



UNITED STATES  
NUCLEAR REGULATORY COMMISSION  
WASHINGTON, D.C. 20555-0001

July 10, 2023

MEMORANDUM TO: Darlene Metter, M.D., Chair  
Advisory Committee on the Medical Uses of Isotopes

FROM: Christian Einberg, Branch Chief  
Medical Safety and Events  
Assessments Branch

Handwritten signature of Christian Einberg in blue ink.

Signed by Einberg, Christian  
on 07/10/23

Division of Materials Safety, Security, State,  
and Tribal Programs  
Office of Nuclear Material Safety  
and Safeguards

SUBJECT: RESPONSES TO THE ADVISORY COMMITTEE ON THE MEDICAL  
USES OF ISOTOPE'S RECOMMENDATIONS ON DRAFT PROPOSED  
REVISION 2 TO REGULATORY GUIDE 8.39, "RELEASE OF PATIENTS  
ADMINISTERED RADIOACTIVE MATERIALS"

Below are the U.S. Nuclear Regulatory Commission's (NRC) staff responses to the recommendations and comments from the Advisory Committee on the Medical Uses of Isotopes (ACMUI) on the draft proposed revision 2 to Regulatory Guide (RG) 8.39, "Release of Patients Administered Radiation Materials". The ACMUI provided these recommendations and comments to the NRC staff on December 15, 2021, following review of the draft regulatory guide (Agencywide Documents Access and Management System [ADAMS] Accession No. [ML21326A168](#) and [ML21348A111](#)). The full report from the ACMUI can be found at Accession No. [ML22021B300](#).

### **Recommendations**

1a. **ACMUI recommendation:** In the Content of Instructions Section (4.2), the subsections should be reordered to the original sequence: (1) Pretreatment Discussions on the Administration of Radiopharmaceuticals, (2) Patient Precautions, (3) Patient Instructions, (4) Patient Acknowledgement of Instructions.

**NRC Response: Accepted.**

1b. **ACMUI recommendation:** It is important to emphasize upfront that the major source of radiation dose to other individuals will be from external exposure from the patient. Therefore, the most important precautions to take are measures to reduce or avoid the external radiation exposure from the patient, especially in the early time period after administration of the radionuclide therapy. This is discussed in the Patient Precautions subsection and so it should precede the Patient Instruction subsection.

**NRC Response: Accepted.** The Patient Instruction subsection was revised to highlight the external radiation exposure to patients is the greatest risk. Language was also added to highlight instructions to minimize contamination and potential for internal uptake should be included as necessary to avoid bystander uptake.

- 1c. **ACMUI recommendation:** While the release instructions may also include measures to limit the transfer of radioactive contamination to others, they should not overshadow or distract from the external precautions, nor should it cause patient anxiety, as the radiation doses from internal exposure have been demonstrated to be small or negligible.<sup>4, 5</sup> Suggested rewording of the patient instructions to make them more clear and easy to understand, and elimination of some precautions that have little effect in reducing bystander dose has been provided in the specific comments.

**Response: Not Accepted.** Revisions were made as stated above to highlight that external exposure is the greatest dose pathway risk. However, patient instructions were revised in Revision 1 and specific changes to the precautions and instructions are outside the scope of this revision. As stated in the draft RG, the instructions should always be tailored to the specific patient situation and type and amount of radioactive material administered or implanted.

2. **ACMUI Recommendation:** The basic administered activity thresholds in Table 1, and corresponding measured dose rates in Table 2, for the release of patients (and for providing instruction) were calculated assuming an occupancy factor of 100% at 1 meter. An occupancy factor of 1.0 is unrealistic and cannot be justified for routine application, even for radionuclides with a physical half-life less than one day. The corresponding activity and dose rate values are extremely conservative, and a factor of four lower than what is currently in RG 8.39 Revision 1. This will result in an increased need for licensees to perform patient-specific dose calculations and provide patient instructions at activity levels much lower than previously required. This guidance is also not consistent with the record keeping requirement in Title 10 of the Code of Federal Regulations (10 CFR) 35.2075(a), which only requires a record of the release if using an occupancy factor less than 0.25 at 1 meter. It is recommended that the activity and dose rate values in Tables 1 and 2 be calculated with an occupancy factor of 0.25 at 1 meter, to be more realistic and compatible with 10 CFR 35.2075(a).

