U.S. Nuclear Regulatory Commission (NRC)
Advisory Committee on the Medical Use of Isotopes (ACMUI)

Subcommittee Review and Comments on

Draft Proposed Regulatory Guide 8.39, "Release of Patients Administered Radioactive Materials," Revision 1 (Phase 1)

Final Report
Submitted: June 19, 2019

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Charge

During the September 20-21, 2018 ACMUI Meeting, ACMUI Chairman, Dr. Christopher Palestro, established a subcommittee to review the NRC staff's draft proposed revision to Regulatory Guide (RG) 8.39, "Release of Patients Administered Radioactive Materials."

Background

The NRC's current RG 8.39, Revision 0, was issued in April 1997, following the rule change in 10 CFR 35.75 to allow the release of patients administered radioactive material on a solely dose-based basis. Since that time, there have been several challenges to the appropriateness of the release criteria and the associated precautions that are required to be provided to minimize radiation exposure to other individuals from the released patient. The NRC requested public comments on the Patient Release Program in 2017 (Docket ID NRC–2017–0094). The NRC also created a webpage to provide potential patients with information on radioactive iodide (RAI) treatment procedures so that the patients will understand the reason for the procedures, the process, and how to reduce radiation exposure to others (https://www.nrc.gov/materials/miau/patient-release.html).

NOTE: RG 8.39 is being revised in two phases. This Phase 1 revision of RG 8.39, updates the patient release guidance, including information for patient instructions and updates to Table 3, "Activities of Radiopharmaceuticals that Require Instructions and Records When Administered to Patients who are Breast-Feeding an Infant or Child." In Phase 2, the dosimetric equations, methodologies, and tables used to calculate dose to members of the public from released patients will be updated. The following Subcommittee comments and recommendations only pertain to the Phase 1 revision.

Changes and Recommendations to Regulatory Guidance Considered by the Subcommittee

General Comment:

The Subcommittee supports the addition of a Table of Contents to the RG and expanding the section on "Content of Instructions" to include subsections on "Pretreatment Discussions", "Patient Precautions", "Patient Instructions", and "Patient Acknowledgement of Instructions".

Specific Comments:

Pg 1, Under Introduction: Change the heading "Applicable Regulations" to "Regulations".

Pg 2, Under "Purpose of Regulatory Guide", 1st sentence: Replace the words "and to provide guidance to applicants" with "and to provide guidance to licensees".

Pg 4, Under "Reason for Revision": Change 2nd sentence "By updating the NRC guidance with this information, the patient will be better informed and can make better choices when following the instructions" to read "By updating the NRC guidance with this information, the licensee will be better informed on what instructions and options should be provided to the patient."

Pg 5, Under "Background", last sentence: Delete reference to Staff Regulatory Guidance Position 2.3, as it does not pertain to breastfeeding infants or children.

Pg 6, Section 1.1 Release of Patients Based on the Administered Activity, last paragraph: Delete reference to Staff Regulatory Guidance Position 1.1, as it does not pertain to breastfeeding infants or children.

Pg 7, Table 1. Activities and Dose Rates for Authorizing Patient Release: This table should be updated to include the new and potential radionuclides used in medicine.

Pg 9, Table 2. Activities and Dose Rates above Which Instructions Should be Given When Authorizing Patient Release: This table should be updated to include the new and potential radionuclides used in medicine.

Pg 9, Table 2. Activities and Dose Rates above Which Instructions Should be Given When Authorizing Patient Release, Notes: Delete the sentences "Although the NRC does not regulate nonbyproduct material, this RG includes information on nonbyproduct material for the licensee's convenience. Agreement State regulations may vary."

Pg 10, Section 2.2 Additional Instructions for Release of Patients Who Could be Breastfeeding after Their Release, 2nd paragraph: Change the sentence "The patient should also be informed if breastfeeding would have no consequences on the infant or child." to read "The patient should also be informed if breastfeeding would not likely result in consequences to the infant or child."

Pg 11, Table 3. Activities of Radiopharmaceuticals That Require Instructions and Records When Administered to Patients Who Are Breastfeeding an Infant or Child: This table should be

updated to include the radionuclides, activities, and recommended duration of interruption of breastfeeding as contained in the ACMUI Subcommittee report on "Nursing Mother Guidelines for the Medical Administration of Radioactive Materials, Final Report, January 31, 2019."

