PRM 35-19
(71FR34285)

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AMERICAN COLLEGE OF RADIOLOGY

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USNRC

August 25, 2006 (2:41pm)

OFFICE OF SECRETARY
RULEMAKINGS AND
ADJUDICATIONS STAFF

(14)

August 24, 2006

Attn: Rulemaking and Adjudications Staff
U.S. Nuclear Regulatory Commission
Washington, DC 20555

Re: Comments in response to William Stein, III, MD Petition
Docket No. PRM-35-19

I am writing on behalf of the American College of Radiology (ACR) in opposition to the petition submitted by William Stein, III, MD (PRM-35-19). The ACR is a professional organization serving more than 32,000 radiologists, interventional radiologists, radiation oncologists, nuclear medicine physicians, and medical physicists who use radiation and radioactive material for the benefit of their patients. The ACR has been an active participant throughout NRC's development and implementation of the new Part 35 Training and Experience (T&E) requirements, and we believe adoption of this petition would undermine the deliberations and decision-making that went into the development of the current rule, with no resultant public benefit.

The petitioner requests that medical oncologists/hematologists be granted authorized user status under 10 CFR Part 35 for therapeutic administrations of ^{153}Sm-lexidronam (Quadramet®), ^{131}I-tositumomab (Bexxar) and ^{90}Y-ibritumomab tiuxetan (Zevalin) with only 80 hours classroom and laboratory experience, work experience, and written attestation. The ACR offers the following observations in opposition to petitioner's request:

1) **Petitioner's proposal contravenes the regulatory construct of the current T&E rules.**

   Notwithstanding petitioner's assertion of an unmet regulatory need as new radiopharmaceutical agents are "coming onto the marketplace," the current T&E rule was intentionally designed to categorize agents according to their properties including their complexities and risks and to delineate T&E requirements accordingly. Throughout the

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rulemaking, NRC staff repeatedly commented that the intent of the rules was not to regulate 'radionuclide by radionuclide,' but to have generally applicable rules to accommodate new agents. The administration of the radiopharmaceuticals in question fits squarely within the current regulatory structure (§35.390 and §35.396).

2) **NRC has already decided upon training requirements for use of these materials and certifying boards and training programs have adjusted their curriculums to meet current requirements.**

The current T&E requirements for parenteral administrations of unsealed sources (including ^{153}Sm-lexidronam (Quadramet®), ^{131}I-tositumomab (Bexxar) and ^{90}Y-ibritumomab tiuxetan (Zevalin)) do not reflect an oversight on the part of NRC regulators, but rather a deliberate decision intended to ensure that authorized users of this material have sufficient knowledge of the safety requirements, hazards and cautions associated with the material, and are capable of handling spills. These radiopharmaceuticals were already on the market when the new T&E rule was being deliberated. Indeed, during the Advisory Committee on Medical Uses of Isotopes (ACMUI) deliberation on the proposed rule, one of the agents referenced in this petition was mentioned by name.

Notwithstanding an ACMUI recommendation related to the number of classroom and laboratory hours for §35.390 uses, NRC opted to require 700 hours of training (to include a minimum of 200 classroom and laboratory training). While we reserve comment on NRC's decision with regard to the number of classroom and laboratory hours required under §35.390, we will note that many certifying boards, including the American Board of Radiology, have since modified their certification requirements in accordance with the new rules; likewise most training programs have modified their curriculum in order to prepare their residents to meet the alternate pathway requirements. To again revise these requirements so soon after the final rule became effective, yet after certifying boards and training programs have acted in reliance of these rules, would be inappropriate.

3) **Petitioner has not demonstrated an unmet public health need.**

Petitioner suggests, but offers no evidence to support the notion, that the current T&E rule limits patient access to treatment. Contrary to this notion, cancer treatment is ideally conducted utilizing a multi-disciplinary team approach. The model of medical oncologists coordinating with radiation oncologists, radiologists, and nuclear medicine physicians to utilize the respective talents of the other

specialties has become standard practice. Administration of these radiopharmaceuticals appropriately falls within this model.

4) **Medical oncologists/hematologists do not have extensive clinical, laboratory or other experience in therapeutic radioactive material and therefore an exception to current requirements is not warranted.**

The T&E rule was not designed to delineate separate requirements based upon prospective users' area of medical specialization, except to the extent that specialties' clinical training and experience ensures extensive experience in radiation safety and radioactive material handling. This is the case in §35.396 which permits radiation oncologists who are authorized users under §35.490 and §35.690 to use unsealed sources as long as they meet the additional requirements under §35.396.

Radiation oncologists undergo a 4-year training program, including training in sealed (brachytherapy) and unsealed sources. Their training includes a comprehensive radiation physics educational program including radiation physics, radiation safety, radiation biology, teratology and related principles which overlap much of the knowledge needed to safely use unsealed sources. Accordingly, radiation oncologists who have already met the T&E requirements for sealed sources (700 hours total including 200 classroom and laboratory) could also provide parenteral administration of unsealed sources with an additional 80 hours training specific to unsealed sources. All new radiation oncologists are being trained to meet the §35.396 requirements. Medical oncologists/hematologists do not have this extensive experience in radiation safety and therefore an exception to current requirements for medical oncologists/ hematologists is not warranted.

As always, ACR appreciates the opportunity to comment upon this petition, and welcomes the opportunity to provide any additional information or answer any questions on this matter. Please do not hesitate to contact me or Gloria Romanelli, ACR's Director of Legislative and Regulatory Relations at (703)716-7550.

Sincerely,

Cassandra Foens MD

Cassandra Foens, M.D., FACR
Chair, Federal Regulatory Committee
American College of Radiology

From: Carol Gallagher
To: Evangeline Ngbea
Date: Fri, Aug 25, 2006 9:39 AM
Subject: Comment letter on PRM 35-19

Attached for docketing is a comment letter on the above noted PRM from Cassandra Foens, American College of Radiology, that I received via the rulemaking website on 8/24/06.

Her address is:
American College of Radiology
1701 Pennsylvania Ave., NW, Suite 610
Washington DC 20006
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Carol

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Subject:	Comment letter on PRM 35-19
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