LICENSING CHECKLIST FOR HOSPITAL-BASED NUCLEAR MEDICINE LICENSES

INSTRUCTIONS FOR USE: Use the checklist below to ensure that all required information is transmitted to the agency with your application for a Radioactive Materials License. INCLUDE a copy of this checklist with the application. Mail **ONE** copy of the appropriately signed application form with enclosures/attachments to: ***Branch Manager, Radioactive Materials Branch, 1645 Mail Service Center, Raleigh, NC 27699-1645.***

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INTRODUCTION

The Radiation Protection Section (the "agency") is publishing this guidance document to provide applicants with direction and guidance on filing applications with the agency. This guidance is applicable to prospective licensees who are applying for a radioactive materials license and to current licensees who are applying for license renewal.

This guide is not intended to be a substitute for the applicants radiation safety program. It is the applicant's responsibility to review the North Carolina Regulations for Protection Against Radiation (15A NCAC 11) for those areas which directly impact the applicant's radiation safety program. In particular, all applicant's must read and understand Sections .0100 "General Provisions," .0300 "Licensing of Radioactive Material," .1000 "Notices: Instructions: Reports and Inspection," .1100 "Fees," and .1600 "Standards for Protection Against Radiation" prior to applying for a radioactive materials license. Other Sections of the North Carolina Regulations may be applicable to the applicant's particular use of radioactive materials. Review the Table of Contents to ensure that ALL applicable sections of 15A NCAC 11 have been properly addressed.

The agency will evaluate an application against two standards: (1) The North Carolina Regulations for Protection Against Radiation, and (2) good health physics practices based upon Federal guidance and industry practice. Included in North Carolina's regulations is the ALARA concept (15A NCAC 11 .1603(b)). This regulation requires the licensee to keep exposures as far below the applicable limits established in Section .1600 as reasonably achievable. License applicants should give due consideration to this philosophy when developing policies and procedures which encompass work with radioactive materials.

After a license is issued, the licensee must conduct the radiation safety program in accordance with (1) The North Carolina Regulations for Protection Against Radiation in 15A NCAC 11 *et seq.*, (2) all aspects of the license and its conditions, and (3) all statements, representations, and procedures contained in the licensee's application.

In order to properly process an application for a radioactive materials license, the application form MUST be completely and properly filled out. The following summary will explain the different parts of the form in greater detail.

HOW TO FILE

Complete Items 1 – 3 & 5 of the application form on the form itself (if space allows). For items 4 & 6 – 15, submit the required information on supplementary pages. You should identify each supplemental page as an attachment or addenda item.

Please note that all materials furnished to the agency for review are public documents once the agency has taken final actions on them (*i.e.*, issuance of a license). As such, do not submit information that is proprietary or confidential unless absolutely necessary. If proprietary or confidential information must be submitted with the application, this information should be separated from the application package and a detailed explanation of why the information should be maintained as proprietary or confidential must accompany the application. The agency does have a mechanism for securing the proprietary/confidential materials if necessary. However, if the agency does not agree with your evaluation of the proprietary or confidential nature of the information, it will be returned to you with a letter of explanation.

The applicant should not make commitments to the agency which are more restrictive than the requirements outlined in the regulations or in this guide. If you wish to be more restrictive than the agency, make an internal policy statement to that effect. Likewise, avoid using "vague" terms to define frequencies for completion of tasks. State that "Task A will be completed at intervals not to exceed six months," rather than stating "Task A will be completed twice per year."

If you wish to request an exemption from any regulation or agency requirement [reference 15A NCAC 11 .0106(a)], this **MUST** be submitted under separate cover. The request should be specific and provide data and/or rationale which supports your request. All requests for exemptions should be directed to ***Branch Manager, Radioactive Materials Branch, 1645 Mail Service Center, Raleigh, NC 27699-1645.***

If your request is granted, the request will be incorporated into the license. If denied, you will receive a letter indicating that the request was denied.

The applicant should retain a copy of the application and attachments, as well as all correspondence with the agency regarding the application. If the license is issued, the application becomes an integral part of your overall radiation protection program.

