As of: 3/31/17 1:53 PM
Received: March 29, 2017
Status: Pending_Post
Tracking No. 1k1-8vj6-f7vw
Comments Due: March 31, 2017
Submission Type: Web

PUBLIC SUBMISSION

Docket: NRC-2016-0122
Consolidated Guidance About Material Licenses: Program-Specific Guidance About Medical Use Licenses

Comment On: NRC-2016-0122-0003
Program-Specific Guidance About Medical Use Licenses; Extension of Comment Period

10

Document: NRC-2016-0122-DRAFT-0011
Comment on FR Doc # 2017-01807

12/6/2016
81 FR 87978

Submitter Information

Name: Richard Martin
Submitter's Representative: Melissa Carol Martin
Organization: American Association of Physicists in Medicine

General Comment

See attached file(s)

Attachments

AAPM NUREG-1556 Vol 9 Rev 3 Comment Final

SUNSI Review Complete
Template = ADM – 013
E-RIDS= ADM-03
Add= K. Tapp (KMS1)

AMERICAN ASSOCIATION
of PHYSICISTS IN MEDICINE

Melissa Carol Martin, MS, FAAPM, FACMP, FACR
Office of the President
Therapy Physics, Inc.
879 W 190th Street, Suite 400
Gardena, CA 90248
Melissa@therapyphysics.com
310.612.8127

March 29, 2017

Cindy Bladey
Office of Administration
Mail Stop: OWFN-12-H08
U.S. Nuclear Regulatory Commission
Washington, DC 20555-0001

RE: Request for Comment: Draft NUREG–1556, Volume 9, Revision 3, "Consolidated Guidance About Materials Licenses: Program-Specific Guidance About Medical Use Licenses" (NRC-2016-0122-0003)

Dear Ms. Bladey:

The American Association of Physicists in Medicine (AAPM)[1] is pleased to submit comments to the U.S. Nuclear Regulatory Commission (NRC) regarding Draft NUREG–1556, Volume 9, Revision 3, "Consolidated Guidance About Materials Licenses: Program-Specific Guidance About Medical Use Licenses."

The AAPM commends the NRC on its work in providing guidance to existing medical licensees and to applicants for a medical use license, as well as, updating guidance to include information on safety culture, security of radioactive materials, protection of sensitive information, and changes in regulatory policies and practices. The AAPM further commends the NRC for its efforts to ensure the entire document is up-to-date with current industry practice and regulatory framework.

[1] The American Association of Physicists in Medicine (AAPM) is the premier organization in medical physics, a broadly-based scientific and professional discipline encompassing physics principles and applications in biology and medicine whose mission is to advance the science, education and professional practice of medical physics. Medical physicists contribute to the effectiveness of radiological imaging procedures by assuring radiation safety and helping to develop improved imaging techniques (e.g., mammography, CT, MR, ultrasound). They contribute to development of therapeutic techniques (e.g., prostate implants, stereotactic radiosurgery), collaborate with radiation oncologists to design treatment plans, and monitor equipment and procedures to insure that cancer patients receive the prescribed dose of radiation to the correct location. Medical physicists are responsible for ensuring that imaging and treatment facilities meet the rules and regulations of the U.S. Nuclear Regulatory Commission (NRC) and various state regulatory agencies. AAPM represents over 8,500 medical physicists.

General Comments

The AAPM understands that this draft guidance does not include any revisions associated with the proposed rule "Medical Use of Byproduct Material-Medical Event Definitions, Training and Experience, and Clarifying Amendments" as that rulemaking is not completed. The proposed rule and proposed changes to NUREG-1556, Volume 9, associated with the proposed rule were published for public comment in the *Federal Register* (79 FR 42409, 79 FR 42224) on July 21, 2014. The AAPM expresses support for the NRC's plan to incorporate the proposed revisions to NUREG-1556, Volume 9 addressing the implementation of the proposed rule into this NUREG-1556, Volume 9, Revision 3 before its final publication, if the proposed rule becomes final.

Much of the NUREG document is focused on I-131 sodium iodide therapy for hyperthyroidism and thyroid cancer. While these therapies are currently the most prevalent, the document should provide generic guidance for all sealed and unsealed radionuclide patient therapy release. The AAPM believes consideration should be given to creating a separate section for the precautions that are specific to I-131 sodium iodide therapy.

