of occupational radiation protection and other matters related to applicable provisions of these regulations and licenses to the extent the inspectors deem necessary for the conduct of an effective and thorough inspection.

6.2 During the course of an inspection, any worker may bring privately to the attention of the inspectors, either orally or in writing, any past or present condition which the worker has reason to believe may have contributed to or caused any violation of the Act, these regulations, or license condition, or any unnecessary exposure of an individual to sources of radiation under the licensee's or registrant's control. Any such notice in writing shall comply with the requirements of subsection 7.1.

6.3 The provisions of subsection 6.2 shall not be interpreted as authorization to disregard instructions pursuant to Section 3.0

7.0 Requests by Workers for Inspections.

7.1 Any worker or representative of workers believing that a violation of the Act, these regulations, or license conditions exists or has occurred in work under a license or registration with regard to radiological working conditions in which the worker is engaged may request an inspection by giving notice of the alleged violation to the Office of Radiation Control. Any such notice shall be in writing, shall set forth the specific grounds for the notice, and shall be signed by the worker or representative of the workers. A copy shall be provided to the licensee or registrant by the Office of Radiation Control no later than at the time of inspection except that, upon the request of the worker giving such notice, such worker's name and the name of individuals referred to therein shall not appear in such copy or on any record published, released, or made available by the Agency, except for good cause shown.

7.2 If, upon receipt of such notice, the Office of Radiation Control determines that the complaint meets the requirements set forth in subsection 7.1, and that there are reasonable grounds to believe that the alleged violation exists or has occurred, an inspection shall be made as soon as practicable to determine if such alleged violation exists or has occurred. Inspections pursuant to Section 7.0 need not be limited to matters referred to in the complaint.

7.3 No licensee, registrant, or contractor or subcontractor of a licensee or registrant shall discharge or in any manner retaliate against any worker because such worker has filed any complaint or instituted or caused to be instituted any proceeding under these regulations or has testified or is about to testify in any such proceeding or because of the exercise by such worker on behalf of such worker or others of any option afforded by this Part.

8.0 Inspections Not Warranted; Review.

8.1 If the Office of Radiation Control determines, with respect to a complaint under Section 7.0, that an inspection is not warranted because there are no reasonable grounds to believe that a violation exists or has occurred, the Office of Radiation Control shall notify the complainant in writing of such determination. The complainant may obtain review of such determination by submitting a written statement of position with the Division of Public Health. Such Agency will provide the licensee or registrant with a copy of such statement by certified mail, excluding, at the request of the complainant, the name of the complainant. The licensee or registrant may submit an opposing written statement of position with the Division of Public Health. The Division of Public Health will provide the complainant with a copy of such statement by certified mail.

8.2 Upon the request of the complainant, the Division of Public Health may hold a conference in which the complainant and the licensee or registrant may orally present their views. A conference may also be held at the request of the licensee or registrant, but disclosure of the identity of the complainant will be made only following receipt of written authorization from the complainant. After considering all written and oral views presented, the Division of Public Health shall affirm, modify, or reverse the determination of the "Office of Radiation Control" and furnish the complainant and the licensee or registrant a written notification of the decision and the reason therefore.

8.3 All decisions of the Division shall be final and conclusive. Where the licensee or registrant is in disagreement with the action of the Division, the licensee or registrant may appeal the Division's decision to the Superior Court within 30 days of service or of the postmarked date of the copy of the decision mailed to the licensee or registrant. The appeal shall be on the record to the Superior Court and shall be as provided in §§10142 - 10145 of Title 29.

8.4 If the Office of Radiation Control determines that an inspection is not warranted because the requirements of subsection 7.1 have not been met, the complainant shall be notified in writing of such determination. Such determination shall be without prejudice to the filing of a new complaint meeting the requirements of subsection 7.1.

APPENDIX A
NOTICE TO WORKERS AGENCY FORM X

STANDARDS FOR PROTECTION AGAINST RADIATION; NOTICES INSTRUCTIONS AND REPORTS TO WORKERS; INSPECTIONS

In Part D of the Delaware Radiation Control Regulations, the Authority on Radiation has established standards for your protection against radiation hazards. In Part J of the Delaware Radiation Control Regulations, the Authority on

Radiation Protection has established certain provisions for the options of workers engaged in work under an agency license or registration.