If the application is being filed for renewal of an existing license, the applicant should begin gathering materials approximately six months prior to the expiration of the license. 15A NCAC 11 .0339(a) specifically addresses renewal of licenses. It is strongly recommended that the applicant submit his renewal application 90 days prior to the expiration of the license. This will allow the agency time to review the application and request additional information if necessary. As a courtesy, the licensee may receive a notification from the agency stating that the license is about to expire. Such notices, if sent, are normally mailed 90 days prior to license expiration. **NOTE: It is the LICENSEE'S RESPONSIBILITY to file a renewal application in a timely manner [*as defined in 15A NCAC 11 .0339(a)*].** Not receiving a courtesy notification from the agency **DOES NOT RELIEVE** the licensee from the filing requirements.

If the applicant is seeking a reactivation of a terminated license or is filing for a new license, submit the appropriate information to the agency at least 90 days prior to the expected first usage of radioactive materials. This will allow the agency time to review the materials and make request for additional information (pursuant to 15A NCAC 11 .0108(a)) as necessary.

The application should be submitted on clean, 8½" x 11", white paper. All pages in the application should be numbered consecutively, beginning with the application form as page 1, in the lower right-hand corner of the page. Drawings and/or floor plans do not have to be drawn "to scale." The application and all attachments and/or addenda should be typewritten. The agency will accept handwritten application forms provided that the information is printed legibly on the form. ***DO NOT SUBMIT A DUPLICATE OF THE APPLICATION***. Applications should be mailed to: ***Branch Manager, Radioactive Materials Branch, 1645 Mail Service Center, Raleigh, NC 27699-1645.***

NOTE: If the agency receives an application that is illegible or that is not signed by the appropriate corporate official, the entire package will be returned to you without review.

NOTE: Text in the "ITEM" column that is in bold typeface indicates that the information has been changed in this revision of the guidance document.

EXPLANATION OF THE INFORMATION REQUESTED IN THE APPLICATION FORM

✓	ITEM	DISCUSSION/REQUIREMENTS
☐	Item 1: Name and Addresses of the Applicant	The name and address of the facility to be licensed. The name MUST be the legal business name of the entity applying for licensure. The address entered in Item 1(a) should be the mailing address and in Item 1(d), the physical (street) address of the place of use and/or storage. All zip codes must be in the "ZIP + 4" format. Telephone and facsimile numbers should begin with area code and telephone extensions should be included where applicable. These telephone numbers should be for the department where radioactive material is used (*i.e.* department listed in Item 2).
☐	Item 2: Department(s) to use Radioactive Materials	Please state the name(s) of the departments which will be using the radioactive materials
☐	Item 3: Previous License Number(s)	If the application is for a new license, indicate "NEW LICENSE" in item 3. Otherwise specify the previous license number if the application is for renewal of an existing license.
NOTE: ***Items 4 and 6 - 15 should be completed on 8½" x 11" paper and attached to the properly signed application form.***		
☐	Item 4: Individual User(s)	In this section of the form, reference the appendices or addenda where the individual users are named. Training for the users listed in this item should be addressed under Items 8. and 9.

