

PART III STANDARDS FOR PROTECTION**SUBPART A GENERAL PROVISIONS**

R2	64E-5.301.. Standards for Protection Against Radiation.....	III-1
	64E-5.302.. Implementation.....	III-1

SUBPART B RADIATION PROTECTION PROGRAMS

R2	64E-5.303.. Radiation Protection Programs	III-2
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SUBPART C OCCUPATIONAL DOSE LIMITS

R6	64E-5.304.. Occupational Dose Limits for Adults	III-2
	64E-5.305.. Compliance with Requirements for Summation of External and Internal Doses	III-3
	64E-5.306.. Determination of External Dose from Airborne Radioactive Material	III-4
R12	64E-5.307.. Determination of Internal Exposure	III-5
R12	64E-5.308.. Determination of Prior Occupational Dose	III-6
R2	64E-5.309.. Planned Special Exposures	III-8
	64E-5.310.. Occupation Dose Limits for Minors	III-9
R2	64E-5.311.. Dose to an Embryo Fetus.....	III-9

SUBPART D..RADIATION DOSE LIMITS FOR INDIVIDUAL MEMBERS OF THE PUBLIC

R10	64E-5.312.. Dose Limits for Individual Members of the Public.....	III-10
R12	64E-5.313.. Compliance with Dose Limits for Individual Members of the Public	III-11

SUBPART E SURVEYS AND MONITORING

R2	64E-5.314.. General	III-12
R12	64E-5.315.. Conditions Requiring Individual Monitoring of External and Internal Occupational Dose	III-13

SUBPART F CONTROL OF EXPOSURE FROM EXTERNAL SOURCES IN RESTRICTED AREAS

	64E-5.316.. Control of Access to High Radiation Areas	III-14
	64E-5.317.. Control of Access to Very High Radiation Areas	III-15

SUBPART G RESPIRATORY PROTECTION AND CONTROLS TO RESTRICT INTERNAL EXPOSURE IN RESTRICTED AREAS

R6	64E-5.318.. Use of Process or Other Engineering Controls	III-15
R6	64E-5.319.. Use of Individual Respiratory Protection Equipment	III-16

SUBPART H STORAGE AND CONTROL OF LICENSED OR REGISTERED SOURCES OF RADIATION

	64E-5.320.. Security of Stored Sources of Radiation.....	III-18
	64E-5.321.. Control of Sources of Radiation Not in Storage.....	III-18

SUBPART I PRECAUTIONARY PROCEDURES

	64E-5.322.. Caution Signs	III-19
R2	64E-5.323.. Posting Requirements	III-20
	64E-5.324.. Exceptions to Posting Requirements.....	III-20
	64E-5.325.. Labeling Containers and Radiation Machines	III-21
R12	64E-5.326.. Exemptions to Labeling Requirements.....	III-21
	64E-5.327.. Procedures for Receiving and Opening Packages	III-22

SUBPART J WASTE MANAGEMENT

	64E-5.328.. General Requirements	III-23
	64E-5.329.. Method of Obtaining Approval of Proposed Disposal Procedures.....	III-24
R12	64E-5.330.. Discharge by Release into Sanitary Sewerage	III-24
R12	64E-5.331.. Disposal of Specific Wastes	III-25
R1	64E-5.332.. Transfer for Disposal and Manifests.....	III-26a
R1	64E-5.333.. Classification and Characteristics of Low Level Radioactive Waste for Near-Surface Land Disposal, Labeling and Manifest Requirements	III-27

SUBPART K RECORDS

R2	64E-5.334.. General Provisions	III-36
	64E-5.335.. Records of Radiation Protection Programs	III-36
	64E-5.336.. Records of Surveys	III-36a
	64E-5.337.. Records of Tests for Leakage or Contamination of Sealed Sources.....	III-36a
	64E-5.338.. Records of Planned Special Exposures	III-37
R2	64E-5.339.. Records of Individual Monitoring Results	III-37
	64E-5.340.. Records of Waste Disposal or Transfers.....	III-38
	64E-5.341.. Records of Testing Entry Control Devices for Very High Radiation Areas ...	III-38
	64E-5.342.. Form of Records	III-39

SUBPART L REPORTS

	64E-5.343.. Reports of Stolen, Lost, or Missing Licensed or Registered Sources of Radiation.....	III-39
R12	64E-5.344.. Notification of Incidents	III-40
R10	64E-5.345.. Reports of Exposure, Radiation Levels, Concentrations of Radioactive Materials Exceeding the Constraint or Limits, and Medical Events and Dose to an embryo/Fetus or a Nursing Child.....	III-44a
	64E-5.346.. Reports of Planned Special Exposures	III-46
R1	64E-5.347.. Notifications and Reports to Individuals	III-46
	64E-5.348.. Reports of Leaking or Contaminated Sealed Sources.....	III-46
	64E-5.349.. Vacating Premises	III-46
R12	64E-5.350... Reports of Transactions Involving Nationally Tracked Sources	III-47
R12	64E-5.351 ... Nationally Tracked Source Thresholds.	III-50

PART III**STANDARDS FOR PROTECTION AGAINST RADIATION****SUBPART A
GENERAL PROVISIONS****64E-5.301 Standards for Protection Against Radiation.**

- (1) The rules in this part control the receipt, possession, use, disposal, and transfer of sources of radiation by any licensee or registrant so the total dose to an individual, including doses resulting from all sources of radiation other than background radiation, does not exceed the standards for protection against radiation prescribed in this part. However, nothing in this part shall be construed to limit actions necessary to protect health and safety.
- (2) Except as specifically provided in other parts of these rules, this part applies to persons licensed or registered by the department to receive, possess, use, or transfer sources of radiation. The limits in this part do not apply to doses from background radiation, to exposure of patients to radiation for medical diagnosis or therapy, to exposure from individuals administered radioactive material and released as specified in Rule 64E-5.622, F.A.C., or to voluntary participation in medical research programs.

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Specific Authority: 404.051(1), F.S.

R2 Law Implemented: 404.022, 404.051(1)(4), 404.181(1)(b) F.S.

R2 History: New January 1, 1994, Amended May 15, 1996, Formerly 10D-91.431, Amended October 8, 2000.

64E-5.302 Implementation.

- (1) Any existing license or registration condition that is more restrictive than Part III remains in force until there is an amendment or renewal of the license or registration.
- (2) If a license or registration condition exempts a licensee or registrant from a provision of the part in effect on or before the effective date of this rule, it also exempts the licensee or registrant from the corresponding provisions of this part.
- (3) If a license or registration condition cites provisions of this part in effect prior to the effective date of this rule which do not correspond to any provisions of this part, 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.

Specific Authority: 404.051, 404.081, F.S.

Law Implemented: 404.022, 404.051(1)(4), 404.081, F.S.

History: New January 1, 1994, Formerly 10D-91.433.

SUBPART B-- RADIATION PROTECTION PROGRAMS

64E-5.303 Radiation Protection Programs.

- (1) Each licensee or registrant shall develop, document, and implement a radiation protection program sufficient to ensure compliance with the provisions of this part. See 64E-5.335 for recordkeeping requirements relating to these programs.
- R2 (2) The licensee or registrant shall use to the extent **practical** procedures and engineering controls based upon sound radiation protection principles to achieve occupational doses and public doses that are as low as reasonably achievable.
- (3) The licensee or registrant shall, at intervals not to exceed 12 months, review the radiation protection program content and implementation.
- (4) Dental and podiatry registrants are exempt from (1) and (3), above.
- R2 (5) **To implement the ALARA requirements of Rule 64E-5.303(2), F.A.C., and notwith-**
 R2 **standing the requirements of Rule 64E-5.312, F.A.C., of this part,**
 R2 **licensees shall establish constraints on air emissions of radioactive material,**
 R2 **excluding radon 222 and its daughters, to the environment so that individual**
 R2 **members of the public who are likely to receive the highest doses are not**
 R2 **expected to receive a total effective dose equivalent in excess of 10 millirems**
 R2 **(0.10 mSv) per year from these emissions. If a licensee subject to this**
 R2 **requirement exceeds this dose constraint, the licensee shall report the**
 R2 **occurrence as specified in Rule 64E-5.345, F.A.C., and promptly take corrective**
 R2 **action to ensure against recurrence.**

R2 Specific Authority: 404.051(4), 404.081(1), F.S.

Law Implemented: 404.022, 404.051(1)(4), 404.081, F.S.

R2 History: New January 1, 1994, Amended November 20, 1994, Formerly 10D-91.434, **Amended October 8, 2000.**

SUBPART C -- OCCUPATIONAL DOSE LIMITS

64E-5.304 Occupational Dose Limits for Adults.

- R2 (1) The licensee or registrant shall control the occupational dose to individual adults,
 R2 except for planned special exposures as specified in **Rule** 64E-5.309, **F.A.C.**, to
 the following dose limits:
- (a) An annual limit, which is the more limiting of:
1. The total effective dose equivalent equal to 5 rem (0.05 sievert); or
 2. The sum of the deep dose equivalent and the committed dose equivalent to any individual organ or tissue other than the lens of the eye equal to 50 rem (0.5 sievert).
- R6 (b) The annual limits to the lens of the eye, to the skin **of the whole body**, and
 R6 to the **skin of the** extremities which are:
1. An **lens** dose equivalent of 15 rem (0.15 sievert), and
 2. A shallow dose equivalent of 50 rem (0.5 sievert) to the skin **of the**
whole body or to **skin of** any extremity.
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- R2 (2) Doses received in excess of the annual limits, including doses received during
R2 accidents, emergencies, and planned **special** exposures, shall be subtracted
R2 from the limits for planned special exposures that the individual **could receive**
R2 during the current year and during the individual's lifetime as specified in **Rule**
R2 64E-5.309(5)(a) and (b), **F.A.C.**
- R12 (3) When the external exposure is determined by measurement with an external
R12 personal monitoring device, the deep-dose equivalent must be used in place of
R12 the effective dose equivalent, unless the effective dose equivalent is determined
R12 by a dosimetry method approved by the Department. The assigned deep dose
R6 equivalent **must** be for the **part** of the body receiving the highest exposure. **The**
assigned shallow dose equivalent must be the dose averaged over the
contiguous 10 square centimeters of skin receiving the highest exposure. The
deep dose equivalent, **lens** dose equivalent and shallow dose equivalent **may** be
assessed from surveys or other radiation measurements to demonstrate
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.
- R12 (4) Derived air concentration (DAC) and annual limit on intake (ALI) values are
R12 presented in State of Florida Bureau of Radiation Control ALIs, DACs, and
Effluent Concentrations, June 2012, Table I, and can be used to determine the
individual's dose and to demonstrate compliance with the occupational dose
limits. See 64E-5.339.
- R12 (5) In addition to the annual dose limits, the licensee shall limit the soluble uranium
R12 intake by an individual to 10 milligrams in a week in consideration of chemical
toxicity. See footnote 3 of State of Florida Bureau of Radiation Control ALIs,
DACs, and Effluent Concentrations, June 2012 (see 64E-5.101, F.A.C.).
- (6) The licensee or registrant shall reduce the dose that an individual can be allowed
to receive in the current year by the amount of occupational dose received while
employed by any other person. See 64E-5.308(5).

Rulemaking Authority: 404.051, F.S.

Law Implemented: 404.022, 404.051(1)(4), F.S.

R12 History: New January 1, 1994, Formerly 10D-91.435, Amended 10-8-00, 9-28-06, 12-26-13.

64E-5.305 Compliance with Requirements for Summation of External and Internal Doses.

- (1) If the licensee is required to monitor as specified in both 64E-5.315(1) and (2), the licensee shall demonstrate compliance with the dose limits by summing external and internal doses. If the licensee or registrant is required to monitor only as specified in 64E-5.315(1) or only as specified in 64E-5.315(2), then summation is not required to demonstrate compliance with the dose limits. The licensee can demonstrate compliance with the requirements for summation of external and internal doses as specified in 64E-5.305(2),(3) and (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.

- (2) Intake by Inhalation. If the only intake of radionuclides is by inhalation, the total effective dose equivalent limit is not exceeded if the sum of the deep dose equivalent divided by the total effective dose equivalent limit and one of the following does not exceed unity:
- (a) The sum of the fractions of the inhalation ALI for each radionuclide;
 - (b) The total number of derived air concentration-hours (DAC-hours) for all radionuclides divided by 2,000; or
 - (c) The sum of the calculated committed effective dose equivalents to all significantly irradiated organs or tissues (T) calculated from bioassay data using appropriate biological models and expressed as a fraction of the annual limit. For purposes of this requirement, an organ or tissue is considered significantly irradiated if, for that organ or tissue, the product of the weighting factors, W_T , and the committed dose equivalent, $H_{T,50}$, per unit intake is greater than 10 percent of the maximum weighted value of H_{50} , or $W_T H_{T,50}$, per unit intake for any organ or tissue.
- (3) Intake by Oral Ingestion. If the occupationally exposed individual also receives an intake of radionuclides by oral ingestion greater than 10 percent of the applicable oral ALI, the licensee shall account for this intake and include it in demonstrating compliance with the limits.
- (4) Intake through Wounds or Absorption through Skin. The licensee shall evaluate and to the extent practical account for intakes through wounds or skin absorption. The intake through intact skin has been included in the calculation of DAC for hydrogen 3 and does not need to be evaluated or accounted for as specified in this subsection.

Specific Authority: 404.051, 404.081, F.S.

