

PART III STANDARDS FOR PROTECTION

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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
R2 notwithstanding 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).
 - (b) The annual limits to the lens of the eye, to the skin, and to the extremities which are:
 - R2 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 or to any extremity.

- R2 (2) Doses received in excess of the annual limits, including doses received during accidents, emergencies, and planned special exposures, shall be subtracted from the limits for planned special exposures that the individual could receive during the current year and during the individual's lifetime as specified in Rule 64E-5.309(5)(a) and (b), F.A.C.
- R2 (3) The assigned deep dose equivalent and shallow dose equivalent shall be for the portion of the body receiving the highest exposure. The deep dose equivalent, lens dose equivalent and shallow dose equivalent can 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.
- R2 (4) Derived air concentration (DAC) and annual limit on intake (ALI) values are presented in State of Florida Bureau of Radiation Control ALIs, DACs, and Effluent Concentrations, July 1993, 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.
- (5) In addition to the annual dose limits, the licensee shall limit the soluble uranium intake by an individual to 10 milligrams in a week in consideration of chemical toxicity. See footnote 3 of State of Florida Bureau of Radiation Control ALIs, DACs, and Effluent Concentrations, July 1993.
- (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).

(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-91.435, Amended October 8, 2000.

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-5.515(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;

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- (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, July 1993, 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.

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-91.437.

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, July 1993.
- (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, July 1993, for each radionuclide in the mixture; or

- (b) The ratio of the total concentration for all radionuclides in the mixture to the most restrictive DAC value for any radionuclide in the mixture.
- (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, July 1993, 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.

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-91.308.

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

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- (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.

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- (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:

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- 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.
- R2 (4) If by the time the woman declares pregnancy to the licensee or registrant the
 R2 dose to the embryo or fetus has exceeded 0.5 rem (5 mSv) or is within 0.05 rem
 R2 (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:
 - R2 (a) Except as specified in Rule 64E-5.312(1)(b), F.A.C., the total effective
 R2 dose equivalent to individual members of the public from the licensed or
 R2 registered operation does not exceed 0.1 rem (1 millisievert) in a year,
 R2 exclusive of the dose contribution from background radiation, from any
 R2 medical administration the individual has received, from exposure to
 R2 individuals administered radioactive materials and released as specified in
 R2 Rule 64E-5.622, F.A.C., from voluntary participation in medical research
 R2 programs and from the licensee's disposal of radioactive material into
 R2 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
 - R2 (c) The dose in any unrestricted area from external sources, exclusive of the
 R2 dose contribution from patients administered radioactive material and
 R2 released as specified in Rule 64E-5.622, F.A.C., does not exceed 0.002
 rem (0.02 millisievert) in any one hour.

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- (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.

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 May 15, 1996, Formerly 10D-91.443, Amended October 8, 2000.

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, July 1993, 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.

- (3) Upon approval from the department, the licensee can adjust the effluent concentration values in State of Florida Bureau of Radiation Control ALIs, DACs, and Effluent Concentrations, July 1993, 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.

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, Amended November 20, 1994, Amended May 15, 1996, Formerly 10D-91.444.

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:
 - (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.;
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 - (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);
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 - (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
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 - (d) Individuals entering a high or very high radiation area.
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- (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:
 - (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 July 1993, Table I, Columns 1 and 2; and
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 - (b) Minors likely to receive in 1 year a committed effective dose equivalent in excess of 0.10 rem (1.0 millisievert); and
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 - (c) Declared pregnant women likely to receive during the entire pregnancy a committed effective dose equivalent in excess of 0.1 rem (1 mSv).
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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-91.446, Amended October 8, 2000.

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 to the extent practicable process or other engineering controls such as containment or ventilation to control the concentrations of radioactive material in air. When it is not practicable to apply process or other engineering controls, 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:

- (1) Control of access;
- (2) Limitation of exposure time;
- (3) Use of respiratory protection equipment; or
- (4) Other controls.

Specific Authority: 404.051, F.S.
Law Implemented: 404.022, 404.051(1)(4), F.S.
History: New January 1, 1994, Amended May 15, 1999, Formerly 10D-91.450.

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:
 - (a) The licensee shall use only respiratory protection equipment that is tested and certified or had certification extended by the National Institute for Occupational Safety and Health and the Mine Safety and Health Administration, except as provided in 64E-5.319(1)(b).
 - (b) If the licensee wishes to use equipment that has not been tested or certified by the National Institute for Occupational Safety and Health and the Mine Safety and Health Administration, has not had certification extended by the National Institute for Occupational Safety and Health and the Mine Safety and Health Administration, or for which there is no schedule for testing or certification, the licensee shall submit an application for authorized use of that equipment, including a demonstration by testing or a demonstration on the basis of reliable test information that the material and performance characteristics of the equipment are capable of providing the proposed degree of protection under anticipated conditions of use.
 - (c) The licensee shall implement and maintain a respiratory protection program that includes:
 - 1. Air sampling sufficient to identify the potential hazard, permit proper equipment selection, and estimate exposures;
 - 2. Surveys and bioassays as needed to evaluate actual intakes;
 - 3. Testing of respirators for operability immediately prior to each use;
 - 4. Written procedures regarding selection, fitting, issuance, maintenance, and testing of respirators, including testing for operability immediately prior to each use; supervision and training of personnel; monitoring, including air sampling and bioassays; and recordkeeping; and
 - 5. Determination by a physician prior to initial fitting of respirators and either every 12 months thereafter or periodically at a frequency determined by a physician that the individual user is medically fit to use the respiratory protection equipment.
 - (d) The licensee shall issue a written policy statement on respirator usage covering:
 - 1. The use of process or other engineering controls instead of respirators;
 - 2. The routine, nonroutine, and emergency use of respirators; and

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3. The length of periods of respirator use and relief from respirator use.
 - (e) 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.
 - (f) The licensee shall use respiratory protection equipment within the equipment manufacturer's expressed limitations for type and mode of use and shall provide proper visual, communication, and other special capabilities such as adequate skin protection when needed.
 - (2) When estimating exposure of individuals to airborne radioactive materials, the licensee can make allowance for respiratory protection equipment used to limit intakes as specified in 64E-5.318 if the following conditions, in addition to those in 64E-5.319(1), are satisfied:
 - (a) The licensee selects respiratory protection equipment that provides a protection factor specified in State of Florida Bureau of Radiation Control Protection Factors for Respirators, July 1993, which is herein incorporated by reference and which is available from the department, greater than the multiple by which peak concentrations of airborne radioactive materials in the working area are expected to exceed the values specified in State of Florida Bureau of Radiation Control ALIs, DACs, and Effluent Concentrations, July 1993, Table I, Column 3. However, if the selection of respiratory protection equipment with a protection factor greater than the peak concentration is inconsistent with the goal specified in 64E-5.318 of keeping the total effective dose equivalent ALARA, the licensee can select respiratory protection equipment with a lower protection factor if such a selection would result in a total effective dose equivalent that is ALARA. The concentration of radioactive material in the air that is inhaled when respirators are worn can be initially estimated by dividing the average concentration in air during each period of uninterrupted use by the protection factor. If the exposure is later found to be greater than initially estimated, the corrected value shall be used; if the exposure is later found to be less than initially estimated, the corrected value can be used.
 - (b) The licensee shall obtain authorization from the department before assigning respiratory protection factors in excess of those specified in State of Florida Bureau of Radiation Control Protection Factors for Respirators, July 1993. 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.
- (3) In an emergency the licensee shall use as emergency equipment only respiratory protection equipment that has been specifically certified or had certification extended for emergency use by the National Institute for Occupational Safety and Health and the Mine Safety and Health Administration.
- (4) The licensee shall notify the department in writing at least 30 days before the date that respiratory protection equipment is first used as specified in either 64E-5.319(1) or (2).

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-91.452, Amended May 18, 1998.

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.

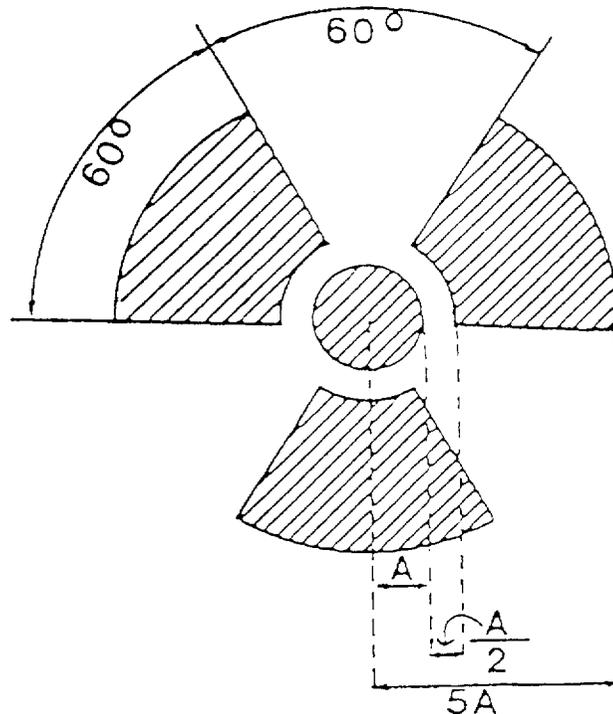
History: New January 1, 1994, Formerly 10D-91.454.

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 1993, 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;

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- (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.

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-91.459, Amended October 8, 2000.

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.

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- (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, July 1993, Table III;
 - (c) If more than one radionuclide is released, the following conditions must also be satisfied;

1. The licensee shall determine the fraction of the limit in 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, July 1993, 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).

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-91.463.

64E-5.331 Disposal of Specific Wastes.

- (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 90 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.
- (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.

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-91.465.

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
R1 the waste generator as specified in 64E-5.333(12). Beginning March 1, 1998,
R1 each 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
R1 disposal, including the waste generator, waste collector, waste processor and
R1 disposal 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			
RADIONUCLIDE	CONCENTRATION (Curies per cubic meter)		
	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 (1) Each licensee or registrant shall use the SI unit becquerel, gray, sievert and
R1 coulomb per kilogram, or the special units curie, rad, rem and roentgen, including
R1 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 (2) The licensee or registrant shall make a clear distinction among the quantities
R2 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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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 (1) Each licensee or registrant shall maintain records of doses received by all
R2 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 (b) The estimated intake of radionuclides as specified in Rule 64E-5.305,
R2 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 (e) The total effective dose equivalent when required by Rule 64E-5.305,
R2 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.

- R2
- (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 64E-5.344 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 64E-5.344(1) and (2) to the department by telephone, telegram, mailgram, or facsimile to the department.
 - (5) The provisions of 64E-5.344 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 64E-5.346.
 - (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;

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, July 1993; 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:
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, July 1993; and
 2. The damage affects the integrity of the licensed material or its container.
- (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 64E-5.344(6) and (7) 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 64E-5.344(1) and (2) 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.

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 , May 15, 1998, Formerly 10D-91.481, Amended October 8, 2000.

**64E-5.345 Reports of Exposures, Radiation Levels, Concentrations of
R2 Radioactive Material Exceeding the Constraints or Limits, and Misadministrations.**

- 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
- (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.;
 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.; or
- R2 5. Any applicable limit in the license or registration;
- R2 6. The ALARA constraints for air emissions specified in Rule
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
- R2 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 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 Rule 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
- R2 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 Rule 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.
- R2 (3) All licensees or registrants who make reports as specified in 64E-5.345(1) shall submit the report in writing to the department.

(4) Reports of Misadministrations.

R2 (a) The licensee or registrant shall notify the department by telephone no
 R2 later than the next calendar day after the discovery of the
 R2 misadministration. The licensee or registrant shall also notify the referring
 R2 physician of the affected individual and the individual's or a responsible
 R2 relative or guardian, unless the referring physician personally informs the
 R2 licensee either that he will inform the individual or believes, based on
 R2 medical judgment, that telling the individual or the individual's responsible
 R2 relative or guardian would be harmful to either. These notifications shall
 R2 be made within 24 hours after the licensee or registrant discovers the
 R2 misadministration. If the referring physician, individual or the individual's
 R2 responsible relative or guardian cannot be reached within 24 hours, the
 R2 licensee or registrant shall notify them as soon as practicable. The
 R2 licensee is not required to notify the individual or the individual's
 R2 responsible relative or guardian without first consulting the referring
 R2 physician; however, the licensee or registrant shall not delay medical care
 R2 for the individual because of this.

R2 (b) Written Report. Within 15 days after the misadministration 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.

R2 (5) Records of Misadministrations. Each licensee or registrant shall retain a record
 R2 of each misadministration 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 requirement, nothing in this section shall affect any rights or duties of licensees, registrants or physicians in relation to each other, the individual, or responsible relatives or guardians.

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-91.482, Amended October 8, 2000.

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
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.

**PART IV RADIATION SAFETY REQUIREMENTS FOR
INDUSTRIAL RADIOGRAPHIC OPERATIONS**

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PART IV

RADIATION SAFETY REQUIREMENTS FOR INDUSTRIAL RADIOGRAPHIC OPERATIONS

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R4 Sections 64E-5.401 - 64E-5.422 repealed September 11, 2001 and replaced with
R4 sections 64E-5.423 - 64E-5.441.

PART IV

RADIATION SAFETY REQUIREMENTS FOR INDUSTRIAL RADIOGRAPHIC OPERATIONS

R4 **64E-5.423 Definitions.** As used in this part, the following definitions apply:

- R4 (1) "Associated equipment" means equipment, such as guide tubes, control tubes,
R4 control cables, removable source stops, J-tubes, and collimators, used in
R4 conjunction with a radiographic exposure device that drives, guides, or comes in
R4 contact with the sealed source.
- R4 (2) "Certifying entity" means:
- R4 (a) For radiographic operations using radioactive materials, an independent
R4 certifying organization that meets the requirements of Appendix A of 10
R4 CFR Part 34, which is herein incorporated by reference and which is
R4 available from the department, or an agreement state that meets the
R4 requirements of Appendix A, Parts II and III of 10 CFR Part 34.
- R4 (b) For radiographic operations using radiation machines, any agreement
R4 state or organization approved by the Conference of Radiation Control
R4 Directors, Inc.
- R4 (3) "Collimator" means a radiation shield that is placed on the end of the guide tube
R4 or directly onto a radiographic exposure device to restrict the size of the radiation
R4 beam when the sealed source is cranked into position to make a radiographic
R4 exposure.
- R4 (4) "Control cable" means the cable that is connected to the source assembly and
R4 used to drive the source from and return it to the shielded position. It also is
R4 known as a drive cable.
- R4 (5) "Control drive mechanism" means a device that enables the source assembly to
R4 be moved to and from the shielded position. It also is known as a crank
R4 assembly.
- R4 (6) "Control tube" means a protective sheath for guiding the control cable. The
R4 control tube connects the control drive mechanism to the radiographic exposure
R4 device.
- R4 (7) "Exposure head" means a device that locates the sealed source in the selected
R4 position. It also is known as a source stop.
- R4 (8) "Guide tube" means a flexible or rigid tube for guiding the source assembly and
R4 the attached control cable from the radiographic exposure device to the exposure
R4 head and includes the connections to attach to the radiographic exposure device
R4 and to the exposure head. It also is known as a projection sheath or source
R4 tube.

- R4 (9) "Industrial cabinet x-ray system" means a cabinet x-ray system used to perform
R4 industrial radiography excluding baggage x-ray systems.
- R4 (10) "Lay-barge radiography" means industrial radiography performed on any water
R4 vessel used for laying pipe.
- R4 (11) "Platform radiography" means industrial radiography performed on an offshore
R4 platform or other structure over a body of water.
- R4 (12) "Radiographer certification" means a written document received from a certifying
R4 entity stating that an individual has met radiation safety training, testing, and
R4 experience criteria satisfactorily.
- R4 (13) "Radiographic operations" means all activities including surveys that involve the
R4 use or transport of radiation machines, radiographic exposure devices, source
R4 changers, or industrial cabinet x-ray systems to conduct industrial radiography.
- R4 (14) "Radiographic personnel" means radiographers and radiographer's assistants.
- R4 (15) "Reference survey" means a survey made with a radiation survey instrument
R4 within 6 inches (15 cm) of the surface of a radiographic exposure device or
R4 source changer at a location established by the licensee. The reference survey
R4 is used to verify that the sealed source is located properly in the shielded position
R4 and to establish a radiation level for reference before, during, and after
R4 radiographic operations.
- R4 (16) "S-tube" means a tube through which the radioactive source travels inside a
R4 radiographic exposure device.
- R4 (17) "Source assembly" means a set of assembled parts consisting of a sealed
R4 source and a connector that attaches the source to the control cable. The
R4 source assembly sometimes includes a stop ball used to secure the source in the
R4 shielded position. It also is known as a pigtail.
- R4 (18) "Special training session" means training not conducted during production
R4 radiography.
- R4 (19) "Transport container" means a package that is designed to provide radiation
R4 safety and security when sealed sources are transported and that meets all
R4 applicable requirements of the U.S. Department of Transportation (USDOT).
- R4 (20) "Underwater radiography" means industrial radiography performed when the
R4 radiation machine, radiographic exposure device, or related equipment are
R4 beneath the surface of the water.

R4 Specific Authority: 404.051, F.S.

R4 Law Implemented: 404.022, 404.031, 404.051(1), (4), (6), F.S.

R4 History: New September 11, 2001.

SUBPART D
(Formerly Subpart A)
EQUIPMENT CONTROL

R4
R4
R4

R4 **64E-5.424 Requirements for Industrial Radiography Equipment Using Sealed**
R4 **Sources.**

R4 (1) Equipment used in radiographic operations shall meet the criteria specified
R4 below.

R4 (a) Each radiographic exposure device, source assembly or sealed source,
R4 and all associated equipment shall meet the requirements specified in
R4 American National Standards Institute (ANSI) N432-1980 "Radiological
R4 Safety for the Design and Construction of Apparatus for Gamma
R4 Radiography," published as National Bureau of Standards Handbook 136,
R4 January 1981, which is herein incorporated by reference and which is
R4 available from the department. Engineering analyses that demonstrate
R4 that the radiography equipment components are equivalent are an
R4 acceptable alternative to actual testing of the component.

R4 (b) Equipment used in radiographic operations is not required to comply with
R4 section 8.9.2(c) of the Endurance Test in ANSI N432-1980 if the prototype
R4 equipment has been tested using a torque value representative of the
R4 torque that an individual using the radiography equipment realistically can
R4 exert on the lever or crankshaft of the drive mechanism.

R4 (2) In addition to the requirements specified in 64E-5.424(1), F.A.C., radiographic
R4 exposure devices, source changers, source assemblies, and sealed sources
R4 must meet the requirements specified below.

R4 (a) Each radiographic exposure device shall have a durable, legible, clearly
R4 visible label attached that specifies:

- R4 1. The chemical symbol and mass number of the radionuclide in the
R4 radiographic exposure device;
- R4 2. The activity of the sealed source and the date on which this activity
R4 was last measured;
- R4 3. The manufacturer's name and the model and serial number of the
R4 sealed source; and
- R4 4. The name, address, and telephone number of the licensee.

R4 (b) Each radiographic exposure device, source changer, storage container,
R4 and transport container shall have a durable, legible, clearly visible
R4 marking or label attached that includes the standard radiation symbol as
R4 specified in 64E-5.322, F.A.C., in conventional colors of magenta, purple,
R4 or black on a yellow background, has a minimum diameter of 25
R4 millimeters, and has the following wording:

CAUTION (or DANGER)

RADIOACTIVE MATERIAL – DO NOT HANDLE

NOTIFY CIVIL AUTHORITIES (or NAME OF COMPANY)

- R4
R4
R4
- R4 (c) Modification of radiographic exposure devices, source changers, source assemblies, and associated equipment is prohibited unless the design of any replacement component, including source holder, source assembly, controls, or guide tubes will not compromise design safety features.
- R4
R4
R4
R4
- R4 (3) Radiographic exposure devices, source assemblies, and associated equipment that allow the source to be moved out of the radiographic exposure device for radiographic operations or to source changers must meet the requirements specified below.
- R4 (a) The coupling between the source assembly and the control cable shall be designed so that the source assembly will not become disconnected if cranked outside the guide tube. The coupling shall be designed so that it cannot be disconnected unintentionally under normal and reasonably foreseeable abnormal conditions.
- R4 (b) The radiographic exposure device shall secure the source assembly automatically when it is cranked back into the fully shielded position within the device. This securing system shall be able to be released only by a deliberate operation on the exposure device.
- R4 (c) The outlet fittings, lock box, and drive cable fittings on each radiographic exposure device shall be equipped with safety plugs or covers that are installed during storage and transportation to protect the source assembly from water, mud, sand, or other foreign matter.
- R4 (d) 1. Each sealed source or source assembly shall have attached to it or engraved on it a durable, legible, visible label with the words: "DANGER – RADIOACTIVE."
- R4 2. The label cannot interfere with the safe operation of the radiographic exposure device, source changer, or associated equipment.
- R4 (e) The guide tube shall be able to withstand a crushing test that approximates closely the crushing forces that are likely to be encountered during use and be able to withstand a kinking resistance test that approximates closely the kinking forces that are likely to be encountered during use.
- R4 (f) Guide tubes shall be used when moving the source out of the device.
- R4 (g) An exposure head or similar device designed to prevent the source assembly from passing out of the end of the guide tube shall be attached to the outermost end of the guide tube during radiographic operations.

- R4 (h) The guide tube exposure head connection shall be able to withstand the
R4 tensile test for control units specified in ANSI N432-1980.
- R4 (i) Source changers shall have a system to ensure that the source will not be
R4 withdrawn from the changer accidentally when connecting or
R4 disconnecting the drive cable to or from a source assembly.
- R4 (4) The maximum exposure rate limits for storage containers and source changers
R4 are 200 millirem (2 mSv) per hour at any exterior surface and 10 millirem (0.1
R4 mSv) per hour at 1 meter from any exterior surface with the sealed source in the
R4 shielded position.
- R4 (5) Each radiographic exposure device, source changer, and storage container shall
R4 have a lock or outer locked container designed to prevent unauthorized or
R4 accidental removal of the sealed source from its shielded position.

R4 Specific Authority: 404.051, F.S.

R4 Law Implemented: 404.022, 404.051(1), (4), (6), F.S.

R4 History: New September 11, 2001.

R4 **64E-5.425 Locking of Sources of Radiation, Storage Precautions, and
Surveillance.**

- R4 (1) Each radiation machine, radiographic exposure device, source changer, and
R4 storage container shall be kept locked with the key removed from any keyed lock
R4 except when under the direct supervision of radiographic personnel or as
R4 specified in section (6), below.
- R4 (2) Each radiation machine, radiographic exposure device, source changer, and
R4 storage container shall be locked and the key removed from any keyed lock
R4 before being moved or transported and before being stored at a given location,
R4 except at permanent radiographic installations as specified in 64E-5.431, F.A.C.
R4 Keys to radiation machines, radiographic exposure devices, source changers,
R4 storage containers, transport containers, and transport vehicles shall be
R4 maintained in the possession of the radiographer or radiographer's assistant
R4 responsible for the equipment in a manner that prevents access to sources of
R4 radiation by unauthorized personnel.
- R4 (3) Locked radiographic exposure devices, source changers, storage containers,
R4 and radiation machines shall be secured physically except when under the direct
R4 surveillance of radiographic personnel or as specified in section (6), below, to
R4 prevent tampering or removal by unauthorized personnel. The licensee shall
R4 store licensed material in a manner that minimizes danger from explosion or fire.
- R4 (4) Each sealed source shall be secured in its shielded position by locking the
R4 radiographic exposure device or source changer each time the sealed source is
R4 returned to the shielded position.
- R4 (5) Transport containers containing licensed material shall be locked and secured in
R4 the transporting vehicle to prevent accidental loss, tampering, or unauthorized
R4 removal of the licensed material from the vehicle.

R4 (6) During each radiographic operation, the radiographer or radiographer's assistant
 R4 shall maintain continuous direct visual surveillance of the operation to protect
 R4 against unauthorized entry into a high radiation area, except at permanent
 R4 radiographic installations where all entryways are locked and the requirements of
 R4 64E-5.431, F.A.C., are met.

R4 (7) During each radiographic operation using an industrial cabinet x-ray system,
 R4 direct surveillance of the operation shall be maintained to protect against
 R4 unauthorized entry into a high radiation area.

R4 Specific Authority: 404.051, F.S.

R4 Law Implemented: 404.022, 404.051(1), (4), (6), F.S.

R4 History: New September 11, 2001.

R4 **64E-5.426 Radiation Survey Instruments.**

R4 (1) The licensee or registrant shall maintain enough calibrated and operable
 R4 radiation survey instruments to make physical radiation surveys as required by
 R4 the rules contained in this part and Chapter 64E-5, Part III, F.A.C. Such
 R4 instrumentation shall be able to measure a range from 2 millirem (0.02 mSv) per
 R4 hour through 1 rem (0.01 Sv) per hour.

R4 (2) Radiation survey instruments used to establish dose rates shall be calibrated:

R4 (a) At intervals not to exceed 6 months and after each instrument servicing
 R4 other than battery replacement;

R4 (b) At energies and geometries appropriate for use;

R4 (c) To demonstrate accuracy within 20% of the true radiation level at each
 R4 point checked;

R4 (d) For linear scale instruments, at two points located approximately 1/3 and
 R4 2/3 of full-scale on each scale; for logarithmic scale instruments, at
 R4 midrange of each decade and at two points at least one decade apart;
 R4 and for digital instruments, at three points between 2 millirem (0.02 mSv)
 R4 per hour and 1 rem (0.01 Sv) per hour; and

R4 (e) By a person licensed by the department, another agreement state,
 R4 licensing state or the NRC.

R4 Specific Authority: 404.051, F.S.

R4 Law Implemented: 404.022, 404.051(1), (4), F.S.

R4 History: New September 11, 2001.

R4 **64E-5.427 Leak Testing, Repairing, Tagging, Opening, Modifying, and Replacing**
 R4 **Sealed Sources and Devices.**

R4 (1) The replacement, leak testing, leak test sample analysis, repair, tagging,
 R4 opening, or any other modification of any sealed source shall be performed only
 R4 by persons authorized specifically to do so by the department, another
 R4 agreement state, licensing state, or the NRC.

- R4 (2) Each sealed source shall be tested for radioactive contamination leakage at
R4 intervals not to exceed 6 months. In the absence of a certificate from a
R4 transferor indicating that a test has been made within the 6 months before the
R4 transfer, the sealed source shall not be used until tested. Sealed sources that
R4 are listed in a department license for storage only do not require leak testing
R4 during storage but shall be tested before use or transfer to another person if the
R4 interval of storage exceeds 6 months.
- R4 (3) Each exposure device using depleted uranium (DU) shielding and an S-tube
R4 configuration shall be tested for DU contamination at intervals not to exceed 12
R4 months. DU shielded devices do not have to be tested for DU contamination
R4 while in storage and not in use. However, the DU devices shall be tested for DU
R4 contamination before use or transfer if the interval of storage exceeds 12
R4 months. Licensees must comply with the DU leak testing requirements of this
R4 section within 6 months after the effective date of this rule.
- R4 (4) Leak testing as specified in 64E-5.427(2) and (3), F.A.C., shall be capable of
R4 detecting the presence of 0.005 microcurie (185 Bq) of removable contamination
R4 on the test sample. The wipe sample shall be taken from the nearest accessible
R4 point to the sealed source when contamination could accumulate.
- R4 (5) If any test conducted pursuant to this section reveals the presence of 0.005
R4 microcurie (185 Bq) or more of removable radioactive material, the licensee
R4 immediately shall withdraw the equipment from use and cause it to be
R4 decontaminated and repaired or disposed of in accordance with the applicable
R4 sections of rules contained in Parts III and XV of Chapter 64E-5, F.A.C. If DU
R4 leak testing reveals the presence of 0.005 microcurie (185 Bq) or more of
R4 removable DU contamination, the exposure device shall be removed from use
R4 until an evaluation of the wear on the S-tube has been made. If the evaluation
R4 reveals that the S-tube is worn through, the device shall not be used. The
R4 licensee shall file a report with the department describing the equipment
R4 involved, the test results, and the corrective action taken within 5 days after
R4 obtaining results of the test.

R4 Specific Authority: 404.051, F.S.

R4 Law Implemented: 404.022, 404.051(1), (4), (6), F.S.

R4 History: New September 11, 2001.

R4 **64E-5.428 Quarterly Inventory.** Each licensee or registrant shall conduct a quarterly
R4 physical inventory to account for all sources of radiation received or possessed during the
R4 quarter. The inventory shall cover all sources of radiation requiring licensure or registration by
R4 the department, including sealed sources, radiation machines, radiographic exposure devices,
R4 and source changers containing DU.

R4 Specific Authority: 404.051, F.S.

R4 Law Implemented: 404.022, 404.051(1), (4), 404.081(1), F.S.

R4 History: New September 11, 2001.

R4
R4 **64E-5.429 Source Movement Logs, Daily Survey Reports, and Individual Dosimeter Logs.**

- R4 (1) Each time a radiation source is removed from storage, the licensee or registrant shall complete and maintain source movement logs for each radiation source with the following information, as applicable:
- R4 (a) The locations where used, the names of the jobs or clients, and the dates of use;
- R4 (b) The manufacturer's name, model, and serial number of the radiographic exposure device, source changer, or radiation machine used;
- R4 (c) The sealed source manufacturer's name, model, and serial number, activity in curies (becquerels) on the date of receipt and each date of use, and the due date of the next leak test;
- R4 (d) The results of the reference survey of the radiographic exposure device or source changer performed upon removal and return to storage; and
- R4 (e) The signature or initials of the radiographer to whom the radiation source has been assigned.
- R4 (2) Before performing industrial radiography, leak tests, source exchanges, or quarterly inspection and maintenance of radiographic equipment, the licensee or registrant shall prepare and maintain a daily survey report for each radiation source with the information described below as it becomes available:
- R4 (a) The location where used, the name of the job or client, and the date of use;
- R4 (b) The manufacturer's name, model, and serial number of the radiographic exposure device, source changer, or radiation machine used;
- R4 (c) The sealed source manufacturer's name, model, and serial number and activity in curies (becquerels) for the date of use;
- R4 (d) The names and titles of the radiographic personnel working with the radiation source;
- R4 (e) The serial number of the personnel monitoring badge, pocket dosimeter, and alarm ratemeter used by each of the radiography crew members;
- R4 (f) The manufacturer's name, model, serial number, and date of calibration or calibration due date for each survey meter used;
- R4 (g) The results of the reference survey performed when the radiographic exposure device or source changer is removed from or returned to storage;

- R4 (h) Evidence of performance of the equipment checks described in 64E-
R4 5.430(1), F.A.C.;
- R4 (i) The results of the survey of the posted perimeter in mR/hr (mSv/hr) and
R4 feet (meters);
- R4 (j) The total exposure time; and
- R4 (k) The start, end, and total pocket dosimeter readings for all radiographic
R4 personnel.
- R4 (3) Radiographic personnel shall maintain an individual log of their daily dosimeter
R4 totals. Each individual shall record the doses measured by his or her dosimeter
R4 at the end of each day of radiographic operations and total the recorded doses at
R4 the end of each week and at the end of each month. Copies of the individual
R4 dosimeter logs shall be provided to the radiation safety officer (RSO) or the
R4 RSO's designee no later than 7 days after each month. The RSO or the RSO's
R4 designee shall review the logs within 7 days of receipt and shall date and sign or
R4 initial the logs at the time of the review. Each log shall include the following
R4 information:
- R4 (a) The name of the individual;
- R4 (b) The dates of the monitoring periods;
- R4 (c) The daily, weekly, and monthly individual radiation dose totals as
R4 measured by the dosimeter; and
- R4 (d) The date the log was reviewed by the RSO or the RSO's designee and the
R4 signature or initials of the RSO or the RSO's designee.

R4 Specific Authority: 404.051, F.S.

R4 Law Implemented: 404.022, 404.051(1), (4), 404.081(1), F.S.

R4 History: New September 11, 2001.

R4 **64E-5.430 Inspection and Maintenance.**

- R4 (1) Each licensee or registrant shall perform visual and operability checks on survey
R4 instruments, radiation machines, radiographic exposure devices, associated
R4 equipment, transport containers, storage containers, and source changers before
R4 use on each day the equipment is to be used to ensure the equipment is in good
R4 working condition, the sources are shielded adequately, and required labeling is
R4 present. All appropriate parts shall be maintained in accordance with the
R4 manufacturer's specifications. Each radiation survey instrument shall be visually
R4 inspected, have its batteries checked, and have its operability checked with a
R4 radiation source at the beginning of each day of use and at the beginning of each
R4 work shift. If equipment problems are found, the equipment shall be removed
R4 from service until repaired.

R4 (2) Each licensee or registrant shall perform equipment inspection and maintenance
R4 as described below.

R4 (a) Inspection and maintenance of survey instruments, radiation machines,
R4 radiographic exposure devices, associated equipment, source changers,
R4 storage containers, and transport containers shall be performed quarterly
R4 to assure proper functioning of components important to safety. All
R4 appropriate parts shall be maintained in accordance with the
R4 manufacturer's specifications. Verification of compliance with radiation
R4 limits specified in 64E-5.424(4), F.A.C., shall be included in each quarterly
R4 inspection. If equipment problems are found, the equipment shall be
R4 labeled as defective and removed from service until repaired.
R4 Replacement components shall meet manufacturer's specifications.

R4 (b) Inspection and maintenance of Type B packages used to transport
R4 radioactive materials shall be performed quarterly in accordance with each
R4 package's certificate of compliance or other approval.

R4 Specific Authority: 404.051, F.S.

R4 Law Implemented: 404.022, 404.051(1), (4), 404.081(1), F.S.

R4 History: New September 11, 2001.

R4 **64E-5.431 Permanent Radiographic Installations.**

R4 (1) Each entrance used for personnel access to a high radiation area in a permanent
R4 radiographic installation shall have either:

R4 (a) An entrance control that reduces the radiation level to below the level at
R4 which an individual might receive a deep dose equivalent of 0.1 rem (1
R4 millisievert) in 1 hour at 30 centimeters from the source of radiation from
R4 any surface the radiation penetrates, or

R4 (b) Conspicuous visible and audible signals to warn of the presence of
R4 radiation. The visible signal shall be actuated by radiation. The audible
R4 signal shall be actuated when an attempt is made to enter the installation
R4 while the source is exposed or the radiation machine is activated.

R4 (2) The alarm system shall be tested for proper operation with a radiation source
R4 each day before radiographic operations. The test shall include a check of both
R4 the visible and audible signals. Entrance control devices that reduce the
R4 radiation level upon entry shall be tested monthly. If an entrance control device
R4 or an alarm is operating improperly, it shall be labeled immediately as defective
R4 and repaired within 7 days. The installation can continue to be used by an
R4 unaccompanied radiographer during this 7-day period if the continuous
R4 surveillance requirements of 64E-5.425(6), F.A.C., are implemented and an
R4 alarming ratemeter is used.

R4 Specific Authority: 404.051, F.S.

R4 Law Implemented: 404.022, 404.051(1), (4), F.S..

R4 History: New September 11, 2001.

R4
R4

SUBPART E
(Formerly Subpart B)
RADIATION SAFETY REQUIREMENTS

R4 **64E-5.432 Radiation Protection Program.** The radiation protection program
R4 specified in 64E-5.303, F.A.C., for registrants performing radiography and license
R4 applications, renewals, and requests for amendments for licensees performing radiography
R4 shall include the components specified below and the location of all records required.

R4 (1) A description of the overall organizational structure pertaining to the licensee's or
R4 registrant's radiation protection program, including specific delegation of authority
R4 and responsibility, the name of the RSO, and the minimum qualifications of the
R4 RSO and the RSO's designees.

R4 (2) A radiation safety training program for radiographic personnel that meets the
R4 requirements of 64E-5.434, F.A.C., and includes the components described
R4 below.

R4 (a) Initial, periodic, and on-the-job training.

R4 (b) Written and practical examinations to determine knowledge,
R4 understanding of, and ability to comply with department and applicable
R4 USDOT rules, licensee or registrant requirements, operating and
R4 emergency procedures, and use of radiographic and related equipment.

R4 (3) Procedures to verify the certification of radiographers and to ensure that the
R4 certification remains valid.

