# MEDICAL AUTHORIZED USERS

## Frequently Asked Questions (FAQ):

If there is a question that is not listed below as an FAQ that you have an interest in or need to have answered feel free to contact the agency. The majority of these FAQs come directly from the "Medical Users Toolkit" on the NRC's webpage. The URL is for the webpage with the FAQs is: http://www.nrc.gov/materials/miau/med-use-toolkit/faqs-part35.html#top

## INTRODUCTORY FAQs

**Why are we even bothering with all the confusing changes to the Nuclear Regulatory Commission (NRC) rules for the medical use of radioactive materials (10 CFR Part 35) when we are North Carolina radioactive materials licensees?**

North Carolina is an agreement state (AS). As an AS our regulations governing the use of radioactive materials must be compatible with, or more conservative than, the NRC regulations governing the same kind of use of radioactive material. Failure to be compatible with the Federal rules may result in a loss of AS status. Loss of AS status would have significant economic impacts upon the use of radioactive material in North Carolina. For example: compare the annual license fee for each type of radioactive materials license NC regulates (listed in 15A NCAC 11. 1106) with the annual license fee for the same use of material under NRC regulation (10 CFR 173.31). In addition, the NRC charges their licensees for health and safety inspections, certain license amendments, and license consultations which are currently covered under the NC annual license fee. Another advantage is that as a licensee of an AS instead of the NRC, you have local, or near local, access to your regulators.

**When did the revised rules become effective?**

Revised Part 35 as published in the *Federal Register* on April 24, 2002 (67 FR 20249) became effective on October 24, 2002. Further amendments to Part 35 training and experience requirements, including recognition of specialty board certification processes and certain other conforming changes, became effective April 29, 2005, thirty days after the publication in the *Federal Register* on March 30, 2005 (70 FR 16336). Until October 24, 2005, licensees had the option of meeting either the training and experience requirements of Subpart J or Subparts B and D-H. Since October 24, 2005, licensees must meet the requirements in Subparts B and D-H of the current Part 35.

As an agreement state the agency had three years to implement these changes. These rules became effective for North Carolina licensees whose licenses authorized the medical use of radioactive materials in November 2007, and the rules governing the qualifications of AUs on these licenses was implemented in June 2008. **The Agency will begin enforcing the implementation beginning September 15, 2008.**

**I'm American Board of Radiology certified in Diagnostic Radiology and I've been an AU on a medical license for several years. I want to expand my practice to another location under a different medical use license. What's all this I heard about some certifications not being accepted anymore?**

FAQs (continued):

The NRC changed it's regulations to set minimum training and experience requirements for the certification boards' certificate processes. The certification boards had to apply to the NRC to have their certification process recognized. The specific requirements the NRC set for the minimum acceptable certification programs are codified in 10 CFR 35 for each of the medical uses of radioactive materials and for RSOs. As a result of this NRC rule making many of the certificates issued prior to 2005 are no longer accepted for licensing purposes. The current list of acceptable certificates is listed on the NRC website under the "Medical Users Toolkit".

As of August 13, 2008, the URL for the most up-to-date version of the medical users' toolkit is http://www.nrc.gov/materials/miau/med-use-toolkit.html. The URL for the page that lists the acceptable certifications is http://www.nrc.gov/materials/miau/med-use-toolkit/spec-board-cert.html. Note that these URLs are maintained by the NRC and the URLs, or access to them, may change over time. It is of special interest to also note that the web page that lists the board certificates that are recognized by the NRC has hyperlinks to *.pdf documents that are examples of the accepted certificates and that they can be viewed, downloaded, or printed.

**The NRC website listing the certificates that are acceptable has the certificates broken down into several categories: 10 CFR 35.50, 10 CFR 35.51, 10 CFR 35.55, 10 CFR 35.190, 10 CFR 35.290, 10 CFR 35.390, 10 CFR 35.392, 10 CFR 35.394, 10 CFR 35.490, 10 CFR 35.590, and 10 CFR 35.690 uses. What does this mean?**