Law Implemented: 404.022, 404.051(1)(4), 404.081, F.S.

History: New January 1, 1994, Formerly 10D-91.436.

64E-5.306 Determination of External Dose from Airborne Radioactive Material.

- (1) Licensees shall include the contribution to the deep dose equivalent, eye dose equivalent, and shallow dose equivalent from external exposure to the radioactive cloud when determining the dose from airborne radioactive material. See State of Florida Bureau of Radiation Control ALIs, DACs, and Effluent Concentrations, June 2012, (see 64E-5.101, F.A.C.) footnotes 1 and 2.
- (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.

Rulemaking Authority: 404.051, 404.081, F.S.

Law Implemented: 404.022, 404.051(1)(4), 404.081, F.S.

R12 History: New January 1, 1994, Formerly 10D-91.437, Amended 12-26-13.

64E-5.307 Determination of Internal Exposure.

- (1) To assess dose used to determine compliance with occupational dose equivalent limits when required as specified in 64E-5.315, the licensee shall take suitable and timely measurements of:
 - (a) Concentrations of radioactive materials in air in work areas;
 - (b) Quantities of radionuclides in the body;
 - (c) Quantities of radionuclides excreted from the body; or
 - (d) Combinations of these measurements.
- (2) Unless respiratory protective equipment is used as specified in 64E-5.319 or the assessment of intake is based on bioassays, the licensee shall assume that an individual inhales radioactive material at the airborne concentration in which the individual is present.
- (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 is permitted to:
 - (a) Use that information to calculate the committed effective dose equivalent, and, if used, the licensee shall document that information in the individual's record;
 - (b) Upon prior approval of the department, adjust the DAC or ALI values to reflect the actual physical and chemical characteristics of airborne radioactive material, for example, aerosol size distribution or density; and
 - (c) Separately assess the contribution of fractional intakes of Class D, W, or Y compounds of a given radionuclide to the committed effective dose equivalent. See State of Florida Bureau of Radiation Control ALIs, DACs, and Effluent Concentrations, June 2012.
- (4) If the licensee chooses to assess intakes of Class Y material using the measurements given in 64E-5.307(1)(b) or (c), the licensee can delay the recording and reporting of the assessments for periods up to 7 months, unless otherwise required by 64E-5.344 or 64E-5.345. This delay permits the licensee to make additional measurements basic to the assessments.
- (5) If the identity and concentration of each radionuclide in a mixture are known, the fraction of the DAC applicable to the mixture for use in calculating DAC-hours shall be either:
 - (a) The sum of the ratios of the concentration to the appropriate DAC value, that is D, W, or Y, from State of Florida Bureau of Radiation Control ALIs, DACs, and Effluent Concentrations, June 2012, for each radionuclide in the mixture; or

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- (b) The ratio of the total concentration for all radionuclides in the mixture to the most restrictive DAC value for any radionuclide in the mixture.
- (6) If the identity of each radionuclide in a mixture is known, but the concentration of one or more of the radionuclides in the mixture is not known, the DAC for the mixture shall be the most restrictive DAC of any radionuclide in the mixture.
- (7) When a mixture of radionuclides in air exists, a licensee is permitted to disregard certain radionuclides in the mixture if:
- (a) The licensee uses the total activity of the mixture in demonstrating compliance with the dose limits in 64E-5.304 and in complying with the monitoring requirements in 64E-5.315(2);
- (b) The concentration of any radionuclide disregarded is less than 10 percent of its DAC; and
- (c) The sum of these percentages for all of the radionuclides disregarded in the mixture does not exceed 30 percent.
- (8) When determining the committed effective dose equivalent, the following information can be considered:
- (a) To calculate the committed effective dose equivalent, the licensee can assume that the inhalation of one ALI or an exposure of 2,000 DAC-hours results in a committed effective dose equivalent of 5 rem (0.05 sievert) for radionuclides that have their ALIs or DACs based on the committed effective dose equivalent.
- (b) For an ALI and the associated DAC determined by the nonstochastic organ dose limit of 50 rem (0.5 sievert), the intake of radionuclides that would result in a committed effective dose equivalent of 5 rem (0.05 sievert), that is, the stochastic ALI, as listed in parentheses in State of Florida Bureau of Radiation Control ALIs, DACs, and Effluent Concentrations, June 2012. (See 64E-5.101, F.A.C.) Table I. The licensee can use the stochastic ALI to determine committed effective dose equivalent as a simplifying assumption. However, if the licensee uses the stochastic ALI, the licensee shall also demonstrate that the limit in 64E-5.304(1)(a)2. is met.

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Rulemaking Authority: 404.051, F.S.

Law Implemented: 404.022, 404.051(1)(4), F.S.

R12 History: New January 1, 1994, Formerly 10D-91.308, Amended 12-26-13.

64E-5.308 Determination of Prior Occupational Dose.

- (1) For each individual who is likely to receive in a year an occupational dose requiring monitoring as specified in 64E-5.315, the licensee or registrant shall:
- (a) Determine the occupational radiation dose received during the current year; and

- (b) Attempt to obtain the records of lifetime cumulative occupational radiation dose.
- (2) Prior to permitting an individual to participate in a planned special exposure, the licensee or registrant shall determine:
- (a) The internal and external doses from all previous planned special exposures;
 - (b) All doses in excess of the limits received during the lifetime of the individual, including doses received during accidents and emergencies; and
 - (c) All lifetime cumulative occupational radiation doses.
- (3) In complying with the requirements of 64E-5.308(1), a licensee or registrant can:
- (a) Accept 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 as a record of the occupational dose that the individual received during the current year;
 - (b) Accept an up-to-date DH Form 1623 July 1993, which is herein incorporated by reference and which is available from the department, or an 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 as the record of lifetime cumulative radiation dose; and
 - (c) Obtain reports of the individual's dose equivalent from the most recent employer for work involving radiation exposure or the individual's current employer if the individual is not employed by the licensee or registrant by telephone, telegram, facsimile, or letter. The licensee or registrant shall request a written verification of the dose data if the authenticity of the transmitted report cannot be established.
- (4) The licensee or registrant shall record the exposure history, as required by 64E-5.308(1), on DH Form 1623 July 1993 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 DH Form 1623 July 1993 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 DH Form 1623 July 1993 or equivalent indicating the periods of time for which data are not available.

- (5) Licensees are not required to reevaluate the separate external dose equivalents and internal committed dose equivalents or intakes of radionuclides assessed as specified in the rules in this part in effect before the effective date of this rule. Further, occupational exposure histories obtained and recorded on DH Form 1623 or equivalent before the effective date of this rule would not have included effective dose equivalents, but can be used in the absence of specific information on the intake of radionuclides by the individual.
- (6) If the licensee or registrant is unable to obtain a complete record of an individual's current and previously accumulated occupational dose, the licensee or registrant shall assume:
 - (a) That the allowable dose limit for the individual is reduced by 1.25 rem (12.5 millisievert) for each quarter for which records were unavailable and the individual was engaged in activities that could have resulted in occupational radiation exposure to establish administrative controls as specified in 64E-5.304(6) for the current year; and
 - (b) That the individual is not available for planned special exposures.
- (7) The licensee or registrant shall retain the records on DH Form 1623 July 1993 or equivalent until the department terminates each pertinent license or registration requiring this record. The licensee or registrant shall retain records used in preparing DH Form 1623 July 1993 or equivalent for 3 years after the record is made.

Specific Authority: 404.051, 404.081, F.S.

Law Implemented: 404.022, 404.051(1)(4), 404.081, F.S.

History: New January 1, 1994, Formerly 10D-91.439.

64E-5.309 Planned Special Exposures. A licensee or registrant can authorize an adult worker to receive doses in addition to and accounted for separately from the doses received under the limits specified in **Rule 64E-5.304, F.A.C.**, if each of the following conditions is satisfied:

- R2 (1) The licensee or registrant authorizes a planned special exposure only in an exceptional situation when alternatives that might avoid the **dose** are unavailable or impractical.
- (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.
- (3) Before a planned special exposure, the licensee or registrant ensures that each individual involved is:
 - (a) Informed of the purpose of the planned operation;
 - (b) Informed of the estimated doses and associated potential risks and specific radiation levels or other conditions that might be involved in performing the task; and

- (c) Instructed in the measures to be taken to keep the dose ALARA considering other risks that might be present.
- (4) The licensee or registrant ascertains prior doses as required by 64E-5.308(2) during the lifetime of each individual involved prior to permitting an individual to participate in a planned special exposure.
- (5) As specified in 64E-5.304(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:
 - (a) The numerical values of any of the dose limits in 64E-5.305(1) in any year; and
 - (b) Five times the annual dose limits in 64E-5.304(1) during the individual's lifetime.
- (6) The licensee or registrant maintains records of the conduct of a planned special exposure as specified in 64E-5.338 and submits a written report to the department as specified in 64E-5.346.
- (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 after 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 as specified in 64E-5.304(1) but shall be included in evaluations required by 64E-5.309(4) and (5).

Specific Authority: 404.051, 404.081, F.S.

Law Implemented: 404.022, 404.051(1)(4), 404.081, F.S.

R2 History: New January 1, 1994, Formerly 10D-91.440, Amended October 8, 2000.

64E-5.310 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 64E-5.304.

Specific Authority: 404.051, 404.081, F.S.

Law Implemented: 404.022, 404.051(1)(4), 404.081, F.S.

History: New January 1, 1994, Formerly 10D-91.441.

64E-5.311 Dose to an Embryo or Fetus.

- (1) The licensee or registrant shall ensure that the dose to an embryo or fetus during the entire pregnancy from occupational exposure of a declared pregnant woman does not exceed 0.5 rem (5 mSv). See 64E-5.339 for recordkeeping requirements.
- (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 64E-5.311(1). It is recommended that no more than 0.05 rem (0.5 mSv) be received by the embryo or fetus in any one month.

- (3) The dose to an embryo or fetus shall be taken as the sum of:
- (a) The deep dose equivalent to the declared pregnant woman; and
 - (b) The dose to the embryo or fetus from radionuclides in the embryo or fetus and radionuclides in the declared pregnant woman.
- (4) If by the time the woman declares pregnancy to the licensee or registrant the dose to the embryo or fetus has exceeded 0.5 rem (5 mSv) or is within 0.05 rem (0.5 mSv) or this dose, the licensee or registrant shall be considered in compliance with Rule 64E-5.311(1), F.A.C., if the additional dose to the embryo or fetus does not exceed 0.05 rem (0.50 mSv) during the remainder of the pregnancy.
- (5) Each individual who has declared pregnancy shall wear a radiation monitor at waist level at all times at work. This monitor shall be used to estimate the fetal deep-dose equivalent. When the declared pregnant worker wears protective clothing, this monitor shall be worn under the protective clothing. The fetal dose is to be kept as low as reasonably achievable, but shall not exceed 10 percent of the standards specified in 64E-5.304. Each declared pregnant worker whose duties require protective clothing shall also wear a radiation monitor outside the protective clothing to estimate dose to the worker, and the standard occupational limits will apply.

Specific Authority: 404.051, 404.081, F.S.

Law Implemented: 404.022, 404.051(1)(4), 404.081, F.S.

R2 History: New January 1, 1994, Formerly 10D-91.442, Amended October 8, 2000.

SUBPART D

RADIATION DOSE LIMITS FOR INDIVIDUAL MEMBERS OF THE PUBLIC

64E-5.312 Dose Limits for Individual Members of the Public.

- (1) Each licensee or registrant shall conduct operations so that:
- (a) Except as specified in Rule 64E-5.312(1)(b), F.A.C., the total effective dose equivalent to individual members of the public from the licensed or registered operation does not exceed 0.1 rem (1 millisievert) in a year, exclusive of the dose contribution from background radiation, from any medical administration the individual has received, from exposure to individuals administered radioactive materials and released as specified in Rule 64E-5.622, F.A.C., from voluntary participation in medical research programs and from the licensee's disposal of radioactive material into sanitary sewerage as specified in Rule 64E-5.330, F.A.C.;
 - (b) In facilities in operation before January 1, 1994, the total effective dose equivalent to individual members of the public from infrequent exposure to radiation from diagnostic and therapeutic radiation machines does not exceed 0.5 rem (5 millisievert) in a year; and
 - (c) The dose in any unrestricted area from external sources, exclusive of the dose contribution from patients administered radioactive material and released as specified in Rule 64E-5.622, F.A.C., does not exceed 0.002 rem (0.02 millisievert) in any one hour.

- (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.
- (3) A licensee, registrant, or an applicant for a license or registration can apply for prior department authorization to operate up to an annual dose limit for an individual member of the public of 0.5 rem (5 millisievert). This application shall include the following information:
 - (a) Demonstration of the need for and the expected duration of operations in excess of the limit in 64E-5.304(1);
 - (b) The licensee's or registrant's program to assess and control dose within the 0.5 rem (5 millisievert) annual limit; and
 - (c) The procedures to be followed to maintain the dose ALARA.
- (4) In addition to the requirements of this part, a licensee subject to the provisions of the U.S. Environmental Protection Agency's generally applicable environmental radiation standards in 40 CFR 190 shall comply with those standards.

- R10 (5) A licensee or applicant for a license may permit visitors to an individual who
R10 cannot be released under Rule 64E-5.622, F.A.C., to receive a radiation dose
R10 greater than 0.1 rem (1 millisievert) provided the following are satisfied:
R10 (a) The radiation dose received does not exceed 0.5 rem (5 millisievert);
R10 (b) The authorized user, as defined in Rule 64E-5.6011, F.A.C., has
R10 determined before the visit that it is appropriate.

