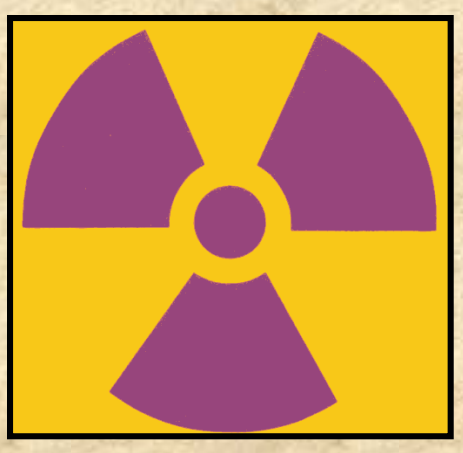
CONTROL OF RADIATION HAZARD REGULATIONS



Chapter 64E-5
Florida Administrative Code

Effective Date July 3, 1997 Includes

Revision 1	May 18, 2000
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Revision 10	February 11, 2010
Revision 11	May 8, 2013
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RULES OF THE STATE OF FLORIDA
DEPARTMENT OF HEALTH
CHAPTER 64E-5
CONTROL OF RADIATION HAZARD REGULATIONS

This copy of the regulations do not contain certain parts applicable to a particular section. Contact the applicable Bureau of Radiation Control Section or the Bureau of Epidemiology – Radon and Indoor Air Quality Program for a copy of parts not herein contained.

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Chronology of Rule Revisions

Revision	Effective Date	Sections Affected
R1	05-18-1998	64E-5.101, 64E-5.204, 64E-5.213, 64E-5.214, 64E-5.319, 64E-5.332, 64E-5.333, 64E-5.334, 64E-5.347, 64E-5.402, 64E-5.422, 64E-5.502, 64E-5.504, 64E-5.510, 64E-5.617, 64E-5.902, 64E-5.1513, Requirements for Transfers of Low-Level Radioactive Waste Intended for Disposal at Licensed Land Disposal Facilities and Manifest, July 1997.
R2	10-8-2000	64E-5.101, 64E-5.201, 64E-5.203, 64E-5.204, 64E-5.214, 64E-5.216, 64E-5.301, 64E-5.303, 64E-5.304, 64E-5.309, 64E-5-311, 64E-5.312, 64E-5.314, 64E-5.315, 64E-5.323, 64E-5.326, 64E-5.334, 64E-5.339, 64E-5.344, 64E-5.345, 64E-5.414, 64E-5.420, 64E-5.422, 64E-5.505, 64E-5.622, 64E-5.625, 64E-5.643, 64E-5.645, 64E-5.1103, 64E-5.1112, 64E-5.1310, 64E-5.1406, 64E-5.1418, 64E-5.1502, 64E-5.1513 Radioactive Material Requiring Labeling, May 2000
R3	8-6-2001	64E-5.101, 64E-5.201, 64E-5.603, 64E-5.606. 64E-5.626, 64E-5.627, 64E-5.630
R4	9-11-2001	64E-5.401 - 64E-5.422 repealed and replaced with sections 64E-5.423, 64E-5.424, 64E-5.425, 64E-5.426, 64E-5.427, 64E-5.428, 64E-5.429, 64E-5.430, 64E-5.431, 64E-5.432, 64E-5.433, 64E-5.434, 64E-5.435, 64E-5.436, 64E-5.437, 64E-5.438, 64E-5.439, 64E-5.440, 64E-5.441
R5	12-19-2001	64E-5.101, 64E-5.214, 64E-5.221, 64E-5.222, 64E-5.223, 64E-5.224, 64E-5.225, 64E-5.226, 64E-5.901, Notice to Employees 3/01
R6	9-28-2006	64E-5.101, 64E-5.204, 64E-5.206, 64E-5.210 , 64E-5.213, 64E-5.304, 64E-5.318, 64E-5.319, 64E-5.427, 64E-5.429, 64E-5.434, 64E-5.440, 64E-5.441, 64E-5.1104, 64E-5.1107, 64E-5.11071, 64E-5.11072, 64E-5.11073, 64E-5.1112, 64E-5.1119, 64E-5.1311, 64E-5.1502, Bureau of Radiation Control Respiratory Protection Factors May 2006, Transfers of Industrial Devices Report 10-2003
R7	8-18-2007	64E-5.101, 64E-5.204, 64E-5.210, 64E-5.502, 64E-5.504, 64E-5.506, 64E-5.511, 64E-5.1508, Transfers of Industrial Devices Report 04/2007, Radiation Machine Facility Registration DH 03/2007
R8	2-28-2008	64E-5.101, 64E-5.206, 64E-5.206, 64E-5.210, 64E-5.216, **New** 64E-5.350, **New** 64E-5.351, 64E-5.430, 64E-5.440, 64E-5.441, 64E-5.1003, 64E-5.11702, 64E-5.1501, 64E-5.1502
R9	3-12-2009	New 64E-5.1601, 64E-51602, 64E-5.1603, 64E-5.1604

