Regulatory Guide Periodic Review

Regulatory Guide Number:	**8.39, Revision 0**
Title:	**Release of Patients Administered Radioactive Materials**
Office/division/branch:	**RES/DSA/RPB**
Technical Lead:	**Vered Shaffer**
Recommended Staff Action:	**Revise**

1. What are the known technical or regulatory issues with the current version of the Regulatory Guide (RG)?

RG 8.39 was issued in April 1997 and provides guidance how a licensee can determine a release of a patient who has been administered radiopharmaceuticals or permanent implants containing radioactive material from a medical institution. Also, it provides information when instructions to the patient are required, and when records are required to be generated and maintained.

This regulatory guide uses the National Council on Radiation Protection and Measurements (NCRP) Report No. 37, “Precautions in the Management of Patients Who Have Received Therapeutic Amounts of Radionuclides," issued in 1970 to determine the activities at which patients could be released. The approaches and methods originally suggested in NCRP Report No. 37 were incorporated and updated in NCRP Report No. 155, “Management of Radionuclide Therapy Patients,” issued in 2006.

In a Staff Requirements Memorandum (SRM) – COMAMM-14-0001/COMWDM-14-0001 – “Background and Proposed Direction to NRC Staff to Verify Assumptions Made Concerning Patient Release Guidance,” dated April 28, 2014, for SECY-12-0011, Data Collection Regarding Patient Release,” dated April 9, 2012, the Commission directed staff to revise RG 8.39, and subsequently also revise NUREG-1556, “Consolidated Guidance about Materials Licenses.” The Commission directed the staff to re-examine the methods used in RG 8.39 for calculating the dose to members of the public, and to recommend changes as deemed appropriate. The staff believes that the methods to assess the dose received by members of the public from released patients could be improved. The staff evaluated these methods and concluded that there are gaps in the available empirical data that pertain to the doses actually being received by members of the public from released patients. Specifically, the identified gaps are related to internal doses to members of the public from close physical contact with patients or radioactive contamination from bodily fluids, and internal and external doses to members of the public from patients released to locations other than their primary residences. These gaps need to be addressed and changed in RG 8.39.

2. What is the impact on internal and external stakeholders of not updating the RG for the known issues, in terms of anticipated numbers of licensing and inspection activities over the next several years?

Stakeholders do not have sufficient information to fully assess the dose received by members of the public from released patients. There is no impact on licensing or inspection activities because licensees typically do not use this RG for licensing actions.

3. What is an estimate of the level of effort needed to address identified issues in terms of full-time equivalent (FTE) and contractor resources?

An estimate of the effort needed to correct the identified issues is between 0.1 and 0.2 FTE.

4. Based on the answers to the questions above, what is the staff action for this guide (Reviewed with no issues identified, Reviewed with issues identified for future consideration, Revise, or Withdraw)?

Revise.

5. Provide a conceptual plan and timeframe to address the issues identified during the review.

The staff has estimated that the development of the technical basis needed for the revision of RG 8.39 should be completed by December 2017 and it will be followed by the revision of RG 8.39. The staff has estimated that the draft of RG 8.39 will be published for public comment by the 4th quarter 2018.

NOTE: This review was conducted in April 2017 and reflects the staff's plans as of that date. These plans are tentative and subject to change.