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

d. If the dose equivalent to the embryo/fetus is found to have exceeded 0.5 rem (5 mSv), or is within 0.05 rem (0.5 mSv) 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 paragraph (a) of this section if the additional dose equivalent to the embryo/fetus does not exceed 0.05 rem (0.5 mSv) 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 dose equivalent to individual members of the public from the licensed or registered operation does not exceed 0.1 rem (1 mSv) in a year, exclusive of the dose contributions from background radiation, from any medical administration the individual has received, from exposure to individuals administered radioactive material and released under G.75, from voluntary participation in medical research programs, and from the licensee's disposal of radioactive material into sanitary sewerage in accordance with D.1003, and

ii. The dose in any unrestricted area from external sources, exclusive of the dose contributions from patients administered radioactive material and released in accordance with Sec. G.75, does not exceed 0.002 rem (0.02 mSv) in any one hour.

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

c. 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.

d. Notwithstanding paragraph (a)(1) of this section, a licensee may permit visitors to an individual who cannot be released, under Sec. G.75, to receive a radiation dose greater than 0.1 rem (1 mSv) if:

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

ii. The authorized user, as defined in Part G, has previously determined that the visit is appropriate.

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

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.301a.i. by:

   i. Demonstrating compliance with D.101a.; and

   ii. (1) Demonstrating by measurement, or calculation, or appropriate simulation model that the total effective dose equivalent to the individual likely to receive the highest dose from the licensed or registered source of radiation does not exceed the annual dose limit of D.301; or

   (2) Demonstrating that:

   (a) 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

   (b) If an individual were continually present in an unrestricted area, at the point of highest potential exposure from the licensed or registered source of radiation, the dose to that individual would not exceed 0.02 mSv (0.002 rem) in an hour and 0.5 mSv (0.05 rem) in any year.

TESTING FOR LEAKAGE OR CONTAMINATION OF SEALED SOURCES

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

a. Each sealed source, other than hydrogen-3, with a half-life greater than 30 days and in any form other than gas, shall be tested for leakage or contamination prior to initial use and, unless otherwise authorized by the Agency, at intervals not to exceed 6 months. If, at any other time, there is reason to suspect that a sealed source might have been damaged or might be leaking, it shall be tested for leakage before further use. In the absence of a certificate from a transferor indicating that a test for leakage has been made within 6 months prior to the transfer, the sealed source shall not be put into use until tested and the results received.

   i. Tests for leakage for all sealed sources, except those 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.

STORAGE AND CONTROL OF LICENSED OR REGISTERED SOURCES OF RADIATION

Sec. D.801 Security of Stored Sources of Radiation. Sources of radiation shall be secured against unauthorized removal or access from the place of storage.

Sec. D.802 Control of Sources of Radiation Not in Storage.

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

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

Section D.803 Security Requirements for Portable Gauges.

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

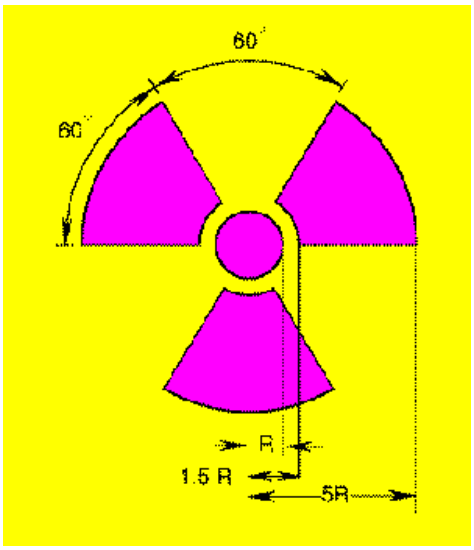
b. The licensee shall ensure that the source locking mechanism for each device is engaged in the secured and fully shielded position during storage and transport.

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:

RADIATION SYMBOL

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



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 shall 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.