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☐	**Item 5: Radiation Protection (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).***
☐	**Item 6: Radioactive Material (element, mass no., physical/chemical form, possession limit**	15A NCAC 11 was recently amended to remove the "Groups of Diagnostic Uses" provision. 15A NCAC 11 .0361 was recently amended and addresses use of unsealed radioactive materials for uptake, dilution, excretion, imaging and localization studies. Briefly, this rule authorizes appropriately licensed facilities to "…use any unsealed radioactive material prepared for use for uptake, dilution, or excretion studies, imaging and localization studies and radiopharmaceutical therapy that is: (1) Obtained from a manufacturer or preparer licensed under 10 CFR 32.72 or equivalent Agreement State requirements; (2) Prepared by: (A) An authorized nuclear pharmacist; (B) A physician who is an authorized user identified on a North Carolina Radioactive Materials License, an Agreement State Radioactive Materials License, or a license issued by the U.S. Nuclear Regulatory Commission or who meets the requirements in 15A NCAC 11 .0117(a)(2); (C) An individual under the supervision, as specified in Rule .0318 of this Section, of the authorized nuclear pharmacist in Part (a)(2)(A) of this Rule or the physician who is an authorized user in Part (a)(2)(B) of this Rule; (3) Obtained from and prepared by an NRC or Agreement State licensee for use in research in accordance with a Radioactive Drug Research Committee-approved protocol or an Investigational New Drug (IND) protocol accepted by the FDA; or (4) Prepared by the licensee for use in research in accordance with a Radioactive Drug Research Committee-approved protocol or an Investigational New Drug (IND) protocol accepted by the FDA. 15A NCAC 11 .0321was further amended to address the use of sources for "check, calibration, or reference" by licensees. The new limits now include: (1) Sealed sources not exceeding 30 millicuries (mCi)(1.11 Gigabecquerel (GBq)) each, manufactured and distributed by a person licensed under 10 CFR 32.74 or equivalent Agreement State regulations; (2) Sealed sources, not exceeding 30 mCi (1.11 GBq) each, redistributed by a licensee authorized to redistribute the sealed sources manufactured and distributed by a person licensed under 10 CFR 32.74, providing the redistributed sealed sources are in the original packaging and shielding and are accompanied by the manufacturer's approved instructions; (3) Any radioactive material with a half-life not longer than 120 days in individual amounts not to exceed 15 mCi (0.56 GBq); (4) Any radioactive material with a half-life greater than 120 days in individual amounts not to exceed the smaller of 200 microcuries (μCi) (7.4 Megabecquerel (MBq)) or 1000 times the quantities in Appendix C of 10 CFR Part 20; and (5) Technetium-99m in amounts as needed. Leak testing and quarterly physical inventory requirements still apply to sealed sources. For all other isotopes, list the isotope, chemical and/or physical form, and quantity of radioactive material needed.

✓	ITEM	DISCUSSION/REQUIREMENTS
☐	**Item 7: Describe the purpose for which the radioactive materials will be used.**	Each use should clearly cross-reference the isotopes listed in Item 6 of the form. Radiopharmaceuticals are to be listed as "To be used for (diagnostic or therapeutic as appropriate) use in humans. Any radioactive materials used for check, calibration, reference or transmission sources should be identified.
☐	**Items 8 & 9: Training of Each Individual Named In Item 4.**	The recent amendments to the NC Regulations for Protection Against Radiation have incorporated the US NRC regulations regarding training and experience (T&E) for authorized users (including authorized medical physicists and authorized nuclear pharmacists). The agency is planning a latter implementation date for this requirement and will be sending advanced notice of these changes. For now, use the "existing" requirements for authorized user T&E.
☐	Item 10: Radiation Detection Instruments Available for Use	Please list all radiation detection instruments which are available to the applicant. This listing should include make, model, radiation detected, range, efficiency (where applicable) and minimum detectable activity (where applicable).
☐	Item 11: Method, frequency, and standards used in calibrating the instruments listed in Item 10.	Please provide procedures on how the instrument(s) will be calibrated. If the applicant plans to contract with a firm to perform the calibrations, submit that firm's name, address, and license number.
☐	Item 12: Film Badges, TLD's, Dosimeters, and Bioassay Procedures Used.	Pursuant to 15A NCAC 11 .1613(c), the dosimetry vendor you choose must be certified by the National Voluntary Laboratory Accreditation Program (NVLAP) for the type of personnel dosimetry ordered. Provide the name and address of the vendor, the type of dosimetry (*i.e.*, TLD or film badge), and the exchange frequency (*i.e.*, monthly or quarterly) in this area of the application. The applicant should also discuss the use of extremity dosimetry if applicable. For dosimeters, please provide the make, model, range and calibration frequency, procedures for calibration (or name of vendor who will provide calibration(s). There should also be copies of the dose recording forms to be used with these dosimeters submitted with the application.
☐	Item 13: Facilities and Equipment	Submit a drawing of the floor plan of each use and/or storage area listed within items 1(a) and 1(d). This includes imaging areas, waste storage areas, treadmills or other "use" locations outside of the nuclear medicine department. Each floor plan should include the use and storage area(s) with all entrances to the room(s) and surrounding areas [see 15A NCAC 11 .0317(a)(4)]. These drawings to not have to be "to scale."
☐	Item 14: Radiation Protection Program	The licensee is responsible for implementing a radiation protection program and for all actions of the licensee's employees. The agency's expectation is that applicants develop and document their radiation protection program in a format similar to a manual. This format should outline all of the areas of the radiation protection program and either contain procedural information or reference that information. In developing a "manual" for radiation protection, this will allow new uses to familiarize themselves with the program elements quickly and allow for ease of review by corporate auditors or the agency. Listed below are the areas which, at a minimum, must be addressed within the "Radiation Protection Program" submitted by the applicant. Please note that this list is a MINIMUM and there may be additional requirements discussed below which MUST be included in the application: A. Radiation Protection (Safety) Officer duties and responsibilities; B. Radiation Safety Committee duties and responsibilities; C. Authorized user training and re-training (if applicable);

