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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

Document: NRC-2023-0086-DRAFT-0012

Comment on FR Doc # 2023-08418

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General Comment

See attached file(s)

Attachments

BAMF Health Comments on Draft Regulatory Guide 8.39

BAMF Health Comments on Draft Regulatory Guide (RG) DG-8061 (Proposed Revision 2 to Regulatory Guide 8.39)

General Comment: We thank NRC for allowing the public and licensees to comment before final issuance. We recognize that NRC is providing additional flexibility for patient release through more detailed modifying factors. However, most of the equations are overly complex and may lead to misuse by some. We suggest also providing more simplified equations or assumptions that are applicable to the typical patient. Because the regulation specifies “not likely to exceed 5 mSv” as the requirement, there is an inherent implication that using the detailed patient post-release interactions specified in the draft RG are not necessary to satisfy the regulation. Furthermore, such detailed information from the patient is likely to have a high degree of uncertainty. Above all, the RG should be practical and easy to follow.

Specific comments:

1. Editorial – the Table of Contents section headings and page numbers do not match correctly with the contents of the document.
2. To be consistent with the regulations and other sections of the draft RG, include both SI and traditional units. For example, the Radionuclide Data Tables in Appendix A, please provide the dose rate constant in traditional units. Doing so will also help eliminate errors from licensees converting the values on their own since many continue to use traditional units.
3. The reference cited for the dose rate constants in Appendix A (Radionuclide Data Tables) is showing in ADAMS as a draft report for ACUMI review. In addition, that draft report further references multiple other reports/sources for the dose rate constants. While licensees can use the values published in Appendix A of the RG, it would be useful to cite one (or multiple) sources that NRC accepts for dose rate constants. With the potential for new therapies involving radionuclides not published in Appendix A, it would be useful for NRC to cite an acceptable reference.
4. Our experience has shown that the occupancy modifying factor is extremely important in determining whether a patient may be released. We further note that the regulations in 35.75 (c) and 35.2075 (a) only require documentation of the basis for release when the occupancy factor is less than 0.25. We believe the application of the formulas and information needed to apply them from the draft RG in Appendix B is not practical. Simplified occupancy factors should be described that have associated bounding conditions.