

GUIDANCE ON MEDICAL AUTHORIZED USERS

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INSTRUCTIONS TO LICENSEES

The following guidance is intended to assist North Carolina Radioactive Materials Licensees whose licenses authorize medical use or the manufacture and distribution of radiopharmaceuticals (nuclear pharmacy) for human use in naming individuals to medical use radioactive materials licenses. To use this guidance submit the numbered items for the applicable use of radioactive material(s) that you seek. Where there is an option between different paths the paths are separated by the word "or" (no quotation marks), centered on the page. The word "and" (no quotation marks) centered on the page in each path means that additional material must be submitted to the agency for that path only.

Using the guidance to add an individual to a license as a radiation safety officer (RSO) as an example: submit items 1, 2, 3, and 4.I or 4.II or 4.III, or 4.IV. Items 4.I, 4.II, 4.III, and 4.IV are the four different paths by which an individual can be qualified to be an RSO and listed on the license. Where options exist under each of these paths these options are further broken down. Using the same example above, there are six (6) different certifications that may be used to qualify an individual as an RSO under item 4.III. Those are listed as 4.III.A, 4.III.B, 4.III.C., etc. Note that when additional material is required it is specified by an "and" (no quotation marks) statement centered on the page in that path and for that path only. If the same additional information is needed across several paths it has been duplicated and listed under each individual path to try to simplify this guidance.

Only one path for each 'specialty' is necessary to use to qualify an individual as an RSO, an Authorized User (AU), an Authorized Nuclear Pharmacist (Radiopharmacist) (ANP) or an Authorized Medical Physicist (AMP).

The same methodology is used for determining the requirements for qualifying a physician to be an Authorized User (AU), a nuclear pharmacist (radiopharmacist) to be an Authorized Nuclear Pharmacist (Radiopharmacist) (ANP) and a medical physicist to be an Authorized Medical Physicist (AMP).

RADIATION SAFETY OFFICER (RSO) QUALIFICATIONS

Regulatory citations:

State of NC: 15A NCAC 11 .0104(80), 15A NCAC 11 .0104(112), 15A NCAC 11 .0117(a)(2), 15A NCAC 11 .0318(l), 15A NCAC 11 0318(z) – (bb)

NRC (incorporated by reference): 10 CFR 30.33(a)(3), 10 CFR 35.2, 10 CFR 35.14, 10 CFR 35.24, 10 CFR 35.50, 10 CFR 35.57, 10 CFR 35.59, 10 CFR 35.2024.

To name an individual as the RSO (the RSO designee) on an existing or new radioactive materials license for medical use submit the following information to the agency. The RSO designee must have successfully completed the applicable training and experience criteria described below within 7 years preceding the date of the application to be named on the license as the RSO or have had related continuing education and experience since initially completing the required training and experience. This time provision also applies to board certifications used to demonstrate qualifications to become an RSO:

1. The licensee must establish and submit in writing, the authority, duties, and

RSO Qualifications (continued)
from item 1.:

responsibilities of the RSO as required by 15A NCAC 11 .0318(aa), and give the RSO sufficient organizational freedom and authority to perform the duties of the RSO as required by 15A NCAC 11 .0318(bb).

and

2. The RSO designee must submit a signed statement acknowledging accepting responsibility for the radiation protection aspects of the activities authorized by the license for which they will function as the RSO (required by 15A NCAC 11 .0318(z)).
- and
3. For renewals the applicant must provide documentation that the medical use of radioactive material has not changed since the individual was last named as the RSO on the license.

For existing licensees that have amended the license to add or change medical use(s) of radioactive materials and/or existing licensees that have submitted an amendment to change RSOs and new licensees: indicate that the individual is qualified by certification or training and experience to be the RSO for the type(s) of medical use(s) authorized by the license or as requested.

and

4. I. Submit a copy of a current medical use license or permit issued by NC, an Agreement State or the NRC listing the RSO designee as the RSO. This license must authorize the same medical use(s) of radioactive material as the license upon which the RSO designee is to be named as the RSO.
- or
- II. Submit a copy of the licensee's current medical use license showing that the RSO designee is listed as an AU, AMP, or ANP along documentation of experience in the radiation safety aspects of similar types of byproduct material use for which the individual has RSO responsibilities. If the individual was the RSO on a license issued to a Government entity or a licensee operating on a federally recognized Indian Tribe, the individual must have been listed on the license prior to August 31, 2005 for medical use of radioactive material, or August 31, 2002 for the medical use of HDR afterloading brachytherapy devices.

