

APPLICATION GUIDE FOR NUCLEAR PHARMACIES

A review of the North Carolina Regulations for Protection Against Radiation 15A NCAC 11 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 establishing 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) .1627 Procedures for Receiving and Opening Packages

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 Radioactive Material 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 departments will be using radioactive material.
- Item 3- Please indicate current license number or if you are applying for a new license, please state.
- Item 4- All users (radiopharmacists) must be listed.
- Item 5- Indicate who will serve as the Radiation Safety Officer.

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

- Item 6- All radioactive material must be listed in 6a with the chemical/physical form and maximum amount to possess in item 6b. Please include all isotopes, even Mo-99 generators with the mCi amounts. Also include sealed sources used for calibration purposes.
- Item 7- Please describe what each isotope will be used for.
- Item 8&9- Please submit resumes or training documents for all individual users. If pharmacists will be supervising other individuals, please describe this supervision and the type of training these individuals will obtain before being allowed to use material under someone's supervision.
- Item 10- All survey meters/friskers must be listed. If your generator exceeds 100 millicuries, a survey meter that detects up to 2 R/hr is required. Please list all dose calibrators, well counters and lab monitors also.
- Item 11- Indicate all information concerning the calibration of the survey meters and who will calibrate them.
- Item 12- Indicate what dosimetry service you will be using and the frequency of exchange.
- Item 13- Indicate which attachment is the sketch of your facility. Indicate where the hot lab

- with hood, sink, work areas, decay in storage and shielding is located. If you have a hood, indicate the face velocity, and frequency of calibration.
- Item 14- This is to be incorporated into the radiation protection program already discussed on page one. Please enclose all information about leak testing sealed sources that exceed 100 microcuries under an attachment and indicate here. State frequency of leak test and who will perform them.
- Item 15- If you hold waste on site, please submit your procedure to assure the waste is at background radiation levels before disposal. Waste must be held for 10 half lives and radiation levels must be at background before disposal. All labels must be defaced or removed before disposal. Please indicate on the sketch of your facility where the storage area of waste for decay is located. If you will be picking up waste for decay or disposal from clients, please address how this will be done.
- 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. Submit samples of forms used for receipt, use, physical inventory of sealed sources and disposal of radioactive materials.
 4. Submit procedures and frequency of tests for these areas:
 - a) Constancy, linearity and accuracy tests and geometric variation (If a consultant performs any of the above tests, indicate the consultant and the test they will perform). If you will use a calibration kit to do the linearity test (Calichek or Lineator), please provide the manufacturer's name and state that you will follow the instruction booklet to calibrate your instrument.
 - b) Molybreakthrough procedure upon elution of generators.
 - c) Surveys and wipes performed prior to shipping doses to clients.
 - d) Emergency procedure for spills and accidents.
 - e) Surveys and wipes of use and storage areas.
 - f) Bioassay procedure if you use volatile forms of I-131.
 - g) Surveys and wipes performed of ammo boxes for incoming receipt of unused doses of radioactive material.
 - h) Frisking requirements of employees upon exiting hot lab.
 - i) Verification of client radioactive material license prior to shipping doses.
 5. If use of Xenon or iodination using I-131 will be done, please address the following information.
 - a) Drawing of room where material used; show where hoods are located in this room.
 - b) Provide information on flow rate of hood.
 - c) Show location of exhaust stack. Must be at least 25 feet from any air intake to building.
 - d) How often will the hood be calibrated?
 - e) Please describe in detail all information pertaining to iodination.
 6. Describe security of hot lab and training of auxiliary personnel in regard to the hazards of radiation.
 7. Please address all training for the delivery drivers who will be delivering radioactive material to your clients. If a test will be given, please submit the test with the minimum score allowed for a passing grade. Please specify the type dosimetry that will be provided to delivery drivers.

8. Describe the type of transportation that will be used for deliveries to include the blocking and bracing used for the ammo boxes. Please address where the bill of lading will be kept during the transporting of material. Please submit a sample copy of a bill of lading.
9. Describe the process in which generators are returned.
10. If sealed sources are distributed to clients, please address all paperwork that is maintained by you and sent to client. NOTE: The agency requires that copies of the Sealed Source & Device Registry Sheets for EACH TYPE /MODEL of sealed source distributed be maintained on file at the pharmacy. Please provide a commitment that this will be done.
11. Describe what type of review process is done in the case of a misadministration occurring at a client's office due to a wrong dose being delivered on your part. What type of reporting will be done to this agency?
12. Please submit ammo box certification and what procedure will be used to determine the proper DOT labeling of boxes for transport.
13. What type of documentation is sent to the client concerning the Mo-99 breakthrough and the results of this test?
14. Please address whether the fire Marshall will be notified and if a survey by the fire department will be done to allow them the chance to see what type of material is maintained on site in case of a fire.
15. Please describe what type of notification will be done to this agency in case of an accident during transportation of radioactive material.
16. Please submit policy on return of generators.
17. Please submit generator redistribution policy and procedures.
18. Please submit procedures for inventory tracking, including waste.
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.
20. All applicants for a Radioactive Materials 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.drp.enr.state.nc.us).