

SUNSI Review
Complete
Template = ADM-013
E-RIDS=ADM-03
ADD: Jazel Parks,
Harriet Karagiannis

COMMENT (8)
PUBLICATION
DATE: 7/26/2019
CITATION 84 FR
36127

As of: 10/1/19 12:45 PM
Received: September 25, 2019
Status: Pending_Post
Tracking No. 1k3-9cdp-4d4o
Comments Due: September 26, 2019
Submission Type: API

PUBLIC SUBMISSION

Docket: NRC-2019-0154

Release of Patients Administered Radioactive Material

Comment On: NRC-2019-0154-0003

Release of Patients Administered Radioactive Material; Extension of comment period

Document: NRC-2019-0154-DRAFT-0009

Comment on FR Doc # 2019-17060

Submitter Information

Name: Anonymous Anonymous

Email: mpeters@acr.org

Organization: American College of Radiology (ACR)

General Comment

Please see the attached comments from the American College of Radiology (ACR).

Attachments

acr_comments_dg-8057_patient-release_9-25-2019



September 25, 2019

Submitted via Regulations.gov

Office of Administration
Mail Stop: TWFN-7A06
U.S. Nuclear Regulatory Commission
Washington, DC 20555-0001
ATTN: Program Management, Announcements and Editing Staff

Re: (Docket ID NRC-2019-0154) Release of Patients Administered Radioactive Material; Comments of the American College of Radiology

The American College of Radiology (ACR)—a professional organization representing more than 38,000 radiologists, radiation oncologists, interventional radiologists, nuclear medicine physicians, and medical physicists—appreciates the opportunity to comment on the draft regulatory guide (DG) from the U.S. Nuclear Regulatory Commission (NRC), DG-8057, “Release of Patients Administered Radioactive Material” (Docket ID NRC-2019-0154; 84 FR 36127).

General Comments

The ACR supports the NRC Advisory Committee on the Medical Uses of Isotopes (ACMUI) recommendations for this draft guide, and we encourage NRC to include all advisory committee-endorsed content.

The ACR also encourages the NRC to consider the availability of information developed for the public by medical experts and freely provided by medical associations. For example, the Radiological Society of North America (RSNA) and the ACR co-sponsor *RadiologyInfo.org*, an online educational resource for patients and caregivers containing basic information on over 260 procedures, exams, and disease descriptions covering diagnostic and interventional radiology, nuclear medicine, and radiation therapy.

Page 5, B. Discussion, Background

The ACR recommends updating all relevant references to National Council on Radiation Protection and Measurements (NCRP) Report No. 155, “Management of Radionuclide Therapy Patients,” on page 5 and throughout the NRC’s revised guidance document. The content of NCRP Report No. 37, “Precautions in the Management of Patients Who Have Received Therapeutic Amounts of Radionuclides,” has been updated and incorporated into NCRP Report No. 155.

Page 7, Harmonization with International Standards

The draft text on page 7 details harmonization with the International Atomic Energy Agency (IAEA) Safety Report Series No. 63 titled “Release of Patients after Radionuclide Therapy,” which is predominantly informed by the European practice of radionuclide therapy and lacks the input of US standards. The ACR recommends incorporating the content on page 7 into a broader discussion of domestic standards, such as NCRP Report No. 155.

Alternatively, the NRC should remove the two paragraphs on international harmonization from the draft guide to avoid potential confusion with domestic standards.

Page 9, Table 1; and Page 11, Table 2 and Appendix A, Table A-1

For simplification and clarification, the ACR recommends that NRC modify the specified tables to display radionuclides actively used in medicine. Tables 1, 2, and A-1 contain radionuclides that are no longer available or used for human use medicine, such as Ag-111, Cr-51, Sc-47, Se-75, and Sn-117m. There are also a number of currently used radionuclides that are not included (e.g., Lu-177, Ra-223, all the positron emitters such as F-18, O-15, Rb-82, Ga-68, etc.).

Page 12, Paragraph 2

The ACR recommends that NRC update the reference (Ref. 6) to more current resources. The 1995 reference (Ref. 6), “Internal Dosimetry in Pediatric Nuclear Medicine,” is described as the primary external resource to use for calculating infant dose from radiopharmaceuticals not listed in Table 3. Our understanding is that the 1995 publication is outdated, and that there are more recently published resources with updated methodology by the same authors:

- Michael G. Stabin, *Radiation Dose Concerns for the Pregnant or Lactating Patient*. Semin Nucl Med. 2014;44:479-488
- M. Stabin, *Fundamentals of Nuclear Medicine Dosimetry*. Springer; 2008
- Michael Stabin and Jeffrey A. Siegel, *RADAR Dose Estimate Report: A Compendium Of Radiopharmaceutical Dose Estimates Based On OLINDA/EXM Version 2.0*. J Nucl Med. 2018;59:154-160.
- RADAR - the Radiation Dose Assessment Resource, <http://doseinfo-radar.com/>

Additionally, the ACR recommends that the guidance clarify that licensees are able to use other resources from relevant professional societies or relevant peer-reviewed literature if they maintain a record of the calculation as required by 10 CFR Part 35.2075(b). Newer or preferred methodologies may become available over time.

Page 14, Section 2.3.1 “Pretreatment Discussions on the Administration of Radiopharmaceuticals”

The ACR recommends deletion of the second paragraph under this subsection, which appears to be an unintentional copy of the final two sentences of the first paragraph.