WASTE DISPOSAL

Sec. D.1001 General Requirement. No licensee shall dispose of any radioactive material except:

a. By transfer to an authorized recipient as provided in D.1007 and C.40 of these regulations, or

b. As authorized pursuant to D.301, D.302, D.1002, D.1003, D.1005, or D.1006.

c. Notwithstanding the provisions of D.1001a and b, the Agency may prohibit by rule, regulation or order any transfer or disposal of radioactive material.

d. For materials that will be managed as biomedical waste after they have been released from the licensee, a licensee must remove or obliterate all radiation labels, except for radiation labels on materials that are within containers, before release from the licensee's control.

Sec. D.1002 Method of Obtaining Approval of Proposed Disposal Procedures.

Any person may apply to the Agency for approval of proposed procedures to dispose of radioactive material in a manner not otherwise authorized in this Part. Each application shall include a description of the radioactive material, including the quantities and kinds of radioactive material and levels of radioactivity involved, and the proposed manner and conditions of disposal. The application, where appropriate, should also include an analysis and evaluation of pertinent information as to the nature of the environment, including topographical, geological, meteorological, and hydrological characteristics; usage of ground and surface waters in the general area; the nature and location of other potentially affected facilities; and procedures to be observed to minimize the risk of unexpected or hazardous exposures.

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

a. No licensee shall discharge licensed material into sanitary sewerage unless each of the following conditions is satisfied.

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

    ii. The quantity of licensed or other radioactive material that the licensee releases into the sewer in 1 month divided by the average monthly volume of water released into the sewer by the licensee does not exceed the concentration listed in Table III of Appendix B; and

    iii. If more than one radionuclide is released, the following conditions must also be satisfied.

        (1) The licensee 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 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.1002a.iii.(1) does not exceed unity; and

    iv. The total quantity of licensed and other radioactive material that the licensee 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 RESERVED.

Sec. D.1005 Treatment or Disposal by Incineration. No licensee shall treat or dispose of licensed material by incineration except for materials listed under Sec. D.1006 or as specifically approved by the Agency pursuant to Sec. D.1002.

Sec. D.1006 Disposal of Specific Wastes.

a. Any licensee may dispose of the following radioactive material without regard to its radioactivity:

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

   ii. 0.05 microcurie (1.85 kBq) or less of hydrogen-3, or carbon-14 per gram of animal tissue averaged over the weight of the entire animal; provided, however, tissue may not be disposed of under D.1006 in a manner that would permit its use either as food for humans or as animal feed.

b. Nothing in D.1006(a), however, relieves the licensee of maintaining records showing the receipt, transfer and disposal of such radioactive material as specified in A.4 of these regulations.

c. Nothing in D.1006(a) relieves the licensee from complying with other applicable federal, state, and local regulations governing any other toxic or hazardous property of these materials.

If the test for leakage or contamination required pursuant to D.401 indicates a sealed source is leaking or contaminated, a written report of the test shall be filed within 5 days with the Agency describing the equipment involved, the test results and the corrective action taken.

Sec. D.1207 Annual Reports from General Licensees.

a. A licensee granted a general license under Section C.22(e), (g), (i), or (j) shall report annually, the following information on a form provided by the Agency:

    i. The amount and kind of radioactive material received during the previous year;

    ii. The form of the radioactive material;

    iii. The amount possessed by the licensee at the time of the report; and

    iv. The pathways and amounts of radioactive material disposed of by that person during the previous year.

b. The information required by D.1207a.iv. shall be estimated using a technique that is acceptable to the Department.

c. The report required by D.1207a. shall cover the calendar year from January 1 to December 31 and shall be forwarded to the Department not later than March 1 of the following year.