Pg 11, Table 3. Activities of Radiopharmaceuticals That Require Instructions and Records When Administered to Patients Who Are Breastfeeding an Infant or Child, Notes: Delete the sentences "Although the NRC does not regulate nonbyproduct material, this RG includes information on nonbyproduct material for the licensee's convenience. Agreement State regulations may vary."

Pg 12, Section 2.3 Content of Instructions, 2nd paragraph: Add "currently" after "I-131 is". Add "iodine" before "(I)-125". Delete the sentence "None of these radioisotopes have the high-energy gamma emission and volatility of I-131; therefore they present a lower external radiation hazard than I-131 does." Add "the treating" before "physician". Change the last sentence "The instructions should include the name of a knowledgeable person and his or her telephone number, to contact if the patient has any questions" to read "The instructions should include a telephone number, to contact if the patient has any questions".

Pg 13, Section 2.3.1 Pretreatment Discussions on the Administration of Radiopharmaceuticals: Change the 1st paragraph to read "Engaging the patient early in the treatment process (i.e., during treatment planning) may help the licensee better familiarize the patient and caregiver with the treatment procedures, posttreatment radiation safety precautions and protective measures to minimize radiation exposure to other individuals. This discussion should also include medical issues such as complications, side effects, dietary and medication changes, as appropriate. Additionally, early engagement with the patient allows the patient to ask the licensee questions that will help him or her comply with the release instructions. It also allows the licensee to determine whether the patient will be able to follow the release instructions."

Pg 13, Section 2.3.1, i: Add "hotel" to the list of examples of post treatment lodging the patient may use.

Pg 13, Section 2.3.1, ii: Delete "2. If the patient is driving, will he or she be too impaired to drive?"

Pg 13, Section 2.3.1, ii: Delete "3. If the patient is driving, will he or she be driving alone (preferred)?"

Pg 13, Section 2.3.1, ii: 4: Add the sentence "Emphasis should be made to minimize the number of traveling companions."

Pg 13, Section 2.3.1, iv: Delete "i. Are there any concerns about breastfeeding or pregnancy?"

Pg 13, Section 2.3.1: Add the pretreatment discussion topic "Potential restrictions on burial or cremation should the patient passes away within a certain period of time following treatment."

Pg 14, Section 2.3.1, last paragraph: Add the sentence "It will also allow the licensee to assess the patient's capacity to understand the procedure and precautions."

Pg 14, Section 2.3.2 Patient Precautions, a: Add the precaution "If the patient is traveling with other individuals to the post treatment lodging location, emphasis should be made to minimize the number of traveling companions and to maximize the distance from the patient."

Pg 14, Section 2.3.2, a. (7): Separate the patient precaution "Emphasize abstention from all forms of intimate contact. Advise the patient on the recommended length of time he or she should wait before becoming pregnant to minimize radiation exposures to a developing fetus." into two different instructions.

Pg 14, Section 2.3.2, a. (8): Replace the word "breast milk" with "urine".

Pg 14, Section 2.3.2, a. (9): Replace the word "Emphasize" with "Evaluate".

Pg 14, Section 2.3.2, a. (9): Change the last sentence "Holding trash to allow for radioactive decay is important because the landfill may detect the radiation and send the trash back to the patient." To read "Holding trash to allow for radioactive decay may be important if the landfill will detect the radiation and send the trash back to the patient."

Pg 15, Section 2.3.2, b.: Add the sentence "Provide information to a family member or caregiver to contact the treating medical facility if the patient has a medical emergency or passes away."

Pg 15, Section 2.3.2, 1st paragraph, last sentence: Add the word "likely" before "exceed 5 mSv (0.5 rem)."

Pg 15, Section 2.3.2, 2nd paragraph, last sentence: Change the word "key" to "important".

Pg 15, Section 2.3.2, 4th paragraph, first sentence: Change the words "3 months or more" to "several weeks or months".

Pg 15, Section 2.3.3 Patient Instruction, 1st paragraph, Change the last two sentences to read "The list below provides some basic posttreatment instructions that the patient may need to follow for managing radiation exposure to other individuals. The instructions should always be tailored to the specific patient situation and type and amount of radioactive material administered or implanted."

Pg 16, Section 2.3.3: Add "Minimize the amount of time spent near other people, especially children and pregnant women" to the list of instructions.

