

Instructions for Therapeutic Radiation Facility Registration

NMED Radiation Control Bureau guide for registration and use of particle accelerators

Note: In addition to the instructions for registration and requirements of Part 2.202.A, all registrants are subject to the requirements of applicable Parts 2, 4, 6, 10 and 20 of the New Mexico Radiation Protection Rules (20.3 NMAC). Other radiation therapy machines used for treatment planning or delivery of a patient dose known as the written directive will be included in this registration process including: fluoroscopic simulators, computed tomography simulators; emerging technologies such as PET/CT simulators, KV imaging devices and electronic brachytherapy devices; or conventional superficial treatment units; orthovoltage units, etc. Registrants whose operations result in the production of radioactive material are subject to the requirements of 20.3 NMAC, Part 3.

I. Registration Procedure

Registration Requirements - No person shall receive, possess, use, transfer, own or acquire a particle accelerator unless such is in compliance with the registration requirements in Part 2, Section 202.A. and the guidance provided herein.

A. General Requirements for the Use of Particle Accelerator Facilities. In accordance with the provisions set forth in Part 2, Sections 205, a registration for the use of a particle accelerator will not be issued unless the Department Radiation Control Bureau (RCB) determines that:

1. The applicant is qualified by training and experience to use the accelerator for the intended purpose, in accordance with the provisions of Part 6, Section 602.A(1)(b.) of this rule in such a manner as to minimize danger to patients, occupational-exposed or non-occupational-exposed workers, public health and safety or property;
2. The applicant's proposed equipment, facilities (described in Part 6, Section 607A/B), the Quality Management Program, operating procedures, and emergency procedures (described in Part 6, Section 602.A(1)(d) and Section 607.C and Section 608) are adequate to protect health and minimize danger to public health and safety or property;
3. The applicant has appointed a Radiation Safety Officer;
4. The applicant and staff have adequate experience and training in the operation of particle accelerators using all applicable modes for the intended purpose in the written directive;
5. The applicant has established a radiation safety committee to approve, in advance, proposals for use of particle accelerators, whenever deemed necessary by the agency; and
6. The applicant has an adequate training program for particle accelerator operators and associated therapy treatment equipment, simulation or dose planning systems.

B. Human Use of Particle Accelerators. In addition to the requirements set forth in this guide, a registration for use of a particle accelerator and associated equipment used in the healing arts will be issued only if:

1. For all therapy systems, the registrant has appointed a medical committee of at least three (3) members to evaluate all proposals for research, diagnostic, and therapeutic use of a particle accelerator. Membership of the committee shall include physicians and qualified experts in internal medicine or hematology, therapeutic radiology or oncology; a therapeutic radiation physicist; and a person experienced in depth dose calculations and protection against radiation; and
2. 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; as required by 20.3 NMAC Part 6, Section 602.A.1(b); and
3. The individual designated on the application as a user to issue written directives for each patient treated must be a physician licensed to practice in New Mexico.

C. Radiation Safety Requirements for the Use of Particle Accelerators

1. General Provisions

a. This application for registration establishes radiation safety requirements for the use of particle accelerators which are in addition to, and not in substitution for, other applicable provisions of the Radiation Protection Rules in 20.3 NMAC.

b. The registrant shall be responsible for assuring that all requirements of this registration are met.

2. Limitations

a. No registrant shall permit any person to act as a particle accelerator operator until such person is a licensed practitioner in the healing arts; or certified in therapeutic radiology by the requirements of 20.3 NMAC Part 20 for the administration of radiation to patients; or a qualified expert registered with the Department according to the requirements of Part 2.204.C; and Part 6.607.C(4) for testing;

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

(2.) Has received copies of and instruction in this part and the applicable requirements of 20.3 NMAC, Parts 4., 6. and 10., pertinent registration conditions and the registrant's operating and emergency procedures, and

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

b. Either 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.

