Duran-Hernandez, Doris

Subject: FW: NIH Submittal of Comments: Docket 2017-0094 Patient Release Program

Attachments: NIH Comment - Docket ID NRC-2017-0094 Comments on Patient Release.pdf

From: Roberson, Michael (NIH/OD/ORS) [E] [mailto:robersom@ors.od.nih.gov]
Sent: Thursday, June 29, 2017 8:53 AM
To: Bladey, Cindy <Cindy.Bladey@nrc.gov>
Cc: Ribaudo, Cathy (NIH/OD/ORS) [E] <ribaudoc@ors.od.nih.gov>
Subject: [External_Sender] NIH Submittal of Comments: Docket 2017-0094 Patient Release Program

Good Morning—

On behalf of Cathy Ribaudo, Radiation Safety Officer, please find attached comments from NIH on Docket 2017-0094, Patient Release Program.

We apologize for the slightly late submission and hope that the NRC will be able to consider NIH's official comments on the subject of patient release.

Thank you-
Mike

1/11/2017
82FR1744

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DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

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June 23, 2017

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

Dear Ms. Bladey,

On behalf of the National Institutes of Health (NIH), please accept the following responses to questions posed by the NRC in Docket ID NRC-2017-0094, Comments on Patient Release Program. The responses are a compilation of the unanimous feedback obtained from physicians of the NIH Nuclear Medicine Department and health physicists of the NIH Division of Radiation Safety.

Question A. *Development of an Activity-Based Patient Release Threshold*
Should the NRC develop an activity-based patient release threshold?

Response A: The NIH presumes this question is meant to inquire whether the NRC should develop a different activity-based patient release threshold than it has already developed. Note that an activity-based threshold has already been published in NUREG 1556, Volume 9, Appendix U. As stated in 10 CFR 35.75(a), licensees may release patients immediately following the administration of a radiopharmaceutical if the administered activity is no greater than the amount listed in Appendix U, Table U.1, based upon a conservative estimate of the radiation exposure this will cause to the general public including family members and caregivers. The guidance from NUREG 1556 Volume 9 has been in place for decades, and NIH as well as countless other hospitals have found the approach simplistic and quite conservative in administering a balance between public safety and clinical care. The activity based default values were obtained by applying an equation from NCRP Report No. 37 to calculate the dose to individuals from the released patient. Using this equation and I-131 as the example pharmaceutical radionuclide (physical half-life = 8.04 days, occupancy factor = 0.25 at 1 meter), an administered activity of 33 mCi (1.2 GBq) NaI-131 will result in a dose of 500 mrem to the person maximally exposed to the patient following release. The equation embodies several conservative assumptions, not accounting for any biological half-life of the radiopharmaceutical in the patient's body, neglecting self-absorption of beta and low energy gamma emitters, and assuming the patient represents an unshielded point source of radioactivity. NIH does not see any benefit to developing a revised activity-based patient release threshold; this would be a step backwards from the current exposure-based release criteria of 10 CFR 35.75. Using a fixed activity without understanding the pharmacokinetics and retention of the radiopharmaceutical and the individual patient situation is not scientifically based and will result in an increased number of patient hospitalizations and an excessive cost to the health care system and to the patient. This will result in many patients not being able to receive necessary medically indicated therapy.

Question B. *Clarification of the Time Covered by the Current Dose Limit in 10 CFR 35.75(a) for Releasing Individuals*
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? For example, should the regulations explicitly state that the criterion is a per year limit? If not, is there a different criterion that the NRC should consider?

Response B: While the NRC provides only general guidance for these precautions, in general the greater the computed general public dose, the longer the time certain activities should be avoided. The length of time for the restrictions targets a maximum dose of 100 mrem, which is the general annual public dose limit set forth in 10 CFR 20. The calculations for determining the amount of time necessary for instructions to remain in effect are calculated using the targeted annual public dose and the calculated effective half time of the radionuclide. Since these times are typically far less than the time frame for the current dose limit in 10 CFR 35.75(a) for releasing individuals, there is no reason to explicitly state that the criterion is a per year limit. In addition, multiple therapeutic administrations given in a year are rare but can occur. The administrations might be performed at different facilities and individual licensees may not be aware of this. While unlikely to occur in one year, defining this time period would require all facilities to find a means to collaboratively track a patient's exposure to the public throughout a year. There should not be a time based limit regarding the administration of therapeutic isotopes to patients.

