

APPLICATION GUIDE FOR MEDICAL ACCELERATOR

A review of the North Carolina Regulations for Protection Against Radiation must be done with particular consideration to the section that is applicable to the license you are applying for and section .1600, Standards for Protection Against Radiation. In general, the requirements for accelerators are found in .0609 and section .0900 of the regulations. Items that need to be addressed that are found in section .1600 include:

- a) .1603 Radiation Protection Program
- b) .1604 Occupational Dose Limits for Adults, including establishment of investigational levels.
- c) .1610 Dose to an Embryo/fetus
- d) .1611 Dose Limits for Individual Members of the Public
- e) .1612 Compliance with Dose Limits for Members of Public
- f) .1613 Surveys
- g) .1615 Control of Access to High Radiation Areas

All of these items need to be addressed in the form of a policy or procedure. These policies and procedures must be written according to the regulations, so you must review each area before you write your policy or procedure.

Fill out the Application for Accelerator License form completely. Use attachments when necessary. ***This form must be signed and dated by your company's highest ranking company officer.***

- Item 1 a- State name and mailing address. This is the mailing address and should include the nine digit Zip Code.
- Item 1 b- This is the physical address at which radioactive materials will be used (DO NOT LIST A P.O. BOX HERE).
- Item 2- Indicate who will serve as the Radiation Safety Officer.
- Item 3- If the individual to be contacted about the license application is someone other than the Radiation Safety Officer, state that individual's name and contact information.
- Item 4- Check if this application is for a new license or the renewal of an existing license. If this is a renewal application, write the license number in the space provided. Check what type of license and what category of use for which you are applying.
- Item 5- Have a company officer sign the application.

NOTE: The information referenced in Items 1 through 19 must be included as attachments to the application for the application to be complete. Incomplete applications may not be processed:

1. Please indicate the accelerator manufacturer and model number in item 6a and energy levels with maximum output of machine in item 6b.
2. Indicate what the accelerator will be used for.
3. Please reference the North Carolina license number on which users of the accelerator are listed. If they are not listed on any license, a preceptor statement or a copy of their board certification must be submitted, specifically for accelerators.
4. All survey meter makes and manufacturers used must be listed. Please review 10A NCAC 15.0909(a) concerning survey meter calibrations. Indicate all information concerning the calibration of the survey meters, who performs calibrations and at what frequency.
5. Indicate what dosimetry service you will be using and frequency of exchange.
6. Describe the facility and indicate which attachment is the sketch of your facility.
7. Attach a copy of your radiation protection program.
8. Describe how you will dispose of your accelerator.

9. Fill out the form ‘Memorandum To All Licensees’. Make sure to designate signature authority for amending your license to those individuals to be authorized to do so. Failing to have authorized signatures on applications to amend your license will result in a lengthier amendment process or may void the action entirely.
10. Read 10A NCAC 15.0900 Requirements for Particle Accelerators. Address specifically all areas in each rule:
 - a) .0903 Radiation Safety Committee
 - b) .0904 Operator/Therapist qualifications
 - c) .0905 Shielding and Safety Design
 - d) .0906 Controls and Interlock systems
 - e) .0907 Warning Devices
 - f) .0908 Operating Procedures
 - g) .0909 Radiation Monitoring Requirements
 - h) .0908 Security of Accelerator
 - i) .0908 Location of Operating and Emergency Procedures
 - j) .0909 Radiation survey due to changes in design
 - k) .0909 Record Retention
11. Read 10A NCAC 15.0609 “X-Ray and Electron Therapy Installations One MeV and Above” and address the following issues:
 - a) Audio/visual systems
 - b) Useful beam monitoring
 - c) Timer
 - d) Monthly Spot Checks
 - e) Yearly Calibration Requirements
 - f) .0609(b)(3) Wedge filters and beam scattering devices
 - g) .0609(b)(5) Dose monitor Units
12. Please submit a copy of your emergency procedures. Commit to posting a copy of your emergency procedures near the accelerator control panel. Emergency procedures should not be covered or obscured by non-emergency related postings.
13. Read 10A NCAC 15.0364 and .0104(86) about medical events. Submit a medical event policy that addresses the following items:
 - a) Reporting any event, except for an event that results from patient intervention, in which the administration of radiation from an accelerator results in:
 - (1) A dose that differs from the prescribed dose or dose that would have resulted from the prescribed dosage by more than 5 rem (0.05 Sievert (Sv)) effective dose equivalent, 50 rem (0.5 Sv) to an organ or tissue, or 50 rem (0.5 Sv) shallow dose equivalent to the skin; and
 - (A) The total dose delivered differs from the prescribed dose by 20 percent or more;
 - (B) The total dosage delivered differs from the prescribed dosage by 20 percent or more or falls outside the prescribed dosage range; or
 - (C) The fractionated dose delivered differs from the prescribed dose, for a single fraction, by 50 percent or more.
 - (2) A dose that exceeds 5 rem (0.05 Sv) effective dose equivalent, 50 rem (0.5 Sv) to an organ or tissue, or 50 rem (0.5 Sv) shallow dose equivalent to the skin from any of the following:
 - (A) An administration of radiation using incorrect electronic or machine setup or conditions;
 - (B) An administration of a radiation dose to the wrong site;
 - (C) An administration of a radiation dose to a wrong individual or human research

- subject;
- D) An administration of radiation by the wrong mode of treatment; or
- (3) A dose to the skin or an organ or tissue other than the treatment site that exceeds by 50 rem (0.5 Sv) and 50 percent or more of the dose expected from the administration defined in the written directive.
- b) Reporting any event resulting from intervention of a patient or human research subject in which the administration of therapeutic radiation machine radiation results, or will result in, unintended permanent functional damage to an organ or a physiological system as determined by a physician, and,
- c) Commit to the reporting and record keeping requirements of .0364(c) – (g)
14. Read 10A NCAC 15.0356 Quality Management Program. Please submit your quality management program to include written directive, recordable events and an annual review.
15. Please describe what type of patient log book/daily schedule is kept.
16. State how often patient charts are reviewed by a physicist to verify calculations of dose totals and how often the patients are seen by the authorized user.
17. Describe what type of accelerator warm up is done every morning by the therapists/physicist. Please indicate if an output check is done everyday. Also indicate what would constitute the accelerator to be put out of service for repair or adjustment by the manufacturer.
18. If the proposed accelerator will produce photons energies of 10 MeV or greater, please provide the agency with information concerning neutron production (γ , n). Additionally, any survey information provided in support of the license should contain neutron measurements.
19. If you do not own the building or property listed in Section 1(d) of the application form, you must supply a notarized letter from the landlord stating that he/she is aware of the storage and/or use of accelerator(s) at the facility.