✓	ITEM	DISCUSSION/REQUIREMENTS
		D. Training and re-training of Ancillary Personnel; E. Leak Testing of Sealed Sources; F. Physical Inventory of Sealed Sources; G. Surveys of use and/or storage areas; H. Transportation of Radioactive Materials (if applicable); I. Dose Limits, Personnel Dosimetry and/or Bioassay (if applicable); J. Labeling and Posting; K. Operating and Emergency Procedures; L. Security and Control of Radioactive Materials; M. Disposal of radioactive materials Remember, this is a limited listing of topics to be included in the Radiation Protection (Safety) Program. See the areas below for additional requirements.
☐	Item 15: Waste Disposal	Please develop and submit policies and procedures for the safe handling and disposal of radioactive waste anticipated under the proposed license. Please refer to 15A NCAC 11 .1628 - .1633 for additional information on waste disposal. Additional information is presented below.
☐	Item 16: Certification **NOTE:** ***Any application packet submitted to the agency for review that does not have the proper signature(s) will be returned to the licensee and all licensing actions will cease until the form is properly signed and returned.***	The application form represents not only a request to become licensed to possess radioactive material in North Carolina, but it is a legal and binding agreement between the licensee and the State of North Carolina. ***Item 16 MUST be completed on the form itself. The form should be signed by: (1) the owner if a sole proprietorship; (2) a general partner if a partnership; or (3) the President or other corporate officer of the company if a corporation.***

ADDITIONAL INFORMATION NECESSARY FOR LICENSING		
Listed below are other areas which MUST be fully addressed prior to a license being issued by the agency. They should be included as attachments or addenda, or incorporated into the radiation protection program. Where possible, the applicable reference from the North Carolina Regulations for Protection Against Radiation (15A NCAC 11) has been cited. The applicant should read and understand all of the cited references. Additionally, the agency has guidance available on its website (*www.drp.enr.state.nc.us*) for some of the areas identified in this licensing checklist.		
✓	**ITEM**	**DISCUSSION/REQUIREMENTS**
☐	15A NCAC 11 .1603(c): Radiation Protection Programs – Annual Review of the Radiation Protection Program	This must be done by the licensee, and is usually done by the Radiation Safety Officer. This review should encompass all areas of the program as outlined in your license application. The applicant is to include its proposed format for conducting the annual review of the program in the license application for review.
☐	15A NCAC 11 .1604: Occupational Dose Limits for Adults	Address this regulation in the form of a policy which states the maximum occupational doses for all workers and has investigational levels established in the policy. The investigational levels should have explicit steps which the RSO and/or RSC will take in investigating violations of these levels.
☐	15A NCAC 11 .1610: Dose to Embryo/Fetus	Provide a policy which addresses this regulation. The policy MUST be voluntary in nature and MUST define a declared pregnant worker [reference 15A NCAC 11 .0104(28)]
☐	15A NCAC 11 .1611 & .1612: Dose Limits For Individual Members of the Public (and compliance)	Provide a commitment to keep radiation doses to unrestricted areas as far below the limits specified in 15A NCAC 11 .1611 as reasonable achievable (ALARA). Additionally, the licensee must submit procedures, policies, calculations, etc. to demonstrate compliance with the above referenced regulation;
☐	15A NCAC 11 .1627: Procedures for Receiving and Opening Packages	Provide the agency with policies/procedures for package receipt. This should include all forms used to document compliance, the instrumentation used to analyze removable contamination wipes, perform exposure rate measurements, efficiency and/or MDA for instruments, action levels for agency and carrier notification, etc. The requirements for receipt of packages containing radioactive materials change effective August 01, 2002. The changes are outlined below: A. Removable Contamination Surveys required when: 1. the package contains radioactive material in a form other than gas or special form, or 2. the package appears to be wet, crushed, or damaged. B. Exposure Rate Measurements required if: 1. the package contains greater than Type A quantities of radioactive material (irregardless of form), or 2. the package appears to be wet, crushed, or damaged.
☐	Authority to sign licensing requests	Use the agency form "Memorandum to All Licensees" if upper management wishes to delegate signature authority to another individual in the organization. If this authority is granted, the agency recommends delegation to a position rather than to a specific individual (*e.g.* R.S.O., Vice President, etc.)

