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Release of Patients Administered Radioactive Material; Extension of comment period

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Submitter Information

Name: Cynthia McCollough
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Organization: American Association of Physicists in Medicine

General Comment

See attached file(s)

Attachments

AAPM Comment NRC Patient Release Guidance Final

AMERICAN ASSOCIATION of PHYSICISTS IN MEDICINE

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Thomas H. Boyce
Chief, Regulatory Guidance and Generic Issues Branch
Division of Engineering
Office of Nuclear Regulatory Research
U.S. Nuclear Regulatory Commission
Washington, DC 20555-0001

VIA email: www.regulations.gov

RE: Request for Comment: Draft Regulatory Guide DG-8057: "Release of Patients Administered Radioactive Material"; Docket Number: NRC-2019-0154

Dear Mr. Boyce:

The American Association of Physicists in Medicine (AAPM)[1], is pleased to submit comments to the Nuclear Regulatory Commission (NRC) regarding its request for comment on draft

[1] The AAPM is the premier organization in medical physics, both in the U.S. and abroad. Medical physics is a scientific and professional discipline that uses physics principles to address a wide range of biological and medical needs. The mission of the AAPM is to advance medicine through excellence in the science, education and professional practice of medical physics. Currently, the AAPM represents over 9,000 medical physicists.

Medical physicists contribute to the effectiveness of medical imaging by ensuring the safe and effective use of radiant energy (e.g., optical, ionizing, ultrasonic, or radiofrequency) to obtain detailed information about the form and function of the human body. Medical physicists continue to play a leading role in the development of novel imaging technologies, as well as in guiding the optimization of existing imaging modalities. In addition, medical physicists contribute to development of new therapeutic technologies in radiation oncology, as well as in other disciplines, such as in thermal ablation or high intensity focused ultrasound. Clinically, medical physicists work side by side with radiation oncologists to design treatment plans and monitor equipment and procedures to ensure that cancer patients receive the prescribed dose of radiation at the correct location.

guidance entitled, "Release of Patients Administered Radioactive Material." We commend the NRC for its work on this guidance, which updates an earlier guidance, provides licensees with more detailed instructions to provide to patients before and after they have been administered radioactive material, provides contemporary and relevant information regarding patients who are breastfeeding, and provides information addressing safety concerns arising when a patient dies subsequent to radiopharmaceutical or implant administrations. We welcome this opportunity to provide comments to the NRC.

General Comments

The AAPM acknowledges the NRC's efforts to update the guidance to reflect contemporary concerns, including advances in radioisotope administrations, developments in our understanding of the impact of radioisotope administrations on breastfeeding, as well as our increasing use of cremation for final disposition.

Some of AAPM's concerns with the draft guidance include the following:

- Tables 1, 2 and A-1 have not been updated to reflect actual therapeutic isotopes in use (most are older diagnostic administrations), both for radiopharmaceutical treatments (e.g., Lu-177, Ra-223) and brachytherapy (e.g, Cs-131).
- Tables 1, 2 and A-1 have not been updated to reflect more recent diagnostic isotopes in use (e.g., F-18, Ga-68), especially in Positron Emission Tomography (PET).
- Patient Release Guidance should distinguish between instructions for alpha emitters, where the risk is contamination and ingestion, as compared to gamma emitters, where the risk is exposure.
- The guidance considers only exposure criteria, but not voiding by the patient, in which often 50% of the activity is lost in the first few hours.
- Guidance does not state that implant exposure rate criteria are for permanent implants but not temporary, which is an issue for I-125 eye plaques.

We have attached an addendum below with our specific comments, including section references.

In summary, the AAPM hopes that the NRC will consider the AAPM's comments and adopt the AAPM's recommendations when crafting its final guidance. We would be happy to provide additional expertise or resources to you during that process. Thank you again for the opportunity to comment on this important document. If you have any questions or require additional information, please contact Richard J. Martin, JD, Government Relations Project Manager, at 571-298-1227 or Richard@aapm.org

Sincerely,

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Addendum to AAPM Comment Letter
Draft Regulatory Guide DG-8057: "Release of Patients Administered Radioactive Material"; Docket Number: NRC-2019-0154

1.2 Release of Patients Based on the Measured Dose Rate

Table 1 Activities and Dose Rates for Authorizing Patient Release
We believe the NRC needs to update the tables in the draft guidance to reflect new therapeutic isotopes such as Lu-177, Cs-131, and an array of alpha emitters (e.g., Ra-223, At-221, At-211, Bi-213).

1.3 Release of Patients Based on Patient-Specific Dose Calculations

Values calculated for Implanted isotopes assume permanent implants; eye plaques with I-125, for example, would not have the same release criteria. This concept should be expanded upon in Section 1.3 as one of the explicit factors.

2.1 Activities and Dose Rates that Require Instructions

Table 2 Activities and Dose Rates Above Which Instructions Should Be Given When Authorizing Patient Release
We believe the NRC needs to update the tables in the draft guidance to reflect new therapeutic isotopes such as Lu-177, Cs-131, and an array of alpha emitters.

