

641—45.4(136C) Radiation safety requirements for the use of particle accelerators for nonhuman use.**45.4(1) Purpose and scope.**

a. This rule establishes procedures for the registration or licensing and the use of particle accelerators.

b. Unless specifically required otherwise by this rule, all registrants or licensees performing operations with a particle accelerator are subject to the requirements of 641—Chapters 38 to 40 and 641—45.1(136C).

c. The requirements of 45.1(10)“b”(2) and (3) and 45.1(10)“d”(1)“2” do not apply to nonradiographic uses.

45.4(2) Definitions. For purposes of this subrule, definitions in 641—Chapters 38 and 40 and subrule 45.1(2) may also apply. As used in this rule, the following definitions apply:

“*Cold pasteurization*” means the process of using radiation for destroying disease-causing microorganisms in commercial products.

“*Self-shielded particle accelerator*” means a particle accelerator with the accelerator installed in an enclosure independent of the existing architectural structures except the floor on which it may be placed. The enclosure must have been evaluated by a qualified expert and that evaluation approved by an appropriate regulatory authority through a device evaluation. The self-shielded accelerator is intended to contain at least that portion of material being irradiated, provide radiation attenuation, and exclude personnel from its interior during generation of radiation. A particle accelerator used within a shielded part of a building, or which may temporarily or occasionally incorporate portable shielding, is not a self-shielded particle accelerator.

“*Shielded facility*” means an accelerator facility where shielding is required to be constructed on site in order to assure compliance with the requirements of 641—Chapter 40, or where shielding supplied with the accelerator has been evaluated by qualified experts and that evaluation approved by an appropriate regulatory authority through a device evaluation.

45.4(3) Registration or license requirements. No person shall receive, possess, use, transfer, own, or acquire a particle accelerator except as authorized in a registration or license issued pursuant to 641—39.1(136C) to 39.4(136C) and the following requirements:

a. Accelerator facilities whose operations result in nuclear transformations that produce or are likely to produce radioactive material more than the exempt quantities and concentrations listed in Appendices A and B of 641—Chapter 39 shall be authorized by the issuance of a radioactive material license in accordance with 641—Chapter 39. Accelerator facilities that produce or are likely to produce radioactive material less than the exempt quantities and concentrations shall be authorized by registration.

b. For accelerator facilities required to be licensed in accordance with 45.4(3), those operations that would require personnel monitoring, pursuant to 641—40.37(136C), due to the presence of radioactive material, shall be performed only by a specific licensee. Such operations would normally include installation, testing and maintenance as well as routine operations.

45.4(4) General requirements for the issuance of a registration or license for particle accelerators. Along with the requirements of 641—39.1(136C) to 39.4(136C), an application for use of a particle accelerator will be approved only if the agency determines that:

a. The applicant is qualified by reason of training and experience to use the accelerator in question for the purpose requested in accordance with this rule and 641—Chapter 40 in such a manner as to minimize danger to public health and safety or property;

b. 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;

c. The issuance of the registration or license will not be inimical to the health and safety of the public, and the applicant satisfies any applicable special requirement in 45.4(4);

d. The applicant has appointed a radiation safety officer responsible for the day-to-day operation of the radiation safety program;

e. The applicant and the applicant's staff have experience in the use of particle accelerators and training sufficient for application to its intended uses;

f. The applicant has an adequate training program for operators of particle accelerators.

45.4(5) Personnel monitoring. In addition to the requirements of 641—Chapter 40, personnel monitoring shall be provided to and used by all individuals entering any area for which interlocks are required unless a survey of the area has determined that radiation levels are below that of a high radiation area; and

a. Power to an accelerator cannot be activated; or

b. An accelerated beam cannot be directed to the area.