D. Shielding and Safety Design Requirements (20.3 NMAC Part 6, Section 6.607.B)

1. A qualified expert specifically registered by the Department shall be consulted in the design of the particle accelerator installation and called upon to perform a radiation survey when the accelerator is first capable of producing radiation. (Part 6, Section 6.607.C.1)

2. Each particle accelerator installation shall be provided with such primary and or secondary barriers as are necessary to assure compliance with dose limits for occupational and non-occupational exposed workers and the public.

E. Particle Accelerator Controls and Interlock Systems

1. Instrumentation, readouts, and operational controls on the particle accelerator control console shall be clearly identified for each function or software command.

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. All safety interlocks shall be fail safe, i.e., designed so that any defect or component failure in the interlock system prevents operation of the accelerator.

4. 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.

F. Warning Devices

1. All locations designated as high radiation areas, and entrances to such locations shall be equipped with easily observable flashing or rotating warning lights that operate when, and only when, radiation is being produced. The operator shall be able to view a warning light in the treatment room and at the control panel.

2. Except in facilities designed for human exposure, each high radiation area shall have any audible warning device which shall be activated for fifteen (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.

3. Barriers, temporary or otherwise, and pathways leading to high radiation areas shall be identified in a scale drawing to identify use and occupancy of adjacent areas.

G. Operating Procedures

1. Particle accelerators, when not in use, shall be secured to prevent unauthorized use.
2. Only a switch on the accelerator control console shall be routinely used to turn the accelerator beam on and off. The safety interlock system shall not be used to turn off the accelerator beam except in an emergency.
3. All safety and warning devices, including interlocks, shall be checked for proper operability at intervals not to exceed three (3) months. Results of such test shall be maintained for inspection by the agency at the accelerator facility.
4. Electrical circuit diagrams of the accelerator, and the associated interlock systems, shall be kept current and maintained for inspection by the agency and available to the operator at each accelerator facility.
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 and/or the radiation safety officer;
 - b. Recorded in a permanent log and a notice posted at the accelerator control console; and
 - c. Terminated as soon as possible.
6. A copy of the current operating and emergency procedures shall be maintained at the accelerator control panel.

H. Radiation Monitoring Requirements

1. 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 one year, and after servicing and repair.
2. A radiation protection survey shall be performed and documented by a qualified expert specifically approved by the agency when changes have been made in shielding, operation, equipment, or occupancy of adjacent areas.
3. Radiation levels in all high radiation areas shall be continuously monitored. The monitoring devices shall be electrically independent of the accelerator control and interlock systems and capable of providing a remote and local readout with visual and/or audible alarms at both the control panel and 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.

4. All area dose rate or exposure rate monitors shall be calibrated at least annually, if installed as a radiation warning device.

5. Whenever applicable, periodic surveys shall be made to determine the amount of airborne particulate radioactivity present in areas of airborne hazards.

6. Whenever applicable, periodic 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 expert or the radiation safety officer of the particulate 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.

II. Ventilation Systems

1. Adequate ventilation shall be provided in areas where airborne radioactivity may be produced.

2. A registrant shall not vent, release or otherwise discharge airborne radioactive material to an unrestricted area which exceeds the limits in 20.3 NMAC Part 4, Section 404. For purposes of this paragraph, concentrations may be averaged over a period not greater than one year. Every reasonable effort should be made to maintain releases of radioactive material to unrestricted areas as far below these limits as practicable.

III. Public Dose Assessment (20.3 NMAC, Part 4, Section 413)

A. Each applicant for registration of therapeutic radiation machines shall conduct operations such that:

1. except as provided in Paragraph (3) of Subsection A of 20.3.4.413 NMAC, the total effective dose equivalent to individual members of the public from the licensed or registered operation does not exceed 0.1 rem (1 mSv) in a year, exclusive of the dose contributions from background radiation, from any medical administration the individual has received, from exposure to individuals administered radioactive material and released; and

2. the dose in any unrestricted area from external sources does not exceed 0.002 rem (0.02 mSv) in any one hour; and

3. the total effective dose equivalent to individual members of the public from infrequent exposure to radiation from radiation machines does not exceed 0.5 rem (5mSv).