R10 Rulemaking Authority: 404.051, 404.081, F.S.
 Law Implemented: 404.022, 404.051(1)(4), 404.081, F.S.
 R10 History: New 1-1-94, Amended 5-15-96, Formerly 10D-91.443, Amended 10-8-00, Amended 02-11-10.

64E-5.313 Compliance with Dose Limits for Individual Members of the Public.

- (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 64E-5.312.
- (2) A licensee or registrant shall show compliance with the annual dose limit in 64E-5.312 by:
 - (a) Demonstrating by measurement or calculation that the total effective dose equivalent to the individual who is likely to receive the highest dose from the licensed or registered operation does not exceed the annual dose limit; or
 - (b) Demonstrating that:
 - 1. The annual average concentrations of radioactive material released in gaseous and liquid effluents at the boundary of the unrestricted area do not exceed the values specified in State of Florida Bureau of Radiation Control ALIs, DACs and Effluent Concentrations, June 2012, Table II ; and
 - 2. The dose from external sources would not exceed 0.002 rem (0.02 millisievert) in an hour and 0.05 rem (0.5 millisievert) in a year if an individual were continually present in an unrestricted area.

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- R12 (3) Upon approval from the department, the licensee can adjust the effluent
R12 concentration values in State of Florida Bureau of Radiation Control ALIs, DACs, and Effluent Concentrations, June 2012, (see 64E-5.101, F.A.C.) for members of the public to take into account the actual physical and chemical characteristics of the effluents, such as aerosol size distribution, solubility, density, radioactive decay equilibrium, and chemical form.
- (4) Dental and podiatry registrants are exempt from (1), (2), and (3), above.
- (5) Each licensee or registrant shall maintain records sufficient to demonstrate compliance with the dose limit for individual members of the public until the department terminates each pertinent license or registration requiring the record.

Rulemaking Authority: 404.051, F.S.

Law Implemented: 404.022, 404.051(1)(4), F.S.

R12 History: New 1-1-94, Amended 11-20-94, 5-15-96, Formerly 10D-91.444, Amended 12-26-13.

SUBPART E SURVEYS AND MONITORING

64E-5.314 General.

- (1) Each licensee or registrant shall make or cause to be made surveys that:
- (a) Are necessary for the licensee or registrant to comply with this part; and
 - (b) Are necessary under the circumstances to evaluate:
 - R2 1. The magnitude and extent of radiation levels;
 - 2. Concentrations or quantities of radioactive material; and
 - R2 3. The potential radiological hazards.
- (2) The licensee or registrant shall ensure that instruments and equipment used for quantitative radiation measurements such as dose rate and effluent monitoring are calibrated annually for the radiation measured.
- (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 64E-5.304, with other applicable provisions of these rules, or with conditions specified in a license or registration shall be processed and evaluated by a dosimetry processor:
- (a) Holding current personnel dosimetry accreditation from the National Voluntary Laboratory Accreditation Program (NVLAP) of the National Institute of Standards and Technology; and

- (b) Approved in this accreditation process for the type of radiation or radiations included in the NVLAP program that most closely approximates the type of radiation or radiations for which the individual wearing the dosimeter is monitored.
- (4) The licensee or registrant shall ensure that adequate precautions are taken to prevent a deceptive exposure of an individual monitoring device.
- (5) Dental and podiatry registrants are exempt from (1) and (2), above.

Specific Authority: 404.051, 404.081, F.S.

Law Implemented: 404.022, 404.051(1)(4), 404.081, F.S.

R2 History: New January 1, 1994, Amended November 20, 1994, Formerly 10D-91.445, Amended October 8, 2000.

64E-5.315 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 this part. As a minimum:

- (1) Each licensee or registrant shall monitor occupational exposure to radiation and shall supply and require the use of individual monitoring devices by:
 - R2 (a) Adults likely to receive in 1 year from sources external to the body a dose in excess of 10 percent of the limits in Rule 64E-5.304(1), F.A.C.;
 - R2 (b) Minors likely to receive in 1 year from radiation sources external to the body a deep dose equivalent in excess of 0.1 rem (1 mSv), a lens dose equivalent in excess of 0.15 rem (1.5 mSv) or a shallow dose equivalent to the skin or to the extremities in excess of 0.5 rem (5 mSv);
 - R2 (c) Declared pregnant women likely to receive during the entire pregnancy from radiation sources external to the body a deep dose equivalent in excess of 0.1 rem (1 mSv); and
 - R2 (d) Individuals entering a high or very high radiation area.
- R2 (2) Each licensee shall monitor to determine compliance with Rule 64E-5.307, F.A.C., the occupational intake of radioactive material by and assess the committed effective dose equivalent to:
 - R12 (a) Adults likely to receive in 1 year an intake in excess of 10 percent of the applicable ALI in State of Florida Bureau of Radiation Control ALIs, DACs, and Effluent Concentrations June 2012 (see 64E-5.101, F.A.C.), Table I, Columns 1 and 2; and
 - R2 (b) Minors likely to receive in 1 year a committed effective dose equivalent in excess of 0.10 rem (1.0 millisievert); and
 - R2 (c) Declared pregnant women likely to receive during the entire pregnancy a committed effective dose equivalent in excess of 0.1 rem (1 mSv).

Rulemaking Authority: 404.051, F.S.

Law Implemented: 404.022, 404.051(1)(4), F.S.

R12 History: New 1-1-94, Formerly 10D-91.446, Amended 10-8-00, 12-26-13.

SUBPART F
CONTROL OF EXPOSURE FROM EXTERNAL SOURCES IN RESTRICTED AREAS

64E-5.316 Control of Access to High Radiation Areas.

- (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:
 - (a) 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 0.1 rem (1 millisievert) in 1 hour at 30 centimeters from the source of radiation from any surface that the radiation penetrates;
 - (b) A control device that energizes a conspicuous visible or audible signal so that the individual entering the high radiation area and the supervisor of the activity are made aware of the entry; or
 - (c) Entryways that are locked except during periods when access to the areas is required with positive control over each individual entry.
- (2) The licensee or registrant can substitute continuous direct or electronic surveillance that is capable of preventing unauthorized entry in place of the controls required by 64E-5.316(1) for a high radiation area.
- (3) The licensee or registrant can apply to the department for approval of alternative methods for controlling access to high radiation areas.
- (4) The licensee or registrant shall establish the controls required by 64E-5.316(1) and (3) in a way that does not prevent individuals from leaving a high radiation area.
- (5) The licensee 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 as specified in the regulations of the U.S. Department of Transportation if:
 - (a) The packages do not remain in the area longer than 3 days; and
 - (b) The dose rate at 1 meter from the external surface of any package does not exceed 0.01 rem (0.1 millisievert) per hour.
- (6) The licensee 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 if 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 this part and to operate within the ALARA provisions of the licensee's radiation protection program.

- (7) 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 64E-5.316 if the registrant has met all the specific requirements for access and control specified in other applicable parts of these rules, such as Part IV for industrial radiographic operations, Part V for x-rays in the healing arts, and Part VIII for particle accelerators.

Specific Authority: 404.051, 404.081, F.S.

Law Implemented: 404.022, 404.051(1)(4), 404.081, F.S.

History: New January 1, 1994, Formerly 10D-91.447.

64E-5.317 Control of Access to Very High Radiation Areas.

- (1) In addition to the requirements in 64E-5.316, 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 500 rad (5 gray) 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.
- (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 64E-5.317(1) if the registrant has met all the specific requirements for access and control specified in other applicable parts of these rules, such as Part IV for industrial radiographic operations, Part V for x-rays in the healing arts, and Part VIII for particle accelerators.

Specific Authority: 404.051, 404.081, F.S.

Law Implemented: 404.022, 404.051(1)(4), 404.081, F.S.

History: New January 1, 1994, Formerly 10D-91.448.

SUBPART G RESPIRATORY PROTECTION AND CONTROLS TO RESTRICT INTERNAL EXPOSURE IN RESTRICTED AREAS

64E-5.318 Use of Process or Other Engineering Controls. The licensee shall use

R6 to the extent **practical** process or other engineering controls such as containment,
R6 **decontamination**, or ventilation to control the concentrations of radioactive material in air.

R6 (1) When it is not **practical** to apply process or other engineering controls, **to control**
R6 **the concentrations of radioactive material in the air to values below those that**
R6 **define an airborne radioactivity area**, the licensee shall, consistent with
maintaining the total effective dose equivalent ALARA, increase monitoring and
limit intakes by one or more of the following means:

- R6 (a) Control of access;
- R6 (b) Limitation of exposure time;
- R6 (c) Use of respiratory protection equipment; or
- R6 (d) Other controls.

R6 (2) **If the licensee performs an ALARA analysis to determine whether or not to use**
R6 **respirators, the licensee can consider safety factors other than radiological**
R6 **factors. The licensee also should consider the impact of respirator use on**
R6 **workers' industrial health and safety.**

Specific Authority: 404.051, F.S.

Law Implemented: 404.022, 404.051(1)(4), F.S.

R6 History: New January 1, 1994, Amended May 15, 199, Formerly 10D-91.450, **Amended September 28, 2006.**

64E-5.319 Use of Individual Respiratory Protection Equipment.

(1) If the licensee uses respiratory protection equipment to limit intakes as specified in 64E-5.318:

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(a) The licensee shall use only respiratory protection equipment that is tested and certified by the National Institute for Occupational Safety, except as provided in 64E-5.319(1)(b).

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(b) If the licensee 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 for authorized use of that equipment, including **evidence** that the material and performance characteristics of the equipment are capable of providing the proposed degree of protection under anticipated conditions of use **demonstrated by testing or on the basis of reliable test information.**

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(c) The licensee shall implement and maintain a respiratory protection program that includes:

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

2. Surveys and bioassays as needed to evaluate actual intakes;

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3. Testing of respirators for operability **including user seal checks for face sealing devices and functional checks for other devices** immediately **before** to each use;

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4. Written procedures regarding supervision and training of respirator users ; monitoring, including air sampling and bioassays; **fit testing; respirator selection; breathing air quality; inventory and control; storage, issuance, maintenance, repair, testing, and quality assurance of respiratory protection equipment; limitations on periods of respirator use and relief from respirator use;** and recordkeeping;

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5. Determination by a physician **before** initial fitting of **face sealing respirators**, **before the first field use of non-face sealing respirators**, and either every 12 months thereafter or periodically at a frequency determined by a physician that the individual user is medically fit to use respiratory protection equipment; **and**

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6. **Fit testing before the first field use of tight fitting face-sealing respirators and periodically thereafter at a frequency not to exceed 1 year with 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. Fit testing shall be performed with the facepiece operating in the negative pressure mode.**

- R6 (d) The licensee shall advise each respirator user that the user can 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.
- R6 (e) The licensee also shall consider limitations appropriate to the type and mode of use. When selecting respiratory devices, the licensee shall provide for vision correction, adequate communication, low temperature work environments, and the concurrent use of other safety or radiological protection equipment. The licensee shall use equipment in such a way as not to interfere with the proper operation of the respirator.
- R6 (f) 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. Standby persons shall 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 through visual, voice, signal line, telephone, radio, or other suitable means and be available immediately 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 shall be available immediately to assist all users of this type of equipment and to provide effective emergency rescue if needed.
- R6 (g) Atmosphere-supplying respirators shall 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, which is herein incorporated by reference and, available from the Compressed Gas Association, Inc., and included in the regulations of the Occupational Safety and Health Administration. Grade D quality air criteria include:
- R6 1. Oxygen content (v/v) of 19.5 – 23.5%;
 - R6 2. Condensed hydrocarbon content of 5 milligrams per cubic meter of air or less;
 - R6 3. Carbon monoxide content of 10 ppm or less;
 - R6 4. Carbon dioxide content of 1,000 ppm or less; and
 - R6 5. Lack of noticeable odor.
- R6 (h) The licensee shall ensure that no objects, materials, or substances such as facial hair, or any conditions that interfere with the face-to-facepiece seal or valve function and that are under the control of the respirator wearer are between the skin of the wearer's face and the sealing surface of a tight-fitting respirator facepiece.

- R6 (2) When estimating the dose to individuals from airborne radioactive materials, the
R6 concentration of radioactive material in the air that is inhaled when respirators
R6 are worn is assumed initially to be the ambient concentration in air without
R6 respiratory protection divided by the assigned protection factor. If the dose later
R6 is found to be greater than the estimated dose, the corrected value shall be used.
R6 If the dose later is found to be less than the estimated dose, the corrected value
R6 can be used.:
- R6 (a) Licensees shall take actions to limit doses to individuals from intakes of
R6 airborne radioactive materials to maintain total effective dose equivalent
R6 ALARA, which could include using process or other engineering controls
R6 and limiting the use of respiratory protection equipment. .
- R6 (b) The licensee shall obtain authorization from the department before using
R6 assigned protection factors in excess of those specified in State of Florida
R6 Bureau of Radiation Control Protection Factors for Respirators, May 2006.
The department can authorize a licensee to use higher protection factors
on receipt of an application that:
1. Describes the situation for which a need exists for higher protection factors; and
 2. Demonstrates that the respiratory protection equipment provides these higher protection factors under the proposed conditions of use.

Specific Authority: 404.051, 404.081, F.S.

