

August 7, 2006 (7:50am)

**COMMENT**  
**10 CFR Part 35**

OFFICE OF SECRETARY  
RULEMAKINGS AND  
ADJUDICATIONS STAFF

**[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 its 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

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

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