✓	ITEM	DISCUSSION/REQUIREMENTS
☐	**Specific training information for Authorized Users (AU's)**	Pursuant to 15A NCAC 11 .0117(a)(2) [and by reference 10 CFR 35, Subpart J], physician must meet certain requirements before being named as authorized users. Therefore, submit either: a. a copy of a board certification from a certifying body listed in this Subpart; b. a copy of a North Carolina Radioactive Materials License which lists the physician(s) as authorized user(s): or c. a completed Supplement A (preceptor statement) for each physician (available on our website). PLEASE NOTE: THE T&E FOR AUTHORIZED USERS IS SET TO CHANGE IN JUNE, 2008. THE REQUIREMENTS NOTED ABOVE WILL REMAIN IN EFFECT UNTIL THAT TIME. THE AGENCY WILL PUBLISH GUIDANCE IN ADVANCE OF THE JUNE, 2008 TIMEFRAME TO ALLOW INDIVIDUALS AND LICENSEES ADEQUATE TIME TO GATHER THE APPROPRIATE DOCUMENTATION.
☐	Radiation Safety Committee (RSC)	15A NCAC 11 .0319(b), applicants for hospital-based radioactive materials licenses shall establish a "medical isotopes committee" (RSC) which will oversee the use of radioactive materials. This regulation addresses the specific composition of the RSC. Please use the form "Memorandum to All Licensees" to document the membership of the RSC. State the frequency with which the committee will meet.
☐	**Adding Authorized Users**	As an institution which has established a RSC to review all uses and users of radioactive materials, the agency will allow hospital licensees to approve certain users "in-house." The requirements for this procedure are contained in DRP Information Notice 96-03, which is available on the agency's website. Review the information notice and ensure that you have the appropriate policies and/or procedures to address this issue. PLEASE NOTE: THE T&E FOR AUTHORIZED USERS IS SET TO CHANGE IN JUNE, 2008. THE REQUIREMENTS NOTED ABOVE WILL REMAIN IN EFFECT UNTIL THAT TIME. THE AGENCY WILL PUBLISH GUIDANCE IN ADVANCE OF THE JUNE, 2008 TIMEFRAME TO ALLOW INDIVIDUALS AND LICENSEES ADEQUATE TIME TO GATHER THE APPROPRIATE DOCUMENTATION.
☐	**Specific Duties of the R.S.O.**	In order to be named as the R.S.O. for a medical use license, the proposed RSO must meet the requirements of 10 CFR 35.900 (now) and by June 1, 2008, the requirements of 10 CFR 35.50. 15A NCAC 11 .0318(l) and (z)– (bb) outline the responsibilities of the Radiation Safety Officer for a medical use licensee. Paragraph (z) of this regulation states *"A licensee's management shall appoint a Radiation Safety Officer (RSO) who agrees in writing to be responsible for implementing the radiation safety program. The licensee, through the RSO, shall ensure that radiation safety activities are being performed in accordance with approved procedures and regulatory requirements in the daily operation of the licensee's radioactive material program."* . Paragraph (aa) further states *" A licensee shall establish in writing the authority, duties and responsibilities of the Radiation Safety Officer."* This information should be submitted along with the application. The applicant should consider the requirements of this regulation and the scope and extent of proposed activities when compiling this listing.