R1 Law Implemented: 404.051(1)(4), 404.081, F.S.

R6 History: New January 1, 1994, Formerly 10D-91.452, Amended May 18, 1998, Amended September 28, 2006.

SUBPART H

STORAGE AND CONTROL OF LICENSED OR REGISTERED SOURCES OF RADIATION

64E-5.320 Security of Stored Sources of Radiation. The licensee shall secure from unauthorized removal or access licensed sources of radiation that are stored in restricted or unrestricted areas.

Specific Authority: 404.051, 404.081, F.S.

Law Implemented: 404.022, 404.051(1)(4), 404.081, F.S.

History: New January 1, 1994, Formerly 10D-91.453.

64E-5.321 Control of Sources of Radiation Not in Storage.

- (1) 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.
- (2) The registrant shall maintain control of radiation machines that are in a restricted or unrestricted area and that are not in storage.

Specific Authority: 404.051, 404.081, F.S.

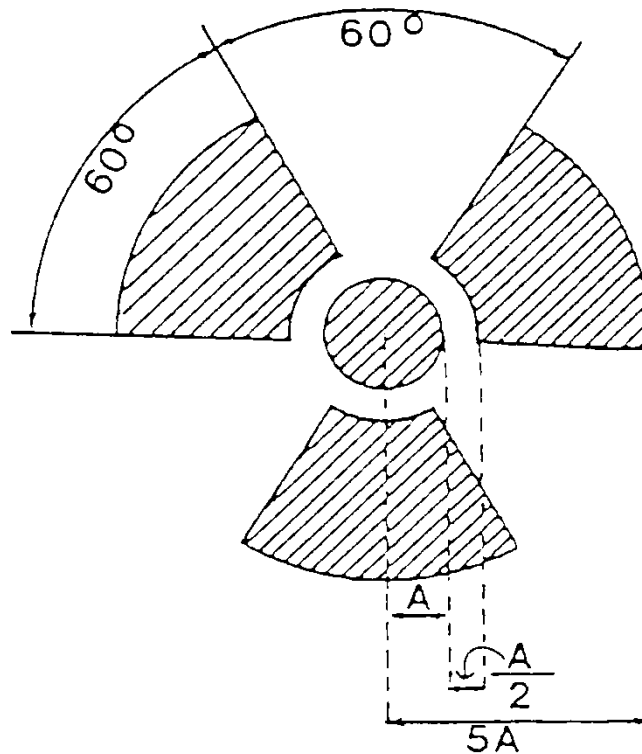
Law Implemented: 404.022, 404.051(1)(4), 404.081, F.S.

History: New January 1, 1994, Formerly 10D-91.454.

SUBPART I PRECAUTIONARY PROCEDURES

64E-5.322 Caution Signs.

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



- (a) Cross-hatched area is to be magenta or purple or black, and
- (b) The background is to be yellow.
- (2) Exception to Color Requirements for Standard Radiation Symbol. In spite of the requirements of 64E-5.322(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.
- (3) Additional Information on Signs and Labels. In addition to contents of signs and labels prescribed in this part, the licensee or registrant shall provide on or near the required signs and labels additional information to make individuals aware of potential radiation exposures and to minimize the exposures.

Specific Authority: 404.051, 404.081, F.S.
Law Implemented: 404.022, 404.051(1)(4), 404.081, F.S.
History: New January 1, 1994, Formerly 10D-91.455.

64E-5.323 Posting Requirements.

- (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."
- (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."
- (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 "GRAVE DANGER, VERY HIGH RADIATION AREA."
- (4) Posting of Airborne Radioactivity Areas. The licensee 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."
- (5) Posting of Areas or Rooms in which Licensed Material is Used or Stored. The licensee shall post each area or room in which there is used or stored an amount of licensed material exceeding 10 times the quantity of such material specified in State of Florida Bureau of Radiation Control Radioactive Material Requiring Labeling, **May 2000**, which is herein incorporated by reference and which is available from the department, with a conspicuous sign or signs bearing the radiation symbol and the words "CAUTION, RADIOACTIVE MATERIAL(S)" or "DANGER, RADIOACTIVE MATERIAL(S)."

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Specific Authority: 404.051, 404.081, F.S.

Law Implemented: 404.022, 404.051(1)(4), 404.081, F.S.

R2 History: New January 1, 1994, Formerly 10D-91.456, **Amended October 8, 2000.**

64E-5.324 Exceptions to Posting Requirements.

- (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:
 - (a) 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 this part; and
 - (b) The area or room is subject to the licensee's or registrant's control.
- (2) Rooms or other areas in hospitals that are occupied by patients are not required to be posted with caution signs as specified in 64E-5.323 if the patient could be released from confinement as specified in 64E-5.622.

- (3) A room or area is not required to be posted with a caution sign because of the presence of a sealed source provided the radiation level at 30 centimeters from the surface of the sealed source container or housing does not exceed 0.005 rem (0.05 millisievert) per hour.
- (4) 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.

Specific Authority: 404.051, 404.081, F.S.

Law Implemented: 404.022, 404.051(1)(4), 404.081, F.S.

History: New January 1, 1994, Formerly 10D-91.457.

64E-5.325 Labeling Containers and Radiation Machines.

- (1) The licensee shall ensure that each container of licensed 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.
- (2) Each licensee prior to removal or disposal of empty uncontaminated containers to unrestricted areas shall remove or deface the radioactive material label or otherwise clearly indicate that the container no longer contains radioactive materials.
- (3) Each registrant shall ensure that each radiation machine is labeled in a conspicuous manner which cautions individuals that radiation is produced when it is energized.

Specific Authority: 404.051, 404.081, F.S.

Law Implemented: 404.022, 404.051(1)(4), 404.081, F.S.

History: New January 1, 1994, Formerly 10D-91.458.

64E-5.326 Exemptions to Labeling Requirements. A licensee is not required to label:

- (1) Containers holding licensed material in quantities less than the quantities listed in State of Florida Bureau of Radiation Control Radioactive Material Requiring Labeling, **May 2000**;
- (2) Containers holding licensed material in concentrations less than those specified in State of Florida Bureau of Radiation Control ALIs, DACs, and Effluent Concentrations, July 2012 (See 64E-5.101, F.A.C.), Table III;
- (3) Containers attended by an individual who takes the precautions necessary to prevent the exposure of individuals in excess of the limits established by this part;

- (4) Containers when they are in transport and packaged and labeled as specified by the rules of the U.S. Department of Transportation;
- (5) Containers that are accessible only to individuals authorized to handle or use them or to work in the vicinity of the containers if the contents are identified to these individuals by a readily available written record. Examples of containers of this type are containers in locations such as water-filled canals, storage vaults, or hot cells. The record shall be retained as long as the containers are in use for the purpose indicated on the record; or
- (6) Installed manufacturing or process equipment, such as piping and tanks.

Rulemaking Authority: 404.051, F.S.

Law Implemented: 404.022, 404.051(1)(4), F.S.

R12 History: New 1-1-94, Formerly 10D-91.459, Amended 10-8-00, 12-26-13.

64E-5.327 Procedures for Receiving and Opening Packages.

- (1) Each licensee who expects to receive a package containing quantities of radioactive material in excess of A_1 or A_2 quantities as defined in Part XV shall make arrangements to receive:
 - (a) The package when the carrier offers it for delivery; or
 - (b) The notification of the arrival of the package at the carrier's terminal and to take possession of the package expeditiously.
- (2) Each licensee shall:
 - (a) Monitor the external surfaces of a package for radioactive contamination that are labeled with a Radioactive White I, Yellow II, or Yellow III label as specified in U.S. Department of Transportation regulations in 49 CFR 172.403 and 172.436.440, unless the package contains only radioactive material in the form of gas or in special form as defined in Part XV;
 - (b) Monitor the external surfaces of a package for radiation levels that are labeled with a Radioactive White I, Yellow II, or Yellow III label as specified in U.S. Department of Transportation regulations in 49 CFR 172.403 and 172.436.440, unless the package contains quantities of radioactive material that are less than or equal to the A_1 or A_2 quantities as defined in Part XV; and
 - (c) 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.
- (3) The licensee or registrant shall perform the monitoring required by 64E-5.327(2) as soon as practicable after receipt of the package but not later than 3 hours after the package is received at the licensee's facility if it is received during the licensee's normal working hours, or not later than 3 hours from the beginning of the next working day if it is received after working hours.

- (4) The licensee shall immediately notify the final delivery carrier and the department by telephone and telegram, mailgram, or facsimile when:
 - (a) Removable radioactive surface contamination exceeds the limits of 64E-5.1505(8); or
 - (b) External radiation levels exceed the limits of 64E-5.1505(9).
- (5) Each licensee shall:
 - (a) Establish, maintain, and retain written procedures for safely opening packages in which radioactive material is received; and
 - (b) Ensure that the procedures are followed and that consideration is given to special instructions for the type of package being opened.
- (6) Licensees transferring special form sources in vehicles owned or operated by the licensee to and from a work site are exempt from the contamination monitoring requirements of 64E-5.327(2)(a), but are not exempt from the monitoring requirement in 64E-5.327(2)(b) for measuring radiation levels that ensures that the source is still properly lodged in its shield.

Specific Authority: 404.051, 404.081, F.S.

Law Implemented: 404.022, 404.051(1)(4), 404.081, F.S.

History: New January 1, 1994, Formerly 10D-91.460.

SUBPART J WASTE MANAGEMENT

64E-5.328 General Requirements.

- (1) Unless otherwise exempted, a licensee shall transfer waste for disposal, discharge, or decay licensed material only:
 - (a) By transfer to an authorized recipient as specified in 64E-5.332 or in Part II of these regulations or to the U.S. Department of Energy;
 - (b) By decay in storage;
 - (c) By release in effluents within the limits in 64E-5.312; or
 - (d) As authorized in this subpart.
- (2) A person shall be specifically licensed to receive waste containing licensed material from other persons for:
 - (a) Treatment prior to disposal;
 - (b) Treatment by incineration;
 - (c) Decay in storage;

- (d) Disposal at a licensed land disposal facility; or
- (e) Storage until transferred to a storage or disposal facility authorized to receive the waste.

Specific Authority: 404.051, 404.081, F.S.
Law Implemented: 404.022, 404.051(1)(4), 404.081, F.S.
History: New January 1, 1994, Formerly 10D-91.461.

64E-5.329 Method of Obtaining Approval of Proposed Disposal Procedures.

- (1) A person can apply to the department 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 of 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 exposure.
- (2) The department will not approve any application for a licensee to receive radioactive material from other persons for disposal on land not owned by a state or the federal government.

Specific Authority: 404.051, 404.081, F.S.
Law Implemented: 404.022, 404.051(1)(4), 404.081, F.S.
History: New January 1, 1994, Formerly 10D-91.462.

64E-5.330 Discharge by Release into Sanitary Sewerage.

- (1) A licensee can discharge licensed material into sanitary sewerage if each of the following conditions is satisfied:
 - (a) The material is readily soluble or is readily dispersible biological material in water;
 - (b) The quantity of licensed 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 State of Florida Bureau of Radiation Control ALIs, DACs, and Effluent Concentrations, June 2012, Table III;
 - (c) If more than one radionuclide is released, the following conditions must also be satisfied;

R12
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1. The licensee shall determine the fraction of the limit in State of Florida Bureau of Radiation Control ALIs, DACs, and Effluent Concentrations, July 1993, Table III 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 State of Florida Bureau of Radiation Control ALIs, DACs, and Effluent Concentrations, June 2012, (See 64E-5.101, F.A.C.) Table III; and
 2. The sum of the fractions for each radionuclide required by 64E-5.330(1)(c)1. does not exceed unity; and
- (d) The total quantity of licensed radioactive material that the licensee releases into the sanitary sewerage in a year does not exceed 5 curies (185 gigabecquerels) of hydrogen 3, 1 curie (37 gigabecquerels) of carbon 14, and 1 curie (37 gigabecquerels) of all other radioactive materials combined.
- (2) Excreta from individuals undergoing medical diagnosis or therapy with radioactive material are not subject to the limitations contained in 64E-5.330(1).

Rulemaking Authority: 404.051, F.S.

Law Implemented: 404.022, 404.051(1)(4), F.S.

R12 History: New 1-1-94, Formerly 10D-91.463, Amended 12-26-13.

64E-5.331 Disposal of Specific Wastes.

R10

- (1) A licensee can dispose of the following licensed material without regard to its radioactivity:
- (a) 0.05 microcurie (1.85 kBq) or less of hydrogen 3 or carbon 14 per gram of medium used for liquid scintillation counting;
 - (b) 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.
 - (c) Any radioactive material which is not a sealed source with a physical half-life of less than 120 days if all of the following are met:
 1. Radioactive material to be disposed is held for decay in storage a minimum of 10 half-lives;
 2. The radioactive material is monitored at the container surface before disposal as ordinary trash and its radioactivity cannot be distinguished from the background radiation level in a low background radiation area with an appropriate radiation survey instrument set on its most sensitive scale and with no interposed shielding;

3. All radiation labels are removed or obliterated, unless specifically authorized in writing or license condition by the department;
4. Each generator column is separated and monitored individually with all radiation shielding removed to ensure that its contents have decayed to background levels before disposal; and
5. The licensee shall retain a record of each disposal for 3 years. The record shall include:
 - a. The date of the disposal;
 - b. The date on which the radioactive material was placed in storage;
 - c. The radionuclides disposed;
 - d. The model and serial number of the radiation survey instrument used;
 - e. The background dose rate;
 - f. The radiation dose rate measured at the surface of each container; and
 - g. The name of the individual who performed the disposal.

