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(68FR 68549)

ACNP/SNM

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American College of Nuclear Physicians/Society of Nuclear Medicine

GOVERNMENT RELATIONS OFFICE

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February 24, 2004 (8:25AM)

Secretary, U.S. Nuclear Regulatory Commission  
ATTN: Rulemakings and Adjudications Staff  
Washington, DC 20555-0001

OFFICE OF SECRETARY  
RULEMAKINGS AND  
ADJUDICATIONS STAFF

Re: RIN 3150-AH19

The Society of Nuclear Medicine (SNM) and the American College of Nuclear Physicians (ACNP) are pleased to submit the following comments related to the U.S. Nuclear Regulatory Commission's (NRC) proposed rule on *Medical Use of Byproduct Material - Recognition of Specialty Boards* issued December 9, 2003 (68 FR 68549).

Together, SNM and ACNP represent more than 15,000 physicians, pharmacists, physicists, scientists and technologists practicing in the field of nuclear medicine who may be affected by the revised regulation. These specialists make up the expert medical team that uses radioisotopes and radiopharmaceuticals to diagnose and treat patients with cancer, heart disease and other ailments.

Although SNM and ACNP are supportive of the revised regulation, we have several concerns about the proposed changes and implementation of this regulation. We continue to have serious concerns as to whether this regulation is truly risk informed and performance based. For example, the proposed regulation requires completion of a nuclear medicine training program which includes 700 hours of training and experience to use unsealed sources for imaging and localization studies (Sec. 35.290(a)) and, for American Board of Nuclear Medicine (ABNM) certification in Sec. 35.390, passing an examination but only requires 80 hours of training for the use of only I-131 by physicians who are not otherwise trained in nuclear medicine, radiology or radiation oncology (Sec. 35.394) with no examination. It is inconsistent to have minimal alternate training pathways while placing much more prescriptive training requirements on specialty boards that already require far more than the alternative pathway.

We suggest that the Commission reconsider formalizing in the Part 35 regulations the inconsistencies in the proposed regulations, as they would apply to any specialty board. The Commission should consider the totality of all work experience possessed by individuals who have completed an American Board of Medical Specialties (ABMS) accredited program in nuclear medicine, radiology or radiation oncology. The rule should recognize that ABMS certified nuclear medicine physicians, radiologists and radiation oncologists have unique training, experience and examinations that go well beyond the minimum requirements of the

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alternate pathway. The NRC therefore should require in 10 CFR 35.390 that any ABMS medical specialty board only needs to meet the same minimal requirements specified for the alternate pathway in proposed 10 CFR 35.390 (b) (1) (ii). In addition, to further remove the proposed inconsistencies, the NRC should eliminate from the regulations any additional requirements for an ABMS board such as an examination and approve ABMS boards based upon their formal training and examination procedures which will be outlined by the boards in their applications for approval.

The following responses are specific to the three questions raised by the NRC in the proposed rule.

**Question 1: "Do the proposed revisions to requirements for training and experience provide reasonable assurance that Radiation Safety Officers, Authorized Medical Physicists, Authorized Nuclear Physicists, and Authorized Users will have adequate training in radiation safety?"**

It is not the regulations per se that provide reasonable assurance that the Radiation Safety Officers (RSOs), Authorized Medical Physicists (AMPs), and Authorized Users (AUs) will have adequate training in radiation safety but rather the rigorous educational programs these individuals complete prior to working as an RSO, AMP or AU. For SNM and ACNP members that serve as AUs, the radiology and nuclear medicine residency programs and fellowships that our members complete include at least 4 months of training in radiation safety and protection as they apply to ensuring adequate protection of the patient and the public from radioactive materials used in nuclear medicine. In addition, as part of the American Board of Nuclear Medicine (ABNM) certification process, all AUs first take an examination that includes questions on radiation protection and safety. These individuals also receive sufficient training in radiation safety and protection to allow them to serve as RSOs.

SNM and ACNP pharmacists, physicists and scientists who serve as radiopharmacists and AMPs complete rigorous training in their respective fields prior to taking examinations offered by their certifying boards. The boards also include questions on radiation safety and protection.

**Question 2: "Should Agreement States establish the requirements to conform with this proposed rule by October 24, 2005, or should they follow the normal process and be given a full 3 years to develop a compatible rule? (See discussion under the topic *"Timing of Agreement State Implementation,"* above. (68 FR 68554)."**

Although SNM and ACNP would prefer that the rule be finalized and effective as quickly as possible, we recognize the impact and limitation for adopting comparable regulations by the Agreement States. The Agreement States should be urged to adopt comparable regulations as soon as practical given the state legislative and regulatory processes. However, we would not contest a full 3 years for adoption being granted providing that the compatibility level for these regulations remains at Compatibility B.

**Question 3: Should the word "attestation" be used in place of the word "certification" in the preceptor statements? (See discussion under the topic *"Recommendations of the ACMUI,"* above. (68 FR 68554).**

SNM and ACNP believe it is absolutely critical to change the word "certification" to "attestation" in all of the preceptor paragraphs. In fact, we believe that the following should be inserted in place of the first sentence of all preceptor paragraphs in the December 9, 2003 draft:

Has obtained written attestation that the individual has satisfactorily completed the required training in paragraph (a)(1) or (b)(1) of this section and has achieved a level of knowledge and demonstrated the ability to safely handle radioisotopes to ensure adequate protection of public health and safety. The written attestation must be signed by a preceptor ...

