| 1  | 10A NCAC 15 .0317 is proposed for amendment as follows:                                |   |  |  |
|----|--|---|--|--|
| 2  |  |   |  |  |
| 3  | 10A NCAC 15 .0317  | SPECIFIC LICENSES: FILING APPLICATION AND GENERAL   |  |  |
| 4  |  | REQUIREMENT   |  |  |
| 5  | (a) Applications for spe   | ecific licenses shall be filed on an agency form in accordance with G.S. 104E-10(b) in lieu of    |  |  |
| 6  | NRC Form 313, and sh   | all meet the requirements of 10 CFR 30.32, 30.37, or 30.38 as applicable for the type of          |  |  |
| 7  | licensing action, except   | that:   |  |  |
| 8  | (1) 10 CF  | FR 30.32(e), 35.18(a)(2), the portions of 36.11 and 39.11 pertaining to payment of fees,          |  |  |
| 9  | 40.310   | (e), 61.20(c) and 70.21(e) are not incorporated by reference;                                     |  |  |
| 10 | (2) the ag   | ency may require an applicant to submit an environmental impact statement to the agency in        |  |  |
| 11 | accord   | lance with Rule .0108 of this Chapter in lieu of the requirements of 10 CFR 30.32(f), 40.31(f),   |  |  |
| 12 | 40.320   | (e), 61.10, or 70.23(a); and  |  |  |
| 13 | (3) applic   | ations for activities listed in 10 CFR 150.7 or excepted activities listed in 10 CFR 150.10 shall |  |  |
| 14 | <u>be file</u>   | d on NRC Form 313 and submitted to the U.S. Nuclear Regulatory Commission at the address          |  |  |
| 15 | shown  | n in 10 CFR 150.4 in lieu of the agency.  |  |  |
| 16 | (b) In addition to Paragraph (a) of this Rule, applications for a specific license to: |   |  |  |
| 17 | (1) manuf  | acture items containing exempt quantities of radioactive material or to manufacture exempt        |  |  |
| 18 | <u>quanti</u>  | ties of radioactive material that is not incorporated into a manufactured item shall meet the     |  |  |
| 19 | applic   | able requirements of 10 CFR Part 32, Subpart A;   |  |  |
| 20 | (2) manuf  | acture or initially transfer generally licensed devices containing byproduct material shall meet  |  |  |
| 21 | the ap   | plicable requirements of 10 CFR Part 32, Subpart B;   |  |  |
| 22 | (3) manuf  | acture radioactive drugs, sources, or devices not containing exempt quantities of radioactive     |  |  |
| 23 | materi   | al for medical use shall meet the applicable requirements of 10 CFR Part 32, Subpart C;           |  |  |
| 24 | (4) condu  | ct broad scope activities shall meet the requirements of 10 CFR 33.12 and 33.16, as applicable    |  |  |
| 25 | to lice  | nsed activities. Broad scope medical licensees meeting the criteria of 10 CFR 33.13(a) shall      |  |  |
| 26 | <u>be exe</u>  | empt from certain licensing and regulatory requirements as specified in 10 CFR 35.15. 10 CFR      |  |  |
| 27 | <u>33.11</u>   | is not incorporated by reference;   |  |  |
| 28 | (5) perfor   | m industrial radiography shall meet the requirements of 10 CFR 34.11;                             |  |  |
| 29 | (6) admin  | ister radioactive material or radiation from a licensed source to humans for medical use when     |  |  |
| 30 | a licer  | ase is required by 10 CFR 35.11 shall meet the requirements of 10 CFR 35.12 and 35.13, as         |  |  |
| 31 | applic   | able to licensed activities. Notifications required by 10 CFR 35.14 shall be sent to the agency   |  |  |
| 32 | at the   | address shown in Rule .0111 of this Chapter;  |  |  |
| 33 | (7) irradia  | te material using gamma radiation from sealed sources in facilities listed in 10 CFR 36.1(b)      |  |  |
| 34 | shall n  | neet the requirements of 10 CFR 36.1;   |  |  |
| 35 | (8) condu  | ct well logging activities shall meet the requirements of 10 CFR 39.11;                           |  |  |
| 36 | (9) posses   | ss, use, or transfer source material shall meet the requirements of 10 CFR 40.31;                 |  |  |

| 1  | (10)               | dispose of radioactive waste received from another person shall meet the requirements of Section        |
|----|--------------------|---|
| 2  | (10)               | .1200 of this Chapter;  |
| 3  | <u>(11)</u>        | receive, possess, or use special nuclear material shall meet the requirements of 10 CFR 70.22(a)        |
| 4  | -                  | 70.22(d), and 70.22(e), 70.33, or 70.34 as applicable to licensed activities; or                        |
| 5  | (12)               | manufacture or initially transfer calibration or reference sources containing plutonium to persons      |
| 6  |                    | generally licensed under Rule .0312 of this Section shall meet the requirements of 10 CFR 70.39.        |
| 7  | (c) Application    | is for sealed source and device registration certification, amendment of sealed source and device       |
| 8  | registration certi | ificates, and inactivation of previously issued sealed source and device registration certificates shal |
| 9  | comply with the    | provisions of 10 CFR Part 32, Subpart D.  |
| 10 | (d) Completed a    | applications shall be sent to the agency at the address shown in Rule .0111 of this Chapter.            |
| 11 | (e) Notwithstan    | ding Rule .0117 of this Chapter, the regulations cited in this Rule from 10 CFR Chapter I (2015) are    |
| 12 | hereby incorpora   | ated by reference, excluding subsequent amendments and editions. Copies of these regulations are        |
| 13 | available          | free of charge at http://www.ecfr.gov/cgi-bin/text  |
| 14 | idx?SID=2beeec     | ce594411a03e50b2468ae31f89b&pitd=20160101&tpl=/ecfrbrowse/Title10/10tab_02.tpl.                         |