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☐	**Technologists qualifications (including re-training)**	Pursuant to 15A NCAC 11 .0318(s) – (w), technologists or other paramedical personnel who will administer radioactive materials to humans shall meet certain training requirements. Review the requirements in these regulations and provide the agency with policies and procedures for acceptance and training of nuclear medicine technologists. Additionally, these regulations provide for continuing training in the areas of nuclear medicine. Please provide a policy / procedure statement on how the applicant will address re-training (continuing education) for technologists.
☐	Training of ancillary personnel	The agency requires that ancillary personnel be given some form of "hazard recognition" training concerning the possession, use and storage of radioactive materials and radioactive waste. The applicant must determine, pursuant to 15A NCAC 11 .1003, the level of that training for individuals who are not radiation workers who must enter restricted areas in the performance of their job duties. Therefore, submit a policy concerning the training of ancillary personnel commensurate with this regulation. License applicants always have the option of not allowing ancillary personnel into restricted area.
☐	**Physical inventory of sources**	The agency requires that all sealed sources used for quality assurance/quality control be inventories at intervals not to exceed three (3) months. The applicant should submit procedures for conducting the inventory and forms used to document the inventory. Information required to be documented in found in 15A NCAC 11 .0321(e).
☐	**Leak testing procedures**	Leak testing of sealed sources is required pursuant to 15A NCAC 11 .0321(c) – (d) Provide procedures for conducting leak tests and what steps will be taken in the event of a leaking source. If the applicant will use a third-party to analyze the test sample, please provide the name and license number for the third party. If the applicant wishes to analyze his own leak test, describe the equipment which will be used to analyze the sample; include make, model, efficiency and MDA for the instrument. Provide an example of a report which will be generated for each leak test sample.
☐	**Survey instrumentation, calibration & response checks**	15A NCAC 11 .0360 requires the possession of survey instrumentation for conducting surveys of all use, preparation, administration and storage areas. Such instrumentation shall be calibrated before the first use and annually thereafter. Please provide information concerning the make, model, and calibration frequency of the portable survey instrumentation which will be used by the applicant. 15A NCAC 11 .0360(g) also requires the daily operational check of the survey instrument with a dedicated check source. This operational check does not have to be documented. However, the licensee should be aware of this requirement and shall have a procedure to address this regulation.
☐	Dosimetry for other than nuclear medicine personnel	The agency requires the applicant to assess dosimetry requirements for individuals who will provide care for a patient containing diagnostic or therapeutic quantities of radioactive materials. This could include the nursing staff and critical care teams. Please provide a policy statement concerning this issue.

✓	ITEM	DISCUSSION/REQUIREMENTS
☐	Bioassay Procedures	The agency requires that bioassay procedures be implemented for persons who handle greater than 33 millicuries of unsealed radioiodine. The procedure should address, at a minimum, the following areas: a. instrumentation used to conduct the bioassay; b. efficiency and MDA of the instrument; c. timeline for conducting bioassay after administration/handling of the radioiodine; and d. baseline bioassays for new employees. If you do not intend on handling radioiodine in individual quantities of greater than 33 millicuries, a bioassay program is not required.
☐	Waste/Disposal Procedures	15A NCAC 11 .0362 provides for decay-in-storage at the applicants facility. If this is the method chosen for disposal of all waste, and no material will be returned to the nuclear pharmacy, simply state that the waste disposal program shall be implemented in accordance with 15A NCAC 11 .0362. If you intend on returning material in the form of unused doses and spent syringes to the pharmacy, then include a "pharmacy agreement" with the application. This agreement should delineate the materials which are allowed to be transferred to the pharmacy (*e.g.* unused doses, spent syringes, etc.), who the "shipper" of the radioactive materials will be, contamination and exposure rate limits for return shipments, etc. It should be noted that nuclear pharmacy licensees are allowed to accept only syringes (used and unused) as well as tubing used to administer the dose to the patient. NO OTHER PARAPHERNALIA CONTAMINATED WITH ANY RADIOACTIVE MATERIALS ARE TO BE TRANSFERRED TO THE PHARMACY. Those items MUST be maintained at the applicant's facility and managed in-house. All forms used to track waste inventory should be submitted with the application.
☐	**Dose calibrator quality assurance/quality control**	15A NCAC 11 .0359 provides for the possession and use of a dose calibrator at all medical use facilities. Licensees are required to develop, implement and maintain written procedures for the use of the dose calibrator. Quality assurance is to be done in accordance with 10 CFR 35.60(b). This rule basically states that licensees must follow either the manufacturer's recommendations or a nationally recognized standard. Whichever you choose to do, it should be part of the written procedures referenced above. The applicant should provide the make and model of the dose calibrator in the application.
☐	Gamma camera quality assurance / quality control	The agency requires that imaging equipment (gamma cameras) be tested on a routine basis to ensure the proper functioning of the equipment. The tests are routinely known as "floods and bars." The "floods" should be conducted on the camera each day prior to patients being imaged. "Bars" should be conducted weekly. Please provide procedures for these two controls. If your camera's manufacturer recommends a different frequency and/or additional testing be done (*e.g.* center of rotation) please provide that information for agency review.