**NRC Response: Not Accepted.** As documented in SECY-18-0015, "Staff Evaluation of the U.S. Nuclear Regulatory Commission's Program Regulating Patient Release After Radioisotope Therapy" ([ML17279B139](#)), the NRC identified that the current baseline assumptions used in RG 8.39 can underestimate exposure to bystanders in some situations, such as when a patient has long-term travel immediately after administration. This was the basis to initiate the revision to the methodology as part of Revision 2. While the baseline assumptions in the draft RG are more conservative, the staff makes it clear that patient-specific information can be used to change the generic assumptions.

Based on this comment, the draft RG was significantly updated to highlight that the complexity of patient-specific information depends on the risk of exceeding the limit in each situation. The draft RG clearly states that conservative modifying factors can be used in combination with patient-specific modifying factors. This provides for an expanded approach, which allows licensees to perform patient-specific calculations without the need to use patient-specific values information are not needed for all four modifying factors. The draft proposed RG provides guidance regarding when and how licensees can use conservative values for the modifying factors instead of using detailed patient-specific information. In addition, this expanded approach provides licensees with different methods to adjust modifying factors with varying degrees of complexity based on each patient's unique situation to demonstrate compliance. This expanded approach is just one method licensees can use to demonstrate compliance with 10 CFR 35.75 for every patient released. Licensees can develop another approach to demonstrate compliance or they could choose to hold the patient for a period of time after administration to reduce the risk of exposure.

The NRC staff recognizes it will take licensees time to learn this expanded approach. However, the staff believes this updated approach allows licensees to release most patients quickly using conservative methods with limited patient-specific information. In addition, since the RG provides additional guidance on how to use detailed patient-specific information, the RG provides licensees a consistent approach to release patients when unique scenarios require the use of additional patient-specific information. Finally, the draft proposed RG clearly states when records are required per regulations.

3. **ACMUI Recommendation:** Sections 1.3 and 3.3 “Release of a Patient After a Hold Time” require the licensee to calculate the amount of time the patient release must be delayed for either radioactive decay or biological elimination to reduce the administered activity down to the threshold value in Table 1. Holding a patient after administration of a radiopharmaceutical to allow for some level of decay or biological elimination is not a current practice in the United States. Licensees will either use an effective half-life for a patient-specific dose calculation or the measured exposure rate for release of the patient. This section should be removed as it is not a practical option due to the length of holding time typically required to reduce the retained activity.

**NRC Response: Not Accepted.** In accordance with 10 CFR 35.75, licensees may only authorize the release of a patient if the exposure to another individual is not likely to exceed 5 mSv. If the licensee cannot demonstrate that exposure is not likely to exceed this limit, then the licensee cannot authorize release for that patient and must have plans to hold a patient to allow for decay or elimination following administration. Sections 1.3 and 3.3 give licensees guidance on how to calculate how long a patient might need to be held in these cases. In addition, some licensees may choose to use the methodology in the regulatory guide to calculate hold time without having to gather patient-specific information. This could occur when a patient needs to be held longer than the calculated hold time for medical reasons.

4. **ACMUI Recommendation:** The Patient-Specific Modifying Factors and Methods presented in Appendix B, and Example Calculations illustrated in Appendix C, are overly complex and require an unrealistic level of knowledge of extended patient behavior following release. While this calculational methodology is an admirable academic exercise, it is not practical for licensees to use for authorizing and documenting patient release using patient-specific factors.

**NRC Response: Not Accepted.** The patient-specific approach was significantly updated throughout the guidance document to highlight that the complexity of patient-specific calculations is dependent on each patient scenario. The guidance highlights that conservative, but simpler, methods can be used for release when licensees demonstrate the exposure from the patient to a bystander will not exceed 5 mSv. However, the guidance retains the more complex approaches to provide licensees with methodologies that use more detailed, patient-specific information, to allow for release of patients when necessary.

- 4a. **ACMUI Recommendation:** Determining “Time Durations” for Travel, Instruction, and Afterward in units of effective half-lives, and the corresponding fraction of time a bystander spends in close contact with the patient during these periods would be unworkable.

