REGULATORY ANALYSIS

DRAFT REGULATORY GUIDE (DG-8061)
"RELEASE OF PATIENTS ADMINISTERED RADIOACTIVE MATERIAL"

(Proposed Revision 2 of Regulatory Guide 8.39, dated April 2020)

1. Statement of the Problem

The U.S. Nuclear Regulatory Commission (NRC) is considering a revision (Revision 2) to Regulatory Guide (RG) 8.39, "Release of Patients Administered Radioactive Material." Revision 2 is an update of Revision 1 to RG 8.39, "Release of Patients Administered Radioactive Material," issued in April 2020. This update is based on the available scientific knowledge and methodologies that can be used when licensees need a more accurate estimation of expected public doses from the released patients and when instructions or records are required.

Revision 2 specifically provides: (1) information for the administered activity and measured dose rate thresholds to demonstrate compliance for commonly used radionuclides, (2) calculational methodologies to accommodate threshold modifications for patient-specific exposure situations with modifying factors for biokinetics, occupancy, geometry, and attenuation, based on patient-specific information, (3) calculations assuming unity for the occupancy factor if patient-specific information is not known, to avoid underestimating exposure, (4) flexibility for emerging radiopharmaceuticals that could be used for diagnostic or therapeutic purposes, (5) radiopharmaceutical activity thresholds for patients who may continue breastfeeding an infant or child after the administration of radioactive material, with recommendations for breastfeeding interruption times for many typical administered radioactive material and (6) a new section on "Sources Separated from the Patient."

2. Objective

The objective of this regulatory action is to assess the need to update NRC guidance and provide applicants with a method to demonstrate compliance with Title 10 of the *U.S. Code of Federal Regulations* (10 CFR) 35.75 requirements for releasing patients administered radioactive material.

If adopted, this RG would provide updated NRC guidance and methods that are acceptable to the NRC staff for releasing patients who have been administered radiopharmaceuticals or implants that contain radioactive material. The RG includes procedures applicable to the NRC and Agreement State licensees for instructing patients before and after they receive medical treatment involving the administration of radioactive material, as well as recordkeeping requirements. The RG also lists dose rates that licensees should use to meet NRC regulatory requirements for the release of such patients.

3. Alternative Approaches

The NRC staff considered the following alternative approaches:

(1) Do not revise RG 8.39.

(2) Withdraw RG 8.39.

(3) Revise RG 8.39.

Alternative 1: Do Not Revise Regulatory Guide 8.39

Under this alternative, the NRC would not issue additional guidance and the current Revision 1 would be retained. If the NRC does not act, there would not be any changes in costs or benefit to the public, licensees, or the NRC. This alternative is considered the "no-action" alternative and provides a baseline condition from which any other alternatives will be assessed. However, the "no-action" alternative would not address the outdated guidance in the current version of the RG.

Alternative 2: Withdraw Regulatory Guide 8.39

Under this alternative, the NRC would withdraw RG 8.39. This alternative would eliminate the staff's guidance regarding patient release, which would leave licensees without instructions for compliance with 10 CFR 35.75. Thus, patients who have been administered unsealed byproduct material or implants containing byproduct material could be released by licensees without guidance, resulting in potential exposures to other individuals above the regulatory dose limits of 5 millisieverts (0.5 rem).

Alternative 3: Revise Regulatory Guide 8.39

Under this alternative, the NRC staff will issue Revision 2 to RG 8.39. As described in SECY-18-0015, "Staff Evaluation of the U.S. Nuclear Regulatory Commission's Program Regulating Patient Release after Radioisotope Therapy," (available in the Agencywide Documents Access and Management System under Accession Number ML17279B139) dated January 29, 2018), the NRC staff found that the methodology used in RG 8.39 Revision 0 was out of date and could result in the underestimation of exposure in certain situations. Revision 1 to RG 8.39 provided updated instructions to patients but the methodology for patient release was not updated. Therefore, this alternative by issuing Revision 2 is providing the most up-to-date staff guidance for applicants and licensees to avoid the potential for licensees to underestimate exposure from released patients.

4. Conclusion

Based on this regulatory analysis, the NRC staff concludes that a revision of RG 8.39 is warranted. The proposed action will delineate the latest staff guidance to licensees regarding the release of patients who have been administered radioactive material.