These federal regulatory rules have been incorporated by reference in 15A NCAC .0117(a)(2) and applicable sections of 15A NCAC 11 .0318. 10 CFR 35.690 falls under what is designated as Subpart H of part 35 in the NC regulations. You can interpret them as follows:

a. 10 CFR 35.50 contains the training and experience requirements to become an RSO on a medical use license;
b. 10 CFR 35.51 contains the training and experience requirements to become an authorized medical physicist on a medical use license;
c. 10 CFR 35.55 contains the training and experience requirements to become an authorized nuclear pharmacist (radiopharmacist) on a medical use license;
d. 10 CFR 35.190 contains the training and experience requirements to perform diagnostic "uptake, dilution and excretion studies" as a physician listed as an AU on a medical use license;
e. 10 CFR 35.290 contains the training and experience requirements to perform diagnostic "imaging and localization studies" as a physician listed as an AU on a medical use license. An AU approved for "imaging and localization studies" is automatically approved to perform "uptake, excretion and dilution studies";
f. 10 CFR 35.390 contains the training and experience requirements to perform therapy with unsealed radioactive materials other than the therapeutic use of I-131 as a physician listed as an AU on a medical use license;
g. 10 CFR 35.392 contains the training and experience requirements to perform therapy using equal to or less than 1.22 gigabecquerels (33 millicuries) I-131 in unsealed form as a physician listed as an AU on a medical use license;
h. 10 CFR 35.394 contains the training and experience requirements to perform therapy using greater than 1.22 gigabecquerels (33 millicuries) I-131 in unsealed form as a physician listed as an AU on a medical use license. Note that although there is no certificate listed on this page, the NRC has recognized same certificate issued for administrations of less than 33mCi as proof of certification to use more than 33mCi I-131 in the federal licensing guidance and instructions to NRC license reviewers;
i. 10 CFR 35.490 contains the training and experience requirements to perform therapy using sealed sources in brachytherapy (except therapy using HDR afterloading brachytherapy devices) and ophthalmic therapy using devices containing Sr-90 as a physician listed as an AU on a medical use license;
j. 10 CFR 35.590 contains the training and experience requirements to perform diagnostic studies using sealed sources as a physician listed as an AU on a medical use license; and

FAQs (continued):

k. 10 CFR 35.690 contains the training and experience requirements to perform therapy using HDR afterloading brachytherapy units, teleptherapy units, and gamma stereotactic radiosurgery (gamma knife) units as a physician listed as an AU on a medical use license. In 15A NCAC 11 .0117(a)(2) of the NC regulations, the 10 CFR 35.690 use of these devices are incorporated and referenced as Subpart H of 10 CFR Part 35 use of radioactive material. Note that each type of therapy unit or modality (HDR, teleptherapy, gamma knife, etc.) has its own training requirement specified by the manufacturer that must be met to become an AU for that type of therapeutic unit. Physicians wishing to become AUs on accelerator licenses in NC must meet the training and experience requirements for teletherapy AUs.

**The NRC issues a wide variety of licenses and permits. The NC regulations only discuss licenses to use radioactive material. If I am a physician and I am authorized on a permit issued by a NRC broad licensee for nuclear cardiology, can I use that as evidence of training and experience to be named on a NC medical use license for nuclear cardiology?**

Yes. 10 CFR 35 lists a litany of different license types. The simplest being a NRC or Agreement State license. Other license types listed include: permits issued by a NRC or Agreement State broad scope licensee, master material license permits and permitees, master material license permits and permitees of broad scope, etc.

For all intents and purposes these are recognized as license documents in NC. The caveat is that an individual that is being listed on a NC medical use license will only be authorized to use the material that he or she is authorized to use on the license submitted to the agency as proof of training and experience.

**What happened to the Publication 97-01: 'The List of Radioactive Materials Approved for the Four "Groups of Diagnostic Uses"'?**

The Groups no longer exist. All unsealed radioactive material used for medical use in humans and select sealed and unsealed radioactive material used for QA/QC in the practice of medicine have been incorporated in 15A NCAC 11 .0321.

## AUTHORIZED MEDICAL PHYSICISTS AND AUTHORIZED NUCLEAR PHARMACISTS AS AUTHORIZED USERS FAQs:

**When must a licensee have an authorized medical physicist (AMP) named on the license?**

An AMP must be named on licenses authorizing the medical uses of strontium-90 ophthalmic applicators, teletherapy units, accelerator licenses, photon-emitting HDR remote after loader brachytherapy units, and gamma stereotactic radiosurgery units.