Sec. D.1208 Report and Notification of a Misadministration.

a. Licensees and registrants shall establish appropriate procedures, through compliance with the written directive, to prevent the occurrence of a misadministration.

b. A licensee or registrant shall report any misadministration in which the administration of radioactive material, or radiation from radioactive material or a radiation machine results in:

    i. A dose from radioactive material that differs from the prescribed dose or dose that would have resulted from the prescribed dosage by more than 5 rem (0.05 Sv) effective dose equivalent, 50 rem (0.5 Sv) to an organ or tissue, or 50 rem (0.5 Sv) shallow dose equivalent to the skin; and

        (1) The total dose delivered differs from the prescribed dose by 20 percent or more;

        (2) The total dosage delivered differs from the prescribed dosage by 20 percent or more or falls outside the prescribed dosage range; or

        (3) The fractionated dose delivered differs from the prescribed dose, for a single fraction, by 50 percent or more.

    ii. A dose that exceeds 5 rem (0.05 Sv) effective dose equivalent, 50 rem (0.5 Sv) to an organ or tissue, or 50 rem (0.5 Sv) shallow dose equivalent to the skin from any of the following:

        (1) An administration of a wrong radioactive drug containing radioactive material;

        (2) An administration of a radioactive drug containing radioactive material by the wrong route of administration;

        (3) An administration of a radioactive material dose or dosage to the wrong individual or human research subject;

        (4) An administration of a radioactive material dose or dosage delivered by the wrong mode of treatment; or

        (5) A leaking sealed source.

iii. A radioactive material dose to the skin or an organ or tissue other than the treatment site that exceeds by 50 rem (0.5 Sv) to an organ or tissue and 50 percent or more of the dose expected from the administration defined in the written directive (excluding, for permanent implants, seeds that were implanted in the correct site but migrated outside the treatment site).

iv. A teletherapy radiation dose or dose from a radiation machine:

(1) Involving the wrong individual, wrong mode of treatment, or wrong treatment site, or of a type other than the one intended; or

(2) When the treatment consists of three or fewer fractions, a difference of the calculated total administered dose from the total prescribed dose by more than 10 percent of the total prescribed dose; or

(3) A calculated weekly administered dose that is 30 percent greater than the weekly prescribed dose; or

(4) A calculated total administered dose that differs from the total prescribed dose by more than 20 percent of the total prescribed dose.

c. The licensee or registrant shall notify by telephone the Agency no later than the next calendar day after discovery of the misadministration.

d. The licensee or registrant shall submit a written report to the Agency within 15 days after discovery of the misadministration.

i. The written report must include:

(1) The licensee's or registrant's name;

(2) The name of the prescribing physician;

(3) A brief description of the misadministration;

(4) Why the misadministration occurred;

(5) The effect, if any, on the individual(s) who received the administration;

(6) What actions, if any, have been taken or are planned to prevent recurrence; and

(7) A verification signed by the appropriate authorized user or registrant that the licensee or registrant notified the individual (or the individual's responsible relative or guardian), and if not, why not.

ii. The report may not contain the individual's name or any other information that could lead to identification of the individual.

e. The licensee or registrant shall provide notification of the misadministration to the referring physician and also notify the individual who is the subject of the misadministration no later than 24 hours after its discovery, unless the referring physician personally informs the licensee or registrant either that he or she will inform the individual or that, based on medical judgment, telling the individual would be harmful. The licensee or registrant is not required to notify the individual without first consulting the referring physician. If the referring physician or the affected individual cannot be reached within 24 hours, the licensee or registrant shall notify the individual as soon as possible thereafter. The licensee or registrant may not delay any appropriate medical care for the individual, including any necessary remedial care as a result of the misadministration, because of any delay in notification. To meet the requirements of this paragraph, the notification of the individual who is the subject of the misadministration may be made instead to that individual's responsible relative or guardian. If a verbal notification is made, the licensee or registrant shall inform the individual, or appropriate responsible relative or guardian, that a written description of the misadministration can be obtained

from the licensee or registrant upon request. The licensee or registrant shall provide such a written description if requested.

f. Aside from the notification requirement, nothing in this section affects any rights or duties of licensees, registrants or physicians in relation to each other, to individuals affected by the misadministration, or to that individual's responsible relatives or guardians.

