American College of Radiology

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February 23, 2004

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

Re: RIN 3150-AH19

The American College of Radiology (ACR), the American Society for Therapeutic Radiology and Oncology (ASTRO), the American Association of Physicists in Medicine (AAPM), the American College of Medical Physicists (ACMP) and the American Board of Science in Nuclear Medicine (ABSNM) 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).

ACR represents approximately 32,000 diagnostic radiologists, radiation oncologists, interventional radiologists, nuclear medicine physicians and medical physicists who may be impacted by the revised regulation. ASTRO has more than 7,500 members, including physicians (radiation oncologists), radiation scientists (radiobiologists, radiological physicists), radiation therapy technologists and radiation oncology nurses. These specialists make up the expert medical team that uses radiation to treat patients with cancer and other diseases. AAPM, which represents more than 4,500 medical physicists, is a Member of the American Institute of Physics and promotes the application of physics to medicine and biology and encourages interest and training in medical physics and related fields. ACMP is an organization devoted to professional activities of medical physicists. The primary objective of the American Board of Science in Nuclear Medicine (ABSNM) is the certification of scientists practicing in nuclear medicine.

Although we support the revised regulation, we have several concerns about the proposed changes and implementation of this regulation. 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?"**

Yes, the proposed revisions to the requirements for training and experience appear to be comprehensive and adequate. However, it is not the regulations per se that provide reasonable assurance the Authorized Users (AUs), Authorized Medical Physicists (AMPs), and Radiation Safety Officers (RSOs), will have adequate training in radiation safety but the rigorous educational programs these individuals complete prior to working as an RSO, AMP or AU. The residency programs and fellowships completed by our members who serve as AUs, include several months training in radiation safety and protection of patients and the public. In addition, during the American Board of Radiology (ABR) certification process, all AUs must take both physics and basic science examinations, which include questions on radiation protection and safety. These individuals also receive sufficient training in radiation safety and protection to allow them to serve as RSOs.

Qualified medical physicists who serve as AMPs, along with their clinical training receive extensive radiation safety and protection training within their medical physics programs. The ABR exam for physicists explicitly includes radiation protection and safety as one of the five categories. Questions frequently asked in the examination include shielding design and barrier calculation, air concentrations of radioactivity, radiation protection principles, radiation regulations and requirements, responsibilities of the radiation protection office, radiation surveys in diagnostic radiology, nuclear medicine and radiation therapy, characteristics of survey equipment, evaluation of radiation hazards, personnel monitoring and related issues.

In order to be awarded Diplomate status by the ABSNM, candidates must complete certain education and professional experience requirements and must successfully pass a two-part examination administered by the Board. ABSNM Diplomates serve as RSOs and practice in the areas of Nuclear Medicine Physics and Instrumentation, Radiation Protection and Radiopharmaceutical Science.

Given the above information, we would request that the Commission consider the totality of all work experience by individuals who have completed an accredited residency program and/or achieved board certification as reasonable assurance they will have adequate training in radiation protection and safety. Most training programs exceed the requirements delineated in the alternative pathway.

Question 2: "Should Agreement States establish the requirements to conform to 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 we would prefer that the rule be finalized and effective as quickly as possible, we recognize potential difficulties in developing comparable regulations for the Agreement States. The Agreement States should be urged to adopt comparable regulations as soon as practical given the states' legislative and regulatory processes. However, we would not object to granting a full three years for adoption providing that the compatibility level for these regulations remains at a "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).
Yes. We believe it is absolutely critical to change the word "certification" to "attestation" in all the preceptor paragraphs. More specifically, we recommend that the following 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 . . .***

In addition to the above responses to specific NRC inquiries, the following paragraphs provide specific comments on selected sections of the proposed regulation.

Preceptor Paragraphs

1. In the *Statements of Consideration* 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 some of the language related to the preceptor paragraphs is unclear and potentially confusing. For example, 10 CFR § 35.390 paragraph (c) 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."

The requirement that the preceptor certify that the individual meets all of the requirements in **paragraph a, and rather than just (a) (1),** appears to assume that this preceptor has knowledge of the individual's having passed a certification exam. This may or may not be true. In fact, a preceptor statement may be signed prior to an individual sitting for final boards. This appears to continue an unintended link between the board process and the preceptor's attestation. Therefore, we request that all preceptor statements be reworded to refer only to paragraph (a)(1) [or (b)(1)] as appropriate.

2. 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.

3. In § 35.2 *Definitions,* the definition of preceptor should be modified to delete the word "the" between "directs" and "training" and 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."**

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

We commend NRC for the additional paragraph in 10 CFR § 35.50 which states that medical physicists who do not qualify as AMPs may also serve as RSOs. This is an important clarification since the term AMP only applies to a medical physicists practicing in therapeutic programs, and excludes qualified medical physicists practicing in other related areas. 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 an RSO. Medical physicists, who are certified in diagnostic radiology or nuclear medicine, need to continue to be able to serve as RSO.

