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General Comment

See attached file(s)

Attachments

HPS Comments To NRC Reg Gude 8.39 Revision 5 - signed

HEALTH PHYSICS SOCIETY

Specialists in Radiation Safety

September 26, 2019

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Subject: Docket ID NRC–2019–0154: DG-8057 "Release of Patients Administered Radioactive Material"

The Health Physics Society[1] (HPS) is a professional organization whose mission is to promote excellence in the science and practice of radiation safety. The HPS appreciates the opportunity to provide comments, in the attached document, as a response to the July 26, 2019 request.

If you have any questions regarding these comments, please contact the HPS Agency Liaison, Craig Little, at 970-260-2810 or by email to agencyliaison@hps.org.

Sincerely,

Eric M. Goldin, CHP

President

cc: Craig Little, PhD, HPS Agency Liaison
Brett Burk, HPS Executive Director

[1] The Health Physics Society is a non-profit scientific professional organization whose mission is to promote the practice of radiation safety. Since its formation in 1956, the Society has grown to include over 4,000 scientists, physicians, engineers, lawyers, and other professionals representing academia, industry, government, national laboratories, the Department of Defense, and other organizations. Society activities include encouraging research in radiation science, developing standards, and disseminating radiation safety information. Society members are involved in understanding, evaluating, and controlling the potential risks from radiation relative to the benefits. Official position statements are prepared and adopted in accordance with standard policies and procedures of the Society.

Health Physics Society Comments on

Revisions to Regulatory Guide 8.39 "Release of Patients Administered Radioactive Material"

General Comments

As a scientific organization of professionals who specialize in radiation safety, the HPS supports the expansive revision of Regulatory Guide (RG) 8.39 to bring the guidance in line with the best practices and evolutions in radiation science since the original publication. To that end, HPS emphasizes that the dosimetric modeling and guidance for determining restriction times for patient activities after release be updated in line with NCRP 155[2] (models which supersede the simplified methodology that the current RG 8.39 is based on) or equivalent models that more comprehensively characterize likely exposures to non-patients under different scenarios and additionally provide a basis for assigning restriction times for certain activities to control radiation exposures to others.

The simplified method and model in RG 8.39 (NRCP 37[3]) provide criteria based on dose rate and administered activity which are likely adequate for most diagnostic uses of radioactive materials, but the overly simple model fails to account for basic human activities such as sleeping with a partner, or the routine close contact due to caring for a small child. In addition, the NRCP 37 model does not provide a basis for determining restriction times to assist licensees in ensuring that appropriate safety precautions are provided.

The assumption that the internal dose is negligible or very small when compared to external dose is not always true using NRC's own method cited in Appendix B.3. Age and population specific dose conversion factors should be used in this assessment and the requisite dose included in the release assessment and design of instructions and appropriate restriction times.

We note that in addition to an updated calculation methodology, Tables 1, 2 and Appendix A, Table A-1 should be updated to reflect radionuclides now commonly used in medicine such as ^{177}Lu (including how to account for metastable contribution) and ^{223}Ra (including daughter contributions).

The majority of the document represents best practices and is appropriate with respect to patient instruction, evaluation for suitability for release from licensee control (considerations, content, etc.). However, there is some concern regarding when and how to discuss patient death (section 2.3.1 e) after administration of radioactive materials. In many cases, such a discussion is likely to only lead to concern or distress on the part of the patient and family, possibly impacting the patient's decision to undergo the procedure. In addition, it is unclear if a licensee can instruct patient family members regarding this provision without consent of the patient.

[2] NCRP Report 155, Management of Radionuclide Therapy Patients. National Council on Radiation Protection and Measurements, Washington, D.C., 2006.
[3] NCRP Report 37, Precautions in the Management of Patients Who Have Received Therapeutic Amounts of Radionuclides. National Council on Radiation Protection and Measurements, Washington, D.C., 1970.

In addition, there are concerns regarding the handling of radioactive decedents. It is laudable that the guidance now includes information on this important issue. There remain however several aspects that should be addressed.

1. In cases where the patient or human research subject becomes deceased while under licensee control, there is no regulatory mechanism for release of the remains (as we understand 10 CFR 35.75 does not apply) other than "decay in storage" or transfer to another licensee.