**NRC Response: Not Accepted.** As documented in SECY-18-0015, significant contact with bystanders immediately following administration, such as travel exposure, can significantly increase the exposure to others. The guidance was revised to point out that licensees can use a single time duration if exposure time is unexpected to change following release. In addition, the guidance was revised to state that the licensees can choose, for simplicity, to use the patient’s most conservative time duration in calculating the patient’s occupancy factor if the calculated exposure to a bystander is found to be lower than the limit. However, the guidance

retains the time duration approach to calculate multiple occupancy factors for situations where licensees need additional realism to demonstrate exposure to a bystander from a patient is unlikely to exceed 5 mSv.

- 4b. **ACMUI Recommendation:** While the Geometric Modifying Factor accounts for varying bystander separation distances and source-receptor configurations, it again requires an unrealistic detailed knowledge of patient and bystander behavior following release.

**NRC Response: Not Accepted.** In most situations, use of a patient-specific geometry factor will remove conservatism that is contained in the baseline method that assumes a point-to-point geometry at 1 meter. However, as documented in SECY-18-0015, significant contact within one meter immediately following administration, such as public travel exposure, can increase the exposure to others. As the baseline calculation has additional conservatism in the other factors, this exposure is unlikely to exceed 5 mSv when a patient is released using the baseline approach. When performing patient-specific calculations that remove conservatism from other factors, licensees should verify patients are not expected to have significant close contact at distances less than 1 meter before using the unity geometry factor. This verification does not need to be time consuming but is necessary to ensure the dose limit is not exceeded. Once this verification is complete, the licensee can use the conservative geometry factor for simplicity. However, when more realism is needed to authorize the release, the guidance document retains guidance on how licensees can calculate patient-specific geometry factors with additional patient-specific information.

- 4c. **ACMUI Recommendation:** The Attenuation Modifying Factor tables account for photon scatter, buildup, and absorption at different patient tissue thicknesses, however, buildup is not applicable for distributed sources within the body and accurately determining the overlying tissue thickness would be much more challenging than simply measuring the dose rate from the patient after administration of the radiopharmaceutical.

**NRC Response: Partially Accepted.** The draft proposed RG was revised to provide a conservative attenuation modifying factor in Table A-1 that can be used without patient-specific information.

- 4d. **ACMUI Recommendation:** To be of practical operational value, the model needs to be simplified, such as that in the current RG 8.39 or the RADAR Patient Exposure Radiation Dose Calculator.<sup>6</sup> Consideration should be given to eliminating the geometric and attenuation modifying factors, keeping the biokinetic modifying factor (effective half-life) and simplifying the occupancy modifying factor to single values of 0.5, 0.33, 0.25, 0.125, and 0.0625 for various patient/bystander conditions or situations. Examples of the possible occupancy conditions could be:
- Patient is unable or unwilling to follow any instructions (0.5)
  - Patient requires significant medical care or living assistance (0.33)
  - Patient will be around other members of the household and public but will follow instructions (0.25)
  - Patient lives alone but will have potential contact with members of the public and will follow instructions (0.125)
  - Patient lives alone and will not have any contact with others and will follow instructions (0.0625)

Attachment 1 contains a sample patient questionnaire that could be used to ascertain the information to assign the appropriate occupancy factor.

**NRC Response: Partially Accepted.** See response to comment 4a which addresses why the proposed occupancy factor methodology was not changed. However, a sample patient questionnaire similar to what the ACMUI provided was included in the revised draft proposed RG.

5. **ACMUI Recommendation:** In Section 6 “Material Separated from the Patient”, it states that the dose limits in 10 CFR Part 20 apply to exposure from radioactive material separated from a released patient. The Subcommittee strongly disagrees with this position. Since the dose limits in 10 CFR Part 20 do not apply to radiation exposure from a patient released in accordance with 10 CFR 35.75, it is only reasonable that this would also apply to exposure from any radioactive material that the patient excretes or physically separates from the patient, with the exception of temporary implants. A licensee cannot practically control or predict, nor would they be able to know or evaluate if an event occurred where radioactive material separated from a patient caused an exposure to a bystander. It is illogical and impractical for radioactive material that separates from a patient released in accordance with 10 CFR 35.75 to become "licensable" again under the licensee that administered it to the patient (with the exception of temporary implants which are still covered under the license even though the patient has been released).