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☐	Use of ^{99m}Tc Generators and return shipments of spent generators	15A NCAC 11 .0361 addresses the use of generators in the clinical environment. Please read this regulation carefully and ensure that you have submitted adequate policies and procedures to address the applicable portions of this regulation. If only unit doses from a nuclear pharmacy will be used, so state. If a generator will be used, the agency requires a policy and/or procedure statement to address the return of a spent generator. The policy/procedure shall include, at a minimum, the following: a. length of time the generator will decay prior to shipment; b. surveys (removable contamination and exposure rate) which will be conducted on the packaged generator prior to shipment; and, c. records which will be maintained to demonstrate compliance with the N.C. Regulations and Department of Transportation (DOT) regulations.
☐	**Surveys of Use/Storage/Preparation areas**	15A NCAC 11 .0360 requires that certain surveys be conducted in areas of use, storage and preparation. Read this regulation carefully and develop policies and procedures to ensure compliance. The recent amendment to this regulation removed the requirement to conduct weekly removable contamination surveys in use, storage and or preparation areas. However, the licensee should evaluate their use of "longer-lived" radioactive materials (e.g., use of I-131 for I-125) may necessitate the performance of removable contamination tests.
☐	Emergency Procedures	Each applicant is responsible for establishing emergency procedures which are commensurate with the scope and extent of the proposed activities listed in the license application. Due consideration should be given to isotope, form, quantity, type of work performed, etc. BE SPECIFIC on the steps to be taken in the event of a spill, loss or theft of radioactive materials. Discuss notifications of the RSO and the agency. NOTE: The agency has emergency contact information on the website.
☐	**Procedures for Administrations Requiring a Written Directive (formerly entitled "Quality Management Program")**	This regulation was amended to remove the quality management program as a discrete concept. However, if you read this rule carefully, licensees are still required to have a written program to ensure certain "aspects" of the former quality management program. You will also note that this is applicable only to those procedures requiring a written directive. Since the regulations do not require a "formal" Quality management program" be established in writing, the requirement for an annual review of the quality management program has also been removed. Again, read this newly amended regulations carefully and develop a program commensurate with the scope and extent of licensed activities. This should be submitted for agency review.

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☐	**Written Directives**	15A NCAC 11 .0104 was recently amended to re-define a written directive. The amended regulation now reads: "Written directive" means an order in writing for a specific patient or human research subject dated and signed by an authorized user prior to the administration of a radiopharmaceutical or radiation from a licensed source, except as specified in Sub-item (e) of this definition, containing the patient or human research subject's name and the following information: (a) for the administration of greater than 30 microcuries (1.11 Megabecquerels (MBq)) of sodium iodide I-131, the dosage; (b) for the therapeutic administration of a radiopharmaceutical other than sodium iodide I-131: (i) radionuclide; (ii) dosage; and (iii) route of administration; (c) for teletherapy or accelerator radiation therapy: (i) total dose; (ii) dose per fraction; (iii) treatment site; and (iv) number of fractions; (d) for high-dose-rate remote afterloading brachytherapy: (i) radionuclide; (ii) treatment site; (iii) dose per fraction (iv) number of fractions; and (v) total dose; (e) for all other brachytherapy: (i) prior to implantation: (A) radionuclide; (B) treatment site; and (C) dose; and (ii) after implantation: (A) radionuclide; (B) treatment site; (C) number of sources; (D) total source strength and exposure time; and (E) total dose; (f) for gamma stereotactic radiosurgery: (i) the total dose; (ii) treatment site; and (iii) values for the target coordinate settings per treatment for each anatomically distinct treatment site. Therefore, for DIAGNOSTIC USE ONLY, a written directive from an authorized user is NOT REQUIRED. PLEASE NOTE: Administrations still must be done in accordance with the Diagnostic Clinical Procedures Manual and the dose MUST be assayed in a dose calibrator PRIOR to administration.
☐	**Medical Events and Dose to an Embryo/Fetus or Nursing Child**	These NEW regulations are found in 15A NCAC 11 .0364 and 0365 and are intended to replace the "misadministration" component of the former Quality Management Program. The agency will begin implementation of these regulations effective March 01, 2008. We are currently developing guidance documents for licensees/applicants in these areas. These documents will be posted to our website PRIOR to March 01, 2008.

