

PART I

RADIATION SAFETY REQUIREMENTS FOR PARTICLE ACCELERATORS

1. Purpose and Scope.

- A. This part establishes procedures for the licensing and the use of all particle accelerators.
- B. In addition to the requirements of this part, all licensees are subject to the requirements of Parts A,B,C,D, and J of these regulations. Licensees engaged in industrial radiographic operations are subject to the requirements of Part E of these regulations and licensees engaged in the healing arts are subject to the requirements of Part F and/or Part G of these regulations. Licensees whose operations result in the production of radioactive material are subject to the requirements of Part C of these regulations.

LICENSE PROCEDURE

2. License Requirements.

No person shall receive, possess, use, transfer, own, or acquire a particle accelerator except as authorized in a license issued pursuant to Parts B and C of these regulations.

3. General Requirements for the Issuance of a License for Particle Accelerators.

In addition to the requirements of Parts B and C of these regulations, a license 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 part and Parts D and J of these regulations in such a manner as to minimize danger to public health and safety or property;
- B. the applicant's proposed or existing equipment, facilities, operating and emergency procedures are adequate to protect health and minimize danger to public health and safety or property;
- C. the issuance of the license will not be inimical to the health and safety of the public, and the applicant satisfies any applicable special requirement in I.4;
- D. the applicant has appointed a radiation safety officer;
- E. the applicant and/or the applicant's staff has substantial experience in the use of particle accelerators and training sufficient for application to its intended uses;
- F. the applicant has established a radiation safety committee to approve, in advance, proposals for uses of particle accelerators, whenever deemed necessary by the Agency; and
- G. the applicant has an adequate training program for operators of particle accelerators.

4. Human Use of Particle Accelerators.

In addition to the requirements set forth in Part B of these regulations a license for use of a particle accelerator in the healing arts will be issued only if:

- A. the applicant has appointed a medical committee of at least three members to evaluate all proposals for research, diagnostic, and therapeutic use of a particle accelerator whenever deemed necessary by the Agency. Membership of the committee should include physicians expert in internal medicine, hematology, therapeutic radiology, and a person experienced in depth dose calculations and protection against radiation;
- B. the individuals designated on the application as the users have substantial training and experience in deep therapy techniques or in the use of particle accelerators to treat humans; and
- C. the individual designated on the application as the user is a physician.

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5. {Reserved}

6. Limitations.

- A. No licensee 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 an instruction in this part and the applicable requirements of Part C and J of these regulations, pertinent license conditions and the licensee'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 committee or the radiation safety officer shall have the authority to terminate the operations at a particle accelerator facility if such action is deemed necessary to protect health and minimize danger to public health and safety or property.

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/or secondary barriers as are necessary to assure compliance with Part D.2 and D.6 of these regulations.

8. Particle Accelerator Controls and Interlock Systems.

- A. Instrumentation, readouts and controls on the particle accelerator control console shall be clearly identified and easily discernible.
- B. Each entrance into a target room or other high radiation area shall be provided with interlocks that shut down the machine under conditions of barrier penetration.
- C. Each safety interlock shall be on a circuit which shall allow its operation 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 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.

9. Warning Devices.

- A. Each location designated as 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. 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 all radiation areas.
- C. Barriers, temporary or otherwise, and pathways leading to high radiation areas shall be identified in accordance with Part D.11 of these regulations.

10. Operating 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.

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- C. All safety and warning devices, including interlocks, shall be checked for proper operability at intervals not to exceed three months. Results of such tests shall be maintained at the accelerator facility for inspection by the Agency.
- D. Electrical circuit diagrams of the accelerator and the associated interlock systems shall be kept current and maintained for inspection by the Agency and shall be available to the operator at each accelerator facility.
- 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 committee and/or radiation safety officer;
 - (2) recorded in a permanent log and a notice posted at the accelerator control console; and
 - (3) terminated as soon as possible.
- F. A copy of the current operating and the emergency procedures shall be maintained at the accelerator control panel.

11. Radiation Monitoring Requirements.

- A. There shall be available at each particle accelerator facility appropriate portable monitoring equipment which is operable and has been calibrated for the appropriate radiations being produced at the facility. Such equipment shall be tested for proper operation daily and calibrated at intervals not to exceed 1 year and after each servicing and repair.
- B. 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.
- C. 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.
- D. All area monitors shall be calibrated at intervals not to exceed 1 year and after each servicing and repair.
- E. Whenever applicable, periodic surveys shall be made to determine the amount of airborne particulate radioactivity present.
- F. Whenever applicable, periodic smear surveys shall be made to determine the degree of contamination.
- G. All area surveys shall be made in accordance with the written procedures established by a Qualified Expert, acceptable to the Agency, or the Radiation Safety Officer.
- H. Records of all radiation protection surveys, calibrations, and instrumentation tests, shall be maintained at the accelerator facility for inspection by the Agency.

12. Ventilation Systems.

- A. Ventilation systems shall be provided to ensure that personnel entering any area where airborne radioactivity may be produced will not be exposed to airborne radioactive material in excess of those limits specified in Part D, Appendix A, Table I of these regulations.
- B. A licensee, as required by Part D.7 of these regulations, shall not vent, release or otherwise discharge airborne radioactive material to an unrestricted area which exceed the limits specified in Part D, Appendix A, Table II of these regulations, except as authorized pursuant to D.17, or D.7.B of these regulations. For purposes of I.12.B, concentrations may be averaged over a period not greater than 1 year. Every effort should be made to maintain releases of radioactive material to unrestricted areas as far below these limits as is reasonably achievable.