*Licensee's whose licenses authorize the activities listed above shall amend their licenses to add AMPs, and submit the appropriate training and experience documentation to the agency during routine amendment or renewal of their license.*

FAQs (continued):

**North Carolina regulations currently defines individuals authorized to use radioactive materials on radioactive materials licenses as "Authorized Users" (AU). 10 CFR Part 35 discusses individuals called "Authorized Medical Physicists" (AMP) and "Authorized Nuclear Pharmacists" (ANP). What are AMPs and ANPs?**

Under North Carolina licensing policies and procedures, physicians and nuclear pharmacists (radiopharmacists) who use or dispense radioactive materials are both defined as authorized users. Medical Physicists were not listed on licenses as AUs or AMPs, but were considered as supervised individuals (technicians) as permitted by 15A NCAC 11 .0318; or qualified experts under 15A NCAC 11 .0609(e) for accelerator licenses.

**Can an individual work under the supervision of an AMP or ANP?**

Yes. For medical use licensees, 15A NCAC 11 .0318(q)(4)(B) provides for a physician to work under the supervision of a physician who is an AU. In addition, 15A NCAC 11 .0318(x) permits an individual to prepare radioactive material for human use under the supervision of an AU or an ANP. For nuclear pharmacy licensees, 15A NCAC 11 .0333(2) references 10 CFR 32.72 which permits a pharmacist or a nuclear pharmacist who is not an AU, to work under the supervision of a ANP [10 CFR 32.72(b)(1)]. Documentation of the supervisory relationship and reviews of the supervised individuals' work is required to be maintained for inspection by the agency. AMPs have previously been considered supervised individuals on a technician level working under the supervision of an AU as permitted by 15A NCAC .0318.

**Does an Authorized Medical Physicist(AMP) have to be registered with the State?**

Only if the AMP is working as a consultant or contractor for a licensee. The AMP must still be added to the specific NC Radioactive Material license via an amendment request. If the AMP is an employee of the licensee then the individual does not have to be registered.

## PHYSICIANS AS AUTHORIZED USERS FAQs:

**If a physician is listed as an AU on an Agreement State (AS) or NRC license for a medical use, will the agency accept that as evidence that the physician may be listed as an AU for the same medical use on a North Carolina medical use license?**

Yes. If a physician is identified as an AU for a medical use on an AS license or an NRC license, the physician may be listed as an AU on a NC license for the same medical use. Also, note that 15A NCAC 11 .0318(q)(4)(B) permits a physician to begin work under a NC license before they are added to that license as an AU as long as that physician's work is supervised and reviewed by an AU listed on the license, and that the reviewed work is documented.

FAQs (continued):

**Can an individual work under the supervision of an AU?**

Yes. For medical use licensees, 15A NCAC 11 .0318(q)(4)(B) provides for a physician to work under the supervision of a physician who is an AU. In addition, 15A NCAC 11 .0318(x) permits an individual to prepare radioactive material for human use under the supervision of an AU or an ANP. For nuclear pharmacy licensees, 15A NCAC 11 .0333(2) references 10 CFR 32.72 which permits a pharmacist or a nuclear pharmacist who is not an AU, to work under the supervision of a ANP [10 CFR 32.72(b)(1)]. Documentation of the supervisory relationship and reviews of the supervised individuals' work is required to be maintained for inspection by the agency. AMPs have previously been considered supervised individuals on a technician level working under the supervision of an AU as permitted by 15A NCAC .0318.

**May clinical work experience that is not related to radiation safety, such as reviewing case histories or interpreting scans, be counted toward the 700 hour training and experience requirements in 10 CFR 35.290(c)(1) and 10 CFR 35.390(b)(1), incorporated by reference in 15A NCAC .0117(a)(2) to add a physician to my license as an authorized user (AU)?**

The regulatory requirements refer to two categories of training: (a) classroom and laboratory training, and (b) supervised work experience. All hours credited to "classroom and laboratory training" must relate directly to radiation safety and safe handling of byproduct material. The "supervised work experience" for physicians must include, but is not limited to, the subject areas listed in the applicable training and experience requirements. This type of supervised clinical experience may be credited toward the "work experience" category to obtain the required total of 700 hours of training and experience, but not to the "classroom and laboratory training" category.