✓	ITEM	DISCUSSION/REQUIREMENTS
☐	**Use of Gas(es) and/or Aerosols**	If there is no intended use of gas(es) and or aerosol(s), so state. Although 15A NCAC 11 .0361 was amended to remove certain language related to use of gas(es) and/or aerosols, licensees should still exercise care when using these certain forms. Existing policies and procedures should be reviewed to ensure that workers and members of the public will not be needlessly exposed to radiation from radioactive gas(es) and/or aerosols.
☐	**Security of use and storage areas**	Pursuant to 15A NCAC 11 .1622, each applicant must address the issue of security. Please discuss the administrative and engineered controls which will be used to secure from unauthorized access or removal all sources of radiation or radioactive materials. This includes waste storage areas also. PLEASE NOTE: The agency has always placed a high priority on ensuring that the licensee's security measures are adequate. However, since the events of 9/11 and changes in the US NRC regulations (e.g., "Increased Controls"), it is even more important that licensees take appropriate measures to ensure security of radioactive materials. When discussing SPECIFIC aspects of your security plan, the agency asks that you please mark these pages as "SECURITY-RELATED MATERIALS" for our convenience.
☐	Release of patients containing radio-pharmaceuticals or permanent implants	15A NCAC 11 .0358 allows licensees to release patients from their control provided the dose to an individual member of the public from the released patient does not exceed 500 millirem. If the applicant chooses to implement the provisions of this regulation, written policies and/or procedures must be submitted for agency review. To assist applicants in formulating the policy, NRC Regulatory Guide 8.39 "Release of Patients Administered Radioactive Materials" is available on our website.
☐	Diagnostic Clinical Procedures Manual	All clinical use licensees must have a Diagnostic Clinical Procedures Manual available for agency review. 15A NCAC 11 .0104(35) provides a definition of the manual. The manual DOES NOT have to be submitted with the application. Simply commit to developing the manual in accordance with the regulations and having it available for agency review at the time of inspection.
☐	Financial Assurance and Record-keeping for Decommissioning	Each applicant is required to determine whether or not they must provide financial assurance for decommissioning. The "test" for making this determination can be found in 15A NCAC 11 .0353. Additionally, the agency has placed guidance on the website (*www.ncradiation.net*) concerning financial assurance. If no financial assurance is required, so state. If the determination indicates that financial assurance is required, consult the website and contact a member of the Radioactive Materials Branch for additional guidance.
☐	Proposed uses other than diagnostic and/or therapeutic use of radio-pharmaceuticals	If your application contains information concerning other uses of radioactive materials (*e.g.* HDR or manual brachytherapy), please consult those specific licensing guides and supply the requested information. Be sure to incorporate ALL information into the radiation protection program noted above.

✓	ITEM	DISCUSSION/REQUIREMENTS
☐	Legal business name information	Pursuant to the North Carolina General Statutes 104E-5(11) and 104E-10(b), radioactive materials licenses are only issued to "persons." A corporation is not a "person" until it has been authorized by the North Carolina Secretary of State to conduct business within North Carolina. For this reason, the corporate applicant must submit documentation of the legal business (operating) name of the facility. A radioactive materials license will NOT be issued until such documentation has been submitted to the agency for review. Normally, the agency will accept either a certificate from the Certificate of Need Section of the Division of Health Service Regulation or the N.C. Secretary of State's Office. If you have questions on what type of documentation you need to submit, contact DHSR at (919)855-3883, or the Secretary of State's Office, Corporations Division at (919) 733-4201.