R12 (d) Licensed material as defined in paragraphs 64E-5.101(21)(c) and (d),
R12 F.A.C., may be disposed of at a licensed low-level radioactive waste
R12 disposal facility, even though it is not defined as low-level radioactive
R12 waste provided the requirements of Rule 64E-5.332, F.A.C., are satisfied
R12 or at a disposal facility authorized to dispose of such material in
R12 accordance with any Federal or State solid or hazardous waste law,
R12 including the Solid Waste Disposal Act, as authorized under the Energy
R12 Policy Act of 2005.

(2) A licensee shall not dispose of tissue as specified in 64E-5.331(1) in a manner that would permit its use either as food for humans or as animal feed.

(3) The licensee shall maintain records as specified in 64E-5.340.

Rulemaking Authority: 404.051, 404.081, F.S.

Law Implemented: 404.022, 404.051(1)(4), 404.081, F.S.

R12 History: New 1-1-94, Formerly 10D-91.465, Amended 2-11-10, 12-26-13.

64E-5.332 Transfer for Disposal and Manifests.

- R1 (1) The requirements of this section, Requirements for Transfers of Low-Level
R1 Radioactive Waste Intended for Disposal at Licensed Land Disposal Facilities
R1 and Manifest, July 1997, hereafter referred to as "Requirements for Low-Level
R1 Radioactive Waste Disposal," which is herein incorporated by reference and
R1 which is available from the department, and Part XV are designed to control
R1 transfers of low-level radioactive waste by any waste generator, waste collector,
R1 or waste processor licensee, as defined in the Requirements for Low-Level
R1 Radioactive Waste Disposal, who ships low-level waste directly or indirectly
R1 through a waste collector or waste processor to a licensed low-level waste land
R1 disposal facility as defined in Requirements for Low-Level Radioactive Waste
R1 Disposal, establish a manifest tracking system, and supplement existing
R1 requirements concerning transfers and recordkeeping for those wastes.
R1 Requirements for Low-Level Radioactive Waste Disposal incorporates NRC
R1 Form 540 (3-95), Uniform Low-Level Radioactive Manifest - Shipping Paper;
R1 NRC Form 541 (11-96), Uniform Low-Level Radioactive Waste Manifest -
R1 Container and Waste Description; and NRC Form 542 (3-95), Uniform Low-Level
R1 Radioactive Waste Manifest - Manifest Index and Regional Compact Tabulation.
- R1 (2) Prior to March 1, 1998, each shipment of radioactive waste designated for
R1 disposal at a licensed low-level radioactive waste disposal facility shall be
R1 accompanied by a shipment manifest as specified in 64E-5.333(12). Beginning
R1 March 1, 1998, any licensee shipping radioactive waste intended for ultimate
R1 disposal at a licensed land disposal facility shall document the information
R1 required on forms specified in Requirements for Low-Level Waste Disposal and
R1 transfer this recorded information to the intended consignee as specified in
R1 Requirements for Low-Level Radioactive Waste Disposal.
- R1 (3) Prior to March 1, 1998, each shipment manifest shall include a certification by the
R1 waste generator as specified in 64E-5.333(12). Beginning March 1, 1998, each
R1 shipment manifest shall include a certification by the waste generator as
R1 specified in Requirements for Low-Level Radioactive Waste Disposal.
- R1 (4) Prior to March 1, 1998, each person involved in the transfer of waste for disposal,
R1 including the waste generator, waste collector, waste processor and disposal
R1 facility operator, shall comply with the requirements specified in
R1 64E-5.333(12). Beginning March 1, 1998, each person participating in the
R1 transfer of waste for disposal, including the waste generator, waste collector,
R1 waste processor and disposal facility operator, shall comply with the
R1 requirements specified in Requirements for Low-Level Radioactive Waste
R1 Disposal.

R1 Specific Authority: 404.051, 404.081, 404.20, F.S.

R1 Law Implemented: 404.051(1)(4), 404.081, 404.20, F.S.

R1 History: New January 1, 1994, Formerly 10D-91.466, Amended May 18, 1998.

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64E-5.333 Classification and Characteristics of Low Level Radioactive Waste for Near-Surface Land Disposal, Labeling and Manifest Requirements.

- (1) Physical Half-life Considerations.
 - (a) Consideration by the licensee must be given to the concentration of long-lived radionuclides, and their shorter-lived precursors, whose potential hazard will persist long after such precautions as institutional controls, improved waste form and deeper disposal have ceased to be effective. These precautions delay the time when long-lived radionuclides could cause exposures. In addition, the magnitude of the potential dose is limited by the concentration and availability of the radionuclide at the time of exposure.
 - (b) Consideration by the licensee must be given to the concentration of shorter-lived radionuclides for which requirements on institutional controls, waste form and disposal methods are effective.
- (2) Classes of Low Level Radioactive Waste.
 - (a) Class A waste is waste that is usually segregated from other waste classes at the disposal site. The physical form and characteristics of Class A waste must meet the minimum requirements set forth in (9)(a), below. If Class A waste also meets the stability requirements set forth in (9)(b), below, it is not necessary to segregate the waste for disposal.
 - (b) Class B waste is waste that must meet more rigorous requirements on waste form to ensure stability after disposal. The physical form and characteristics of Class B waste must meet both the minimum and stability requirements set forth in (9), below.
 - (c) Class C waste is waste that not only must meet more rigorous requirements on waste form to ensure stability but also requires additional measures at the disposal facility to protect against inadvertent intrusion. The physical form and characteristics of Class C waste must meet both the minimum and stability requirements set forth in (9), below.
- (3) Classification of Low Level Radioactive Waste Determined by Long-Lived Radionuclides Present. If the low-level radioactive waste contains only radionuclides listed in Table 1, classification shall be determined as follows:

- (a) If the concentration does not exceed 0.1 times the value in Table 1, the waste is Class A.
- (b) If the concentration exceeds 0.1 times the value in Table 1, the waste is Class C.
- (c) If the concentration exceeds the value in Table 1, the waste is not generally acceptable for near-surface disposal.
- (d) For wastes containing mixtures of radionuclides listed in Table 1, the total concentration shall be determined by the sum of fractions rule described in (7), below.

TABLE 1	
RADIONUCLIDE	CONCENTRATION (Curies per cubic meter)
C-14	8
C-14 in activated metal	80
Ni-59 in activated metal	220
Nb-94 in activated metal	0.20
Tc-99	3
I-129	0.08
RADIONUCLIDE	(Nanocuries per gram)
Alpha emitting transuranic radionuclides with a half-life greater than 5 years	100
Pu-241	3,100
Cm-242	20,000
Ra-226	100

- (e) To convert nanocuries to becquerels (Bq), multiply by 37. To convert curies to gigabecquerels (GBq), multiply by 37.
- (4) Classification of Low Level Radioactive Waste Determined by Short-Lived Radionuclides Present. If the low level radioactive waste does not contain any of the radionuclides listed in Table 1, classification shall be determined based on the concentrations shown in Table 2.
- (a) If the radioactive waste does not contain any radionuclides listed in either Table 1 or 2, the waste is Class A.
 - (b) If the concentration does not exceed the value in Table 2, Column 1, the waste is Class A.
 - (c) If the concentration exceeds the value in Table 2, Column 1, but does not exceed the value in Column 2, the waste is Class B.

- (d) If the concentration exceeds the value in Table 2, Column 2, but does not exceed the value in Column 3, the waste is Class C.
- (e) If the concentration exceeds the value in Table 2, Column 3, the waste is not generally acceptable for near-surface disposal.
- (f) For wastes containing mixtures of the radionuclides listed in Table 2, the total concentration shall be determined by the sum of fractions rule described in (7), below.

TABLE 2			
	CONCENTRATION (Curies per cubic meter)		
RADIONUCLIDE	Column 1	Column 2	Column 3
Total of all radionuclides with less than 5 year half-life	700	See (4)(g), below	See (4)(g)
H-3	40	See (4)(g), below	See (4)(g)
Co-60	700	See (4)(g), below	See (4)(g)
Ni-63	3.5	70	700
Ni-63 in activated metal	35	700	7,000
Sr-90	0.04	150	7,000
Cs-137	1	44	4,600

- (g) There are not limits established for the radionuclides specified in Table 2 for Class B or C wastes. Practical considerations such as the effects of external radiation and internal heat generation on transportation, handling and disposal will limit the concentrations for such wastes. Such wastes shall be Class B unless the concentrations of other radionuclides in Table 2 determine the waste to be Class C, independent of these radionuclides.
- (5) Classification of Low Level Radioactive Waste Determined by Both Long- and Short-Lived Radionuclides Present. If the radioactive waste contains a mixture of radionuclides, some of which are listed in Table 1, and some of which are listed in Table 2, classification shall be determined as follows:
- (a) If the concentration of a radionuclide listed in Table 1 is less than 0.1 times the value listed in Table 1, the class shall be that determined by the concentration of radionuclides listed in Table 2.
 - (b) If the concentration of a radionuclide listed in Table 1 exceeds 0.1 times the value listed in Table 1, the waste shall be Class C, provided the concentration of radionuclides listed in Table 2 does not exceed the value shown in Table 2, Column 3.
- (6) Classification of Low Level Radioactive Wastes with Radionuclides Other Than Those Listed in Tables 1 and 2. If the radioactive waste does not contain any radionuclides listed in either Table 1 or 2, it is Class A.

- (7) The Sum of the Fractions Rule for Mixtures of Radionuclides. For determining classification for waste that contains a mixture of radionuclides, it is necessary to determine the sum of fractions by dividing each radionuclide's concentration by the appropriate limit and adding the resulting values. The appropriate limits must all be taken from the same column of the same table. The sum of the fractions for the column must be less than 1.0 if the waste class is to be determined by that column. Example: A waste contains Sr-90 in a concentration of 50 Ci per m³ (1.85 TBq per m³) and Cs-137 in a concentration of 22 Ci per m³ (814 GBq per m³). Since the concentrations both exceed the values in Table 2, Column 1, they must be compared to Column 2 values. For Sr-90 fraction $50/150 = 0.33$; for Cs-137 fraction, $22/44 = 0.5$; the sum of the fractions = 0.83. Since the sum is less than 1.0, the waste is Class B.
- (8) Determination of Concentrations in Low Level Radioactive Wastes. The concentration of a radionuclide may be determined by indirect methods such as use of scaling factors which relate the inferred concentration of one radionuclide to another that is measured, or radionuclide material accountability, if there is reasonable assurance that the indirect methods can be correlated with actual measurements. The concentration of a radionuclide may be averaged over the volume of the waste, or weight of the waste, if the units are expressed as nanocuries per gram.
- (9) Low Level Radioactive Waste Characteristics.
- (a) The following are minimum requirements for all three classes of radioactive waste specified in (2), above, and are intended to facilitate handling and provide protection of health and safety of personnel at the disposal site.
1. Radioactive wastes should be packaged in conformance with the conditions of the license issued to the site operator to which the waste will be shipped.
 2. Radioactive wastes shall not be packaged for disposal in cardboard or fiberboard boxes.
 3. Liquid radioactive waste must be solidified or packaged in sufficient absorbent material to absorb twice the volume of the liquid.
 4. Solid radioactive waste containing liquid shall contain as little freestanding and noncorrosive liquid as is reasonably achievable, but in no case shall the liquid be corrosive or exceed 1 percent of the volume.

5. Radioactive waste shall not be readily capable of detonation or of explosive decomposition or reaction at normal pressures and temperatures, or of explosive reaction with water.
6. Radioactive waste shall not contain, or be capable of generating, quantities of toxic gases, vapors or fumes harmful to persons transporting, handling or disposing of the waste. This does not apply to radioactive gaseous waste packaged in accordance with (9)(a)8., below.
7. Pyrophoric materials contained in radioactive wastes shall be treated, prepared and packaged to be nonflammable.
8. Radioactive wastes in gaseous form shall be packaged at a gauge pressure that does not exceed 1.5 atmospheres at 20 degrees Celsius. Total activity shall not exceed 100 curies (3.7 TBq) per container.
9. Radioactive wastes containing hazardous, biological, pathogenic or infectious material shall be treated to reduce to the maximum extent practicable the potential hazard from the nonradiological materials.
 - (b) Radioactive waste shall have structural stability. A structurally stable waste form will generally maintain its physical dimensions and its form, under the expected disposal conditions such as weight of overburden and compaction equipment, the presence of moisture, and microbial activity, and internal factors such as radiation effects and chemical changes. Structural stability can be provided by the waste form itself, processing the waste to a stable form, or placing the waste in a disposal container or structure that provides stability after disposal.
 - (c) Notwithstanding the provisions in (9)(a)3. and 4., above, liquid radioactive wastes, or radioactive wastes containing liquid, shall be converted into a form that contains as little freestanding and noncorrosive liquid as reasonably achievable, but in no case shall the liquid be corrosive or exceed 1 percent of the volume of the waste when the waste is in a disposal container designed to ensure stability, or 0.5 percent of the volume of the waste for waste processed to a stable form.
 - (d) Void spaces within the radioactive waste and between the waste and its package shall be reduced to the extent practicable.
- (10) Package Labeling of Low Level Radioactive Waste. Each package of radioactive waste shall be clearly labeled to identify whether it is Class A, Class B or Class C waste, in accordance with (1) through (8), above.
- (11) Reserved.
- (12) Transfer for Disposal and Manifests of Low Level Radioactive Waste.

