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PATIENT RELEASE PROGRAM

This purpose of this letter is to respond 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 a certified Nuclear Medicine Technologist with 2 years of experience administering therapeutic radiopharmaceuticals. 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. It is financially beneficial to my patients to return home with restrictions rather than be hospitalized. 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.

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.

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.

In addition, we provide each patient with a copy of dose-specific, instructions on the limitations for their radioactive treatment procedure. Following their consultation with our radiologist, each patient is given a copy of these safety instructions, and are given thorough explanations for each stipulation. The instructions list many activities and the advised period of time to refrain from each; such as returning to work, spending time near family members, and other common daily activities. We ensure that each patient going through a therapeutic process is fully aware of the necessary steps to follow their procedure, whereas we have never been able to educate regular nursing staff as thoroughly on the radioactive therapy aftercare. I believe that the therapeutic patients released are able to take more attentive precautions specific to their procedure as we have personally reviewed the instructions with them and ensured their understanding.

Moreover, I believe there are patient care-related issues that would arise in a hospitalized therapy patient which would be eliminated by allowing them to return to their own homes. Firstly, it is financially more realistic for many of our patients to be able to return home after their therapeutic procedure rather than having to spend multiple days in the hospital. Secondly, many of our therapy patients have anxiety for such procedures. By allowing them to follow safety instructions in their own home, this eliminates the added unnecessary stress of being quarantined in an unfamiliar hospital room. It makes a big difference in patient morale when we are able to flexibly schedule them into a time when the therapy can almost fly "under the radar" with their schedules. Many patients do not want to make the procedure seem any more intimidating that it already is, and by releasing them under our safety criteria, they are able to safely minimize the stress that comes along with receiving one of our therapy procedures.

Lastly, the NRC should not change the existing patient release regulations. 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.

Sincerely,



Amanda Beyer CNMT, RT(N)