The values calculated for implanted isotopes assume permanent implants. We believe this must be clarified and expanded upon. Eye plaques with I-125, for example, would not have the same release criteria.

2.2 Additional Instructions for Release of Patients Who Could Be Breastfeeding after Their Release

Table 3 Activities of Radiopharmaceuticals that Require Instructions and Records When Administered to Patients Who Are Breastfeeding an Infant or Child
This table includes a lot of new radionuclides that are not included on Table 1 or Table 2. We believe additional consideration should be given to adding these new radionuclides to Tables 1 or 2.

2.3.1 Pretreatment Discussions on the Administration of Radiopharmaceuticals

Recommendation (3). Most radiopharmaceuticals will see a voiding on the order of 50% of the administered activity within the first few hours. For therapeutic administrations of beta-emitting radiopharmaceutical treatments (RPTs), which usually have administered activities in the hundreds of millicuries (Sm-153, Lu-177, etc.), this represents a large amount of activity and almost invariably some contamination in the restroom where the patent first voids. We believe it would be reasonable to suggest or mandate that the patient stay in the treating facility and use a designated quarantined restroom, regardless of whether the activity or dose rate is below threshold. As stated, the calculations are based on gamma radiation, but concerns of contamination and potential ingestion should also be considered, consistent with patient guidelines given.

We believe this section should also include the following question: What are the notification requirements if the patient requires emergency medical care? Both ambulances and emergency rooms potentially could be impacted.

Paragraphs 1 and 2 (Page 14) contain duplicative language as follows: “Additionally, early engagement. . . release instructions.” We recommend deleting one of those sentences.

We recommend changing the awkward wording of the burial/cremation question. We suggest using one of these alternatives:

- What are the potential restrictions on burial or cremation if the patient should pass away within a certain period of time following treatment?

- What are the potential restrictions on burial or cremation if the patient were to pass away within a certain period of time following treatment?

2.3.3 Patient Instructions

We recommend considering having separate instructions or at least a different emphasis for patients regarding the nature of the radiation concern between beta- and alpha- emitters. While alpha- emitters used in therapy typically have low administered activities, such that gamma radiation is not a concern, the danger from contamination and ingestion is much greater.

2.4 Death of a Patient Following Radiopharmaceutical Administration or Implants

We believe the first sentence is awkwardly worded. We recommend changing this language to: If the licensee learns that a patient has died shortly after a therapeutic quantity of radioactive material was administered, then the treating medical practitioner and the radiation safety officer (RSO) should be notified immediately. The RSO or designee should perform an assessment of the type and amount of retained activity, based on the patient records.

We added "or designee" above because many RSOs are physicians at small hospitals, and they rely on others to perform dose calculations for them. Often these would be consulting physicists, so they may not be technically a part of the radiation safety office or committee.

We recommend that the language, "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." be changed to: When an RSO has been notified that a patient has died shortly after a therapeutic quantity of administration of radioactive material, 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 or cremation. These include the use of gloves and protective clothing and proper cleaning of equipment.

We note that we are not aware of any standard mechanism for informing RSOs about the death of a patient, specifically if patients have been treated and are living further away.

We note, as well, that Section 2.4 places much emphasis on the RSO providing precaution information, however, there are times when the RSO is not immediately informed that a patient has died shortly after a therapeutic quantity of administration of radioactive material (e.g, when a patient is released from hospital care and expires at home or in another town/county/state).

Therefore, it would be more appropriate for Section 2.4 to place emphasis on available guidance already in place for funeral directors:

Low risk of radioactive contamination from cremation when proper safety procedures followed (AAPM): https://w3.aapm.org/media/releases/LowRiskRadioactiveContaminationFromCremation.php

Guidelines for Handling Decedents Contaminated with Radioactive Materials (CDC): https://emergency.cdc.gov/radiation/pdf/radiation-decedent-guidelines.pdf

Model Procedure for Medical Examiners/Coroners Handling body/remains potentially contaminated (USDOE): https://www.energy.gov/sites/prod/files/em/TEPP/2-b4MedicalExaminer-CoronerGuideforHandlingBody-HumanRemains.pdf

Radiation Protection Guidelines for Safe Handling of Decedents (National Funeral Director's Association): http://www.nfda.org/news/in-the-news/nfda-news/id/4153

While the draft talks about cremating a body, it says nothing about release limits to the air of the volatile radionuclide from cremation. We believe a table of these limits should be included in this guidance.

Appendix B Procedures for Calculating Doses Based on Patient- Specific Factors

We suggest that the NRC give consideration to eliminating repetitive information from page 5 “Discussion.”

We believe that Appendix B should include a reference to alternative acceptable procedures for calculating doses based on patient-specific factors that are provided in NCRP Report No. 155.

We believe that Appendix B should include a specific example on temporary implant exposure rate criteria, which differ from exposure rate criteria for permanent implants. Values calculated for Implanted isotopes assume permanent implants; eye plaques with I-125, for example, would not have the same release criteria.