THE REGISTRANT RESPONSIBILITY The Registrant is required to:

1. **Apply these regulations to work involving sources of radiation.**

2. **Post or otherwise make available to you a copy of the Delaware Radiation Control Regulations, and the operating procedures which apply to work you are engaged in, and explain their provisions to you.**

3. **Post Notice of Violation involving radiological working conditions, and any proposed imposition of administrative penalties and orders.**

YOUR RESPONSIBILITY AS A WORKER

You should familiarize yourself with provisions of the Delaware Radiation Control Regulations listed below and facility procedures for safe operation of radiation sources in your workplace . You should observe these provisions for your own protection, and the protection of your co-workers.

WHAT IS COVERED BY THESE REGULATIONS

1. **Limits on exposure to radiation and radioactive material in restricted and unrestricted areas;**

2. **Measures to be taken after accidental exposure;**

3. **Personnel monitoring, surveys and equipment;**

4. **Caution signs, labels, and safety interlock equipment;**

5. **Exposure records and reports;**

6. **Options for workers regarding Agency inspections; and**

7. **Related matters.**

POSTING REQUIREMENT

COPIES OF THIS NOTICE MUST BE POSTED IN A SUFFICIENT NUMBER OF PLACES IN EVERY ESTABLISHMENT WHERE WORKERS ARE ENGAGED IN ACTIVITIES LICENSED OR REGISTERED, PURSUANT TO PART B OR PART C, BY THE OFFICE OF RADIATION CONTROL, TO PERMIT INDIVIDUALS WORKING IN OR FREQUENTING ANY PORTION OF A RESTRICTED AREA TO OBSERVE A COPY ON THE WAY TO OR FROM THEIR PLACE OF WORK.

REPORTS ON YOUR RADIATION EXPOSURE HISTORY

1. **The Delaware Radiation Control Regulations require that the registrant give you a written report if you receive an exposure in excess of any applicable limit set forth in these regulations. The basic limits for exposure to workers are set forth in Part D, Sections 5.0, 6.0, 7 .0, 8.0, 9.0 and 12.0 of the regulations.**

2. **If personnel monitoring is required for your job, and if you request information on your radiation exposures;**

   (a) The registrant or your employer/or supervisor must advise you annually of your exposure to radiation while you are working, as set forth in Part J, subsections 4.1 and 4.2;

   (b) The registrant or your employer/or supervisor must give you a written report, of your radiation exposures upon leaving work in the registered facility as set forth in Part J, subsections 4.3 and 4.5.

INSPECTIONS

All licensed or registered activities are subject to inspection by representatives of the Office of Radiation Control. In addition, any worker or representative of workers who believes that there is a violation of the Delaware Radiation Control Act, the regulations issued thereunder, or the terms of the facility license or registration with regard to radiological working conditions in which the worker is engaged, may request an inspection by sending a notice of the alleged violation to the Office of Radiation Control. The written request must set forth the specific grounds for the notice, and must be signed by the worker as the representative of the workers. During inspections, Agency inspectors may confer privately with workers, and any worker may bring to the attention of the inspectors any past or present condition which they believe contributed to or caused any violation as described above.