R10	02-11-2010	64E-5.101, 64E-5.207, 64E-5.210, 64E-5.213, 64E-5.216, 64E-5.312, 64E-5.331, 64E-5.344, 64E-5.345, 64E-5.601, **New** 64E-5.6011, 64E-5.602, 64E-5.603, 64E-5.604, 64E-5.605, 64E-5.606, 64E-5.607, 64E-5.608, 64E-5.609, 64E-5.610, 64E-5.611, 64E-5.612, 64E-5.614, 64E-5.615, 64E-5.616, 64E-5.617, 64E-5.618, 64E-5.621, 64E-5.622, 64E-5.624, 64E-5.625, **New** 64E-5.6251, 64E-5.626, 64E-5.627, 64E-5.628, 64E-5.629, 64E-5.630, 64E-5.631, 64E-5.633, **New** 64E-5.6331, **New** 64E-5.6332, 64E-5.634, 64E-5.635, 64E-5.636, 64E-5.637, 64E-5.638, 64E-5.639, 64E-5.640, 64E-5.641, **New** 64E-5.6411, **New** 64E-5.6412, 64E-5.642, **New** 64E-5.6421, **New** 64E-5.6422, **New** 64E-5.6423, 64E-5.643, 64E-5.644, 64E-5.645, 64E-5.647, 64E-5.648, 64E-5.649, 64E-5.650, **Repealed** 64E-5.651, 64E-5.652, 64E-5.653, 64E-5.654, 64E-5.655, 64E-5.656, 64E-5.657, 64E-5.658, **New** 64E-5.659, **New** 64E-5.660, **New** 64E-5.661, **New** 64E-5.662, **New** 64E-5.663, **New** 64E-5.664, 64E-5.1301, **New** 64E-5.1320, Application for Radioactive Materials License Non-Human Use, DH Form 1054 12/09, (See 64E-5.207), Application for Radioactive Materials Human Use DH Form 1322 12/09 (See 64E-5.207), **New** Federal Policy for the Protection of Human Subjects (Federal Policy), as described in 45 CFR Part 46, dated 11/9/2009 (See 64E-5.601)
R11	5-8-2013	64E-5.101, 64E-5.504
R12	12-26-2013	64E-5.101, 64E-5.203, 64E-5..204, 64E-5.206, 64E-5.210, 64E-5.213, 64E-5.216, 64E-5.304, 64E-5.306, 64E-5.307, 64E-5.313, 64E-5.315, 64E-5.326, 64E-5.330, 64E-5.331, 64E-5.344, 64E-5.350, 64E-5.351, 64E-5.6011, 64E-5.607, 64E-5.609, 64E-5.614, 64E-5.6251, 64E-5.626, 64E-5.627, 64E-5.629, 64E-5.630, 64E-5.632, 64E-5., 64E-5.633, 64E-5.6412, 64E-5.6422, 64E-5.643, 64E-5.645, 64E-5.649, 64E-5.650, 64E-5.652, 64E-5.653, 64E-5.654, 64E-5.655, 64E-5.656, 64E-5.660, 64E-5.661, 64E-5.662, 64E-5.663, 64E-5.810, 64E-5.1115, 64E-5.1317, 64E-5.1419, 64E-5.1420, 64E-5.1501, 64E-5.1502
R13	6-3-2015	64E-5.220, 64E-5.508, 64E-5.510, 64E-5.511, 64E-5.801, 64E-5.1602
R14	7-1-2015	64E-5.206, 64E-5.217
R15	3-21-2016	64E-E-5.502, 64E-5.801, 64E-5.1602

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ATTACHMENTS

(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.