R4 (4) A written policy to maintain radiation doses as low as reasonably achievable as
R4 specified in 64E-5.303, F.A.C. The policy shall include:

R4 (a) A commitment by management to keep radiation doses as low as
R4 reasonably achievable and a description of the participation of
R4 management, the RSO, and radiographic personnel in the implementation
R4 of the policy;

R4 (b) Investigation within 30 days by the RSO of any exposure level that
R4 exceeds established monthly and quarterly levels and implementation of
R4 corrective actions to halt unnecessary exposures and prevent recurrence;
R4 and

R4 (c) An audit of the program to evaluate its effectiveness in minimizing
R4 exposures in conjunction with the annual review of the radiation protection
R4 program specified in 64E-5.303(3), F.A.C. A summary of the results of
R4 each audit, including a description of corrective actions taken, shall be
R4 prepared by the RSO and approved by the licensee or registrant.

R4 (5) An auditing program for internal inspections of the job performance of all
R4 radiographic personnel at intervals not to exceed 6 months as described in 64E-
R4 5.434, F.A.C.

- R4 (6) Written operating and emergency procedures as described in 64E-5.436, F.A.C.
R4
- R4 (7) Leak testing procedures, including a description of:
- R4 (a) The method of taking wipes and preparing samples for analysis using only
R4 radiographers or radiographer's assistants working under the personal
R4 supervision of a radiographer or persons specifically licensed by the
R4 department, another agreement state, licensing state, or the NRC to
R4 perform such services; and
- R4 (b) The method of performing leak test sample analyses, including
R4 instrumentation to be used and experience of the individuals who will
R4 perform the analyses or a commitment to use vendors specifically
R4 licensed to perform such analyses by the department, another agreement
R4 state, licensing state, or the NRC.
- R4 (8) Procedures for the semiannual calibration of survey instruments and the annual
R4 calibration of alarm ratemeters, including a description of the calibration
R4 instrumentation and the experience of the person who will perform the
R4 calibrations or a commitment to use persons specifically licensed to perform such
R4 calibrations by the department, another agreement state, licensing state, or the
R4 NRC. All survey instrument calibrations shall be performed in accordance with
R4 64E-5.426(2), F.A.C.
- R4 (9) Procedures for quarterly inspection and maintenance of survey instruments,
R4 radiation machines, radiographic exposure devices, associated equipment,
R4 source changers, storage containers, and transport containers to assure proper
R4 function of components important to safety, performed in accordance with 64E-
R4 5.430, F.A.C.
- R4 (10) Procedures for annual calibration of pocket or electronic dosimeters, including a
R4 description of the calibration instrumentation and the experience of the person
R4 who will perform the calibrations or a commitment to use persons specifically
R4 licensed to perform such calibrations by the department, another agreement
R4 state, licensing state, or the NRC.
- R4 (11) Procedures for lay-barge, offshore platform and underwater radiography if
R4 conducting such activities.

R4 Specific Authority: 404.051, 404.061, F.S.

R4 Law Implemented: Implemented 404.022; 404.051(1), (4), (6), (9), (10), 404.061(2); 404.081(1); 404.141, F.S.

R4 History: New September 11, 2001.

R4 **64E-5.433 Radiation Safety Officer.**

R4 (1) The licensee or registrant shall appoint an RSO and delegate the authority
R4 needed to fulfill the duties of the position. Except as specified in 64E-5.433(2),
R4 F.A.C., below, the minimum qualifications, training, and experience for the RSO
R4 shall be:

R4 (a) One year of documented industrial radiography experience as a
R4 radiographer; and

R4 (b) Sixteen hours of formal instruction in the establishment and maintenance
R4 of a radiation protection program, including training to perform internal
R4 audits and mitigation of radiological incidents. Individuals identified as an
R4 RSO on an industrial radiography license or registration before the
R4 effective date of this rule are not required to comply with the training
R4 requirements of this paragraph.

R4 (2) Equivalent alternative radiation and safety training and experience in
R4 radiographic operations and formal training in the establishment and
R4 maintenance of a radiation protection program can substitute for the
R4 requirements specified in 64E-5.433(1)(a) and (b), F.A.C., above.

R4 (3) In addition to other duties specified in this part, the RSO shall:

R4 (a) Ensure compliance with all components of the licensee's or registrant's
R4 radiation protection program as specified in 64E-5.432, F.A.C., the terms
R4 and conditions of the license, and this rule;

R4 (b) Investigate incidents and direct corrective actions, including halting
R4 operations when necessary;

R4 (c) Serve as the licensee's or registrant's contact with the department; and

R4 (d) Ensure that radiation safety activities are performed using approved
R4 procedures and requirements in Chapter 64E-5, F.A.C., in the daily
R4 operation of the licensee's program.

R4 Specific Authority: 404.051, 404.061, F.S.

R4 Law Implemented: 404.022, 404.051(1), (4), 404.061(2), F.S.

R4 History: New September 11, 2001.

- R4 (3) Radiographers who work for an out-of-state radioactive materials license under
R4 reciprocal recognition are authorized to conduct radiographic operations within
R4 the state if they have a valid certification from a certifying entity for the activities
R4 being conducted before entering the state.
- R4 (4) Any individual who has completed all requirements specified in 64E-5.434(2),
R4 F.A.C., above, and begins work for a different Florida licensee or registrant shall
R4 complete 4 hours of additional training and testing before conducting
R4 radiographic operations. The training shall consist of instructions in the
R4 licensee's or registrant's operating and emergency procedures and supervised
R4 instruction during a special training session in the use of the licensee's or
R4 registrant's radiographic and safety equipment. The testing shall consist of
R4 successful completion of the written and practical examinations described in
R4 64E-5.434(1)(c), F.A.C. The RSO shall document how the prior radiation training
R4 and experience was verified.
- R4 (5) Personnel using industrial cabinet x-ray systems for industrial radiography shall
R4 complete 16 hours of training and testing as described below:
- R4 (a) Ten hours of training and testing as described in 64E-5.434(6), F.A.C.;
R4 and
- R4 (b) Two hours of instruction in the registrant's operating and emergency
R4 procedures pertaining to industrial radiography using industrial cabinet x-
R4 ray systems, 2 hours of supervised instruction during a special training
R4 session in the use of the registrant's industrial cabinet x-ray system,
R4 related handling tools, radiation survey instruments, and personnel
R4 monitoring devices, and 2 hours of testing, which shall consist of a written
R4 examination covering operating and emergency procedures and
R4 equipment use and a practical examination to demonstrate competence in
R4 the use of the registrant's industrial cabinet x-ray system and related
R4 equipment.
- R4 (6) The subjects to be covered during the instruction of radiographers shall include:
- R4 (a) Fundamentals of radiation safety, including characteristics of radiation,
R4 units of radiation dose, quantities of radioactivity, hazards of radiation
R4 exposure, radiation protection standards, radiation levels from sources of
R4 radiation, and methods of minimizing radiation dose.
R4
- R4 (b) Radiation detection instruments, including:
- R4 1. Use, operation, calibration, and limitations of radiation survey
R4 instruments;
- R4 2. Survey techniques; and
- R4 3. Use of personnel monitoring equipment.

- R4 (c) Equipment to be used, including, as applicable:
- R4 1. Operation and control of radiation machines, radiographic exposure
R4 equipment, remote handling equipment, source changers, storage
R4 containers, and transport containers, including pictures or models
R4 of source assemblies;
- R4 2. Storage, control, and disposal of licensed material; and
- R4 3. Inspection and maintenance of equipment.
- R4 (d) The applicable requirements of these rules and NRC and USDOT
R4 regulations.
- R4 (e) The licensee's or registrant's operating and emergency procedures.
- R4 (f) Case histories of industrial radiography accidents.
- R4 (7) Each licensee or registrant shall provide 8 hours of annual radiation safety
R4 training to all radiographic personnel, which can be conducted in multiple
R4 sessions.
- R4 (8) The RSO or the RSO's designee shall audit the job performance of each
R4 radiographer and radiographer's assistant to ensure that the department's
R4 regulations, license requirements, and the licensee's or registrant's operating and
R4 emergency procedures are followed. The audits shall include observation of the
R4 performance of each radiographer or radiographer's assistant during an actual
R4 radiographic operation at intervals not to exceed 6 months. Radiographers or
R4 radiographer's assistants who have not participated in a radiographic operation
R4 for more than 6 months since the last audit shall demonstrate knowledge of the
R4 licensee's or registrant's operating and emergency procedures and safe use of
R4 radiographic and related equipment by a practical examination before
R4 participating in a radiographic operation. Audits of the RSO are not required.
- R4 (9) Individuals conducting internal radiation safety training or audits shall meet the
R4 minimum qualifications specified in 64E-5.433(1), F.A.C., for the RSO.

R4 Specific Authority: 404.051404.061, F.S.

R4 Law Implemented: 404.022, 404.051(1), (4), 404.061(2), F.S.

R4 History: New September 11, 2001.

R4 **64E-5.435 Conducting Industrial Radiographic Operations.**

- R4 (1) With the exception of industrial cabinet x-ray systems, the radiographer shall be
 R4 accompanied by at least one other radiographer or radiographer's assistant
 R4 whenever radiography is performed at a location other than a permanent
 R4 radiographic installation. The additional qualified individual shall observe the
 R4 radiographic operations and be capable of providing immediate assistance to
 R4 prevent unauthorized entry. Radiography is prohibited if only one qualified
 R4 individual is present. Radiography performed in an industrial cabinet x-ray
 R4 system by a single individual meeting the training and testing requirements
 R4 specified in 64E-5.434(5), F.A.C., is permitted.
- R4 (2) The radiographer's assistant shall be under the personal supervision of a
 R4 radiographer when using a radiation machine, radiographic exposure device,
 R4 source changer, or related source handling tools or conducting radiation surveys
 R4 to determine that the sealed source has returned to the shielded position or that
 R4 the radiation machine is off after an exposure.
- R4 (3) All radiographic operations conducted at a licensee's or registrant's permanent
 R4 facility shall be conducted in a permanent radiographic installation or an
 R4 industrial cabinet x-ray system or using equipment, facilities, and procedures that
 R4 are adequate to protect public health, safety, and property and included in the
 R4 radiation protection program specified in 64E-5.432, F.A.C.

R4 Specific Authority: 404.051, F.S.

R4 Law Implemented: 404.022, 404.051(1), (4), (11), 404.081(1), F.S.

R4 History: New September 11, 2001.

R4 **64E-5.436 Operating and Emergency Procedures.** The licensee's or registrant's
 R4 procedures shall include instructions in the following:

- R4 (1) Handling and use of sources of radiation to be used so that exposures are
 R4 maintained as low as reasonably achievable and no individual is likely to be
 R4 exposed to radiation doses in excess of the limits established in rules contained
 R4 in Part III of Chapter 64E-5, F.A.C.;
- R4 (2) Methods and occasions to conduct radiation surveys;
- R4 (3) Methods to control access to radiographic areas;
- R4 (4) Methods and occasions to lock and secure sources of radiation;
- R4 (5) Personnel monitoring and the use of personnel monitoring equipment, including
 R4 steps to be taken immediately by radiography personnel when a pocket
 R4 dosimeter is found off-scale, an alarm ratemeter alarms unexpectedly, or a
 R4 personnel monitoring badge is damaged or lost;
- R4 (6) Transportation of licensed material to field locations and preparation of packages
 R4 for shipment by common or contract carriers, including packaging, marking,
 R4 labeling, shipping papers, emergency response information, blocking and
 R4 bracing, security, surveys, and vehicle placarding in accordance with applicable
 R4 requirements of the USDOT;

- R4 (7) Leak testing, quarterly inventories, and equipment inspection, maintenance and
R4 operability checks, and disposal of licensed material;
- R4 (8) Source exchanges for licensees who perform source exchanges;
- R4 (9) Calibration of survey instruments, dosimeters, and alarm ratemeters for
R4 licensees who perform calibrations;
- R4 (10) Emergency response, including response to loss, damage, or theft of sources of
R4 radiation, unauthorized entries into restricted areas, notifications, exposure
R4 minimization, and source recovery;
- R4 (11) Identifying and reporting equipment defects and noncompliance issues; and
- R4 (12) Maintenance of records.

R4 Specific Authority: 404.051, 404.20, F.S.

R4 Law Implemented: 404.022, 404.051(1), (4), (6), 404.081, 404.20(1), F.S..

R4 History: New September 11, 2001.

R4 **64E-5.437 Personnel Monitoring.**

- R4 (1) The licensee or registrant shall not permit any individual to act as a radiographer
R4 or a radiographer's assistant unless the individual wears on the trunk of his or her
R4 body at all times during radiographic operations:
- R4 (a) A NVLAP-approved personnel monitoring badge such as a film badge,
R4 thermoluminescent dosimeter (TLD) or optically stimulated luminescent
R4 device (OSLD);
- R4 (b) A direct reading pocket dosimeter, which can be either an ion chamber or
R4 electronic personal dosimeter; and
- R4 (c) An alarming ratemeter. Alarm ratemeters are not required for radiography
R4 performed in an approved permanent radiographic installation meeting the
R4 requirements of 64E-5.431, F.A.C.
- R4 (2) Each personnel monitoring badge shall be assigned to and worn by only one
R4 individual and shall be exchanged monthly. After exchange each badge shall be
R4 processed as soon as possible. If a report is received from the badge processor
R4 that indicates an individual has received a radiation exposure in excess of 5 rem
R4 (0.05 Sv), the licensee or registrant shall notify the department within 24 hours as
R4 specified in 64E-5.344(2), F.A.C. If a personnel monitoring badge is lost or
R4 damaged, the worker shall cease work immediately until a replacement badge is
R4 provided and the exposure is calculated by the RSO or the RSO's designee for
R4 the time period from issuance to loss or damage of the badge. The results of the
R4 calculated exposure and the time period for which the personnel monitoring
R4 badge was lost or damaged shall be provided to the processor to adjust the
R4 individual's occupational exposure record.

- R4 (3) Pocket dosimeters shall have a range from 0 to 200 millirem (2 mSv) and shall
R4 be recharged at the start of each shift and when 75% of the full scale of the
R4 dosimeter is exceeded. Initial, final, and total pocket dosimeter readings shall be
R4 recorded at the start and end of each shift.
- R4 (4) If an individual's pocket dosimeter is found to be off-scale or if an individual's
R4 electronic personal dosimeter reads more than 200 millirem (2 mSv) and the
R4 possibility of radiation exposure cannot be ruled out as the cause, the individual's
R4 personnel monitoring badge shall be sent for processing within 24 hours. In
R4 addition, the individual shall not resume radiographic operations until a
R4 determination of the individual's radiation exposure has been made by the RSO
R4 or the RSO's designee. The results of this determination shall be reported in
R4 writing to the department within 30 days of the determination.
- R4 (5) Each alarming ratemeter shall:
- R4 (a) Have a function test without being exposed to radiation to ensure that the
R4 audible alarm is functioning properly before use at the start of each work
R4 shift;
- R4 (b) Give an alarm at a preset dose rate of no more than 500 millirem (0.5
R4 mSv) per hour; and
- R4 (c) Require special means to change the preset alarm function.
- R4 (6) Pocket dosimeters and alarm ratemeters shall be calibrated annually for correct
R4 response to radiation by a person licensed by the department, another
R4 agreement state, licensing state, or the NRC. Acceptable dosimeters shall read
R4 within 20% of the true radiation exposure. Ion chamber dosimeters also shall be
R4 checked for response to drift by setting the dosimeter at zero and storing it in a
R4 low background area for at least 24 hours and for electrical leakage, which shall
R4 be no more than 1% of full scale for each 24 hours. Acceptable ratemeters shall
R4 alarm within 20% of the true radiation dose rate.

R4 Specific Authority: 404.051, F.S.

R4 Law Implemented: 404.022, 404.051(1), (4), 404.081(1), (2), F.S.

R4 History: New September 11, 2001.

R4
R4

SUBPART F
(Formerly Subpart C)
PRECAUTIONARY PROCEDURES IN RADIOGRAPHIC OPERATIONS

R4 **64E-5.438 Radiation Surveys.**

- R4 (1) No radiographic operations shall be conducted unless at least one calibrated and
R4 operable radiation survey instrument meeting the requirements of 64E-5.426,
R4 F.A.C., is available for each radiographic exposure device and radiation machine
R4 in use at each site where radiographic exposures are made. All radiation
R4 surveys shall be performed with a calibrated and operable radiation survey
R4 instrument meeting the requirements of 64E-5.426, F.A.C.
- R4 (2) The surveys described below shall be performed by the licensee or registrant
R4 where applicable.
- R4 (a) A reference survey of each radiographic exposure device or source
R4 changer immediately following removal from a storage area, including
R4 removal from storage following transportation.
- R4 (b) An area survey during the first radiographic exposure to verify that the
R4 posting requirements specified in 64E-5.439(1), F.A.C., have been met
R4 and that unrestricted areas do not have radiation levels in excess of the
R4 limits specified in 64E-5.312(1)(c), F.A.C.
- R4 (c) A survey of the radiographic exposure device and the length of the guide
R4 tube after each exposure when approaching the device or guide tube,
R4 concluding with a reference survey of the radiographic exposure device at
R4 the location established by the licensee after each radiographic exposure.
R4 The surveys shall be performed before exchanging film, repositioning the
R4 exposure head, or dismantling equipment.
- R4 (d) A reference survey of the radiographic exposure device and source
R4 changer before and after source exchanges.
- R4 (e) A reference survey of the radiographic exposure device, source changer,
R4 or storage container after returning the sealed source to a storage area.
- R4 (f) A survey after each radiographic exposure using radiation machines to
R4 verify that the machine is off.

R4 Specific Authority: 404.051, F.S.

R4 Law Implemented: 404.022, 404.051(1), (4), 404.081(1), F.S.

R4 History: New September 11, 2001.

R4 **64E-5.439 Posting.** In addition to the posting requirements specified in
R4 64E-5.901, F.A.C., the licensee or registrant shall comply with the requirements described
R4 below.

R4 (1) Radiation areas and high radiation areas created by radiographic operations
R4 shall be posted conspicuously as specified in 64E-5.323(1) and (2), F.A.C.
R4 Areas or rooms in which licensed material is used or stored shall be posted as
R4 specified in 64E-5.323(5), F.A.C. The exceptions to posting specified in 64E-
R4 5.324(1), F.A.C., do not apply to industrial radiography.

R4 (2) Source movement logs specified in 64E-5.429, F.A.C., that document the current
R4 location of each source of radiation and source movements for the previous 30
R4 days shall be posted conspicuously adjacent to the area where the source of
R4 radiation is stored.

R4 Specific Authority: 404.051, F.S.

R4 Law Implemented: 404.022, 404.051(1), (4), 404.081(1), 404.20, F.S.

R4 History: New September 11, 2001.

R4 **64E-5.440 Records.**

R4 (1) Each licensee or registrant shall maintain the following records for 3 years after
R4 the event at the location specified in 64E-5.432, F.A.C., for inspection by the
R4 department:

R4 (a) Survey instrument, dosimeter, and alarm ratemeter calibrations specified
R4 in 64E-5.426 and 64E-5.437(5) – (6), F.A.C.;

R4 (b) Leak test results specified in 64E-5.427, F.A.C., which shall contain the
R4 manufacturer's name, model, and serial number of each sealed source or
R4 device tested, including the device the source was stored in, the identity of
R4 each radionuclide, the estimated activity of each sealed source, the
R4 measured activity of each test sample expressed in microcuries
R4 (becquerels), the date of the test, and the signature or initials of the RSO
R4 or the RSO's designee;

R4 (c) Quarterly inventories specified in 64E-5.428, F.A.C., which shall include
R4 the name of the person conducting the inventory, the radionuclide,
R4 number of curies (becquerels) or mass in each device, location of each
R4 sealed source, device, and machine, the manufacturer, model, and serial
R4 number of each sealed source, device, and machine, the date of the
R4 inventory, and the signature or initials of the RSO or the RSO's designee;

R4 (d) Source movement logs and daily survey reports specified in 64E-5.429,
R4 F.A.C.

R4 (e) Quarterly equipment inspection and maintenance specified in 64E-
R4 5.430(2), F.A.C., including the date of the inspection, the name of
R4 inspector, the equipment involved, any problems found, and what repair or
R4 maintenance was done;

- R4 (f) Operation tests on permanent radiographic installation entrance controls
R4 and audible and visual alarms specified in 64E-5.431, F.A.C.;
- R4 (g) Records of internal audits specified in 64E-5.434(8), F.A.C., including lists
R4 of audit items checked and any violations observed;
- R4 (h) Records showing receipts and transfers of sealed sources and devices
R4 using DU for shielding, including the date, the name of the individual
R4 making the record, radionuclide, number of curies (becquerels) or mass,
R4 manufacturer, model, and serial number of each sealed source and
R4 device, as appropriate.
- R4 (2) Each licensee or registrant shall maintain the following records until the
R4 department terminates the license or registration requiring the record:
- R4 (a) Individual dosimeter logs specified in 64E-5.429, F.A.C.;
- R4 (b) Initial and refresher radiation safety training specified in 64E-5.434,
R4 F.A.C., including lists of the topics discussed, dates the training was
R4 conducted, names of the instructors and attendees, and written and
R4 practical examinations;
- R4 (c) Verification of previous radiography experience;
- R4 (d) Radiographer certification documents specified in
R4 64E-5.434(2)(e) – (f), F.A.C., and verification of certification status;
- R4 (e) Records of personnel exposure investigations specified in
R4 64E-5.432(4)(b), F.A.C., including the names of the individuals involved,
R4 the exposures received, the dates the exposures were received, a
R4 description of the cause of the exposures, the corrective actions taken,
R4 and the signature of the RSO;
- R4 (f) Records of estimates of exposures as a result of off-scale dosimeters or
R4 lost or damaged personnel monitoring badges, including records of
R4 surveys used to determine an individual's exposure and reports submitted
R4 to the department as specified in 64E-5.437(3), F.A.C.;
- R4 (g) Records of annual ALARA audits specified in 64E-5.432(3)(c), F.A.C.; and
R4
- R4 (h) Operating and emergency procedures.
- R4 (3) Each licensee or registrant conducting industrial radiography at a temporary job
R4 site shall have the following records available at that site for inspection by the
R4 department:
- R4 (a) Appropriate license or registration;
- R4 (b) Certification by a certifying entity;

- R4 (c) Operating and emergency procedures;
- R4 (d) Rules contained in Chapter 64E-5, Parts I – IV, IX, and XV, F.A.C.;
- R4 (e) Calibration records for the survey instruments, pocket dosimeters, and
R4 alarm ratemeters used at the site or calibration tags or labels that are
R4 affixed to the devices;
- R4 (f) Records of the latest leak test results for the specific devices in use at the
R4 site or leak test tags or labels that are affixed to the devices; and
- R4 (g) Source movement logs and daily survey reports for the period of operation
R4 at the site.

R4 Specific Authority: 404.051, F.S.

R4 Law Implemented: 404.022, 404.051(1), (4), 404.081(1), 404.20, F.S.

R4 History: New September 11, 2001.

R4 **64E-5.441 Reporting Requirements.**

- R4 (1) In addition to the reporting requirements specified in rules contained in Chapter
R4 64E-5, Parts III, IX, F.A.C., and other sections of this part, each licensee shall
R4 provide a written report to the department within 30 days of the occurrence of
R4 any of the incidents involving radiographic equipment described below. Such
R4 reports shall be mailed to the Bureau of Radiation Control, Radioactive Materials
R4 Section, Bin C21, 4052 Bald Cypress Way, Tallahassee, Florida 32399-1741 for
R4 incidents involving radioactive materials or to the Bureau of Radiation Control,
R4 Radiation Machine Section, P. O. Box 210, Jacksonville, Florida 32231 for
R4 incidents involving radiation machines.
- R4 (a) Unintentional disconnection of the source assembly from the control
R4 cable.
- R4 (b) Inability to retract and secure the source assembly to the fully shielded
R4 position.
- R4 (c) Failure of any component critical to safe operation of the device to perform
R4 its intended function properly.
- R4 (2) The licensee shall include the information described below in each report
R4 submitted as specified in this section.
- R4 (a) A description of the equipment problem.
- R4 (b) Cause of each incident if known.
- R4 (c) Manufacturer name and model number of the equipment involved in the
R4 incident.
- R4 (d) Place, time, and date of the incident.
- R4 (e) Actions taken to establish normal operations.

- R4 (f) Corrective actions taken or planned to prevent recurrence.
- R4 (g) Qualifications of the personnel involved in the incident.
- R4 (3) Reports of overexposures submitted as specified in rules contained in Part III of
R4 Chapter 64E-5, F.A.C., that involve failure of safety components of radiography
R4 equipment also must include the information specified in 64E-5.441(2), F.A.C.
R4

R4 Specific Authority: 404.051, F.S.

R4 Law Implemented: 404.022, 404.051(1), (4), 404.081(1), F.S.

R4 History: New September 11, 2001.

PART V X-RAYS IN THE HEALING ARTS

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PART V

X-RAY IN THE HEALING ARTS

64E-5.501 Definitions. As used in this part, the following definitions apply:

- (1) "Accessible surface" means the external surface of any enclosure or housing
- (2) "Added filtration" means any filtration which is in addition to the inherent filtration.
- (3) "Aluminum equivalent" means the thickness of type 1100 aluminum alloy affording the same degree of radiation attenuation, under specified conditions, as the material in question. The nominal chemical composition of type 1100 aluminum alloy is 99.00 percent minimum aluminum, 0.12 percent copper.
- (4) "Assembler" means any person engaged in the business of assembling, replacing or installing one or more components into an x-ray system or subsystem. The term includes the owner of an x-ray system or his employee or agent who assembles components into an x-ray system that is subsequently used to provide professional or commercial services.
- (5) "Attenuation block" means a block or stack, having dimensions 20 centimeters by 20 centimeters by 3.8 centimeters, of type 1100 aluminum alloy or other materials having equivalent attenuation.
- (6) "Automatic exposure control" means a device which automatically controls one or more technique factors in order to obtain, at a preselected location, a required quantity of radiation. See also "Phototimer".
- (7) "Barrier". See "Protective barrier".
- (8) "Beam axis" means a line from the source through the centers of the x-ray field.
- (9) "Beam-limiting device" means a device which provides a means to restrict the dimensions of the x-ray field, except for beam-blocking or beam-shaping devices used in radiation therapy.
- (10) "Beam monitoring system" means a system designed to detect and measure the radiation present in the useful beam.
- (11) "Cephalometric device" means a device intended for the radiographic visualization and measurement of the dimensions of the human head.
- (12) "Certified components" means components of x-ray systems which are subject to regulations promulgated under Public Law 90-602, the Radiation Control for Health and Safety Act of 1968.
- (13) "Certified system" means any x-ray system which has one or more certified components.

- (14) "Changeable filters" means any filter which can be readily removed from the useful beam through any electronic, mechanical or physical process.
- (15) "Contact therapy system" means an x-ray system used for therapy with the x-ray tube port placed in contact with or within five centimeters of the surface being treated.
- (16) "Control panel" means that part of the x-ray control upon which are mounted the switches, knobs, push buttons and other hardware necessary for manually setting the technique factors and operating modes.
- (17) "Cooling curve" means the graphical relationship between the heat units stored and cooling time.
- (18) "Dead-man switch" means a switch so constructed that a circuit closing contact can be maintained only by continuous pressure on the switch by the operator.
- (19) "Diagnostic source assembly" means the tube housing assembly with a beam-limiting device attached.
- (20) "Diagnostic x-ray system" means an x-ray system designed for irradiation of any part of the human body as an aid to diagnosis through visualization of anatomical parts.
- (21) "Direct scattered radiation" means that radiation which has been deviated in direction only by materials irradiated by the useful beam. See also "Scattered radiation".
- (22) "Entrance exposure rate" means the roentgens (C per kg) per unit time at the point where the center of the useful beam enters the patient.
- (23) "Equipment". See "X-ray equipment".
- (24) "Field emission equipment" means equipment which uses an x-ray tube in which electron emission from the cathode is due solely to the action of an electric field.
- (25) "Filter" means material placed in the useful beam to preferentially absorb selected radiation.
- (26) "Fluoroscopic imaging assembly" means a subsystem in which x-ray photons produce a fluoroscopic image. It includes the image receptors such as the image intensifier and spot film device, equipment housings, electrical interlocks, if any, the primary protective barrier, and structural material providing linkage between the image receptor and the diagnostic source assembly.
- (27) "General purpose radiographic x-ray system" means any diagnostic radiographic x-ray system, except computed tomography systems, which, by design, is not limited to radiographic examination of a specific anatomical region.
- (28) "Gonad shield" means a primary protective barrier for the testes or ovaries.

- (29) "Half-value layer (HVL)" means the thickness of specified material which attenuates the beam of radiation to an extent such that the exposure rate is reduced to one-half of its original value. In this definition, the contribution of all scattered radiation, other than any which might be present initially in the beam concerned, is deemed to be excluded.
- (30) "Healing arts self-referral" means the testing of human beings using x-ray machines for the detection or evaluation of health indications when such tests are not specifically and individually ordered by a licensed practitioner of the healing arts legally authorized to prescribe such x-ray tests for the purposes of diagnosis or medical treatment.
- (31) "Heat unit" means a unit of energy equal to the product of the peak kilovoltage, milliamperes, seconds, and a quality factor dependent on the voltage wave form (QF=1 for single phase, 1.35 for three phase) or kVp x mA x seconds x QF.
- (32) "Image intensifier" means a device, when installed in its housing, that instantaneously converts an x-ray pattern into a corresponding light image of higher energy density.
- (33) "Image receptor" means any device, such as a fluorescent screen or radiographic film, which transforms incident x-ray photons either into a visible image or into another form which can be made into a visible image by further electronic or chemical transformations.
- (34) "Image receptor support" means that part of a mammographic system designed to support the image receptor in a horizontal plane during the mammographic examination.
- (35) "Inherent filtration" means the filtration of the useful beam provided by the permanently installed components of the x-ray tube housing assembly.
- (36) "Irradiation" means the exposure of matter to ionizing radiation.
- (37) "Kilovolts peak(kVp)". See "Peak tube potential".
- (38) "kV" means kilovolts.
- (39) "kWs" means kilowatt second. It is equivalent to kV x mA x seconds x 10⁻³.
- (40) "Lead equivalent" means the thickness of lead affording the same attenuation, under specified conditions, as the material in question.
- (41) "Leakage radiation" means radiation emanating from the diagnostic or therapeutic source assembly, except for the useful beam and radiation produced when the exposure switch or timer is not activated.
- (42) "Leakage technique factors" means the technique factors associated with the diagnostic or therapeutic source assembly which are used in measuring leakage radiation. They are defined as follows:

- (a) For diagnostic source assemblies intended for capacitor energy storage equipment, the maximum rated peak tube potential and the maximum rated number of exposures in an hour for operation at the maximum rated peak tube potential with the quantity of charge per exposure being ten milliamperere seconds(10 mAs) or the minimum obtainable from the unit, whichever is larger.
 - (b) For diagnostic source assemblies intended for field emission equipment rated for pulsed operation, the maximum rated peak tube potential and the maximum rated number of x-ray pulses in an hour for operation at the maximum rated peak tube potential.
 - (c) For all other diagnostic or therapeutic source assemblies, the maximum rated peak tube potential and the maximum rated continuous tube current for the maximum rated peak tube potential.
- (43) "Light field" means that area of the intersection of the light beam from the beam-limiting device and one of the sets of planes parallel to and including the plane of the image receptor, whose perimeter is the locus of points at which the illumination is one-fourth of the maximum in the intersection.
- (44) "Line-voltage regulation" means the difference between the no-load and the load line potentials expressed as a percent of the load line potential. It is calculated using the following equation: $\text{Percent line-voltage regulation} = 100(V_n - V_1)/V_1$ where V_n = no-load line potential and V_1 = load line potential.
- (45) "mAs" means milliamperere second.
- (46) "Maximum line current" means the root-mean-square current in the supply line of an x-ray machine operating at its maximum rating.
- (47) "Mobile x-ray equipment". See "X-ray equipment".
- (48) "Peak tube potential" means the maximum value of the potential difference across the x-ray tube during an exposure.
- (49) "Phantom" means a volume of material behaving in a manner similar to tissue with respect to the attenuation and scattering of radiation.
- (50) "Photofluorographic" means an x-ray system designed to superimpose a patient's anatomical x-ray image from a fluoroscopic input phosphor onto a film strip through a system of lenses.
- (51) "Phototimer" means a device for controlling radiation exposures to image receptors by the amount of radiation which reaches a radiation monitoring device. The radiation monitoring device is part of an electronic circuit which controls the duration of time the tube is energized. See also "Automatic exposure control".
- (52) "Portable x-ray equipment". See "X-ray equipment".

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- (53) "Position indicating device (PID)" means a device on dental x-ray equipment used to indicate the beam position and to establish a definite source-skin distance. It may or may not incorporate or serve as a beam-limiting device.
- (54) "Primary dose monitoring system" means a system which will monitor the useful beam during irradiation and which will terminate irradiation when a preselected number of dose monitor units have been delivered.
- (55) "Primary protective barrier". See "Protective barrier".
- (56) "Protective apron" means an apron made of radiation absorbing material used to reduce radiation exposure.
- (57) "Protective barrier" means a barrier containing radiation absorbing material used to reduce radiation exposure. The types of protective barriers are as follows:
- (a) "Primary protective barrier" means the material, excluding filters, placed in the useful beam to reduce the radiation exposure by a required degree, for protection purposes.
 - (b) "Secondary protective barrier" means a barrier sufficient to attenuate the stray radiation by a required degree, for protection purposes.
- (58) "Protective glove" means a glove made of radiation absorbing material and used to reduce radiation exposure.
- (59) "Qualified person" means an individual who has the knowledge and training to measure ionizing radiation, to evaluate safety techniques and to advise regarding radiation protection needs.
- (60) "Radiation detector" means a device which, in the presence of radiation, provides a signal or other indication suitable for use in measuring single or multiple quantities of incident radiation.
- (61) "Radiation therapy simulation system" means a radiographic or fluoroscopic x-ray system, intended for localizing the volume to be exposed during radiation therapy, and confirming the position and size of the therapeutic irradiation field.
- (62) "Radiograph" means an image receptor on which the image is created directly or indirectly by an x-ray pattern and results in a permanent record.
- (63) "Radiographic imaging system" means any system whereby a permanent or semi-permanent image is recorded on an image receptor by the action of ionizing radiation.
- (64) "Radiological physicist" means an individual who meets one of the following criteria:
- (a) Is certified by the American Board of Radiology in therapeutic radiological physics, radiological physics, or x and gamma ray physics; or

- (b) Has a bachelor's degree in a physical science or engineering and three years full-time experience working in therapeutic radiological physics under the direction of a physicist certified by the American Board of Radiology. The work duties must include duties involving the calibration and spot checks of a medical accelerator or a sealed source teletherapy unit; or
 - (c) Has a master's or a doctor's degree in physics, biophysics, radiological physics, health physics or engineering; has had one year of full-time training in therapeutic radiological physics; and has had one year of full-time work experience in a radiotherapy facility where the individual's duties involved calibration and spot checks of a medical accelerator or a sealed source teletherapy unit; or
 - (d) Has performed radiation physics work for a period of at least ten years full time, prior to the effective date of these rules, in the field of therapeutic radiological physics in radiotherapy facilities where the individual's duties involved calibration and spot checks of a medical accelerator or a sealed source teletherapy unit.
- (65) "Rating" means the operating limits of a component as specified by the component manufacturer.
- (66) "Recording" means producing a permanent form of an image resulting from x-ray photons, such as film or video tape.
- (67) "Registrant", as used in this part and in Parts IV, VI and VIII, means any person who possesses and administratively controls an x-ray system or other radiation producing machine and is required by the provisions in Part I to register with this department.
- (68) "Response time" means the time required for an instrument system to reach 90 percent of its final reading when the radiation-sensitive volume of the instrument system is exposed to a step change in radiation flux from zero sufficient to provide a steady state midscale reading.
- (69) "Scattered radiation" means radiation that, during passage through matter, has been deviated in direction. See "Direct scattered radiation".
- (70) "Secondary dose monitoring system" means a system which will terminate irradiation in the event of failure of the primary system
- (71) "Secondary protective barrier". See "Protective barrier".
- (72) "Shutter" means a device attached to the tube housing assembly which can totally intercept the useful beam and which has a lead equivalency not less than that of the tube housing assembly.
- (73) "Source" means the focal spot of the x-ray tube.

