PRM 35-19
(71FR34285)

American College of Radiation Oncology

5272 River Road • Suite 630 • Bethesda, MD 20816
(301) 718-6515 • FAX (301) 656-0989 • EMAIL acro@paimgmt.com

August 31, 2006

DOCKETED
USNRC

September 5, 2006 (10:42am)

OFFICE OF SECRETARY
RULEMAKINGS AND
ADJUDICATIONS STAFF

Dale E. Klein, PhD
Chairman
U.S. Nuclear Regulatory Commission
One White Flint North
11555 Rockville Pike
Rockville, MD 20852-2738

Dear Dr. Klein:

The American College of radiation Oncology (ACRO) is an organization of approximately 1000 radiation oncologists dedicated to developing and maintaining the highest possible standards of radiation therapy. ACRO strives to ensure the highest quality care for radiation therapy patients and promote success in the practice of radiation oncology through education, responsible socioeconomic advocacy, and integration of science and technology into clinical practice.

ACRO has become aware of the petition presented by Dr. William Stein, III, which proposes that NRC training guidelines for the authorized use of radiopharmaceutical be drastically reduced. We strongly oppose this motion and we appreciate this opportunity to comment on the petition. We wish to express our concern in terms of public and patient safety and the efficacious use of radionuclides. This proposal requests a dramatic reduction in the accepted length and type of training and experience needed to become an authorized user of radionuclides

Currently authorized user status is granted after a minimum of 700 hours of training in accordance with the version of 10 CFR 35. It is our conviction that full training radiation oncology or nuclear medicine correctly meets the requirements necessary to ensure patient and public safety. These agents must be acquired, stored, and handled according to strict guidelines of radiation safety. Administration requires a deep knowledge of the effects of radiation on normal and cancer tissues. For example, many patients will have previously received radiation to critical organs that may be at risk of serious injury from cumulative doses of radiation. The four-year residency training in radiation oncology (recently increased from 3 years) involves repeated practical and supervised experience in radiation safety, radiation physics, radiation biology, normal tissue tolerance, and the clinical effects of radiation therapy on virtually every kind tissue and cancer. Such training is necessary to properly and safely administer such agents. We do not believe that this essential knowledge and experience can be acquired with less than the accepted standard training.

Template = SECY-067

SECY-02

We firmly believe that short course of 80 hours will put the both patient and the public at serious risk of unnecessary exposure to radiation through mishandling of the radionuclide. Furthermore, radionuclides delivered to patients by inexperienced or inadequately trained persons will increase the risk of misadministration. A complete knowledge of radiation effects on normal or previously irradiated tissues is an essential prerequisite to the use of these agents that cannot be learned in anything short of a fully approved residency in radiation oncology or nuclear medicine.

Aside from the important issues of public and patient radiation safety, quality of patient care is a critical concern. We agree that medical oncologist have an important role to play the management of patients who undergo treatment with targeted radionuclide (monoclonal antibodies with chelated radionuclides) and similar agents. We do not believe, however, that medical oncology training includes any of the components (radiation safety, biology, physics, or clinical applications of radiation) necessary for safe and effective primary management of radionuclide therapy. Their certifying boards do not require any such knowledge or training and do not examine in these disciplines. The entire premise of quality of care expected from certification by the American Board of Radiology for the use of these and other radioactive agents would be subverted by the implementation of the proposed reduction in training requirements. We believe that board certification and the long training requirements described by the current regulations ensure patient and public safety. Since there is no shortage of fully trained and capable practitioners, we hope the Nuclear Regulatory Commission will agree that the best policy is to maintain the current training standards for the clinical use of radionuclides.

The proposal is limited to only three products (Quadramet, Bexxar and Zevalin). These agents are representative of an important class of agents that is currently in a rapid phase of development and expansion. Failure to maintain proper training standards may lead to widespread use of such agents by inadequately trained physicians. We believe that the NRC will be most concerned about the nature and extent of the risk and consequences of such a policy change.

We are grateful to have the opportunity to comment to the NRC on the matter of the training requirements for the use of radionculides. We firmly oppose changing training requirements and we ask that the Commission maintain the current excellent standards for radiation and public safely already in place.

Respectfully Submitted,

D. Jeffrey Demanes, MD, FACRO
President

Copies: Mr. Mohammad Saba, NRC
ACRO Executive Committee