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

Response C: Yes. On January 29, 1997, the NRC published a final rule in the Federal Register on the "Criteria for the Release of Individuals Administered Radioactive Material", 62 FR 4120 (RIS, 2008). This rule amended the criteria for the release of patients administered radioactive materials in 10 CFR 35.75, based on limiting the total effective dose equivalent (TEDE) to < 500 mrem for the individual maximally exposed as a result of their time with a patient released after therapeutic administration of radionuclide (NRC, 2008). This exposure of 500 mrem is a reasonable one at which there is no scientific evidence of harm. Furthermore, if an individual's dose could exceed 100 mrem (1 mSv), (the public dose limit was set forth by 10 CFR 20 in 1991), the patient must be given straight-forward instructions on how to maintain doses to others ALARA. A regulatory analysis of this criteria concluded that this approach is safe, results in shorter hospital stays, reduces healthcare costs, and has personal and psychological benefits for the patients and their family members. Additionally, a separate study supported the NRC's position that the use of this criteria to release patients would not lead to a member of the general public exceeding the intended dose limits (Grigsby PW, 2000). Adopting a more restrictive dose criteria to members of the general public and/or family members and caregivers would result in increased rates of hospitalization, for no benefit to the patient or the hospital.

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

Response D: Before administering a radiopharmaceutical, licensees do conduct a patient interview to be considered when generating written instructions regarding radiation safety precautions to maintain doses to other individuals of <500 mrem and ALARA. The interview will focus on the patient's living and working conditions, their ability to care for themselves and whether the patient's living or working conditions are such that it is practical to recommend that the patient maintain specific distances while around others. Common lifestyle behaviors that will increase the dose to others and those more sensitive to radiation exposure should be identified. Activities such as sleeping with a partner or traveling in close proximity with others must be considered because these activities involve long time periods where the patient is very close to the individual that is exposed. Each instruction should specify how long the patient is to adhere to the specific recommendation. Therefore, it is recommended that prior to releasing patients the instructions must be written and discussed with the patient, the patient should be given a clear understanding of the risk to others, and the patient must be given a copy. There is no need for a specific requirement for the release of a patient who is likely to expose young children or pregnant women because licensees should discuss the risks to all individuals exposed to doses above the public dose limit. Despite the concept that a fetus or a child is more radiosensitive than an adult, there is no convincing data that doses of 500 mrem are detrimental to this population. Further regulation of patients released to the vicinity of pregnant women or small children will increase the cost of patient care but do nothing towards improving safety.

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

Response E: No. It is already good practice when discussing any radionuclide therapy with the patient to inform the patient of the procedure. This includes rationale, methods, general outcomes, what to expect, what precautions, what restrictions related to the procedure, and what follow-up may be needed. The licensee is already aware, from pre-therapy evaluation of the patient, what pharmacokinetics to expect of the therapeutic administration of radioactive material, and what isolation requirements will be needed. Additionally, to promulgate that patients be given time to make isolation arrangements implies that such arrangements are still needed beyond the licensee's release of the patient, which is not true.

Question F. *Requirement To Ensure Patients Are Given Instructions Prior to the Procedure*
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 F: No. If instructions are provided prior to the procedure the instructions given to the patient for release will become standardized. This will result in patients being given all encompassing instructions that are not easy to follow and may not match any one patient's specific living circumstances. This could result in a patient ignoring the given instructions due to an assumption that the given instructions are of minimal concern. Conversely, the patient may further isolate themselves from family and friends due to an unrealistic fear that they may present a danger to others. In order for the instruction to be meaningful to the patient, licensees must evaluate the patient's exposure potential on a case-by-case basis to determine what, if any, release restriction apply. For patients undergoing treatment with alpha or pure beta emitting

isotopes, typically no restriction are necessary and thus the instruction could safely given at the time of treatment. Instructions given at the time of treatment are more likely to be followed than instructions given days or weeks before treatment is delivered.

I hope that this summary of responses is beneficial to your efforts in considering the need for additional regulation. If you have any further questions or need clarification on these responses, please contact Ms. Cathy Ribaudo, NIH Radiation Safety Officer, at 301-594-1303 or at cribaudo@nih.gov.

Sincerely,

Michael Gottesman

Michael Gottesman, M.D.
Deputy Director for Intramural Research

cc: Ms. Catherine Ribaudo, NIH RSO
Dr. Bradford Wood, Chair, NIH RSC
Mr. Alfred Johnson, Deputy Director for Management, NIH
Mr. Timothy Tosten, Acting Director, Office of Research Services, NIH