



## LICENSING CHECKLIST FOR BRACHYTHERAPY 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: **Head, Radioactive Materials Branch, 1645 Mail Service Center, Raleigh, NC 27699-1645.**

*This Guide is not intended to, and does not, create any rights or privileges, substantive or procedural, which are enforceable by person. The publication of this guide, or any version thereof, does not place any limitation of the otherwise lawful prerogatives or discretion of the Radiation Protection Section.*

### 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 applicant's 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 [reference 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 **Head, 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: ***Head, 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.***

**EXPLANATION OF THE INFORMATION REQUESTED IN THE APPLICATION FORM**

4	ITEM	DISCUSSION/REQUIREMENTS
<input type="checkbox"/>	Item 1: Name and Addresses of the Applicant	The name and address of the facility to be licensed. The name <b>MUST</b> 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>i.e.</i> department listed in Item 2).
<input type="checkbox"/>	Item 2: Department(s) to use Radioactive Materials	Please state the name(s) of the departments which will be using the radioactive materials
<input type="checkbox"/>	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(s) if the application is for renewal of an existing license. If you are applying to reactivate a terminated license, please include the words "Reactivation of License No. XXX-XXXX-X" in this area of the form. If you are/were a licensee of the Nuclear Regulatory Commission (NRC) or another Agreement State (AS), please indicate which state or NRC Region where the license was issued. You may provide a copy of that license as an attachment.
<b>NOTE: Items 4 and 6 - 15 should be completed on 8½" x 11" paper and attached to the properly signed application form.</b>		
<input type="checkbox"/>	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.

4	ITEM	DISCUSSION/REQUIREMENTS						
<input type="checkbox"/>	<b>Item 5: Radiation Protection (Safety) Officer</b>	The Radiation Protection (Safety) Officer (R.S.O.) <b>MUST</b> 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. <i>See detailed information on RSO required qualifications at <a href="http://ncradiation.net/rms/rmsmultoolkit.htm">http://ncradiation.net/rms/rmsmultoolkit.htm</a>.</i>						
<input type="checkbox"/>	Item 6: Radioactive Material (element, mass no., physical/chemical form, possession limit)	For Item 6.a., list the element and mass number for each radionuclide being requested. For Item 6.b., list the chemical and/or physical form and the possession limit. This may be done in tabular form as shown below. The agency does allow either a per source limit or a total possession limit.  <table style="width: 100%; border-collapse: collapse;"> <tr> <td style="width: 30%;">6.A. Cesium 137</td> <td style="width: 30%;">Sealed Source</td> <td style="width: 40%;">No single source to exceed 60 millicuries</td> </tr> <tr> <td>6.B. Iodine 125</td> <td>Seeds</td> <td>3000 millicuries total possession</td> </tr> </table> <p>Additionally, please review the section on financial assurance below.</p>	6.A. Cesium 137	Sealed Source	No single source to exceed 60 millicuries	6.B. Iodine 125	Seeds	3000 millicuries total possession
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6.B. Iodine 125	Seeds	3000 millicuries total possession						
<input type="checkbox"/>	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 (e.g. 7.A. To be used for the interstitial and intercavitary treatment of disease in humans)						
<input type="checkbox"/>	<b>Items 8 &amp; 9: Training of Each Individual Named In Item 4.</b>	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. <b>Authorized users, and authorized medical physicists must meet the training and experience requirements in 15A NCAC 11 .0318, and appropriate sections of 10 CFR 35. An authorized medical physicist (AMP) must be named if your license authorizes Strontium 90 eye applicator, or remote afterloading device. See detailed information on required training and experience qualifications at <a href="http://ncradiation.net/rms/rmsmultoolkit.htm">http://ncradiation.net/rms/rmsmultoolkit.htm</a>.</b>						
<input type="checkbox"/>	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).						
<input type="checkbox"/>	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.						
<input type="checkbox"/>	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.						
<input type="checkbox"/>	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). Each floor plan should indicate all entrances/exits to the room(s) and surrounding areas [see 15A NCAC 11 .0317(a)(4)]. These drawings to not have to be “to scale.”						