**Response: Not Accepted.** As stated in 10 CFR 20.2002, “Scope”, the dose limits in 10 CFR Part 20 do not apply to exposure of patients to radiation or to exposure from individuals administered radioactive material and released under 10 CFR 35.75. However, once the byproduct material is separated from the body, whether unsealed or sealed, the limits in 10 CFR Part 20 apply as described in the guidance.

6. **ACMUI Recommendation:** In Section 4.3 “Death of a Patient Following Radiopharmaceutical Administration or Implants,” the results of an analysis indicate that for several radionuclides, dose rates exceeding 0.02 mSv/h or total doses in excess of 1 mSv are possible if unexpected death were to occur within days of release and knowledge of the radioactive administration is not communicated. It should be noted that the analysis made very conservative assumptions. The dose rate was calculated only 6 hours after administration with no account (sic) for biological elimination, and the total dose was calculated for an exposure from hour 12 to 32 at a distance of 1 meter with full occupancy and no account for biological elimination. Therefore, the likelihood of these dose rates and integrated doses occurring from a decedent previously administered radionuclide therapy is exceedingly small. It would be helpful if a similar type of analysis were performed of the potential exposures from cremation of a body containing radioactive material, specifically, exposure to crematorium staff and exposure to the public from effluent releases.

**NRC Response: Not Accepted.** The guidance notes that the calculations use very conservative assumptions. The purpose of this guidance is to use conservative assumptions to highlight when further analysis by the licensee might be necessary following the death of a patient. The licensee is responsible to ensure public dose limits are not exceeded following the death of the patient and should calculate the risk based on specific scenarios, such as cremation.

### **Specific Comments:**

**ACMUI Comment:** Pg 1, Purpose: Continue the sentence “This RG also provides licensees with a methodology to modify the threshold in the first paragraph and start a new paragraph with the sentence “In addition, the RG provides licensees with instructions for patients”.

**NRC Response: Accepted.**

**ACMUI Comment:** Pg 2, Applicable Regulations, 10 CFR 35.75(b): Change last sentence to read “If the dose to a breastfeeding infant or child could exceed an effective dose equivalent of 1 mSv (0.1 rem) without the patient’s interruption of breastfeeding, written instructions must be given to the nursing mother on (1) guidance on the interruption or discontinuation of breastfeeding and (2) information on the potential adverse consequences if breastfeeding is not ceased or discontinued.

**NRC Response: Accepted.** The sentence was revised to use TEDE in place of effective dose equivalent to match regulatory text.

**ACMUI Comment:** Pg 3, Table of Contents: Delete Section 3.3 Release of Patients After a Hold Time.

**NRC Response: Not Accepted.** See response to comment number 3.

**ACMUI Comment:** Pg 3, Table of Contents: 4.2 Content of Instructions, Reorder sequence of subsections to: (1) Pretreatment Discussions on the Administration of Radiopharmaceuticals, (2) Patient Precautions, (3) Patient Instructions, (4) Patient Acknowledgement of Instructions.

**NRC Response: Accepted.**

**ACMUI Comment:** Pg 4, Background: In first sentence change 1979 to 1997.

**NRC Response: Accepted.**

**ACMUI Comment:** Pg 5, Consideration of International Standards: Second paragraph, change (rem) to (tenths of rem).

**NRC Response: No Longer Applicable.** The section has been revised and this comment is no longer applicable.

**ACMUI Comment:** Pg 7, Section 1 release Criteria: Consider using the exposure rate constant readily available in the literature<sup>5,6</sup> for  $\Delta_{pr}$  instead of a calculated dose rate constant. It will be much simpler to obtain for new radionuclides and it does not differ significantly from the calculated dose rate constant.

**NRC Response: Not Accepted.** Literature values are calculated using a variety of methods, resulting in slightly inconsistent results. The RG and supporting referenced technical information document ([ML21348A111](#)) provide sufficient details on how to calculate exposure rate constants for new radionuclides using the same method as the RG. However, it should be noted that the draft proposed RG provides one method to meet the regulations, and licensees could use other acceptable methods to determine exposure rate constants.

