ASTRO
American Society for Therapeutic Radiology and Oncology

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OFFICE OF SECRETARY
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ADJUDICATIONS STAFF

PRM 35-19
(71FR34285)

August 28, 2006

Dale E. Klein, Ph.D.
Chair
U.S. Nuclear Regulatory Commission
Washington, D.C. 20555-0001

Dear Dr. Klein,

The American Society for Therapeutic Radiology and Oncology (ASTRO) appreciates the opportunity to respond to the petition filed by William Stein III, M.D. on March 20, 2006. ASTRO is the largest radiation oncology society in the world, with more than 8,500 members who specialize in treating patients with radiation therapies. As the leading organization in radiation oncology, biology and physics, the Society is dedicated to the advancement of the practice of radiation oncology by promoting excellence in patient care, providing opportunities for educational and professional development, promoting research and disseminating research results and representing radiation oncology in a rapidly changing healthcare environment. ASTRO fully supports the current regulations at 10 CFR Part 35 required to obtain authorized user status for parenteral administration of unsealed byproduct material. ASTRO believes granting this petition would open patients up to potential risk.

Quadramet, Bexxar, and Zevalin are all potentially hazardous drugs with possible harmful effects to both the patient and the public if not used correctly under the supervision of a highly trained physician. Decreasing the training required for physicians to administer radiopharmaceuticals places the patient at risk for higher rates of misadministration and treatment-related toxicities. As you are well aware, significant knowledge regarding radiation dose distribution, radiation dose tolerance of normal tissues, and the safe use and handling of radiopharmaceuticals cannot be imparted with limited training. Concerns also exist regarding the ability of inadequately trained physicians to identify and report misadministration and treatment-related toxicities of radiopharmaceuticals.

The Nuclear Regulatory Commission (NRC) appropriately focuses on patient safety and the safety of the general public as it develops training and experience requirements (T&E). With this is mind, the NRC determined that the level of training required to administer these and similar treatments must include 700 hours of training T&E. Indeed, during the multi-year process of revising the (now-implemented) Part 35 regulations, the ACMUI many times specifically debated the appropriate training and experience requirements, both through the Board Certification process and the Alternative Pathway process, for authorized user status for the parenteral administration of these unsealed radioisotopes. The current requirements were carefully considered, and ASTRO disagrees with the petitioner's assertion that these requirements were applied to the aforementioned agents unintentionally.

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The NRC intentionally designed these T&E requirements to allow new agents to come to market, so the NRC does not have the burden of writing different T&E regulations for every new drug that is developed. The rule was intended to classify agents by their similar properties and particular risk profiles. The classroom and clinical experiences encompassed by radiation oncology training programs will provide appropriate levels of knowledge and skill for any current and future radioactive agents. ASTRO supports the NRC's intention of a generally applicable rule rather than one that necessitates a specific review of each new radionuclide that becomes commercially available. ASTRO disagrees with the petitioner's request to establish different T&E regulations solely for these three specific agents.

ASTRO would also like to note that there is no access to care issue related to the administration of these radiopharmaceuticals. Since there is no underlying public need for expansion of authorized users, the public should not be placed in a position of heightened and unnecessary risk. The main safety precaution that remains in the system is the standard of training for authorized users set appropriately by the NRC.

ASTRO has been and will continue to be a leader in supporting quality assurance and patient safety efforts in the administration of radiation therapy. We have worked closely with the NRC to develop the most appropriate T&E guidelines for the use of unsealed sources as well as other radioactive agents and have an established history of comprehensive training, clinical experience and regulatory oversight with regard to the therapeutic use of such agents. ASTRO believes that incorporating the proposed reduction in training requirements as outlined in Dr. Stein's petition would be a great disservice to patients and the safety of the public, and we support the current NRC T&E requirements for unsealed source use at 10 CFR Part 35. Lessening the current standards would place patients in unnecessary risk.

ASTRO looks forward to a continued close collaboration with the NRC on these issues, and we appreciate the opportunity to comment upon this petition. We would be happy to provide any additional information that is required.

Sincerely,

Laura Thevenot /JG

Laura I. Thevenot
Chief Executive Officer

From: "Jamie Gale" <jamieg@astro.org>
To: <SECY@nrc.gov>
Date: Mon, Aug 28, 2006 5:03 PM
Subject: Stein Petition Comments from ASTRO

Dear Madam or Sir,

ASTRO's comments on the Stein petition are attached to this email.
Please submit to Dr. Dale E. Klein, Chair.

Thank you,

Jamie Gale

Government Relations and Research

Administrative Assistant

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Please plan to join us at ASTRO's upcoming meetings.

* September 8-10, 2006: Translational Research in Radiation Oncology, Physics and Biology - Boston

* September 15-16, 2006: Health Services/Outcomes Research in Oncology - San Diego

* November 5-9, 2006: 48th Annual Scientific Meeting - Philadelphia

Visit here <http://www.astro.org/education_and_meetings/meeting_minders/index.htm> for more information.

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Creation Date	Mon, Aug 28, 2006 5:03 PM
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