2. In cases where the patient or human research subject becomes deceased after release from licensee control, the draft document recommends that the radiation safety officer (RSO) of the treating facility take an active advisory role in handling the remains and with funerary services / crematoriums. While such actions have the possibility to enhance the safety of those handling the remains, since the material had already been released from licensee control, it is unclear where the ultimate liability lies with respect to these consultative services, nor is it clear what the regulatory basis for the licensee assuming such liability would be. For example, would the licensee be responsible for remediation of a contaminated facility when the patient was already released from regulatory control? The licensee in this situation does not have a reliable notification pathway to learn of a situation and so may be completely unaware of the issue.

3. The guidance does not address the issue of how the notification process to funeral services / coroner / crematoriums impacts the duty of the health care organization to protect patient information (HIPAA). Who makes the determination if / when dissemination of this information is in the interest of public health and at what level of potential exposure should notification be considered? Such information (a reference for example) would be useful to many licensees.

4. Guidance on visitation and handling of cremains should be included. For example, what are appropriate dose constraints? Is the licensee expected to assess exposure risks through direct measurement? What happens when the remains are not local to the treating hospital?

5. To what extent is the administering licensee responsible for assessment of radiation dose and exposure associated with the processing and disposition of remains? In the case of cremation, what responsibility does the administering licensee have with respect to radioactive stack release? How should this be determined and what limits should apply?

6. In the absence of standardized regulations or a statutory remedy, there is no consistent framework to be applied in the handling and disposition of the remains of radioactive decedents. There have been cases when the remains have been refused until such time as they are "no longer radioactive". Such instances may cause undue burden on the decedents' family when there may be no meaningful risk for those who would handle the remains for ultimate disposition.

   It may be beneficial for the NRC to include some outside references on handling contaminated decedents such as:

- 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

Specific comments:

Page 16, Section 2.3.2 specifies that the licensee under certain circumstances may be required to hold a patient until they "can be released without having to follow any specific instructions". There is some concern whether a patient's insurance would pay for such an admission that may not be medically necessary, and the subsequent impact on ability of the patient to receive care. Does the licensee only need to show that the likely dose to the maximally exposed individual is < 1 mSv (100 mrem) as per 10 CFR 35.75 by use of a patient specific calculation and appropriate instructions that they may be capable of following for example?

Page 20, 3.1 specifies that records of release should include patient identifiers but later states that the patients identifying information should not contain the patient "name or any other identifying information that could identify the patient". These statements appear contradictory.

Appendix A, Table A-1 - Exposure rate constants could be obtained from a single, more up-to-date reference, such as the recent publication by Smith DS and Stabin MG. Health Phys 2010; 102(3):271-291.

Appendix A, Table A-1 Footnote e.
Consider changing "release activity is not based on beta emissions" to "radionuclide is a pure beta emitter (and there is no single exposure rate constant associated with the secondary bremsstrahlung radiation applicable for such radionuclides)."

Appendix B, Section B-2
"The behavior of I-131 can be modeled using two components" should be qualified as sodium iodide throughout Appendix B, as appropriate.

Page B-5. "In the example above, the thyroidal fraction, F2 = 0.05, is a conservative assumption for persons who have had surgery to remove thyroidal tissue. If F2 has been measured for a specific patient, the measured value may be used" (along with F1 calculated as 1 - F2).

Page B-6. "In the example above, the thyroidal fraction, F2 = 0.8, is a conservative assumption for persons who have this treatment for hyperthyroidism. If F2 has been measured for a specific patient, the measured value may be used" (along with F1 calculated as 1 - F2).

Appendix B, Section B-3
"For some radionuclides, such as I-131, the concern is that the internal dose of an individual from exposure to a released patient could be significant." This is not necessarily true for bound I-131, e.g., I-131 MIBG or an I-131 radiolabeled antibody. In addition, when assessing internal dose it should be clarified that the appropriate chemical form should be used in the assessment.

Summary

There have been significant advances in understanding the likely radiation exposures to others from the release of radioactive patients and human subjects since the regulatory analysis in NUREG 1492[4] and the publication of NCRP 37. NRC should revise the methodologies in Regulatory Guide 8.39 to adopt more realistic models that include the determination of restriction times for various activities that are risk informed.

Recent advances in therapy with radioactive materials have highlighted the issues surrounding radioactive decedents, with more sick patients undergoing treatment with products such as Y-90 microspheres, I-131 MIBG and Lu-177 Dotatate. A reasonable, consistent standard that allows for adequate protection of the public while permitting for compassionate disposition of remains should be established.

[4] NUREG-1492, "Regulatory Analysis on Criteria for the Release of Patients Administered Radioactive Material". US Nuclear Regulatory Commission, 2120 L Street NW., Washington, DC. , February 1997.