**ACMUI Comment:** Pg 8, Section 1, fourth paragraph: Delete the last sentence, “In addition, licensees may need to consider both internal and external exposure to a bystander from byproduct material which could have become separated or excreted from a patient”. It is impractical for a

licensee to control or predict the exposure to a bystander from radioactive material separated (excreted) from a patient.

**NRC Response: Not Accepted.** However, this sentence was revised to note that licensees may need to consider internal exposure in unique patient specific situations as described in section 6.

**ACMUI Comment:** Pg 9, Table 1: The activity threshold for C-14 is unrealistically low due to its extremely long half-life and theoretical exposure from a patient.

**NRC Response: Accepted.** The table was updated to remove values for carbon (C)-14 and other long lived radionuclides. A footnote to table A-1 was added to state that the basic methodology presented in this guide is not acceptable for radionuclides with half-lives greater than 10 years. Dosages normally administered for current diagnostic purposes using these radionuclides are unlikely to lead to significant bystander exposure.

**ACMUI Comment:** Pgs 9, 11, and 14: Add Ac-225 to Tables 1, 2, and 3.

**NRC Response: Partially Accepted.** Values for alpha-emitting radionuclides such as actinium (Ac)-225, thorium (Th)-227, lead (Pb)-212, and radium (Ra)-224 were not included in the tables because external exposures to members of the public resulting from the dosages normally administered for therapeutic purposes are expected to be minimal. However, a footnote was added to Table A-1 to state this was the reason they were excluded from the document.

**ACMUI Comment:** Pg 11, Table 2: The measurement thresholds for C-14, Ru-106, and Sr-90 are less than background levels (approximately 0.02 mR/hr) and cannot be accurately measured. A footnote should be added to state "Activity and dose rate limits do not apply to these radionuclides because of the minimal exposures to members of the public resulting from dosages normally administered for diagnostic or therapeutic purposes." Also, listing PET isotope measurement thresholds over 1 R/hr is imprudent.

**NRC Response: Partially Accepted.** The table was updated to remove C-14 values. However, the staff retained ruthenium (Ru)-106 and strontium (Sr)-90 values as these isotopes are still used for therapeutic purposes which could result in exposure in excess of the limits without guidance. The staff retained positron emission tomography (PET) isotope values but included a footnote that dose thresholds do not apply to these radionuclides because of the minimal exposures to bystanders resulting from dosages normally administered for diagnostic purposes.

**ACMUI Comment:** Pg 12, Section 1.3 Release of a Patient After a Hold Time: This section should be deleted as it is not a practical option due to the length of holding time for physical decay. Licensees will either use an effective half-life for a patient-specific dose calculation or the measured exposure rate for release of the patient.

**NRC Response: Not Accepted.** See response to ACMUI comment number 3.

**ACMUI Comment:** Pg 13, Section 2 Breastfeeding Patients: First paragraph, 1<sup>st</sup> sentence, add the word "written" before "instructions and change the word "were" to "was". Second paragraph, 3<sup>rd</sup> sentence, Change the word "were" to "was".

**NRC Response: Partially Accepted.** The word written was added. However, the term "were" was not revised as it is referring to the plural thresholds.

**ACMUI Comment:** Pg 14, Section 2, Table 3: Values in Column 1 and Column 2 that are less than 1 microcurie (or some similarly low value) should just be noted as record/instructions required. Listing nanocurie or lower values is not helpful with respect to medical use quantities.

**NRC Response: Accepted.**

**ACMUI Comment:** Pg 15, Section 2, Table 4: For the very long recommended interruption times, it would be better for the guidance to say, “complete cessation for this child”. Having a specific number 1400 hours vs. 1700 hours etc. is not practical for patients to follow. No nursing mother should be led to think that a 1400-hour interruption should be considered.

**NRC Response: Not Accepted.** Staff believes that there may be mothers that want to be able to nurse after a month or two of interruption, and therefore, the NRC should provide guidance to determine more accurate interruption times.

**ACMUI Comment:** Pg 16, Section 3 Patient-specific Dose Calculations: First paragraph, in the sentence “In the basis, licensees must document any patient-specific modifying factors used in the calculation and a general description of how that information was acquired,” Change the word “must” to “should” as there is no regulatory requirement to document how patient-specific information was obtained.