- (74) "Source-image receptor distance (SID)" means the distance from the source to the center of the input surface of the image receptor.
- (75) "Spot check" means a procedure which is performed to assure that a previous calibration continues to be valid.
- (76) "Spot film" means a radiograph which is made during a fluoroscopic examination to permanently record conditions which exist during that fluoroscopic procedure.
- (77) "Spot-film device" means a device intended to transport or position a radiographic image receptor between the x-ray source and fluoroscopic image receptor. It includes a device intended to hold a cassette over the input end of an image intensifier for the purpose of making a radiograph.
- (78) "SSD" means the distance between the source and the skin of the patient.
- (79) "Stationary x-ray equipment". See "X-ray equipment".
- (80) "Stray radiation" means the sum of leakage and scattered radiation.
- (81) "Technique factors" means the conditions of operation. They are specified as follows:
- (a) For capacitor energy storage equipment, peak tube potential in kV and quantity of charge in mAs;
 - (b) For field emission equipment rated for pulsed operation, peak tube potential in kV and number of x-ray pulses; and
 - (c) For all other equipment, peak tube potential in kV and either tube current in mA and exposure time in seconds, or the product of tube current and exposure time in mAs.
- (82) "Termination of irradiation" means the stopping of irradiation in a fashion which will not permit continuance of irradiation without the resetting of operating conditions at the control panel.
- (83) "Traceable to a national standard" means that a quantity or a measurement has been compared to a national standard directly or indirectly through one or more intermediate steps and that all comparisons have been documented.
- (84) "Tube" means an x-ray tube, unless otherwise specified. See "X-ray tube".
- (85) "Tube housing assembly" means the tube housing with tube installed. It includes high voltage or filament transformers and other appropriate elements when such are contained within the tube housing.
- (86) "Tube rating chart" means the set of curves provided by the manufacturer which specify the rated limits of operation of the tube in terms of the technique factors.

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- (87) "Useful beam" means the radiation emanating from the tube housing port or the radiation head and passing through the aperture of the beam limiting device when the exposure controls are in a mode to cause the system to produce radiation.
- (88) "Variable-aperture beam-limiting device" means a beam-limiting device which has capacity for stepless adjustment of the x-ray field size at a given SID.
- (89) "Visible area" means that portion of the input surface of the image receptor over which incident x-ray photons are producing a visible image.
- (90) "Wedge filter" means an added filter effecting continuous progressive attenuation on all or part of the useful beam.
- (91) "X-ray control" means a device which controls input power to the x-ray high-voltage generator or the x-ray tube. It includes equipment such as timers, phototimers, automatic brightness stabilizers and similar devices, which control the technique factors of an x-ray exposure.
- (92) "X-ray equipment" means an x-ray system, subsystem or component thereof.
- (a) "Mobile" means x-ray equipment mounted on a permanent base with wheels or casters for moving while completely assembled.
 - (b) "Portable" means x-ray equipment designed to be hand-carried.
 - (c) "Stationary" means x-ray equipment which is installed in a fixed location.
 - (d) "Special Purpose" means x-ray equipment or a system designed for radiographic examinations of a specific anatomical area of the human body utilizing image receptors of more than one size; for example, the head or the spinal column.
- (93) "X-ray field" means that area of the intersection of the useful beam and any one of the set of planes parallel to and including the plane of the image receptor, whose perimeter is the locus of points at which the exposure rate is one-fourth of the maximum in the intersection.
- (94) "X-ray high-voltage generator" means a device which transforms electrical energy from the potential supplied by the x-ray control to the tube operating potential. The device may also include means for transforming alternating current to direct current, filament transformers for the x-ray tube, high-voltage switches, electrical protective devices and other appropriate elements.
- (95) "X-ray system" means an assemblage of components for the controlled production of x-rays. It minimally includes an x-ray high-voltage generator, an x-ray control, a tube housing assembly, a beam-limiting device and the necessary supporting structures. Additional components which function with the system are considered integral parts of the system.

- (96) "X-ray subsystem" means any combination of two or more components of an x-ray system.
- (97) "X-ray tube" means any electron tube which is designed for the conversion of electrical energy into x-ray energy.
- (98) "Medical physicist" means a person who practices the branch of physics that is associated with the practice of medicine.
- (99) "Clinical image" means a radiograph.
- (100) "Pulsed mode" means operation of the x-ray system such that the x-ray tube current is pulsed by the x-ray control to produce one or more exposure intervals of duration less than one-half second.

Specific Authority: 404.051, F.S.

Law Implemented: 404.022, 404.031, 404.051(1)(4), F.S.

History: New July 17, 1985, amended April 4, 1989.,

Amended November 20, 1994, Amended January 5, 1995, Amended , May 15, 1996, Formerly 10D-91.602

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64E-5.502 General Requirements.

(1) Administrative Controls.

- (a) Registrant. The registrant shall be responsible for directing the operation of the x-ray systems which are subject to registration as described in 64E-5.511. The registrant or the registrant's agent shall assure that the following requirements are met in the operation of the x-ray system.
1. Any x-ray system which does not meet the provisions of these regulations shall not be operated for diagnostic or therapeutic purposes unless the department determines that such operation will not endanger the public health, safety and welfare.
 2. Individuals who will be operating any x-ray system shall be adequately instructed in the safe operating procedures and be competent in the safe use of the equipment. Nonphysician operators of medical x-ray systems shall be certified in accordance with 64E-3, FAC.
 3. A chart shall be provided in the vicinity of the diagnostic x-ray system's control panel, which specifies techniques and procedures to be used for all examinations performed by that system.
 4. Except for patients who cannot be moved out of the room, only the staff and ancillary personnel required for the medical procedure or training shall be in the room during the radiographic exposure. Other than the patient being examined:
 - a. All individuals shall be positioned such that no part of the body will be struck by the useful beam unless protected by 0.5 millimeter lead equivalent.
 - b. Staff and ancillary personnel shall be protected from the direct scatter radiation by protective aprons or whole body protective barriers of not less than 0.25 millimeter lead equivalent.
 - c. Other patients who cannot be removed from the room shall be protected from the direct scatter radiation by whole body protective barriers of 0.25 millimeter lead equivalent or shall be so positioned that the nearest portion of the body is at least two meters from both the tube head and the nearest edge of the useful beam.
 - d. When a portion of the body of any staff or ancillary personnel is potentially subjected to stray radiation which could result in that individual receiving one-fourth of the maximum permissible dose as defined in Part III, additional protective devices may be required by the department.

5. Gonad shields of not less than 0.25 millimeter lead equivalent shall be used for patients who have not passed the reproductive age, during radiographic procedures in which the gonads are in the useful beam, except for cases in which this would interfere with the diagnostic procedure.
6. Individuals shall not be exposed to the useful beam except for healing arts purposes and unless such exposure has been authorized by a licensed practitioner of the healing arts. This provision specifically prohibits the following:
 - a. Exposure of an individual for training, demonstration or other purposes unless there are also healing arts requirements and a proper prescription has been provided.
 - b. Exposure of an individual for the purpose of healing arts self-referral program except when authorized by 64E-5.502(1)(a)10.
 - c. Advertisement of free x-ray examinations unless the advertisement states that a determination of need will be made prior to the x-ray examination.
7. When a patient or film must be provided with auxiliary support during a radiation exposure:
 - a. Mechanical holding devices shall be used when the technique permits;
 - b. Written safety procedures shall be available to indicate the requirements for selecting a holder, list the individual projections where holding devices cannot be used and describe the procedure the holder shall follow;
 - c. The human holder shall be protected as required by (1)(a)4., above; and,
 - d. No individual shall be used routinely to hold film or patients.
8. Exposure Procedures Designed to Minimize Patient and Personal Exposure
 - a. The speed of film or screen and film combinations shall be the fastest speed consistent with the diagnostic objectives of the examination.
 - b. The radiation exposure to the patient shall be the minimum required to produce images of good diagnostic quality.

- c. Portable or mobile equipment shall be used only for examinations where it is impractical to transfer the patient to a stationary radiographic installation.
 - d. X-ray systems subject to 64E-5.505 shall not be utilized in procedures where the source to patient distance is less than 30 centimeters.
 - e. Persons who are not licensed to practice the healing arts shall not be permitted to perform fluoroscopic examinations or otherwise to expose humans to x-rays from fluoroscopic systems unless:
 - (I) The individual is certified in accordance with the requirements of Chapter 468, Part IV, FS;
 - (II) Such persons have been trained and authorized in writing by the licensed practitioner in charge to perform specified procedures;
 - (III) The specified procedures do not involve diagnostic interpretation by the unlicensed person; and
 - (IV) The specified procedures are designed to prevent or reduce exposure to patients by facilitating proper location and positioning for radiographic procedures.
9. Personnel Monitoring. All individuals who are associated with the operation of an x-ray system are subject to the occupational exposure limits and the requirements for the determination of the doses stated in 64E-5.304 and 64E-5.308, FAC. In addition, when protective clothing or devices are worn on portions of the body and a personnel monitoring device is required, at least one such device shall be utilized as follows:
- a. When a protective apron is worn, the monitoring device shall be worn at the collar outside of the apron
 - b. The dose to the whole body shall be recorded in the records required by 64E-5.339, FAC. If more than one device is used and a record is made of the data, each dose shall be identified with the area where the device was worn on the body.
10. Healing arts self-referral. Only healing arts self-referral programs for mammography screening will be authorized by the department.

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- (b) Information and Maintenance Records and Associated Information. The registrant shall maintain at least the following information for each x-ray system:
1. Tube rating charts and cooling curves.
 2. Record of surveys, calibrations, maintenance, modifications from the original schematics and drawings performed on the x-ray machine along with the names of persons who performed the service.
 3. A copy of all correspondence with the department regarding each x-ray system.
 4. An x-ray log containing the patient's name, the type of examination and the dates the examinations were performed. When the patient or film must be provided with human auxiliary support, the name of the human holder shall be recorded.
- (c) Maintenance of x-ray Equipment. X-ray systems and accessory devices shall be maintained in good working condition, both mechanically and electrically, so that the clinical objectives may be fulfilled without risk of unproductive exposure due to equipment failure or malfunction.
- (2) Shielding.
- (a) Each x-ray facility shall have primary and secondary protective barriers as needed to assure that an individual will not receive a radiation dose in excess of the limits specified in Part III of these regulations.
 - (b) Structural shielding in walls and other vertical barriers required for personnel protection shall extend without breach from the floor to a height of at least seven feet (2.1 m).
 - (c) Doors, door frames, windows and window frames shall have the same lead equivalent shielding as that required in the wall or other barrier in which they are installed.
 - (d) In computation of protective barrier requirements, the maximum anticipated workload, use factors, occupancy factors and the potential for radiation exposure from other sources shall be taken into consideration.

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- (e) Prior to construction, the floor plans and equipment arrangement of all new installations, or modifications of existing installations, utilizing x-ray energies of 200 keV and above for diagnostic or therapeutic purposes shall be submitted to the department for review and approval.
1. The plans shall show, as a minimum, the following:
 - a. The normal location of the x-ray system's radiation port; the port's travel and traverse limits; general direction of the useful beam; locations of any windows and doors; the location of the operator's booth; and the location of the x-ray control panel.
 - b. The structural composition and thickness or lead equivalent of all walls, doors, partitions, floor and ceiling of the room concerned.
 - c. The dimensions of the room concerned.
 - d. The type of occupancy of all adjacent areas inclusive of space above and below the room concerned. If there is an exterior wall, the distance to the closest area where it is likely that individuals may be present.
 - e. The make and model of the x-ray equipment and the maximum technique factors.
 - f. The type of examinations or treatments which will be performed with the equipment.
 2. Information on the anticipated maximum workload of the x-ray system.
 3. If the services of a qualified person have been utilized to determine the shielding requirements, a copy of the report, including all basic assumptions used, shall be submitted with the plans.
- (3) X-ray Film Processing Facilities and Practices.
- (a) Processing Facilities. Each installation using a radiographic x-ray system shall provide suitable equipment for handling and processing radiographic film in accordance with the following provisions:
 1. The area in which undeveloped films are handled for processing shall be devoid of light with the exception of light in the wave lengths having no significant effect on the radiographic film.
 2. Film pass boxes, if provided, shall be so constructed as to exclude light when film is placed in or removed from the boxes, and shall incorporate adequate shielding to prevent exposure of undeveloped film to stray radiation.

3. Darkrooms used by more than one individual shall be provided a positive method to prevent accidental entry while undeveloped films are being handled or processed.
4. Where film is developed manually,
 - a. At least one tri-sectional tank made of mechanically rigid, corrosion resistant material shall be utilized; and
 - b. The temperature of each solution shall be maintained within the range of 60 °F to 80 °F (16 °C to 27 °C). Film shall be developed in accordance with the time-temperature relationships specified by the film manufacturer, or, in the absence of such recommendations by the film manufacturer, with the following time temperature chart:

TIME-TEMPERATURE CHART		
Thermometer Reading		Minimum Developing Time (minutes)
°C	°F	
26.7	80	2
26.1	79	2
25.6	78	2 ½
25.0	77	2 ½
24.4	76	3
23.9	75	3
23.3	74	3 ½
22.8	73	3 ½
22.2	72	4
21.7	71	4
21.1	70	4 ½
20.6	69	4 ½
20.0	68	5
19.4	67	5 ½
18.9	66	5 ½
18.3	65	6
17.8	64	6 ½
17.2	63	7
16.7	62	8
16.1	61	8 ½
15.6	60	9 ½

- c. Devices shall be utilized which will:
 - (I) Indicate the actual temperature of the developer; and
 - (II) Signal the passage of a preset time as short as two minutes.

- (b) Precautionary Practices.
1. Film shall be stored in a cool, dry place and shall be protected from exposure to stray radiation. Film in open packages shall be stored in a light tight container.
 2. Film cassettes and intensifying screens shall be inspected periodically and shall be cleaned and replaced as necessary to best assure radiographs of good diagnostic quality.
 3. Outdated x-ray film shall not be used for human diagnostic radiographs, unless the film has been stored in accordance with the manufacturer's recommendations and a sample of the film passes a sensitometric test for normal ranges of base fog and speed.
 4. Film developing solutions shall be prepared in accordance with the directions given by the manufacturer, and shall be maintained in strength by replenishment or renewal so that full development is accomplished within the time specified by the manufacturer.
 5. Safe light and darkroom fog shall be such that, when a radiographic film is exposed to radiation to achieve a density of 1.0 and is exposed for one minute on any darkroom working surface, the film shall not have a density change greater than 0.1.
- (c) Automatic Processors and Other Closed Processing Systems. Preventive maintenance shall be performed on the unit, except for extended periods of nonuse, on a frequency basis which is not less than that schedule recommended by the manufacturer. In the event that no schedule is available from the manufacturer, a maintenance schedule shall be established which will preserve good diagnostic film quality.
- (d) Radiographic Film Quality.
1. Developed radiographs of patients or phantoms shall have an optical density of 0.5 to 2.0 in the area of clinical interest to allow for diagnostic interpretation of the image, unless justified due to special circumstances. Radiographs which provide the necessary diagnostic information shall not be repeated for the sole purpose of meeting the stated density range.
 2. Radiographic film used for diagnostic purposes shall be free from light fog and artifacts.

Specific Authority: 404.051, 404.081, 404.141, 404.22, F.S.

R1 Law Implemented: 404.051(1)(4)(5)(6), 404.081(1), 404.141, 404.22(1)(2)(3), F.S.

History: New July 17, 1985, amended April 4, 1989, Amended January 1, 1994, Amended November 20, 1994,

R1 Amended January 1, 1995, Formerly 10D-91.603, Amended May 18, 1998.

64E-5.503 General Requirements for All Diagnostic X-ray Systems. In addition to other requirements of this part, all diagnostic x-ray systems shall meet the following requirements:

- (1) **Warning label.** The main control panel and all auxiliary control panels of the x-ray system shall bear the equivalent warning statement, legible and accessible to view, "WARNING: This x-ray unit may be dangerous to patient and operator unless safe exposure factors and operating instructions are observed."
- (2) **Battery Charge Indicator.** Visual means shall be provided on the control panel of battery-powered x-ray generators to indicate whether the battery is in a state of charge adequate for proper operation.
- (3) **Leakage Radiation from the Diagnostic Source Assembly.** The leakage radiation from the diagnostic source assembly measured at a distance of one meter in any direction from the source shall not exceed 100 milliroentgens (25.8 μC per kg) in one hour when the x-ray tube is operated at its leakage technique factors. Compliance shall be determined by measurements averaged over an area of 100 square centimeters with no linear dimension greater than 20 centimeters.
- (4) **Radiation from Components Other than the Diagnostic Source Assembly.** The radiation emitted by a component other than the diagnostic source assembly shall not exceed two milliroentgens (0.516 μC per kg) in one hour at five centimeters from any accessible surface of the component when it is operated in an assembled x-ray system under any conditions for which it was designed. Compliance shall be determined by measurements averaged over an area of 100 square centimeters with no linear dimension greater than 20 centimeters.
- (5) **Beam Quality.**
 - (a) **Half-value Layer.** The half-value layer (HVL) of the useful beam for a given x-ray tube potential shall not be less than the values shown below. If it is necessary to determine such half-value layer at an x-ray tube potential which is not listed below, linear interpolation or extrapolation may be made.

Design Operating Range (kVp)	Measured Potential (kVp)	Half-value Layer (mm of Al)
Below 50	30	0.3
	40	0.4
	49	0.5
50 to 70	50	1.2
	60	1.3
	70	1.5
Above 70	71	2.1
	80	2.3
	90	2.5
	100	2.7
	110	3.0
	120	3.2
	130	3.5
	140	3.8
	150	4.1

- The above HVL criteria will be considered to have been met if it can be demonstrated that the aluminum equivalent of the total filtration in the primary beam is not less than that shown below:

Filtration Required vs. Operation Voltage	
Operating Voltage (kVp)	Total Filtration (inherent plus added)
Below 50	0.5 mm Al equivalent
50 to 70	1.5 mm Al equivalent
Above 70	2.5 mm Al equivalent

- Beryllium window tubes shall have a minimum of 0.5 mm aluminum equivalent filtration permanently mounted in the useful beam.
- For capacitor energy storage equipment, compliance shall be determined with the maximum quantity of charge per exposure
- The required minimum aluminum equivalent filtration shall include the filtration contributed by all materials which are always present between the focal spot of the tube and the patient.
- In addition to the requirements of (5)(a)1., above, all intraoral dental radiographic systems manufactured on and after December 1, 1980, shall have a minimum half-value layer not less than 1.5 mm aluminum equivalent filtration permanently installed in the useful beam.

- (b) Filtration Controls. For x-ray systems which have variable kVp and changeable filters, and which are used for low filtration techniques, a positive means shall be provided that will prevent an exposure unless the minimum required amount of filtration is in the useful beam for the selected kVp.
- (6) Aluminum equivalent of material between patient and image receptor. The aluminum equivalent of each of the items listed below, which are used between the patient and image receptor, shall not exceed the indicated limits. This requirement is applicable to the front panel of cassette holders and film changers provided by the manufacturer for purposes of patient support or to prevent foreign object intrusions. It does not apply to such items as a screen and its associated mechanical support panel or grids.

Item	Maximum Aluminum Equivalent
Front panel of cassette holder (total of all)	1.0 mm
Front panel of film changer (total of all)	1.0 mm
Stationary tabletop	1.0 mm
Movable tabletop (including stationary subtop)	1.5 mm
Cradle Above 70	2.0 mm

- (7) Multiple Tube Heads. Where two or more radiographic tubes are controlled by one exposure switch, the tube or tubes which have been selected shall be clearly indicated prior to initiation of the exposure. This indication shall be both on the x-ray control panel and at or near the selected tube housing assembly.
- (8) Mechanical Support of Tube Head. The tube housing assembly supports shall be adjusted such that the tube housing assembly will remain stable during an exposure unless the tube housing movement is a designed function of the x-ray system.
- (9) Technique Indicators.
- (a) Each x-ray system shall be equipped with devices, such as labeled control settings or meters, correctly indicating the physical factors and modes of operation used for exposures. x-ray systems utilizing arbitrary number or letter designators for kVp, time and milliamperage shall be accompanied by a chart giving the value of physical factors for each arbitrary designator.
- (b) The technique factors to be used during an exposure shall be indicated before the exposure begins, except when automatic exposure controls are used, in which case the technique factors which are set prior to the exposure shall be indicated.

- (c) On equipment having fixed technique factors, the requirement in (9)(a), above, may be met by permanent markings. Indication of technique factors shall be visible from the operator's position except in the case of fluoroscopy or spot films made by the fluoroscopist.
- (d) Reproducible technique factor indicators may be relabeled to meet the accuracy requirements of this part. Such relabeling shall be conspicuous and clearly legible and shall be utilized by the registrant in setting technique factors.
- (10) Accuracy of Technique Factors. Meters, labeled control settings, exposure time selectors and other physical factor indicators shall be accurate within the following tolerances:
- (a) Milliamperage (mA) for Radiographic: $\pm 10\%$
- (b) Milliamperage (mA) for Fluoroscopic: ± 0.2 mA
- (c) Kilovolt peak (kVp): $\pm 5\%$
- (d) Timer at settings
- Greater than ten seconds: \pm one second
 - Ten seconds or less: $\pm 10\%$
- (11) Timer Reproducibility. When four timer tests are performed at the same timer settings, the average time period (T_{mean}) shall be greater than or equal to 12 times the maximum time period (T_{max}) less the minimum time period (T_{min}). Expressed mathematically, $T_{\text{mean}} \geq 12 (T_{\text{max}} - T_{\text{min}})$.
- (12) Exposure Reproducibility. The x-ray exposure produced by radiographic systems shall be reproducible to within the following criteria: When all technique factors are held constant and four or more exposures at the same technique factors are made, the value of the average exposure (E_{mean}) shall be greater than or equal to 12 times the quantity of maximum exposure (E_{max}) minus the minimum exposure (E_{min}). Expressed mathematically, $E_{\text{mean}} \geq 12 (E_{\text{max}} - E_{\text{min}})$.
- (13) Exposure Linearity. The x-ray output produced by radiographic systems utilizing means other than automatic exposure controls shall be linear to within the following criteria:
- (a) When a choice of two or more current settings (mA) or current-time product settings (mAs) may be selected and where $X_{1\text{mean}}$ and $X_{2\text{mean}}$ are the average mR per mAs values obtained from four exposures on each of two mA or mAs settings at a fixed tube potential (kVp) setting, within the range of 40 to 100 percent of the maximum tube rating, the average of four exposures (mR) for a given milliamperere-second (mAs) product in mR per mAs shall not differ by more than:

1. Five hundredths times the sum of any two consecutive mA or mAs averaged settings; expressed mathematically,
$$|X_{1\text{mean}} - X_{2\text{mean}}| \leq 0.05 (X_{1\text{mean}} + X_{2\text{mean}});$$
 and
 2. One tenth times the sum of any other two mA or mAs averaged settings; expressed mathematically,
$$|X_{1\text{mean}} - X_{2\text{mean}}| \leq 0.10 (X_{1\text{mean}} + X_{2\text{mean}});$$
- (b) Equipment, which after calibration cannot be made to meet the requirements of (13)(a) above, may be relabeled to indicate the effective mA or mAs, providing that use of such relabeled stations will meet the requirements of (13)(a), above.
- (c) Equipment, which after calibration cannot be made to meet the requirements of (13)(a) or (b) above, shall not be used unless written approval is obtained from the department. Approval shall not be granted when the linearity determination exceeds the federal standard for certified systems.
- (14) Automatic Exposure Controls. When automatic exposure control is provided
- (a) Indication shall be made on the control panel when this mode of operation is selected.
 - (b) When the x-ray tube potential is greater than or equal to 50 kVp, the minimum exposure time for field emission equipment rated for pulsed operation shall be less than or equal to a time interval equivalent to two pulses.
 - (c) The minimum exposure time for all equipment other than that specified in (14)(b), above, shall be less than or equal to 1/60 second or a time interval required to deliver five mAs, whichever is greater.
 - (d) Either the product of peak x-ray tube potential, current, and exposure time shall be limited to not more than 60 kW per exposure, or the product of x-ray tube current and exposure time shall be limited to not more than 600 mAs per exposure except when the x-ray tube potential is less than 50 kVp, in which case the product of x-ray tube current and exposure time shall be limited to not more than 2,000 mAs per exposure.
 - (e) A visible signal shall indicate when an exposure has been terminated at the limits described in (14)(d), above, and manual resetting shall be required before further automatically timed exposures can be made.

- (f) Exposure Linearity. When a choice of two or more tube current settings (mA) may be selected, the average of four consecutive exposures ($E_{1\text{mean}}$) made at any one tube current setting minus the average of four consecutive exposures ($E_{2\text{mean}}$) made at any other tube current setting shall be less than or equal to 0.05 times the sum of the two averages. Expressed mathematically, $|E_{1\text{mean}} - E_{2\text{mean}}| \leq 0.05 (E_{1\text{mean}} + E_{2\text{mean}})$. Measuring compliance for the above shall be based on the following criteria:
1. An attenuation block as described in 64E-5.501(5) shall be in the useful beam.
 2. Exposure (mR) shall be measured on the exit side of the attenuation block.
 3. The tube potential (kVp) shall be maintained at a fixed setting within the range of 40 to 100 percent of the maximum tube rating.
- (15) Beam Limiting Devices.
- (a) Beam limiting devices capable of restricting the useful beam to the area of clinical interest shall be used during exposures.
 - (b) Beam limiting devices shall provide a degree of attenuation not less than that required for the tube housing.
- (16) Remote Exposure Switches. Where an x-ray control is equipped with two or more remote exposure switches, each remote switch shall serve a single x-ray tube, and exposures with any tube shall be possible only by the remote switch with which that particular tube is associated.
- (17) Electrical Power Supply. The electrical power supply and service lines to x-ray systems shall be of sufficient capacity to permit operation without significant variation in voltage or machine output.

Specific Authority: 404.051, 404.151, 404.22, F.S.
Law Implemented: 404.022, 404.051(1)(4)(6), 404.141, 404.22(1)(3), F.S.
History: New July 17, 1985, Formerly 10D-91.604

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64E-5.504 Fluoroscopic X-ray Systems. All fluoroscopic x-ray systems shall meet the following requirements:

- (1) Limitation of the Useful Beam.
 - (a) The fluoroscopic tube shall not produce x-rays unless the primary protective barrier is in position to intercept the entire cross section of the useful beam.
 - (b) A means shall be provided between the x-ray source and the patient for stepless adjustment of the size of the x-ray field.
 - (c) With the collimating shutters adjusted to the closed position, the minimum field size at the maximum SID shall not be greater than five by five centimeters when measured at the point where the beam enters the patient.
 - (d) Limitation to the Imaging Surface.
 1. The x-ray field produced by nonimage-intensified fluoroscopic equipment shall not extend beyond the useable area of the largest image receptor at any SID.
 2. The longitudinal and transverse dimensions of the x-ray field produced by image-intensified fluoroscopic equipment shall not extend beyond the corresponding dimensions of the image receptor by more than three percent of the SID in either dimension in the plane of the image receptor and the sum of the excess shall be no greater than four percent of the SID. If the collimation is automatically accomplished between the tube and patient, the x-ray field dimension criteria above shall apply to all film sizes and portions thereof that the spot film device accommodates and to the dimensions of the input phosphor, as appropriate. If collimation is not automatic, the x-ray field dimension criteria shall apply to the input phosphor.
 3. Compliance shall be determined with the beam axis perpendicular to the plane of the image receptor. For rectangular x-ray fields used with circular image receptors, the error in alignment shall be determined along the length and width dimensions of the x-ray field which passes through the center of the visible area of the image receptor.
 4. The center of the x-ray field in the plane of the image receptor shall be aligned with the center of the selected portion of the image receptor to within two percent of the SID.
 5. Adjustable automatic and manual collimators shall operate smoothly throughout the entire range of use.

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6. For fluoroscopic systems with spot film capability, means shall be provided for adjustment of the x-ray field size in the plane of the film to a size smaller than the selected portion of the film.
- (e) The requirements of (1)(b) and (c), above, are not applicable to mobile fluoroscopic systems.
- (2) Activation of the Fluoroscopic Tube. A control of the dead-man type shall be incorporated into each fluoroscopic system such that x-ray production will be terminated at any time pressure is released from the switch except during the recording of serial fluoroscopic images with equipment in which means have been provided to permit completion of any single exposure of the series in progress.
- R1 (3) Allowable Entrance Exposure Rate Limits for Fluoroscopic Equipment.
- R1 (a) Fluoroscopic equipment manufactured after June, 1995, operable at any combination of tube potential and current that results in an exposure rate greater than five roentgens (1.29×10^{-3} C per kg) per minute at the point where the center of the useful beam enters the patient shall be equipped with automatic exposure control. Provision for manual selection of technique factors can be provided.
- (b) Fluoroscopic equipment shall not be operable at any combination of tube potential and current that will result in an exposure rate in excess of ten roentgens (2.58×10^{-3} C per kg) per minute at the point where the center of the useful beam enters the patient except:
1. During the recording of images from an x-ray image-intensifier tube using photographic film or a video camera when the x-ray source is operated in a pulsed mode.
 2. When an optional high-level control is activated. When the high-level control is activated, the equipment shall not be operable at any combination of tube potential and current that will result in an exposure rate in excess of 20 roentgens (5.16×10^{-3} C per kg) per minute at the point where the center of the useful beam enters the patient. Special means to activate high-level controls shall be required. The high-level control shall only be operable when continuous manual activation is provided by the operator.
- (c) Special means to activate high level controls such as additional pressure applied continuously by the operator shall be required to avoid accidental use.
- (d) A continuous signal audible to the fluoroscopist shall indicate when the high level control is being employed.
- (e) Measuring Compliance of Entrance Exposure Rate Limits. Compliance with this subsection shall be determined as follows:

1. Movable grids and compression devices shall be removed from the useful beam during the measurement.
2. If the source is below the table, the exposure rate shall be measured at least one centimeter above the tabletop or cradle and corrected for distance to show the actual entrance exposure rate.
3. If the source is above the table, the exposure rate shall be measured at 30 centimeters above the tabletop with the end of the beam-limiting device or spacer assembly positioned as closely as possible to the point of measurement.
4. In a C-arm type of fluoroscope, the exposure rate shall be measured at 30 centimeters from the input surface of the fluoroscopic imaging assembly with the source positioned at any available SID, provided that the end of the beam-limiting device or spacer is no closer than 30 centimeters from the input surface of the fluoroscopic imaging assembly.
5. In a lateral type of fluoroscope, the exposure rate shall be measured at a point 15 centimeters from the centerline of the x-ray table and in the direction of the x-ray source with the end of the beam-limiting device or spacer positioned as closely as possible to the point of measurement. If the tabletop is movable, it shall be positioned as closely as possible to the lateral x-ray source with the end of the beam-limiting device or spacer no closer than 15 centimeters to the centerline of the x-ray table.
6. X-ray systems that incorporate automatic exposure controls such as automatic brightness control shall have sufficient lead or lead equivalent placed in the useful beam to produce the maximum output of the x-ray system.
7. X-ray systems that do not incorporate automatic exposure control shall use the maximum combination of current and potential to produce the highest output. Attenuating materials shall be placed in the useful beam to protect the imaging system.

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- (f) Periodic Measurement of Entrance Exposure Rates. The entrance exposure rate shall be measured before use on humans after the completion of any initial or subsequent installation and after any maintenance of the system that might affect the exposure rate.

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- (g) For cinefluoroscopy, the maximum exposure at the face of the input phosphor with the grid removed and with an attenuation block in the beam shall not exceed 40 microentgens (0.01 μC per kg) per frame. The maximum exposure shall be measured before use on humans after the completion of any initial or subsequent installation and after any maintenance of the system which might affect the maximum exposure.

- R1 (4) Barrier Transmitted Radiation Limits.
- R1 (a) The exposure rate due to transmission through the primary protective
R1 barrier and frame assembly with the attenuation block in the useful beam
R1 combined with radiation from the image intensifier if provided shall not
R1 exceed 2 milliroentgens (0.516 μC per kg) per hour at 10 centimeters from
R1 any accessible surface of the fluoroscopic image assembly beyond the
R1 plane of the image receptor for each roentgen per minute of entrance
R1 exposure rate.
- R1 (b) Measuring Compliance with Barrier Transmission Limits
- R1 1. The exposure rate due to transmission through the primary
R1 protective barrier combined with radiation from the image intensifier
R1 shall be determined by measurements averaged over an area no
R1 greater than 100 square centimeters with no linear dimension
R1 greater than 20 centimeters.
- R1 2. If the source is below the tabletop, the measurement shall be made
R1 with the input surface of the fluoroscopic imaging assembly position
R1 30 centimeters above the tabletop.
- R1 3. If the source is above the tabletop and the SID is variable, the
R1 measurement shall be made with the end of the beam limiting
R1 device or spacer assembly as close to the table top as it can be
R1 placed but not closer than 30 centimeters.
- R1 4. Movable grids and compression devices shall be removed from the
R1 useful beam during the measurements.
- R1 5. The attenuation block shall be positioned in the useful beam 10
R1 centimeters toward the input surface of the imaging assembly from
the point at which the entrance exposure rate was measured.
- R1 6. The maximum beam size shall be used during measurements.
- R1 (5) Indication of Potential and Current. During fluoroscopy and cinefluorography,
x-ray tube potential and current shall be continuously indicated.
- R1 (6) Source-to-Skin Distance. Positive means shall be provided to assure the
source-to-skin distance shall not be less than:
- (a) Thirty-eight centimeters on stationary fluoroscopes installed after
January 1, 1977,
- (b) Thirty-five and one-half centimeters on stationary fluoroscopes installed
prior to January 1, 1977,
- (c) Thirty centimeters on all mobile fluoroscopes,

- (d) Twenty centimeters for image intensified fluoroscopes used for specific surgical applications. Written safety procedures must be provided and precautionary measures followed during the use of this device.
- R1 (7) Fluoroscopic Timer: A cumulative timing device activated by the fluoroscopic exposure switch shall be provided, the maximum cumulative time of which shall not exceed five minutes without resetting. The timer shall indicate the passage of the predetermined period of exposure by an audible signal or termination of the exposure. If such a signal is utilized, it shall continue while x-rays are produced until the timing device is reset.
- R1 (8) Mobile Fluoroscopes. In addition to the other requirements of this section, mobile fluoroscopes shall provide intensified imaging.
- R1 (9) Control of Scatter Radiation.
- (a) Fluoroscopic table designs shall be such that scattered radiation which originates beneath the tabletop is attenuated by not less than 0.25 mm lead equivalent, and that no unprotected part of any staff or ancillary person's body shall be exposed to unattenuated scattered radiation.
- (b) Fluoroscopic equipment configuration shall be such that no portion of any staff or ancillary person's body, except the extremities, shall be exposed to the unattenuated scattered radiation emanating from above the tabletop unless:
1. Such person is at least 120 centimeters from the center of the useful beam, or
 2. The radiation has passed through not less than 0.25 millimeter lead equivalent material.
- (c) Exceptions to (10)(b), above, may be made in some special procedures where a sterile field will not permit the use of the normal protective barriers. Where the use of prefitted sterilized covers for the barriers is practical, the department shall not permit such exception.
- R1 (10) Photofluorographic Medical x-ray Systems.
- (a) In addition to other applicable sections of these regulations, photofluorographic x-ray systems shall conform with the following requirements:
1. Usage shall be limited to diagnostic radiography of the lungs and other soft tissues of the thoracic region.
 2. Personnel monitoring shall be provided for all individuals who operate photofluorographic apparatus.
 3. The average exposure, including backscatter, for chests measuring 25 centimeters in thickness shall not exceed 100 millirems (1.0 mSv) at the point where the x-ray beam enters the patient.

(b) Photofluorographic x-ray systems shall not be installed unless specifically approved by the department.

R1 (11) Radiation Therapy Simulation Systems. Radiation therapy simulation systems shall be exempt from all the requirements of (1), (3), (4), (5) and (8), above, provided that:

(a) Such systems are designed and used in such a manner that no person other than the patient is in an unprotected area during periods of time when the system is producing x-rays; and

(b) Systems that do not meet the requirements of (8), above, are provided with a means of indicating the cumulative time that an individual patient has been exposed to x-rays. In such cases, the timer shall be reset between examinations

(c) The exposure rate measured at the point where the center of the useful beam enters the patient shall not exceed 20 roentgens (5.16 mC per kg) per minute, except during the recording of fluoroscopic images.