and

written attestation signed by a preceptor RSO that the individual has met the training requirements for an RSO and has sufficient knowledge to function independently as an RSO;

or

- III. Certification as listed in a. through f., below or a certificate that is approved by the NRC for documenting training and experience listed in the most recent version of the "Medical Users Toolkit" (located at <http://www.nrc.gov/materials/miau/med-use-toolkit.html>):
 - A. American Board of Health Physics certificate from January 1, 2005 to present, or
 - B. American Board of Science in Nuclear Medicine (ABSNM) certificate in [Nuclear Medicine Physics and Instrumentation](#) from June 2006 to present, or
 - C. the ABSNM certificate in [Radiation Protection](#) from June 2006 to present, or
 - D. American Board of Radiology (ABR) certificate for the [Radiologic Physics - Medical Nuclear Physics](#) with the words "RSO Eligible" appearing above the ABR seal, or
 - E. the ABR certificate in [Radiologic Physics - Diagnostic Radiologic Physics](#) with the words "RSO Eligible" appearing above the ABR seal, or
 - F. the ABR certificate in [Radiologic Physics - Therapeutic Radiologic Physics](#) with the words "AMP Eligible" appearing above the ABR seal,

and

written attestation signed by a preceptor RSO that the individual has met the training requirements for an RSO and has sufficient knowledge to function independently as an RSO;

or

RSO Qualifications (continued):

4. IV. A. Completion of classroom and laboratory training consisting of 200 hours in radiation physics and instrumentation, radiation protection, mathematics pertaining to the use and measurement of radioactivity, radiation biology and radiation dosimetry.
and
 - B. Documentation of one (1) year of full-time radiation safety experience under the supervision of the individual identified as the Radiation Safety Officer on a NC, NRC or Agreement State license that authorizes similar type(s) of use(s) of radioactive material involving: shipping, receiving, and performing related radiation surveys; using and performing checks for proper operation of instruments used to determine the activity of dosages, survey meters, and instruments used to measure radionuclides; securing and controlling byproduct material; using administrative controls to avoid mistakes in the administration of byproduct material; using procedures to prevent or minimize radioactive contamination and using proper decontamination procedures; using emergency procedures to control byproduct material; and disposing of byproduct material.
and
- Written attestation signed by a preceptor RSO that the individual has successfully met the training requirements of an RSO and has sufficient knowledge to function independently as an RSO.

PHYSICIAN AUTHORIZED USERS (AUs) QUALIFICATIONS

Regulatory references:

State of NC: 15A NCAC 11 .0104(17), 15A NCAC 11 .0104(80), 15A NCAC 11 .0104(94), 15A NCAC 11 .0117(a)(2), 15A NCAC 11 .0318(c)
NRC (incorporated by reference): 10 CFR 30.33(a)(3), 10 CFR 35.2, 10 CFR 35.11, 10 CFR 35.14, 10 CFR 35.27, 10 CFR 35.57, 10 CFR 35.59, 10 CFR 35.190, 10 CFR 35.290, 10 CFR 35.390, 10 CFR 35.392, 10 CFR 35.394, 10 CFR 35.396, 10 CFR 35.490, 10 CFR 35.491, 10 CFR 35.590, Subpart H of 10 CFR 35 [10 CFR 35.690], 10 CFR 35.1000

To name a physician as an Authorized User (AU) on an existing or new radioactive materials license for medical use, or an accelerator used for the treatment of humans, submit the following information to the agency. The physician must have successfully completed the applicable training and experience criteria described below within 7 years preceding the date of the application to be named on the license as an AU or have had related continuing education and experience since initially completing the required training and experience. This time provision also applies to board certification used to demonstrate qualifications to become an AU. **When qualifying a physician as an AU under 3.II or 3.III do not overlook the written attestation which is the last required element for each of those two paths:**

1. The physician must be registered with the North Carolina Medical Board as a physician in the appropriate medical field and this registration must be current;
and
2. Documentation must indicate that the physician will only use radioactive material or an accelerator for the medical use(s) that the physician is approved for as an AU on a current medical use license, or as the physician is qualified to use based upon recognized certification or training and experience as listed below.
and
3. I. Submit a copy of the medical use license on which the physician is specifically named as an AU. For physicians using radioactive material in the practice of medicine at a Government agency or on an Indian Tribe, documentation that the physician used only accelerator-produced radioactive material, discrete sources of Ra-226, or both, in the practice of medicine, before or during the effective period of NRC's waiver of August 31, 2005, is required.