**NRC Response: Accepted.** This specific reference was no longer in the document but we changed similar language throughout the guidance from “shall” to “should” when appropriate.

**ACMUI Comment:** Pg 16, Section 3 Patient-specific Dose Calculations: First paragraph, Delete the sentence “Patient instructions must match or be more limiting than patient-specific factors used to release patients” as there is no requirement to match patient instructions to patient-specific dose calculations.

**NRC Response: Not Accepted.** If instructions are less limiting than what is needed to ensure dose to a bystander is likely less than 5 mSv, then the licensee is not demonstrating compliance with 10 CFR 35.75. The sentence was revised to tie it to the dose limits in 10 CFR 35.75.

**ACMUI Comment:** Pg 17, Section 3.1 Release of Patients Based on the Administered Activity: First sentence, “licensees may calculate patient-specific thresholds on a case-by-case basis”. There should be an option to create a class or category of general patient-specific factors applicable to multiple patients.

**NRC Response: No Longer Applicable.** This language was removed from the document during revision.

**ACMUI Comment:** Pg 17, Section 3.1 Release of Patients Based on the Administered Activity: Second paragraph, delete “or based on a calculated hold time in Section 3.3”. Pg 17, Section 3.2 Release of Patients Based on the Measured Dose Rate: Delete “c. Calculate a hold time described in Section 3.3”. Pg 17, Section 3.3 Release of a Patient After a Hold Time: Delete section as it is not practical to hold a patient to allow for decay or biological elimination in order to allow for release.

**NRC Response: Not Accepted.** See response to comment number 3 in Recommendations Section.

**ACMUI Comment:** Pg 20, Second paragraph: Delete the sentence “I-131 is currently the medical radioisotope of highest concern, as it is the most commonly used radionuclide in

radiopharmaceutical therapy” as it will soon be surpassed by other radiopharmaceuticals and volatility is not an issue with I-131 inside a patient’s body.

**NRC Response: Accepted.**

**ACMUI Comment:** Pg 20, Second paragraph: Change second sentence to read “The regulations in 10 CFR 35.75 apply to all medical radioisotope therapies such as iodine (I)-131, yttrium (Y)-90, I-125, cesium (Cs)-131, lutetium (Lu)-177, radium (Ra)-223, and actinium (Ac)-225.

**NRC Response: Accepted.**

**ACMUI Comment:** Pg 21, Under (3): Change second sentence to read “Patients who travel via motor vehicle, boat, or airplane through international border checkpoints are subject to screening for radiation.

**NRC Response: Accepted.**

**ACMUI Comment:** Pg 21, Section 4.2.4 Patient Precautions should follow Section 4.2.1 Pretreatment Discussions on the Administration of Radiopharmaceuticals to place the emphasis on external exposures and precautions.

**NRC Response: Accepted.**

**ACMUI Comment:** Pg 22, Third paragraph: Delete the sentences “To ensure dose limits are not likely to be exceeded, licensees must ensure patients can follow instructions if they are used to justify patient-specific modifying factors to demonstrate exposures will be less than 5 mSv (0.5 rem). Pre-treatment discussions with patients, or caregivers, such as those described in the section above, can help a licensee determine if a patient is able to follow the instructions and identify patients who cannot. If a patient is unable or unwilling to follow necessary instructions for release, they may need to be held longer than others with similar administrations.” as it is redundant with what is stated in the previous paragraph.

**NRC Response: Accepted.**

**ACMUI Comment:** Pg 22, Patient Instructions a-l: Suggest replacing the patient instructions a-l with the following to be more clear, concise, and consistent with the Patient Precaution section.

**NRC Response: Not Accepted.** The patient instructions and precautions were updated in Revision 1. While editorial changes are acceptable, changing significant content or scope is outside the scope of this revision.

**ACMUI Comment:** Pg 23, First paragraph: Delete the sentence “The licensee should also inform the patient on how to clean up an area contaminated with body fluids (e.g., urine, vomit) and how to dispose of the cleaning materials.” As it has been previously stated multiple times and the emphasis should be on external exposures.