Specific Authority: 404.051, 404.22, F.S.

Law Implemented: 404.051(1)(4), 404.22(1)(3), F.S.

R1 History: New July 17, 1985, amended April 4, 1989., March 17, 1992,

R1 Amended January 5, 1995, Formerly 10D-91.605, Amended May 18, 1998.

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Next page number is 30.

64E-5.505 Diagnostic Radiography Systems, Other than Fluoroscopic, Mammographic, Dental Intraoral or Veterinary Systems.

- (1) Beam Limitation. The useful beam shall be limited to the area of clinical interest.
 - (a) General Purpose Stationary and Mobile X-ray Systems.
 1. A means for stepless adjustment of the size of the x-ray field shall be provided.
 2. Means shall be provided for visually defining the perimeter of the x-ray field. The total misalignment of the edges of the visually defined field with the respective edges of the x-ray field along either the length or width of the visually defined field shall not exceed two percent of the distance from the source to the center of the visually defined field when the surface upon which it appears is perpendicular to the axis of the x-ray beam.
 3. Mobile x-ray systems shall be equipped with an attached rule to accurately measure the SID at any distance up to 72 in (183 cm).
 - (b) Stationary general purpose diagnostic x-ray systems shall be equipped with the following additional features:
 1. Positive means shall be provided to indicate when the axis of the x-ray beam is perpendicular to the plane of the image receptor; to align the center of the x-ray field with the center of the image receptor to within two percent of the SID; and to indicate the SID to within two percent.
 2. The beam-limiting device shall numerically indicate the field size in the plane of the image receptor to which it is adjusted.
 3. Indication of field size dimensions and SID's shall be specified in inches or centimeters, and shall be such that aperture adjustments result in x-ray field dimensions in the plane of the image receptor which correspond to those indicated by the beam limiting device to within two percent of the SID when the beam axis is perpendicular to the plane of the image receptor.
 - (c) X-ray Systems Used for One Image Receptor Size. Radiographic equipment used for only one image receptor size shall have a fixed SID and shall be provided with positive means to limit the x-ray field at the plane of the image receptor to the area of the image receptor, and to align the center of the x-ray field with the center of the image receptor to within two percent of the SID.

(d) Special Purpose x-ray Systems.

1. For x-ray systems with more than one image receptor size,
 - a. Means shall be provided to limit the x-ray field in the plane of the image receptor so that such field does not exceed each dimension of the image receptor by more than two percent of the SID when the axis of the x-ray beam is perpendicular to the plane of the image receptor.
 - b. Means shall be provided to align the center of the x-ray field with the center of the image receptor to within two percent of the SID, or means shall be provided to both size and align the x-ray field such that the x-ray field at the plane of the image receptor does not extend beyond any edge of the image receptor.
2. The requirements in this paragraph are met by a system that meets the requirements for a general purpose x-ray system as specified in (1)(a), above, or, when positive alignment means are also provided, may be met with either:
 - a. An assortment of removable, fixed-aperture, beam-limiting devices sufficient to meet the requirement for each combination of image receptor size and SID for which the unit is designed; each such device shall have clear markings to indicate the image receptor size and SID for which it is designed; or
 - b. A beam-limiting device having multiple fixed apertures sufficient to meet the requirements for each combination of image receptor size and SID for which the unit is designed. Permanent, clearly legible markings shall indicate the image receptor size and SID for which each aperture is designed and shall indicate which aperture is in position for use.

(2) Radiation Exposure Control Devices.

- (a) Timers. Means shall be provided to terminate the exposure at a preset time interval, preset product of current and time (mAs), a preset number of pulses, or a preset radiation exposure to the image receptor.
 1. Except for dental panoramic systems, termination of exposure shall cause automatic resetting of the timer to its initial setting or to 0.
 2. It shall not be possible to make an exposure when the timer is set to a zero or off position, if either position is provided.

- (b) X-ray Exposure Control Switch Type and Location.
1. A control of the dead-man type shall be incorporated into each x-ray system such that an exposure will be terminated at any time pressure is released from the switch, except during serial radiography, when means have been provided to permit completion of any single exposure of the series in progress.
 2. Each x-ray control shall be located in such a way as to meet the following requirements:
 - a. The operator's station at the control panel shall be behind a protective barrier so positioned that leakage radiation and once scattered radiation will be intercepted.
 - b. For panoramic dental units with intensifying screens and a beam stop, the operator shall stand at least four feet (1.25 m) from the patient and the tube head or behind a protective barrier during exposures.
 - c. The operator's protective barrier shall be equipped with a window or mirror system so arranged that the operator may keep the patient under constant visual surveillance during exposures. The window shall have lead equivalent shielding equal to that required in the operator's protective barrier.
 - d. Each exposure switch, except those used in conjunction with fluoroscopic spot film devices and movable protective barriers, shall be securely fixed so that the operator cannot conveniently make exposures from an unshielded position.
 - e. Provision shall be made for aural communication with the patient from the control panel.
 - f. Mobile and portable x-ray systems which are:
 - (I) Used continually in a single location for a period greater than one week shall be considered a stationary radiographic system and shall meet the requirements for such an installation.
 - (II) Used at multiple locations shall be provided either with an adequate protective barrier or protective apron for the operator and with a method of control which will permit the operator to be at least 12 feet (3.75 m) from the tube head and the nearest edge of the useful beam during exposures.
 3. The x-ray control shall provide a visual indication observable from the operator's protected position whenever x-rays are produced.

4. A sound audible to the operator shall indicate that the exposure has terminated or is in progress.
- (3) Source-to-Skin Distance Limitations. All mobile or portable radiographic systems shall be provided with a positive means to limit the source-to-skin distance to not less than 30 centimeters.
- (4) Standby Radiation from Capacitor Energy Storage Equipment. Radiation emitted from the x-ray tube when the exposure switch or timer is not activated shall not exceed a rate of two milliroentgens (0.516 mC per kg) per hour at five centimeters from any accessible surface of the diagnostic source assembly, with the beam-limiting device fully open.
- (5) Intracavitary x-ray Systems. Use of intracavitary x-ray systems on humans is prohibited unless specific approval has been granted by the department. Application for such use must include evidence attesting to the exclusive advantages to be gained in the use of intracavitary radiographic techniques as opposed to conventional radiographic procedures.

Specific Authority: 404.051, 404.141, 404.22, F.S.

Law Implemented: 404.022, 404.051(1)(4)(6), 404.141, 404.22(1)(3), F.S.

History: New July 17, 1985, amended March 17, 1993, Amended January 5, 1995, Formerly 10D-91.606

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64E-5.506 Intraoral Dental Radiographic Systems.

- (1) Source-to-Skin Distance. X-ray systems designed for use with an intraoral image receptor shall be provided with means to limit source-to-skin distance to not less than:
 - (a) 18 centimeters if operable at or above 50 kVp, or
 - (b) Ten centimeters if not operable above 50 kVp.
- (2) Field Limitation. Radiographic systems designed for use with an intraoral image receptor shall be provided with means to limit the x-ray beam such that:
 - (a) If the minimum source-to-skin distance (SSD) is 18 centimeters or more, the x-ray field at the minimum SSD shall be containable in a circle having a diameter of no more than seven centimeters; and
 - (b) If the minimum SSD is less than 18 centimeters, the x-ray field at the minimum SSD shall be containable in a circle having a diameter of no more than six centimeters.
 - (c) An open-ended position indicating device shall be used on machines procured after September 19, 1972. The attenuation shall be equivalent to that required for the diagnostic source assembly as described in 64E-5.503(3).
- (3) Timers. Means shall be provided to terminate the exposure at a preset time interval, preset product of current and time (mAs), a preset number of pulses, or a preset radiation exposure to the image receptor. In addition:
 - (a) Termination of exposure shall cause automatic resetting of the timer to its initial setting or to zero; and
 - (b) It shall not be possible to make an exposure when the timer is set to a zero or off position, if either position is provided.
- (4) X-ray Exposure Control Switch.
 - (a) A control shall be incorporated into each x-ray system such that an exposure can be terminated at any time. This switch shall be of the dead-man type.
 - (b) Each x-ray control shall be located in such a way as to meet the following criteria:
 1. The operator shall observe the patient during an exposure.
 2. The operator shall stand as far as practicable and at least six feet (1.8 m) from the patient and tube head and outside the useful beam or behind a protective barrier during exposures.

- (c) The x-ray control shall provide visual indication observable at or from the operator's position whenever x-rays are produced.
 - (d) A sound audible to the operator shall indicate that the exposure has terminated or is in progress.
- (5) Operating Controls.
- (a) The dentist, operator or assistant shall not hold the film in place for the patient during the exposure. Patient and film holding devices shall be used when the techniques permit.
 - (b) No person other than the patient shall be exposed to the useful beam.
 - (c) Neither the tube housing nor the position indicating device shall be held during an exposure.
 - (d) The x-ray system shall be arranged and operated in such a manner that the useful beam at the patient's skin does not exceed the dimensions specified in (2)(a), above.
 - (e) Dental fluoroscopy without image intensification is prohibited.

Specific Authority: 404.051, 404.22, F.S.

Law Implemented: 404.022, 404.051(1)(4)(6), 404.22(1)(3), F.S.

History: New July 17, 1985, amended April 4, 1989, Formerly 10D-91.607

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64E-5.507 Therapeutic X-Ray Systems of Less Than 1 MeV.

(1) Equipment Requirements.

- (a) Leakage Radiation. When the tube is operated at its leakage technique factors, the leakage radiation shall not exceed the value specified at the distance specified for the following classification of that x-ray system:
 - 1. Contact Therapy Systems. Leakage radiation shall not exceed 100 milliroentgens (25.8 $\mu\text{C}/\text{kg}$) per hour at five centimeters from the surface of the tube housing assembly.
 - 2. Zero to 150 kVp Systems. Leakage radiation shall not exceed 100 milliroentgens (25.8 $\mu\text{C}/\text{kg}$) per hour at one meter from the source.
 - 3. 151 to 999 kVp Systems. The leakage radiation shall not exceed 0.1 percent of the useful beam one meter from the source, for any of its operating conditions.
- (b) Permanent Beam Limiting Devices. Permanent fixed diaphragms or cones used for limiting the useful beam shall provide the same or a higher degree of protection as required for the tube housing assembly.
- (c) Removable and Adjustable Beam Limiting Devices.
 - 1. Removable beam limiting devices shall, for the portion of the useful beam to be blocked by these devices, transmit not more than one percent of the useful beam at the maximum kilovoltage and maximum treatment filter. This requirement does not apply to auxiliary blocks or materials placed in the useful beam to shape the useful beam to the individual patient.
 - 2. Adjustable beam limiting devices shall transmit not more than five percent of the useful beam at the maximum kilovoltage and with the maximum treatment filter in the useful beam.
- (d) Filter System. The filter system shall be so designed that:
 - 1. The filters cannot be accidentally displaced at any possible tube orientation;
 - 2. The radiation at five centimeters from the filter insertion slot opening does not exceed 30 roentgens (7.7 mC per kg) per hour under any operating conditions;
 - 3. Each filter is marked as to its material of construction and its thickness. For wedge filters, the wedge angle shall appear on the wedge or wedge tray; and

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4. A filter indication system shall be used on all therapy machines using changeable filters. It shall be designed to permit easy recognition of any added filter in place. The presence or absence of any filter shall be discernible at the control panel.
- (e) Tube Immobilization. The tube housing assembly shall be capable of being immobilized for stationary treatments.
 - (f) Focal Spot Marking. The tube housing assembly shall be so marked that it is possible to determine the location of the focal spot to within five millimeters, and such marking shall be readily accessible for use during calibration procedures.
 - (g) Beam Block. Contact therapy tube housing assemblies shall have a removable shield of at least 0.5 millimeter lead equivalency at 100 kVp that can be positioned over the entire useful beam exit port during periods when the beam is not in use.
 - (h) Beam Monitor System. Systems of greater than 150 kVp manufactured after January 1, 1985, shall be provided with a beam monitor system which:
 1. Shall have the detector of the monitor system interlocked to prevent incorrect positioning;
 2. Shall not allow irradiation until a pre-selected value of exposure has been made at the treatment control panel;
 3. Shall independently terminate irradiation when the preselected exposure has been reached;
 4. Shall be so designed that, in the event of a system malfunction or electrical power failure, the dose administered to a patient prior to the system malfunction or power failure can be accurately determined;
 5. Shall have a display at the control panel from which the dose at a reference point in soft tissue can be calculated;
 6. Shall have a control panel display which maintains the administered dose reading until intentionally reset to zero; and
 7. Shall have a control panel display which does not have scale multiplying factors and utilizes a design such that increasing dose is displayed by increasing numbers.
 - (i) Timer.

1. A timer which has a display shall be provided at the treatment control panel. The timer shall have a pre-set time selector and an elapsed time indicator.
 2. The timer shall be a cumulative timer which activates with the production of radiation and retains its reading after irradiation is interrupted or terminated. After irradiation is terminated and before irradiation can be reinitiated, it shall be necessary to reset the elapsed time indicator to zero.
 3. The timer shall terminate irradiation when a preselected time has elapsed if any dose monitoring system present has not previously terminated irradiation.
 4. The timer shall permit accurate presetting and determination of exposure times as short as one second.
 5. The timer shall not activate until the shutter is opened when irradiation is controlled by a shutter mechanism.
- (j) Control Panel Functions. The control panel, in addition to the displays required in other provisions of this section, shall have:
1. An indication of whether electrical power is available at the control panel and if activation of the x-ray tube is possible;
 2. An indication of whether x-rays are being produced;
 3. Means for indicating x-ray tube potential and current;
 4. Means for terminating an exposure at any time; and
 5. A locking device which will prevent unauthorized use of the x-ray system.
- (k) Multiple Tubes. When a control panel may energize more than one x-ray tube
1. It shall be possible to activate only one x-ray tube at any time;
 2. There shall be an indication at the control panel identifying which x-ray tube is energized; and
 3. There shall be an indication at the tube housing assembly when that tube is energized.
- (l) Source-to-Skin Distance (SSD). There shall be means of determining the SSD to within one centimeter.
- (m) Low Filtration x-ray Tubes. Each x-ray system equipped with a beryllium or other low-filtration window shall be clearly labeled as such upon the tube housing assembly and at the control panel.

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- (2) Facility Design Requirements for x-ray Systems Operable Above 50 kVp.
- (a) Aural Communication. Provision shall be made for two-way aural communication between the patient and the operator at the control panel. However, where excessive noise levels or treatment requirements make aural communication impractical, other methods of communication shall be used.
 - (b) Viewing Systems. Windows, mirrors, closed-circuit television, or an equivalent system shall be provided to permit continuous observation of the patient during irradiation and shall be so located that the operator can observe the patient from the control panel.
 - (c) Additional Requirements for x-ray Systems Operable Above 150 kVp:
 - 1. All protective barriers shall be fixed except for entrance doors or beam interceptors.
 - 2. The control panel shall be located outside the treatment room.
 - 3. Interlocks shall be provided such that all entrance doors must be closed before treatment can be initiated or continued. If the radiation beam is interrupted by any door opening:
 - a. The exposure at a distance of one meter from the source shall be reduced to less than ten milliroentgens ($2.58 \mu\text{C}/\text{kg}$) per hour; and
 - b. It shall not be possible to restore the machine to operation without closing the door and reinitiating irradiation by manual action at the control panel.
 - 4. Treatment rooms to which access is possible through more than one entrance shall be provided with flashing warning lights located in a readily observable position near the outside of all access doors to indicate when the useful beam is on.
- (3) Surveys, Calibrations, Spot Checks and Operating Procedures.
- (a) Surveys.
 - 1. All new facilities, and existing facilities not previously surveyed, shall have a survey made by, or under the direction of, a qualified person. In addition, such surveys shall be done after any change in the facility or equipment which might cause a significant increase in radiation hazard.
 - 2. The registrant shall transmit a copy of the survey report to the department within 30 days of the receipt of the report.

3. The survey and report shall indicate all instances where the installation, in the opinion of the qualified person, is in violation of applicable regulations.
- (b) Calibrations.
1. The calibration of an x-ray system shall be performed at intervals not to exceed one year and after any change or replacement of components which could cause a change in the radiation output.
 2. The calibration of the radiation output of an x-ray system shall be performed by or under the direction of a radiological physicist who is physically present at the facility during such calibration.
 3. Calibration of the radiation output of an x-ray system shall be performed with a calibrated dosimetry system. The calibration of such system shall be traceable to a national standard. The system shall have been calibrated within the preceding two years.
 4. The calibration shall be such that the dose at a reference point in soft tissue can be calculated to within an uncertainty not to exceed five percent.
 5. The calibration of the x-ray system shall include, but not be limited to, the following determinations:
 - a. Verification that the x-ray system is operating in compliance with the design specifications;
 - b. The exposure rates as a function of field size, technique factors, filter and treatment distance used;
 - c. The degree of congruence between the radiation field and the field indicated by the localizing device if such device is present; and
 - d. An evaluation of the uniformity of the largest radiation field used.
 6. Records of calibration shall be maintained by the registrant for five years after completion of the calibration.
 7. A copy of the most recent x-ray system calibration shall be available at the facility for inspection by the department.
- (c) Spot-checks. Spot-checks shall be performed on x-ray systems operable at greater than 150 kVp. Such spot-checks shall meet the following requirements:

1. The spot-check procedures shall be in writing and shall have been developed by a radiological physicist.
 2. If a radiological physicist does not perform the spot-check measurement, the results of the spot-check measurements shall be reviewed by a radiological physicist within 15 days.
 3. The spot-check procedures shall specify the frequency at which tests or measurements are to be performed. The spot-check procedures shall specify that the spot-check shall be performed during the calibration specified in (3)(b), above. The acceptable tolerance for each parameter measured in the spot-check when compared to the value for that parameter determined in the calibration specified in (3)(a), above, shall be stated.
 4. The cause for a parameter exceeding a tolerance set by the radiological physicist shall be investigated and corrected before the system is used for patient irradiation.
 5. Whenever a spot-check indicates a significant change in the operating characteristics of a system, the system shall be recalibrated as required in (3)(b), above.
 6. Records of spot-check measurements and any necessary corrective actions shall be maintained by the registrant for two years.
 7. Where a spot-check involves a radiation measurement, such measurement shall be obtained using a system satisfying the requirements of (3)(b), above, or which has been compared within the previous year with a system meeting those requirements.
- (d) Operating Procedures.
1. X-ray systems shall not be left unattended unless the system is secured against unauthorized use.
 2. When a patient must be held in position for radiation therapy, mechanical supporting or restraining devices shall be used.
 3. The tube housing assembly shall not be held by hand during operation unless the system is designed to require such holding and the peak tube potential of the system does not exceed 50 kVp. In such cases, the holder shall wear protective gloves and apron of not less than 0.5 millimeter lead equivalency at 100 kVp.

4. No individual other than the patient shall be in the treatment room unless such individual is protected by a barrier sufficient to meet the requirements of 64E-5.304. No individual other than the patient shall be in the treatment room during exposures from x-ray systems operating above 150 kVp.
5. Machines capable of having an output of more than 1,000 roentgens (258 mC per kg) per minute at any accessible place shall not be left unattended without the power being shut off at the disconnect switch in addition to the control panel switch.

Specific Authority: 404.051, 404.081, 404.141, 404.22, F.S.

Law Implemented: 404.022, 404.051(1)(4)(5)(6), 404.081(1) 404.22(1)(3), F.S.

History: New July 17, 1985, Amended January 1, 1994, Formerly 10D-91.608

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64E-5.508 X-ray and Electron Therapy Systems with Energies of 1 MeV and Above.

- (1) Definitions. In addition to the definitions provided in 64E-5.501, the following definitions shall be applicable to this section:
- (a) "Applicator" means a structure which determines the extent of the treatment field at a given distance from the virtual source.
 - (b) "Beam scattering filter" means a filter used in order to scatter a beam of electrons.
 - (c) "Central axis of the beam" means a line passing through the virtual source and the center of the plane figure formed by the edge of the first beam limiting device.
 - (d) "Dose monitoring system" means a system of devices for the detection, measurement and display of quantities of radiation.
 - (e) "Dose monitor unit" means a unit response from the dose monitoring system from which the absorbed dose can be calculated.
 - (f) "Existing equipment" means therapy systems subject to this section which were manufactured on or before January 1, 1985.
 - (g) "Field-flattening filter" means a filter used to provide dose uniformity over the area of a useful beam of x-rays at a specified depth.
 - (h) "Field size" means the dimensions along the major axes of an area in a plane perpendicular to the specified direction of the beam of incident radiation at the normal treatment distance and defined by the intersection of the major axes and the 50 percent isodose line. Material shall be placed in the beam such that dose maximum is produced at the normal treatment distance when field size is being determined.
 - (i) "Gantry" means that part of the system supporting and allowing possible movements of the radiation head.
 - (j) "Interruption of irradiation" means the stopping of irradiation with the possibility of continuing irradiation without resetting of operating conditions at the control panel.
 - (k) "Isocenter" means a fixed point in space located at the center of the smallest sphere through which the central axis of the beam passes in all conditions.
 - (l) "Moving beam therapy" means radiation therapy with relative displacement of the useful beam and the patient during irradiation. It includes arc therapy, skip therapy and rotational therapy.

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- (m) "New equipment" means systems subject to this section which were manufactured after January 1, 1985.
- (n) "Normal treatment distance" means:
1. For electron irradiation, the virtual source to surface distance along the central axis of the useful beam as specified by the manufacturer for the applicator.
 2. For x-ray irradiation, the virtual source to isocenter distance along the central axis of the useful beam. For nonisocentric equipment, this distance shall be that specified by the manufacturer.
- (o) "Radiation head" means the structure from which the useful beam emerges.
- (p) "Shadow tray" means a device attached to the radiation head to support auxiliary beam limiting material.
- (q) "Stationary beam therapy" means radiation therapy without relative displacement of the useful beam or the patient during irradiation.
- (r) "Target" means that part of a radiation head which by design intercepts a beam of accelerated particles with subsequent emission of other radiation
- (s) "Virtual source" means a point from which radiation appears to originate.
- (2) Requirements for Equipment.
- (a) Leakage Radiation to the Patient Area.
1. New equipment shall meet the following requirement: For operating conditions producing maximum leakage radiation, the absorbed dose in rads (grays) due to leakage radiation, including x rays, electrons, and neutrons, at any point in a circular plane of two meters radius centered on and perpendicular to the central axis of the beam at the isocenter or normal treatment distance and outside the maximum useful beam size, shall not exceed 0.1 percent of the maximum absorbed dose in rads (grays) of the unattenuated useful beam measured at the point of intersection of the central axis of the beam and the plane surface. Measurements, excluding those for neutrons, shall be averaged over an area up to, but not exceeding, 100 square centimeters at the positions specified. Measurements of the portion of the leakage radiation dose contributed by neutrons may be obtained from the manufacturer and shall be averaged over an area up to, but not exceeding, 200 square centimeters.

2. Existing equipment shall meet the following requirement: For operating conditions producing maximum leakage radiation, the absorbed dose in rads (grays) due to leakage radiation excluding neutrons at any point in a circular plane of two meters radius centered on a perpendicular to the central axis of the beam one meter from the virtual source, and outside the maximum size useful beam, shall not exceed 0.1 percent of the maximum absorbed dose in rads (grays) of the unattenuated useful beam measured at the point of intersection of the central axis of the beam and the surface of the circular plane. Measurements shall be averaged over an area up to, but not exceeding, 100 square centimeters at the positions specified.
 3. For each system, the registrant shall determine or obtain from the manufacturer the leakage radiation existing at the positions specified and for the specified operating conditions. Records on radiation leakage shall be maintained for inspection by the department.
- (b) Leakage of Radiation Outside the Patient Area for New Equipment.
1. The absorbed dose in rads (grays) due to leakage radiation, except in the area specified in (2)(a), above, when measured at any point one meter from the path of the charged particle, before the charged particle strikes the target or window, shall not exceed 0.1 percent for x-ray leakage nor 0.05 percent for neutron leakage of the maximum absorbed dose in rads (grays) of the unattenuated useful beam measured at the point of intersection of the central axis of the beam and the circular plane specified in (2)(a), above.
 2. The registrant shall determine or obtain from the manufacturer the actual leakage radiation existing at the positions specified and for specified operating conditions. Radiation measurements, excluding neutrons, shall be averaged over an area up to, but not exceeding, 100 square centimeters. Neutron measurements shall be averaged over an area up to, but not exceeding, 200 square centimeters.
- (c) Beam Limiting Devices. Adjustable or interchangeable beam-limiting devices shall be provided, and such devices shall transmit no more than five percent of the useful beam at the normal treatment distance for the portion of the useful beam which is to be attenuated by the beam limiting device. The neutron component of the useful beam shall not be included in this requirement.
- (d) Filters.

1. Each filter which is removable from the system shall be clearly marked with an identification number. Documentation available at the control panel shall contain a description of the filter. For wedge filters, the wedge angle shall appear on the wedge or wedge tray.
 2. If the absorbed dose rate data indicated at the control panel relates exclusively to operation with a field flattening or beam scattering filter in place, such filter shall be removable only by the use of tools.
 3. For new equipment which utilizes a system of wedge filters, interchangeable field flattening filters or interchangeable beam scattering filters:
 - a. Irradiation shall not be possible until a selection of a filter has been made at the treatment control panel;
 - b. An interlock system shall be provided to prevent irradiation if the filter selected is not in the correct position;
 - c. A display shall be provided at the treatment control panel showing the filter in use; and
 - d. An interlock shall be provided to prevent irradiation if any filter selection operation carried out in the treatment room does not agree with the filter selection operation carried out at the treatment control panel.
- (e) Beam Quality. The registrant shall determine, or obtain from the manufacturer, data sufficient to assure that the following beam quality requirements are met:
1. The absorbed dose resulting from x-rays in a useful electron beam at a point on the central axis of the beam ten centimeters greater than the practical range of the electrons shall not exceed the values stated below. Linear interpolation shall be used for values not stated.

Maximum Energy of Electron Beam in MeV	X-Ray Absorbed Dose as a Fraction or maximum Absorbed Dose
1	0.03
15	0.05
35	0.10
50	0.20

2. Compliance with (2)(e)1., above, shall be determined using:

- a. A measurement within a phantom with the incident surface of the phantom at the normal treatment distance and normal to the central axis of the beam;
 - b. The largest field size available which does not exceed 15 by 15 centimeters; and
 - c. A phantom whose cross-sectional dimensions exceed the measurement radiation field by at least five centimeters and whose depth is sufficient to perform the required measurement.
- (f) Beam Monitors. All therapy systems shall be provided with radiation detectors in the radiation head.
1. New equipment shall be provided with at least two radiation detectors. The detectors shall be incorporated into two separate dose monitoring systems.
 2. Existing equipment shall be provided with at least one radiation detector. This detector shall be incorporated into a primary dose monitoring system.
 3. The detector and the system into which that detector is incorporated shall meet the following requirements:
 - a. Each detector shall be removable only with tools and shall be designed to prevent incorrect positioning.
 - b. Each detector shall form part of a dose monitoring system from whose readings in dose monitor units the absorbed dose at a reference point in the treatment volume can be calculated.
 - c. Each dose monitoring system shall be capable of independently monitoring, interrupting and terminating irradiation.
 - d. For new equipment, the design of the dose monitoring systems shall assure that:
 - (I) The malfunctioning of one system shall not affect the correct functioning of the second system; and
 - (II) The failure of any element common to both systems which could affect the correct function of both systems shall terminate irradiation.

- e. Each dose monitoring system shall have a legible display at the treatment control panel. For new equipment, each display shall
 - (I) Maintain a reading until intentionally reset to zero;
 - (II) Have only one scale and no scale multiplying factors;
 - (III) Utilize a design such that increasing dose is displayed by increasing numbers and shall be so designed that, in the event of an overdosage of radiation, the absorbed dose may be accurately determined; and
 - (IV) In the event of power failure, the dose monitoring information required to be displayed at the control panel at the time of failure shall be retrievable in at least one system for a 20 minute period of time.

- (g) **Beam Symmetry.** In new equipment inherently capable of producing useful beams with asymmetry exceeding five percent, the asymmetry of the radiation beam in two orthogonal directions shall be monitored before the beam passes through the beam limiting device. Facilities shall be provided so that, if the difference in dose rate between one region and another region symmetrically displaced from the central axis of the beam exceeds five percent of the central axis dose rate, indication of this condition is made at the control panel; and if this difference exceeds ten percent, the irradiation is terminated.

- (h) **Selection and Display of Dose Monitor Units.**
 - 1. Irradiation shall not be possible until a selection of a number of dose monitor units or exposure time has been made at the treatment control panel.
 - 2. The pre-selected number of dose monitor units or exposure time shall be displayed at the treatment control panel until reset manually for the next irradiation.
 - 3. After termination of irradiation, it shall be necessary to reset the dosimeter display to zero before subsequent treatment can be initiated
 - 4. For new equipment, after termination of irradiation, it shall be necessary to manually reset the pre-selected dose monitor units before irradiation can be initiated.

- (i) **Termination of Irradiation by the Dose Monitoring System or Systems During Stationary Beam Therapy.**

1. Each primary system shall terminate irradiation when the pre-selected number of dose monitor units has been detected by the system.
 2. If original design of the equipment included a second dose monitoring system, that system shall be capable of terminating irradiation when not more than 15 percent or 40 dose monitor units above the pre-selected number of dose monitor units set at the control panel has been detected by the second dose monitoring system.
 3. For new equipment, a second dose monitoring system shall be present. That system shall be capable of terminating irradiation when not more than ten percent or 30 dose monitoring units above the pre-selected number of dose monitor units set at the control panel has been detected by the second dose monitoring system.
 4. For new equipment, an indicator on the control panel shall show which dose monitoring system has terminated irradiation.
- (j) Interruption Switches. It shall be possible to interrupt irradiation and equipment movements at any time from the operator's position at the treatment control panel. Following an interruption, it shall be possible to restart irradiation by operator action without any reselection of operating conditions. If any change is made of a pre-selected value during an interruption, irradiation and equipment movements shall be automatically terminated.
- (k) Termination Switches. It shall be possible to terminate irradiation and equipment movements, or go from an interruption condition to termination conditions, at any time from the operator's position at the treatment control panel.
- (l) Timer.
1. A timer which has a display shall be provided at the treatment control panel. The timer shall have a pre-set time selector and an elapsed time indicator.
 2. The timer shall be a cumulative timer which activates with the production of radiation and retains its reading after irradiation is interrupted or terminated. After irradiation is terminated and before irradiation can be reinitiated, it shall be necessary to reset the elapsed time indicator to zero.
 3. For new equipment, after termination of irradiation and before irradiation can be reinitiated, it shall be necessary to manually reset the preset time selector.

4. The timer shall terminate irradiation when a pre-selected time has elapsed if the dose monitoring systems have not previously terminated irradiation.
- (m) Selection of Radiation Type. Equipment capable of both x-ray therapy and electron therapy shall meet the following additional requirements:
1. Irradiation shall not be possible until a selection of radiation type has been made at the treatment control panel.
 2. An interlock system shall be provided to ensure that the equipment can emit only the radiation type which has been selected.
 3. An interlock system shall be provided to prevent irradiation if any selected operations carried out in the treatment room do not agree with the selected operations carried out at the treatment control panel.
 4. An interlock system shall be provided to prevent irradiation with x-rays except to obtain a port film when electron applicators are fitted.
 5. An interlock system shall be provided to prevent irradiation with electrons when accessories specific for x-ray therapy are fitted.
 6. The radiation type selected shall be displayed at the treatment control panel before and during irradiation.
- (n) Selection of Energy. Equipment capable of generating radiation beams of different energies shall meet the following requirements:
1. Irradiation shall not be possible until a selection of energy has been made at the treatment control panel.
 2. An interlock system shall be provided to prevent irradiation if any selected operations carried out in the treatment room do not agree with the selected operations carried out at the treatment control panel.
 3. The nominal energy value selected shall be displayed at the treatment control panel before and during irradiation.
- (o) Selection of Stationary Beam Therapy or Moving Beam Therapy. Equipment capable of both stationary beam therapy and moving beam therapy shall meet the following requirements:
1. Irradiation shall not be possible until a selection of stationary beam therapy or moving beam therapy has been made at the treatment control panel.

2. An interlock system shall be provided to ensure that the equipment can operate only in the mode which has been selected.
 3. An interlock system shall be provided to prevent irradiation if any selected operations carried out in the treatment room do not agree with the selected operations carried out at the treatment control panel.
 4. The mode of operation shall be displayed at the treatment control panel.
 5. For new equipment, an interlock system shall be provided to terminate irradiation if:
 - a. Movement of the gantry occurs during stationary beam therapy; or
 - b. Movement of the gantry stops during moving beam therapy unless such stoppage is a preplanned function.
 6. Moving beam therapy shall be controlled to obtain the selected relationships between incremental dose monitor units and incremental angle of movement.
 - a. For new equipment, an interlock system shall be provided to terminate irradiation if the number of dose monitor units delivered in any ten degrees of arc differs by more than 20 percent from the selected value.
 - b. For new equipment, where gantry angle terminates the irradiation in arc therapy, the dose monitor units shall differ by less than five percent from the value calculated from the absorbed dose per unit angle relationship.
 7. Where the dose monitor system terminates the irradiation in arc therapy, the termination of irradiation shall be as required by (2)(i), above.
- (p) Absorbed Dose Rate. For new equipment, a system shall be provided from whose readings the absorbed dose rate at a reference point in the treatment volume can be calculated. In addition:
1. The dose monitor unit rate shall be displayed at the treatment control panel.
 2. The radiation detectors specified in (2)(f), above, may form part of this system.

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- (q) Location of Virtual Source and Beam Orientation. The registrant shall determine, or obtain from the manufacturer, the location with reference to an accessible point on the radiation head of:
1. The x-ray target or the virtual source of x rays; and
 2. The electron window or the virtual source of electrons if the system has electron beam capabilities.
- (r) System Checking Facilities. Capabilities shall be provided so that all radiation safety interlocks can be checked for correct operation. When preselection of any of the operating conditions requires action in the treatment room and at the treatment control panel, selection at one location shall not give a display at the other location until the requisite selected operations in both locations have been completed.
- (3) Facility and Shielding Requirements. In addition to Part III, the following design requirements shall apply:
- (a) Protective Barriers. All protective barriers shall be fixed except for entrance doors or beam interceptors.
 - (b) Control Panel. The control panel shall be located outside the treatment room.
 - (c) Viewing System. Windows, mirrors, closed-circuit television, or an equivalent system shall be provided to permit continuous observation of the patient during irradiation and shall be so located that the operator may observe the patient from the control panel.
 - (d) Aural Communication. Provision shall be made for two-way aural communication between the patient and the operator at the control panel. However, where excessive noise levels or treatment requirements make aural communication impractical, other methods of communication shall be used.
 - (e) Room Entrance. Treatment room entrances shall be provided with warning lights in readily observable positions near the outside of all access doors or other entrances to indicate when the useful beam is on.
 - (f) Entrance Interlocks. Interlocks shall be provided such that all entrance doors must be closed before treatment can be initiated or continued. If the radiation beam is interrupted by any barrier penetration or door opening, it shall not be possible to restore the machine to operation without closing the door and reinitiating irradiation by manual action at the control panel.
- (4) Surveys, Calibrations, Spot Checks and Operating Procedures.
- (a) Surveys.

1. All new facilities, and existing facilities not previously surveyed, shall have a survey made by, or under the direction of, a qualified person. In addition, such surveys shall be done after any change in the facility or equipment which might cause a significant increase in radiation hazard.
2. The registrant shall obtain a written report of the survey from the qualified person, and a copy of the report shall be transmitted by the registrant to the department within 30 days of receipt of the report.
3. The survey and report shall indicate all instances where the installation, in the opinion of the qualified person, is in violation of applicable regulations.

(b) Calibration.

