DOCKET NUMBER
PROPOSED RULE PR 35
(68FR 68549)

St. Joseph Mercy Hospital
Radiation Safety Office
5301 E. Huron River Dr.
Ann Arbor, MI 48106-0995

February 23, 2004

DOCKETED
USNRC
(19)

February 24, 2004 (2:30PM)

OFFICE OF THE SECRETARY
RULEMAKINGS AND
ADJUDICATIONS STAFF

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

Re: RIN 3150-AH19

I am a medical physicist submitting 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).

I support the revised regulation but 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 physicians who serve as AUs, include 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 for general hospital settings.

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 the radiation protection and safety as one of the five categories. Questions frequently asked in the examination include shielding design and barrier calculation, releases 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.

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 Diplomats in the areas of Nuclear Medicine Physics and Instrumentation, Radiation Protection, and Radiopharmaceutical Science serve as Radiation Safety Officers.

Template= SECY-067

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Given the above information, I 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.

Another important issue is time for implementation of a resident or fellow currently in training. There was no requirement to document training and experience case by case and such physicians would be adversely affected by this new requirement, which would require a retrospective analysis of data that may not have been kept. Accordingly, the proposed training and experience requirements must be applicable only to those who begin training after the date of implementation.

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?

Although the rule should be finalized and effective as quickly as possible, I 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. However, there would be no objection to granting a full three years for adoption but the compatibility level for these regulations must remain 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. I strongly recommend that the NRC change the word "certification" to "attestation" in all the preceptor paragraphs. More specifically, I 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 (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 attest 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 completing their board examination. This appears to continue an unintended link between the board process and the preceptor's attestation. Therefore, I 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."**
The definition must be flexible and not burdensome and allow the preceptor to be a person who is not the one providing the training & experience, such as a program director.

4. Most importantly, I would strongly recommend that the preceptor statement be eliminated for Board certified Authorized Users, Authorized Medical Physicists, and Authorized Nuclear Pharmacists. Preceptor statements should be required only for those requesting authorization via the alternate pathway and RSO. Board certification and continued experience is satisfactory demonstration for meeting the radiation safety requirements to perform those authorized activities as AU, AMP, or ANP. There has been absolutely no evidence to support that a preceptor statement for these individuals would provide any added radiation safety benefit. This would also minimize the delay in approval of these individuals by the appropriate regulatory agency or Radiation Safety Committee.

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

I 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. Accordingly, the phrase "*under §35.51(a)*" must be deleted from §35.50(d)(2)(i). Otherwise this

link 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, and certified health physicists 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 I 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, and (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. In order to have an initial pool of AMPs to serve as preceptors, this issue must be addressed and clarified. 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.
I recommend 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 alternate pathway requirements specified in 10 CFR 35.51, and (b) has clinical experience in performing AMP duties in the past seven years should be automatically grandfathered as an AMP independent of whether this role has been explicitly recognized in an Agreement State license.

10 CFR 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 §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."

I request the following change 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 recommended change from the existing 10 CFR 35.390 is intended to recognize radiation therapy and nuclear medicine residency programs respectively 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, I 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 American Board of Radiology 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, I 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 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.*
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 the individual is requesting AU status." This language must be clarified so that it allows an individual who is applying for authorized user status with multiple devices to present separate preceptor statements for each modality. Although it may not be the intention of this provision, the submission of one single preceptor statement for multiple modalities could prove too burdensome and quite problematic for the applicant.

The 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.

Sincerely,

Ralph P. Lieto, MSE DABR FAAPM
Nuclear Medical Physicist
Radiation Safety Officer