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RULES AND DIRECTIVES BRANCH USNRC

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PATIENT RELEASE PROGRAM

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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.

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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.

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***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.

Based on my past experience with thyroid therapies, I see no reason to change the current protocol. I believe that the risk of causing harm to the general public does not exist. We thoroughly explain the precautions to the patient and their families. Each patient I have treated, leaves our care with a firm understanding of their responsibilities. I believe that for the patient's best interest, allowing them to return to their home surroundings is a much better way to provide patient care. This is a procedure that is life changing for them and allowing them to have safe interactions with their supporting family is important. Confining them to a room for multiple days does not give them a comfortable environment to start the treatment process.

Patient care and comfort is of the utmost importance, however, the cost of staying within the hospital must also be considered. My concern with cost is that some people may not be able to undergo this treatment if insurance is not able to provide the coverage for all that would be involved with a lengthy hospital stay. The isotope is already a large expense but adding additional charges may make this procedure not possible in some cases.

Thank you for your time in establishing the best method for future patient care.

Sincerely,

Justin Schumacher

Justin Schumacher CNMT, RT(N)