1. The calibration of systems subject to 64E-5.508 shall be performed in accordance with an established calibration protocol acceptable to the department, such as the calibration protocol published by the American Association of Physicists in Medicine, before the system is first used for irradiation of a patient and thereafter at time intervals which do not exceed 12 months and after any change which might significantly alter the calibration, spatial distribution or other characteristics of the therapy beam.
2. The calibration shall be performed under the direct supervision of a radiological physicist who is physically present at the facility during the calibration.
3. Calibration radiation measurements required by (4)(b), above, shall be performed using a dosimetry system:
 - a. Having a calibration factor for cobalt 60 gamma rays traceable to a national standard;
 - b. Which has been calibrated within the previous two years and after any servicing that may have affected its calibration;
 - c. Which has been calibrated in such a fashion that an uncertainty can be stated for the radiation quantities monitored by the system; and
 - d. Which has had constancy checks performed on the system as specified by a radiological physicist.
4. Calibrations shall be in sufficient detail that the dose at a reference point in soft tissue may be calculated to within an uncertainty of five percent.

5. The calibration of the therapy beam shall include the following determinations:
 - a. Verification that the equipment is operating in compliance with the design specifications concerning the light localizer, side light, and back-pointer alignment with the isocenter when applicable, variation in the axis of rotation for the table, gantry, and jaw system, and beam flatness and symmetry at the specified depth.
 - b. The absorbed dose rate at various depths of water for the range of field sizes used, for each effective energy, that will verify the accuracy of the dosimetry of all therapy procedures utilized with that therapy beam.
 - c. The uniformity of the radiation field and any dependency upon the direction of the useful beam.
 - d. Verification that existing depth-dose data and isodose charts applicable to the specific machine continue to be valid or are updated to existing machine conditions.
 - e. Verification of transmission and electron buildup factors for all accessories such as wedges, shadow trays, and compensators.
 6. Records of calibration measurements and dosimetry system calibrations required in (4)(b), above, shall be maintained for five years after completion of the full calibration.
 7. A copy of the latest calibration performed shall be available in the facility for inspection by the department.
- (c) Spot-checks. Spot-checks shall be performed on systems subject to this section during calibrations and thereafter at intervals not to exceed one month. Such spot-checks shall meet the following requirements:
1. The spot-check procedures shall be in writing and shall have been developed by a radiological physicist. Acceptable tolerance for each parameter measured in the spot-check shall not exceed manufacturer's recommendations.
 2. If a radiological physicist does not perform the spot-check measurements, the results of the spot-check measurements shall be reviewed by a radiological physicist within 15 days.

3. The spot-check procedures shall specify the frequency at which tests or measurements are to be performed and the acceptable tolerance for each parameter measured in the spot-check when compared to the value for that parameter determined in the calibration.
 4. At intervals established in the spot-check procedures, spot-checks shall be made of absorbed dose measurements at a minimum of two depths in a phantom.
 5. Where a system has built-in devices which provide a measurement of any parameter during irradiation, such measurement shall not be utilized as a spot-check measurement.
 6. The cause for a parameter exceeding a tolerance set by the radiological physicist shall be investigated and corrected before the system is used for patient irradiation.
 7. Whenever a spot-check indicates a significant change in the operating characteristics of a system, as specified in the radiological physicist's spot-check procedures, the system shall be recalibrated as required in (4)(b), above.
 8. Records of spot-check measurements and any necessary corrective actions shall be maintained by the registrant for a period of two years.
 9. Where a spot-check involves an absolute radiation measurement, such measurement shall be obtained using a system satisfying the requirements of (4)(b)3, above, or which has been compared with a system meeting those requirements within the previous year.
- (d) Additional Operating Procedures.
1. No individual other than the patient shall be in the treatment room during treatment of a patient.
 2. If a patient must be held in position during treatment, mechanical supporting or restraining devices shall be used
 3. The system shall not be used in the administration of radiation therapy unless the requirements of (4)(a), (4)(b) and (4)(c), above, have been met.

Specific Authority: 404.031, 404.051, 404.071, 404.081, 404.141, 404.22, F.S.

Law Implemented: 404.022, 404.031, 404.051(1)(4)(5)(6), 404.071(1), 404.081(1), 404.141, 404.22(1)(3), F.S.

History: New July 17, 1985, amended April 4, 1989, Formerly 10D-91.609

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64E-5.509 Veterinary Medicine X-ray Operations.

- (1) Applicable Regulations. Veterinary medical x-ray operations shall conform with requirements of the following sections of these regulations:
 - (a) 64E-5.502, General Requirements, except 64E-5.502(1)(a)5., 64E-5.502(1)(a)6., 64E-5.502(1)(a)7. and 64E-5.502(1)(a)8.
 - (b) 64E-5.503, General Requirements for all Diagnostic X-Ray Systems.
 - (c) 64E-5.504, Fluoroscopic x-ray Systems.
- (2) Additional Requirements.
 - (a) Positive means of beam alignment shall be provided in the form of accurate linear rulings, beam defining or beam centering lights, optical viewing devices or the equivalent. Such alignment means or devices shall be adjusted to indicate the beam center or beam area to within two percent of the SID.
 - (b) Means shall be provided to limit the useful beam to the area of diagnostic interest or to the area of the image receptor used in each particular case. Beam limitation may be accomplished by any of the means described in 64E-5.505(1).
 - (c) Each x-ray system shall be equipped with a device which will terminate the exposure after a preset time or exposure.
 - (d) Each exposure switch shall be of the dead-man type.
 - (e) Each exposure switch shall be located in such a way as to meet the following criteria:
 1. The operator shall stand as far as practicable and at least six feet (1.8 m) from the animal and tube head and outside the useful beam or behind a protective barrier during exposures.
 2. In lieu of distance or a protective barrier the operator shall wear a protective apron and monitoring device as provided in (3)(c), below.
- (3) Operating Procedures.
 - (a) The operator shall stand in a protected position as indicated in (2)(e), above, during radiographic exposures with no other individuals in the x-ray room unless assistance of the nature described in (3)(c), below, is required.

- (b) To the greatest practicable extent, animals must be immobilized by anesthetics, straps, sandbags, foam wedges, and other supporting or restraining devices.
- (c) If an animal must be held by an individual, that individual shall be protected by appropriate shielding devices such as a protective apron and gloves, and the holder shall be so positioned that no part of his body will be struck by the useful beam. The exposure of that individual shall be monitored when engaged in such purposes.

Specific Authority: 404.051, 404.141, 404.22, F.S.

Law Implemented: 404.022, 404.051(1)(4)(6), 404.141, 404.22(1)(3), F.S.

History: New July 17, 1985, amended April 4, 1989, Formerly 10D-91.610

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64E-5.510 Mammographic Systems.

- (1) Mammographic medical x-ray systems shall meet the requirements of 64E-5.502 and 64E-5.503. Registrants who provide mammography services shall:
 - (a) Have a written quality assurance program specific to mammography imaging that includes an equipment quality control program for performance monitoring and an evaluation of all components of the equipment from the x-ray generator to the image processor.
 - (b) Establish standards for clinical image evaluations that include breast positioning, compression and overall image quality.
 - (c) Assign qualified and trained personnel to each part of the quality assurance program.
 - (d) Conduct a general review of the effectiveness of the quality assurance program annually and maintain a written report of the review.
 - (e) Have available the services of a medical physicist to furnish diagnostic x-ray physics support who is able to establish and conduct the equipment quality control program and who meets the requirements specified in (12), below. The specific duties of the medical physicist must include:
 1. Monitoring equipment performance or verifying the qualifications and training of others to monitor equipment performance.
 2. Evaluating the monitoring results to identify problems.
 3. Verifying that corrections are effective and meet regulatory requirements.
- (2) Mammographic x-ray examinations shall be performed on systems specifically designed for and used only for mammography. Mammographic medical x-ray systems shall meet the following requirements:
 - (a) Image receptor. The image receptor systems and their individual components must be designed for mammography.
 - (b) Target/filter. The x-ray system must be able to provide kVp/target/filter combinations that are compatible with the image receptor systems.
 - (c) Focal spot size measurement. Focal spot dimensions shall be measured both parallel and perpendicular to the anode-cathode axis with a slit camera or star pattern. Measured focal spot size shall result in minimal acceptable phantom image as specified in (8)(c) or comply with the manufacturer's specified nominal focal spot size within the following tolerances:

Nominal Focal Spot Size (mm)	Maximum Measured Dimensions*	
	Width (mm)	Length (mm)
0.01	0.15	0.15
0.15	0.23	0.23
0.20	0.30	0.30
0.30	0.45	0.65
0.40	0.60	0.85
0.60	0.90	1.30

* Width is the dimension perpendicular to the anode-cathode axis, length is the dimension parallel to the anode-cathode axis.

- (d) Compression. Devices parallel to the imaging plane must be available to immobilize and compress the breast. These devices must be able to compress the breast with a force of at least 25 pounds and be able to maintain this compression for at least 15 seconds. For systems with automatic compression, the maximum force applied without manual assistance shall not be allowed to exceed 40 pounds. The chest wall edge of the compression paddle must be aligned with the chest wall edge of the image receptor to within one percent of the SID when the compression paddle is placed six centimeters above the patient support device.
- (e) Anti-scatter grids. A mammographic x-ray system using screen-film image receptors shall be able to use anti-scatter grids that are integral to the x-ray system and available for all image receptor sizes of the system.
- (f) Automatic exposure control. The department recommends that all x-ray equipment installed after September 1, 1993 have automatic exposure control that meets the requirements of 64E-5.503(14). The automatic exposure control shall be able to maintain constant film density within the diagnostic range of 1.05 to 1.60 optical density for 2, 4, and six centimeters of acrylic or of BR-12 phantoms. Density selection and kVp can be manually adjusted and recorded on technique charts if necessary to maintain film density.
- (3) Beam quality. The useful beam shall have a half-value layer between the values of measured kVp/100 and measured kVp/100 \pm 0.1 millimeter aluminum equivalent when used with screen-film image receptors and the contribution to filtration made by the compression device is included. For xeroradiography, the half-value layer of the useful beam with the compression device in place shall be at least 1.0 and not more than 1.6 mm aluminum equivalent, tested at the kVp recommended by the manufacturer. Mammographic units using only rhodium filters and anodes are exempt from these beam quality requirements.

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- (4) The x-ray system shall meet safety standards and be free from unnecessary hazards to patients, personnel and others. Identified hazards must be corrected promptly. Technique charts, procedures for all equipment use, proper safety precautions for both mechanical and electrical operation, adequate shielding, and emergency procedures must be available to the equipment operator. Staff or a medical physicist as specified in (12), below, shall conduct and document periodic inspections of the equipment and of the adequacy of procedures as part of the annual quality assurance review.
- (5) Collimation. The mammographic system shall be able to limit the useful beam so that the x-ray field at the plane of the image receptor at any SID does not extend beyond the left, right, and nipple edges of the image receptor and does not extend beyond the image receptor adjacent to the chest wall by more than two percent of the SID. The sum of the collimated light field edges shall not differ from the sum of the respective edges of the x-ray field along either the length or the width of the visually defined field by more than two percent of the SID.
- (6) Average glandular tissue dose. The average glandular tissue dose for one craniocaudal view of a 4.5 centimeter compressed breast with 50 percent adipose/50 percent glandular tissue shall not exceed the following values:
- (a) One hundred millirads (one milligray) for film/screen without grid.
 - (b) Three hundred millirads (three milligray) for film/screen with grid.
 - (c) Four hundred millirads (four milligray) for Xeroradiographic systems.
- (7) The film processor shall be optimized for the specific mammography film used by the facility. Its performance shall be checked for consistency of speed, contrast, and base plus fog prior to processing patient films and after being idle more than six hours.
- (a) These performance checks shall be plotted and compared to established limits. If these limits are exceeded, documented corrective actions including an image quality check as specified in (8), below, are required.
 - (b) Corrective action shall be taken when:
 - 1. Optical density deviates by more than 0.15 from established operating levels for readings of mid-density and density difference on the sensitometric control charts
 - 2. Base plus fog exceeds the established operating level by more than 0.03 optical density.
 - (c) These records for processor optimization, performance, image quality checks and documented corrective actions shall be maintained for inspection by the department for at least one year.

- (8) Mammographic x-ray systems shall be monitored and evaluated using the following standards:
- (a) The image quality shall be checked using a standard phantom approved by the U.S. Food and Drug Administration which meets the criteria below at least monthly and whenever service which could affect image quality is performed on the x-ray system or the film processor. The image quality shall be scored on the ability to image fibers, specks, and low density masses. If quality control limits are exceeded, image quality checks also must be performed after any corrective actions have been taken. This standard phantom must be designed to evaluate image quality in the 1.05 to 1.60 optical density range, shall not change more than 0.2 optical density from its previous reading, and must be composed of material that is equivalent to a nominal 4.5 centimeter compressed breast of average density of approximately 50 percent adipose and 50 percent glandular tissue. It shall contain the following objects:
 1. Nylon fibers with thicknesses of 1.56, 1.12, 0.89, 0.75, 0.54, and 0.40 millimeters.
 2. Aluminum oxide specks with diameters of 0.54, 0.40, 0.32, 0.24, and 0.16 millimeters.
 3. Phenolic plastic spherical masses with thicknesses of 2.00, 1.00, 0.75, 0.50, and 0.25 millimeters.
 - (b) Phantom checks which indicate a decrease in image quality shall require immediate investigation of possible corrective actions.
 - (c) The minimum acceptable image quality of a standard phantom described in (8)(a), above, shall demonstrate the ability to image at least 1.56, 1.12, 0.89, and 0.75 millimeter fibers; 0.54, 0.40, and 0.32 millimeter specks; and 2.00, 1.00, and 0.75 millimeter spherical masses. Mammographic examinations shall not be performed on systems which do not meet the minimum image quality standard.
 - (d) The registrant must document in the annual review required in (1), above, that the following equipment quality control items were performed under the direction and approval of the medical physicist when the equipment or components were initially installed or replaced and were performed thereafter at least as often as the frequency specified in (8)(e), below. When the results of performed tests do not meet established limits, corrective action must be taken and documented. The equipment quality control items which must be monitored are:
 1. Processor performance through sensitometric-densitometric means, before processing patient films and as specified in (7), above.
 2. Darkroom cleaning, daily.

3. Screen cleaning, weekly.
 4. Image quality, monthly and as specified in (8)(a),(b) and (c), above.
 5. Equipment observation check, monthly.
 6. Analysis of fixer retention in film, quarterly
 7. Compression device performance, semiannually
 8. Screen film contact and screen artifact detection, semiannually.
 9. Uniformity of screen speed, annually.
 10. Beam limiting device alignment, annually.
 11. Accuracy of kVp, annually.
 12. Output reproducibility and linearity, annually.
 13. Automatic exposure control reproducibility, kVp response and phantom thickness response, annually.
 14. Half-value layer, annually.
 15. Average glandular tissue dose, annually.
 16. Focal spot size, annually.
 17. Analysis of clinical images repeated or rejected, quarterly.
Corrective action shall be taken and documented if the retake rate of the facility exceeds five percent.
 18. Viewbox uniformity and integrity of devices used to block extraneous light, semiannually. A means shall be provided to block extraneous light from the viewer's eye when the illuminated surface of the viewbox is larger than the film size or area of clinical interest.
 19. Darkroom integrity, semiannually. Darkroom fog shall not exceed 0.05 optical density when sensitized film is exposed to darkroom conditions with the safelight on for two minutes.
- (e) Mammography system performance must be evaluated regularly. The registrant must document the evaluation of the equipment quality control tests in the annual review specified in (1), above. Those components and parameters of the equipment quality control program tested for performance daily, weekly, monthly or quarterly shall be evaluated quarterly. The annual evaluation by the medical physicist must include a summary of the quarterly evaluations and the following:

1. Unit assembly.
 2. Collimation assessment.
 3. Focal spot size measurement.
 4. Accuracy and reproducibility of the kVp.
 5. Beam quality assessment.
 6. Automatic exposure control system performance.
 7. Uniformity of screen speed.
 8. Breast entrance exposure and average glandular tissue dose.
 9. Image quality.
 10. Artifacts.
- (f) The registrant shall document the qualifications and training of the personnel responsible for each part of the mammography quality assurance program, including the clinical image review, the establishment, monitoring, and evaluation of the equipment quality control program, and the annual review of the quality assurance program effectiveness.
- (9) All image receptors shall be clearly marked to indicate on the film which receptor was used on any given examination to facilitate the detection and removal of artifacts.
- (10) Xerox mammography systems shall be exempt from the requirements of (2)(e), (2)(f), (7), (8)(d)1., 2., 3., 6., 8., 9., 13., 18., 19., (8)(e)6., and 7 above.
- (11) Xerox mammography systems which exceed an average glandular dose for one craniocaudal view of a 4.5 centimeter compressed breast with a 50/50 percent ratio of glandular/fat tissue of 400 mrad (4 mGy) shall have the exposure techniques, processing, and image quality of the system investigated by a medical physicist, as specified in (12), below.
- (12) The following requirements apply to personnel involved in any aspect of mammography, including the production, processing, and interpretation of mammograms and related quality assurance activities.
- (a) Interpreting physicians shall meet the following requirements
1. Licensed to practice medicine in the State of Florida, as specified in Chapters 458 and 459, Florida Statutes.
 2. a. Certified by a certifying body approved by the U.S. Food and Drug Administration; or

- b. (I) Holds a Master of Science, Master of Arts, or a higher degree in an appropriate field from an accredited institution. Appropriate fields include physics, applied physics, radiological physics, biophysics, health physics, engineering, and public health when the Bachelor's degree is in a physical science; and
- (II) Has had training in biological sciences; and
- (III) Has had at least 1 year of training in medical physics in the area of diagnostic radiological physics; and
- (IV) Has had at least 2 years of experience conducting mammography equipment performance evaluations..
- R1 c. Has received or taught at least an average of 5 hours of documented continuing education related to mammography per year.
- R1 2. After April 28, 1999, the medical physicist must meet the criteria
- R1 specified in 1.a. and 1.b.(I), above, and the qualification and
- R1 experience specified in 21 CFR 900.12(a)(3)(i), (iii), and (iv), which
- R1 is herein incorporated by reference and which is available from the
- R1 department.

(13) Documentation, records and surveys. Each facility shall maintain records, policies, procedures and documentation to demonstrate compliance with these requirements, including corrective actions taken.

- (a) Clinical images. Each facility shall establish and maintain a clinical image quality control program, including:
1. Monitoring of mammograms repeated because of poor image quality; and
 2. Maintaining records, analysis of results, and a description of any remedial action taken as a result of this monitoring.

(b) Clinical image interpretation. To ensure that quality clinical images are produced routinely at the facility, each facility shall submit clinical images to the department for review as required by the department. Each facility also will establish a system to review outcome data from all mammography performed, including follow-up on the disposition of positive mammograms and correlation of surgical biopsy results with mammogram reports.

R1

(c) Surveys. A medical physicist who meets the qualifications specified in (12), above, and who establishes, monitors, evaluates, and directs the equipment quality control program must perform an on-site survey of the facility to assure that it meets quality control and equipment standards. These surveys shall be performed at least annually and shall be available for inspection by the department. Each survey report shall be retained by the facility until the next annual survey is completed satisfactorily.

(d) Medical records.

1. Each facility shall maintain mammograms and associated records in a permanent medical record of the patient as follows:

a. For at least five years, or, if no additional mammograms of the patient are performed at the facility, for at least ten years; or

b. Until the records are transferred as requested by the patient to a medical institution, to a physician of the patient, or to the patient.

R1

2. Each facility shall prepare a written report of the results of each mammography examination. This report shall be completed as soon as reasonably possible and shall:

a. Be signed by the interpreting physician; and

b. Be provided to the patient's physician or to the patient if the patient's physician is not available or if the patient does not have a physician. If this report is sent to the patient, it shall include a summary written in language easily understood by a lay person. A copy of the report shall be maintained in the patient's medical record.

(14) In addition to the above requirements, effective October 1, 1994, no facility can conduct mammography procedures unless the facility also obtains a certificate issued by the U.S. Food and Drug Administration as described in Public Law 102-539, the Mammography Quality Standards Act of 1992.

R1 Specific Authority: 404.051, 404.22, F.S.

R1 Law Implemented: 404.051(1)(4), 404.141, 404.22(1)(3)(6), F.S.

History: New March 17, 1992, Amended January 1, 1994

R1 Amended November 20, 1994, Formerly 10D-91.611, Amended May 18, 1998

64E-5.511 Registration of Radiation Machines.

- (1) Exemptions.
 - (a) Electronic equipment that produces radiation incidental to its operation for other purposes is exempt from registration and notification requirements if the dose equivalent rate averaged over an area of ten square centimeters does not exceed 0.5 millirem (five μ Sv) per hour at five centimeters from any accessible surface of the equipment. The production, testing or factory servicing of such equipment shall not be exempt.
 - (b) Radiation machines while in transit or storage incident thereto are exempt from the requirements of this part.

(2) Application and Fees for Registration of Radiation Machines.

- (a) Each person who acquires a radiation machine or an additional radiation machine shall:
 - 1. Apply for registration of the radiation machine with the department within 30 days after acquisition. Application for registration shall be on DH Form 1107, which is herein incorporated by reference and available from the department.
 - 2. Designate an individual who will be responsible for radiation protection.
 - 3. Prohibit any person who is not registered with the department as a provider of services as specified in (3), below, from furnishing radiation machine servicing or services to his radiation machine
- (b) An annual fee for the registration and inspection of radiation machines shall be paid according to the following schedule:

Medical or Chiropractic or Osteopathic or Naturopathic	One Tube.....	\$ 145
	Each Additional Tube.....	\$ 85
Veterinary	One Tube.....	\$ 50
	Each Additional Tube.....	\$ 34
Educational or Industrial	One Tube.....	\$ 47
	Each Additional Tube.....	\$ 23
Dental or Podiatry	One Tube.....	\$ 31
	Each Additional Tube.....	\$ 11
Medical Accelerator	One Unit.....	\$ 258
	Each Additional Unit	\$ 148

Non Medical	One Unit.....	\$ 81
	Each Additional Unit	\$ 48

1. Renewal fees are due before October 28 annually.
 2. Registration fees are due within 30 days after acquiring a radiation machine. If the machine is acquired within 120 days before the October 28 annual renewal date, the registration fee will be due on October 28 and shall be the annual renewal fee.
- (3) Application for Registration of Servicing and Services.
- (a) Each person who installs or offers to install radiation machines or furnishes or offers to furnish radiation machine servicing or services in Florida shall apply to the department to register such services before furnishing or offering to furnish such services.
 - (b) Application for registration shall be completed on DH Form 1113, which is herein incorporated by reference and which is available from the department.
 - (c) Services include the installation or servicing of radiation machines and associated radiation machine components.
- (4) Report of Changes. The registrant shall report in writing within 30 days any changes to the information in the Certificate of Registration. The report shall include name, address of installation change, receipt, sale, transfer, or disposal of any radiation machine or major component.
- (5) Assembler or Transferor Obligation.
- (a) Any person who sells, leases, transfers, relocates, lends, assembles, installs or disposes of radiation machines or major components of such machines shall notify the department within 15 days after such action. Notification shall be made on DH Form 1114, which is herein incorporated by reference and available from the department, or, if the system contains certified components, on FORM FDA 2579, which is herein incorporated by reference and which is available from the department.
 - (b) No person shall sell, offer to sell, lease, transfer, lend or install radiation machines unless such machines meet the requirements of these regulations.

- (6) Out-of-State Radiation Machines.
- (a) Any person proposing to bring a radiation machine into Florida shall notify the department in writing at least ten days before the machine is to be used in the state. The notice shall include the type of radiation machine; the nature, duration and scope of use; and the exact location where the radiation machine will be used. If the 10-day period is an undue hardship, the department can grant permission to proceed sooner.
 - (b) Any person proposing to bring a radiation machine into Florida shall register the machine with the department and pay the registration fee.
 - (c) Any out-of-state person using a radiation machine in Florida shall notify the department when the use of the machine has been completed.
- (7) Enforcement. The General Statement of Policy and Procedure for Radiation Machine Enforcement Actions, August 1996, which is available from the department and which is herein incorporated by reference, will be used to determine enforcement actions to be taken.

Specific Authority 404.

Law Implemented 404.071, 404.091, 404.101, 404.141, 404.161, 404.162, 404.163, 404.22, F.S.051 F.S.

History--New December 12, 1996, Formerly 10D-91.612

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PART VI**USE OF RADIONUCLIDES IN THE HEALING ARTS****64E-5.601 License Required.**

- (1) Radioactive materials shall not be manufactured, produced, acquired, received, possessed, used, or transferred for medical use except as provided in a specific license.
- (2) Any licensee who is licensed for one or more of the medical uses in 64E-5.626, 64E-5.627, 64E-5.630, or 64E-5.632 also is authorized to use radioactive material under a general license in 64E-5.206(8) for specified in vitro uses without filing the certificate required by 64E-5.206(8)(b), but is subject to the other provisions of 64E-5.206(8).
- (3) Unless prohibited by license condition, a physician, dentist, or podiatrist in training may receive, possess, use, or transfer radioactive materials as provided in these regulations under the supervision of an authorized user as provided in 64E-5.608.
- (4) Unless authorized by the department, no individual shall manufacture, produce, acquire, receive, possess, use, or transfer radioactive materials for medical use unless:
 - (a) That individual is listed on the licensee's specific license as an authorized user or an authorized nuclear pharmacist;
 - (b) Authorized by 64E-5.609;
 - (c) Authorized by 64E-5.601(2) with approval of the radiation safety committee at medical institutions or by management for licensees that are not medical institutions; or
 - (d) Authorized by 64E-5.601(3) and Subpart I of Part VI.

R3

Specific Authority: 404.022, 404.051, 404.061, 404.071, 404.081, 404.141, F.S.

Law Implemented: 404.022, 404.051(1), (4), (5), (6), (8), (9), (10), (11), 404.061(2), (3), 404.071(1), 404.081, 404.141, F.S.

R3

History: New August 25, 1991, Amended May 12, 1993, Formerly 10D-91.707, Amended August 6, 2001.

64E-5.602 License Amendments. A licensee shall apply for and receive a license amendment or departmental approval:

- (1) Before using radioactive material for a method or type of medical use not permitted by the license;
- (2) Before permitting anyone, except a visiting authorized user described in 64E-5.609, to work as an authorized user;
- (3) Before changing a radiation safety officer or teletherapy physicist;

- (4) Before ordering or receiving radioactive material in excess of the amount authorized on the license;
- (5) Before adding to or changing the areas of use or address or addresses of use identified in the application or on the license; and
- (6) Before changing statements, representations, and procedures which are incorporated into the license.

Specific Authority: 404.022, 404.051, 404.061, 404.071, 404.081, 404.141, F.S.

Law Implemented: 404.022, 404.051(1) (4), (5), (6), (8), (9), (10), (11), 404.061(2), (3), 404.071(1), 404.081, 404.141, F.S.

History: New August 25, 1991, Formerly 10D-91.708.

64E-5.603 Notification. A licensee shall notify the department in writing within
R3 30 days when an authorized user, radiation safety officer, authorized nuclear pharmacist, or teletherapy physicist permanently discontinues performance of these duties for the licensee.

Specific Authority: 404.022, 404.051, 404.061, 404.071, 404.081, 404.141, F.S.

Law Implemented: 404.022, 404.051(1), (4), (5), (6), (8), (9), (10), (11), 404.061(2), (3), 404.071(1), 404.081, 404.141, F.S.

R3 History: New August 25, 1991, Formerly 10D-91.709, Amended August 6, 2001.

SUBPART A

GENERAL ADMINISTRATIVE REQUIREMENTS

64E-5.604 ALARA Program.

- (1) Each licensee shall develop and implement a written program to maintain radiation doses and releases of radioactive material in effluents to unrestricted areas as low as reasonably achievable as provided in 64E-5.303.
- (2) The management, radiation safety officer, and all authorized users shall participate in the establishment, implementation, and operation of the program as required by these regulations or the radiation safety committee.
- (3) For licensees that are not medical institutions, management and all authorized users shall participate in the program as required by the radiation safety officer.
- (4) The ALARA program shall include an annual review by the radiation safety committee for medical institution licensees, or by management and the radiation safety officer for licensees that are not medical institutions. The review shall include summaries of the types, amounts and purposes of radioactive material used; occupational dose reports; and continuing education and training of all personnel who work with or in the vicinity of radioactive material. The purpose of the review is to ensure that individuals make every reasonable effort to maintain occupational doses, doses to the general public, and releases of radioactive material as low as reasonably achievable, taking into account the state of technology and the cost of improvements in relation to benefits.

-
- (5) The licensee shall retain a current written description of the ALARA program for the duration of the license. The written description shall include:
- (a) A commitment by management to keep occupational doses as low as reasonably achievable;
 - (b) A requirement that the radiation safety officer annually report to management in writing on the radiation safety program; and
 - (c) Categories of personnel exposure levels that, when exceeded, will initiate investigation by the radiation safety officer of the cause of the exposure and actions taken to reduce the probability of recurrence.

Specific Authority: 404.022, 404.051, 404.061, 404.071, 404.081, 404.141, F.S.

Law Implemented: 404.022, 404.051(1)(4)(5)(6)(8)(9)(10)(11), 404.061(2)(3), 404.071(1), 404.081, 404.141, F.S.

History: New August 25, 1991, Amended January 1, 1994, Formerly 10D-91.710.

64E-5.605 Radiation Safety Officer.

- (1) A licensee shall appoint a radiation safety officer responsible for implementing the radiation safety program. The licensee, through the radiation safety officer, shall ensure that radiation safety activities are performed with approved procedures and regulatory requirements in the daily operation of the licensee's radioactive materials program.
- (2) The radiation safety officer shall promptly investigate and implement corrective actions as necessary regarding:
- (a) Overexposures;
 - (b) Accidents;
 - (c) Spills;
 - (d) Losses;
 - (e) Thefts;
 - (f) Unauthorized receipts, uses, transfers, and disposals; and
 - (g) Other deviations from approved radiation safety practice. A written report of these investigations and the corrective actions taken shall be given to management.
- (3) The radiation safety officer shall implement written policies and procedures to:
- (a) Authorize the purchase of radioactive material;
 - (b) Receive and open packages of radioactive material;
 - (c) Store radioactive material;

- (d) Keep an inventory record of radioactive material;
 - (e) Use radioactive material safely;
 - (f) Take emergency action if control of radioactive material is lost;
 - (g) Perform periodic radiation surveys;
 - (h) Perform checks of survey instruments and other safety equipment;
 - (i) Dispose of radioactive material;
 - (j) Train personnel who work in or frequent areas where radioactive material is used or stored; and
 - (k) Keep a copy of all records and reports required by department regulations, a copy of these regulations, a copy of each licensing request and license including amendments, and the written policies and procedures required by the regulations.
- (4) The radiation safety officer shall approve radiation safety program changes for medical use not at a medical institution with the consent of management prior to sending to the department for licensing action.
- (5) The radiation safety officer shall assist the radiation safety committee for medical use at a medical institution.
- (6) The radiation safety officer shall review at least every 3 months the occupational radiation exposure records of all personnel working with radioactive material.

Specific Authority: 404.022, 404.051, 404.061, 404.071, 404.081, 404.141, F.S.

Law Implemented: 404.022, 404.051(1)(4)(5)(6)(8)(9)(10)(11), 404.061(2)(3), 404.071(1), 404.081, 404.141, F.S.

History: New August 25, 1991, Formerly 10D-91.711.

64E-5.606 Radiation Safety Committee. Each medical institution licensee shall establish a radiation safety committee to oversee the use of radioactive material.

- (1) Membership of the radiation safety committee shall consist of at least four individuals and shall include an authorized user of each type of use permitted by the license, the radiation safety officer, a representative of the nursing service, a representative of management who is neither an authorized user nor a radiation safety officer, and a person experienced in the assay of radioactive material and protection against radiation, such as a radiological physicist or a nuclear medicine technologist employed by or working under contract with the institution. Other members may be included as appropriate.
- (2) The committee shall meet at least every 6 months. To establish a quorum and to conduct business, one-half of the committee's membership shall be present, including the radiation safety officer and the management representative.

- (3) The minutes of each radiation safety committee meeting shall include:
- (a) The date of the meeting;
 - (b) Members present;
 - (c) Members absent;
 - (d) Summary of deliberations and discussions;
 - (e) Recommended actions and the numerical results of all ballots; and
 - (f) Documentation of any reviews required in 64E-5.604 and 64E-5.606.
- (4) The committee shall provide each member with a copy of the meeting minutes and shall retain a copy for 5 years or until the department authorizes its disposition.
- (5) The committee shall be responsible for monitoring the institutional program to maintain occupational doses as low as reasonably achievable.
- R3 (6) The committee shall review and approve any individual to be an authorized user,
R3 an authorized nuclear pharmacist, the radiation safety officer, or teletherapy physicist based on safety and the training and experience standards of this part before sending a license application or request for amendment or renewal.
- (7) The committee shall review and approve each proposed method of use of radioactive material based on safety.
- (8) The committee shall review and approve procedures and radiation safety program changes based on safety and with the advice of the radiation safety officer and the management representative prior to sending to the department for licensing action.
- (9) The committee shall review occupational radiation exposure records of all personnel working with radioactive material and all incidents involving radioactive material at least every 6 months, with the assistance of the radiation safety officer, to determine cause and review subsequent actions taken.
- (10) The committee shall review the radioactive materials program at least every 12 months with the assistance of the radiation safety officer as described in 64E-5.604(4).
- (11) The committee shall establish levels for occupational dose that will result in investigations and considerations of action by the radiation safety officer when exceeded.

Specific Authority: 404.022, 404.051, 404.061, 404.071, 404.081, 404.141, F.S.

Law Implemented: 404.022, 404.051(1), (4), (5), (6), (8), (9), (10), (11), 404.061(2), (3), 404.071(1), 404.081, 404.141, F.S.

R3 History: New August 25, 1991, Formerly 10D-91.712, Amended August 6, 2001.

64E-5.607 Authority and Responsibilities.

- (1) A licensee shall provide sufficient authority and organizational freedom to the radiation safety officer and the radiation safety committee to:
 - (a) Identify radiation safety problems;
 - (b) Initiate, recommend, or provide solutions; and
 - (c) Require and verify implementation of corrective actions.
- (2) A licensee shall establish in writing and keep current the authority, duties, responsibilities, and radiation safety activities of the radiation safety officer and the radiation safety committee.
- (3) Authorized users shall have the following special responsibilities:
 - (a) Review personally the patient's case or develop and implement adequate written procedures to assure that the diagnostic radiation procedure is appropriate;
 - (b) Review personally the patient's case to assure that the therapeutic radiation procedure is appropriate;
 - (c) For therapy procedures or diagnostic procedures involving more than 30 microcuries (1.11 MBq) of iodine 123, iodine 125 or iodine 131 as sodium iodide, prepare a written directive;
 - (d) For all other diagnostic procedures, prepare a written directive or assure that the procedure is in accordance with a diagnostic clinical procedures manual;
 - (e) Use radioactive material or direct technologists and physicians in training in using radioactive material;
 - (f) Interpret results of diagnostic procedures; and
 - (g) Review regularly the progress of the patient receiving therapy and modify the originally prescribed dose if needed.

Specific Authority: 404.022, 404.051, 404.061, 404.071, 404.081, 404.141, F.S.

Law Implemented: 404.022, 404.051(1), (4), (5), (6), (8), (9), (10), (11), 404.061(2), (3), 404.071(1), 404.081, 404.141, F.S.

History: New August 25, 1991, Amended May 12, 1993, Formerly 10D-91.713.

64E-5.608 Supervision.

- (1) A licensee who permits the receipt, possession, use, or transfer of radioactive material by an individual under the supervision of an authorized user as allowed by 64E-5.601 shall:

- (a) Instruct the supervised individual in the principles of radiation safety appropriate to that individual's use of radioactive material and in the licensee's written quality management program;
 - (b) Review the supervised individual's use of radioactive material, provide reinstruction as needed and review records kept to reflect this use;
 - (c) Require the authorized user to be immediately available to communicate with the supervised individual;
 - (d) Require the authorized user to be able to be physically present and available to the supervised individual within 1 hour; and
 - (e) Require that only those individuals specifically designated by the authorized user be permitted to administer radionuclides or radiation to patients.
- (2) A licensee shall require the supervised individual receiving, possessing, using or transferring radioactive material specified in 64E-5.601 to:
- (a) Follow the instructions of the supervising authorized user;
 - (b) Follow the written radiation and quality management program procedures established by the licensee; and
 - (c) Comply with these regulations and the license conditions regarding the use of radioactive material.

Specific Authority: 404.022, 404.051, 404.061, 404.071, 404.081, 404.141, F.S.