**Can the authorized user (AU) delegate supervisory responsibilities to a chief technician who supervises others in specific tasks associated with using or preparing byproduct material?**

Only AUs and authorized nuclear pharmacists (ANPs) are authorized to use or prepare, respectively, byproduct material in the practice of medicine. However, it is frequently necessary for an AU or ANP to delegate specific tasks associated with the use or preparation of byproduct material in the practice of medicine to other individuals. 15A NCAC 11 .0318 allows for this delegation of tasks as long as the individuals are properly supervised and instructed. The AUs and ANPs are best suited for determining tasks that supervised individuals can perform and the degree of supervision that each individual needs.

**In the past we have been allowed to add our own AUs via a license condition. Since the AUs are not specifically listed on the license, must we request an amendment to add them now? What documentation is necessary?**

Yes. As of September 15, 2008 all AUs must appear on the license. An amendment request must be submitted with documentation which allowed the licensee to add them via the license condition (eg. 1. the proper certification or NC radioactive material/accelerator license with their name appearing on it; 2. the approval , in writing, by both the Radiation Safety Committee and the Radiation Safety Officer; and 3. their license to practice medicine in the State of North Carolina)

FAQs (continued):

## EMERGING TECHNOLOGIES FAQs

**What are the training and experience (T&E) requirements for individuals involved with the medical use of radioactive material in emerging technologies?**

North Carolina regulations do not not include specific training and experience requirements for AUs of emerging technologies [10 CFR 35.1000] because training requirements necessary for the safe use of byproduct material in new technologies are not known in advance.

## RADIATION SAFETY OFFICER FAQs

**Can a licensee appoint deputy or assistant radiation safety officers (RSO)?**

Nothing in the regulations prohibits a licensee from appointing deputy and/or assistant RSOs, but only one RSO can be designated by a licensee and identified on the license. A licensee or its RSO can assign or delegate radiation safety program tasks and duties to other individuals. However, the RSO identified on the license retains overall responsibility for implementing the total radiation protection program.

**If an AU, ANP, or AMP is listed as an RSO on an Agreement State (AS) or NRC license for a medical use as an RSO, will the agency accept that as evidence that the physician may be listed as an RSO for the same medical use on a North Carolina medical use license?**

Yes. An individual who is listed as a Radiation Safety Officer (RSO) on an Agreement State (AS) or NRC medical use license may be approved as an RSO on a NC medical use license for those uses for which he or she has been previously approved. A license amendment is needed before the individual can begin work as the RSO for the licensee.

**When can an AU be appointed as the RSO for a medical use license?**

An AU can be appointed as the RSO for a license if the AU (1) is identified as an AU in the license, (2) has experience with the radiation safety aspects of similar types of use of byproduct material for which the individual will have RSO responsibilities, (3) has training in the radiation safety, regulatory issues, and emergency procedures for the types of use for which a licensee seeks approval, (4) has obtained written attestation, signed by a preceptor RSO, that: (a) the individual is an AU identified on the licensee's license; (b) the AU has satisfactorily completed the training in (3); and (c) the AU has achieved a level of radiation safety knowledge sufficient to function independently as an RSO for a medical use licensee. Additionally, the AU must agree, in writing to be responsible for implementing the radiation protection program.

Note that a license amendment is needed before the individual can begin work as the RSO for the license.

FAQs (continued):

**Can a Nuclear Medicine Technician, Therapist, or other individual be designated as the radiation safety officer (RSO) for a medical use license?**

Yes. If they meet the requirements of an RSO as listed in 15A NCAC 11 .0318(l)(1); or are listed as the RSO on a current agreement state (AS) or NRC medical use license as the RSO for the same medical use as permitted by 15A NCAC 11 .0318(l)(2). However, if the scope of medical use changes that individual may no longer be qualified as the RSO and an individual qualified to be the RSO under 15A NCAC 11 .0318(l)(1) must be named as the RSO on the license. For example, a Nuclear Medicine Technologist grandfathered in as an RSO on a nuclear cardiology license under 15A NCAC 11 .0318(l)(2) but who does not meet the training and experience requirements listed in 15A NCAC 11 .0318(l)(1) cannot remain the RSO if therapeutic radioactive materials are added as an authorized use on the license. Likewise, a Therapist listed as the RSO on an accelerator license is not qualified to remain the RSO if HDR afterloading brachytherapy is added as a use to the license unless they are qualified by experience and training as listed in 15A NCAC 11 .0318(l)(1). In all cases the individual must and agree, in writing, to be responsible for implementing the radiation protection program.