4	ITEM	DISCUSSION/REQUIREMENTS
<input type="checkbox"/>	Item 14: Radiation Protection Program	<p>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 users 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:</p> <ul style="list-style-type: none"> <li>A. Radiation Protection (Safety) Officer duties and responsibilities;</li> <li>B. Radiation Safety Committee duties and responsibilities;</li> <li>C. Authorized user training and re-training (if applicable);</li> <li>D. Training and re-training of Ancillary Personnel;</li> <li>E. Leak Testing of Sealed Sources;</li> <li>F. Physical Inventory of Sealed Sources;</li> <li>G. Surveys of use and/or storage areas;</li> <li>H. Transportation of Radioactive Materials (if applicable);</li> <li>I. Dose Limits, Personnel Dosimetry and/or Bioassay (if applicable);</li> <li>J. Labeling and Posting;</li> <li>K. Operating and Emergency Procedures;</li> <li>L. Security and Control of Radioactive Materials;</li> <li>M. Disposal of radioactive materials</li> </ul> <p>Remember, this is a limited listing of topics to be included in the Radiation Protection (Safety) Program. See the areas below for additional requirements.</p>
<input type="checkbox"/>	Item 15: Waste Disposal	<p>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.</p>
<input type="checkbox"/>	Item 16: Certification	<p>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.</p> <div style="border: 1px solid black; padding: 5px; margin-top: 10px;"> <p style="text-align: center;"><b><i>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.</i></b></p> </div>

***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.***

<b>ADDITIONAL INFORMATION NECESSARY FOR LICENSING</b>		
<p>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 (<a href="http://www.drp.enr.state.nc.us">www.drp.enr.state.nc.us</a>) for some of the areas identified in this licensing checklist.</p>		
<b>4</b>	<b>ITEM</b>	<b>DISCUSSION/REQUIREMENTS</b>
<input type="checkbox"/>	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.
<input type="checkbox"/>	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.
<input type="checkbox"/>	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(31)].
<input type="checkbox"/>	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;
<input type="checkbox"/>	15A NCAC 11 .1627: Procedures for Receiving and Opening Packages	<p>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.</p> <p>The requirements for receipt of packages containing radioactive materials change effective August 01, 2002. The changes are outlined below:</p> <p><u>A. Removable Contamination Surveys required when:</u></p> <ol style="list-style-type: none"> <li>1. the package contains radioactive material in a form other than gas or special form, or</li> <li>2. the package appears to be wet, crushed, or damaged.</li> </ol> <p><u>B. Exposure Rate Measurements required if:</u></p> <ol style="list-style-type: none"> <li>1. the package contains greater than Type A quantities of radioactive material (irregardless of form), or</li> <li>2. the package appears to be wet, crushed, or damaged.</li> </ol>
<input type="checkbox"/>	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.)

4	ITEM	DISCUSSION/REQUIREMENTS
<input type="checkbox"/>	<b>Specific training information for Authorized Users (AU's)</b>	Pursuant to 15A NCAC 11 .0117(a)(2) and 15A NCAC 11 .0318 (c) [and by reference 10 CFR 35], physicians must meet certain requirements before being named as authorized users. Please see detailed guidance on our website, <a href="http://ncradiation.net/rms/rmsmultoolkit.htm">http://ncradiation.net/rms/rmsmultoolkit.htm</a> for documentation that must be submitted for Authorized Users, and Authorized Medical Physicists, if applicable. <b>An Authorized Medical Physicist must be named on your license if the license authorizes a Strontium 90 eye applicator, or remote afterloading device.</b>
<input type="checkbox"/>	Radiation Safety Committee (RSC)	<p><u>Hospitals:</u> Pursuant to 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.</p> <p><u>Private Practice Facilities:</u> The N.C. Regulations do not require the formation of a Radiation Safety Committee.</p>
<input type="checkbox"/>	<b>Specific Duties of the R.S.O.</b>	<p><b>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 35.50. Please see detailed guidance on our website, <a href="http://ncradiation.net/rms/rmsmultoolkit.htm">http://ncradiation.net/rms/rmsmultoolkit.htm</a> for documentation that must be submitted for Radiation Safety Officers.</b></p> <p>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.”</p> <p>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.</p>
<input type="checkbox"/>	Therapist qualifications (including re-training)	<p>Pursuant to 15A NCAC 11 .0318(c) – (h), 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 their acceptance and training.</p> <p>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.</p>