Law Implemented: 404.022, 404.051(1)(4)(5)(6)(8)(9)(10)(11), 404.061(2)(3), 404.071(1), 404.081, 404.141, F.S.

History: New August 25, 1991, Amended January 1, 1994, Formerly 10D-91.714.

64E-5.609 Visiting Authorized User.

- (1) A licensee may permit any visiting authorized user to use licensed material for medical use under the terms of the licensee's license for 60 days each year if:
- (a) The visiting authorized user has the prior written permission of the licensee's management and, if the use occurs on behalf of a medical institution, the institution's radiation safety committee;
 - (b) The licensee has a copy of a license issued by the department, the U.S. Nuclear Regulatory Commission, an agreement state or a licensing state that identifies the visiting authorized user by name as an authorized user for medical use; and
 - (c) The visiting authorized user performs only those procedures for which he is specifically authorized by the license described in 64E-5.609(1)(b) above.

- (2) A license amendment is not needed to permit a visiting authorized user to use licensed material as described in 64E-5.609(1).
- (3) A licensee shall retain copies of the records specified in 64E-5.609(1) for 5 years after the last visit.

Specific Authority: 404.022, 404.051, 404.061, 404.071, 404.081, 404.141, F.S.

Law Implemented: 404.022, 404.051(1)(4)(5)(6)(8)(9)(10)(11), 404.061(2)(3), 404.071(1), 404.081, 404.141, F.S.

History: New August 25, 1991, Formerly 10D-91.715.

64E-5.610 Mobile Nuclear Medicine Service Requirements. The department shall license mobile nuclear medicine services or clients of such services. The mobile nuclear medicine service shall be licensed if the service receives, uses or possesses radioactive material. The client of the mobile nuclear medicine service shall be licensed if the client receives or possesses radioactive material to be used by a mobile nuclear medicine service.

- (1) Mobile nuclear medicine service licensees shall retain for the duration of service a letter signed by the management of each location where services are rendered that authorizes use of radioactive material.
- (2) Mobile nuclear medicine service licensees shall secure or keep under constant surveillance and immediate control all radioactive material when in transit or at a location of use.
- (3) Mobile nuclear medicine service licensees shall check dose calibrators as required by 64E-5.614, and shall perform all required gamma camera quality control tests before medical use at each location of use.
- (4) Mobile nuclear medicine service licensees shall perform a survey of all areas of radiopharmaceutical use with a radiation survey instrument before leaving a client location.
- (5) Mobile nuclear medicine service licensees shall retain a record of each survey required above for 3 years. The record must include the date of the survey, a plan of each area that was surveyed, the measured dose rate at several points in each area of use in millirems (microsieverts) per hour, the model and serial number of the instrument used to make the survey, and the initials of the individual who performed the survey.
- (6) A physician shall be on site at each client's address at the time radiopharmaceuticals are administered. An authorized user shall be able to be physically present and available within 1 hour.
- (7) Radioactive material shall not be stored in the mobile vehicle overnight when vehicle is located at its permanent location. The vehicle shall be monitored for contamination after all sources of radiation have been removed.
- (8) Radioactive material will be received at the permanent location of the mobile nuclear medicine service or delivered directly to an authorized individual in the vehicle at a place of use.

- (9) All use of radioactive material shall be in the mobile vehicle unless there is written documentation by the attending physician that the use of radioactive materials within the facility is in the best interest of the patient. All radioactive waste generated shall be stored on the vehicle for subsequent removal at the permanent location of the mobile nuclear medicine service.
- (10) Restrooms contained in mobile vehicles shall not routinely be used by patients who have been administered radioactive material. If the patient's condition requires the use of the restroom, the sewage holding tank of the vehicle shall be emptied and thoroughly rinsed into a sanitary sewer system at the permanent location of the mobile nuclear medicine service.
- (11) Radioactive gases shall not be used in mobile vehicles.

Specific Authority: 404.022, 404.051, 404.061, 404.071, 404.081, 404.141, F.S.

Law Implemented: 404.022, 404.051(1)(4)(5)(6)(8)(9)(10)(11), 404.061(2)(3), 404.071(1), 404.081, 404.141, F.S.

History: New August 25, 1991, Formerly 10D-91.716.

64E-5.611 Quality Management Program and Notifications, Records and Reports of Misadministrations.

- (1) Each applicant or licensee under this part, as applicable, shall establish and maintain a written quality management program to provide a high confidence that radioactive material or radiation from radioactive material will be administered as directed by the authorized user. The quality management program must include written policies and procedures to meet the following objectives:
- (a) Except where a delay to provide a written directive would jeopardize the patient's health as specified in (b) and (c) of this section, a written directive is prepared prior to administration for the following:
1. Any teletherapy radiation dose;
 2. Any gamma stereotactic radiosurgery radiation dose;
 3. Any brachytherapy radiation dose;
 4. Any administration of iodine 123, iodine 125 or iodine 131 as sodium iodide in quantities greater than 30 microcuries (1.11 megabecquerels); or
 5. Any therapeutic administration of a radiopharmaceutical other than iodine 123, iodine 125, or iodine 131 as sodium iodide;
- (b) An oral directive is acceptable when a delay to provide a written directive would jeopardize the patient's health because of the emergent nature of the patient's condition. The information contained in the oral directive must be documented immediately in the patient's record and a written directive prepared within 24 hours of the oral directive.

- (c) An oral revision to an existing written directive is acceptable when a delay to provide a written revision to an existing written directive would jeopardize the patient's health. The oral revision must be documented immediately in the patient's record and a revised written directive must be signed by the authorized user within 48 hours of the oral revision.
 - (d) A written directive which changes an existing written directive can be made for any diagnostic or therapeutic procedure if the revision is dated and signed by an authorized user prior to the administration of the radiopharmaceutical dosage, the brachytherapy dose, the gamma stereotactic radiosurgery dose, the teletherapy dose, or the next teletherapy fractional dose.
 - (e) The patient's identity is verified by more than one method as the individual named in the written directive prior to administration;
 - (f) The final plans of treatment and related calculations for brachytherapy, teletherapy, and gamma stereotactic radiosurgery agree with the respective written directives:
 - (g) Each administration agrees with the written directive; and
 - (h) Any unintended deviation from the written directive is identified and evaluated and appropriate action is taken.
- (2) The licensee shall develop procedures for and conduct a review of the quality management program including an evaluation of the following:
- (a) A representative sample of patient administrations within the review period;
 - (b) All recordable events within the review period; and
 - (c) All misadministrations within the review period to verify compliance with all aspects of the quality management program.
- (3) The review of the quality management program specified in (2) above shall be conducted at intervals not to exceed 12 months. A record of each review shall be maintained for inspection by the department in an auditable form for 3 years and shall include evaluations and findings of the review.
- (4) The licensee shall evaluate each of these reviews to determine the effectiveness of the quality management program and make modifications to meet the objectives in 64E-5.611(1).
- (5) Within 30 days of discovery of each recordable event, the licensee shall:
- (a) Assemble the relevant facts including the cause;
 - (b) Identify any corrective action required to prevent recurrence;

- (c) Retain a record in an auditable form for 3 years of the relevant facts and any corrective action taken.
- (6) The licensee shall retain in an auditable form for 3 years each written directive and a record of each administered radiation dose or radiopharmaceutical dosage where a written directive is required by 64E-5.611(1).
- (7) The licensee may make modifications to the quality management program to increase the program's efficiency if the program's effectiveness is not decreased. The licensee is required to submit the modifications to the department within 30 days after the modifications have been made.
- (8) Each applicant for a new license shall submit to the department a quality management program as part of the application for a license and implement the program upon issuance of the license by the department.
- (9) Each existing licensee shall submit to the department by July 1, 1994, a copy of their quality management program with a written certification that the quality management program has been implemented.
- (10) Each licensee shall submit and maintain records and reports of misadministrations as required by 64E-5.345(4) and (5).

Specific Authority: 404.022, 404.051, 404.061, 404.071, 404.081, 404.141, F.S.

Law Implemented: 404.022, 404.051(1)(4)(5)(6)(8)(9)(10)(11), 404.061(2)(3), 404.071(1), 404.081, 404.141, F.S.

History: New August 25, 1991, Amended January 1, 1994, Formerly 10D-91.717.

64E-5.612 Suppliers. A licensee shall use for medical use only:

- (1) Radioactive material manufactured, labeled, packaged, and distributed as specified in a license issued by the department or by another agreement state, a licensing state or the U.S. Nuclear Regulatory Commission;
- (2) Generators and reagent kits that have been manufactured, labeled, packaged, and distributed as specified in an approval issued by the U.S. Department of Health and Human Services, Food and Drug Administration unless the kits are not subject to the Federal Food, Drug, and Cosmetics Act and the Public Health Services Act.
- (3) Teletherapy sources manufactured and distributed as specified in a license issued by the department or by another agreement state, a licensing state or the U.S. Nuclear Regulatory Commission.

Specific Authority: 404.022, 404.051, 404.061, 404.071, 404.081, 404.141, F.S.

Law Implemented: 404.022, 404.051(1)(4)(5)(6)(8)(9)(10)(11), 404.061(2)(3), 404.071(1), 404.081, 404.141, F.S.

History: New August 25, 1991, Formerly 10D-91.718.

SUBPART B GENERAL TECHNICAL REQUIREMENTS

64E-5.613 Quality Control of Diagnostic Instrumentation. Each licensee shall establish written quality control procedures for all equipment used to obtain images or information from radionuclide studies. The procedures shall be recommended by equipment manufacturers or be approved by the department. The licensee shall perform quality control as specified in written procedures and retain a copy of the quality control results for 3 years.

Specific Authority: 404.022, 404.051, 404.061, 404.071, 404.081, 404.141, F.S.

Law Implemented: 404.022, 404.051(1)(4)(5)(6)(8)(9)(10)(11), 404.061(2)(3), 404.071(1), 404.081, 404.141, F.S.

History: New August 25, 1991, Amended May 13, 1993, Formerly 10D-91.719.

64E-5.614 Possession, Use, Calibration, and Check of Dose Calibrators.

- (1) A medical use licensee authorized to administer radiopharmaceuticals shall possess a dose calibrator and use it to measure the amount of activity administered to each patient.
- (2) A licensee shall check each dose calibrator before use each day of use for constancy with a dedicated check source. The check shall be performed on a frequently used setting with a sealed source of not less than 10 microcuries (370 kBq) of radium 226 or 50 microcuries (1.85 MBq) of any other photon-emitting radionuclide with a half-life greater than 90 days. A record shall be made of each check, which shall include:
 - (a) The model and serial number of the dose calibrator;
 - (b) The identity and decay corrected activity of the radionuclide contained in the check source;
 - (c) The date of the check;
 - (d) The activity measured;
 - (e) The percent error;
 - (f) The instrument settings; and
 - (g) The initials of the individual who performed the check.
- (3) The licensee shall test each dose calibrator for accuracy at the time of installation and at least every 12 months. The test shall be completed by assaying at least two sealed sources containing different radionuclides, the activity of which has been determined by the National Institute of Standards and Technology or by the manufacturer who has compared their source to a source calibrated by the National Institute of Standards and Technology. The sources shall have a minimum activity of 10 microcuries (370 kBq) for radium 226 and 50 microcuries (1.85 MBq) for any other photon-emitting radionuclide. At least one of the sources shall have a principal photon energy between 100 kiloelectron volts and 500 kiloelectron volts. A record shall be made of each test, which shall include:

- (a) The model and serial number of the dose calibrator;
 - (b) The model and serial number of each source used and the identity of the radionuclide contained in the source and its activity;
 - (c) The date of the test;
 - (d) The results of the test;
 - (e) The instrument settings; and
 - (f) The signature of the radiation safety officer.
- (4) The licensee shall test each dose calibrator for linearity at the time of installation and at least every 3 months over the range of use between 10 microcuries (370 kBq) and the highest dosage that will be administered. A record shall be made of each test, which shall include:
- (a) The model and serial number of the dose calibrator;
 - (b) The calculated activities;
 - (c) The measured activities;
 - (d) The date of the test; and
 - (e) The signature of the radiation safety officer.
- (5) The licensee shall test each dose calibrator for geometry dependence at the time of installation over the range of volumes and volume configurations for which it will be used. The licensee shall keep a record of this test for the duration of the use of the dose calibrator. A record shall be made of each test, which shall include:
- (a) The model and serial number of the dose calibrator;
 - (b) The configuration of the source measured;
 - (c) The activity measured and the instrument setting for each volume measured;
 - (d) The date of the test; and
 - (e) The signature of the radiation safety officer.
- (6) A licensee shall correct mathematically dosage readings for any geometry or linearity error that exceeds 10 percent if the dosage is greater than 10 microcuries (370 kBq) and shall repair or replace the dose calibrator if the accuracy or constancy error exceeds 10 percent.

- (7) A licensee shall also perform checks and tests required by 64E-5.614 following adjustment or repair of the dose calibrator.
- (8) A licensee shall retain a record of each check and test required by 64E-5.614 for 3 years.

Specific Authority: 404.022, 404.051, 404.061, 404.071, 404.081, 404.141, F.S.

Law Implemented: 404.022, 404.051(1)(4)(5)(6)(8)(9)(10)(11), 404.061(2)(3), 404.071(1), 404.081, 404.141, F.S.

History: New August 25, 1991, Formerly 10D-91.720.

64E-5.615 Use, Calibration and Check of Survey Instruments.

- (1) A licensee shall ensure that the survey instruments used to comply with this part have been calibrated before first use, at least every 12 months, and after repair. A record shall be made of each calibration, which shall include:
 - (a) A description of the source used;
 - (b) The certified dose rates from the source;
 - (c) The rates indicated by the instrument being calibrated;
 - (d) The correction factors deduced from the calibration data;
 - (e) The signature of the individual who performed the calibration; and
 - (f) The date of calibration.
- (2) The licensee shall:
 - (a) Calibrate all required scale readings up to 1,000 millirems (10 mSv) per hour with a radiation source;
 - (b) Calibrate each linear scale instrument at two points located approximately 1/3 and 2/3 of full-scale, calibrate each logarithmic scale instrument at midrange of each decade and at two points of at least one decade, and calibrate each digital instrument at appropriate points; and
- (3) The licensee shall:
 - (a) Consider a point as calibrated if the indicated dose rate differs from the calculated dose rate by not more than 10 percent; and
 - (b) Consider a point as calibrated if the indicated dose rate differs from the calculated dose rate by not more than 20 percent and a correction chart or graph is attached conspicuously to the instrument.
- (4) A licensee shall check each survey instrument for proper operation with a dedicated check source before each use. The licensee is not required to keep records of these checks.

- (5) The licensee shall retain a record of each calibration required in 64E-5.615(1), for 3 years.
- (6) The licensee may use persons licensed by the department, the U.S. Nuclear Regulatory Commission, an agreement state, or a licensing state to perform calibrations of survey instruments. Records of calibrations required by 64E-5.615(1) shall be maintained by the licensee.
- (7) A licensee authorized to use radioactive material for uptake, dilution, and excretion studies or sealed sources for diagnostic purposes shall possess a portable radiation survey instrument with a range from 0.1 millirem (1.0 μ Sv) per hour to 50 millirem (500 μ Sv) per hour.
- (8) A licensee authorized to use radioactive material for imaging and localization studies, radiopharmaceutical therapy or implant therapy shall possess portable radiation survey instruments with a range from 0.1 millirem (1.0 μ Sv) per hour to 1,000 millirem (10 mSv) per hour.
- (9) A licensee authorized to use radioactive material in a teletherapy unit shall possess a radiation survey instrument as described in (7) or (8), above.

Specific Authority: 404.051, 404.061 404.081, 404.141, F.S.

Law Implemented: 404.022, 404.051(1)(4)(6)(10)(11), 404.061(2)(3), 404.081, 404.141, F.S.

History: New August 25, 1991, Amended May 15, 1996, Formerly 10D-91.721.

64E-5.616 Assay of Radiopharmaceutical Dosages.

- (1) A licensee shall assay within 30 minutes before use the activity of each photon-emitting radiopharmaceutical dosage. A record of the assay shall be made, which shall include:
 - (a) The generic name, trade name, or abbreviation of the radiopharmaceutical; its lot number; expiration date; and the radionuclide;
 - (b) The patient's name and identification number if one has been assigned;
 - (c) The prescribed dosage and activity of the dosage at the time of assay or a notation that the total activity assayed is less than 10 microcuries (370 kBq);
 - (d) The date and time of the assay and administration; and
 - (e) The initials of the individual who performed the assay.
- (2) A licensee shall retain a record of the assays required by 64E-5.616(1), for 3 years.

Specific Authority: 404.022, 404.051, 404.061, 404.071, 404.081, 404.141, F.S.

Law Implemented: 404.022, 404.051(1)(4)(5)(6)(8)(9)(10)(11), 404.061(2)(3), 404.071(1), 404.081, 404.141, F.S.

History: New August 25, 1991, Amended May 12, 1993, Formerly 10D-91.722.

64E-5.617 Authorization for Calibration and Reference Sources. Any person authorized by 64E-5.601 for medical use of radioactive material may receive, possess, and use the following radioactive material for check, calibration and reference use:

- R1
- (1) Sealed sources manufactured and distributed by persons specifically licensed by the department, the U.S. Nuclear Regulatory Commission, an agreement state, or a licensing state that do not exceed 15 millicuries (555 MBq) each;
 - (2) Samarium 153 and any radioactive material listed in 64E-5.626 or 64E-5.627 with a half-life of 100 days or less in individual amounts not to exceed 15 millicuries (555 MBq) each;
 - (3) Any radioactive material listed in 64E-5.626 or 64E-5.627 with a half-life greater than 100 days in individual amounts not to exceed 200 microcuries (7.4 MBq) each; and
 - (4) Technetium 99m in individual amounts not to exceed 100 millicuries (3.7 GBq) each.

R1 Specific Authority: 404.051, 404.061, 404.141, F.S.

R1 Law Implemented: 404.051(1)(4)(6)(10), 404.061(2), 404.141, F.S.

R1 History: New August 25, 1991, Formerly 10D-91.723, Amended May 18, 1998.

64E-5.618 Requirements for Possession of Sealed Sources and Brachytherapy Sources.

- (1) A licensee who possesses any sealed source or brachytherapy source shall follow the radiation safety and handling instructions supplied by the manufacturer or equivalent instructions approved by the department and shall maintain the instructions for the duration of source use in a legible form and convenient to users.
- (2) A licensee in possession of a sealed source shall assure that:
 - (a) The source is tested for leakage before its first use unless the licensee has a certificate from the supplier indicating that the source was tested within 6 months before transfer to the licensee; and
 - (b) The source is tested for leakage at least every 6 months or at intervals approved by the department, another agreement state, a licensing state or the U.S. Nuclear Regulatory Commission.
 - (c) Leak tests are capable of detecting the presence of 0.005 microcurie (185 Bq) of radioactive material on the test sample, or, in the case of radium, the escape of radon at the rate of 0.001 microcurie (37 Bq) each 24 hours;
 - (d) Test samples are taken from the source or from the surfaces of the device in which the source is mounted or stored on which radioactive contamination might be expected to accumulate; and

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- (e) Teletherapy and other device source samples are taken when the source is in the off position.
 - (f) Leak tests are analyzed by individuals who are licensed by the department, U.S. Nuclear Regulatory Commission, an agreement state or licensing state to perform leak test services.
- (3) A licensee shall retain leak test records for 3 years. The records shall contain the model number and serial number if assigned of each source tested, the identity of each source radionuclide and its estimated activity, the measured activity of each test sample expressed in microcuries (becquerels), the date of the test, and the signature of the radiation safety officer.
- (4) If the leak test reveals the presence of 0.005 microcurie (185 Bq) or more of removable contamination, the licensee shall:
- (a) Immediately withdraw the sealed source from use and cause it to be decontaminated and repaired or to be disposed of in accordance with these regulations; and
 - (b) File a report with the department within 5 days of receiving the leak test results describing the equipment involved, the test results, and the action taken.
- (5) A leak test is not required on the following sources:
- (a) Sources containing only radioactive material with a half-life of less than 30 days;
 - (b) Sources containing only radioactive material as a gas;
 - (c) Sources containing 100 microcuries (3.7 MBq) or less of beta or photon-emitting material or 10 microcuries (370 kBq) or less of alpha-emitting material; and
 - (d) Seeds of iridium 192 encased in nylon ribbon.
- (6) Leak tests are not required on calibration and reference sources stored and not being used. The licensee shall, however, clearly indicate on the inventory records that these sources are for storage only and the date placed in storage. The licensee shall test each such source for leakage before any use or transfer unless it has been tested for leakage within 6 months before the date of use or transfer.
- (7) Leak tests are not required on brachytherapy and teletherapy sources that are listed on a department license for storage only. The licensee shall test each such source for leakage before any use or transfer unless it has been tested for leakage within 6 months before the date of use or transfer.

- (8) A licensee who possesses a brachytherapy or teletherapy source shall conduct a physical inventory of all such sources at least every 3 months. A licensee who possesses other sealed sources shall conduct a physical inventory of all such sources at least every 6 months. The licensee shall retain each inventory record for 3 years. The inventory records shall contain the model number of each source and serial number if one has been assigned, the identity of each source radionuclide and its estimated activity, the location of each source, the date of the inventory, and the signature of the radiation safety officer.
- (9) A licensee who possesses a sealed source or brachytherapy source shall survey all areas where such sources are stored with a radiation survey instrument at least every 3 months. This does not apply to teletherapy sources in teletherapy units or sealed sources in diagnostic devices.
- (10) A licensee shall retain a record of each survey required in 64E-5.618(9) for 3 years. The record shall include the date of the survey, a sketch of each area that was surveyed, the measured dose rate at several points in each area expressed in millirems (microsieverts) per hour, the model number and serial number of the survey instrument used to make the survey, and the signature of the radiation safety officer.

Specific Authority: 404.022, 404.051, 404.061, 404.071, 404.081, 404.141, F.S.

Law Implemented: 404.022, 404.051(1)(4)(5)(6)(8)(9)(10)(11), 404.061(2)(3), 404.071(1), 404.081, 404.141, F.S.

History: New August 25, 1991, Amended May 12, 1993, Formerly 10D-91.724.

64E-5.619 Syringe Shields and Labels.

- (1) A licensee shall keep syringes that contain radioactive material to be administered in a radiation shield. Each individual who prepares or administers radiopharmaceuticals shall use a syringe radiation shield unless the use of the shield is contraindicated for that patient.
- (2) Unless used immediately, a licensee shall label conspicuously each syringe or syringe radiation shield that contains a syringe with a radiopharmaceutical with the patient's name or the radiopharmaceutical name or its abbreviation and the type of diagnostic study or therapy procedure to be performed.

Specific Authority: 404.051, 404.061, 404.081, 404.141, F.S.

Law Implemented: 404.022, 404.051(1)(4)(6)(10)(11), 404.061(2)(3), 404.081, 404.141, F.S.

History: New August 25, 1991, Amended May 15, 1996, Formerly 10D-91.725.

64E-5.620 Vial Shields and Labels. A licensee shall require each individual preparing or handling a vial that contains a radiopharmaceutical to keep the vial in a vial radiation shield and conspicuously label each vial with the radiopharmaceutical name or its abbreviation.

Specific Authority: 404.022, 404.051, 404.061, 404.081, 404.141, F.S.

Law Implemented: 404.022, 404.051(1)(4)(6)(10)(11), 404.061(2)(3), 404.081, 404.141, F.S.

History: New August 25, 1991, Amended May 15, 1996, Formerly 10D-91.727.

64E-5.621 Surveys for Contamination and Ambient Radiation Dose Rate.

- (1) A licensee shall survey with a radiation survey instrument at the end of each day of use all areas where radiopharmaceuticals are routinely prepared for use or administered.
- (2) A licensee shall survey all areas where radiopharmaceuticals or radioactive wastes are stored with a radiation survey instrument at least once each week.
- (3) A licensee shall conduct the surveys required by 64E-5.621(1) and (2) with an instrument capable of measuring dose rates as low as 0.1 millirem (1 μ Sv) per hour.
- (4) A licensee shall establish dose rate action levels for the surveys required by 64E-5.621(1) and (2) and shall require that the individual performing the survey immediately notify the radiation safety officer if a dose rate exceeds an action level.
- (5) A licensee shall perform a wipe survey for removable contamination weekly of all areas where radiopharmaceuticals are routinely prepared for use, administered or stored.
- (6) A licensee shall analyze the wipe surveys required by 64E-5.621(5) with an instrument capable of detecting contamination of 2,000 disintegrations per minute (33.3 Bq) or shall monitor each wipe sample in a low background area with a radiation survey instrument using a probe with a maximum window thickness of 2.0 mg/cm² and a minimum probe diameter of 1.5 inches.
- (7) A licensee shall establish removable contamination action levels for the wipe surveys required by 64E-5.621(5) and shall require that the individual performing the survey immediately notify the radiation safety officer if contamination exceeds action levels.
- (8) A licensee shall retain a record of each survey required by 64E-5.621(1), (2), and (5) for 3 years. The record shall include:
 - (a) The date of the survey;
 - (b) A sketch of each area surveyed;
 - (c) Action levels established for each area;
 - (d) The measured dose rate at several points in each area expressed in millirems (microsieverts) per hour or the removable contamination in each area expressed in disintegrations per minute (becquerels) per 100 square centimeters, or counts per minute if performed with a radiation survey instrument as described in 64E-5.621(6);
 - (e) The serial number and the model number of the instrument used to make the survey or analyze the samples; and
 - (f) The initials of the person who performed the survey.

Specific Authority: 404.022, 404.051, 404.061, 404.071, 404.081, 04.141, F.S.

Law Implemented: 404.022, 404.051(1)(4)(5)(6)(8)(9)(10)(11), 404.061(2)(3), 404.071(1), 404.081, 404.141, F.S.

History: New August 25, 1991, Formerly 10D-91.729.

64E-5.622 Release of Patients Containing Radiopharmaceuticals or Permanent Implants.

- R2 (1) Except as authorized by 64E-Rule 5.622(4), F.A.C., a licensee shall not authorize release from confinement for medical care any patient administered a radiopharmaceutical until:
- (a) The dose rate from the patient is less than 5 millirems (50 μ Sv) per hour at a distance of 1 meter; or
- (b) The activity in the patient is less than 30 millicuries (1.11 GBq).
- R2 (2) Except as authorized by Rule 64E-5.622(4), F.A.C., a licensee shall not authorize release from confinement for medical care any patient administered a permanent implant until the dose rate from the patient is less than 5 millirems (50 μ Sv) per hour at a distance of 1 meter.
- (3) Immediately after removing the last temporary implant source from a patient, the licensee shall make a radiation survey of the patient with a radiation survey instrument to confirm that all sources have been removed. The licensee shall not release a patient treated by temporary implant from confinement for medical care until all sources have been removed.
- R2 (4) Licensees and license applicants whose proposed procedures to release
R2 individuals who have been administered radiopharmaceuticals or permanent
R2 implants containing radioactive material from the control of licensees differ from
R2 those specified in (1) and (2), above, must submit their proposed procedures to
R2 the department for approval. The procedures must:
- (a) Demonstrate that the total effective dose equivalent to any other individual from exposure to the released individual is not likely to exceed 500 millirem (5 μ Sv);
- (b) Contain a copy of the instructions including written instructions to be given to the released individual on actions recommended to maintain doses to other individuals as low as is reasonably achievable if the total effective dose equivalent to another individual is likely to exceed 100 millirem (1 μ Sv). If the dose to a breast-feeding infant or child could exceed 100 millirem (1 μ Sv) if there were no interruption of breast-feeding, the instructions also shall include:
1. Guidance on the interruption or discontinuance of breast-feeding and
 2. Information on the consequences of failing to follow the guidance.

R2 (c) Specify that the licensee shall maintain a record of the basis for
 R2 authorizing the release of an individual from their control who has been
 R2 administered radiopharmaceuticals or permanent implants containing
 R2 radioactive material for 3 years after the date of release.

R2 (5) A licensee shall maintain a record of patient surveys which demonstrates
 R2 compliance with Rule 64E-5.622(3), F.A.C., for 3 years. Each record shall
 include the date of the survey, the name of the patient, the dose rate from the
 patient expressed as millirems (microsieverts) per hour and measured within 1
 meter from the patient, and the initials of the individual who made the survey.

Specific Authority: 404.051, 404.061, 404.081, 404.141, F.S.

Law Implemented: 404.022, 404.051(1)(4)(6)(10)(11), 404.061(2)(3), 404.081, 404.141, F.S.

R2 History: New August 25, 1991, Amended May 15, 1996, Formerly 10D-91.730, Amended October 8, 2000.

64E-5.623 Storage of Volatiles and Gases. A licensee shall store volatile radiopharmaceuticals and radioactive gases in the shippers' radiation shield and container or an equivalent shield and container. A licensee shall store and use a multidose container in a properly functioning fume hood.

Specific Authority: 404.022, 404.051, 404.061, 404.071, 404.081, 404.141, F.S.

Law Implemented: 404.022, 404.051(1)(4)(5)(6)(8)(9)(10)(11), 404.061(2)(3), 404.071(1), 404.081, 404.141, F.S.

History: New August 25, 1991, Formerly 10D-91.731.

64E-5.624 Decay In Storage.

(1) A licensee shall hold radioactive material with a physical half life of less than 90 days for decay in storage before disposal as ordinary trash. A licensee is exempt from the requirements of 64E-5.328 of these regulations if:

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- (a) The radioactive material is held for decay a minimum of 10 half-lives;
 - (b) 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 a radiation survey instrument set on its most sensitive scale and with no interposed shielding;
 - (c) All radiation labels are removed or obliterated; and
 - (d) Each generator column is separated and monitored individually with all radiation shielding removed to ensure that its contents have decayed to background radiation levels before disposal.
- (2) 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 waste container; and
 - (g) The name of the individual who performed the disposal.

Specific Authority: 404.022, 404.051, 404.061, 404.071, 404.081, 404.141, F.S.

Law Implemented: 404.022, 404.051(1)(4)(5)(6)(8)(9)(10)(11), 404.061(2)(3), 404.071(1), 404.081, 404.141, F.S.

History: New August 25, 1991, Amended January 1, 1994, Formerly 10D-91.732.

64E-5.625 Safety Instruction and Precautions for Radiopharmaceutical Therapy, Brachytherapy, and Teletherapy.

- (1) A licensee shall provide oral and written radiation safety instructions to all personnel caring for patients undergoing radiopharmaceutical therapy or brachytherapy and to personnel who operate a teletherapy unit. Refresher training shall be provided at least every 12 months. The instruction shall describe the licensee's procedures for notification of the radiation safety officer or authorized user in case of the patient's death or medical emergency.
- (2) The instruction for radiopharmaceutical therapy shall describe the procedures for:
 - (a) Patient control;
 - (b) Visitor control;

- (c) Contamination control; and
 - (d) Waste control.
- R2 (3) The instruction for brachytherapy shall describe:
 - (a) Size and appearance of the brachytherapy sources;
 - (b) Safe handling and shielding instructions in case of a dislodged source;
 - (c) Procedures for patient control; and
 - (d) Procedures for visitor control.
- R2 (4) A licensee shall provide instruction and post conspicuously written instructions at the teletherapy unit console. These instructions shall inform the operator of:
 - (a) The procedure to be followed to ensure that only the patient is in the treatment room before turning on the primary beam of radiation or after a door interlock interruption;
 - (b) The procedure to be followed if the operator is unable to turn off the primary beam of radiation with controls outside the treatment room or any other abnormal operation occurs; and
 - (c) The names and telephone numbers of the authorized users and radiation safety officer to be immediately contacted if the teletherapy unit or console operates abnormally.
- R2 (5) A licensee shall keep a record of individuals receiving instruction required by (1), (2), and (3), above, which includes a description of the instruction, the date of instruction, and the name of the individual who gave the instruction. Such record shall be maintained for inspection by the department for 3 years.
- R2 (6) A licensee shall take the following safety precautions for each patient receiving brachytherapy or radiopharmaceutical therapy and hospitalized.
 - (a) Post the patient's door with a "Caution: Radioactive Material" sign and note on the door or on the patient's chart where and how long visitors may stay in the patient's room.
 - (b) Authorize visits by individuals under 18 years of age only with the approval of the authorized user after consultation with the radiation safety officer.

- (c) Measure promptly, after administration of the dosage, the dose rates in contiguous restricted and unrestricted areas with a radiation measurement survey instrument to demonstrate compliance with the requirements of 64E-5.312. Retain for 3 years a record of each survey that includes the time and date of the survey, a plan of the area or list of points surveyed, the measured dose rate at several points expressed in millirems per hour, the instrument used to make the survey, and the initials of the individual who made the survey.
 - (d) Provide the patient with radiation safety guidance before authorizing release of the patient that will help to keep radiation dose to household members and the public as low as reasonably achievable.
 - (e) Notify the radiation safety officer or the authorized user immediately if the patient dies or has a medical emergency.
- R2 (7) A licensee shall provide a private room with a private sanitary facility for a radiopharmaceutical therapy patient. The licensee shall not place a brachytherapy patient in the same room with a patient who is not receiving radiation therapy unless the licensee can demonstrate compliance with the requirements of 64E-5.312(1)(c), at a distance of 1 meter from the implant.
- R2 (8) A licensee shall take these additional safety precautions for radiopharmaceutical therapy patients who are hospitalized:
- (a) Monitor material and items removed from the patient's room to determine that any contamination cannot be distinguished from the natural background radiation level with a radiation detection survey instrument set on its most sensitive scale and with no interposed shielding, or handle these materials and items as radioactive waste.
 - (b) Survey the patient's room and private sanitary facility for removable contamination before assigning another patient to the room. The room shall not be reassigned until removable contamination is less than 200 disintegrations per minute (3.33 Bq) per 100 square centimeters or the wipe samples are equal to background when surveyed with an instrument using a probe with a maximum window thickness of 2.0 mg/cm² and a minimum probe diameter of 1.5 inches.
 - (c) Establish a bioassay program to measure the thyroid burden of each individual who helped prepare or administer a dosage of liquid iodine 131 within 3 days after administering the dosage, and retain for the period required by 64E-5.339(5) a record of each thyroid burden measurement, the date of measurement, the name of the individual whose thyroid burden was measured, and the initials of the individual who made the measurements. Action levels and corresponding actions will be in accordance with the U.S. Nuclear Regulatory Commission's Regulatory Guide 8.20, Revision 1, September, 1979.

Specific Authority 404.051, 404.061, 404.081, 404.141, F.S.

Law Implemented: 404.022, 404.051(1), (4), (6), (10), (11), 404.061(2), (3), 404.081, 404.141 F.S.

History: New May 15, 1996, Formerly 10D-91.721.

SUBPART C UPTAKE, DILUTION, AND EXCRETION

64E-5.626 Use of Radiopharmaceuticals for Uptake, Dilution, or Excretion

R3 **Studies.** A licensee is allowed to use any radioactive material in a radiopharmaceutical for a
R3 diagnostic use involving measurements of uptake, dilution, or excretion for medical use that is
R3 either:

- R3 (1) Obtained from a manufacturer or pharmacy licensed as specified in
R3 64E-5.210(10), F.A.C., or in equivalent U.S. Nuclear Regulatory Commission or
R3 Agreement State regulations; or
- R3 (2) Prepared by an authorized nuclear pharmacist as specified in Rule
R3 64B16-28.903, F.A.C., or by a physician who is an authorized user.

Specific Authority: 404.022, 404.051, 404.061, 404.071, 404.081, 404.141, F.S.

Law Implemented: 404.022, 404.051(1), (4), (5), (6), (8), (9), (10), (11), 404.061(2), (3), 404.071(1), 404.081, 404.141, F.S.

R3 History: New August 25, 1991, Formerly 10D-91.733, Amended August 6, 2001.

SUBPART D IMAGING AND LOCALIZATION

64E-5.627 Use of Radiopharmaceuticals, Generators, and Reagent Kits for Imaging and Localization Studies.

- (1) A licensee is allowed to use any radioactive material in a diagnostic radiopharmaceutical, except in an aerosol or gaseous form, or any generator or reagent kit for preparation and diagnostic use of a radiopharmaceutical containing radioactive material for medical use that is either:

- R3 (a) Obtained from a manufacturer or pharmacy licensed as specified in
R3 64E-5.210(10), F.A.C., or in equivalent U.S. Nuclear Regulatory
R3 Commission or Agreement State regulations; or
- R3 (b) Prepared by an authorized nuclear pharmacist as specified in Rule
R3 64B16-28.903, F.A.C., or by a physician who is an authorized user.