We have also deleted "competency" from the preceptor statement, as we believe that the statement, "... has achieved a level of knowledge and demonstrated the ability..." is a demonstration of competency.

To be consistent, the definition of "preceptor" in Sec. 35.2 should be amended to read as follows:

Preceptor means an individual who provides or directs training and experience required for an individual to become an authorized user, an authorized medical physicist, an authorized nuclear pharmacist, or a Radiation Safety Officer.

The following provide specific comments on other sections of the proposed regulation.

#### Preceptor Paragraphs

In the Statement of Considerations for the proposed rule, NRC stated that the requirement for a preceptor statement would be "removed from the requirements for recognition of specialty boards." However, it appears the NRC in drafting the rule made a grammatical mistake in the language related to the preceptor paragraphs. For example, if you look at the wording of 10 CFR § 35.390 paragraph (c) it states:

"Has obtained written certification that the individual has satisfactorily completed the requirements in paragraph (a) or (b) (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 Sec. 35.300. The written certification must be signed by a preceptor authorized user who meets the requirements in Sec. 35.390(a), Sec. 35.390 (b), or, before October 24, 2004, Sec. 35.390, or equivalent Agreement State requirements. The preceptor authorized user, who meets the requirements in Sec. 35.390(b), or, before October 24, 2004, Sec. 35.930(b), must have experience in administering dosages in the same dosage category or categories (i.e., Sec. 35.390(b)(1)(ii)(G)(1), (2), (3), or (4)) as the individual requesting authorized user status."

By requesting that the preceptor certify that the individual meets all of the requirements in paragraph a, and not just (a) (1) you are assuming that this individual has knowledge of the individual passing their certification exam. This may or may not be true. In fact, many preceptor statements may be signed prior to an individual sitting for their final boards. This appears to

continue an unintended link between the board process and the individual signing a preceptor statement. SNM and ACNP request that all preceptor statements be corrected to refer back only to paragraph (a)(1) as appropriate in each of the preceptor paragraphs. The language in Sec.35.290 should be used as the model when making these corrections. Clarification needs to be provided in the Statements of Consideration that individuals may submit more than one preceptor statement, as applicable, for all categories of AU, AMP, or RSO.

#### **10 CFR § 35.50 *Training for Radiation Safety Officer (RSO)***

We commend NRC for the additional paragraph in 10 CFR § 35.50 which recognizes that medical physicists who do not qualify as AMPs may also serve as RSOs. This is an important addition since AMP only applies to medical physicists practicing in therapeutic programs. However, the phrase "*under § 35.51 (a)*" should be deleted from § 35.50 (d) (2) (i) because including the tie will limit RSO medical physicists to medical physicists practicing in therapy. It is absolutely critical that qualified medical physicists other than AMPs be able to serve as RSOs. Medical physicists, who are certified in diagnostic radiology or nuclear medicine, need to continue to be able to serve as RSOs.

#### **10 CFR § 35.390 *Training for use of unsealed byproduct material for which a written directive is required.***

As 10 CFR § 35.390 applies to nuclear medicine physicians Section 35.390 (a) (1) states:

"(1) Successfully complete a minimum of 3 years of residency training in a radiation therapy or nuclear medicine training program or a program in a related medical specialty that includes 700 hours of training and experience as described in paragraph (b)(1) of this section."

As indicated above, the SNM and ACNP believe that the NRC should not specify in Part 35, training requirements for ABMS boards that exceed the minimum requirements of the alternate pathway. If the NRC insists on maintaining the current language in the training requirements we suggest the following change to 10 CFR § 35.390 (a) (1):

(1) Successfully complete a minimum of 3 years of residency training in a radiation therapy training program, or a nuclear medicine training program, or a program in a related medical specialty that includes 700 hours of training and experience as described in paragraph (b)(1) of this section.

Currently nuclear medicine residency programs are 2 years in duration. The offered change removes the confusion of whether the 3 years of residency applies to radiation therapy training programs as well as nuclear medicine training programs. The language in the proposed rule is a change from the existing 10 CFR § 35.390 and was suggested by the Advisory Committee on the Medical Uses of Isotopes (ACMUI) to reflect the recognition of radiation therapy residency programs in 10 CFR § 35.390. Apparently the need for the added punctuation and language we are suggesting was overlooked.

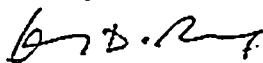
10 CFR § 35.390(G)(3) and (4) *"parenteral administration"*

Sec. 35.390 (G) deals with the therapeutic administration of certain unsealed source radionuclides orally and by parenteral administration, i.e. "by way of the intestines." As radiopharmaceutical therapies are now delivered by a variety of routes, we believe that "Parenteral administration" should be changed to "Administration by any route" to make the section all encompassing.

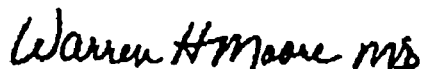
We commend the NRC's commitment to developing regulations through an interactive process with the medical community and we look forward to working with the Commissioners and staff to implement this rule in a timely fashion.

If you have any questions regarding our concerns on implementation of this rule, please let us know. Representatives of SNM and ACNP would be pleased to meet with you at your convenience to discuss this regulation. You may contact Bill Uffelman at 703-708-9773 or by email at [wuffelman@snm.org](mailto:wuffelman@snm.org) to arrange a meeting or conference call.

Sincerely,



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