Physician AU Qualifications (continued):

- or
3. II. If the physician is not listed as an AU on a medical use license and the physician is certified for the medical use of radioactive materials, the certificate must be listed as specified in items A. through I., below, or the certificate must be listed in the most recent version of the "Medical Users Toolkit" located at the following URL, <http://www.nrc.gov/materials/miau/med-use-toolkit.html>):

- A. For uptake, dilution and excretion diagnostic studies (10 CFR 35.100 uses) physicians must have a certificate issued by the American Board of Nuclear Medicine with the word "United States" appearing under the certification number.

Note: Physicians authorized for imaging and localization diagnostic studies (10 CFR 35.200 uses) and/or the therapeutic use of unsealed radioactive materials (10 CFR 35.300 uses), including the therapeutic use of I-131 (10 CFR 35.392 and 10 CFR 25.394 uses), are also authorized to perform uptake, dilution and excretion diagnostic studies.

- B. For imaging and localization diagnostic studies (10 CFR 35.200 uses) physicians must have one of the certificates listed in B.i. through B.vi., below:
- i. American Board of Nuclear Medicine certificate with the word "United States" appearing under the certification number; or
 - ii. Board of Nuclear Cardiology certificate issued from October 29, 2000 through October, 2005, with the wording "for physicians residing in the United States"; or
 - iii. Board of Nuclear Cardiology certificate issued after October 2006 with the wording "for physicians trained in the United States."; or
 - iv. American Osteopathic Board of Radiology (AOBR) certificate issued after July 1, 2000, for the Diagnostic Radiology specialty; or
 - v. American Osteopathic Board of Nuclear Medicine (AOBNM) certificate issued after May 18, 2006, for the Nuclear Medicine specialty; or
 - vi. American Board of Radiology (ABR) certificate in Diagnostic Radiology with the words "AU eligible" appearing above the ABR seal.

Note: Physicians authorized for the therapeutic use of unsealed radioactive materials (10 CFR 35.300 uses), including the therapeutic use of I-131 (10 CFR 35.392 and 10 CFR 25.394 uses), are also authorized to perform uptake, dilution and excretion diagnostic and imaging and localization diagnostic studies (10 CFR 35.100 and 10 CFR 35.200 uses respectively).

- C. For the therapeutic use of radioactive materials (10 CFR 35.300 uses) in unsealed form except I-131, physicians must have one of the certificates listed in C.i. through C.iii., below:
- i. American Board of Nuclear Medicine certificate with the word "United States" appearing under the certification number; or
 - ii. American Board of Radiology (ABR) certificate issued during or after June, 2007 in Radiation Oncology with the words "AU eligible" appearing above the ABR seal; or
 - iii. American Osteopathic Board of Radiology (AOBR) certificate issued on or after May 1, 2007 in Radiation Oncology.
- D. For the therapeutic use of quantities of I-131 less than or equal to 33mCi (1.22GBq) in unsealed form (10 CFR 35.392 uses) physicians must have one of the certificates listed in D.i through D.v. below:
- i. American Board of Nuclear Medicine certificate with the word "United States" appearing under the certification number; or

Physician AU Qualifications (continued)
from item 3.II.D.i.:

- ii. American Board of Radiology (ABR) certificate issued during or after June, 2007 in Radiation Oncology with the words "AU eligible" appearing above the ABR seal; or
- iii. American Board of Radiology (ABR) certificate in Diagnostic Radiology with the words "AU eligible" appearing above the ABR seal; or
- iv. American Osteopathic Board of Radiology (AOBR) certificate issued on or after May 1, 2007 in Radiation Oncology; or
- v. American Osteopathic Board of Radiology (AOBR) certificate in Diagnostic Radiology.

Note: Physicians authorized to use I-131 in quantities greater than 33mCi (1.22GBq) (10 CFR 35.394 use) are also authorized to use I-131 in quantities less than or equal to 33mCi (1.22GBq) for therapeutic use.

- E. For the therapeutic use of quantities of I-131 greater than 33mCi (1.22GBq) in unsealed form (10 CFR 35.394 uses) physicians must have one of the certificates listed in E.i through E.iii. below:
 - i. American Board of Nuclear Medicine certificate with the word "United States" appearing under the certification number; or
 - ii. American Board of Radiology (ABR) certificate issued during or after June, 2007 in Radiation Oncology with the words "AU eligible" appearing above the ABR seal; or
 - iii. American Osteopathic Board of Radiology (AOBR) certificate issued on or after May 1, 2007 in Radiation Oncology.

