REGULATORY ANALYSIS

DRAFT REGULATORY GUIDE (DG-8057)
"RELEASE OF PATIENTS ADMINISTERED RADIOACTIVE MATERIAL"
(Proposed Revision 1 of Regulatory Guide 8039, dated April 1997)

1. Statement of the Problem

The U.S. Nuclear Regulatory Commission (NRC) is considering a revision to Regulatory Guide (RG) 8.39, "Release of Patients Administered Radioactive Materials." The Commission provided direction in a Staff Requirements Memorandum-COMAMM-14-0001/COMWDM-14-0001-"Background and Proposed Direction to NRC Staff to Verify Assumptions Made Concerning Patient Release Guidance," to "Revise Regulatory Guide 8.39, and subsequently NUREG-1556, to specify guidelines for patient information and instructional guidance."

The revision would include more detailed instructions for licensees to provide to patients before and after they have been administered radioactive material. In addition, the guide will include new information regarding death of patients following radiopharmaceutical or implants administrations, as well as additional guidance for requirements for recordkeeping.

Also, Table 3 of RG 8.39, Revision 0, "Dosages of Radiopharmaceuticals That Require Instructions and Records When Administered to Patients Who Are Breastfeeding an Infant or Child," could be revised to provide information for the recommended duration of interruption of breastfeeding to ensure that the dose to an infant or child meet NRC and Agreement State regulatory requirements.

The NRC published Revision 0 of Regulatory Guide 8.39, "Release of Patients Administered Radioactive Material, in April 1997, to provide licensees with agency-approved guidance for complying with the then-current version of Title 10, of the *Code of Federal Regulations*, Part 35, Section 35.75, "Release of Individuals Containing Unsealed Byproduct Material or Implants Containing Byproduct Material." Revision 0 of RG 8.39 does not include detailed information regarding instructions that the patients need to be given before and after they have been administered radioactive material.

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 the 10 CFR Part 35.75 requirements for release of patients administered radioactive material.

If adopted, this regulatory action would update NRC guidance and provide methods that are acceptable to the NRC staff for release of patients who have been administered radiopharmaceuticals or implants that contain radioactive material. The RG also would include procedures applicable to NRC and Agreement State medical licensees for instructions to patients before and after they receive medical procedures involving the administration of radioactive material, as well as additional recordkeeping requirements.

3. Alternative Approaches

The NRC staff considered the following alternative approaches.

1. Do not revise Regulatory Guide 8.39

2. Withdraw Regulatory Guide 8.39

3. Revise Regulatory Guide 8.39 to address new information for patients

Alternative 1: Do not Revise Regulatory Guide 8.39

Under this alternative, the NRC would not issue additional guidance and the current guidance would be retained. This alternative is considered the "no-action" alternative and provides a baseline condition from which any other alternatives will be assessed. If NRC does not take action, there would not be any changes in costs or benefit to the public, licensees or NRC. 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 guidance for compliance with 10 CFR 35.75. Thus, patients who have been administered radioactive material could be released by licensees resulting in exposures to other individuals above the regulatory dose limits of 5 millisieverts (mSv) (0.5 rem).

Alternative 3: Revise Regulatory Guide 8.39

Under this alternative, the NRC staff will issue Revision 1 to RG 8.39 and follow the Commission's direction in Staff Requirements Memorandum-COMAMM-14-0001/COMWDM-14-0001-"Background and Proposed Direction to NRC Staff to Verify Assumptions Made Concerning Patient Release Guidance," to "Revise Regulatory Guide 8.39, and subsequently NUREG-1556, to specify guidelines for patient information and instructional guidance."

This alternative provides the most up-to-date staff guidance for applicants and licensees. By updating the guidance in Revision 1, the patient will be better informed of the effects of radiation and can make better choices when following the more detailed instructions to minimize exposures to their families and other individuals. Also, licensees will use the updated information in Table 3 for the release of patients in order to meet the regulatory requirements, as well as new section on "Death of a Patient Following Radiopharmaceutical or Implants Administrations."

The impact to the NRC would be the costs associated with preparing and issuing the regulatory guide revision. The impact to the public would be the voluntary costs associated with reviewing and providing comments to NRC during the public comment period. The value to NRC staff and its applicants would be the benefits associated with enhanced efficiency and effectiveness in using a common guidance document as the technical basis for license applications and other interactions between the NRC and its regulated entities.

Conclusion

Based on this regulatory analysis, the NRC staff concludes that a revision of RG 8.39 is warranted. The proposed action will provide the latest staff guidance to licensees regarding

patient release and could lead to cost savings due to elimination of issues that could result from patient releases after administration of radioactive material.