

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. Items that need to be addressed 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

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.

1. Fill out the enclosed Application for Accelerator License form completely. Use attachments when necessary. ***This form must be signed and dated by highest ranking company officer..*** Please state who may sign for future amendments in the form of a memorandum from the president.

- Item 1 a- State name and mailing address. This is the mailing address and should include the nine digit Zip Code.
- Item 1 b- Provide telephone number and extension if applicable.
- Item 1 c- Provide facsimile number.
- Item 1 d- This is the physical address at which radioactive materials will be used (DO NOT LIST A P.O. BOX HERE).
- Item 2- Please indicate what department will be using the accelerator.
- Item 3- Please indicate current license number or if you are applying for a new license, please state.
- Item 4- All individual users must be listed. **Pursuant to 15A NCAC 11 .0117(a)(2), and by reference 10 CFR 35, Subpart H, physicians must meet certain requirements before being named as authorized users. Please see detailed guidance on our website, <http://ncradiation.net/rms/rmsmultoolkit.htm> for documentation that must be submitted for Authorized Users, and Authorized Medical Physicists. An Authorized Medical Physicist must be named on your license.**
- Item 5- Indicate who will serve as the Radiation Safety Officer. The Radiation Protection (Safety) Officer (R.S.O.) MUST be named in this section. **The applicant must demonstrate that the individual named in this section meets the requirements for R.S.O. that are defined in 15A NCAC 11 .0318(l) and (z) – (bb) and 10 CFR 35.50. See detailed information on RSO required qualifications at <http://ncradiation.net/rms/rmsmultoolkit.htm>.**

NOTE: The information referenced in Items 6 through 15 should be included as attachments to the application

- Item 6- Please indicate the accelerator manufacturer and model number in item 6a and energy levels with maximum output of machine in item 6b.
- Item 7- Indicate what the accelerator will be used for.

- Item 8&9- Pursuant to 15A NCAC 11 .0117(a)(2), and by reference 10 CFR 35, Subpart H, physicians must meet certain requirements before being named as authorized users. Please see detailed guidance on our website, <http://ncradiation.net/rms/rmsmultoolkit.htm> for documentation that must be submitted for Authorized Users, and Authorized Medical Physicists. An Authorized Medical Physicist must be named on your license.
- Item 10- All survey meters used must be listed.
- Item 11- Please review 15A NCAC 11.0909(a) concerning survey meter calibrations. Indicate all information concerning the calibration of the survey meters, who performs calibrations and at what frequency.
- Item 12- Indicate what dosimetry service you will be using and frequency of exchange.
- Item 13- Describe the facility and indicate which attachment is the sketch of your facility.
- Item 14- Please indicate which attachment is your radiation protection program.
- Item 15- Describe how you will dispose of your accelerator.
- Item 16- ***The application must be dated and signed by the highest ranking corporate official (e.g., President, CEO, etc.). Mail the entire application packet to Chief, Radioactive Materials Section, Division of Radiation Protection, 3825 Barrett Drive, Raleigh, NC 27609-7221. Be sure to retain a copy for your records. If the form is not signed, the application will be mailed back to you.***
2. Fill out the enclosed form-Memorandum To All Licensees.
3. Read 15A NCAC 11.0900 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
4. Read 15A NCAC 11.0609 “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
5. Please submit a copy of your emergency procedures.

6. Read 15A NCAC 11.0364 & .0365 about Medical Events and Reporting Dose to an Embryo/Fetus or a Nursing Child. Please submit policies and procedures to address the referenced regulations.
7. Please submit your procedures for administrations requiring a written directive. Please read 15A NCAC 11.0356 to reference your procedures.
8. Please describe what type of patient log book/daily schedule is kept.
9. 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.
10. 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.
11. 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.
12. 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.
13. All applicants for an Accelerator License must provide documentation from the N.C. Secretary of State which indicates their legal business name in North Carolina. Other forms of this documentation may be acceptable to the agency. If you have questions, call the Radioactive Materials Branch for assistance.

Additional information is being compiled for inclusion in our website. Please visit the site often to check for the most up-to-date information (www.ncradiation.net).