CUMULATIVE OCCUPATIONAL DOSE HISTORY
AGENCY FORM Y

1. NAME(LAST, FIRST, MIDDLE INITIAL)		2.IDENTIFICATION NUMBER		3.ID TYPE	4.SEX MALE ___ FEMALE ___		5.DATE OF BIRTH (MM/DD/YY)
6. MONITORING PERIOD (MM/DD/YYYY – MM/DD/YYYY)		7. REGISTRANT NAME		8. REGISTRATION NUMBER		9. RECORD ESTIMATE NO RECORD	10. ROUTINE PSE
11. DDE	12. LDE	13. SDE,WB	14. SDE, ME	15. CEDE	16. CDE	17. TEDE	18. TODE
6. MONITORING PERIOD (MM/DD/YYYY – MM/DD/YYYY)		7. REGISTRANT NAME		8. REGISTRATION NUMBER		9. RECORD ESTIMATE NO RECORD	10. ROUTINE PSE
11. DDE	12. LDE	13. SDE,WB	14. SDE, ME	15. CEDE	16. CDE	17. TEDE	18. TODE
6. MONITORING PERIOD (MM/DD/YYYY – MM/DD/YYYY)		7. REGISTRANT NAME		8. REGISTRATION NUMBER		9. RECORD ESTIMATE NO RECORD	10. ROUTINE PSE
11. DDE	12. LDE	13. SDE,WB	14. SDE, ME	15. CEDE	16. CDE	17. TEDE	18. TODE
6. MONITORING PERIOD (MM/DD/YYYY – MM/DD/YYYY)		7. REGISTRANT NAME		8. REGISTRATION NUMBER		9. RECORD ESTIMATE NO RECORD	10. ROUTINE PSE
11. DDE	12. LDE	13. SDE,WB	14. SDE, ME	15. CEDE	16. CDE	17. TEDE	18. TODE
6. MONITORING PERIOD (MM/DD/YYYY – MM/DD/YYYY)		7. REGISTRANT NAME		8. REGISTRATION NUMBER		9. RECORD ESTIMATE NO RECORD	10. ROUTINE PSE
11. DDE	12. LDE	13. SDE,WB	14. SDE, ME	15. CEDE	16. CDE	17. TEDE	18. TODE
6. MONITORING PERIOD (MM/DD/YYYY – MM/DD/YYYY)		7. REGISTRANT NAME		8. REGISTRATION NUMBER		9. RECORD ESTIMATE NO RECORD	10. ROUTINE PSE
11. DDE	12. LDE	13. SDE,WB	14. SDE, ME	15. CEDE	16. CDE	17. TEDE	18. TODE
19. SIGNATURE OF MONITORED INDIVIDUAL		20. DATE SIGNED	21. CERTIFYING ORGANIZATION		22. SIGNATURE OF DESIGNEE		23. DATE SIGNED

INSTRUCTIONS AND ADDITIONAL INFORMATION PERTINENT TO THE COMPLETION OF AGENCY FORM Y
(All doses should be stated in rems)

1. Type or print the full name of the monitored individual in the order of last name (include "Jr," "Sr," "III," etc.), first name, middle initial (if applicable).

2. Enter the individual's unique identification number, including punctuation. This number should preferably be the employee number (EN). If the EN is unavailable; enter the 9-digit social security number (SSN). If the individual has no social security number, enter the number from another official identification such as a passport or work permit.

3. Enter the code for the type of identification used as shown below:

Code	ID Type
EN	Employee Number
SSN	U.S. Social Security Number
PPN	Passport Number
WPN	Work Permit Number
OTH	Other

4. Check the box that denotes the sex of the individual being monitored.

5. Enter the date of birth of the individual being monitored in the format MM/DD/YYYY.

6. Enter the monitoring period for which this report is filed. The format should be MM/DD/YYYY - MM/DD/YYYY.

7. Enter the name of the licensee or facility not licensed by NRC that provided monitoring.

8. Enter the NRC license number or numbers.

9. Place an "X" in Record, Estimate, or No Record. Choose "Record" if the dose data listed represent a final determination of the dose received to the best of the licensee's knowledge. Choose "Estimate" only if the listed dose data are preliminary and will be superseded by a final determination resulting in a subsequent report. An example of such an instance would be dose data based on self-reading dosimeter results and the licensee intends to assign the record dose on the basis of TLD results that are not yet available.

10. Place an "X" in either Routine or “PSE” (Planned Special Exposure). Choose "Routine" if the data represent the results of monitoring for routine exposures. Choose "PSE" if the listed dose data represents the results of monitoring of planned special exposures received during the monitoring period. If more than one PSE was received in a single year, the licensee should sum them and report the total of all planned special exposures.

OF AGENCY FORM Y (Con’t.) All doses should be stated in rems

11. Enter the deep dose equivalent (DDE) to the whole body.

12. Enter the eye dose equivalent (LDE) recorded for the lens of the eye.

13. Enter the shallow dose equivalent recorded for the skin of the whole body (SDE, WB).

14. Enter the shallow dose equivalent recorded for the skin of the extremity receiving the maximum dose (SDE, ME).

15. Enter the committed effective dose equivalent (CEDE).

16. Enter the committed dose equivalent (CDE) recorded for the maximally exposed organ.

17. Enter the committed dose equivalent (TEDE). The TEDE is the sum of items 11 and 15.

18. Enter the total organ dose equivalent (TODE) for the maximally exposed organ. The TODE is the sum of items 11 and 16.