- (2) A licensee shall use radioactive aerosols or gases only if specific application is made to and approved by the department and the requirements of 64E-5.629 are met.

Specific Authority: 404.022, 404.051, 404.061, 404.071, 404.081, 404.141, F.S.

Law Implemented: 404.022, 404.051(1), (4), (5), (6), (8), (9), (10), (11), 404.061(2), (3), 404.071(1), 404.081, 404.141, F.S.

R3 History: New August 25, 1991, Amended May 12, 1993, Formerly 10D-91.735, Amended August 6, 2001.

64E-5.628 Permissible Molybdenum 99 Concentration.

- (1) A licensee shall not administer a radiopharmaceutical containing more than 0.15 microcurie of molybdenum 99 per millicurie of technetium 99m (5.55 kilobecquerel of molybdenum 99 per 37 megabecquerel of technetium 99m).
- (2) A licensee preparing technetium 99m radiopharmaceuticals from molybdenum 99/technetium 99m generators shall measure the molybdenum 99 concentration in each eluate or extract.
- (3) A licensee who is required to measure molybdenum concentrations shall retain a record of each measurement for 3 years. The record shall include for each elution or extraction of technetium 99m:

- (a) The measured activity of the technetium expressed in millicuries (megabecquerels);
 - (b) The measured activity of molybdenum expressed in microcuries (kilobecquerels);
 - (c) The ratio of the measures expressed as microcuries of molybdenum per millicurie of technetium (kilobecquerels of molybdenum per megabecquerel of technetium);
 - (d) The date of the test; and
 - (e) The initials of the individual who performed the test.
- (4) A licensee shall report immediately to the department each occurrence of molybdenum 99 concentration exceeding the limits specified in 64E-5.628(1).

Specific Authority: 404.022, 404.051, 404.061, 404.071, 404.081, 404.141, F.S.

Law Implemented: 404.022, 404.051(1), (4), (5), (6), (8), (9), (10), (11), 404.061(2), (3), 404.071(1), 404.081, 404.141, F.S.

History: New August 25, 1991, Formerly 10D-91.736.

64E-5.629 Control of Aerosols and Gases.

- (1) A licensee shall only administer radioactive aerosols or gases when airborne concentrations are within the limits prescribed by State of Florida Bureau of Radiation Control ALIs, DACs, and Effluent Concentrations, July 1993, Table I, Column 3, and Table II.
- (2) The system shall either be directly vented to the atmosphere through an air exhaust or provide for collection and decay or disposal of the aerosol or gas in a shielded container.
- (3) A licensee shall only administer radioactive gases in rooms that are at negative pressure compared to surrounding rooms.
- (4) Before receiving, using, or storing radioactive gas, the licensee shall calculate the time needed after a release to reduce the concentration in the area of use to the occupational limit listed in State of Florida Bureau of Radiation Control ALIs, DACs, and Effluent Concentrations, July 1993. The calculation shall be based on the highest activity of gas handled in a single container and the measured available air exhaust rate.
- (5) A licensee shall post the time calculated in 64E-5.629(4) at the area of use and require that individuals evacuate the room until the posted time has elapsed if a gas spill occurs.
- (6) A licensee shall check the operation of collection systems monthly and measure the ventilation rates in areas of use every 6 months. Records of these checks and measurements shall be maintained for 3 years.

- (7) A copy of the calculations required in 64E-5.629(4) shall be recorded and retained for the duration of the license.

Specific Authority: 404.022, 404.051, 404.061, 404.071, 404.081, 404.141, F.S.

Law Implemented: 404.022, 404.051(1)(4)(5)(6)(8)(9)(10)(11), 404.061(2)(3), 404.071(1), 404.081, 404.141, F.S.

History: New August 25, 1991, Amended January 1, 1994, Formerly 10D-91.737.

SUBPART E RADIOPHARMACEUTICALS FOR THERAPY

64E-5.630 Use of Radiopharmaceuticals for Therapy. A licensee may use any R3 radioactive material in a radiopharmaceutical and for a therapeutic medical use that is either:

- R3 (1) Obtained from a manufacturer or pharmacy licensed as specified in
R3 64E-5.210(10), F.A.C., or in equivalent U.S. Nuclear Regulatory Commission or
R3 Agreement State regulations; or
- R3 (2) Prepared by an authorized nuclear pharmacist as specified in Rule
R3 64B16-28.903, F.A.C., or by a physician who is an authorized user.

Specific Authority: 404.022, 404.051, 404.061, 404.071, 404.081, 404.141, F.S.

Law Implemented: 404.022, 404.051(1), (4), (5), (6), (8), (9), (10), (11), 404.061(2), (3), 404.071(1), 404.081, 404.141, F.S.

R3 History: New August 25, 1991, Amended May 12, 1993, Formerly 10D-91.739, Amended August 6, 2001.

SUBPART F SEALED SOURCES FOR DIAGNOSIS

64E-5.631 Use of Sealed Sources for Diagnosis. A licensee shall follow the manufacturer's radiation safety and handling instructions and use only the following sealed sources for diagnosis:

- (1) Iodine 125 as a sealed source in a device for bone mineral analysis;
- (2) Iodine 125 as a sealed source in a portable device for imaging;
- (3) Gadolinium 153 as a sealed source in a device for bone mineral analysis; and
- (4) Americium 241 as a sealed source in a device for bone mineral analysis.

Specific Authority: 404.022, 404.051, 404.061, 404.071, 404.081, 404.141, F.S.

Law Implemented: 404.022, 404.051(1), (4), (5), (6), (8), (9), (10), (11), 404.061(2), (3), 404.071(1), 404.081, 404.141, F.S.

History: New August 25, 1991, Formerly 10D-91.743.

SUBPART G SOURCES FOR BRACHYTHERAPY

64E-5.632 Use of Sources for Brachytherapy. A licensee shall follow the manufacturer's radiation safety and handling instructions and use only the following sealed sources for brachytherapy:

- (1) Cobalt 60 as a sealed source in needles and applicator cells for topical, interstitial, and intracavitary treatment of cancer;
- (2) Strontium 90 as a sealed source in an applicator for treatment of superficial eye conditions;
- (3) Palladium 103 as a sealed source in seeds for interstitial treatment of cancer;
- (4) Iodine 125 as a sealed source in seeds for interstitial treatment of cancer;

- (a) The measured activity of the technetium expressed in millicuries (megabecquerels);
 - (b) The measured activity of molybdenum expressed in microcuries (kilobecquerels);
 - (c) The ratio of the measures expressed as microcuries of molybdenum per millicurie of technetium (kilobecquerels of molybdenum per megabecquerel of technetium);
 - (d) The date of the test; and
 - (e) The initials of the individual who performed the test.
- (4) A licensee shall report immediately to the department each occurrence of molybdenum 99 concentration exceeding the limits specified in 64E-5.628(1).

Specific Authority: 404.022, 404.051, 404.061, 404.071, 404.081, 404.141, F.S.

Law Implemented: 404.022, 404.051(1)(4)(5)(6)(8)(9)(10)(11), 404.061(2)(3), 404.071(1), 404.081, 404.141, F.S.

History: New August 25, 1991, Formerly 10D-91.736.

64E-5.629 Control of Aerosols and Gases.

- (1) A licensee shall only administer radioactive aerosols or gases when airborne concentrations are within the limits prescribed by State of Florida Bureau of Radiation Control ALIs, DACs, and Effluent Concentrations, July 1993, Table I, Column 3, and Table II.
- (2) The system shall either be directly vented to the atmosphere through an air exhaust or provide for collection and decay or disposal of the aerosol or gas in a shielded container.
- (3) A licensee shall only administer radioactive gases in rooms that are at negative pressure compared to surrounding rooms.
- (4) Before receiving, using, or storing radioactive gas, the licensee shall calculate the time needed after a release to reduce the concentration in the area of use to the occupational limit listed in State of Florida Bureau of Radiation Control ALIs, DACs, and Effluent Concentrations, July 1993. The calculation shall be based on the highest activity of gas handled in a single container and the measured available air exhaust rate.
- (5) A licensee shall post the time calculated in 64E-5.629(4) at the area of use and require that individuals evacuate the room until the posted time has elapsed if a gas spill occurs.
- (6) A licensee shall check the operation of collection systems monthly and measure the ventilation rates in areas of use every 6 months. Records of these checks and measurements shall be maintained for 3 years.

- (7) A copy of the calculations required in 64E-5.629(4) shall be recorded and retained for the duration of the license.

Specific Authority: 404.022, 404.051, 404.061, 404.071, 404.081, 404.141, F.S.

Law Implemented: 404.022, 404.051(1)(4)(5)(6)(8)(9)(10)(11), 404.061(2)(3), 404.071(1), 404.081, 404.141, F.S.

History: New August 25, 1991, Amended January 1, 1994, Formerly 10D-91.737.

SUBPART E RADIOPHARMACEUTICALS FOR THERAPY

64E-5.630 Use of Radiopharmaceuticals for Therapy. A licensee may use any radioactive material in a radiopharmaceutical and for a therapeutic use for which the Food and Drug Administration has accepted an Investigational New Drug Application or approved a New Drug Application.

Specific Authority: 404.022, 404.051, 404.061, 404.071, 404.081, 404.141, F.S.

Law Implemented: 404.022, 404.051(1)(4)(5)(6)(8)(9)(10)(11), 404.061(2)(3), 404.071(1), 404.081, 404.141, F.S.

History: New August 25, 1991, Amended May 12, 1993, Formerly 10D-91.739.

SUBPART F SEALED SOURCES FOR DIAGNOSIS

64E-5.631 Use of Sealed Sources for Diagnosis. A licensee shall follow the manufacturer's radiation safety and handling instructions and use only the following sealed sources for diagnosis:

- (1) Iodine 125 as a sealed source in a device for bone mineral analysis;
- (2) Iodine 125 as a sealed source in a portable device for imaging;
- (3) Gadolinium 153 as a sealed source in a device for bone mineral analysis; and
- (4) Americium 241 as a sealed source in a device for bone mineral analysis.

Specific Authority: 404.022, 404.051, 404.061, 404.071, 404.081, 404.141, F.S.

Law Implemented: 404.022, 404.051(1)(4)(5)(6)(8)(9)(10)(11), 404.061(2)(3), 404.071(1), 404.081, 404.141, F.S.

History: New August 25, 1991, Formerly 10D-91.743.

SUBPART G SOURCES FOR BRACHYTHERAPY

64E-5.632 Use of Sources for Brachytherapy. A licensee shall follow the manufacturer's radiation safety and handling instructions and use only the following sealed sources for brachytherapy:

- (1) Cobalt 60 as a sealed source in needles and applicator cells for topical, interstitial, and intracavitary treatment of cancer;
- (2) Strontium 90 as a sealed source in an applicator for treatment of superficial eye conditions;
- (3) Palladium 103 as a sealed source in seeds for interstitial treatment of cancer;
- (4) Iodine 125 as a sealed source in seeds for interstitial treatment of cancer;

- (5) Cesium 137 as a sealed source in needles and applicator cells for topical, interstitial, and intracavitary treatment of cancer;
- (6) Iridium 192 as seeds encased in nylon ribbon for interstitial treatment of cancer;
- (7) Gold 198 as a sealed source in seeds for interstitial treatment of cancer;
- (8) Radon 222 as seeds for interstitial treatment of cancer; and
- (9) Radium 226 as a sealed source in needles or applicator cells for topical, interstitial, and intracavitary treatment of cancer.

Specific Authority: 404.022, 404.051, 404.061, 404.071, 404.081, 404.141, F.S.

Law Implemented: 404.022, 404.051(1)(4)(5)(6)(8)(9)(10)(11), 404.061(2)(3), 404.071(1), 404.081, 404.141, F.S.

History: New August 25, 1991, Formerly 10D-91.745.

64E-5.633 Brachytherapy Sources Inventory.

- (1) Each time brachytherapy sources are returned to an area of storage from an area of use, the licensee shall immediately count or otherwise verify the number returned to ensure that all sources taken from the storage area have been returned.
- (2) A licensee shall make a record of the use of brachytherapy sources which includes:
 - (a) The names of the individuals permitted to handle the sources;
 - (b) The number and activity of sources removed from storage, the room number of use and patient's name, the time and date they were removed from storage, the number and activity of sources in storage after the removal, and the initials of the individual who removed the sources from storage; and
 - (c) The number and activity of sources returned to storage, the room number of use and patient's name, the time and date they were returned to storage, the number and activity of sources in storage after the return, and the initials of the individual who returned the sources to storage.
- (3) Immediately after implanting sources in a patient and immediately after removal of sources from a patient, the licensee shall make a radiation survey of the patient and the area of use to confirm that no sources have been misplaced. The licensee shall make a record of each survey.
- (4) A licensee shall maintain the records required in 64E-5.633(2) and (3) for 3 years.

Specific Authority: 404.022, 404.051, 404.061, 404.071, 404.081, 404.141, F.S.

Law Implemented: 404.022, 404.051(1)(4)(5)(6)(8)(9)(10)(11), 404.061(2)(3), 404.071(1), 404.081, 404.141, F.S.

History: New August 25, 1991, Formerly 10D-91.748.

SUBPART H TELETHERAPY

64E-5.634 Use of Sealed Source in a Teletherapy Unit. A licensee shall follow the manufacturer's radiation safety and operating instructions and use only cobalt 60 or cesium 137 as a sealed source in a teletherapy unit for medical use.

Specific Authority: 404.022, 404.051, 404.061, 404.071, 404.081, 404.141, F.S.

Law Implemented: 404.022, 404.051(1)(4)(5)(6)(8)(9)(10)(11), 404.061(2)(3), 404.071(1), 404.081, 404.141, F.S.

History: New August 25, 1991, Formerly 10D-91.751.

64E-5.635 Maintenance and Repair Restrictions. Only a person specifically licensed by the department, the U.S. Nuclear Regulatory Commission, or an agreement state to perform teletherapy unit maintenance and repair shall install, relocate, or remove a teletherapy sealed source or a teletherapy unit that contains a sealed source. Only such a person shall maintain, adjust, or repair the source drawer, the shutter or other mechanism of a teletherapy unit that could expose the source, reduce the shielding around the source, or result in increased radiation levels.

Specific Authority: 404.022, 404.051, 404.061, 404.071, 404.081, 404.141, F.S.

Law Implemented: 404.022, 404.051(1)(4)(5)(6)(8)(9)(10)(11), 404.061(2)(3), 404.071(1), 404.081, 404.141, F.S.

History: New August 25, 1991, Formerly 10D-91.752.

64E-5.636 Amendments. In addition to the requirements specified in 64E-5.602, a licensee shall apply for and receive a license amendment or departmental approval before:

- (1) Making any change in the treatment room shielding;
- (2) Making any change in the location of the teletherapy unit within the treatment room;
- (3) Using the teletherapy unit in a manner that could increase radiation levels in areas outside the teletherapy treatment room;
- (4) Relocating the teletherapy unit; or
- (5) Allowing an individual not listed on the licensee's license to perform the duties of the teletherapy physicist.

Specific Authority: 404.022, 404.051, 404.061, 404.071, 404.081, 404.141, F.S.

Law Implemented: 404.022, 404.051(1)(4)(5)(6)(8)(9)(10)(11), 404.061(2)(3), 404.071(1), 404.081, 404.141, F.S.

History: New August 25, 1991, Formerly 10D-91.753.

64E-5.637 Doors, Interlocks, and Warning Systems.

- (1) A licensee shall control access to the teletherapy room by a door at each entrance.
- (2) A licensee shall equip each entrance to the teletherapy room with an electrical interlock system that shall:
 - (a) Prevent the operator from turning on the primary beam of radiation unless each treatment room entrance door is closed;
 - (b) Turn off the beam of radiation immediately when an entrance door is

opened; and

- (c) Prevent the primary beam of radiation from being turned on following an interlock interruption until all treatment room entrance doors are closed and the beam on-off control is reset at the console.

- (3) A licensee shall equip each entrance to the teletherapy room with a conspicuously visible beam condition indicator light.

Specific Authority: 404.022, 404.051, 404.061, 404.071, 404.081, 404.141, F.S.

Law Implemented: 404.022, 404.051(1)(4)(5)(6)(8)(9)(10)(11), 404.061(2)(3), 404.071(1), 404.081, 404.141, F.S.

History: New August 25, 1991, Formerly 10D-91.755.

64E-5.638 Radiation Monitoring Devices.

- (1) A licensee shall have a permanent radiation monitor in each teletherapy room capable of continuously monitoring beam status.
- (2) Each radiation monitor shall be capable of providing visible notice of a teletherapy unit malfunction that results in an exposed or partially exposed source. The visible indicator of high radiation levels shall be observable by an individual entering the teletherapy room.
- (3) Each radiation monitor shall be equipped with a backup power supply separate from the power supply to the teletherapy unit. This backup power supply may be a battery system.
- (4) Each radiation monitor shall be checked daily with a dedicated check source for proper operation before the teletherapy unit is used.
- (5) A licensee shall maintain a record of the check required by 64E-5.638(4) for 3 years. The record shall include the date of the check, notation what the monitor indicates when its detector is and is not exposed to the source, and the initials of the individual who performed the check.
- (6) If a radiation monitor is inoperable, the licensee shall require any individual entering the teletherapy room to use a radiation survey instrument or audible alarm personal dosimeter to monitor for any malfunction of the source exposure mechanism that may result in an exposed or partially exposed source. The radiation survey instrument or dosimeter shall be checked with a dedicated check source for proper operation at the beginning of each day of use. The licensee shall keep a record as described in 64E-5.638(5).
- (7) A licensee shall promptly repair or replace the radiation monitor if it is inoperable.

Specific Authority: 404.022, 404.051, 404.061, 404.071, 404.081, 404.141, F.S.

Law Implemented: 404.022, 404.051(1)(4)(5)(6)(8)(9)(10)(11), 404.061(2)(3), 404.071(1), 404.081, 404.141, F.S.

History: New August 25, 1991, Formerly 10D-91.757.

64E-5.639 Viewing Systems. A licensee shall construct or equip each teletherapy room to permit continuous observation of the patient from the teletherapy unit console during irradiation.

Specific Authority: 404.022, 404.051, 404.061, 404.071, 404.081, 404.141, F.S.

Law Implemented: 404.022, 404.051(1)(4)(5)(6)(8)(9)(10)(11), 404.061(2)(3), 404.071(1), 404.081, 404.141, F.S.

History: New August 25, 1991, Formerly 10D-91.758.

64E-5.640 Dosimetry Equipment.

- (1) A licensee shall have a dosimetry system available for use calibrated by (a) or (b) below.
 - (a) The system shall have been calibrated by the National Institute of Standards and Technology or by a calibration laboratory accredited by the American Association of Physicists in Medicine within the previous 2 years and after any servicing that may have affected the system calibration.
 - (b) The system shall have been calibrated within the previous 4 years and shall have been intercompared 18 to 30 months after the calibration at an intercomparison meeting with another dosimetry system that has been calibrated within the previous 2 years by the National Institute of Standards and Technology or by a calibration laboratory accredited by the American Association of Physicists in Medicine. The intercomparison meeting shall be sanctioned by a calibration laboratory or radiologic physics center accredited by the American Association of Physicists in Medicine. The calibration factor of the licensee's system shall not have changed by more than 2 percent. The licensee shall not use the intercomparison result to change the calibration factor. When intercomparing dosimetry systems to be used for calibrating cobalt 60 teletherapy units, the licensee shall use a teletherapy unit with a cobalt 60 source. When intercomparing dosimetry systems to be used for calibrating cesium 137 teletherapy units, the licensee shall use a teletherapy unit with a cesium 137 source.
- (2) The licensee shall have available for use a dosimetry system for spot-check measurements. The spot-check system shall be the same system used to meet the requirement in 64E-5.640(1), or shall be a system that has been compared with a system that has been calibrated as provided in 64E-5.640(1). This comparison shall have been performed within the previous year and after each servicing that may have affected system calibration.
- (3) The licensee shall maintain a record of each calibration, intercomparison, and comparison for the duration of the license. For each calibration, intercomparison, or comparison, the record shall include:
 - (a) The date, the model numbers and serial numbers of the instruments that were calibrated, intercompared, or compared as required by 64E-5.640(1) and (2);
 - (b) The correction factors that were determined;

- (c) The names of the individuals who performed the calibration, intercomparison, or comparison; and
- (d) Evidence that the intercomparison meeting was sanctioned by a calibration laboratory or radiologic physics center accredited by the American Association of Physicists in Medicine.

Specific Authority: 404.022, 404.051, 404.061, 404.071, 404.081, 404.141, F.S.

Law Implemented: 404.022, 404.051(1)(4)(5)(6)(8)(9)(10)(11), 404.061(2)(3), 404.071(1), 404.081, 404.141, F.S.

History: New August 25, 1991, Formerly 10D-91.759.

64E-5.641 Full Calibration Measurements.

- (1) A licensee authorized to use a teletherapy unit for medical use shall perform full calibration measurements on each teletherapy unit:
 - (a) Before the first medical use of the unit;
 - (b) Before medical use whenever spot-check measurements indicate that the output differs by more than 5 percent from the output obtained at the last full calibration corrected mathematically for radioactive decay;
 - (c) Before medical use following replacement of the source or following reinstallation of the teletherapy unit in a new location;
 - (d) Before medical use following any repair of the teletherapy unit that includes removal of the source or major repair of the components associated with the source exposure assembly; and
 - (e) At least every 12 months.
- (2) Full calibration measurements shall include the determination of:
 - (a) The output within 3 percent for the range of field sizes and for the distance or range of distances used for medical use;
 - (b) The coincidence of the radiation field and the field indicated by the light beam localizing device;
 - (c) The uniformity of the radiation field and its dependence on the orientation of the useful beam;
 - (d) Timer constancy and linearity over the range of use;
 - (e) On-off error; and
 - (f) The accuracy of all distance measuring and localization devices in medical use.

- (3) A licensee shall use the dosimetry system described in 64E-5.640 to measure the output for one set of exposure conditions. The remaining radiation measurements required in 64E-5.641(2)(a) may be made using a dosimetry system that indicates relative dose rates.
- (4) A licensee shall make full calibration measurements required by 64E-5.641(1) using either the procedures recommended by the Scientific Committee on Radiation Dosimetry of the American Association of Physicists in Medicine that are described in Physics in Medicine and Biology Vol. 16, No. 3, 1971, pp. 379-396, which is herein incorporated by reference effective May 12, 1993; or procedures recommended by Task Group 21 of the Radiation Therapy Committee of the American Association of Physicists in Medicine that are described in Medical Physics Vol. 10, No. 6, 1983, pp. 741-771, and Vol. 11, No. 2, 1984, p. 213, which is herein incorporated by reference effective May 12, 1993; or equivalent procedures that have been approved by the department.
- (5) A licensee shall correct mathematically the outputs determined in 64E-5.641(2)(a) for physical decay monthly for cobalt 60 and at least every 6 months for cesium 137.
- (6) Full calibration measurements required by 64E-5.641(1) and physical decay corrections required by 64E-5.641(5) shall be performed by the teletherapy physicist named on the licensee's license.
- (7) A licensee shall maintain a record of each calibration for the duration of the license. The record shall include:
 - (a) The date of the calibration;
 - (b) The manufacturer's name, model number, and serial number for both the teletherapy unit and the source;
 - (c) The model numbers and serial numbers of the instruments used to calibrate the teletherapy unit;
 - (d) The tables that describe the output of the unit over the range of field sizes and for the range of distances used in radiation therapy;
 - (e) A determination of the coincidence of the radiation field and the field indicated by the light beam localizing device;
 - (f) The measured timer accuracy for a typical treatment time;
 - (g) The calculated on-off error;
 - (h) The estimated accuracy of each distance measuring or localization device; and
 - (i) The signature of the teletherapy physicist.

Specific Authority: 404.022, 404.051, 404.061, 404.071, 404.081, 404.141, F.S.
Law Implemented: 404.022, 404.051(1)(4)(5)(6)(8)(9)(10)(11), 404.061(2)(3), 404.071(1), 404.081, 404.141, F.S.
History: New August 25, 1991, Amended May 12, 1993, Formerly 10D-91.760.

64E-5.642 Periodic Spot-Checks.

- (1) A licensee authorized to use teletherapy units for medical use shall perform output spot-checks on each teletherapy unit at least every month.
- (2) Spot-checks shall include the determination of:
 - (a) Timer constancy and timer linearity over the range of use;
 - (b) On-off error;
 - (c) The coincidence of the radiation field and the field indicated by the light beam localizing device;
 - (d) The accuracy of all distance measuring and localization devices used for medical use;
 - (e) The output for one typical set of operating conditions; and
 - (f) The difference between the measurement made in 64E-5.642(2)(e) and the anticipated output, expressed as a percentage of the anticipated output, which is the value obtained at the last full calibration corrected mathematically for physical decay.
- (3) A licensee shall use the dosimetry system described in 64E-5.640 to make the spot-check required in 64E-5.642(2)(e).
- (4) A licensee shall perform spot-checks required by 64E-5.642(1) following procedures established by the teletherapy physicist.
- (5) A licensee shall have the teletherapy physicist review the results of each output spot-check within 15 days and promptly notify the licensee in writing of the results of each output spot-check. The licensee shall keep a copy of each written notification for 3 years.
- (6) A licensee authorized to use a teletherapy unit for medical use shall perform safety spot-checks of each teletherapy facility monthly.
- (7) Safety spot-checks shall assure proper operation of:
 - (a) Electrical interlocks at each teletherapy room entrance;
 - (b) Electrical or mechanical stops installed to limit use of the primary beam of radiation, restriction of source housing angulation or elevation, carriage or stand travel, and operation of the beam on-off mechanism;
 - (c) Beam condition indicator lights on the teletherapy unit, on the control console, and in the facility;

- (d) Viewing systems;
 - (e) Treatment room doors from inside and outside the treatment room; and
 - (f) Electrically assisted treatment room doors with the teletherapy unit electrical power turned off.
- (8) A licensee shall lock the control console in the off position if any door interlock malfunctions. No licensee shall use the unit until the interlock system is repaired unless specifically authorized by the department.
- (9) A licensee shall promptly repair any system identified in 64E-5.642(7) that is not operating properly. The teletherapy unit shall not be used until all repairs are completed.
- (10) A licensee shall maintain a record of each spot-check required by 64E-5.642(1) and (6) for 3 years. The record shall include:
- (a) The date of the spot-check;
 - (b) The manufacturer's name, model number, and serial number for both the teletherapy unit and source;
 - (c) The manufacturer's name, model number and serial number of the instrument used to measure the output of the teletherapy unit;
 - (d) The timer linearity and constancy;
 - (e) The calculated on-off error;
 - (f) A determination of the coincidence of the radiation field and the field indicated by the light beam localizing device;
 - (g) The determined accuracy of each distance measuring or localization device;
 - (h) The difference between the anticipated output and the measured output;
 - (i) Notations indicating the operability of each entrance door electrical interlock, each electrical or mechanical stop, each beam condition indicator light, the viewing system and doors; and
 - (j) The signature of the individual who performed the periodic spot-check.

Specific Authority: 404.022, 404.051, 404.061, 404.071, 404.081, 404.141, F.S.

Law Implemented: 404.022, 404.051(1)(4)(5)(6)(8)(9)(10)(11), 404.061(2)(3), 404.071(1), 404.081, 404.141, F.S.

History: New August 25, 1991, Formerly 10D-91.761.

64E-5.643 Radiation Surveys for Teletherapy Facilities.

- R2 (1) The licensee shall perform radiation surveys with an operable radiation survey instrument calibrated as provided in Rule 64E-5.615, F.A.C., before medical use, after each installation of a teletherapy source, and after making any change for which an amendment is required by Rule 64E-5.636, F.A.C.
- R2 (a) The maximum and average radiation levels at 1 meter from the teletherapy source with the source in the off position and the collimators set for a normal treatment field shall not exceed 10 millirems (100 μ Sv) per hour and 2 millirems (20 μ Sv) per hour.
- R2 (b) With the teletherapy source in the on position with the largest clinically available treatment field and with a scattering phantom in the primary beam of radiation, radiation levels in restricted areas shall be unlikely to cause any occupationally exposed individuals to receive a dose in excess of the limits specified in Rule 64E-5.304, F.A.C.; and radiation dose rates of any individual member of the public in unrestricted areas shall not exceed the limits specified in Rule 64E-5.312(1)(c), F.A.C.
- R2 (2) If the results of the surveys required in 64E-5.643(1) indicate any radiation levels in excess of the limits specified, the licensee shall lock the control in the off position and shall not use the unit:
- R2 (a) Except to repair, replace, or test the teletherapy unit, the teletherapy unit shielding, or the treatment room shielding; or
- R2 (b) Until the licensee has received a specific exemption from the department.
- R2 (3) A licensee shall maintain a record of the radiation measurements made following installation of a source for the duration of the license. The record shall include:
- R2 (a) The date of the measurements;
- (b) The reason the survey is required;
- (c) The manufacturer's name, model number and serial number of the teletherapy unit, the source, and the instrument used to measure radiation levels;
- (d) Each dose rate measured around the teletherapy source while in the off position and the average of all measurements;
- (e) A plan of the areas surrounding the treatment room that were surveyed;
- (f) The measured dose rate at several points in each area expressed in millirems (microsieverts) per hour;
- (g) The calculated maximum level of radiation over a period of 1 week for each restricted and unrestricted area; and

(h) The signature of the radiation safety officer or the teletherapy physicist.

Specific Authority: 404.022, 404.051, 404.061, 404.071, 404.081, 404.141, F.S.

Law Implemented: 404.022, 404.051(1)(4)(5)(6)(8)(9)(10)(11), 404.061(2)(3), 404.071(1), 404.081, 404.141, F.S.

R2 History: New August 25, 1991, Amended January 1, 1994, Formerly 10D-91.762, Amended October 8, 2000.

64E-5.644 Safety Spot-Checks for Teletherapy Facilities.

- (1) A licensee shall promptly spot-check all systems listed in 64E-5.642(7) for proper functioning after each installation of a teletherapy source and after making any change for which an amendment is required by 64E-5.636.
- (2) If the results of the safety spot-checks required in 64E-5.644(1) indicate the malfunction of any system specified in 64E-5.642, the licensee shall lock the control console in the off position and not use the unit except to repair, replace, or check the malfunctioning system.
- (3) A licensee shall maintain a record of the facility spot-checks following installation of a source for 3 years. The record shall include notations indicating the operability of each entrance door interlock, each electrical or mechanical stop, each beam condition indicator light, the viewing system, doors, and the signature of the radiation safety officer or the teletherapy physicist.

Specific Authority: 404.022, 404.051, 404.061, 404.071, 404.081, 404.141, F.S.

Law Implemented: 404.022, 404.051(1)(4)(5)(6)(8)(9)(10)(11), 404.061(2)(3), 404.071(1), 404.081, 404.141, F.S.

History: New August 25, 1991, Formerly 10D-91.763.

64E-5.645 Modification of Teletherapy Unit or Room Before Beginning a

R2 **Treatment Program.** If the survey required by Rule 64E-5.643, F.A.C., indicates that any
 R2 individual member of the public is likely to receive a dose in excess of those specified in Rule
 R2 64E-5.312(1)(c), F.A.C., before beginning the treatment program the licensee shall comply
 R2 with (1) or (2) below:

- (1) Equip the unit with stops or add additional radiation shielding to ensure
 R2 compliance with Rule 64E-5.312(1)(c), F.A.C.; perform the survey required by
 R2 Rule 64E-5.643, F.A.C., again; and include in the report required by Rule
 R2 64E-5.646, F.A.C., the results of the initial survey, a description of the
 R2 modification made to comply with Rule 64E-5.645(1), F.A.C., and the results of
 the second survey.
- (2) Request and receive a license amendment as provided in 64E-5.312(3) that
 authorizes radiation levels in unrestricted areas greater than those permitted by
 64E-5.312(1)(c).

Specific Authority: 404.022, 404.051, 404.061, 404.071, 404.081, 404.141, F.S.

Law Implemented: 404.022, 404.051(1)(4)(5)(6)(8)(9)(10)(11), 404.061(2)(3), 404.071(1), 404.081, 404.141, F.S.

R2 History: New August 25, 1991, Amended January 1, 1994, Formerly 10D-91.764, Amended October 8, 2000.

64E-5.646 Reports of Teletherapy Surveys, Checks, Tests, and Measurements.

A licensee shall furnish a copy of the records required in 64E-5.643, 64E-5.644, and 64E-5.645 and the output from the teletherapy source expressed as rads (grays) per hour at 1 meter from the source as determined during the full calibration required in 64E-5.641 to the department within 30 days following completion of the action that initiated the record requirement.

Specific Authority: 404.022, 404.051, 404.061, 404.071, 404.081, 404.141, F.S.

Law Implemented: 404.022, 404.051(1)(4)(5)(6)(8)(9)(10)(11), 404.061(2)(3), 404.071(1), 404.081, 404.141, F.S.

History: New August 25, 1991, Formerly 10D-91.765.

64E-5.647 Five Year Inspection.

- (1) A licensee shall have each teletherapy unit fully inspected and serviced during teletherapy source replacement or at least every 5 years, whichever comes first, to assure proper functioning of the source exposure mechanism.
- (2) This inspection and servicing shall only be performed by persons specifically licensed to do so by the department, an agreement state, or the U.S. Nuclear Regulatory Commission.
- (3) A licensee shall maintain a record of the inspection and servicing for the duration of the license. The record shall contain:
 - (a) The inspector's name;
 - (b) The inspector's license number;
 - (c) The date of inspection;
 - (d) The manufacturer's name and model number and serial number for both the teletherapy unit and source;
 - (e) A list of components inspected;
 - (f) A list of components serviced and the type of service;
 - (g) A list of components replaced; and
 - (h) The signature of the inspector.

Specific Authority: 404.022, 404.051, 404.061, 404.071, 404.081, 404.141, F.S.

Law Implemented: 404.022, 404.051(1)(4)(5)(6)(8)(9)(10)(11), 404.061(2)(3), 404.071(1), 404.081, 404.141, F.S.

History: New August 25, 1991, Formerly 10D-91.766.

SUBPART I TRAINING AND EXPERIENCE REQUIREMENTS

64E-5.648 Radiation Safety Officer. Except as provided in 64E-5.657, the licensee shall require the radiation safety officer to be certified as specified in (1) below or to complete 200 hours of classroom and laboratory training as specified in (2) below or to be an authorized user identified on the licensee's license.

- (1) Certification shall be by:
 - (a) American Board of Health Physics in Comprehensive Health Physics;
 - (b) American Board of Radiology in Radiological Physics, Therapeutic Radiological Physics, or Medical Nuclear Physics;

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- (c) American Board of Nuclear Medicine;
 - (d) American Board of Science in Nuclear Medicine; or
 - (e) Board of Pharmaceutical Specialties in Nuclear Pharmacy or Science.
- (2) Classroom and laboratory training shall consist of the following:
- (a) One hundred hours of radiation physics and instrumentation;
 - (b) Thirty hours of radiation protection;
 - (c) Twenty hours of mathematics pertaining to the use and measurement of radioactivity;
 - (d) Twenty hours of radiation biology;
 - (e) Thirty hours of radiopharmaceutical chemistry; and
 - (f) One year of full time experience in radiation safety at a medical institution under the supervision of the individual identified as the radiation safety officer on a department, agreement state, licensing state, or U.S. Nuclear Regulatory Commission license that authorizes the medical use of radioactive material.

Specific Authority: 404.022, 404.051, 404.061, 404.071, 404.081, 404.141, F.S.

Law Implemented: 404.022, 404.051(1)(4)(5)(6)(8)(9)(10)(11), 404.061(2)(3), 404.071(1), 404.081, 404.141, F.S.

History: New August 25, 1991, Formerly 10D-91.767.

64E-5.649 Training for Uptake, Dilution, or Excretion Studies. Except as provided in 64E-5.657, the licensee shall require the authorized user of a radiopharmaceutical listed in 64E-5.626 to be certified as specified in (1) below or to complete training and experience as specified in (2) below or to complete training as specified in (3) below.

