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General Comment

See attached file(s)

Attachments

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June 23, 2017

Donna-Beth Howe
Office of Nuclear Materials Safety and Safeguards
U. S. Nuclear Regulatory Commission
Washington, DC 20555-0001

Subject: Docket NRC 2017-0094, Patient Release Programs

Ms. Howe,

Please accept the following comments in response to the request for information in Docket NRC 2017-0094, regarding patient release programs.

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. A dose-based release requirement is safe and effective, and should remain in place. Dose-based criteria allow flexibility for patients and their families, as well as for the provider, without a significant reduction in public health and safety. The regulatory guidance for dose-based release is based on sound and very conservative models rather than being a "best case" scenario, thus building in an additional margin of safety. An activity-based activity limit would likely result in the unnecessary extended hospital stays for otherwise healthy individuals, and would potentially prohibit individuals with no health insurance or a health plan that will not pay for a hospital stay, to forgo necessary medical care. Also, reverting to an activity-based released criteria would reduce the pool of providers that could administer a dosage that exceeds the threshold (i.e., freestanding clinics). The Commission should not take actions that have the potential obstacle to patient care.

B. "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?"

No. As currently written, the limit in 35.75(a) is clearly **not** expressed as an annual limit, nor should it be. The release limit as written is most accurately interpreted as being applicable to a single administration to a specific patient. If the Commission had intended to express the limit as a per year limit, it is difficult to understand how current regulation was written, reviewed, published for comment, and approved by the Commission without specifying the limit as an annual limit. It should be noted that the exposure limit for a visitor to a patient who cannot be released under 35.75 is expressed in 10 CFR 20.1301(c) as 0.5 rem (5mSv), likewise without a specified timeframe. If the intent was to express the limit in 35.75(a) as a per year limit, then it

appears that the intent of 20.1301(c) was to express the dose limit as an annual limit. Please clarify the intent of 20.1301(c).

The Commission should consider amending Part 35 to include the language from 20 CFR 1301(c), or to add a pointer in Part 35 to that requirement. It is confusing to have the limits for a member of the public to exceed 0.1 rem (1mSv) in Part 20 and another in Part 35 when both are specific to medical use under Part 35.

Use of an annual timeframe for exposure limits is appropriate for licensed facilities where radioactive materials are used daily (routinely), and occupational exposure can occur daily. On the other hand, patient releases are single isolated events and the exposure limits are appropriately evaluated on a case by case basis, i.e., per patient release.

Please note that if the current limit for patient release were to be changed to an annual limit, a member of the public (e.g., a family member of an I-131 patient) could receive a total dose of 1 rem depending on when the patient is released, and the license could be compliant. A patient released in December or in January could span two years and would be permitted to receive 500 mrem in each of those years from a single patient release event. (Note: The beginning of a year is a date in January as set by the licensee – see the definition in 20.1003.)

Also, note that the footnote in 35.75(a) refers to the methods in NUREG 1556, Vol. 9 (Appendix U) for methods for calculating doses to other individuals and contains tables of activities not likely to cause doses exceeding 5 mSv (0.5 rem). The guidance in Appendix U, as well as section 8.36, are written for a single patient release event, as is consistent with 35.75, as written.

Rather than amending Part 35 to change the limit to an annual limit, guidance should be revised to recommend that licensees should consider the projected course of treatment for a patient to account for the potential of multiple administrations and tailor the release instructions and patient precautions accordingly to achieve doses that are ALARA.

The release limit in 35.75 as written is not an annual limit. If the Commission's position is that the limit was intended to be an annual limit, then the Commission would need to revise the regulation via a rulemaking effort. The limit cannot be arbitrarily changed by issuance of a statement of clarification.

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

The Commission should be consistent with respect to application of the dose criteria under 35.75 and 20.1301(c) (patient release criteria and patient visitor criteria, respectively). Neither criteria make a distinction in regards to the individual being exposed by the patient (family member, children, pregnancy status, etc.). What is different in these regulations is that

exposure to the visitor permitted under 20.1203(c) must be authorized and controlled by an Authorized User, whereas the exposure to individuals from patients released under the provision of 35.75 is effectively an honor system, and does not specifically require approval by an Authorized User. 10 CFR 20.1301(c) permits visitors; under specific conditions and under that approval of an Authorized User, to receive up to 500 millirem from an inpatient. The visitor is aware of the exposure issue and voluntarily subjects himself/herself to a dose that exceeds the annual limit of 100 millirem for a member of the public that would otherwise apply to a visitor/member of the public.

20.1208 limits the dose equivalent to an embryo/fetus of an occupationally exposed declared pregnant woman to 500 millirem during the entire pregnancy. In this scenario, the woman is aware of the exposure issue and dose limit. However, in the case of 35.75, there is no requirement for a pregnant woman to be informed of her potential to receive a dose from a released patient, which could exceed 100 millirem.

The patient release guidance should be modified to recommend that an Authorized User or Radiation Safety Officer should approve the release of a patient that will be released to an environment that includes young children and/or a pregnant woman.

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?"

An Authorized User or Radiation Safety Officer should approve, in writing, the release of a patient who is likely to expose young children and/or pregnant women to an exposure exceeding 100 millirem. This could be implemented by licensing guidance. Written directions for the pregnant woman and for the guardian of young children should be given to the patient, and the patient should be requested/directed to furnish that written information to the applicable party.

E. "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?"

Yes. For situations that will require isolation to meet the release criteria, the patient (or patient's guardian as applicable) needs adequate time to understand instructions and to make appropriate temporary living arrangements prior to administration. The isolation discussion should be conducted face to face at least 2 days prior to administration. Failure to allow the patient sufficient time to make the necessary arrangements will likely result in a delay in the patient being able to isolate himself/herself or result in no isolation being implemented, leading to an exceedance of the 500 millirem limit.

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, without exception, be provided prior to the procedure. (See the response to Question E.)

If you have any questions regarding this correspondence, please contact me at (518) 402-7550 or *robert.dansereau@health.ny.gov*.

Sincerely,

Robert E. Dansereau
Assistant Bureau Director
Bureau of Environmental Radiation Protection