R15 R15 R15 R15

2. An x-ray system operator shall receive instruction on and be competent in the safe use of the x-ray system. A medical x-ray system operator shall also be certified or authorized in accordance with Chapter 468, Part IV, F.S.

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)11.

   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.

R15 7. An x-ray system is exempt from the requirements of subparagraph
R15 64E-5.502(1)(a)6., F.A.C., only if:

R15 a. The system is a stationary, non-mobile system installed and
R15 used only in a jail or penal institution;

R15 b. The system is used only on legal detainees in a jail or penal
R15 institution, and never on detainees' family members,
R15 children, institution employees, contractors, visitors, the
R15 public, or any other persons;

R15 c. The system is manufactured, maintained, and operated
R15 solely for security screening purposes in strict compliance
R15 with, and fully according to, the most restrictive standards
R15 found in ANSI/HPS N43.17-2009, "Radiation Safety for
R15 Personnel Security Screening Systems Using X-Ray or
R15 Gamma Radiation," which is herein incorporated by
R15 reference. This ANSI publication may be examined and
R15 inspected at the Florida Department of Health, Bureau of
R15 Radiation Control at Building 4042 Bald Cypress Way, Suite
R15 210, Tallahassee, Florida 32399-1741, and at the Florida
R15 Department of State, Room 701, The Capitol, Tallahassee,
R15 Florida 32399-0250, and is available from the American
R15 National Standards Institute, Inc., at http://www.hps.org/#.
R15 The agency has determined that posting the publication on
R15 the internet for purposes of public inspection and
R15 examination would constitute a violation of federal copyright
law; and,

R15 d. The institution tracks radiation dose for each detainee, as
R15 specified by ANSI/HPS N43.17-2009, “Radiation Safety for
R15 Personnel Security Screening Systems Using X-Ray or
R15 Gamma Radiation,” to ensure the detainee does not exceed
R15 the recommended dose limit.

R15 8. 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.

R15 9. 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.

R7 e. A person shall not perform fluoroscopic imaging or otherwise
R7 expose a human to x-rays from a fluoroscopic system unless
R7 the person is a:

R7 (I) Licensed practitioner as that term is defined in section
R7 468.301, Florida Statutes; or

R7 (II) Certified radiologist assistant practicing in accordance
R7 with the requirements of Chapter 468, Part IV, Florida
R7 Statutes; or

R7 (III) Certified general radiographer practicing in
R7 accordance with the requirements of Chapter 468,
R7 Part IV, Florida Statutes; and

R7 R7 R7 (A) The general radiographer has been trained and authorized in writing by the licensed practitioner in charge to perform the specified imaging; and

R7 R7 R7 R7 R7 (B) The specified imaging does not rely upon the general radiographer to provide any diagnostic interpretation, or to determine suspicious areas for additional imaging, or to otherwise modify the scope of authorization for the imaging; and

R7 R7 R7 R7 (C) The specified imaging is designed to prevent or reduce exposure to patients by facilitating proper location and positioning for the authorized radiographic imaging.

R15 10. 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.

R15 R1 11. 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.

(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 ºF to 80 ºF (16 ºC to 27 ºC). 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**
ºC	**ºF**	(minutes)
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.
R7 Law Implemented: 404.051, 404.081, 404.141, 404.22, F.S.
History: New July 17, 1985, amended April 4, 1989, Amended January 1, 1994, Amended November 20,1994,
R15 Amended 01-01-1995, Formerly 10D-91.603, Amended 05-18-1998, 08-16-2007, 03-21-2016.