10 CFR § 35.51 ***Training for an Authorized Medical Physicist (AMP)***

As written, 10 CFR § 35.51 (a) (2) (i) would allow candidates with no clinical experience (e.g., research post-docs supervised by a boarded physicist) to sit for board certification examinations. Therefore we recommend the following changes to 10 CFR § 35.51 (a) (2):

"(2) Have 2 years of full-time practical training and/or experience in a clinical radiation oncology facility providing high energy external beam therapy and brachytherapy services under the supervision of (i) a medical physicist who is certified by a board recognized by the Commission or an Agreement State, or (ii)

physicians who meet the requirements for 10 CFR §§ 35.490 or 35.690 authorized users."

An additional concern pertains to the implementation of this new section of the regulation. It is unclear how individuals will be grandfathered or listed on current licenses as AMPs, since the concept of an AMP did not exist prior to October 24, 2002. In many cases, the physicists presently serving in what will now be "AMP" positions are not currently listed on existing licenses as such except for therapy physicists utilizing cobalt-60 teletherapy. Some agreement states have not established processes for credentialing physicists authorized to perform critical QA and safety checks for intravascular brachytherapy, or gamma stereotactic treatments. Other agreement states that have training and experience requirements for these duties do not explicitly list the qualified individuals on licenses. In order to have an initial pool of AMPs to serve as preceptors, this issue needs to be clarified. We believe that any physicist who (a) either is certified by a board recognized by the Commission in accordance with 10 CFR § 35.51 or satisfies the alternative pathway requirements as specified in 10 CFR § 35.51 and (b) who has clinical experience in performing AMP duties in the past seven years should be automatically grandfathered as an AMP independently of whether this role has been explicitly recognized in an agreement state license.

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

As 10 CFR § 35.390 apply to nuclear medicine physicians:

Section 35.390 (a) (1) states:

> "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."

We request the following punctuation changes to 10 CFR § 35.390 (a) (1):

> ***"successfully complete a minimum of 3 years of residency training in a radiation therapy, or 2 years of nuclear medicine residency 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."***

Our proposed change is offered to help eliminate potential confusion about whether the three years of residency applies to nuclear medicine training programs. Current nuclear medicine residency programs are two years in duration. This is a change from the existing 10 CFR § 35.390 and seems to be intended to recognize radiation therapy residency programs in 10 CFR § 35.390 rather than to affect nuclear medicine programs, as they now exist.

As 10 CFR § 35.390 applies to radiation oncologists:

This provision states that to be recognized by the Commission, a "specialty board shall require all candidates for certification to complete a minimum three years of residency training in radiation therapy." First, we would note that the five-year radiation oncology residency program far exceeds the three-year minimum specified by the Commission. The five-year program requires a minimum of four years in radiation oncology and includes instruction in physics, radiation biology, and clinical applicability in unsealed sources. The curriculum in medical physics must include didactic lectures and laboratory demonstrations of radiation safety procedures, calibration of radiation therapy machines, and the safe handling of unsealed radionuclides. In addition to these training requirements, each student is required to pass a written examination administered by the ABR that focuses on the basic sciences of physics, cancer and radiation biology, the clinical practice of radiation oncology, and radiation treatment planning and technique. Clearly physicians who complete a radiation oncology residency possess the requisite training and experience to use unsealed sources as mandated in 10 CFR § 35.390.

Accordingly, we request that the Commission consider the totality of all work experience possessed by individuals who have completed an accredited residency program in radiation oncology. The rule should recognize that radiation oncologists have unique experience that qualifies them to perform therapeutic procedures utilizing unsealed sources and, therefore, should be exempt from the specifically enumerated requirements delineated in 10 CFR § 35.390 (b) (1) (ii).

10 CFR § 35.490 ***Training for use of manual brachytherapy and*** **10 CFR § 35.690** ***Training for use of remote afterloader units, teletherapy units, and gamma stereotactic radiosurgery units.***

In both 10 CFR §§ 35.490 and 35.690, provision (c) states that the preceptor must be an Authorized User "of each type of medical unit for which individual is requesting AU status." We request clarification that this language does not preclude an individual who is applying for authorized user status in multiple devices from presenting separate preceptor statements for each modality. Although we do not feel that this is the intent of this provision, the submission of one single preceptor statement for multiple modalities could prove too burdensome and quite problematic for the applicant.

We commend NRC's commitment to an interactive process with the medical community in developing regulations impacting the practice of medicine as well as the safety of our patients.

If you have any questions regarding our concerns on implementation of this rule, please let us know. We would be pleased to meet with you at your convenience to discuss our comments on this regulation. You may contact Lynne Fairobent, ACR at (703) 716-7550 or by email at lynnef@acr.org, Roshunda Drummond, ASTRO at (703) 227-0147 or by email at roshundad@astro.org, Angela Keyser, AAPM at (301) 209-3385 or by email at akeyser@aapm.org, William Uffelman, ABSNM at (703) 708-9773 or by email at

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Sincerely,

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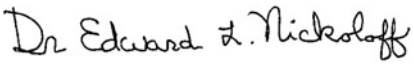

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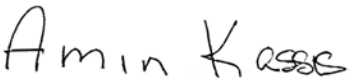

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