Note: Physicians authorized to use I-131 in quantities greater than 33mCi (1.22GBq) are also authorized to use I-131 in quantities less than or equal to 33mCi (1.22GBq) for therapeutic use (10 CFR 35.392 use).

- F. For the therapeutic use of sealed radioactive sources in manual brachytherapy and ophthalmic devices containing Sr-90 (10 CFR 35.400) physicians must have one of the certificates listed in F.i. or F.ii., below:
 - i. American Board of Radiology (ABR) certificate issued on or after June, 2007, in radiation oncology with the words "AU eligible" appearing above the ABR seal; or
 - ii. American Osteopathic Board of Radiology (AOBR) certificate issued on or after from May 1, 2007 in Radiation Oncology.
- G. For the diagnostic use of sealed radioactive sources (10 CFR 35.500) there is no recognized certificate and AUs will be approved by the agency on a case-to-case basis using applicable certification and/or training and experience as recommended by the device manufacturer and/or approved by the NRC.
- H. For therapeutic use of sealed sources in teletherapy, HDR afterloading brachtherapy devices, and gamma stereotactic radiosurgery (gamma knife) units (Subpart H of 10 CFR uses) a physician must have one of the following certifications listed in H.i or H.ii., below:
 - i. Radiology (ABR) certificate issued on or after June, 2007, in radiation oncology with the words "AU eligible" appearing above the ABR seal; or
 - ii. American Osteopathic Board of Radiology (AOBR) certificate issued on or after from May 1, 2007 in Radiation Oncology, or
- I. For the use of radioactive material in emerging technologies (10 CFR 35.1000 use) there is no recognized certificate and AUs will be approved by the agency on a case-by-case basis using applicable certification and/or training and experience as recommended by the device manufacturer and/or approved by the NRC.

Physician AU Qualifications (continued)
from 3.II.1.:

and

Written attestation that the physician possesses sufficient knowledge of the safe use of radioactive material and the applicable NC regulations governing the use of radioactive material for medical use signed by a preceptor AU. The preceptor AU must be familiar with the physician's work, be named or eligible to be named on a radioactive materials license for medical use, and authorized by that license for the same use(s) as those the physician seeking AU status.

or

3. III. Physicians who are not certified, or whose certification is not listed above, or whose certification is not recognized for the type of medical use requested, must submit a preceptors' statement to demonstrate that they have successfully completed the training and experience for the medical use of radioactive material as specified in A. through H., below, for the use of material requested:
 - A. For uptake, dilution and excretion diagnostic studies (10 CFR 35.100 uses) physicians must have completed 60 hours of training and experience, including a minimum of 8 hours of classroom and laboratory training in basic radionuclide handling techniques applicable to the medical use of unsealed radioactive material. The training and experience must include:
 - i. Classroom and laboratory training in radiation physics and instrumentation; radiation protection; mathematics pertaining to the use and measurement of radioactivity; chemistry of byproduct material for medical use; radiation biology; and,
 - ii. Work experience, under the supervision of an AU who is listed on a radioactive materials license authorizing uptake, dilution and excretion diagnostic studies (10 CFR 35.100 use), imaging and localization diagnostic studies (10 CFR 35.200 use) or the therapeutic use of radioactive material in unsealed form (10 CFR 35.300 use) involving: ordering, receiving, and unpacking radioactive materials safely and performing the related radiation surveys; performing quality control procedures on instruments used to determine the activity of dosages and performing checks for proper operation of survey meters; calculating, measuring, and safely preparing patient or human research subject dosages; using administrative controls to prevent a medical event involving the use of unsealed byproduct material; using procedures to contain spilled byproduct material safely and using proper decontamination procedures; and administering dosages of radioactive drugs to patients or human research subjects.

Note: Physicians authorized for imaging and localization diagnostic studies (10 CFR 35.200 uses) and/or the therapeutic use of unsealed radioactive materials (10 CFR 35.300 uses), including the therapeutic use of I-131 (10 CFR 35.392 and 10 CFR 25.394 uses), are also authorized to perform uptake, dilution and excretion diagnostic studies.