Pg 16, Section 2.3.4 Patient Acknowledgement of Instructions, c. (4): Delete "in accordance with NRC, State, and local requirements".

Pg 16, Section 2.3.4, c. (6): Change the sentence "contact information (i.e., the name and telephone number of a knowledgeable person) in the event that questions arise during the recovery

period" to "contact information in the event that questions arise about the radiation safety instruction".

Pg 17, Section 2.4 Death of a Patient Following Radiopharmaceutical Administration or Implants, 1st paragraph: Add the word "therapeutic" before "quantity of radioactive material". Add a second sentence to read "The RSO should perform an assessment of the type and amount of retained activity, based on the patient records."

Pg 17, Section 2.4, 1st paragraph: Begin a new paragraph with "If the death occurs in a hospital…" to read "If the death occurs in a hospital, access to the room occupied by the deceased should be controlled until the room has been surveyed, and decontaminated if necessary. A specified form of identifier (e.g., bracelet, badge) should be used to identify the radioactive body. A body bag may need to be used to contain the leakage of radioactive material. To minimize external radiation, the body may need to be retained in a secured area. Radiation safety procedures to be applied in practice for handling the body should be determined in close consultation with the RSO at the facility where the therapy was administered."

Pg 17, Section 2.4, 3rd paragraph: Begin a new paragraph after the sentence "Wearing a face shield or eye protection and a face mask can prevent an intake of airborne material inadvertently released during the cutting or movement of radioactive tissue or organs." to read "The RSO should notify the morgue or funeral home that the body contains therapeutic quantities of radioactive material and provide precautions to minimize radiation exposures and radioactive contamination for embalming and burial. These include the use of gloves and protective clothing and proper cleaning of equipment."

Pg 17, Section 2.4: Begin a new paragraph after the one above to read "If the body is to be cremated, the RSO should provide precautions on handling the body to crematorium employees who may receive external exposure from the radioactive body or from contamination of the crematorium or internal exposure from inhalation of radioactive particles while handling the ashes. A proportion of the activity retained will appear in cremated remains and may be a concern, particularly in the case of long-lived radionuclides, that will require specified controls. The main concern is in regard to the scattering of ashes, although contact dose rates with the container may have to be considered if cremation takes place shortly after administration of the treatment."

Pg 17, Section 2.4, 4th paragraph: Delete the sentences "Bodies that contain gamma-emitting radionuclides will result in some external exposure to crematorium employees." and "Each crematorium should maintain records of the type and activity in bodies cremated, when known (Ref. 9)."

Pg 17, Section 2.4, last paragraph: Change the last paragraph to read "The RSO should be consulted to determine the amount of activity remaining in the deceased patient and a determination should be made if there are any state or municipal restrictions on cremation."

Pg 18, Section 2.5 Precautions for Long-Lived Contaminants in Radiopharmaceutical Therapy, 1st sentence: Change the words "radioactive decay" to "their method of production".

Other Recommendations

1. In the Patient Precautions and Instructions Sections, it should be emphasized that the major source of radiation dose to other individuals will be from external exposure from the patient (Ref 1). After completion of the Phase II revisions, these sections should also include the recommended time period for following the precautions.
2. While there is adequate guidance on the precautions to take to minimize radiation exposure for post mortem activities of a patient who has died after being administered a therapeutic quantity of radioactive material (Ref 2, 3), there is little or no consistent guidance on what retained activity or time period when the precautions should be followed. The Subcommittee recommends that a dose based model be developed to provide guidance on when precautions or restrictions would be appropriate following the death of a patient administered a therapeutic quantity of radioactive material.

References

1. ICRP Publication 94, Release of Patients After Therapy with Unsealed Radionuclides, 2004
2. NCRP Report No. 155, Management of Radionuclide Therapy Patients, 2006
3. Canadian Nuclear Safety Commission, Radiation Protection Guidelines for Safe Handling of Decedents, Regulatory document REGDOC-2.7.3, 2018

The ACMUI unanimously approved this report, during its public teleconference meeting on June 10, 2019.

Respectfully submitted, June 19, 2019,

**Subcommittee on Regulatory Guide 8.39 Release of Patients Administered Radioactive Materials,
Advisory Committee on the Medical Use of Isotopes (ACMUI),
U.S. Nuclear Regulatory Commission (NRC)**