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Draft Regulatory Guide: Release of Patients Administered Radioactive Material

Comment On: NRC-2023-0086-0001

Draft Regulatory Guide: Release of Patients Administered Radioactive Material; Extension of Comment Period

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General Comment

Please see attached letter.

Attachments

PittUPMC_RG839_Comments



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To Whom It May Concern:

I am writing to provide my comments on the proposed revision of Regulatory Guide 8.39, which pertains to radiation dose assessments and release criteria. After reviewing the new draft and considering its implications, I would like to express the following concerns and suggestions:

Summary:

1. Conservative Calculations and Appreciation for Dose-Rate Constants:

I appreciate the simple and conservative calculations for first-tier activity thresholds, which provide simple yet accurate estimations. Additionally, I would like to express my gratitude for the use of dose-rate constants over exposure rate constants for activity calculations, as this approach aligns with best practices in the field.

2. Inclusion of Emerging Radionuclides:

The addition of emerging radionuclides to the list of pre-calculated release criteria is greatly appreciated. This inclusion ensures that guidance remains up-to-date and relevant to evolving practices in the industry and, in my opinion, is a primary need for this revision process.

3. Need for Additional Guidance on Dose-Rate Constants:

I would like to request further guidance regarding the use of dose-rate constants. Specifically, clarification is needed regarding the acceptability of previously published values, such as those from the Radiological Health Handbook, or other peer-reviewed sources, and the consideration of future values compared to the regulatory guide values. While the provision of these values is

appreciated and helps reduce ambiguity, it would be beneficial to have more clarity on their long-term usage.

4. Standardized Table of Activities and Exposures:

To maintain consistency and facilitate compliance, I suggest the inclusion of a table of activities and exposures that incorporates at least the 0.25 occupancy factor. This table would serve as a reference for licensees, ensuring a standardized approach to record keeping in accordance with regulatory requirements. Keeping with NCRP 155, additional tables of select occupancy factors in between would also be beneficial in reducing the burden to licensees to calculate, when it can be listed once in this regulatory guide.

5. Consistency and Clarity Regarding Recordkeeping:

The introduction section and records section of the guidance document references 10 CFR 35.75(c) and 10 CFR 35.2075(a), which outline the recordkeeping requirements for authorizing the release of an individual, provided the occupancy factor used is not less than 0.25. However, other sections that describe methodology imply that recordkeeping is required whenever any type of modifying factor is used, including an occupancy factor other than one. This inconsistency with the regulations and the contradictory nature within the document itself, raises concerns. More consistency and clarity are needed to ensure alignment with regulatory requirements.

6. Consideration of Handling Deceased Patients:

The guidance provided in the document concerning the death of patients after the administration or implants of radiopharmaceuticals is inadequate and may present challenges as an official document. While it is logical and scientifically understandable to view the deceased individual as radioactive material rather than as a patient, this perspective lacks sensitivity towards the emotional impact and cultural practices associated with the family's grieving process. Although the guidance raises valid concerns regarding dose rates and public exposure, it neglects to address the specific emotional and cultural needs of the deceased individual's family. Moreover, it opens potential difficulties in establishing radiation safety procedures for handling the deceased, and regulatory bodies have largely refrained from ruling on this issue. The current guidance primarily suggests using "best judgment/practices," which can result in significant variations across different healthcare facilities. This section should either be revised to provide more comprehensive and generalized recommendations or removed entirely to avoid potential misinterpretation or misunderstanding.

7. Unit of Dose-Rate Constants:

For ease of use and consistency with current practices in the United States, I recommend expressing dose-rate constants in units of $\frac{\text{mrem}}{\text{mCi}\cdot\text{h}}$ rather than $\frac{\text{mSv}}{\text{GBq}\cdot\text{h}}$. This change would align with

the continued use of millicuries (mCi) in many hospitals and facilitate accurate and efficient calculations.

8. Unnecessarily Complex Occupancy Modifier:

The proposed approach to the occupancy modifier is overly complex, and while it can replace certain aspects of a multi-compartment model, the level of detail it requires is unnecessary for most patient release criteria. Instead of suggesting its elimination, a more straightforward and streamlined method for determining the occupancy factor should be established. Occupancy factors should be less convoluted to determine, and the existing practice of utilizing a standard questionnaire to assess a patient's lifestyle and living situation, along with their trustworthiness to follow instructions, adequately addresses the requirements for most cases and should continue to be included in this document.

9. Insufficient Biokinetic Modifier Guidance:

The guidance document falls short in providing sufficient guidance on biokinetic modifiers. Many radiopharmaceuticals, such as Lu-177 and I-131 therapies, do not follow a consistent effective half-life. The occupancy modifier allows for combining different "compartments" into a single modifier, when it is unrealistic for licensees to control what a patient does once they leave the hospital; however, the biokinetic modifier, which relies on well-understood and predictable effects, utilizes a single effective half-life and retention period in an inappropriate manner. A prime example of this is the I-131 calculation from Revision 1 of this document, which represents a regression of this document from its predecessor. This modifier underscores the inadequacy of a generalized formula when biokinetics become a factor in patient release. Considering the substantial effort invested in calculating a patient's specific biokinetics, there are far more effective approaches available for accurately calculating public dose at that stage.

10. Removal of I-131 Therapy Default Values:

This document has removed guidelines for I-131 therapies that was included in its predecessor. Specifically, Revision 1 lists default uptake fractions and effective half-lives that can be used for I-131 treatments. This was particularly useful guidance in situations where a patient cannot undergo a dosimetry procedure and the uptake fraction cannot be determined. As a regulatory guide, this is the type of information that licensees rely on in order to comply with regulations while reasonably limiting the burden that a patient of a radiopharmaceutical treatment must endure.

11. Geometric Modifiers and Official Values:

The provision of geometric modifiers is appreciated, as most licensees would likely rely on release using exposure rates at 1 meter if activity calculations could not facilitate patient release. Having an official set of values to refer to in such cases is helpful for maintaining consistency and accuracy.

As this revision progresses, it is evident that the document is expanding in complexity beyond its original scope. To ensure clarity and maintain the intended purpose of this regulatory guide as a reference, it may be prudent to consider revising a current NUREG (such as NUREG-1556) or publishing a new NUREG document that provides a comprehensive technical basis, allowing Regulatory Guide 8.39 to be simplified. By separating the technical details into a dedicated document, this regulatory guide can then serve its intended function as a reference guide with added information specifically addressing daily practical circumstances for which medical licensees need adequate guidance. Whether separated or left as one, the guidance should include tables that encompass the various scenarios already calculated out as a reference for licensees, so that Authorized Users, medical physicists, and RSOs only need to reference which table applies to the situation, and not perform detailed calculations on a patient by patient basis. As the volume of theranostics increases, clinical use of radiopharmaceuticals needs to incorporate a turnkey approach to minimize human performance errors.

Thank you for considering these comments on the proposed revision of Regulatory Guide 8.39. I believe that addressing these concerns and implementing the suggested improvements will enhance the effectiveness and applicability of the guidance document.

Sincerely,

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