- (a) Each shipment of radioactive waste to a licensed land disposal facility shall be accompanied by a shipment manifest that contains the name, address and telephone number of the person generating the waste. The manifest shall also include the name, address and telephone number or the name and U.S. Environmental Protection Agency hazardous waste identification number of the person transporting the waste to the land disposal facility. The manifest shall also indicate as completely as practicable:
1. A physical description of the waste;
 2. The waste volume;
 3. Radionuclide identity and quantity;
 4. The total radioactivity; and
 5. The principal chemical form.

The solidification agent, if used, shall be specified. Wastes containing more than 0.1 percent chelating agents by weight shall be identified and the weight percentage of the chelating agent estimated. Wastes classified as Class A, Class B or Class C in (1) through (8), above, shall be clearly identified as such in the manifest. The total quantity of the radionuclides H-3, C-14, Tc-99 and I-129 shall be shown.

- (b) The manifest required in (12)(a), above, may be shipping papers used to meet U.S. Department of Transportation or U.S. Environmental Protection Agency regulations or requirements of the receiver, provided all the required information is included.
- (c) Each manifest shall include a certification by the radioactive waste generator that the transported materials are properly classified, described, packaged, marked, and labeled and are in proper condition for transportation according to the applicable regulations of the U.S. Department of Transportation and the department. An authorized representative of the waste generator shall sign and date the manifest.
- (d) Any licensee who transfers radioactive waste to a land disposal facility or a licensed waste collector shall comply with the following requirements. Any licensee who transfers waste to a licensed waste processor who treats or repackages waste shall comply with the requirements of (12)(d)4. through 8., below. A licensee shall:
1. Prepare all radioactive wastes so that the waste is classified according to (1) through (8), above, and meets the waste characteristics requirements in (9), above;
 2. Label each package of waste to identify whether it is Class A waste, Class B waste or Class C waste, in accordance with (1) through (8), above;

3. Conduct a quality control program to assure compliance with (1) through (9), above; the program must include management evaluation of audits;
 4. Prepare shipping manifests to meet the requirements of (12)(a) and (c), above;
 5. Forward a copy of the manifest to the intended recipient at the time of shipment; or, deliver to a collector at the time the radioactive waste is collected, obtaining acknowledgment of receipt in the form of a signed copy of the manifest from the collector;
 6. Include one copy of the manifest with the shipment;
 7. Retain a copy of the manifest with documentation of acknowledgment of receipt as the record of transfer of licensed material as required by these regulations; and
 8. For any low level radioactive waste shipments or any part of a shipment for which acknowledgment of receipt has not been received within the times set forth in this subsection, conduct an investigation in accordance with (12)(g), below.
- (e) Any waste collector licensee who handles only radioactive wastes that have been prepackaged shall:
1. Acknowledge receipt of the radioactive waste from the generator within 1 week of receipt by returning a signed copy of the manifest;
 2. Prepare a new manifest to reflect consolidated shipments; the new manifest shall serve as a listing or index for the detailed generator manifests. Copies of the generator manifests shall be a part of the new manifest. The waste collector may prepare a new manifest without attaching the generator manifests, provided the new manifest contains for each package the information specified in (12)(a), above. The collector licensee shall certify that nothing has been done to the waste which would invalidate the generator's certification;
 3. Forward a copy of the new manifest to the land disposal facility operator at the time of shipment;
 4. Include the new manifest with the radioactive waste shipment to the disposal site;
 5. Retain a copy of the manifest with documentation of acknowledgment of receipt as the record of transfer of licensed material as required by these regulations, and retain information from generator manifests until disposition

is authorized by the department; and

6. For any low level radioactive waste shipments or any part of a shipment for which acknowledgment of receipt is not received within the times set forth in this subsection, conduct an investigation in accordance with (12)(g), below.
- (f) Any licensed waste processor who treats or repackages low level radioactive wastes shall:
1. Acknowledge receipt of the radioactive waste from the generator within 1 week of receipt by returning a signed copy of the manifest or equivalent documentation;
 2. Prepare a new manifest that meets the requirements of (12)(a) and (c), above. Preparation of the new manifest reflects that the processor is responsible for the waste;
 3. Prepare all low level radioactive wastes so that the waste is classified according to (1) through (8), above, and meets the waste characteristics requirement in (9), above;
 4. Label each package of waste to identify whether it is Class A waste, Class B waste or Class C waste, as specified in (1) through (8) and (10), above;
 5. Conduct a quality control program to assure compliance with (1) through (9), above. The program shall include management evaluation of audits;
 6. Forward a copy of the new manifest to the disposal site operator or waste collector at the time of shipment, or deliver to a collector at the time the radioactive waste is collected, obtaining acknowledgment of receipt in the form of a signed copy of the manifest by the collector;
 7. Include the new manifest with the shipment;
 8. Retain copies of original manifests and new manifests with documentation of acknowledgment of receipt as the record or transfer of licensed material required by these regulations; and
 9. For any low level waste shipment or part of a shipment for which acknowledgment if not received within the times set forth in this section, conduct an investigation in accordance with (12)(g), below.

- (g) The land disposal facility operator shall:
1. Acknowledge receipt of the waste within 1 week of receipt by returning a signed copy of the manifest or equivalent documentation to the shipper. The shipper to be notified is the licensee who last possessed the waste and transferred the waste to the operator. The returned copy of the manifest or equivalent documentation shall indicate any discrepancies between materials listed on the manifest and materials received;
 2. Maintain copies of all completed manifests or equivalent documentation until the department authorizes their disposition; and
 3. Notify the shipper and the department when any shipment or portion of a shipment has not arrived within 60 days after the advance manifest was received.
- (h) Any low level radioactive waste shipment or part of a shipment for which acknowledgment is not received within the times set forth in this section must:
1. Be investigated by the shipper if the shipper has not received notification of receipt within 20 days after transfer; and
 2. Be traced and reported. The investigation shall include tracing the shipment and filing a report with the department. Each licensee who conducts a trace investigation shall file a written report with the department within 2 weeks of completion of the investigation.

- R1 (13) Beginning March 1, 1998, all licensees shall comply with Requirements for Low-
R1 Level Radioactive Waste Disposal. Prior to March 1, 1998, a low-level waste
R1 disposal facility operator or its regulatory authority can require the shipper to use
R1 requirements specified in (12), above.

Specific Authority: 404.051, 404.061, 404.20, F.S.

R1 Law Implemented: 404.051(1)(4), 404.061(2), 404.20(1), F.S.

R1 History: New January 1, 1994, Amended May 15, 1996, Formerly 10D-91.468, Amended May 18, 1998.

SUBPART K RECORDS

64E-5.334 General Provisions.

- R1
R1
R1
- (1) Each licensee or registrant shall use the SI unit 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 this part. The information on shipping manifests, specified in 64E-5.332(2) shall be recorded in SI units or in SI and special units curie, rad, rem and roentgen.
- R2
R2
- (2) The licensee or registrant shall make a clear distinction among the quantities entered on the records required by this part, such as total effective dose equivalent, shallow dose equivalent, **lens** dose equivalent, deep dose equivalent, or committed effective dose equivalent.

Specific Authority: 404.051, 404.081, F.S.

R1 Law Implemented: 404.051(1)(4), 404.081, F.S.

R2 History: New January 1, 1994, Formerly 10D-91.469, Amended May 18, 1998, **Amended October 8, 2000.**

64E-5.335 Records of Radiation Protection Programs.

- (1) Each licensee or registrant shall maintain records of the radiation protection program, including:
- (a) The provisions of the program; and
 - (b) Audits and other reviews of program content and implementation.
- (2) The licensee or registrant shall retain the records required by 64E-5.335(1)(a) until the department terminates each pertinent license or registration requiring the record. The licensee or registrant shall retain the records required by 64E-5.335(1)(b) for 3 years after the record is made.

Specific Authority: 404.051, 404.081, F.S.

Law Implemented: 404.022, 404.051(1)(4), 404.081, F.S.

History: New January 1, 1994, Formerly 10D-91.470.

64E-5.336 Records of Surveys.

- (1) Each licensee or registrant shall maintain records showing the results of surveys and calibrations required by 64E-5.314 and 64E-5.327(2). The licensee or registrant shall retain these records for 3 years after the record is made.
- (2) The licensee or registrant shall retain each of the following records until the department terminates each pertinent license or registration requiring the record:
 - (a) Records of the results of surveys to determine the dose from external sources of radiation used in the assessment of individual dose equivalents in the absence of or in combination with individual monitoring data;
 - (b) Records of the results of measurements and calculations used to determine individual intakes of radioactive material and used in the assessment of internal dose;
 - (c) Records showing the results of air sampling, surveys, and bioassays specified in 64E-5.319(1)(c)1. and 2.; and
 - (d) Records of the results of measurements and calculations used to evaluate the release of radioactive effluents to the environment.

Specific Authority: 404.051, 404.081, F.S.

Law Implemented: 404.022, 404.051(1)(4), 404.081, F.S.

History: New January 1, 1994, Formerly 10D-91.471.

64E-5.337 Records of Tests for Leakage or Contamination of Sealed Sources.

Records of tests for leakage or contamination of sealed sources required by these regulations shall be kept in units of becquerel or microcurie and maintained for inspection by the department for 3 years after the records are made.

Specific Authority: 404.051, 404.081, F.S.

Law Implemented: 404.022, 404.051(1)(4), 404.081, F.S.

History: New January 1, 1994, Formerly 10D-91.472.

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Next page number is 37

64E-5.338 Records of Planned Special Exposures.

- (1) For each planned special exposure, the licensee or registrant shall maintain records that describe:
 - (a) The exceptional circumstances requiring the use of a planned special exposure;
 - (b) The name of the management official who authorized the planned special exposure and a copy of the signed authorization;
 - (c) What actions were necessary;
 - (d) Why the actions were necessary;
 - (e) What precautions were taken to assure that doses were maintained ALARA;
 - (f) What individual and collective doses were expected to result; and
 - (g) The doses actually received in the planned special exposure.
- (2) The licensee or registrant shall retain the records until the department terminates each pertinent license or registration requiring these records.

Specific Authority: 404.051, 404.081, F.S.

Law Implemented: 404.022, 404.051(1)(4), 404.081, F.S.

History: New January 1, 1994, Formerly 10D-91.474.

64E-5.339 Records of Individual Monitoring Results.

- R2
R2 (1) Each licensee or registrant shall maintain records of doses received by all individuals for whom monitoring is required as specified in **Rule** 64E-5.315, **F.A.C.**, 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 the effective date of the rule need not be changed. These records shall include when applicable:
 - R2 (a) The deep dose equivalent to the whole body, **lens** dose equivalent, shallow dose equivalent to the skin, and shallow dose equivalent to the extremities;
 - R2
R2 (b) The estimated intake of radionuclides as specified in **Rule** 64E-5.305, **F.A.C.**;
 - (c) The committed effective dose equivalent assigned to the intake of radionuclides;
 - R2 (d) The specific information used to calculate the committed effective dose equivalent as specified in **Rule** 64E-5.307(3), **F.A.C.**;
 - R2
R2 (e) The total effective dose equivalent when required by **Rule** 64E-5.305, **F.A.C.**; and

- (f) The total of the deep dose equivalent and the committed dose to the organ receiving the highest total dose.
- (2) Recordkeeping Frequency. The licensee or registrant shall make entries of the records specified in 64E-5.339(1) annually.
- (3) Recordkeeping Format. The licensee or registrant shall maintain the records specified in 64E-5.339(1) on DH Form 1622 July 1993, which is herein incorporated by reference and which is available from the department, according to the instructions for DH Form 1622 July 1993, or in clear and legible records containing all the information required by DH Form 1622 July 1993.
- (4) The licensee or registrant shall maintain the records of dose to an embryo or 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 can be maintained separately from the dose records.
- (5) The licensee or registrant shall retain each required form or record until the department terminates each pertinent license or registration requiring the record.

Specific Authority: 404.051, 404.081, F.S.

Law Implemented: 404.022, 404.051(1)(4), 404.081, F.S.

R2 History: New January 1, 1994, Formerly 10D-91.475, Amended October 8, 2000.

64E-5.340 Records of Waste Disposal or Transfers.

- (1) Each licensee shall maintain records of the disposal of licensed materials.
- (2) The licensee shall retain the records required by 64E-5.340(1) until the department terminates each pertinent license requiring the record, except as provided in 64E-5.331(1)(c)5. and 64E-5.624(2).

Specific Authority: 404.051, 404.081, F.S.

Law Implemented: 404.022, 404.051(1)(4), 404.081, F.S.

History: New January 1, 1994, Formerly 10D-91.477.

64E-5.341 Records of Testing Entry Control Devices for Very High Radiation Areas.

- (1) Each licensee or registrant shall maintain records of tests specified in 64E-5.317(2)(a) on entry control devices for very high radiation areas. The records must include the date, time, and results of each such test of function.
- (2) The licensee or registrant shall retain the records required by 64E-5.341(1) for 3 years after the record is made.

Specific Authority: 404.051, 404.081, F.S.

Law Implemented: 404.022, 404.051(1)(4), 404.081, F.S.

History: New January 1, 1994, Formerly 10D-91.478.

