

PRM 35-19
(71FR34285)



American Association of Physicists in Medicine

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DOCKETED
USNRC

September 7, 2006 (10:58am)

OFFICE OF SECRETARY
RULEMAKINGS AND
ADJUDICATIONS STAFF

August 28, 2006

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

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

The American Association of Physicists in Medicine¹ (AAPM) offers the following comments in opposition to the Petition for Rulemaking (PRM-35-19) from William Stein, III, M.D. regarding relaxed Training and Experience (T&E) requirements for Authorized Users who wish to administer certain radiopharmaceuticals for therapeutic purposes [¹⁵³Sm-lexidronam – (Quadramet[®]), ¹³¹I-tositumomab (Bexxar), and ⁹⁰Y-ibritumomab (Zevalin)].

We note that the current 10 CFR Part 35 T&E requirements, as well as the categorization of classes of radiopharmaceuticals, were developed over a number of years with substantial opportunity for public comment. The radiopharmaceuticals referenced by the Petitioner present these the same radiation safety issues as those within the same Part 35 classification. There is no inherent reason that they are safer and should be excluded from the classification.

The NRC received substantive comments from numerous professional societies during more than a decade of rule consideration. The current classifications were intended to properly encompass existing uses of radioactive materials as well as new technology in the healing arts. The current classification system properly addresses the radiopharmaceuticals described in the petition.

¹ The American Association of Physicists in Medicine's (AAPM) mission is to advance the practice of physics in medicine and biology by encouraging innovative research and development, disseminating scientific and technical information, fostering the education and professional development of medical physicists, and promoting the highest quality medical services for patients. Medical physicists contribute to the effectiveness of radiological imaging procedures by assuring radiation safety and helping to develop improved imaging techniques (e.g., mammography CT, MR, ultrasound). They contribute to development of therapeutic techniques (e.g., prostate implants, stereotactic radiosurgery), collaborate with radiation oncologists to design treatment plans, and monitor equipment and procedures to insure that cancer patients receive the prescribed dose of radiation to the correct location. Medical physicists are responsible for ensuring that imaging and treatment facilities meet the rules and regulations of the U.S. Nuclear Regulatory Commission (NRC) and various State regulatory agencies. AAPM represents over 6,000 medical physicists.

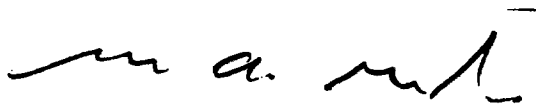
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We do not believe that there is, or is likely to be, a problem with access to quality care that requires use of the material in question under the current T&E requirements.

AAPM recognizes the importance of substantial training for Authorized Users in radiation physics, radiobiology, radiation safety and radioisotope measurement and handling techniques as well as clinical training to assure the safe application of therapeutic radiopharmaceuticals in medical practice. We are familiar with the scope of knowledge and clinical training required for safe use of therapeutic radiopharmaceuticals. In fact, our members provide a substantial portion of the residency and post-residency training for physicians who desire to become Authorized Users. The Medical Physics community stands ready to participate in both the training of Authorized Users and the delivery of care to patients for the materials described in the petition. We are opposed to the petitioner's request for a less rigorous preparation process for Physicians who will be required to safely administer these radiopharmaceuticals to patients.

We are grateful for the opportunity to comment on this Petition for Rulemaking.

Sincerely,

A handwritten signature in black ink, appearing to read "G. L. White, Jr.", written in a cursive style.

Gerald L. White, Jr., FAAPM
Chair AAPM Professional Council

From: Carol Gallagher
To: Evangeline Ngbea
Date: Tue, Aug 29, 2006 10:32 AM
Subject: Comment letter on PRM-35-19

Attached for docketing is a comment letter on the above noted PRM from Gerald L. White, Jr., American Association of Physicists in Medicine, that I received via the Rulemaking website on 8/28/06.

Carol

Mail Envelope Properties (44F45001.35A : 5 : 35764)

Subject: Comment letter on PRM-35-19
Creation Date: 08/29/2006 10:32:33 AM
From: Carol Gallagher
Created By: CAG@nrc.gov

Recipients

nrc.gov
 TWGWPO01.HQGWDO01
 ESN (Evangeline Ngbea)

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Files	Size	Date & Time
MESSAGE	500	08/29/2006 10:32:33 AM
TEXT.htm	479	
1736-0011.pdf	126542	08/29/2006 10:32:04 AM

Options

Expiration Date: None
Priority: Standard
ReplyRequested: No
Return Notification: None

Concealed Subject: No
Security: Standard

Junk Mail Handling Evaluation Results

Message is not eligible for Junk Mail handling
 Message is from an internal sender

Junk Mail settings when this message was delivered

Junk Mail handling disabled by User
 Junk Mail handling disabled by Administrator
 Junk List is not enabled
 Junk Mail using personal address books is not enabled
 Block List is not enabled