

PRM 35-19
(71FR34285)

7

DOCKETED
USNRC

August 7, 2006 (7:50am)

OFFICE OF SECRETARY
RULEMAKINGS AND
ADJUDICATIONS STAFF

COMMENT
10 CFR Part 35

[Docket No. PRM-35-19]

Dr. William Stein III raises some interesting questions with his petition, the least of which would be where was he when 10 CFR Part 35 was going through it's lengthy implementation including comments on the proposed changes prior to rule.

The NRC and Agreement States are concerned with "Public Health and Safety" when addressing the use of radiopharmaceuticals for diagnosis and therapy. The standards for Authorized Users are in place to help insure "Public Health and Safety". It is too bad that the petitioner believes that those requirements are too restrictive and burdensome.

The petitioner states that these radiopharmaceuticals are usually prepared at a commercial facility and then supplied as a unit dose. The operative word is usually. The NRC and Agreement States do have licensees who do not use a nuclear pharmacy, therefore all the preparation is done at their facility. As a regulatory agency, the NRC had to look at all situations, not just the usual, when determining the requirements for Authorized Users.

Dr. Stein III states that the use of these drugs should be considered a medical issue, not a radiation safety issue. The NRC and Agreement States have regulatory authority over possession and use of radioactive materials for a reason, but it is not to interfere with medical practice and patient care. These medications are termed radiopharmaceuticals for a reason --- they contain some radioactive materials. As such, there are radiation safety issues.

The petitioner believes that the requirements to be an Authorized User are so burdensome that this prohibition would prevent physicians from administering these radiopharmaceuticals and limit patients' access to treatments for life threatening disease. The hope can only be that physicians can communicate adequately physician to physician that patients would not only receive these radiopharmaceuticals, but the Authorized User can discuss any radiation safety issues the patient and their family may have.

As an Agreements State, the State of Iowa does not believe that the NRC should consider any changes to 10 CFR 35 pertaining to Authorized Users based on Docket No. PRM-35-19.

Iowa Department of Public Health, Bureau of Radiological Health August 4, 2006

Template = SECY-067

SECY-02

From: "Farrington, Nancy" <nfarring@idph.state.ia.us>
To: <SECY@nrc.gov>
Date: Fri, Aug 4, 2006 11:50 AM
Subject: Comment, 10 CFR Part 35, Docket No. PRM-35-19

The Iowa Department of Public Health, Bureau of Radiological Health staff, respectfully submits comment on PRM-35-19.

Nancy A. Farrington

Department of Public Health

Bureau of Radiological Health

(515) 281-0422

nfarring@idph.state.ia.us

This email message and its attachments may contain confidential information that is exempt from disclosure under Iowa Code chapters 22, 139A, and other applicable law. Confidential information is for the sole use of the intended recipient. If you believe that you have received this transmission in error, please reply to the sender, and then delete all copies of this message and any attachments. If you are not the intended recipient, you are hereby notified that any review, use, retention, dissemination, distribution, or copying of this message is strictly prohibited by law.

CC: "Flater, Don" <dflater@idph.state.ia.us>, "McGhee, Dan" <dmcghee@idph.state.ia.us>, "Dahlin, Randal" <rdahlin@idph.state.ia.us>

Mail Envelope Properties (44D36CD8.ED1 : 5 : 3793)

Subject: Comment, 10 CFR Part 35, Docket No. PRM-35-19
Creation Date Fri, Aug 4, 2006 11:50 AM
From: "Farrington, Nancy" <nfarring@idph.state.ia.us>
Created By: nfarring@idph.state.ia.us

Recipients

nrc.gov

TWGWPO02.HQGWDO01
 SECY (SECY)

idph.state.ia.us

rdahlin CC (Randal Dahlin)
 dmcghee CC (Dan McGhee)
 dflater CC (Don Flater)

Post Office

TWGWPO02.HQGWDO01

Route

nrc.gov
 idph.state.ia.us

Files

Files	Size	Date & Time
MESSAGE	836	Friday, August 4, 2006 11:50 AM
TEXT.htm	2778	
NRC Docket No PRM-35-19.doc		29184
Mime.822	46277	

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