**NRC Response: Accepted.** This is already stated in the list of instructions.

**ACMUI Comment:** Pg 23, Section 4.2.4 Patient Precautions, a. (1): Change first sentence to read “Emphasize the importance of keeping an adequate distance from others, especially children and pregnant women and to also minimize the time near others.” Delete the sentences “Can arrangements be made for family members (including children and any pregnant household members) to lodge elsewhere temporarily? Or can another individual come and take care of the

children and any pregnant household member in their home.” The emphasis is simply to maintain an adequate distance from others, especially children and pregnant women.

**NRC Response: Accepted.**

**ACMUI Comment:** Pg 24, Section 4.2.4 Patient Precautions, a. (3): Change sentence to read “Emphasize for the patient to sleep separately and abstain from all forms of intimate contact.”

**NRC Response: Accepted.**

**ACMUI Comment:** Pg 24, Section 4.2.4 Patient Precautions, b. (1): Change sentence to read “Encourage the patient not to prepare or share food with others and to use separate dishware and eating utensils.”

**NRC Response: Not Accepted.** The patient instructions and precautions were updated in Revision 1. While editorial changes are acceptable, changing significant content or scope is outside the scope of this revision.

**ACMUI Comment:** Pg 24, Section 4.2.4 Patient Precautions, b.: Delete items (3), (4), and (5) as they are excessive, arbitrary, and not likely to reduce exposure to others.

**NRC Response: Not Accepted.** The patient instructions and precautions were updated in Revision 1. While editorial changes are acceptable, changing significant content or scope is outside the scope of this revision.

**ACMUI Comment:** Pg 25: Delete first full paragraph “The licensee may encourage patients to have available plastic bags, disposable gloves and wipes before treatment,” as this is redundant with the previous statement in this section.

**NRC Response: Not Accepted.** The patient instructions and precautions were updated in Revision 1. While editorial changes are acceptable, changing significant content or scope is outside the scope of this revision.

**ACMUI Comment:** Pg 25, Section 4.3 Death of a Patient Following Radiopharmaceutical Administration or Implants: It should be noted that the analysis made very conservative assumptions. The dose rate was calculated only 6 hours after administration with no account for biological elimination, and the total dose was calculated for an exposure from hour 12 to 32 at a distance of 1 meter with full occupancy and no account for biological elimination.

**NRC Response: Accepted.** The guidance was updated to state the analysis was made using conservative assumptions.

**ACMUI Comment:** Pg 26, Section 4.3 Death of a Patient Following Radiopharmaceutical Administration or Implants: Change last sentence to read “The administering licensee should provide precautions to the funeral director for family members and the public to follow during visitation prior to burial or interment.”

**NRC Response: Accepted.**

**ACMUI Comment:** Pg 26, Records of Release: First paragraph, last sentence: Delete “or greater than 1” as this is unrealistic for exposures from a patient.

**NRC Response: Not Accepted.** As stated in the draft RG, attenuation factors can be greater than 1. See response to comment number 4c for methods licensees can use conservative values instead of patient specific values.

**ACMUI Comment:** Pg 26, Records of Release: Delete "c. For Delayed Release of a Patient Based on a Radioactive Decay Calculation" as this is not used.

**NRC Response: Not Accepted.** See response to comment number 3.

**ACMUI Comment:** Pg 27, Section 6 Material Separated from the Patient: The dose limits in 10 CFR Part 20 do not apply to radiation exposure from a patient released in accordance with 10 CFR 35.75. This would also apply to exposure from any radioactive material that the patient excretes or physically separates from the patient, with the exception of temporary implants. A licensee cannot practically control or predict, nor would they be able to know or evaluate, if an event occurred where radioactive material separated from a patient caused an exposure to a bystander. It is illogical and impractical for radioactive material that separates from a patient who has been released in accordance with 10 CFR 35.75 to become "licensable" again under the licensee that administered it to the patient (with the exception of temporary implants which are still covered under the license even though the patient has been released).

**NRC Response: Not Accepted.** See response to comment number 3.

RESPONSES TO THE ADVISORY COMMITTEE ON THE MEDICAL USES OF ISOTOPE'S  
RECOMMENDATIONS DATE July 10, 2023

DISTRIBUTION:

**ADAMS Accession No.: Ltr ML23178A090**

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