## SEALED SOURCES (SUBPART H OF 10 CFR 35 USE) OTHER THAN EMERGING TECHNOLOGIES FAQs:

**When a licensee is authorized to perform ophthalmic treatments, is the licensee required to have an authorized medical physicist (AMP) listed on the license in order to meet the requirement of 10 CFR 35.433(a), incorporated by reference in 15A NCAC 11 .0117(2)?**

Yes. 10 CFR 35.433(a) specifies that only an AMP shall calculate the activity of each Sr-90 source that is used to determine the treatment times for ophthalmic treatments. Therefore, the licensee must identify individual(s) to work as AMP(s) under the license.

**Can a physician be granted authorized user status for multiple therapeutic units (teletherapy units and/or remote afterloader units and/or gamma stereotactic radiosurgery units) based on completion of a single structured educational program?**

Yes, if the program covers the requirements in Subpart H of 10 CFR 35.

**Does 10 CFR 35.600 (Subpart H to 10 CFR Part 35) apply to beta-emitting remote afterloaders in addition to addressing photon-emitting afterloader units?**

No. Use of beta-emitting afterloader devices must be addressed under 10 CFR 35.1000.

**With respect to the requirements for performing calibrations on therapy units, Subpart H of 10 CFR 35 [10 CFR 35.600] incorporated by reference in 15A NCAC 11 .0117(a)(2), requires that the calibrations to be performed by an authorized medical physicist (AMP). In practice, the actual work is often performed under the supervision of the AMP. Will this continue to be an acceptable practice?**

FAQs (continued):

No. The regulations incorporated by reference require that full calibrations and physical decay corrections of teletherapy, remote afterloader, and gamma stereotactic radiosurgery units be performed by an AMP [10 CFR 35.632(f), 10 CFR 35.633(h), and 10 CFR 35.635(f), respectively].

This requirement does not preclude an AMP from providing training and experience in therapy unit calibration to a medical physicist in training as long as the AMP is physically present during and directly involved in all required calibrations of such units.

**Do neurosurgeons qualify as authorized users (AUs) on gamma stereotactic radiosurgery (gamma knife) licenses with regard to the Subpart H of 10 CFR 35 requirement, incorporated by reference in 15A NCAC 11 .0117(a)(2), for an AU to be physically present throughout the entire patient treatment involving the unit?**

No. If a neurosurgeon is named on the license for gamma stereotactic radiosurgery (gamma knife) that individual does not qualify as an AU and cannot meet the physical presence requirement of an AU unless that neurosurgeon meets the definition of an AU in 15A NCAC 11 .0318(c) or the training and experience requirements in 10 CFR 35.690. Note that 10 CFR 35.615 requires that an authorized medical physicist (AMP) is also required to be physically present during all gamma stereotactic radiosurgery patient treatments.

## ACCELERATOR FAQs:

**How do I add Authorized Users (AU) or a Radiation Safety Officer (RSO) to my accelerator license?**

Use the guidance in this document for teletherapy licensees when adding AUs and RSOs to your accelerator license.

Also, you will have to amend your license during the next routine amendment or renewal to add Authorized Medical Physicists (AMPs) to your accelerator license to perform the annual calibrations and monthly spot checks on your accelerator unit(s) [15A NCAC 11 .0609(e)(3) and 15A NCAC 11 .0609(e)(4) respectively]. AMPs are considered qualified experts for the purposes of this guidance and *do not* have to register with the agency as a “qualified expert” as required by 15A NCAC 11 .0205 and 15A NCAC 11 .0602(45) *if* the AMP is an employee of the licensee and is listed on the licensee’s medical use license. AMPs who are not employees of the licensee must register with the agency as a “qualified expert” before providing the services required by 15A NCAC .0609(e) and must be listed on the license.

**Does my medical physicist have to be registered with the State of NC?**

Yes. If your medical physicist is not an employee of your company (or your practice) and is acting in the capacity of a contractor or subcontractor.