g. A licensee or registrant shall:

i. Append to a copy of the report provided to the Agency the:

(1) Name of the individual who is the subject of the misadministration; and

(2) Social security number or other identification number, if one has been assigned, of the individual who is the subject of the misadministration; and

ii. Provide the appended report in Sec. D.1208g.i. to the referring physician, if other than the licensee, no later than 15 days after the discovery of the misadministration.

h. Each licensee or registrant shall retain a record of each misadministration for five years. The record must contain the names of all individuals involved (including the prescribing physician, allied health personnel, the individual who received the misadministration, and that individual's referring physician, if applicable), the individual's social security number or identification number if one has been assigned, a brief description of the misadministration, why it occurred, the effect on the individual, what improvements are needed to prevent recurrence, and the actions taken to prevent recurrence.

Sec. D.1209 Reserved.

Sec. D.1210 Report and Notification of a Dose to an Embryo/fetus or a Nursing Child.

a. A licensee shall report any dose to an embryo/fetus that is greater than 5 rem (50 mSv) dose equivalent that is a result of an administration of radioactive material or radiation from radioactive material to a pregnant individual unless the dose to the embryo/fetus was specifically approved, in advance, by the authorized user.

b. A licensee shall report any dose to a nursing child that is a result of an administration of radioactive material to a breast-feeding individual that:

i. Is greater than 5 rem (50 mSv) total effective dose equivalent; or

ii. Has resulted in unintended permanent functional damage to an organ or a physiological system of the child, as determined by a physician.

c. The licensee shall notify by telephone the Agency no later than the next calendar day after discovery of a dose to the embryo/fetus or nursing child that requires a report in D.1210a. or b.

d. The licensee shall submit a written report to the Agency within 15 days after discovery of a dose to the embryo/fetus or nursing child that requires a report in D.1210(a) or (b).

i. The written report must include:

(1) The licensee's name;

(2) The name of the prescribing physician;

(3) A brief description of the misadministration;

(4) Why the misadministration occurred;

(5) The effect, if any, on the embryo/fetus or the nursing child;

(6) What actions, if any, have been taken or are planned to prevent recurrence; and

(7) Certification that the licensee notified the pregnant individual or mother (or the mother's or child's responsible relative or guardian), and if not, why not.

ii. The report must not contain the individual's or child's name or any other information that could lead to identification of the individual or child.

e. The licensee shall provide notification of the misadministration to the referring physician and also notify the pregnant individual or mother, both hereafter referred to as the mother, no later than 24 hours after discovery of a misadministration that would require reporting under D.1210a. or b., unless the referring physician personally informs the licensee either that he or she will inform the mother or that, based on medical judgment, telling the mother would be harmful. The licensee is not required to notify the mother without first consulting with the referring physician. If the referring physician or mother cannot be reached within 24 hours, the licensee shall make the appropriate notifications as soon as possible thereafter. The licensee may not delay any appropriate medical care for the embryo/fetus or for the nursing child, including any necessary remedial care as a result of the misadministration, because of any delay in notification. To meet the requirements of D.1210e., the notification may be made to the mother's or child's responsible relative or guardian instead of the mother. If a verbal notification is made, the licensee shall inform the mother, or the mother's or child's responsible relative or guardian, that a written description of the misadministration can be obtained from the licensee upon request. The licensee shall provide such a written description if requested.

f. A licensee shall:

i. Append to a copy of the report provided to the Agency the:

(1) Name of the pregnant individual or the nursing child who is the subject of the misadministration; and

(2) Social security number or other identification number, if one has been assigned, of the pregnant individual or the nursing child who is the subject of the misadministration; and

ii. Provide the appended report in D.1210f.i. to the referring physician, if other than the licensee, no later than 15 days after the discovery of the misadministration.

