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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 more than 20 years 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.

Additionally, we provide instructions to the patients in order to limit the dose to their family members and the general public. These instructions were provided prior to scheduling their therapeutic administration. Some patients were able to make the necessary arrangements quickly and others required significantly more time, so their therapy would have been scheduled at their convenience. I am not aware of any of the patients we have treated and released in accordance with the current patient release regulations caused harm or emotional distress to their family members or the general public. There are many issues arising from patients treated and hospitalized until they had reached the former activity-based release criteria of 30 mCi NaI-131. Issues such as:

- Staff who did not read the door postings and entered the patient rooms unauthorized;
- Patients who would leave their room despite instructions to the contrary;
- Visitors who refused to comply with the distance restrictions;
- Emotional distress of the patient from being isolated in unfamiliar surroundings;
- Emotional distress of the patient over the costs associated with hospitalization;
- Treatment delay while the patient is off their thyroid medication due to lack of an appropriate inpatient room which would allow compliance with Part 20 regulations.

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,



E. Corey Christenson PA-C, RT (N)