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General Comment

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Attachments

NMAA NRC final

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A mid-level provider trained specifically in all aspects of radiation safety, radiation biology, radiation physics, instrumentation and radiation protection is now available in the position of the Nuclear Medicine Advanced Associate. These mid-level providers have extensive laboratory training and are extremely qualified to be authorized users, as they have been trained specifically to perform duties to alleviate the workload of physicians. Calculating doses, ordering, receiving and unpacking radioactive materials, performing quality control on all instruments used in the nuclear medicine department, preparing kits, patient assessment and numerous other tasks are daily routine work for the NMAA. The NMAA is not a technologist, but a physician extender in Nuclear Medicine who has been trained at the Master's level, tested, and board certified in advanced nuclear medicine practice. The NMAA is required to complete 40 hours of continuing education per biennium, 20 hours are at the physician level CME. Per the Scope of Practice created by the Society of Nuclear Medicine and Molecular Imaging:

A nuclear medicine advanced associate prescribes and administers pharmacologic and nonpharmacologic interventions under the direction of the supervising physician and as indicated by patient profile and diagnostic procedure as allowable by state and federal statutes, which includes, but is not limited to:

1. Perform pre-procedure requirements and interventions as may be required.

2. Perform intra-procedure requirements as may be required.

3. Perform post-procedure requirements as may be required.

As with other physician extenders, i.e. physician assistants and nurse practitioners, NMAA's are allowed to prescribe substances which are allowed under their scope of practice, such as radiopharmaceuticals. This opens the pathway for physician extenders in nuclear medicine to become authorized users, just as physician assistants and nurse practitioners are allowed to prescribe medications on behalf of their supervising physicians. The training and practical experience of Nuclear Medicine Advanced Associates creates ideal candidates for authorized users. The NMAA has met the qualifications required under 10 CFR35.200 to become authorized users.

As the goal of 10CFR 30.33(a) (3) of the NRC regulations is to ensure authorized users "protect health and minimize danger to life or property", the NMAA will add an increased level of protection and professionalism. With unsurpassed practical experience in receiving, shipping and administering all radiopharmceuticals, addition of the NMAA as authorized user will no doubt result in a decline of: violation, patient concern, and physician's workload.

It is highly recommended that these specialized mid level providers be added to the candidates for authorized user for radioactive byproduct use encompassing uptake, dilution, excretion, imaging and localization. Whereas the language would be altered to now state:

Except as provided in § 35.57, the licensee shall require an authorized user of unsealed byproduct material for the uses authorized under § 35.200 and 35.100 to be a physician or ***Nuclear Medicine Advanced Associate*** *who—*

(a) Is certified by a medical specialty board whose certification process has been recognized by the Commission or an Agreement State and who meets the requirements in paragraph (c)(2) of this section. (The names of board certifications which have been recognized by the Commission

or an Agreement State will be posted on the NRC's Web page- ***recognizing the NMTCB as a specialty board.)*** *To have its certification process recognized, a specialty board shall require all candidates for certification to:*

(1) Complete 700 hours of training and experience in basic radionuclide handling techniques and radiation safety applicable to the medical use of unsealed byproduct material for imaging and localization studies as described in paragraphs (c)(1)(i) through (c)(1)(ii)(G) of this section; and

(2) Pass an examination, administered by diplomates of the specialty board, which assesses knowledge and competence in radiation safety, radionuclide handling, and quality control; or

(b) Is an authorized user under § 35.390 and meets the requirements in § 35.290(c)(1)(ii)(G), or equivalent Agreement State requirements; or

(c)(1) Has 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, at a minimum-

(i) Classroom and laboratory training in the following areas—

(A) Radiation physics and instrumentation;

(B) Radiation protection;

(C) Mathematics pertaining to the use and measurement of radioactivity;

(D) Chemistry of byproduct material for medical use;

(E) Radiation biology; and

(ii) Work experience, under the supervision of an authorized user who meets the requirements in §§ 35.57, 35.290, or 35.390 and 35.290(c)(1)(ii)(G), or equivalent Agreement State requirements, involving—

(A) Ordering, receiving, and unpacking radioactive materials safely and performing the related radiation surveys;

(B) Performing quality control procedures on instruments used to determine the activity of dosages and performing checks for proper operation of survey meters;

(C) Calculating, measuring, and safely preparing patient or human research subject dosages;

(D) Using administrative controls to prevent a medical event involving the use of unsealed byproduct material;

(E) Using procedures to safely contain spilled radioactive material and using proper decontamination procedures;

(F) Administering dosages of radioactive drugs to patients or human research subjects; and

(G) Eluting generator systems appropriate for preparation of radioactive drugs for imaging and localization studies, measuring and testing the eluate for radionuclidic purity, and processing the eluate with reagent kits to prepare labeled radioactive drugs; and

(2) Has obtained written attestation, signed by a preceptor authorized user who meets the requirements in §§ 35.57, 35.290, or 35.390 and 35.290(c)(1)(ii)(G), or equivalent Agreement State requirements, that the individual has satisfactorily completed the requirements in paragraph (a)(1) or (c)(1) of this section and has achieved a level of competency sufficient to function independently as an authorized user for the medical uses authorized under §§ 35.100 and 35.200

Thank you,

Vicki LaRue, MIS, NMAA

***Denver**, CO.*