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

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

2. Beryllium window tubes shall have a minimum of 0.5 mm aluminum equivalent filtration permanently mounted in the useful beam.

3. For capacitor energy storage equipment, compliance shall be determined with the maximum quantity of charge per exposure

4. 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.

5. 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.

R13 (c) Surveys. A medical physicist who meets the qualifications specified in (4), above, and who establishes, monitors, evaluates, and directs the
R1 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.

R13 (6) In addition to the above requirements, effective October 1, 1994, no facility can conduct mammography procedures unless the facility also obtains and maintains a certificate issued by the FDA as described in Public Law 102-539, the Mammography Quality Standards Act of 199, and , and complies with all requirements of 21 CFR Part 900, April 1, 2014 edition, which is incorporated herein by reference and available from the internet at
R13 http://www.gpo.gov/fdsys/pkg/CFR-2014-title21-vol8/pdf/CFR-2014-title21-vol8-
R13 chapI-subchapI.pdf, and at
R13 https://www.flrules.org/Gateway/reference.asp?No=Ref-05440.

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.
R13 History: New 03-17-1992, Amended 01-01-1994, 11-20-1994, Formerly 10D-91.611, Amended 05-18-1998, 06-03-2015

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 requirements if the dose equivalent rate averaged over an area of ten square centimeters does not exceed 0.5 mR (five μSv) 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 that are non-operational and under the control of a registered vendor prior to final installation are exempt from the registration and fee requirements of this section.

(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 and before use. Application for registration shall be DH Form 1107, 10/15, “Radiation Machine Facility Registration,” which is herein incorporated by reference and available from the internet at http://www.floridahealth.gov/radiation, or at https://www.flrules.org/gateway/reference.asp?No=Ref-06528.

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) 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 or before October 28 and will be the annual renewal fee. Otherwise, the renewal fee is due annually on or before October 28.

R13 (c) An annual fee for the registration and inspection of radiation machines shall be paid according to the following schedule:

R13	First Tube/Unit	Each Additional Tube/Unit
R13 Medical or Chiropractic or Osteopathic	$145	$ 85
Veterinary	$ 50	$ 34
Educational or Industrial	$ 47	$ 23
Dental or Podiatry	$ 31	$ 11
Medical Accelerator	$258	$148
Non-Medical	$ 81	$ 48

(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.

R13 (b) Application for registration shall be completed on DH Form 1113, 09/14, R13 "Radiation Machine Vendor Registration Form," which is herein R13 incorporated by reference and which is available from the internet at R13 http://www.floridahealth.gov/radiation, and at R13 https://www.flrules.org/Gateway/reference.asp?No=Ref-05442.

(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.

R15 (a) 1. Any registrant or person who sells, leases, transfers, relocates, lends or disposes of one or more radiation machines or major components of one or more such machines shall notify the Department within 15 days after such action. Notification shall be made on DH Form 1107, 10/15, "Radiation Machine Facility R15 Registration."

R15 (a) 2. Any assembler who relocates, assembles, installs or disposes of one or more radiation machines or major components of one or more such machines shall notify the Department within 15 days after such action. Notification shall be made on DH Form 1114, 10/15, “Report of Assembly of Certified or Non-Certified X-Ray Systems,” which is herein incorporated by reference and available from the internet at http://www.floridahealth.gov/radiation and at https://www.flrules.org/Gateway/reference.asp?No=Ref-06529, or a similar form which captures all the information required on DH Form 1114, 10/15.

(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.

(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.

R13 (7) Enforcement. The General Statement of Policy and Procedure for Radiation R13 Machine Enforcement Actions, September 2014, which is herein incorporated by reference, will be used to determine enforcement actions to be taken. This publication can be obtained from the internet at R13 http://www.floridahealth.gov/radiation, and at R13 https://www.flrules.org/Gateway/reference.asp?No=Ref-05444.