64E-5.342 Form of Records. Each record required by this part shall be legible throughout the specified retention period. The record shall be the original or a reproduced copy or a microform if the copy or microform is authenticated by authorized personnel and the microform is capable of producing a clear copy throughout the required retention period. The record can also be stored in electronic media capable of 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 or registrant shall maintain adequate safeguards against tampering with and loss of records.

Specific Authority: 404.051, 404.081, F.S.

Law Implemented: 404.022, 404.051(1)(4), 404.081, F.S.

History: New January 1, 1994, Formerly 10D-91.479.

SUBPART L REPORTS

64E-5.343 Reports of Stolen, Lost, or Missing Licensed or Registered Sources of Radiation.

- (1) Telephone Reports. Each licensee or registrant shall report to the department by telephone the following:
- (a) Stolen, lost or missing licensed radioactive material in an aggregate quantity equal to or greater than 1,000 times the quantity specified in State of Florida Bureau of Radiation Control Radioactive Material Requiring Labeling, **May 2000**, immediately after its occurrence becomes known to the licensee if it appears to the licensee that an exposure could result to individuals in unrestricted areas; or
 - (b) Lost, stolen, or missing licensed radioactive material in an aggregate quantity greater than 10 times the quantity specified in State of Florida Bureau of Radiation Control Radioactive Material Requiring Labeling **May 2000**, that is still missing within 30 days after its occurrence becomes known.
 - (c) A stolen, lost, or missing radiation machine immediately after its occurrence becomes known.
- (2) Written Reports. Each licensee or registrant required to make a report as specified in 64E-5.343(1) shall make a written report to the department setting forth the following information within 30 days after making the telephone report:
- (a) A description of the licensed or registered source of radiation involved, including, for radioactive material, the kind, quantity, and chemical and physical form; and, for radiation machines, the manufacturer, model and serial number, type and maximum energy of radiation emitted;
 - (b) A description of the circumstances under which the loss or theft occurred;

- (c) A statement of disposition or probable disposition of the licensed or registered source of radiation involved;
 - (d) Exposures of individuals to radiation, circumstances under which the exposures occurred, and the possible total effective dose equivalent to persons in unrestricted areas;
 - (e) Actions that have been or will be taken to recover the source of radiation; and
 - (f) 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.
- (3) Subsequent to filing the written report, the licensee or registrant shall also report additional substantive information on the loss or theft within 30 days after the licensee or registrant learns of such information.
- (4) The licensee or registrant shall prepare any report filed with the department as specified in 64E-5.343 so that names of individuals who have received exposure to radiation are stated in a separate and detachable portion of the report.

Specific Authority: 404.051, 404.081, F.S.

Law Implemented: 404.022, 404.051(1)(4), 404.081, F.S.

R2 History: New January 1, 1994, Formerly 10D-91.480, Amended October 8, 2000.

64E-5.344 Notification of Incidents.

- (1) Immediate Notification. Regardless of 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 might have caused or threatens to cause any of the following conditions:
- (a) An individual to receive:
 - 1. A total effective dose equivalent of 25 rem (0.25 sievert) or more;
 - 2. **A lens** dose equivalent of 75 rem (0.75 sievert) or more; or
 - 3. A shallow dose equivalent to the skin or extremities or a total organ dose equivalent of 250 rad (2.5 gray) or more; or
 - (b) The release of radioactive material inside or outside of a restricted area so that if an individual had 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.

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- (2) Twenty-Four Hour Notification. Each licensee or registrant shall report to the department within 24 hours of discovery of the event each event involving loss of control of a licensed or registered source of radiation possessed by the licensee or registrant that might have caused or threatens to cause any of the following conditions:
- (a) An individual to receive in a period of 24 hours:
1. A total effective dose equivalent exceeding 5 rem (0.05 sievert);
 2. A lens dose equivalent exceeding 15 rem (0.15 sievert); or
 3. A shallow dose equivalent to the skin or extremities or a total organ dose equivalent exceeding 50 rem (0.5 sievert); or
- (b) The release of radioactive material inside or outside of a restricted area so that if an individual had 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.
- (3) The licensee or registrant shall prepare each report filed with the department as specified in Rule 64E-5.344, F.A.C., so that names of individuals who have received exposure to sources of radiation are stated in a separate and detachable portion of the report.
- (4) Licensees or registrants shall make the reports required by subsections 64E-5.344(1) and (2), F.A.C., to the department by telephone, telegram, mailgram, or facsimile to the department.
- (5) The provisions of Rule 64E-5.344, F.A.C., do not apply to doses that result from planned special exposures if such doses are within the limits for planned special exposures and are reported as specified in Rule 64E-5.346, F.A.C.
- (6) Immediate notification. In addition to the other reporting requirements in these regulations, each licensee shall notify the department as soon as possible but not later than 4 hours after the discovery of an event, such as a fire, explosion, or toxic gas release, that prevents immediate protective actions necessary to avoid exposure to radiation or radioactive materials that could exceed regulatory limits or to avoid releases of licensed material that could exceed regulatory limits.
- (7) Twenty-four hour report. Each licensee shall notify the department within 24 hours after the discovery of any of the following events involving licensed material:
- (a) 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;

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2. Involves a quantity of material greater than five times the lowest annual limit on intake of materials as specified in State of Florida Bureau of Radiation Control ALIs, DACs, and Effluent Concentrations, June 2012 (see 64E-5.101, F.A.C.); 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.

(b) 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 exposure 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.

(c) 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;

(d) An unplanned fire or explosion damaging any licensed material or any device, container, or equipment containing licensed materials when:

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1. The quantity of material involved is five times the lowest annual limit on intake for material specified in State of Florida Bureau of Radiation Control ALIs, DACs, and Effluent Concentrations, June 2012; and
2. The damage affects the integrity of the licensed material or its container.

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(e) Dose to an embryo/fetus that is greater than 50 mSv (5 rem) 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 as defined in Rule 64E-5.6011, F.A.C.

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(f) Dose to a nursing child that is a result of an administration of radioactive material to a breast-feeding individual that meets one of the following:

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1. Greater than 50 mSv (5 rem) total effective dose equivalent; or

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

- (8) Preparation and submission of reports. Reports made by licensees in response to the requirements of this section must be made as follows:
- (a) Licensees shall make reports required by subsections 64E-5.344(6) and (7), F.A.C., by telephone to the department. If the information is available at the time of notification, the information provided in these reports must include:
1. The caller's name and call back telephone number;
 2. A description of the event, including date and time;
 3. The exact location of the event;
 4. The isotopes, quantities, and chemical and physical forms of the licensed material involved; and
 5. Any personnel radiation exposure data available.
- (b) Written report. Each licensee who makes a report required by subsections 64E-5.344(6) and (7), F.A.C., shall submit a written follow-up report within 30 days of the initial report. Written reports prepared as required by other regulations may be submitted to fulfill this requirement if the reports contain all of the necessary information. The reports must include the following:
1. A description of the event, including the probable cause and the manufacturer and model number of any equipment that failed or malfunctioned;
 2. The exact location of the event;
 3. The isotopes, quantities, and chemical and physical form of the licensed material involved;
 4. Date and time of the event;
 5. 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 the individuals by name.

Rulemaking Authority: 404.051, F.S.

Law Implemented: 404.022, 404.051(1)(4), 404.081, F.S.

R12 History: New 1-1-94, Amended 5-15-96, Formerly 10D-91.481, Amended 10-8-00, 2-11-10, 12-26-13.

64E-5.345 Reports of Exposures, Radiation Levels, Concentrations of**R10 Radioactive Material Exceeding the Constraints or Limits, Medical Events and Dose to
R10 an Embryo/Fetus or a Nursing Child.**

- R2 (1) Reportable Events. In addition to the notification required by Rule 64E-5.344,
R2 F.A.C., each licensee or registrant shall submit a written report within 30 days
after learning of any of the following occurrences:
- R2 (a) Incidents for which notification is required by Rule 64E-5.344, F.A.C.; or
- R2 (b) Doses in excess of any of the following:
- R2 1. The occupational dose limits for adults in Rule 64E-5.304, F.A.C.;
- R2 2. The occupational dose limits for a minor in Rule 64E-5.310, F.A.C.;
- R2 3. The limits for an embryo or fetus of a declared pregnant woman in
R2 Rule 64E-5.311, F.A.C.;
- R2 4. The limits for an individual member of the public in Rule 64E-5.312,
R2 F.A.C.;
- R2 5. Any applicable limit in the license or registration;
- R2 6. The ALARA constraints for air emissions specified in subsection
R2 64E-5.303(5), F.A.C.; or
- (c) 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 this part or in the license or registration, whether or not
involving exposure of any individual in excess of the limits in
R2 Rule 64E-5.312, F.A.C.; or
- (d) For licensees subject to the provisions of U.S. 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.

(2) Contents of Reports.

- R2 (a) Each report required by subsection 64E-5.345(1), F.A.C., shall describe the extent of exposure of individuals to radiation and radioactive material, including as appropriate:
1. Estimates of each individual's dose;
 2. The levels of radiation and concentrations of radioactive material involved;
 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, ALARA constraints, generally applicable environmental standards, and associated license or registration conditions.
- R2 (b) Each report filed as specified in subsection 64E-5.345(1), F.A.C., shall include for each occupationally overexposed individual: the name, social security account number, and date of birth. With respect to the limit for the embryo or fetus in Rule 64E-5.311, F.A.C., 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.
- (3) All licensees or registrants who make reports as specified in subsection 64E-5.345(1), F.A.C., shall submit the report in writing to the department.
- R10 (4) Reports of Medical Events.
- R10 (a) The licensee or registrant shall notify the department by telephone no later than the next calendar day after the discovery of the medical event. The licensee or registrant shall also notify the referring physician of the affected individual and the individual or a responsible relative or guardian, unless the referring physician personally informs the licensee either that he will inform the individual or believes, based on medical judgment, that telling the individual or the individual's responsible relative or guardian would be harmful to either. These notifications shall be made within 24 hours after the licensee or registrant discovers the medical event. If the referring physician, individual or the individual's responsible relative or guardian cannot be reached within 24 hours, the licensee or registrant shall notify them as soon as practicable. The licensee is not required to notify the individual or the individual's responsible relative or guardian without first consulting the referring physician; however, the licensee or registrant shall not delay medical care for the individual because of this. If a verbal notification is made, the licensee shall inform the individual, or appropriate responsible relative or guardian, that a written description of the event can be obtained from the licensee upon request. The licensee shall provide such a written description if requested.

- R10 (b) Written Report. Within 15 days after the **medical event** report to the
 R2 department, the licensee or registrant shall report in writing to the
 R2 department and to the referring physician and furnish a copy of the report
 R2 to the **individual** or the **individual's** responsible relative or guardian if either
 R2 was previously notified by the licensee or registrant as specified in (4)(a),
 R2 above, or a brief description of both event and consequences as they
 R2 affect the **individual** or the **individual's** responsible relative or guardian if a
 R2 statement is included that the report submitted to the department can be
 R2 obtained from the licensee or registrant. The written report shall include
 R2 the licensee's or registrant's name; the prescribing physician's name; the
 R2 referring physician's name; a brief description of the event; why the event
 R2 occurred; the effect on the **individual**; the action taken to prevent
 R2 recurrence; whether the licensee or registrant informed the **individual** or
 R2 the **individual's** responsible relative or guardian and what information was
 R2 provided to the **individual** or **individual's** responsible relative or guardian,
 R2 and if not, a written medical justification. The report shall not include the
 R2 **individual's** name or other information that could lead to identification of
 R2 the **individual**.
- R10 (5) Records of **medical event**. Each licensee or registrant shall retain a record of
 R10 each **medical event** for 20 years. The record shall contain the names of all
 R2 individuals involved in the event, including the prescribing physician, the allied
 R2 health personnel, the **individual**, and the **individual's** referring physician, the
 R2 **individual's** identification number if one has been assigned, a brief description of
 R2 the event, why it occurred, the effect on the **individual**, what improvements are
 R2 needed to prevent recurrence, and the actions taken, if any, to prevent
 R2 recurrence.
- R2 (6) Rights and Duties of Licensees or Registrants. Aside from the notification
 R2 requirement, nothing in this section shall affect any rights or duties of licensees,
 R2 registrants or physicians in relation to each other, the **individual**, or responsible
 R2 relatives or guardians.

R10 (7) Reports of a dose to an embryo/fetus or a nursing child.

R10 (a) The licensee shall provide notification of the event to the referring
R10 physician and also notify the pregnant individual or mother, both hereafter
R10 referred to as the mother, no later than 24 hours after discovery of an
R10 event that would require reporting under paragraph 64E-5.344(7)(e) or (f),
R10 F.A.C., unless the referring physician personally informs the licensee
R10 either that he or she will inform the mother or that, based on medical
R10 judgment, telling the mother would be harmful. The licensee is not
R10 required to notify the mother without first consulting with the referring
R10 physician. If the referring physician or mother cannot be reached within
R10 24 hours, the licensee shall make the appropriate notifications as soon as
R10 possible thereafter. The licensee may not delay any appropriate medical
R10 care for the embryo/fetus or for the nursing child, including any necessary
R10 remedial care as a result of the event, because of any delay in notification.
R10 To meet the requirements of this subsection, the notification may be made
R10 to the mother or child's responsible relative or guardian instead of the
R10 mother. If a verbal notification is made, the licensee shall inform the
R10 mother, or the mother or child's responsible relative or guardian, that a
R10 written description of the event can be obtained from the licensee upon
R10 request. The licensee shall provide such a written description if
R10 requested.