19. Signature of the monitored individual.The signature of the monitored individual on this form indicates that the information contained on the form is complete and correct to the best of his or her knowledge.

20. [OPTIONAL] Enter the date this form was signed by the monitored individual.

21. Enter the name of the licensee or facility not licensed by the Agency providing monitoring for exposure to radiation (such as a VA facility) or the employer if the individual is not employed by the licensee and the employer chooses to maintain exposure records for its employees.

22. [OPTIONAL] Signature of the person designated to represent the licensee or employer entered in item

21. The licensee or employer who chooses to countersign the form should have on file documentation of all the information on the Agency Form 4 being signed.

23. [OPTIONAL] Enter the date this form was signed by the designated representative.

OCCUPATIONAL DOSE RECORD FOR A MONITORING PERIOD
AGENCY FORM Z

1. NAME(LAST, FIRST, MIDDLE INITIAL)	2.IDENTIFICATION NUMBER	3.ID TYPE	4.SEX MALE FEMALE ___	5.DATE OF BIRTH (MM/DD/YY)

6. MONITORING PERIOD (MM/DD/YYYY – MM/DD/YYYY)	7. REGISTRANT NAME	8. REGISTRATION NUMBER	9. RECORD ESTIMATE	10. ROUTINE PSE

INTAKES				DOSES (in rems)	
10A. RADIONUCLIDE	10B. CLASS	10C. MODE	10D. INTAKE Ci	DEEP DOSE EQUIVALENT (DDE)	11.
				LENS (EYE) DOSE EQUIVALENT (LDE)	12.
				SHALLOW DOSE EQUIVALENT, WHOLE BODY (SDE, WB)	13.
				SHALLOW DOSE EQUIVALENT, MAX EXTREMITY (SDE, ME)	14.
				COMMITTED EFFECTIVE DOSE EQUIVALENT (CEDE)	15.
				COMMITTED DOSE EQUIVALENT, MAXIMALLY EXPOSED ORGAN (CDE)	16.
				TOTAL EFFECTIVE DOSE EQUIVALENT (ADD BLOCKS 11 AND 15) (TEDE)	17.
				TOTAL ORGAN DOSE EQUIVALENT, MAX ORGAN (ADD BLOCKS 11 AND 16) (TODE)	18.
				19. COMMENTS	

20. SIGNATURE - REGISTRANT	21. DATE PREPARED

INSTRUCTIONS AND ADDITIONAL INFORMATION PERTINENT TO THE COMPLETION OF AGENCY FORM Z
(All doses should be stated in rems)

1. Type or print the full name of the monitored individual in the order of last name (include "Jr," "Sr," "III," etc.), first name, middle initial (if applicable).

2. Enter the individual's unique identification number, including punctuation. This number should preferably be the employee number (EN). If the EN is unavailable the 9-digit social security number (SSN). If the individual has no social security number, enter the number from another official identification such as a passport or work permit.

3. Enter the code for the type of identification used as shown below:

Code	ID Type
EN	Employee Number
SSN	U.S. Social Security Number
PPN	Passport Number
WPN	Work Permit Number
OTH	Other

4. Check the box that denotes the sex of the individual being monitored.

5. Enter the date of birth of the individual being monitored in the format MM/DD/YYYY.

6. Enter the monitoring period for which this report is filed. The format should be MM/DD/YYYY - MM/DD/YYYY.

7. Enter the name of the registered facility not licensed by NRC that provided monitoring.

8. Enter the registration number or numbers.

9. Place an "X" in Record, Estimate, or No Record. Choose "Record" if the dose data listed represent a final determination of the dose received to the best of the licensee's knowledge. Choose "Estimate" only if the listed dose data are preliminary and will be superseded by a final determination resulting in a subsequent report. An example of such an instance would be dose data based on self-reading dosimeter results and the licensee intends to assign the record dose on the basis of TLD results that are not yet available.

10. Place an "X" in either Routine or “PSE” (Planned Special Exposure). Choose "Routine" if the data represent the results of monitoring for routine exposures. Choose "PSE" if the listed dose data represents the results of monitoring of planned special exposures received during the monitoring period. If more than one PSE was received in a single year, the licensee should sum them and report the total of all planned special exposures.

Part J, Agency Form Z