Specific Authority 404.051, F.S.
R7 Law Implemented 404.071, 404.091, 404.101, 404.141, 404.161, 404.162, 404.163, 404.22, F.S.
R15 History--New 12-12-1996, Formerly 10D-91.612, Amended 08-16-2007, 06-03-2015, 03-21-2016

PART VIII RADIATION SAFETY REQUIREMENTS FOR ANALYTICAL PARTICLE ACCELERATORS

SUBPART A REGISTRATION PROCEDURE

SUBPART B RADIATION SAFETY REQUIREMENTS FOR THE USE OF PARTICLE ACCELERATORS

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.

R15
R13 (2) Application for registration shall be made on DOH Form 1107, 10/15, “Radiation Machine Facility Registration,” (see Rule 64E-5.511, F.A.C.) 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.
R15 History: New 07-17-1985 Amended 05-15-1996, 06-03-2015, 03-21-2016 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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PART XVI ELECTRONIC BRACHYTHERAPY

Rules 64E-5.1601 — 64E 5.1604 are effective March 12, 2009 and are designated as Revision 9 (R9).

PART XVI
ELECTRONIC BRACHYTHERAPY

R9 **64E-5.1601 Definitions.** The following definitions apply only in this part.

R9 (1) "AAPM" means the American Association of Physicists in Medicine, R9 www.aapm.org.

R9 (2) "Authorized user" means a person who has met the requirements of subsection R9 64E-5.1603(1), F.A.C.

R9 (3) "Authorized medical physicist" means a person who has met the requirements of R9 subsection 64E-5.1603(2), F.A.C.

R9 (4) "Authorized operator" means a person who has met the requirements of R9 subsection 64E-5.1603(3), F.A.C.

R9 (5) "Electronic brachytherapy" means a method of radiation therapy using R9 electrically-generated x-rays to deliver a radiation dose at a distance of up to a R9 few centimeters by intracavitary, intraluminal or interstitial application, or by R9 applications with the source in contact with the body surface or very close to the R9 body surface.

R9 (6) "Electronic brachytherapy device" or "device" means the system used to produce R9 and deliver therapeutic radiation including the x-ray tube, the control mechanism, R9 the cooling system, and the power source.

R9 (7) "Electronic brachytherapy source" or "source" means the x-ray tube component R9 used in an electronic brachytherapy device.

R9 (8) "Medical event" means any event, except for an event that results from patient R9 intervention, in which the administration of radiation results in:

R9 (a) A total dose delivered that differs from the prescribed dose by 20 percent R9 or more;

R9 (b) A fractionated dose delivered that differs from the prescribed dose, for a R9 single fraction, by 50 percent or more; or

R9 (c) A dose to the wrong individual or the wrong treatment site.

R9 (9) "Mobile electronic brachytherapy device" means a device which is transported R9 from one address to be used at another address.

R9 (10) "Portable shielding" means shielding that can be easily moved into the primary or R9 secondary beam in order to reduce the radiation exposure to the patient, R9 occupational worker or a member of the public.

R9 Specific Authority: 404.051(4), 404.20, F.S.
R9 Law Implemented: 404.031, 404.051, 404.22, F.S
R9 History: New 03-12-2009

R9 **64E-5.1602 Administrative Requirements.**

R9 (1) Registration and Notification.

R9 (a) No electronic brachytherapy device may be used on a human without a
R9 current certificate of registration from the department.

R9 (b) An electronic brachytherapy device that is not operational and that is
R9 under the control of a registered vendor prior to final installation is exempt
R9 from the registration and fee requirements of this section.

R9 (c) A separate registration and radiation protection program are required for
R9 facilities for which one or more of the following applies:

R9 1. The facilities are not at the same physical address;

R9 2. The facilities are not under the same radiation safety program; or

R9 3. The facilities are not under the same management.

