

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

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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 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.

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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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 Rule 64E-5.501, F.A.C., 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 Rule 64E-5.501, F.A.C., 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.

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- (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, (see 64E-5.101, F.A.C.) June 2012, Table I., Column 3.

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- (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, June 2012, (see 64E-5.101, F.A.C.) Table II, 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.

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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, Amended 12-26-13.