45.4(6) Operations.

a. No registrant shall permit any individual to act as an operator of a particle accelerator until such individual:

(1) Has been instructed in radiation safety and shall have demonstrated an understanding thereof;

(2) Has received copies of and instruction in this rule and the applicable requirements of 641—Chapter 40, pertinent registration and the registrant's operating and emergency procedures, and shall have demonstrated understanding thereof; and

(3) Has demonstrated competence to use the particle accelerator, related equipment, and survey instruments which will be employed.

b. The radiation safety officer or radiation safety committee, if applicable, shall have the authority to terminate the operations at a particle accelerator facility if such action is deemed necessary to minimize danger to public health and safety or property.

c. Along with the audit required in 641—subrule 40.10(3), each operator's performance during an actual accelerator operation shall be audited by the radiation safety officer or designee at intervals not to exceed six months. If an operator has not participated in an accelerator operation for more than six months since the last audit, the individual's performance shall be observed and recorded at the first opportunity the individual participates in an accelerator operation. Records of the audits shall be maintained by the registrant for the agency inspection for three years from the date of the audit.

d. Operators of particle accelerators used for industrial radiography shall meet the requirements of 45.1(10).

45.4(7) Shielding and safety design requirements.

a. A qualified expert acceptable to the agency shall be consulted in the design of a particle accelerator installation and called upon to perform a radiation survey when the accelerator is first capable of producing radiation.

b. Each particle accelerator installation shall be provided with such primary and secondary barriers as are necessary to ensure compliance with 641—40.15(136C) and 641—40.26(136C).

c. In addition to the requirements of 45.4(8) "a" and "b," shielded facilities or self-shielded particle accelerators shall meet the following requirements:

(1) Authorization, by issuance of a construction permit, shall be granted upon a determination of adequacy being made pursuant to the review of an initial application of the shielding design, physical plant, and site specifications, and of the applicant's proposed equipment, uses and workloads. For a shielded facility, the applicant shall submit an evaluation of the shielding design by a qualified expert. For a self-shielded particle accelerator, the applicant need not submit an evaluation of a shielding design if an evaluation by an appropriate regulatory authority has been performed. The applicant may instead reference this evaluation. The applicant shall maintain a copy of the evaluation of shielding design for agency review.

(2) Authorization for installation and testing of an accelerator shall be given only after a determination of adequacy of testing protocols, testing safety procedures, staff training, and radiation detection instrumentation has been made; and

(3) Operational use of an accelerator shall be authorized only after determination of adequacy of the items listed in 45.4(4) has been made by the agency.

45.4(8) Particle accelerator controls and interlock systems.

a. Instrumentation, readouts, and controls on the particle accelerator control console shall be clearly identified, easily discernible and located outside the high radiation area.

b. Each entrance into a target area or other high radiation area shall be provided with two safety interlocks that shut down the machine when the barrier is breached.

c. Each safety interlock shall be on a circuit that allows it to operate independently of all other safety interlocks.

d. All safety interlocks shall be designed so that any defect or component failure in the safety interlock system prevents operation of the accelerator.

e. When a safety 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 safety interlock has been tripped and, lastly, at the main control console.

f. 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.

45.4(9) Warning devices.

a. Each location designated as a high radiation area, and each entrance to such location, shall be equipped with easily observable warning lights that operate when, and only when, radiation is being produced.

b. Each high radiation area shall have an audible warning device that 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.

c. Barriers, temporary or otherwise, and pathways leading to high radiation areas shall be posted in accordance with 641—40.61(136C).

45.4(10) Operating and emergency procedures.

a. Particle accelerators, when not in operation, shall be secured to prevent unauthorized use.

b. The safety interlock system shall not be used to turn off the accelerator beam except in an emergency.

c. All safety and warning devices, including interlocks, shall be checked for proper operation intervals not to exceed three months. Results of such tests shall be maintained at the accelerator facility for inspection by the agency for three years.

d. All incidents in which the interlock system fails to operate properly or where the operation is terminated by the interlock system shall be investigated and reported to the radiation safety officer or, if applicable, the radiation safety committee. Documentation shall be maintained for inspection by the agency for three years.

e. If, for any reason, it is necessary to intentionally bypass a safety interlock or interlocks, such action shall be:

- (1) Authorized by the radiation safety officer and, if applicable, the radiation safety committee;
- (2) Recorded in a permanent log and a notice posted at the accelerator control console; and
- (3) Terminated as soon as possible.

f. The registrant's operating and emergency procedures shall include the following:

- (1) Operation and safety instructions on the accelerator(s) to be used;
- (2) Methods for controlling access to restricted areas;
- (3) Methods and occasions for locking and securing sources of radiation;
- (4) Use of personnel monitoring equipment;
- (5) The procedure for notifying proper personnel in the event of an accident;
- (6) Maintenance of records;
- (7) Inspections and maintenance of the accelerator; and
- (8) Steps to be taken in the case of an emergency.

g. A copy of the current operating and emergency procedures shall be maintained at the accelerator control panel.