- B. For imaging and localization diagnostic studies (10 CFR 35.200 uses) physicians must have completed 700 hours of training and experience, including a minimum of 80 hours of classroom and laboratory training, in basic radionuclide handling techniques applicable to the medical use of unsealed byproduct material for imaging and localization studies. The training and experience must include:
 - i. classroom and laboratory training in radiation physics and instrumentation; radiation protection; mathematics pertaining to the use and measurement of radioactivity; chemistry of byproduct material for medical use; radiation biology; and,
 - ii. work experience, under the supervision of an Authorized User who is listed on a radioactive materials license authorizing imaging and localization diagnostic studies (10 CFR 35.200 use) or the therapeutic

Physician AU Qualifications (continued)
from item 3.III.B.ii.:

use of radioactive material in unsealed form (10 CFR 35.300 use) involving: ordering, receiving, and unpacking radioactive materials safely and performing the related radiation surveys; performing quality control procedures on instruments used to determine the activity of dosages and performing checks for proper operation of survey meters; calculating, measuring, and safely preparing patient or human research subject dosages; using administrative controls to prevent a medical event involving the use of unsealed byproduct material; using procedures to safely contain spilled radioactive material and using proper decontamination procedures; administering dosages of radioactive drugs to patients or human research subjects; and eluting generator systems appropriate for preparation of radioactive drugs for imaging and localization studies, measuring and testing the eluate for radionuclide purity, and processing the eluate with reagent kits to prepare labeled radioactive drugs.

Note: Physicians authorized for the therapeutic use of unsealed radioactive materials (10 CFR 35.300 uses) are also authorized to perform imaging and localization diagnostic studies.

3. III. C. For the therapeutic use of radioactive materials in unsealed form, including the therapeutic administration of I-131 in any quantity and the parenteral administration any radionuclide for medical use for which a written directive is required (10 CFR 35.300 uses), physicians must have completed 700 hours of training and experience, including a minimum of 200 hours of classroom and laboratory training in the basic radionuclide handling techniques applicable to the medical use of unsealed byproduct material requiring a written directive. The training and experience must include:
- i. classroom and laboratory training in: radiation physics and instrumentation; radiation protection; mathematics pertaining to the use and measurement of radioactivity; chemistry of byproduct material for medical use; radiation biology; and
 - ii. work experience, under the supervision of an Authorized User under the supervision of an Authorized User who is listed on a radioactive materials license authorizing the therapeutic use of radioactive material in unsealed form (10 CFR 35.300 use) and who has experience in administering dosages in the same dosage category or categories as the individual requesting Authorized User status. The work experience must include: ordering, receiving, and unpacking radioactive materials safely and performing the related radiation surveys; performing quality control procedures on instruments used to determine the activity of dosages, and performing checks for proper operation of survey meters; calculating, measuring, and safely preparing patient or human research subject dosages; using administrative controls to prevent a medical event involving the use of unsealed byproduct material; using procedures to contain spilled byproduct material safely and using proper decontamination procedures; and if applicable,
 - iii. the administration of radioactive material for medical use to patients or human research subjects involving a minimum of three (3) cases in each of the following categories for which the individual is requesting Authorized User status:
 - a. oral administration of less than or equal to 33mCi (1.22GBq) I-131 for therapeutic use requiring a written directive, (10 CFR 10.392 use): successful completion of 80 hours of classroom and laboratory training applicable to the medical use of sodium iodide I-131 for procedures requiring a written directive, and work experience under the supervision of an AU who is listed on

Physician AU Qualifications (continued)
from item 3.III.C.iii.a.:

- a medical use license for the therapeutic use of less than, equal to, or greater than 33mCi (1.22GBq) I-131. Note: an AU authorized to administer quantities of I-131 greater than 33mCi (1.22GBq) is also authorized to administer less than or equal to 33mCi (1.22GBq) for therapeutic purposes. And/or
3. III. C. iii. b. oral administration of greater than to 33mCi (1.22GBq) I-131 for therapeutic use requiring a written directive, (10 CFR 10.394 use): successful completion of 80 hours of classroom and laboratory training applicable to the medical use of sodium iodide I-131 for procedures requiring a written directive, and work experience under the supervision of an AU who is listed on a medical use license for the therapeutic use of greater 33mCi (1.22GBq) I-131; and/or
- c. parenteral administration for medical use of any radionuclide for which a written directive is required: successful completion of 80 hours of classroom and laboratory training applicable to parenteral administrations of radioactive material requiring a written directive for medical use, and work experience under the supervision of an AU who is listed on a medical use license for perenteral administration of radioactive material, or an AU listed on a medical use license for the therapeutic use of sealed sources.
- D. For the therapeutic use of sealed radioactive sources in manual brachytherapy (10 CFR 35.400 use) physicians must have completed a structured educational program in basic radionuclide handling techniques applicable to the use of manual brachytherapy sources that included:
- i. 200 hours of classroom and laboratory training in radiation physics and instrumentation; radiation protection; mathematics pertaining to the use and measurement of radioactivity; radiation biology;
- ii. 500 hours of work experience, under the supervision of an AU who is listed on a medical use license for the use of sealed sources for manual brachytherapy in: ordering, receiving, and unpacking radioactive materials safely and performing the related radiation surveys; checking survey meters for proper operation; preparing, implanting, and removing brachytherapy sources; maintaining running inventories of material on hand; using administrative controls to prevent a medical event involving the use of byproduct material; using emergency procedures to control byproduct material; and
- iii. three(3) years of supervised clinical experience in radiation oncology, under an AU listed on a medical use license who is authorized to use sealed sources in manual brachytherapy, as part of a formal training program approved by the Residency Review Committee for Radiation Oncology of the Accreditation Council for Graduate Medical Education or the Royal College of Physicians and Surgeons of Canada or the Committee on Postdoctoral Training of the American Osteopathic Association. This experience may be obtained concurrently with the supervised work experience listed in d.i and d.ii., above.
- E. For the ophthalmic use of Sr-90 (10 CFR 35.400 use) physicians must have completed the training listed in D., above, and be listed on a current license as an AU for the use of manual brachytherapy sources for medical use, or have completed 24 hours of classroom and laboratory training applicable to the medical use of strontium-90 for ophthalmic radiotherapy that included:
- i. radiation physics and instrumentation; radiation protection; mathematics pertaining to the use and measurement of radioactivity; radiation biology;

Physician AU Qualifications (continued)
from item 3.III.E.i.:

- ii. supervised clinical training in ophthalmic radiotherapy under the supervision of an AU listed on a medical use license who is approved for the use of strontium-90 for ophthalmic treatment of humans; and
 - iii. The treatment of five patients under the supervision of an AU listed on a medical use license who is approved for the use of strontium-90 for the ophthalmic treatment of humans. This must include the examination of each patient to be treated; calculation of the dose to be administered; administration of the dose; and follow up and review of each patient's case history.
3. III. F. For the diagnostic use of sealed sources (10 CFR 35.500 uses) physicians must have completed 8 hours of classroom and laboratory training in basic radionuclide handling techniques specifically applicable to the use of the device. The training must include radiation physics and instrumentation; radiation protection; mathematics pertaining to the use and measurement of radioactivity; radiation biology; and training in the use of the device for the uses requested.
- G. For the therapeutic use of sealed sources in Teletherapy, HDR afterloading brachtherapy devices, and/or gamma stereotactic radiosurgery (gamma knife) units (Subpart H of 10 CFR 35 uses) a physician must have completed a structured educational program in basic radionuclide techniques applicable to the use of sealed sources in therapeutic medical units that includes:
- i. 200 hours of classroom and laboratory training in radiation physics and instrumentation; radiation protection; mathematics pertaining to the use and measurement of radioactivity; radiation biology;
 - ii. 500 hours of work experience under the supervision of an AU listed on a radioactive materials license who is authorized to use the device for which the physician seeks training that includes reviewing full calibration measurements and periodic spot-checks; preparing treatment plans and calculating treatment doses and times; using administrative controls to prevent a medical event involving the use of byproduct material; implementing emergency procedures to be followed in the event of the abnormal operation of the medical unit or console; checking and using survey meters; selecting the proper dose and how it is to be administered; and
 - iii. three (3) years of supervised clinical experience in radiation therapy under the supervision of an AU listed on a radioactive materials license who is authorized to use the device for which the physician seeks training, as part of a formal training program approved by the Residency Review Committee for Radiation Oncology of the Accreditation Council for Graduate Medical Education or the Royal College of Physicians and Surgeons of Canada or the Committee on Postdoctoral Training of the American Osteopathic Association. This experience may be obtained concurrently with the supervised work experience listed in g.i and g.ii., above.
- H. For the use of emerging technologies (10 CFR 35.1000 use) training and experience must be commensurate for the medical use of radioactive material in or on humans, and must be recognized by the manufacturer of the device and/or the NRC as appropriate for the use(s) of the device.

and

Written attestation that the physician possesses sufficient knowledge of the safe use of radioactive material and the applicable NC regulations governing the use of radioactive material for medical use signed by a preceptor AU. The preceptor AU must be familiar with the physician's work, be named or eligible to be named on a radioactive materials license for medical use, and authorized by that license for the same use(s) as those of the physician seeking AU status.