Page 18, Section 2.4 “Death of a Patient Following Radiopharmaceutical Administration or Implants,” Paragraph 2

The ACR recommends the following sentence revision (strikethrough indicates deletion and underlined text indicates addition): “A specified form of identifier (e.g., bracelet, ~~badge~~ body tag) should be ~~used to~~ attached with relevant information to ~~identify~~ the radioactive body.”

Page 19, Paragraph 2

The ACR recommends the following sentence revision (strikethrough indicates deletion and underlined text indicates addition): “Autopsy and pathology staff should ~~wear standard protective clothing~~ follow protective measures meeting standard infection control procedures (i.e., gloves, laboratory coats, and eye protection), and personnel monitoring should be considered, if significant activity of photon emitting radionuclides are involved.”

Page 19, Paragraph 3

The ACR recommends the following sentence revision (strikethrough indicates deletion and underlined text indicates addition): “When an RSO has been notified that a patient has died shortly after an administration of therapeutic quantities 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~~ during embalming and burial. These include the use of gloves and protective clothing and proper cleaning of equipment.”

Pages 19+, Section 2.4, “Death of a Patient Following Radiopharmaceutical Administration or Implants”

The ACR recommends that NRC emphasize at the beginning of Section 2.4 the exceedingly low radiation risk that recently deceased patients of radionuclide therapies generally pose to crematorium/funeral home workers. The concern of contamination of these workers and the general public from such releases is hypothetical, undocumented, and of such low risk that it is currently immeasurable.

The overarching implication of Section 2.4 is that RSOs have a responsibility to provide precautionary information to crematoriums, morgues, and funeral homes. The ACR supports prudent and risk-based precautions when prior information is provided; however, the activities seem to be most feasible in scenarios in which a patient’s death occurred at the treating facility and the RSO was onsite and readily available. The guide does not consider the additive roles in information exchange of treating AU-physicians, care managers/referring physicians, family members/caregivers, health care administrators for the licensed facility, regulators, professional/trade associations, and others. The guide also does not consider potential scenarios such as:

- The RSO was not present in the facility at the time of death;
- The death occurred post-release from the licensee;
- The death occurred in a healthcare facility unaffiliated with the treating licensee; or,

- The RSO was provided insufficient or inaccurate information and was thus rendered unable to complete the described responsibilities (for example, the RSO was not explicitly informed of the funeral home/crematorium the deceased was taken to).

Many RSOs on NRC and Agreement State licenses are AU-physicians with patient care responsibilities, or are physicist-contractors providing RSO services to multiple healthcare facilities. NRC should consider the practical availability of such RSOs to perform the precautionary activities described in Section 2.4, and should clarify that these activities are aspirational out of an overabundance of caution and not universally practical or feasible.

Additionally, the ACR recommends that NRC play a more proactive role in education of the crematorium and funeral home industries that could reduce or eliminate RSOs' administrative burden in Section 2.4. Two such examples of potential NRC outreach activities:

- NRC could issue a general communication for crematorium and funeral home facilities. This general communication could educate these facilities about the low radiation risk and suggest that hospital morgues, funeral homes, and crematoriums voluntarily install simple, low cost radiation detectors.
- NRC could also sponsor (or co-sponsor with public health agencies) the participation of national medical physics/health physics organizations in the conferences and workshops of trade associations that represent the crematorium and funeral home industries.

Finally, the ACR believes it would be most useful for NRC to place emphasis on the available resources and guidance documents from the Centers for Disease Control and Prevention (CDC), U.S. Department of Energy (DOE), American Association of Physicists in Medicine (AAPM), and the National Funeral Directors Association (NFDA), among others:

- 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-b-4MedicalExaminer-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>

Page 19, Section 2.5, Precautions for Long-Lived Contaminants

The ACR recommends elimination of Section 2.5. The issue in the reference (Ref. 11) addresses a disposal concern for Lu-177 syringes/vials that are not permitted to decay-in-storage because the long-

lived contaminants are greater than 120 days. The information from that reference is being extrapolated without sufficient evidence as a hypothetical patient release concern.

Page 20, Section 3.1, Records of Release

The ACR recommends the following sentence revision (strikethrough indicates deletion and underlined text indicates addition): “Records should be kept in a manner that ensures the patient’s privacy/confidentiality ~~(i.e., the records should not contain the patient’s name or any other information that could identify the patient).~~” This specification provides unnecessary detail outside NRC’s regulatory purview and indicates a patient privacy consideration addressed by other federal regulatory agencies.

Appendix B

As with other relevant areas of the draft guide, Revision 1, the ACR recommends that NRC reassess and update Appendix B with respect to the current NCRP Report No. 155.

Additionally, the ACR recommends that NRC include a reference in Appendix B to alternative acceptable procedures for calculating doses based on patient-specific factors that are provided by peer-reviewed literature.

The ACR appreciates NRC’s consideration of these comments and we welcome questions and further dialog on all issues of shared interest. Please contact Gloria Romanelli, JD, ACR Senior Director of Government Relations, at gromanelli@acr.org; or Michael Peters, ACR Director of Legislative and Regulatory Affairs, at mpeters@acr.org | (202) 223-1670, with questions or concerns.

Sincerely,

A handwritten signature in black ink, appearing to read 'G. McGinty', with a stylized, cursive script.

Geraldine B. McGinty, MD, MBA, FACR
Chair, Board of Chancellors
American College of Radiology