4	ITEM	DISCUSSION/REQUIREMENTS
<input type="checkbox"/>	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.
<input type="checkbox"/>	Physical inventory of sources	<p>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(c)(5)(H)(iii).</p> <p>15A NCAC 11 .0702(a) states the requirement for performing physical inventories on sources used in the healing arts. The records required shall be consistent with 15A NCAC 11 .0321(e)(3).</p> <p>Additionally, the applicant should discuss the proposed inventory tracking system. The discussion should include examples of forms (if applicable), responsible individuals, notifications, etc.</p>
<input type="checkbox"/>	Leak testing procedures	Leak testing of sealed sources is required pursuant to 15A NCAC 11 .0702(b). 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.
<input type="checkbox"/>	Dosimetry for other than oncology 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.
<input type="checkbox"/>	Waste/Disposal Procedures	<p>The applicant should include procedures which address disposal of waste. If you have sources which are not utilized during a permanent implant procedure, you may hold them for decay-in-storage or return them to the manufacturer. If holding for DIS, the following conditions must be met:</p> <ol style="list-style-type: none"> <li>a. the radioactive material must have a physical half-life of less than 65 days;</li> <li>b. licensee conducts a physical inventory of the sources in accordance with .0702(a); and,</li> <li>c. licensee complies with the provisions of 15A NCAC 11 .0362(a)(1) – (3).</li> </ol> <p>If all of these provisions are met, the licensee is exempted form the leak test requirements in .0702(b).</p> <p>All forms used to track waste inventory should be submitted with the application.</p>

4	ITEM	DISCUSSION/REQUIREMENTS
<input type="checkbox"/>	Utilization Logs	Pursuant to 15A NCAC 11 .0702(a)(1) and (d), each licensee is responsible for ensuring accountability for sources of radiation. Please read these sections and develop a utilization log/tracking system for brachytherapy sources.
<input type="checkbox"/>	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.
<input type="checkbox"/>	Surveys of Use/Storage/Preparation areas	15A NCAC 11 .1613(a) requires that certain licensees make surveys that are reasonable to determine the extent of radiation levels, concentrations or quantities of radioactive material or potential radiological hazards. Therefore, applicants are required to submit procedures for conducting surveys of the use, storage, and preparation areas commensurate with the scope and extent of licensed activities. Be sure to include the action levels for the surveys as appropriate. List all instrumentation which will be used, along with efficiencies and MDA's (where applicable).
<input type="checkbox"/>	Room Selection	Please read 15A NCAC 11 .0702(c)(2)(C). Discuss room selection criteria and provide a sketch of where in-patient rooms will be located.
<input type="checkbox"/>	Survey instrumentation, calibration & response checks	<p>Pursuant to 15A NCAC 11 .0360(i) – (k) each medical use licensee is required to possess survey instrumentation. 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.</p> <p>15A NCAC 11 .0360(k) 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 requirements and shall have a procedure to address this regulation.</p>
<input type="checkbox"/>	Patient Surveys	Pursuant to 15A NCAC 11 .0702(c)(1), (3) & (4), surveys of patients are required to be conducted. Please read these regulations and develop a policy/procedure to address them.
<input type="checkbox"/>	Area Surveys	Both 15A NCAC 11 .1613 and .0702 (c) require that surveys be conducted to demonstrate compliance with .1604, .1609, and .1611. Please provide a policy which addresses these required surveys. Records of the surveys should be addressed. Submit any forms which will be used to document the surveys. .0702(g) contains details on required information.
<input type="checkbox"/>	Implant Records	15A NCAC 11 .0702(e) & (f) prescribe the information that is required for permanent and temporary implants. Read these regulations and provide a policy/procedure to address them. Submit any forms which will be used.
<input type="checkbox"/>	Chart Information	15A NCAC 11 .0702(g) requires that certain information be entered into the patient's chart. The licensee/applicant may provide a commitment that this information will be entered into the charts.

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<input type="checkbox"/>	Emergency Procedures	<p>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.</p> <p>NOTE: The agency has emergency contact information on the website.</p>
<input type="checkbox"/>	<b>Procedures for Administrations Requiring a Written Directive (formerly entitled “Quality Management Program”)</b>	<p>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.</p> <p>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.</p> <p>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.</p>
<input type="checkbox"/>	<b>Medical Events and Dose to an Embryo/Fetus or Nursing Child</b>	<p>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. Reporting Forms are available on our website.</p>
<input type="checkbox"/>	Release of patients containing radio-pharmaceuticals or permanent implants	<p>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.</p> <p>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.</p>
<input type="checkbox"/>	Financial Assurance and Record-keeping for Decommissioning	<p>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(f). The agency has placed general guidance on the website (<a href="http://www.drp.enr.state.nc.us">www.drp.enr.state.nc.us</a>) concerning financial assurance.</p> <p>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.</p>

4	ITEM	DISCUSSION/REQUIREMENTS
<input type="checkbox"/>	Legal business name information	<p>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.</p> <p>Normally, the agency will accept either a certificate from the Division of Facility Services (DFS) or the N.C. Secretary of State’s Office. If you have questions on what type of documentation you need to submit, contact DFS at (919) 733-6360, or the Secretary of State’s Office, Corporations Division at (919) 733-4201.</p>