- (1) Certification shall be in:
 - (a) Nuclear medicine by the American Board of Nuclear Medicine;
 - (b) Diagnostic radiology by the American Board of Radiology;
 - (c) Diagnostic radiology or radiology within the previous 5 years by the American Osteopathic Board of Radiology; or
 - (d) Nuclear medicine by the American Osteopathic Board of Nuclear Medicine.
- (2) Training and experience shall be as follows:
 - (a) Forty hours of instruction in basic radionuclide handling techniques applicable to the use of prepared radiopharmaceuticals, including:
 - 1. Fifteen hours of radiation physics and instrumentation;

2. Ten hours of radiation protection;
 3. Five hours of mathematics pertaining to the use and measurement of radioactivity;
 4. Five hours of radiation biology; and
 5. Five hours of radiopharmaceutical chemistry.
- (b) Twenty hours of training under the supervision of an authorized user including:
1. Examining patients and reviewing their case histories to determine their suitability for radionuclide diagnosis, limitations, or contraindications;
 2. Selecting the suitable radiopharmaceuticals and calculating and measuring the dosages;
 3. Administering dosages to patients and using syringe radiation shields;
 4. Collaborating with the authorized user in the interpretation of radionuclide test results; and
 5. Patient follow-up.
- (3) Training shall be a 6 month training program in nuclear medicine as part of a training program that has been approved by the Accreditation Council for Graduate Medical Education and shall include classroom and laboratory training, work experience, and supervised clinical experience in all the topics identified in 64E-5.649(2).

Specific Authority: 404.022, 404.051, 404.061, 404.071, 404.081, 404.141, F.S.

Law Implemented: 404.022, 404.051(1)(4)(5)(6)(8)(9)(10)(11), 404.061(2)(3), 404.071(1), 404.081, 404.141, F.S.

History: New August 25, 1991, Formerly 10D-91.769.

64E-5.650 Training for Imaging and Localization Studies. Except as provided in 64E-5.657, the licensee shall require the authorized user of a radiopharmaceutical, generator, or reagent kit specified in 64E-5.627 to be certified as specified in (1) below or to complete training and experience as specified in (2) below or to complete training as specified in (3) below.

- (1) Certification shall be in:
 - (a) Nuclear medicine by the American Board of Nuclear Medicine;
 - (b) Diagnostic radiology by the American Board of Radiology;
 - (c) Diagnostic radiology or radiology within the previous 5 years by the American Osteopathic Board of Radiology; or
 - (d) Nuclear medicine by the American Osteopathic Board of Nuclear

Medicine.

- (2) Training and experience shall be as follows:
- (a) Two hundred hours of instruction in basic radionuclide handling techniques applicable to the use of prepared radiopharmaceuticals, generators, and reagent kits, including:
1. One hundred hours of radiation physics and instrumentation;
 2. Thirty hours of radiation protection;
 3. Twenty hours of mathematics pertaining to the use and measurement of radioactivity;
 4. Thirty hours of radiopharmaceutical chemistry; and
 5. Twenty hours of radiation biology.
- (b) Five hundred hours of work experience under the supervision of an authorized user at a medical institution including:
1. Ordering, receiving, and unpacking radioactive materials safely and performing the related radiation surveys;
 2. Calibrating dose calibrators and diagnostic instruments and performing checks for proper operation of survey meters;
 3. Calculating and safely preparing patient dosages;
 4. Using administrative controls to prevent the misadministration of radioactive material;
 5. Using emergency procedures to contain spilled radioactive material safely and using proper decontamination procedures; and
 6. Eluting technetium 99m from generator systems, assaying and testing the eluate for molybdenum 99 and alumina contamination, and processing the eluate with reagent kits to prepare technetium 99m labeled radiopharmaceuticals.
- (c) Five hundred hours of clinical experience under the supervision of an authorized user at a medical institution including:
1. Examining patients and reviewing their case histories to determine their suitability for radionuclide diagnosis, limitations, or contraindications;
 2. Selecting the suitable radiopharmaceuticals and calculating and measuring the dosages;

3. Administering dosages to patients and using syringe radiation shields;
 4. Collaborating with the authorized user in the interpretation of radionuclide test results; and
 5. Patient follow-up.
- (d) The radiation safety committee shall approve in writing any training of a physician, dentist or podiatrist to receive, possess or use radioactive material under the supervision of an authorized user at a medical institution. After training has been completed, the radiation safety committee shall provide documentation to the supervised individual that he has received the training and experience required by this section.
- (3) Training shall be a 6 month training program in nuclear medicine that has been approved by the Accreditation Council for Graduate Medical Education and shall include classroom and laboratory training, work experience, and supervised clinical experience in all the topics identified in 64E-5.650(2).

Specific Authority: 404.022, 404.051, 404.061, 404.071, 404.081, 404.141, F.S.

Law Implemented: 404.022, 404.051(1)(4)(5)(6)(8)(9)(10)(11), 404.061(2)(3), 404.071(1), 404.081, 404.141, F.S.

History: New August 25, 1991, Formerly 10D-91.770.

64E-5.651 Training for Therapeutic Use of Radiopharmaceuticals. Except as provided in 64E-5.657, the licensee shall require the authorized user of a radiopharmaceutical listed in 64E-5.630 for therapy to be certified as specified in (1) below or to complete training and experience as specified in (2) below.

- (1) Certification shall be by one of the following groups:
 - (a) The American Board of Nuclear Medicine; or
 - (b) The American Board of Radiology in radiology, radiation oncology, or therapeutic radiology.
- (2) Training and experience shall be as follows:
 - (a) Eighty hours of instruction in basic radionuclide handling techniques applicable to the use of therapeutic radiopharmaceuticals including:
 1. Twenty five hours of radiation physics and instrumentation;
 2. Twenty five hours of radiation protection;
 3. Ten hours of mathematics pertaining to the use and measurement of radioactivity; and
 4. Twenty hours of radiation biology.
 - (b) Clinical experience under the supervision of an authorized user at a medical institution, including:

1. Use of iodine 131 for diagnosis of thyroid function and the treatment of hyperthyroidism or cardiac dysfunction in 10 individuals;
 2. Use of soluble phosphorus 32 for the treatment of ascites, polycythemia vera, leukemia, or bone metastases in three individuals;
 3. Use of iodine 131 for treatment of thyroid carcinoma in three individuals; and
 4. Use of colloidal chromic phosphorus 32 or of colloidal gold 198 for intracavitary treatment of malignant effusions in three individuals.
- (c) The radiation safety committee shall approve in writing any training of a physician, dentist or podiatrist to receive, possess or use radioactive material under the supervision of an authorized user at a medical institution. After training has been completed, the radiation safety committee shall provide documentation to the supervised individual that he has received the training and experience required by this section.

Specific Authority: 404.022, 404.051, 404.061, 404.071, 404.081, 404.141, F.S.

Law Implemented: 404.022, 404.051(1)(4)(5)(6)(8)(9)(10)(11), 404.061(2)(3), 404.071(1), 404.081, 404.141, F.S.

History: New August 25, 1991, Formerly 10D-91.771.

64E-5.652 Training for Therapeutic Use of Brachytherapy Sources. Except as provided in 64E-5.657, the licensee shall require the authorized user of a brachytherapy source specified in 64E-5.632 to be in the active practice of therapeutic radiology. In addition, the individual shall be certified as specified in (1) below or shall complete training and experience as specified in (2) below.

- (1) Certification shall be in:
 - (a) Radiology, radiation oncology or therapeutic radiology by the American Board of Radiology;
 - (b) Radiation oncology by the American Osteopathic Board of Radiology;
 - (c) Radiology, with a specialization in radiotherapy, as a British Fellow of the Faculty of Radiology or Fellow of the Royal College of Radiology; or
 - (d) Therapeutic radiology by the Canadian Royal College of Physicians and Surgeons.
- (2) Training and experience shall be as follows:
 - (a) Two hundred hours of instruction in basic radionuclide handling techniques applicable to the therapeutic use of brachytherapy sources including:

1. One hundred and ten hours of radiation physics and instrumentation;
 2. Forty hours of radiation protection;
 3. Twenty five hours of mathematics pertaining to the use and measurement of radioactivity; and
 4. Twenty five hours of radiation biology.
- (b) Five hundred hours of work experience under the supervision of an authorized user at a medical institution including:
1. Ordering, receiving, and unpacking radioactive materials safely and performing the related radiation surveys;
 2. Checking survey meters for proper operation;
 3. Preparing, implanting, and removing sealed sources;
 4. Using administrative controls to prevent the misadministration of radioactive material; and
 5. Using emergency procedures to control radioactive material.
- (c) Three years of supervised clinical experience including 1 year in a formal training program approved by the Residency Review Committee for Radiology of the Accreditation Council for Graduate Medical Education or the Committee on Postdoctoral Training of the American Osteopathic Association, and an additional 2 years of clinical experience in therapeutic radiology under the supervision of an authorized user at a medical institution, including:
1. Examining individuals and reviewing their case histories to determine their suitability for brachytherapy treatment, and any limitations or contraindications;
 2. Selecting the proper brachytherapy source, dose, and method of administration;
 3. Calculating the dose; and
 4. Post-administration follow-up and review of case histories in collaboration with the authorized user.

- (d) The radiation safety committee shall approve in writing any training of a physician, dentist or podiatrist to receive, possess or use radioactive material under the supervision of an authorized user at a medical institution. After training has been completed, the radiation safety committee shall provide documentation to the supervised individual that he has received the training and experience required by this section.

Specific Authority: 404.022, 404.051, 404.061, 404.071, 404.081, 404.141, F.S.

Law Implemented: 404.022, 404.051(1)(4)(5)(6)(8)(9)(10)(11), 404.061(2)(3), 404.071(1), 404.081, 404.141, F.S.

History: New August 25, 1991, Formerly 10D-91.772.

64E-5.653 Training for Ophthalmic Use of Strontium 90. Except as provided in 64E-5.657, the licensee shall require the authorized user of only strontium 90 for ophthalmic radiotherapy to be in the active practice of therapeutic radiology or ophthalmology. In addition, the individual shall be certified as specified in (1) below or shall complete training and experience as specified in (2) below.

- (1) Certification shall be in radiology, radiation oncology or therapeutic radiology by the American Board of Radiology.
- (2) Training and experience shall be as follows:
- (a) Twenty four hours of instruction in basic radionuclide handling techniques applicable to the use of strontium 90 for ophthalmic radiotherapy, including:
1. Six hours of radiation physics and instrumentation;
 2. Six hours of radiation protection;
 3. Four hours of mathematics pertaining to the use and measurement of radioactivity; and
 4. Eight hours of radiation biology.
- (b) Clinical training in ophthalmic radiotherapy under the supervision of an authorized user at a medical institution, including the use of strontium 90 for the ophthalmic treatment of five individuals that includes:
1. Examination of each individual to be treated;
 2. Calculation of the dose to be administered;
 3. Administration of the dose; and
 4. Follow-up and review of each individual's case history.
- (c) The radiation safety committee shall approve in writing any training of a physician, dentist or podiatrist to receive, possess or use radioactive material under the supervision of an authorized user at a medical institution. After training has been completed, the radiation safety committee shall provide documentation to the supervised individual that he has received the training and experience required by this section.

Specific Authority: 404.022, 404.051, 404.061, 404.071, 404.081, 404.141, F.S.

Law Implemented: 404.022, 404.051(1)(4)(5)(6)(8)(9)(10)(11), 404.061(2)(3), 404.071(1), 404.081, 404.141, F.S.

History: New August 25, 1991, Formerly 10D-91.773.

64E-5.654 Training for Use of Sealed Sources for Diagnosis. Except as provided in 64E-5.657, the licensee shall require the authorized user of a sealed source in a device specified in 64E-5.631 to be a physician, dentist, or podiatrist who is certified as specified in (1) below or who has completed the training as specified in (2) below.

- (1) Certification shall be in:
 - (a) Radiology, diagnostic radiology, radiation oncology, or therapeutic radiology by the American Board of Radiology;
 - (b) Nuclear medicine by the American Board of Nuclear Medicine;
 - (c) Diagnostic radiology or radiology by the American Osteopathic Board of Radiology; or
 - (d) Nuclear Medicine by the American Osteopathic Board of Nuclear Medicine.
- (2) Training shall be 8 hours of instruction in basic radionuclide handling techniques specifically applicable to the use of the device, including:
 - (a) Three hours of radiation physics, mathematics pertaining to the use and measurement of radioactivity, and instrumentation;
 - (b) Three hours of radiation biology; and
 - (c) Two hours of radiation protection and training in the use of the device for the purposes authorized by the license.

Specific Authority: 404.022, 404.051, 404.061, 404.071, 404.081, 404.141, F.S.

Law Implemented: 404.022, 404.051(1)(4)(5)(6)(8)(9)(10)(11), 404.061(2)(3), 404.071(1), 404.081, 404.141, F.S.

History: New August 25, 1991, Formerly 10D-91.774.

64E-5.655 Training for Teletherapy. Except as provided in 64E-5.657, the licensee shall require the authorized user of a sealed source specified in 64E-5.634 in a teletherapy unit to be in the active practice of therapeutic radiology. In addition, the individual shall be certified as specified in (1) below or shall complete training and experience as specified in (2) below.

- (1) Certification shall be in:
 - (a) Radiology, radiation oncology, or therapeutic radiology by the American Board of Radiology;
 - (b) Radiation oncology by the American Osteopathic Board of Radiology;
 - (c) Radiology, with specialization in radiotherapy, as a British Fellow of the Faculty of Radiology or Fellow of the Royal College of Radiology; or

- (d) Therapeutic radiology by the Canadian Royal College of Physicians and Surgeons.
- (2) Training and experience shall be as follows:
- (a) Two hundred hours of instruction in basic radionuclide techniques applicable to the use of a sealed source in a teletherapy unit, including:
 - 1. One hundred and ten hours of radiation physics and instrumentation;
 - 2. Forty hours of radiation protection;
 - 3. Twenty five hours of mathematics pertaining to the use and measurement of radioactivity; and
 - 4. Twenty five hours of radiation biology.
 - (b) Five hundred hours of work experience under the supervision of an authorized user at a medical institution, including:
 - 1. Review of the full calibration measurements and periodic spot checks;
 - 2. Preparing treatment plans and calculating treatment times;
 - 3. Using administrative controls to prevent misadministrations;
 - 4. Implementing emergency procedures to be followed in the event of the abnormal operation of a teletherapy unit or console; and
 - 5. Checking and using survey meters.
 - (c) Three years of supervised clinical experience including 1 year in a formal training program approved by the Residency Review Committee for Radiology of the Accreditation Council for Graduate Medical Education or the Committee on Postdoctoral Training of the American Osteopathic Association and an additional 2 years of clinical experience in therapeutic radiology under the supervision of an authorized user at a medical institution, including:
 - 1. Examining individuals and reviewing their case histories to determine their suitability for teletherapy treatment, and any limitations or contraindications;
 - 2. Selecting the proper dose and how it is to be administered;
 - 3. Calculating the teletherapy doses and collaborating with the authorized user in the review of patient's progress and consideration of the need to modify originally prescribed doses as warranted by patient's reaction to radiation; and

4. Post administration follow-up and review of case histories.

- (d) The radiation safety committee shall approve in writing any training of a physician, dentist or podiatrist to receive, possess or use radioactive material under the supervision of an authorized user at a medical institution. After training has been completed, the radiation safety committee shall provide documentation to the supervised individual that he has received the training and experience required by this section.

Specific Authority: 404.022, 404.051, 404.061, 404.071, 404.081, 404.141, F.S.

Law Implemented: 404.022, 404.051(1)(4)(5)(6)(8)(9)(10)(11), 404.061(2)(3), 404.071(1), 404.081, 404.141, F.S.

History: New August 25, 1991, Formerly 10D-91.775.

64E-5.656 Training for Teletherapy Physicist. The licensee shall require the teletherapy physicist to be certified as specified in (1) below or meet the requirements specified in (2) below.

- (1) Certification shall be by the American Board of Radiology in:
- (a) Therapeutic radiological physics;
 - (b) Roentgen-ray and gamma-ray physics;
 - (c) X-ray and radium physics; or
 - (d) Radiological physics.
- (2) Education and training shall be a master's or doctor's degree in physics, biophysics, radiological physics, or health physics, and have completed 1 year of full-time training in therapeutic radiological physics and also 1 year of full-time work experience under the supervision of a teletherapy physicist at a medical institution. To meet this requirement, the individual shall have performed the tasks listed in 64E-5.618, 64E-5.641, 64E-5.642, and 64E-5.643 under the supervision of a teletherapy physicist during the year of work experience.

Specific Authority: 404.022, 404.051, 404.061, 404.071, 404.081, 404.141, F.S.

Law Implemented: 404.022, 404.051(1)(4)(5)(6)(8)(9)(10)(11), 404.061(2)(3), 404.071(1), 404.081, 404.141, F.S.

History: New August 25, 1991, Formerly 10D-91.776.

64E-5.657 Training for Experienced Authorized Users or Radiation Safety Officers. Authorized users or radiation safety officers identified on a department, U.S. Nuclear Regulatory Commission, agreement state or licensing state license on August 25, 1991 who perform only those methods of use for which they were authorized on that date need not comply with the applicable training requirements of 64E-5.648 through 64E-5.658.

Specific Authority: 404.051, 404.061, 404.071, F.S.

Law Implemented: 404.022, 404.051(1)(4)(10)(11), 404.061(2)(3), 404.071(3) 404.141, F.S.

History: New August 25, 1991, Amended May 15, 1996, Formerly 10D-91.777.

64E-5.658 Recentness of Training. The training and experience specified in 64E-5.648 through 64E-5.656 shall have been obtained within the 5 years preceding the date of application or the individual shall have had related continuing education or experience since the required training and experience was completed and within the 5 years preceding the date of application.

Specific Authority: 404.022, 404.051, 404.061, 404.071, 404.081, 404.141, F.S.

Law Implemented: 404.022, 404.051(1)(4)(5)(6)(8)(9)(10)(11), 404.061(2)(3), 404.071(1), 404.081, 404.141, F.S.

History: New August 25, 1991, Formerly 10D-91.779.

**PART VII RADIATION SAFETY REQUIREMENTS FOR
ANALYTICAL X-RAY EQUIPMENT**

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PART VII

RADIATION SAFETY REQUIREMENTS FOR ANALYTICAL X-RAY EQUIPMENT

64E-5.701 Equipment Requirements.

- (1) Safety Device. A device which prevents the entry of any portion of an individual's body into the primary x-ray beam path or which causes the beam to be shut off upon entry into its path shall be provided on all open-beam configurations. A registrant may apply to the department for an exemption from the requirement of a safety device. Such application shall include:
 - (a) A description of the various safety devices that have been evaluated;
 - (b) The reason each of these devices cannot be used; and
 - (c) A description of the alternative methods that will be employed to minimize the possibility of an accidental exposure, including procedures to assure that the operator and others in the area will be informed of the absence of safety devices.
- (2) Warning Devices.
 - (a) Open-beam configurations shall be provided with a readily discernible indication of:
 1. X-ray tube on-off status located near the radiation source housing, if the primary beam is controlled in this manner; or
 2. Shutter open-closed status located near each port on the radiation source housing, if the primary beam is controlled in this manner.
 - (b) Warning devices shall be labeled so that their purpose is easily identified.
 - (c) Warning devices shall have fail-safe characteristics.
- (3) Ports. Unused ports on radiation source housings shall be secured in the closed position in a manner which will prevent inadvertent opening.
- (4) Labeling. All analytical x-ray equipment shall be labeled with a readily discernible sign or signs bearing the radiation symbol and the words:
 - (a) "CAUTION - HIGH INTENSITY X-RAY BEAM", or words having a similar intent, on the x-ray source housing; and
 - (b) "CAUTION RADIATION -- THIS EQUIPMENT PRODUCES RADIATION WHEN ENERGIZED", or words having a similar intent, near any switch that energizes an x-ray tube if the radiation source is an x-ray tube.
- (5) Shutters. On open-beam configurations, each port on the radiation source

housing shall be equipped with a shutter that cannot be opened unless a collimator or a coupling has been connected to the port.

- (6) **Warning Lights.** An easily visible warning light labeled with the words "X-RAY ON", or words having a similar intent, having fail-safe characteristics, shall be located near any switch that energizes an x-ray tube and shall be illuminated only when the tube is energized.
- (7) **Radiation Source Housing.** Each x-ray tube housing installed after the effective date of these regulations shall be so constructed that, with all shutters closed, the leakage radiation measured at a distance of 5 cm from its surface is not capable of producing a dose in excess of 2.5 mrem (0.025 mSv) in any given hour at any specified tube rating.
- (8) Each x-ray generator shall be supplied with a protective cabinet which limits leakage radiation measured at a distance of 5 cm from its surface such that it is not capable of producing a dose in excess of 0.25 mrem (2.5 uSv) in any given hour.

Specific Authority: 404.051, 404.141, 404.22, F.S.
Law Implemented: 404.051(1)(4)(6), 404.141, 404.22, F.S.
History: New July 17, 1985, Formerly 10D-91.803.

64E-5.702 Area Requirements.

- (1) **Radiation Levels.** The local components of an analytical x-ray system shall be located and arranged and shall include sufficient shielding or have access control such that no radiation levels exist in any area surrounding the local component group which could result in a dose to an individual present therein in excess of the dose limits given in 64E-5.312. For systems utilizing x-ray tubes, these levels shall be met at any specified tube rating.
- (2) **Surveys.**
 - (a) Radiation surveys, as required by 64E-5.314, of all analytical x-ray systems sufficient to show compliance with (1), above, shall be performed:
 1. Upon installation of the equipment and at least once every 12 months thereafter;
 2. Following any change in the initial arrangement, number or type of local components in the system;
 3. Following any maintenance requiring the disassembly or removal of a local component of the system;

4. During the performance of maintenance and alignment procedures if the procedures require the presence of a primary x-ray beam when any local component in the system is disassembled or removed;
 5. Any time a visual inspection of the local components of the system reveals an abnormal condition; and
 6. Whenever personnel monitoring devices show a significant increase over the previous monitoring period or the readings are approaching the limits specified in 64E-5.312.
- (b) Radiation survey measurements shall not be required if a registrant can demonstrate compliance with (1), above, to the satisfaction of the department.
- (3) Posting. Each area or room containing analytical x-ray equipment shall be conspicuously posted with a sign or signs bearing the radiation symbol and the words "CAUTION -- X-RAY EQUIPMENT", or words having a similar intent.

Specific Authority: 404.051, 404.141, 404.22, F.S.

Law Implemented: 404.051(1)(4)(6), 404.141, 404.22, F.S.

History: New July 17, 1985, Amended January 1, 1994, Formerly 10D-91.804.

64E-5.703 Operating Requirements.

- (1) Procedures. Normal operating procedures shall be written and available to all analytical x-ray equipment workers. No individual shall be permitted to operate analytical x-ray equipment in any manner other than that specified in the procedures unless such individual has obtained the written approval of the radiation safety officer.
- (2) Bypassing. No individual shall bypass a safety device or interlock unless such individual has obtained the written approval of the radiation safety officer. Such approval shall be for a specified period of time. When a safety device or interlock has been bypassed, a readily discernible sign bearing the words "SAFETY DEVICE NOT WORKING", or words having a similar intent, shall be placed on the radiation source housing.
- (3) Repair or Modification of X-ray Tube Systems. Except as specified in (2), above, no operation involving removal of covers, shielding materials or tube housings or modifications to shutters, collimators or beam stops shall be performed without first ascertaining that the tube is off and will remain off until safe conditions have been restored. The main switch, rather than interlocks, shall be used for routine shutdown in preparation for repairs.

Specific Authority: 404.051, 404.081, 404.22, F.S.

Law Implemented: 404.051(1)(4)(6), 404.081(1), 404.22, F.S.

History: New July 17, 1985, Formerly 10D-91.805.

64E-5.704 Personnel Requirements.

- (1) Instruction. No person shall be permitted to operate or maintain analytical x-ray equipment unless such person has received instruction in and demonstrated competence as to:
 - (a) Identification of radiation hazards associated with the use of the equipment;
 - (b) Significance of the various radiation warning and safety devices incorporated into the equipment, or the reasons they have not been installed on certain pieces of equipment and the extra precautions required in such cases;
 - (c) Proper operating procedures for the equipment;
 - (d) Symptoms of an acute localized overexposure; and
 - (e) Proper procedures for reporting an actual or suspected overexposure.
- (2) Personnel Monitoring.
 - (a) Finger or wrist dosimetric devices shall be provided to and shall be used by:
 1. Analytical x-ray equipment workers using systems having an open-beam configuration and not equipped with a safety device; and
 2. Personnel maintaining analytical x-ray equipment, if the maintenance procedures require the presence of a primary x-ray beam when any local component in the analytical x-ray system is disassembled or removed.
 - (b) Reported dose values shall not be used for the purpose of determining compliance with 64E-5.304 unless evaluated by a qualified person, as defined in 64E-5.501(61).

Specific Authority: 04.051, 404.22, F.S.

Law Implemented: 404.051(1)(4), 404.22, F.S.

History: New July 17, 1985, Amended January 1, 1994, Formerly 10D-91.806.

**PART VIII RADIATION SAFETY REQUIREMENTS FOR ANALYTICAL
PARTICLE ACCELERATORS**

SUBPART A REGISTRATION PROCEDURE

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PART VIII

RADIATION SAFETY REQUIREMENTS FOR ANALYTICAL PARTICLE ACCELERATORS

SUBPART A REGISTRATION PROCEDURE

64E-5.801 Registration Requirements.

- (1) No person shall receive, possess, use, transfer, or acquire a particle accelerator facility or a particle accelerator except as authorized by a registration certificate issued by the department pursuant to these rules.
- (2) Application for registration shall be made on DH Form 1107, which is incorporated by reference herein effective July 17, 1989 furnished by the department, and shall contain all information required by the form and accompanying instructions. Part V contains rules concerning registration and the payment of registration fees.

Specific Authority: 404.051, 404.22, F.S.

Law Implemented: 404.022, 404.051(1)(4)(9), 404.22(1), F.S.

History: New July 17, 1985, Amended May 15, 1996, Formerly 10D-91.902.

64E-5.802 General Requirements for the Issuance of a Registration Certificate for Particle Accelerators. A registration application for acquisition and use of a particle accelerator or particle accelerator facility will be approved only if the department determines that:

- (1) The applicant is qualified by reason of training and experience to use the accelerator in question for the purpose requested in accordance with this part and Parts III and IX in such a manner as to minimize danger to public health and safety or property;
- (2) The applicant's proposed or existing equipment, facilities, and operating and emergency procedures are adequate to protect health and minimize danger to public health and safety or property;
- (3) The issuance of the registration certificate will not be inimical to the health and safety of the public, and the applicant satisfies any applicable special requirement in 64E-5.803;
- (4) The applicant has appointed a radiation safety officer;
- (5) The applicant or the applicant's staff have substantial experience in the use of particle accelerators and training sufficient to properly use the accelerator for accomplishment of the intended objectives; and
- (6) The applicant has a radiation safety training program for operators of particle accelerators.

Specific Authority: 404.051, 404.22, F.S.

Law Implemented: 404.022, 404.051(1)(4)(8)(9), 404.22(1), F.S.

History: New July 17, 1985, Formerly 10D-91.903.

64E-5.803 Particle Accelerators for Therapeutic Use on Humans. In addition to the general registration requirements set forth in 64E-5.802, accelerators used for treatment of humans will be registered only if the department determines that:

- (1) The applicant agrees to appoint a medical committee of at least two physicians, one of whom is expert in radiation therapy, plus a person experienced in depth dose calculations and radiation protection, for the purpose of evaluating and approving all proposed uses involving exposure of human beings;
- (2) Persons designated on the application as the authorized users have had training and experience in treatment of humans utilizing radiations of the type and at energies near those produced by the accelerator to be employed;
- (3) Individuals designated on the registration application as authorized users are physicians, as defined in 64E-5.101; and
- (4) The applicable provisions of 64E-5.508 are met.

Specific Authority: 404.051, 404.081, 404.141, 404.22, F.S.

Law Implemented: 404.022, 404.081(1), 404.141, 404.051(1)(4)(8)(9), 404.22(1), F.S.

History: New July 17, 1985, Amended August 29, 1994, Formerly 10D-91.904.

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SUBPART B
RADIATION SAFETY REQUIREMENTS
FOR THE USE OF PARTICLE ACCELERATORS

64E-5.804 Limitations.

- (1) The registrant shall not permit any person to act as a particle accelerator operator until such person:
 - (a) Has been instructed in accelerator radiation safety and has demonstrated an understanding thereof;
 - (b) Has received copies of and instructions in this part and the applicable requirements of Parts III and IX, pertinent registration conditions and the registrant's operating and emergency procedures, and has demonstrated an understanding thereof; and
 - (c) Has demonstrated competence to use the particle accelerator, related equipment and survey instruments which will be employed in assignment.
- (2) The radiation safety officer shall have the authority to terminate the operations at a particular accelerator facility if such action is deemed necessary to protect health and minimize danger to public health and safety or property.

Specific Authority: 404.051, 404.22, F.S.

Law Implemented: 404.022, 404.051(1)(4), 404.22(1), F.S.

History: New July 17, 1985, Formerly 10D-91.906.

64E-5.805 Shielding and Safety Design Requirements.

- (1) A radiological physicist, as defined in 64E-5.501(66), shall be consulted in the design of each particle accelerator installation and shall be responsible for specification of barrier materials and thicknesses. Plans and specifications, along with assumptions and calculations on which the shielding design is based, shall be filed with the department.
- (2) Each particle accelerator installation shall be provided with the primary and secondary barriers necessary to comply with 64E-5.304 and 64E-5.312.
- (3) A qualified person, as defined in 64E-5.501(61), not necessarily the consultant involved in the design, shall be engaged to perform a radiation survey of the facility when the accelerator is first capable of producing radiation, and such survey shall include measurements of all types of radiation produced under all modes of operation at maximum operating potential.

Specific Authority: 404.051, 404.22, F.S.

Law Implemented: 404.022, 404.051(1)(4)(5)(6), 404.22(1), F.S.

History: New July 17, 1985, Amended January 1, 1994, Formerly 10D-91.907.

64E-5.806 Particle Accelerator Controls and Interlock Systems.

- (1) Instrumentation, readouts and controls on the particle accelerator control console shall be clearly identified and easily discernible.

- (2) All entrances into a target room or other high radiation area shall be provided with interlocks that shut down the machine under conditions of barrier penetration.
- (3) When an interlock system has been tripped, it shall only be possible to resume operation of the accelerator by manually resetting controls at the position where the interlock has been tripped, and lastly at the main control console. The approval of such plans shall not preclude the requirement of additional modifications should a subsequent analysis of operating conditions indicate the possibility of an individual receiving a dose in excess of the limits prescribed in 64E-5.304, 64E-5.310 and 64E-5.312.
- (4) Each safety interlock shall be on a circuit which shall allow its operation independently of all other safety interlocks.
- (5) All safety interlocks shall function to the extent that any defect or component failure in an interlock system will either prevent operation of the accelerator or will produce a conspicuous audible signal or flashing warning light both at the control and at the barrier involved. Warning signals, where employed, shall not be disconnected or otherwise disabled, but shall continue to produce the warning signal during accelerator operation until the interlock has been restored to proper operation. Any failure of the warning system shall prevent operation of the accelerator.
- (6) A scram button or other emergency power cutoff switch shall be located and easily identifiable in all high radiation areas. Such a cutoff switch shall include a manual reset so that the accelerator cannot be restarted from the accelerator control console without resetting the cutoff switch.

Specific Authority: 404.051, 404.22, F.S.

Law Implemented: 404.022, 404.051(1)(4), 404.22(1), F.S.

History: New July 17, 1985, Amended January 1, 1994, Formerly 10D-91.908.

64E-5.807 Warning Devices.

- (1) All locations designated as high radiation areas, and all entrances to such locations shall be equipped with easily observable warning lights that operate when and only when radiation is being produced.
- (2) Except in facilities designed for human exposure, each high radiation area shall have an audible warning device which shall be activated for 15 seconds prior to the possible creation of such high radiation area. Such warning device shall be clearly discernible in all high radiation areas and in any adjacent radiation areas.
- (3) Barriers, temporary or otherwise, and pathways leading to high radiation areas shall be identified in accordance with 64E-5.322 and 64E-5.323.

Specific Authority: 404.051, 404.022, F.S.

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

History: New July 17, 1985, Amended January 1, 1994, Formerly 10D-91.909.

64E-5.808 Operating Procedures.

- (1) Particle accelerators, when not in operation, shall be secured to prevent unauthorized use.
- (2) The safety interlock system shall not be used to turn off the accelerator beam except in an emergency or test situation.
- (3) All safety and warning devices, including interlocks, shall be checked for proper operability at intervals not to exceed 1 month. Results of such tests shall be maintained for inspection by the department at the accelerator facility.
- (4) Electrical circuit diagrams of the accelerator, and the associated interlock systems, shall be kept current and available to the operator at each accelerator facility and maintained for inspection by the department.
- (5) If, for any reason, it is necessary to intentionally bypass a safety interlock or interlocks, such action shall be:
 - (a) Authorized by the radiation safety committee or radiation safety officer;
 - (b) Recorded in a permanent log and notice posted at the accelerator control console; and
 - (c) Terminated as soon as possible.
- (6) A copy of the current operating and the emergency procedures shall be maintained at the accelerator control panel.

Specific Authority: 404.051, 404.081, 404.22, F.S.

Law Implemented: 404.022, 404.051(1)(4), 404.081(1), 404.22(1), F.S.

History: New July 17, 1985, Formerly 10D-91.910.

64E-5.809 Radiation Monitoring Requirements.

- (1) At each particle accelerator facility capable of producing radioactive materials by activation, the registrant shall provide appropriate portable monitoring equipment which is operable and has been calibrated for the radiations being produced at the facility. Such equipment shall be tested for proper operation each day of use and calibrated at intervals not to exceed 12 months and after each servicing or repair.
- (2) A radiation survey shall be performed and documented by a qualified person, as defined in 64E-5.501(61), when changes have been made in shielding, operation, or equipment within the facility or in the occupancy of adjacent areas.

- (3) Radiation levels in all high radiation areas shall be continuously monitored. The monitoring device shall be electrically independent of the accelerator control and interlock systems and capable of providing a visual or audible alarm at the entrance to high radiation areas, and other appropriate locations, so that people entering or present become aware of the existence of the hazard. A remote readout shall be located at the control panel when the production of radioactive materials by activation could cause a high radiation area.
- (4) Area monitors designed and intended to display the exposure rate shall be calibrated at intervals not to exceed 1 year and after each servicing and repair.
- (5) Whenever applicable, surveys shall be made to determine the amount of airborne particulate radioactivity present in areas of airborne hazards.
- (6) Whenever applicable, smear surveys shall be made to determine the degree of contamination in target and other pertinent areas
- (7) All area surveys shall be made in accordance with the written procedures established by a qualified person, as defined in 64E-5.501(61), or the radiation safety officer of the particle accelerator facility.
- (8) Records of all radiation protection surveys, calibration results, instrumentation tests, and smear results shall be kept current and on file at each accelerator facility for inspection by the department for 3 years.

Specific Authority: 404.051, 404.061, 404.081, 404.22, F.S.

Law Implemented: 404.022, 404.051(1)(4)(6), 404.061(1), 404.081(1), 404.22, F.S.

History: New July 17, 1985, Formerly 10D-91.911.

64E-5.810 Ventilation Systems.

- (1) Means shall be provided to ensure that personnel entering any area where airborne radioactivity may be produced will not be exposed to concentrations in excess of the limits specified in State of Florida Bureau of Radiation Control ALIs, DACs, and Effluent Concentrations, July 1993, Table I., Column 3.
- (2) A registrant shall not vent, release or otherwise discharge airborne radioactive material to an uncontrolled area in concentrations which exceed the limits specified in State of Florida Bureau of Radiation Control ALIs, DACs, and Effluent Concentrations, July 1993, Table I., Column 3, except as authorized pursuant to 64E-5.329. For purposes of this paragraph, concentrations may be averaged over a period not greater than 1 year. Every reasonable effort should be made to maintain releases of radioactive material to uncontrolled areas, as far below these limits as reasonably achievable.

Specific Authority: 404.051, 404.061, 404.081, F.S.

Law Implemented: 404.022, 404.051(1)(4), 404.061(1), 404.081(1), F.S.

History: New July 17, 1985, Amended January 1, 1994, Formerly 10D-91.912.