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General Comment

See attached file(s)

Attachments

TMK - NRC Response Patient Release 0517

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May 23, 2017

I am a Medical Nuclear Physicist and have been working in Nuclear Medicine since 1974. My comments for the proposed questions regarding patient release are as follows:

COMMENTS ON DOCKET ID: NRC-2017-0094
PATIENT RELEASE PROGRAM

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?

Response: There is no need to develop a dosage or activity-based release threshold. Presently, NUREG-1556 Vol. 9 Rev. 2 as "guidance" uses overly conservative assumptions (no biological elimination or decay, no self-shielding, etc.) to provide licensees a very large margin of safety by over estimating the "assumed" dose to those in contact with the patient. NRC's own analysis of the risk verses benefits of such a program (NUREG-1492) shows no detriment from the existing patient release methodology. Wording within this proposed question is confusing with regards to "a clinic-sponsored facility" as a temporary holding area. The implied either/or suggestion of a "medical facility" which could be met by a multitude of definitions verses "facility under the licensee's control" which is very prescriptive would lead to questionable interpretations for methods of compliance with no benefit to the patient or general public. Furthermore, the ability of a patient to return home verses being housed in a "clinic-sponsored facility" has been shown to be beneficial to the patient's well-being with minimal or no "risk" to others. The added expense of the cost to healthcare to house these patients unnecessarily is not justifiable.

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?

Response: The existing 500 mrem (5 mSv) dose limit has no clear time limitation presently. A mandated time limit can only be reasonably applied as a "per administration" issue. Otherwise licensees would be required to accurately gather dosimetry data for all administrations of radioactive material for each patient during the mandated time frame. This could be a near impossible task to accomplish to prove compliance. Additionally, the "risk" to others from 500 mrem (5 mSv) or even 1000 mrem (10 mSv) is based on an extrapolation from the linear no threshold hypothesis, not hard data and has been shown time and again to be near zero or at best negligible. If due to the patient's presentation, multiple administrations within a time frame are clinically required, regulations must not prevent this clinical decision or run the risk of interfering with the practice of medicine.

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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?

Response: It is appropriate to apply this same dose limit for all mentioned groups. In the same train of thought it would be appropriate to use the 500 mrem (5 mSv) limit across the board for all members of the "general public" verses the existing 100 mrem/yr. (1 mSv) limit. Both the NRC (NUREG-1492) and the NCRP (Commentary No. 9) have noted that even with doses of 5000 mrem (50 mSv) "no harm from deterministic effects and the risk of stochastic effects is less than one(1) percent". Therefore, the risk from 10% of this dose level would be again negligible.

With regards to the suggestion of increasing the current 100 mrem/yr. public limit to 500 mrem/yr. one must consider the variations in natural background within the United States and the lack of evidence of diminished general well-being or hard data to support a suggestion of increased risk to those populations that incur doses above the average. Again, the real benefit to a patient and the family of being allowed to go home verses the negligible risk of 100 mrem or even 500 mrem must be considered on the basis of scientific evidence.

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?

Response: This should not be a regulatory requirement but issued as "guidance", based on a requirement of the provision of simple written instructions to the patient. These instructions must address that the "risk" to others, associated with the procedure are estimated and should be viewed as "potential" rather than proven. The time honored simple use of increased distance and minimized time can solve this issue.

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?

Response: The regulation of and therefore compliance with "sufficient time" would be impossible for every case because each is different in their clinical presentation. Again, common sense and the issuance of "guidance" would be prudent. It has always been known that regarding radiation safety issues, an informed patient is crucial to a procedures success. However, the "regulation" of "sufficient time" is not possible.

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)?

Response: The answer is no, see response to question "E". Again, "guidance" verses regulation makes sense

Sincerely,

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