R10 (b) Written Report.

R10 1. Within 15 days after the discovery of an event that would require
R10 reporting under paragraph 64E-5.344(7)(e) or (f), F.A.C., the
R10 licensee or registrant shall report in writing as described below, to
R10 the department and to the referring physician

R10 2. Within 15 days after the discovery of an event that would require
R10 reporting under paragraph 64E-5.344(7)(e) or (f), F.A.C., the
R10 licensee or registrant shall also furnish a copy of the report or a
R10 brief description of both the event and the consequences of the
R10 event as they affect the embryo/fetus or nursing child, to the
R10 mother, or the mother or child's responsible relative or guardian if
R10 either was previously notified by the licensee or registrant as
R10 specified in paragraph (7)(a), above. If a brief description of both
R10 the event and consequences of the event is provided in lieu of the
R10 report, such description shall include a statement that the report
R10 submitted to the department can be obtained from the licensee or
R10 registrant.

R10 3. The written report shall include the licensee's or registrant's name,
R10 the prescribing physician's name, the referring physician's name, a
R10 brief description of the event, why the event occurred, the effect on
R10 the embryo/fetus or nursing child, the action taken to prevent
R10 recurrence, whether the licensee or registrant informed the
R10 pregnant individual or mother or the mother's or child's responsible
R10 relative or guardian and what information was provided to the
R10 individual or individual's responsible relative or guardian, and if not,
R10 a written medical justification. The report shall not include the
R10 individual's or child's name or other information that could lead to
R10 identification of the individual or child.

R10 (8) Records of reports of dose to an embryo/fetus or a nursing child. Each licensee
R10 or registrant shall retain a record of each report of dose to an embryo/fetus or a
R10 nursing child for 20 years. The record shall contain the names of all individuals
R10 involved in the event, including the prescribing physician, the allied health
R10 personnel, mother or the nursing child's name, and the mother or nursing child's
R10 referring physician, the social security number of the mother, the nursing child's
R10 social security number or identification number if either has been assigned, a
R10 brief description of the event, why it occurred, the effect on the individual, what
R10 improvements are needed to prevent recurrence, and the actions taken, if any, to
R10 prevent recurrence.

R10 Rulemaking Authority: 404.051, 404.081, F.S.

Law Implemented: 404.022, 404.051(1)(4), 404.081, F.S.

R10 History: New 1-1-94, Formerly 10D-91.482, Amended 10-8-00, Amended 02-11-10.

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64E-5.346 Reports of Planned Special Exposures. The licensee or registrant shall submit a written report to the department within 30 days following any planned special exposure as specified in 64E-5.309, informing the department that a planned special exposure was conducted and indicating the date the planned special exposure occurred and the information required by 64E-5.338.

Specific Authority: 404.051, 404.081, F.S.

Law Implemented: 404.022, 404.051(1)(4), 404.081, F.S.

History: New January 1, 1994, Formerly 10D-91.483.

64E-5.347 Notifications and Reports to Individuals.

(1) Requirements for notification and reports to individuals of exposure to radiation or radioactive material are specified in Part IX of these regulations.

R1 (2) When a licensee or registrant is required by 64E-5.345, 64E-5.346 or 64E-5.347
R1 to report to the department any occupational exposure of an individual or an
R1 identified member of the public to radiation or radioactive material, the licensee
R1 or registrant shall also provide a copy of the report submitted to the department
R1 to the individual. Such notice shall be transmitted no later than the transmittal to
R1 the department, and shall comply with the provisions of Part IX.

Specific Authority: 404.051, 404.081, F.S.

R1 Law Implemented: 404.051(1)(4), 404.081, F.S.

R1 History: New January 1, 1994, Formerly 10D-91.484, Amended May 18, 1998.

64E-5.348 Reports of Leaking or Contaminated Sealed Sources. The licensee shall immediately notify the department if the test for leakage or contamination required by these regulations indicates a sealed source is leaking or contaminated. A written report of a leaking or contaminated source shall be submitted to the department within 5 days. The report shall include the equipment involved, the test results and the corrective action taken.

Specific Authority: 404.051, 404.081, F.S.

Law Implemented: 404.022, 404.051(1)(4), 404.081, F.S.

History: New January 1, 1994, Formerly 10D-91.485.

64E-5.349 Vacating Premises. Each specific licensee or registrant shall notify the department in writing of the intent to vacate no less than 30 days before vacating or relinquishing possession or control of premises which might have been contaminated with radioactive material as a result of his activities. The licensee shall decommission the premises for subsequent use as an unrestricted area.

Specific Authority: 404.051, 404.081, F.S.

Law Implemented: 404.022, 404.051(1)(4), 404.081, F.S.

History: New January 1, 1994, Formerly 10D-91.486.

R8 **64E-5.350 Reports of Transactions Involving Nationally Tracked Sources.** Each
R8 licensee who manufactures, transfers, receives, disassembles, or disposes of a nationally
R8 tracked source shall complete and submit to the NRC a National Source Tracking Transaction
R8 Report as specified in paragraphs (1) through (5) of this section for each type of transaction.

R8 (1) Each licensee who manufactures a nationally tracked source shall complete and
R8 submit a National Source Tracking Transaction Report. The report must include
R8 the following information:

R8 (a) The name, address, and license number of the reporting licensee;

R8 (b) The name of the individual preparing the report;

R8 (c) The manufacturer, model, and serial number of the source;

R8 (d) The radioactive material in the source;

R8 (e) The initial source strength in becquerels (curies) at the time of
R8 manufacture; and

R8 (f) The manufacture date of the source.

R8 (2) Each licensee that transfers a nationally tracked source to another person shall
R8 complete and submit a National Source Tracking Transaction Report. The report
R8 must include the following information:

R8 (a) The name, address, and license number of the reporting licensee;

R8 (b) The name of the individual preparing the report;

R8 (c) The name and license number of the recipient facility and the shipping
R8 address;

R8 (d) The manufacturer, model, and serial number of the source or, if not
R8 available, other information to uniquely identify the source;

R8 (e) The radioactive material in the source;

R8 (f) The initial or current source strength in becquerels (curies);

R8 (g) The date for which the source strength is reported;

R8 (h) The shipping date;

R8 (i) The estimated arrival date; and

R8 (j) For nationally tracked sources transferred as waste under a Uniform Low-
R8 Level Radioactive Waste Manifest, the waste manifest number and the
R8 container identification of the container with the nationally tracked source.

- R8 (3) Each licensee that receives a nationally tracked source shall complete and
R8 submit a National Source Tracking Transaction Report. The report must include
R8 the following information:
- R8 (a) The name, address, and license number of the reporting licensee;
 - R8 (b) The name of the individual preparing the report;
 - R8 (c) The name, address, and license number of the person that provided the
R8 source;
 - R8 (d) The manufacturer, model, and serial number of the source or, if not
R8 available, other information to uniquely identify the source;
 - R8 (e) The radioactive material in the source;
 - R8 (f) The initial or current source strength in becquerels (curies);
 - R8 (g) The date for which the source strength is reported;
 - R8 (h) The date of receipt; and
 - R8 (i) For material received under a Uniform Low-Level Radioactive Waste
R8 Manifest, the waste manifest number and the container identification with
R8 the nationally tracked source.
- R8 (4) Each licensee that disassembles a nationally tracked source shall complete and
R8 submit a National Source Tracking Transaction Report. The report must include
R8 the following information:
- R8 (a) The name, address, and license number of the reporting licensee;
 - R8 (b) The name of the individual preparing the report;
 - R8 (c) The manufacturer, model, and serial number of the source or, if not
R8 available, other information to uniquely identify the source;
 - R8 (d) The radioactive material in the source;
 - R8 (e) The initial or current source strength in becquerels (curies);
 - R8 (f) The date for which the source strength is reported;
 - R8 (g) The disassemble date of the source.

- R8 (5) Each licensee who disposes of a nationally tracked source shall complete and
R8 submit a National Source Tracking Transaction Report. The report must include
R8 the following information:
- R8 (a) The name, address, and license number of the reporting licensee;
- R8 (b) The name of the individual preparing the report;
- R8 (c) The waste manifest number;
- R8 (d) The container identification with the nationally tracked source;
- R8 (e) The date of disposal; and
- R8 (f) The method of disposal.
- R8 (6) The National Source Tracking Transaction Report discussed in subsections (1)
R8 through (5) of this section must be submitted to the NRC by the close of the next
R8 business day after the transaction. A single report may be submitted for multiple
R8 sources and transactions. The reports must be submitted to the National Source
R8 Tracking System by using:
- R8 (a) The on-line National Source Tracking System;
- R8 (b) Electronically using a computer-readable format;
- R8 (c) By facsimile;
- R8 (d) By mail to the address on the NRC Form 748 National Source Tracking
R8 Transaction Report Form; or
- R8 (e) By telephone with followup by facsimile or mail.
- R8 (7) (a) Each licensee shall correct any error in previously filed reports or
R8 file a new report for any missed transaction within 5 business days of the
R8 discovery of the error or missed transaction. Such errors may be detected
R8 by a variety of methods such as administrative reviews or by physical
R8 inventories required by regulation.
- R8 (b) In addition, every year each licensee shall reconcile the inventory of
R8 nationally tracked sources possessed by the licensee against that
R8 licensee's data in the National Source Tracking System. The reconciliation
R8 must be conducted during the month of January in each year. The
R8 reconciliation process must include resolving any discrepancies between
R8 the National Source Tracking System and the actual inventory by filing the
R8 reports identified by paragraphs (1) through (5) of this section. In order to
R8 reconcile each transaction, the licensee shall file a report for missed
R8 transactions or file a corrected report for previously submitted reports
R8 containing inaccuracies. By January 31 of each year, each licensee must
R8 submit to the National Source Tracking System confirmation that the data
R8 in the National Source Tracking System is correct.

- R8 (8) Each licensee that possesses Category 1 nationally tracked sources shall report
R8 its initial inventory of Category 1 nationally tracked sources to the National
R12 Source Tracking System by January 31, 2009 or as specified in 10 C.F.R.
R12 section 20.2207(h), 1-1-13 edition, which is herein incorporated by reference and
R12 is available at <http://www.flrules.org/Gateway/reference.asp?No=Ref-03456> or
R12 [http://www.gpo.gov/fdsys/pkg/CFR-2013-title10-vol1/pdf/CFR-2013-title10-vol1-
R12 sec20-2207.pdf](http://www.gpo.gov/fdsys/pkg/CFR-2013-title10-vol1/pdf/CFR-2013-title10-vol1-sec20-2207.pdf). Each licensee that possesses Category 2 nationally tracked
R8 sources shall report its initial inventory of Category 2 nationally tracked sources
R8 to the National Source Tracking System by January 31, 2009 or as specified in
R12 10 C.F.R. section 20.2207(h), 1-1-13 edition. The information may be submitted
R8 by using any of the methods identified by paragraph (6)(a) through (6)(e) of this
R8 section. The initial inventory report must include the following information:
- R8 (a) The name, address, and license number of the reporting licensee;
- R8 (b) The name of the individual preparing the report;
- R8 (c) The manufacturer, model, and serial number of each nationally tracked
R8 source or, if not available, other information to uniquely identify the source;
R8
- R8 (d) The radioactive material in the sealed source;
- (e) The initial or current source strength in becquerels (curies); and
- R8 (f) The date for which the source strength is reported.

R8 Rulemaking Authority: 404.051, F.S.

R8 Law Implemented: 404.022, 404.051, 404.081, F.S.

R12 History: New 2-28-08, Amended 12-26-13.

R8 **64E-5.351 Nationally Tracked Source Thresholds.** The nationally tracked source
R8 thresholds are listed in table 1 below with the Terabecquerel (TBq) values as the regulatory
R8 standard. The curie (Ci) values specified are obtained by converting from the TBq value. The
R8 curie values are provided for practical usefulness only and are rounded after conversion.

R8

Table 1

R8	Radioactive material	Category 1 (TBq)	Category 1 (Ci)	Category 2 (TBq)	Category 2 (Ci)
R8	Actinium-227	20	540	0.2	5.4
R8	Americium-241	60	1,600	0.6	16
R8	Americium-241/Be	60	1,600	0.6	16
R8	Californium-252	20	540	0.2	5.4
R8	Cobalt-60	30	810	0.3	8.1
R8	Curium-244	50	1,400	0.5	14
R8	Cesium-137	100	2,700	1	27
R8	Gadolinium-153	1,000	27,000	10	270
R8	Iridium-192	80	2,200	0.8	22
R8	Plutonium-238	60	1,600	0.6	16
R8	Plutonium-239/Be	60	1,600	0.6	16
R8	Polonium-210	60	1,600	0.6	16
R8	Promethium-147	40,000	1,100,000	400	11,000
R8	Radium-226	40	1,100	0.4	11
R8	Selenium-75	200	5,400	2	54
R8	Strontium-90	1,000	27,000	10	270
R8	Thorium-228	20	540	0.2	5.4
R8	Thorium-229	20	540	0.2	5.4
R8	Thulium-170	20,000	540,000	200	5,400
R8	Ytterbium-169	300	8,100	3	81

R12 Rulemaking Authority: 404.051, F.S.

R8 Law Implemented: 404.022, 404.051, 404.081, F.S.

R12 History: New 2-28-08, Amended 12-26-13

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