FAQs (continued):

## GRANDFATHERING EXPERIENCED INDIVIDUALS

**Will an experienced RSO, teletherapy or medical physicist, ANP, or AU need to comply with the training requirements in the current 2005 Part 35?**

No. If the individual was listed on a license, the individual is a "grandfathered" individual provided he/she performs only those medical activities for which he or she was authorized.

**The NC, agreement state (AS) or NRC medical use license listing the individual I want to add to my license as an authorized user (AU), radiation safety officer (RSO), authorized medical physicist (ANP), or authorized nuclear pharmacist (ANP) has expired or was terminated. Can I use it to show that the individual was listed on a medical use license, and have them added to my medical use license?**

No. Only current unexpired licenses or licenses that have not been terminated can be used to demonstrate AU, AMP, ANP or RSO status for the purposes of adding these individuals to your license.

**What do you mean by a "current" license or "current" certification or registration?**

Any license, certificate, registration, or training and experience document that was issued less than seven (7) years before application is made to amend a NC medical use license is current.

All applicable training and experience criteria must be completed within seven (7) years preceding the date of application to name an individual on a medical use license as an AU, AMP, ANP, or RSO. This time provision also applies to board certifications used to demonstrate qualifications to become an AU, ANP, AMP, or RSO.

However, an individual with continuing education and experience related to the medical use of radioactive material within the seven (7) year period preceding the date of application to amend a NC license may use this continuing education and experience to substitute for the required certification and/or training and experience long as this continuing education and experience is for the same medical use as the individual was qualified to perform based upon their initial certification or training and experience.

**If I received training and experience to qualify as an AU during the time between the publication in the *Federal Register* of the "Medical Use of Byproduct Material - Recognition of Specialty Boards; Final Rule (March 30, 2005)" and the April 29, 2005 effective date of the revised Part 35, am I "grandfathered" as an AU or do I need to obtain the training and experience specified in the 2005 current Part 35?**

You are grandfathered if you were identified on or before April 29, 2005, the effective date of the 2005 current Part 35, as an AU for medical use of byproduct material on a license issued by the Commission or an AS, a permit issued by a Commission master material licensee, a permit issued by a Commission or AS broad scope licensee, or a permit issued by a Commission master material license broad scope permittee, as long as you only perform those medical uses for which you were authorized on that date. If you were not identified as an AU on April 29, 2005, you must comply with the training requirements of Subparts D-H of the 2005 current Part 35 or, until October 24, 2005, the training requirements of Subpart J.

FAQs (continued):

**Prior to the 2002 revised 10 CFR Part 35 and under NRC Policy and Guidance Directive 3-05, all brachytherapy AUs were authorized for use of 10 CFR 35.400 materials. The 2002 revised Part 35 moved all remote afterloading brachytherapy uses from 10 CFR 35.400 to 10 CFR 35.600. Many of the remote afterloader AUs may not have been authorized for usage under Part H of 10 CFR 35.600 [10 CFR 35.600], nor were they necessarily qualified to receive such an authorization under the 2002 revised Part 35 requirements. Are these AUs "grandfathered" as not needing to comply with the training requirements in Subpart H?** ***Note: 10 CFR Part 35.400 and Subpart H of 10 CFR 35, which includes 10 CFR 35.600, are incorporated by reference in 15A NCAC 11 .0117(a)(2).***

Yes, as long as such physicians were identified on or before the October 24, 2002 effective date of the rule as AUs for remote afterloading brachytherapy on a license issued by the Commission or an AS, a permit issued by a Commission master material licensee, a permit issued by a Commission or an AS broad scope licensee, or a permit issued by a Commission master material license broad scope permittee, they are "grandfathered" (i.e., maintain their AU status for remote afterloading brachytherapy without having to comply with the relevant training requirements) provided they only perform those medical uses for which they were authorized on that date.

**Under 10 CFR 35.57, would a presently-authorized medical physicist (AMP) or authorized user (AU) be grandfathered for all modalities in Subpart H of 10 CFR 35, incorporated by reference in 15A NCAC 11 .0117(a)(2), even if the individual was only authorized for one or two of these modalities on the implementation date of the new rule [10 CFR 35.600]?**

No. There would be no change in what the individual is authorized to do. For example, an individual currently recognized as a "teletherapy physicist" would be recognized as an AMP for teletherapy units under the revised Part 35. AUs would continue to be recognized as AUs for the type(s) of use of byproduct material for which they had approval under the previous rule. An AMP or AU cannot be authorized for a type of use for which training and experience is inadequate or not documented.

