

Advanced
Diagnostic
Imaging, PC.



10 Jun 2017

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Mail Stop: TWFN-8-D36M
U.S. Nuclear Regulatory Commission
Washington, DC 20555-0001

To Whom It May Concern:

COMMENTS ON DOCKET ID: NRC-2017-0094
PATIENT RELEASE PROGRAM

This letter is written in response to questions posed during the Patient Release Program Regulatory Issues Public Meeting held April 25, 2017. I do not believe that properly instructed patients pose undue risk to their family members or the general public if they are released in accordance with current patient release regulations and guidelines found in Regulatory Guide 8.39. I am an Authorized User for Group 35.300 with 31 years experience prescribing therapeutic radiopharmaceuticals. My physician colleagues, our Nuclear Medicine Technologists, and I instruct the patient's and their family members in appropriate radiation safety precautions. I do not believe the current dose-based patient release criteria places the public or the patient's family at undue risk from potential radiation exposure. **I do not believe the Patient Release regulations need to be changed. I believe returning to the former activity-based release criteria which required patients receiving more than 30 mCi of NaI-131 to be hospitalized would cause financial hardship for many of our patients. I am not aware of any unsafe situations resulting from our current patient release procedures.**

Response to Questions Posed

Question A "Should NRC require an activity-based patient release threshold under which patients would be required to be maintained in a clinic-sponsored facility (e.g., a medical facility or facility under the licensee's control) until the standard for release is met?"

No. NUREG 1492 Regulatory Analysis on Criteria for the Release of Patients Administered Radioactive Material published in February 1997 analyzed the risks and benefits of continuing with the existing activity-based release threshold or adopting a dose-based release criteria. I believe the existing system provides an emotional and financial benefit to my patients. Allowing my patients to return home with appropriate precautions reduces their emotional stress and financial hardship, and in the long run helps reduce unnecessary medical costs. We allow our patients sufficient time to make any necessary arrangements so that they can follow the precautions and restrictions we give them.

Question B "Should the NRC amend the regulations to clarify the time frame for the current dose limit in 10CFR35.75(a) for releasing individuals?"

No. The dose limit can only be applied to a single administration and cannot reasonably be applied on a yearly basis or other time period.

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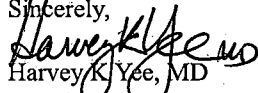
Question E "Should the NRC include a specific requirement for the licensee to have a patient isolation discussion with patients in sufficient time prior to the administration to provide the patient time to make isolation arrangements or the licensee to make plans to hold the patient, if the patient cannot be immediately released?"

No. A specific requirement is not necessary. A licensee cannot be compliant with the current regulations if a patient is not given sufficient time to comply with the release instructions. The time necessary to make the needed arrangements varies and so would be difficult to regulate. We allow our patients sufficient time to make any necessary arrangements so that they can follow the precautions and restrictions we give them. The time varies from patient to patient. When patients play an active role in their treatment, they are much more compliant with instructions.

Question F "Should the NRC explicitly include the time frame for providing instructions in the regulations (e.g., the instructions should be given prior to the procedure)?"

The instructions should be required to be given in advance but the specific time frame should not be regulated. The timing of providing instructions to patients and their family members is a clinical decision and will vary from patient to patient.

Sincerely,


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