AUTHORIZED NUCLEAR PHARMACIST (RADIOPHARMACIST) (ANP) QUALIFICATIONS

Regulatory References:

State of NC: 15A NCAC 11 .0104(17), 15A NCAC 11 .0104(80), 15A NCAC 11 .0104(93), 15A NCAC 11 .0117(a)(2), 15A NCAC 11 .0318(b)

NRC (incorporated by reference): 10 CFR 30.33(a)(3), 10 CFR 32.72(b)(2), 10 CFR 35.2, 10 CFR 35.11, 10 CFR 35.14, 10 CFR 35.27, 10 CFR 35.55, 10 CFR 35.57, 10 CFR 35.59.

To be named on a license as an Authorized Nuclear Pharmacist (Radiopharmacist) the pharmacist must be licensed or registered with the North Carolina Board of Pharmacy as a pharmacist and this license or registration must be current. The pharmacist must also have successfully completed the applicable training and experience criteria described below within 7 years preceding the date of the application to be named on the license as an AU or have had related continuing education and experience since initially completing the required training and experience. This time provision also applies to board certifications used to demonstrate qualifications to become an AU:

1. Documentation must indicate that the pharmacist will only use radioactive material for the medical use(s) that the pharmacist is approved for as an AU on a current medical use license, or as the pharmacist is qualified to use based upon recognized certification or training and experience as listed below.
and
2. I. If the pharmacist is listed as an AU or an ANP on a current nuclear pharmacy license or a current medical use license authorizing the use and distribution of radiopharmaceuticals: submit a copy of the license on which the pharmacist is specifically named as an AU or an ANP. For a pharmacist using radioactive material in the practice of nuclear pharmacy at a Government agency or on an Indian Tribe, documentation that the pharmacist used only accelerator-produced radioactive material, discrete sources of Ra-226, or both, in the practice of pharmacy, before or during the effective period of NRC's waiver of August 31, 2005, is required;
or
II. If the pharmacist is not listed as an AU or an ANP on a nuclear pharmacy license or a medical use license authorizing the use and distribution of radiopharmaceuticals and the pharmacist is certified, the only acceptable certificate is the Board Certified Nuclear Pharmacist (BCNP) certificate from the Board of Pharmaceutical Specialties issued on or after March 6, 1996, or a certificate listed in the most recent version of the "Medical Users Toolkit" posted on the NRC's web site <http://www.nrc.gov/materials/miau/med-use-toolkit.html> that is approved by the NRC for use in approving ANPs.
and
Written attestation, signed by a preceptor Authorized Nuclear Pharmacist (Radiopharmacist) who is listed on a nuclear pharmacy license or eligible to be listed on a nuclear pharmacy license, that the individual has satisfactorily completed the requirements in paragraph 2.II., above, and has achieved a level of knowledge sufficient to function independently as an Authorized Nuclear Pharmacist (Radiopharmacist).
or
III. Submit documentation of training and experience that the pharmacist has completed 700 hours in a structured educational program consisting of both:
 - A. 200 hours of classroom and laboratory training in radiation physics and instrumentation, radiation protection, mathematics pertaining to the use and measurement of radioactivity, chemistry of byproduct material for medical use, radiation biology, and
 - B. Supervised practical experience in a nuclear pharmacy involving shipping, receiving, and performing related radiation surveys, using and performing checks for proper operation of instruments used to determine the activity of

ANP Qualifications (continued)
from 2.III.B.:

dosages, survey meters, and, if appropriate, instruments used to measure alpha- or beta-emitting radionuclides, calculating, assaying, and safely preparing dosages for patients or human research subjects, using administrative controls to avoid medical events in the administration of byproduct material, using procedures to prevent or minimize radioactive contamination and using proper decontamination procedures,

and

Written attestation, signed by a preceptor Authorized Nuclear Pharmacist (Radiopharmacist) who is listed on a nuclear pharmacy license or eligible to be listed on a nuclear pharmacy license, that the individual has satisfactorily completed the requirements in paragraphs 2.III.a. and b., above, and has achieved a level of knowledge sufficient to function independently as an Authorized Nuclear Pharmacist (Radiopharmacist).