R9 (d) Each person who acquires an electronic brachytherapy device shall apply
R9 for registration of the radiation device with the department within 30 days
R13 after acquisition. Application for registration shall be on Form DH 1107,
R15 10/15, “Radiation Machine Facility Registration,” as incorporated in sub-
R9 paragraph 64E-5.511(2)(a)1., F.A.C. The application must include the
following documents:

R9 1. A list identifying the radiation safety officer and all authorized
R9 medical physicists, authorized operators, and authorized users
R9 except visiting authorized users, together with documentation of
R9 their training and education as described in Rule 64E-5.1603,
R9 F.A.C.;

R9 2. A copy of the most current record of surveys, calculations and
R9 quality assurance checks on each device;

R9 3. A current copy of the quality management program as described in
R9 subsection 64E-5.1604(3), F.A.C.;

R9 4. A current copy of the quality assurance program as described in
R9 subsection 64E-5.1604(4), F.A.C.; and

R9 5. A copy of the device manufacturer’s U.S. Food and Drug
R9 Administration certification; and

R9 6. Facility design information, which at a minimum must include:

R9 a. A diagram of the physical facility showing the location of the
R9 electronic brachytherapy treatment rooms;

R9 b. Whether the facility is a new structure or a modification to an
R9 existing structure; and

R9 c. The type and thickness of the portable shielding used for
R9 compliance and a procedure demonstrating the use of the
R9 shielding prior to treatment

R9 (e) The registrant shall update the registration on file with the department
R9 within 30 days of any change to any information reported in paragraph
R9 64E-5.1602(1)(d), F.A.C.

R9 (2) Installation, Maintenance or Repair.

R9 (a) Only a manufacturer's representative registered as a vendor under
R9 subsection 64E-5.511(3), F.A.C., shall install an electronic brachytherapy
R9 device.

R9 (b) Only a manufacturer's representative registered as a vendor under
R9 subsection 64E-5.511(3), F.A.C., or an authorized medical physicist shall
R9 adjust, repair, maintain, or service an electronic brachytherapy device in
R9 accordance with the manufacturer's guidelines.

R9 (c) A registrant shall retain a record of the installation, maintenance,
R9 adjustment, service and repair of an electronic brachytherapy device for 5
R9 years.

R9 (3) Fees. The registrant of an electronic brachytherapy device shall comply with the
R9 requirements of paragraph 64E-5.511(2)(b), F.A.C., and pay the fees for a
R9 medical accelerator unit.

Specific Authority: 404.051(4), 404.22, F.S.
Law Implemented: 404.051, 404.081(1), 404.22, F.S.
R15 History: New 03-12-2009, Amended 06-03-2015, 03-21-16

64E-5.1603 Training And Education.

R9 (1) Qualification of Authorized User.

R9 (a) The registrant shall require the authorized user to be a physician who:

R9 1. Is licensed by the department as a medical doctor or doctor of
R9 osteopathy;

R9 2. Has completed a manufacturer’s device-specific training as
R9 specified in subsection 64E-5.1603(5), F.AC.; and

R9 3. Is certified in:

R9 a. Radiation oncology or therapeutic radiology by the American
R9 Board of Radiology;

R9 b. Radiation oncology by the American Osteopathic Board of
R9 Radiology;

R9 c. Radiology, with specialization in radiotherapy, as a British
R9 "Fellow of the Faculty of Radiology" or "Fellow of the Royal
R9 College of Radiology"; or

R9 d. Therapeutic radiology by the Canadian Royal College of
R9 Physicians and Surgeons.

R9 (b) A physician shall not act as an authorized user for any electronic
R9 brachytherapy device until such time as said physician's training has been
R9 reviewed and approved by the department.

R9 (2) Qualification of Authorized Medical Physicist.

R9 (a) The registrant shall require the authorized medical physicist to be a
R9 person who:

R9 1. Is currently licensed pursuant to Section 483.901, F.S., as a
R9 therapeutic radiological physicist; and

R9 2. Has completed a manufacturer’s device-specific training as
R9 specified in subsection 64E-5.1603(5), F.A.C.

R9 (b) A medical physicist shall not act as an authorized medical physicist for any
R9 electronic brachytherapy device until such time as said physicist’s training
R9 has been reviewed and approved by the department