| 15 | (a) Application    | s for specific licenses shall be filed on an agency form. Completed applications shall include the      |
| 16 | following inform   | mation and other information necessary for the agency to determine if the applicant meets the           |
| 17 | requirements for   | that license:   |
| 18 | (1)                | name, address and use location of the applicant;  |
| 19 | (2)                | training and experience of radioactive material users and of the person responsible for radiation       |
| 20 |                    | <del>protection;</del>  |
| 21 | (3)                | types, quantities and uses of radioactive materials;  |
| 22 | (4)                | description of facilities, equipment and safety program;  |
| 23 | (5)                | procedures for disposal of radioactive material; and  |
| 24 | (6)                | how facility design and procedures for operation will minimize, to the extent practicable               |
| 25 |                    | contamination of the facility and the environment, facilitate eventual decommissioning, and             |
| 26 |                    | minimize, to the extent practical, the generation of radioactive waste.                                 |
| 27 | (b) The agency     | may at any time after the filing of the original application, and before the expiration of the license  |
| 28 | require further s  | statements in order to enable the agency to determine whether the application should be granted or      |
| 29 | denied or whether  | er a license should be modified or revoked.   |
| 30 | (c) Each applica   | ation shall be signed by the applicant or licensee or a person authorized to act on his behalf.         |
| 31 | (d) An applicati   | on for a license may include a request for a license authorizing one or more activities.                |
| 32 | (e) An applicati   | ion for a specific license to use byproduct material in the form of a sealed source or in a device tha  |
| 33 | contains the seal  | led source must:  |
| 34 | (1)                | identify the source or device by manufacturer and model number as registered with the US Nuclear        |
| 35 |                    | Regulatory Commission under 10 CFR 32.210, with an Agreement State. A source or device                  |
| 36 |                    | containing radium 226 or accelerator produced radioactive material must identify the manufacture        |
| 37 |                    | and model number if registered with a state under provisions comparable to 10 CFR 32.210;               |

| 1  | (2)   | contain the information identified in 10 CFR 32.210(c); or  |  |
|----|---|---|--|
| 2  | (3)   | for sources or devices containing naturally occurring or accelerator produced radioactive material      |  |
| 3  |   | manufactured prior to November 30, 2007 that are not registered with the U.S. Nuclear Regulatory        |  |
| 4  |   | Commission under 10 CFR 32.210 or with an Agreement State, and for which the applicant is unable        |  |
| 5  |   | to provide all categories of information specified in 10 CFR 32.210(c), the applicant must provide:     |  |
| 6  |   | (A) all available information identified in 10 CFR 32.210(c) concerning the source, and, if             |  |
| 7  |   | applicable, the device; and   |  |
| 8  |   | (B) sufficient additional information to demonstrate that there is reasonable assurance that the        |  |
| 9  |   | radiation safety properties of the source or device are adequate to protect health and                  |  |
| 10 |   | minimize danger to life and property. Such information must include a description of the                |  |
| 11 |   | source or device, a description of radiation safety features, the intended use and associated           |  |
| 12 |   | operating experience, and the results of a recent leak test.  |  |
| 13 | (f) Applications  | and documents submitted to the agency shall be made available for public inspection except as are       |  |
| 14 | determined otherwise by the agency pursuant to the provisions of G.S. 104E 9(4).  |   |  |
| 15 | (g) A license application shall be approved if the agency determines that:  |   |  |
| 16 | (1)   | the applicant is qualified by reason of training and experience to use the material in question for the |  |
| 17 |   | purpose requested in accordance with these Rules in such a manner as to minimize danger to public       |  |
| 18 |   | health and safety or property;  |  |
| 19 | (2)   | the applicant's proposed equipment, facilities, and procedures are adequate to protect public health    |  |
| 20 |   | from radiation hazards and minimize radiological danger to life or property;                            |  |
| 21 | (3)   | the issuance of the license will not be inimical to the health and safety of the public; and            |  |
| 22 | (4)   | the applicant satisfies any applicable special requirements in Rules .0318 to .0336 of this Section.    |  |
| 23 | (h) If required by Rule .0353 of this Section, applications for specific licenses filed under this Section must contain |   |  |
| 24 | proposed decom  | missioning funding plan or a certification of financial assurance for decommissioning.                  |  |
| 25 |   |   |  |
| 26 | History Note:   | Authority G.S. 104E-7; 104E-10(b); 104E-12; 104E-18;  |  |
| 27 |   | Eff. February 1, 1980;  |  |
| 28 |   | Amended Eff. October 1, 2013; April 1, 1999; May 1, 1992; November 1, 1989;                             |  |
| 29 |   | Transferred and Recodified from 15A NCAC 11 .0317 Eff. February 1, 2015;                                |  |
| 30 |   | Amended Eff. August 1, 2016.  |  |