Sec. D.1211 Additional Reporting Requirements for Radioactive Materials.

a. Immediate report. Each licensee shall notify the Agency as soon as possible but no later than 4 hours after the discovery of an event that prevents immediate protective actions necessary to avoid exposures to radiation or radioactive materials that could exceed regulatory limits or release of licensed material that could exceed regulatory limits (events may include fires, explosions, toxic gas releases, etc.).

b. Twenty-four hour report. Each licensee shall notify the Agency within 24 hours after the discovery of any of the following events involving licensed material:

i. An unplanned contamination event that:

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

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

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

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

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

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

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

iii. An event that requires unplanned medical treatment at a medical facility of an individual with spreadable radioactive contamination on the individual's clothing or body.

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

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

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

c. Preparation and submission of reports. Reports made by licensees in response to the requirements of this section must be made as follows:

i. Licensees shall make reports required by paragraphs a. and b. of this section by telephone to the Agency. To the extent that the information is available at the time of notification, the information provided in these reports must include:

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

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

(3) The exact location of the event;

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

(5) Any personnel radiation exposure data available.

ii. Written report. Each licensee who makes a report required by paragraph a. or b. of this section shall submit a written follow-up report within 30 days of the initial report. Written reports prepared pursuant to other regulations may be submitted to fulfill this requirement if the reports contain all of the necessary information and the appropriate distribution is made. These reports must be sent to the Agency. The reports must include the following:

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

(2) The exact location of the event;

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

(4) Date and time of event;

(5) Corrective actions taken or planned and the results of any evaluations or assessments; and

(6) The extent of exposure of individuals to radiation or to radioactive materials without identification of individuals by name.

d. Each specific licensee, or general licensee possessing radioactive material as defined in C.22(k)(5)(i), shall notify the Agency in writing immediately following the filing of a voluntary or involuntary petition for bankruptcy under any Chapter of Title 11 (Bankruptcy) of the United States Code by or against:

i. The licensee;

ii. An entity (as that term is defined in 11 U.S.C. 101(14)) controlling the licensee or listing the license or licensee as property of the estate; or

iii. An affiliate (as that term is defined in 11 U.S.C. 101(2)) of the licensee.

e. The notification specified in D.1211d. shall indicate the bankruptcy court in which the petition for bankruptcy was filed, a copy of the bankruptcy petition, and the date of the filing of the petition.

Sec. D.1220 Notification of Failure To Comply or Existence of a Defect and Its Evaluation.

a. Each individual, corporation, partnership, dedicating entity, or other entity subject to the regulations in this part shall adopt appropriate procedures to--

1. Evaluate deviations and failures to comply to identify defects and failures to comply associated with substantial safety hazards as soon as practicable, and, except as provided in paragraph (a)(2) of this section, in all cases within 60 days of discovery, in order to identify a reportable defect or failure to comply that could create a substantial safety hazard, were it to remain uncorrected;

2. Ensure that if an evaluation of an identified deviation or failure to comply potentially associated with a substantial safety hazard cannot be completed within 60 days from discovery of the deviation or failure to comply, an interim report is prepared and submitted to the Department through a director or responsible officer or designated person as discussed in Sec. D.1220(c)(5). The interim report should describe the deviation or failure to comply that is being evaluated and should also state when the evaluation will be completed. This interim report must be submitted in writing within 60 days of discovery of the deviation or failure to comply; and

3. Ensure that a director or responsible officer subject to the regulations of this part is informed as soon as practicable, and, in all cases, within the 5 working days after completion of the evaluation described in Sec. D.1220(a)(1) or Sec. D.1220(a)(2) if the construction or operation of a facility or activity, or a basic component supplied for such facility or activity--

i. Fails to comply with COMAR 26.12.01.01 Regulations for the Control of Ionizing Radiation (1994), or any applicable rule, order, or license of the Department relating to a substantial safety hazard, or

ii. Contains a defect.

b. If the deviation or failure to comply is discovered by a supplier of basic components, or services associated with basic components, and the supplier determines that it does not have the capability to perform the evaluation to determine if a defect exists, then the supplier must inform the purchasers