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Patient Release Program

Comment On: NRC-2017-0094-0004
Patient Release Program; Extension of Comment Period

Document: NRC-2017-0094-DRAFT-0098
Comment on FR Doc # 2017-11027

4/11/2017
82 FR 17465

Submitter Information

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112

General Comment

Cindy Bladey
Office of Administration
Mail Stop: OWFN-12-H08
U.S. Nuclear Regulatory Commission,
Washington, DC 20555-0001

COMMENTS ON DOCKET ID: NRC-2017-0094

Dear Ms. Bladey,
I am a Medical Physicist in Nuclear Medicine at Beaumont since 1998. During this time, I have been part of a health care team that has treated over 2,300 patients with NaI-131 >33 mCi and over 120 other radiopharmaceutical therapies through our dose and release program. This program has been very successful and we have had no experiences like the anecdotal ones mentioned in the NRC webcast on April 25, 2017 from either our patients, family members or the general public. My comments and answers to the proposed questions regarding patient release are uploaded in the attached file.

Thank you for this opportunity.
Janice M. Campbell, PhD, DABR, FAAPM

SUNSI Review Complete
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Add= *D-B Howe (DBH)*

Attachments

Beaumont Comments to NRC on Patient Release Docket NRC 17-0094

Beaumont

Beaumont Hospital, Royal Oak
3601 West 13 Mile Road
Royal Oak, MI 48073

June 23, 2017

Cindy Bladey
Office of Administration
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Washington, DC 20555-0001

COMMENTS ON DOCKET ID: NRC-2017-0094

Dear Ms. Bladey,

I am a Medical Physicist in Nuclear Medicine at Beaumont since 1998. During this time, I have been part of a health care team that has treated over 2,300 patients with NaI-131 >33 mCi and over 120 other radiopharmaceutical therapies through our dose and release program. This program has been very successful and we have had no experiences like the anecdotal ones mentioned in the NRC webcast on April 25, 2017 from either our patients, family members or the general public. My comments and answers for the proposed questions regarding patient release are as follows:

PATIENT RELEASE PROGRAM

Question A: *Should the 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?*

Answer A: No, the current approach using an exposure based method allows the release of the patient based on their individual body size, condition, clearance of radioactivity and the administered dosage.

Benefit to the patient: This is more flexible and healthy for our patients, allowing them to return to their home; an environment where they can rest and recover more quickly. The only medical facility under our control would be one of our hospitals. The cost to the patient would increase dramatically from the expense of an unnecessary hospitalization. For some patients, there may also be loss of income when they could work from home.

Effect on individual members of the public: Patients are released to their home and educated as to how to keep exposures to others within the patient's home environment ALARA. Because the conservatively set maximum exposure would be to an individual in their home, there is no risk to others in the general public from this patient. In addition, based on our extensive experience with high dose inpatient treatments, we have found that the NUREG assumptions for exposure to others is very conservative.

Question B: *Should the NRC amend the regulations to clarify the timeframe for the current dose limit in 10 CFR 35.75(a) for releasing individuals?*

Answer B: No, the dose and release criteria should remain as per procedure.

Benefit to the patient: There would be no benefit to the patient to spread out treatment doses to comply with a regulation. In fact, it could interfere with an appropriate treatment plan for a patient.

Effect on individual members of the public: There is no demonstrable additional risk to the public from a patient treated and released to their home more than once within a certain timeframe.

Question C: *Should the NRC continue to apply the same dose criteria of 5 mSv (500 mrem) 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?*

Answer C: Yes, applying the same exposure limit to all is appropriate.

Benefit to the patient: The benefit is continuing the current flexibility that the dose and release program allows to the patient and their family.

Effect on individual members of the public: These populations reside in all areas of the United States with variations in natural background which are greater than this level. Radiation exposures of less than 100 mSv have not been shown to statistically increase the risk of radiation effects.

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 limit?*

Answer D: No, special regulation is not required.

Benefit to the patient: The benefit is continuing the current flexibility that the dose and release program allows to the patient and their family. However, when the home includes children or pregnant women, the previous NRC guidance recommends discussing the precautions with emphasis on limiting their exposure.

Effect on individual members of the public: These populations reside in all areas of the United States with variations in natural background which are greater than this level. While the age of exposure to radiation does matter, the current dose and release limit of 5 mSv is well below the level at which an increase in radiation effects have been seen.

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?*

Answer E: No, special regulation is not required.

Benefit to the patient: Establishing a best practice similar to what is recommended in the NRC's recent Information Notice 2017-02 would be of the most benefit to the patient and their family in terms of preparing for the patient's treatment.

Effect on individual members of the public: In addition, establishing a best practice similar to what is recommended in the NRC's recent Information Notice 2017-02 would also minimize public perception of radiation risks.

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)?

Answer F: No, special regulation is not required.

Benefit to the patient: My answer to question E above applies.

Effect on individual members of the public: My answer to question E above applies.

Thank you for your time and consideration,

Janice M. Campbell, PhD, DABR, FAAPM

Corporate Nuclear Medicine Physicist

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