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General Comment

122

See attached file(s)

Attachments

Patient Release-signed

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June 27, 2017

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

RE: Response to NRC Request for Comment **NRC Docket ID NRC-2017-0094**

The purpose of this letter is to respond to the request for public comment on the potential regulatory changes to the 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.

I am ABR certified in Medical Nuclear Physics, am a previous Authorized Medical Physicist, and I currently consult over 25 Nuclear Medicine departments. I assist these departments in complying with the current patient release regulations. I review their patient release records including the calculations they perform to demonstrate compliance with the dose limit due to the treatments they administer as well as the instructions they provide patients prior to release.

Additionally, I administered both hyperthyroid and thyroid cancer NaI-131 treatments to over 200 patients as a hospital-based physicist between 2003 and 2013. During this time period, I also assisted with over 300 NaI-125 prostate seed implants. I was responsible for instructing the patients in the necessary behavior modifications following their therapeutic treatment and for answering any related questions arising at that time or any time thereafter. We provided 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. I am not aware of any of the patients I treated and released in accordance with the current patient release regulations causing harm or emotional distress to their family members or the general public.

I began consulting in Nuclear Medicine in 1986 and so am familiar with both the inpatient and outpatient methods. Issues arising from patients treated and hospitalized until they had reached the former activity-based release criteria of 30 mCi NaI-131 were common. 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;
- delay of treatment while the patient is off their thyroid medication because the facility does not have available an appropriate inpatient room which would allow compliance with Part 20 regulations.

Based on this experience, 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.

Response to Questions

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. An activity based release requirement would require that all patients follow restrictions that are applicable to the most restrictive situation. For example, the restrictions appropriate for someone who resides with small children would be unnecessarily restrictive for a patient who lives alone or only with another adult. The dose-based patient release limit allows a licensee to tailor the restrictions to the patient's actual situation.

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

No. The dose limit can only be applied to a single administration. Attempts to apply the dose limit to a time frame would require all of the procedures utilizing radioactive material to be tracked and integrated into the dose calculation. This is not feasible given that patient may have other diagnostic or therapeutic administrations at other medical centers. Also, requiring a licensee to limit the dose per time period could also result in delay of care if the patient should require additional therapies.

Question C "Should the NRC continue to apply the same dose criteria of 5 mSv (0.5 rem), to all members of the general public, including family members, young children, pregnant women, caregivers, hotel workers, and other members of the public when considering the release of patients?"

No. The dose-based release criteria is meant for the most highly exposed individual as noted in the **Federal Register Vol. 62, No. 19 January 29, 1997** "Using a dose-based system based on a dose to the most highly exposed individual of 5 millisieverts (0.5 rem) would, in some circumstances, allow release of a patient with more than 1,110 megabecquerels (30 millicuries) of activity."

Additionally, the NRC currently requires the licensee to provide written instructions to the patient on ways to keep the radiation dose ALARA or less than 1 mSv or 100 mrem for children, pregnant women, and non-caregivers.

We agree that additional precautions and instructions are appropriate and may be necessary to keep the likely dose to pregnant women, children, and non-caregiving individuals both as low as reasonably achievable and below 100 mrem.

Question D "Should the NRC include a specific requirement for the release of a patient who is likely to expose young children or pregnant women to doses above the public dose limit?"

Unfortunately, Regulatory Guide 8.39 lacks guidance on precautions and instructions for individuals who may expose children (family members or otherwise) and pregnant women. Additional guidance is necessary.

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. I do not believe this regulation is necessary because 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.

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)?"

No, a specific time frame should not be regulated. The timing of providing instructions to patients and their household members and/or caregivers is a clinical decision and will vary from patient to patient.

Thank you for your time.

Respectfully submitted,



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