AUTHORIZED MEDICAL PHYSICIST (AMP) QUALIFICATIONS

Regulatory References:

State of NC: 15A NCAC 11 .0104(17), 15A NCAC 11 .0104(80), 15A NCAC 11 .0117(a)(2), 15A NCAC 11 .0318(a)

NRC (incorporated by reference): 10 CFR 30.33(a)(3), 10 CFR 35.2, 10 CFR 35.14, 10 CFR 35.51, 10 CFR 35.57, 10 CFR 35.59, 10 CFR 35.433

To add a medical physicist (AMP designee) to a radioactive materials license for medical use submit the following information to the agency. The medical physicist must have successfully completed the applicable training and experience criteria described below within 7 years preceding the date of the application to be named on the license as an AU or an AMP or have had related continuing education and experience since initially completing the required training and experience. This time provision also applies to board certifications used to demonstrate qualifications to become an AU or an AMP.

1. Documentation must indicate that the medical physicist will only use radioactive material or therapeutic device(s) for the medical use(s) that the medical physicist is approved for as an AU or an AMP on a current medical use license, or as the medical physicist is qualified to use based upon recognized certification or training and experience as listed below.

and

2. If the medical physicist is listed as an AU or an AMP on a current medical use license: submit a copy of the license on which the medical physicist is specifically named as an AU or an AMP;

or

3. If the medical physicist is not listed as an AU or an AMP on a medical use license and the medical physicist is certified, the only acceptable certificate is the American Board of Radiology (ABR) certificate in Radiologic Physics - Therapeutic Radiologic Physics with the words "AMP Eligible" appearing above the ABR seal, or a certificate listed in the most recent version of the "Medical Users Toolkit" posted on the NRC's web site <http://www.nrc.gov/materials/miau/med-use-toolkit.html> that is approved by the NRC for approving AMPs.

and

Written attestation, signed by a preceptor AMP that the medical physicist has achieved a level of competency sufficient to function independently as an Authorized Medical Physicist for each type of therapeutic medical unit for which the individual is requesting Authorized Medical Physicist status. The preceptor AMP must be listed or eligible to be listed on a current medical use license for each type of therapeutic medical unit for which the individual is requesting Authorized Medical Physicist status.

This written attestation must indicate that the individual is requesting Authorized Medical Physicist status has training for the type(s) of use for which authorization is sought that

AMP Qualifications (continued)

from item 3.:

includes hands-on device operation, safety procedures, clinical use, and the operation of a treatment planning system. This training requirement may be satisfied by satisfactorily completing either a training program provided by the vendor or by training supervised by an Authorized Medical Physicist authorized for the type(s) of use for which the individual is seeking authorization,

or

4. Holds a master's or doctor's degree in physics, medical physics, other physical science, engineering, or applied mathematics from an accredited college or university; and has completed 1 year of full-time training in medical physics and an additional year of full-time work experience under the supervision an Authorized Medical Physicist named on a medical use license for the type(s) of use for which the individual is seeking authorization. This training and work experience must be conducted in clinical radiation facilities that provide high-energy, external beam therapy (photons and electrons with energies greater than or equal to 1 million electron volts) and brachytherapy services and must include: performing sealed source leak tests and inventories; performing decay corrections; performing full calibration and periodic spot checks of external beam treatment units, stereotactic radiosurgery units, and remote afterloading units as applicable; and conducting radiation surveys around external beam treatment units, stereotactic radiosurgery units, and remote afterloading units as applicable.

and

Written attestation, signed by a preceptor AMP that the medical physicist has achieved a level of competency sufficient to function independently as an Authorized Medical Physicist for each type of therapeutic medical unit for which the individual is requesting Authorized Medical Physicist status. The preceptor AMP must be listed or eligible to be listed on a current medical use license for each type of therapeutic medical unit for which the individual is requesting Authorized Medical Physicist status.

This written attestation must indicate that the individual is requesting Authorized Medical Physicist status has training for the type(s) of use for which authorization is sought that includes hands-on device operation, safety procedures, clinical use, and the operation of a treatment planning system. This training requirement may be satisfied by satisfactorily completing either a training program provided by the vendor or by training supervised by an Authorized Medical Physicist authorized for the type(s) of use for which the individual is seeking authorization.

This guidance was taken from NUREG - 1556, Vol. 9, Rev. 2, and 10 CFR Part 35 (2005) as it is incorporated into the [North Carolina Regulations for Protection Against Radiation](#) (15A NCAC 11), as well as applicable sections of the North Carolina regulations (cited above). All of these documents are in the public domain and can be found on the web sites of the respective agencies.