

PRM 35-19
(71FR34285)

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From: "Adams, Linda" <LAdams@salco.net>
To: "SECY@NRC.GOV" <SECY@NRC.GOV>
Date: Tue, Aug 22, 2006 11:36 AM
Subject: Comments to Petition for Rulemaking Submitted by Dr. Stein, Docket No. PRM-35-19

Annette L. Vietti-Cook, Secretary
U.S. Nuclear Regulatory Commission
Washington, D.C. 20555-0001
Attention: Rulemakings and Adjudications Staff

DOCKETED
USNRC

August 23, 2006 (12:28pm)

Re: Comments to Petition for Rulemaking Submitted by Dr. Stein, Docket No. PRM-35-19

OFFICE OF SECRETARY
RULEMAKINGS AND
ADJUDICATIONS STAFF

Dear Ms. Vietti-Cook:

I strongly support The Petition for Rulemaking (PRM) submitted by Dr. Stein (PRM-35-19) requesting that the NRC amend its regulations to recognize that an 80-hour training and experience requirement is appropriate and sufficient for medical oncologists/hematologists to attain AU status for the administration of Quadramet, Bexxar, and Zevalin. Each of these activity administrations is from a radiation safety perspective generally much less hazardous than oral 131I administrations. The NRC has already stipulated and codified that any physician, most notably endocrinologists, can administer oral Na131I to treat thyroid disorders with only 80 hours of classroom and laboratory training (as well as appropriate work experience and written attestation). Administration of the agents specified in the petition is therefore, a medical issue rather than a radiation safety issue. I recognize that the petition refers only to activity administrations; any related imaging studies that may be required would obviously have to be performed by an appropriately authorized user, unrelated to the granting of this petition.

Several of my patients are candidates for these therapies including Na131I and I have been unable to find a radiation oncologist or nuclear medicine specialist who is willing or able to administer these new (and some older) agents. I am concerned that if other arrangements are not made, such as the PRM submitted by Dr. Stein, my patients will be unable to receive these agents or have to travel a great distance to do so.

I believe therefore that unless this petition is granted expeditiously, the NRC will be intruding into the practice of medicine and unfairly discouraging a class of physicians from treating their patients; thus, limiting patient access to potentially very effective therapies and increasing health care costs without any appropriate radiation safety justification.

Sincerely,
Jack E. Saux, M.D.

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