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General Comment

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See attached file(s)

Attachments

9

Comments on NRC 2017 Patient Release Program Request

SUNSI Review Complete
Template = ADM – 013
E-RIDS= ADM-03
Add= D-B. Howe (DBH)
C. Rasapakse (CJR2)

A. Development of an Activity-Based Patient Release Threshold

Question: Should the NRC develop an activity-based patient release threshold?

No. The regulations themselves regarding radioactive patients exposing others are dose-based, not activity-based. Scientifically sound models for calculating the estimated dose to others have been developed by the NRC (NUREG 1556, Volume 9, Revision 2, Appendix U), nationally-recognized advisory bodies such as NCRP (Report No. 155), as well as, experts in the field who have published their work in various reputable scientific journals. Results of various studies of actual exposures have also been published, and suggest that the current dose-based regulations are adequately conservative.

Reverting to an activity-based threshold would naturally result in a substantial increase in hospital stays of long duration, which would be a burden to both the healthcare system and patients; a burden to the healthcare system in terms of added costs (which is contradictory to the current drive to reduce the overall high cost of healthcare in the US); and a burden to patients due to extended hospital stays in isolation, away from loved ones.

The current regulations require documentation for the release of patients above the 1 mSv limit, demonstrating that the estimated dose to the most exposed person will not exceed 5 mSv and that the patient has been given instructions designed to keep the exposure to others as low as reasonably achievable and below the regulatory limit.

(I note here, that 1 mSv and 5 mSv are a mere $1/3^{rd}$ and 1 and $2/3^{rd}$ times the average 3 mSv annual dose to an individual in the US from background sources. In some areas of the country, e.g., higher elevations, the annual background dose is much higher than 3 mSv, yet there is no evidence of increased harm to individuals exposed to such chronically higher background doses.)

B. Clarification of the Time Covered by the Current Dose Limit in 10 CFR 35.75(a) for Releasing Individuals

Question: Should the NRC amend the regulations to clarify the time frame for the current dose limit in 10 CFR 35.75(a) for releasing Individuals?

Yes, the dose limits should be clarified in the regulations, but I am of the opinion that the clarification should be that the dose limits are per release and not annual. Requiring the release of radioactive patients to be based on an annual (as opposed to the current widely-interpreted per release) dose limit to others would place an incredibly onerous regulatory burden on all licensees. Licensees would have to take into account all prior and future diagnostic and therapeutic radioactive administrations within a twelve-month period, when calculating how much exposure to others would be allowed for any single therapeutic administration for each and every patient. At face value, this is impractical, as a particular licensee would not necessarily know about all past and/or future administrations a patient may have had or may have from other licensees within a twelve month period.

A reasonable amendment might be a requirement to fractionate the dose limits for therapeutic radiopharmaceutical treatment regimens that consist of multiple administrations separated in time within a twelve-month period. For example, if a regimen consists of four administrations, than the limits for release without and with instructions after each administration could be set at 0.25 mSv (1 mSv/4) and 1.25 mSv (5 mSv/4), respectively, for each of the four releases. Dose limit fractionation would only apply to those likely to be repeatedly exposed after each administration (e.g., family members, co-workers), and not members of the general public (i.e., strangers with whom the released individual may have only one brief encounter in a lifetime).

In my opinion, it is important to keep in mind that the probability a particular individual will receive an exposure from one or more therapeutically radioactive patients beyond background in his or her lifetime remains quite small; and regardless, the cumulative dose from that exposure is likely to be small compared to the lifetime cumulative dose from background.

C. Appropriateness of Applying the Same Limit on Dose From Patient Exposure to All Members of the General Public

Question: 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. Per the recommendations of the NCRP (NCRP 155), the per-release dose limits for anyone other than the most exposed person (assumed to be a non-pregnant adult) should be set to that for members of the general public (1 mSv). The 5 mSv limit would still apply to the most exposed person, which under normal circumstances is a non-pregnant adult family member or other person in a close relationship with the patient and whose role is that of caretaker. (It should be a rare circumstance under which the most exposed person would not be a caretaker. In such an instance, a 1 mSv limit might be required for release.)

I am of the opinion that a 1 mSv per release limit for all others besides the most-exposed person provides a reasonable balance between the desire to protect those more vulnerable to the effects of radiation exposure as well as members of the general public, versus allowing the most-exposed person, who has an interest in the well-being of the patient and is willing, to receive a higher dose. The latter allows the patient to spend less time in the hospital in isolation, which lowers the cost of healthcare and burden on licensees, and would be the preference of most, if not all, patients.

D. Requirements for Releasing Individuals Who Are Likely To Expose Young Children and Pregnant Women

Question: 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?

Yes, with the caveat that the requirement should simply be that the per release limit for pregnant women and children be set at 1 mSv. (See my reponse to C. above as to the benefits.)

E. Requirement for Timely Discussion With the Patient About Patient Isolation to Provide Time for Licensee and Patient Planning

Question: Should the NRC have 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. The regulations would have to be too prescriptive and difficult for the NRC to enforce. How long before would the regulations require such a discussion to take place (i.e., what would be a "reasonable" time frame)? What would be "reasonable" content of such a discussion required by regulation? Regulatory guidelines could be developed, which provide recommendations for pre-screening patients to determine whether or not hospitalization in isolation is needed (i.e., whether or not the patient is eligible to be released when the most-exposed person is estimated to receive a dose greater than 1 mSv).

This will allow licensees flexibility in their operational model for radiopharmaceutical therapy, while at the same time providing adequate protection of the public. The practice of most licensees already includes some sort of pre-screening and/or pre-planning of inpatient versus outpatient treatment (by the referring physician and/or the AU physician), as it makes sense from an operational standpoint (e.g., reserving inpatient isolation rooms).

F. Requirement To Ensure Patients Are Given Instructions Prior to the Procedure

Question: 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. However, guidelines could be developed, that provide licensees with various options as to how to comply with the patient instruction aspect of the regulations. Most licensees already pre-plan each inpatient and outpatient release for operational purposes, and provide and discuss with the patient, written and verbal instructions prior to the therapeutic administration. Current regulations require instructions to be given to the patient and a record of same to be maintained, if a patient is released when the most-exposed person is estimated to receive more than 1 mSv; and the NRC has the ability to enforce the current instructions requirement via licensee inspection. (See my comment on E. above regarding the benefits.)