**Can I use certificates issued by certification boards recognized by the NRC that are not specifically listed on the NRC website as documentation-of-certification or proof of training-and-experience for the various uses of radioactive materials for medical use for individual(s) I want to add as the radiation safety officer (RSO), authorized user(s) (AU), authorized nuclear pharmacist(s) (ANP), or authorized medical physicist(s) (AMP) to my license?**

No. The only certificates that the agency can accept as documentation-of-certification or proof-of-training for the purpose of qualifying an individual as an RSO, AU, ANP, or AMP are those certificates that are specifically listed in the most current version of the “medical users’ toolkit” on the NRC’s web site.

As of August 13, 2008, the URL for the most up-to-date version of the medical users’ toolkit is http://www.nrc.gov/materials/miau/med-use-toolkit.html. The URL for the page that lists the acceptable certifications is http://www.nrc.gov/materials/miau/med-use-toolkit/spec-board-cert.html. Note that these URLs are maintained by the NRC and the URLs, or access to them, may change over time. It is of special interest to note that the web page that lists the board certificates that are recognized by the NRC has hyperlinks to *.pdf documents that are examples of the accepted certificates and that they can be viewed, downloaded, or printed.

FAQs (continued):

## MISCELLANEOUS:

**Is anyone supposed to be "physically present" during therapeutic medical procedures; and if so, who are they and when are they supposed to be "physically present"?**

15A NCAC 11 .0117(a)(2) incorporates Subpart H of 10 CFR Part 35 into the North Carolina regulations. Subpart H requires that certain specific individuals be "physically present" during therapy using medium dose-rate, pulsed dose rate, and high dose rate afterloaders, and therapy using gamma stereotactic radiosurgery units (gamma knife). These requirements are specified below:

1) Medium dose-rate and pulsed dose-rate remote afterloader units: an authorized medical physicist and either an authorized user or a physician, under the supervision of an authorized user, who has been trained in the operation and emergency response for the unit must be "physically present" during the initiation of all patient treatments involving the unit.

   An authorized medical physicist and either an authorized user or an individual, under the supervision of an authorized user, who has been trained to remove the source applicator(s) in the event of an emergency involving the unit, must be "immediately available" during continuation of all patient treatments involving the unit.

2) High dose-rate remote afterloader units: an authorized user and an authorized medical physicist must be "physically present" during the initiation of all patient treatments involving the unit.

   An authorized medical physicist and either an authorized user or a physician, under the supervision of an authorized user, who has been trained in the operation and emergency response procedures for the unit, must be "physically present" during continuation of all patient treatments involving the unit.

3) Gamma stereotactic radiosurgery units: an authorized user and an authorized medical physicist must be "physically present" throughout all patient treatments involving the unit.

**What does "physically present" mean?**

The individual would need to be within hearing distance of normal voice without the aid of communication devices.

**Does the use of quantities greater than 30 microcuries I-125 for diagnostic purposes require a written directive?**

No. However, if I-131 is used the answer is yes. 15A NCAC 11 .0104(167) and 15A NCAC 11 .0356(a) (except as provided by 15A NCAC 11 .0356(d)) require a written directive for any administration greater than 30µCi (1.11MBq) of I-131. Both regulations also specify the information that must be documented for this written directive.

FAQs (continued):

**Are visiting AUs, ANPs, AMPs still allowed under the new regulations?**

Yes. Visiting AUs, ANPs, AMPs are allowed to use radioactive material or accelerators provided that the following condition is specifically on their license. A license amendment is not required to be submitted to add the names, but the licensee is expected to maintain the required documentation for agency inspection.

*For a period not to exceed 60 days in any calendar year, a visiting physician, nuclear pharmacist or medical physicist is authorized to use radioactive material or the accelerator under the terms of this license provided the individual:*

*A. Has prior written permission of the hospital administrator and its Radiation Safety Committee; and*

*B. Is specifically named as a user on a N.C. Department of Environment and Natural Resources license authorizing use; and*

*C. Performs only those procedures for which specifically authorized by the N.C. Department of Environment and Natural Resources license.*