PRM 35-19
(71FR34285)

DOCKETED
USNRC

(12)

August 24, 2006 (4:00pm)

OFFICE OF SECRETARY
RULEMAKINGS AND
ADJUDICATIONS STAFF

From: <kimhoward@cablelynx.com>
To: <SECY@nrc.gov>
Date: Thu, Aug 24, 2006 12:29 PM
Subject: Stein Petition PRM-35-19

Dr. Dale Klein, Chairman
U. S. Nuclear Regulatory Commmission
Washington, DC 20555-0001

Dear Dr. Klein:

I would like to respond to the petition filed by William Stein, III, MD for reducing the training needed to utilize certain radiopharmaceauticals for treatment of patients. As someone who is a RSO at a hospital and a practicing radiologist who administers isotopes for the benefit of patients, both for diagnosis and treatment, I consider myself qualified to discuss this topic. Also, as chair of the Medical Committee of the Texas Radiation Advisory Board, I have a better understanding of some of the issues here. Unfortunately, the TRAB did not find out about this issue until it was too late to respond as a board. Therefore, the following comments are my own.

In considering the request for petition, I believe several questions must be asked.

First, is there a need to lower the current standard? There is no data to suggest that there exists a shortage of radiation therapists, nuclear physicians, radiologists or other physicians already capable of performing these treatments.

Second, is there a substantial benefit to the patient that would arise from lowering the standards? None. Treatments such as the Zevalin therapy require the cooperation of a team of physicians over a two week period to perform preliminary uptake studies, dose calculations and subsequently the treatment itself. These radiation treatments have great potential for harm to the patient and others if every aspect of the process is not followed precisely. In fact, by breaking down the team approach, there is more room for error at each step along the way. An example would be the team approach that was utilized for intracoronary brachytherapy where the cardiologist evaluated the stenoses and placed the catheter, the radiation therapist calculated and placed dose, and the radiation safety office provided logistical back-up for surveys and other safety issues. This team approach provided a higher level of care for the patient and increased employee safety.

Third, would the changes proposes increase the risk to patients and employees? High standards of training are required not only for simply administering an injection or a pill, but in tracking of the ordered dose, in storage and isolation of the dose as well as any contamination, in waste disposal of used syringes, etc. It is not just about the administration of a single dose, but also the process itself and how to respond when the process breaks down. The proposal would not allow adequate training to prepare an authorized user for such problems. There is currently no training whatsoever for medical oncologists in radiation safety or radiobiology so there is no background on which to build specific training for a single procedure.

In addition, changing the rules to allow multiple exceptions to training makes the whole process of regulating the industry and ensuring patient protection much more complex. Here in Texas, where the Department of State Health Services is already looking at decreasing inspections of

Template = SECY-067

SECY-02

dental, veterinary, and podiatric use of radiation due to budget restraints, having multiple sets of rules for multiple sets of authorized users is simply untenable.
In summary, I think breaking down the basic rule by allowing this and additions exemptions for "limited" authorized users would be a disservice to our patients and employees.
I appreciate the opportunity to send this response to you. If I can be of any further assistance, please feel free to contact me.
Good luck in your new role with the NRC. We all miss you back here in the Lone Star State.

Sincerely,

Walter Kim Howard, MD
kimhoward@cablelynx.com

Mail Envelope Properties (44EDD3E5.D23 : 12 : 7459)

Subject:	Stein Petition PRM-35-19
Creation Date	Thu, Aug 24, 2006 12:29 PM
From:	<kimhoward@cablelynx.com>
Created By:	kimhoward@cablelynx.com

Recipients
nrc.gov
TWGWPO02.HQGWDO01
SECY (SECY)

Post Office	**Route**
TWGWPO02.HQGWDO01	nrc.gov

Files	**Size**	**Date & Time**
MESSAGE	3719	Thursday, August 24, 2006 12:29 PM
Mime.822	5011	

Options

Expiration Date:	None
Priority:	Standard
ReplyRequested:	No
Return Notification:	None
Concealed Subject:	No
Security:	Standard

Junk Mail Handling Evaluation Results
Message is eligible for Junk Mail handling
This message was not classified as Junk Mail

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