45.4(11) Radiation monitoring requirements.

a. A radiation protection survey shall be performed and documented by a qualified expert, acceptable to the agency, when changes have been made in shielding, operation, equipment, or occupancy of adjacent areas.

b. Accelerator facilities shall survey with a radiation detection instrument at intervals not to exceed 12 months. Records of this survey shall be maintained for agency review for three years.

c. Accelerator facilities registered or licensed pursuant to 45.4(3) "a" shall survey for removable contamination at intervals not to exceed six months to determine the degree of contamination.

d. Each time removable shields on self-shielded particle accelerators are opened, a visual survey of the shielding must be performed to observe physical damage. In addition, when these shields are returned to the closed position, a physical radiation survey shall be conducted upon initial reactivating of the accelerator. Records of this survey shall be maintained for agency review for three years.

e. Accelerator facilities registered or licensed pursuant to 45.4(3) "a" shall perform a survey with a radiation detection instrument and surveys for removable contamination before maintenance or servicing of its particle accelerator(s) or associated equipment located in the high radiation area.

f. Radiation levels in all high radiation areas shall be continuously monitored. The monitoring devices shall be electrically independent of the accelerator control and safety interlock systems and capable of providing a readout at the control panel.

g. Upon installation, all area monitoring equipment shall be tested to assure proper operation under operating conditions of the particle accelerator. All area monitors shall be calibrated at intervals not to exceed one year and after each servicing and repair.

h. Whenever applicable, accelerator facilities registered or licensed pursuant to 45.4(3) "a" shall perform surveys at intervals not to exceed six months to determine the amount of airborne particulate radioactivity present.

i. All surveys shall be made in accordance with the written procedures established by the radiation safety officer or a qualified expert who is acceptable to the agency.

j. Records of all radiation protection surveys, calibrations, and instrumentation tests shall be maintained at the accelerator facility for inspection by the agency.

45.4(12) Radiation safety officer.

a. Each registrant shall appoint a radiation safety officer that meets the following requirements:

(1) Possesses a high school diploma or a certificate of high school equivalency based on the GED test;

(2) Documents two years of radiation protection experience.

b. The specific duties of the RSO include, but are not limited to, the following:

(1) To establish and oversee operating, emergency, and ALARA procedures and to review them regularly to ensure that the procedures are current and conform with these rules;

(2) To oversee and approve all phases of the training program for accelerator operators so that appropriate and effective radiation protection practices are taught;

(3) To ensure that required radiation surveys are performed and documented in accordance with these rules, including any corrective measures when levels of radiation exceed established limits;

(4) To ensure that personnel monitoring devices are calibrated and used properly by occupationally exposed personnel, that records are kept of the monitoring results, and that timely notifications are made as required by 641—Chapter 40;

(5) To ensure that any required interlock switches and warning signals are functioning and that radiation signs, ropes, and barriers are properly posted and positioned;

(6) To investigate and report to the agency each known or suspected case of radiation exposure to an individual or radiation level detected in excess of limits established by these rules and each theft or loss of source(s) of radiation, to determine the cause, and to take steps to prevent its recurrence;

(7) To have a thorough knowledge of management policies and administrative procedures of the licensee or registrant;

(8) To assume control and have the authority to institute corrective actions including shutdown of operations when necessary in emergency situations or unsafe conditions;

- (9) To maintain records as required by these rules;
- (10) To ensure the proper storing, labeling, and use of the accelerator;
- (11) To ensure that inspection and maintenance programs are performed in accordance with 45.1(6), 45.1(8), 45.4(10) "c"; and
- (12) To ensure that personnel are complying with these rules and the operating and emergency procedures of the registrant.