Specific Comments on Appendix U

The AAPM has the following specific comments on "Model Procedures for Release of Patients or Human Research Subjects Administered Radioactive Materials" (Appendix U):

1. **Page U-1, Lines 10-13,** "However, a patient who meets the release criteria in 10 CFR 35.75 is not required to be released immediately following administration of radioactive materials. Inpatient treatment is always an option and may be the appropriate choice, given the patient's specific situation."

   This statement is suggestive of inpatient treatment, where the decision as to whether the patient should be admitted is primarily a medical decision to be made by the Authorized User. The AAPM believes the guidance should be focused on how to comply with the release criteria in 10 CFR 35.75 and not make suggestions that presume medical practice.

2. **Page U-1, Lines 21-22,** "Although the regulations are not explicit, licensees should consider implementing the 5 mSv as an annual limit for multiple administrations during a calendar year."

   The AAPM believes this statement is not consistent with interpretation of the current rule. In the Final Rule statements "The NRC is establishing a dose limit of 5 millisieverts (0.5 rem) total effective dose equivalent to an individual from exposure to the released patient for each patient release" (62 FR 4122, 1/29/97). This is why the NRC said in their RIS 2008-07 that they would have to pursue rulemaking to "incorporate the NRC's intent" to make the patient release criteria an annual dose limit. Until the current rule is changed, AAPM believes, licensees should not be encouraged or expected to implement a 5 mSv annual limit for multiple administrations during a calendar year.

3. **Page U-1, Lines 25-32,** "Although 10 CFR 35.75 does not expressly prohibit the release of a radioactive patient to a location other than a private residence, the U.S. Nuclear Regulatory Commission (NRC) strongly discourages this practice, because it can result in radiation exposures to members of the public for which the licensee may not be able to fully assess compliance with 10 CFR 35.75(a) and may result in doses that are not as low as is reasonably achievable (ALARA). For more information on this topic, see RIS 2011-01, "NRC Policy on Release of Iodine-13131 Therapy Patients Under 10 CFR 35.75 to Locations Other Than Private Residences," January 25, 2011."

   The AAPM asserts there is no data or study to support the statement that release of a radioactive patient to a location other than a private residence will result in radiation exposures to members of the public in excess of that permitted by 10 CFR 35.75(a). In an ACMUI subcommittee report[2] to review the patient release criteria, it addressed the release of I-131 therapy patients to locations other than a private residence. "As part of the analysis, the subcommittee calculated the radiation dose to other individuals from release of an I-131 therapy patient to a hotel using overly

[2] **U.S. Nuclear Regulatory Commission. Advisory Committee on the Medical Uses of Isotopes (ACMUI): Patient release report. 2010. Available at: http://pbadupws.nrc.gov/docs/ML1034/ML103481099.pdf. Accessed March 8, 2017.**

conservative assumptions and parameters, to demonstrate that even highly unlikely dose projections do not exceed the release criteria". The ICRP[3] also suggested that a patient could "stay at a nonhospital living facility, such as a hotel, for several days" when the patient's home situation would put the patient in close contact with children due to physical or social constraints, because this "is less expensive than staying in a hospital". Accordingly, the AAPM suggests the guidance document should emphasize that the licensee assess the radioactive patient's planned living situation upon release, and provide the patient with any additional radiation safety precautions that may be appropriate for such locations.

4. **Page U-2, Lines 33-36,** "For radionuclides with a physical half-life less than or equal to 1 day, it is difficult to justify an occupancy factor of 0.25, because relatively long-term averaging of behavior cannot be assumed. Under this situation, occupancy factors from 0.75 to 1.0 may be more appropriate."

   We believe this is an example of an unrealistically conservative assumption that results in a gross overestimate of the dose to an exposed individual. The half-life of the radionuclide does not affect the amount of time someone spends in close proximity to the released patient. The AAPM believes an occupancy factor of 0.25 should also be applicable and conservative for short lived nuclides. The AAPM asserts that "Reasonable assumptions should be employed for calculating realistic doses to people from a released patient."[1]

5. **Page U-4, Lines 2-3,** "an occupancy factor of 1 at 1 meter for physical half-lives less than or equal to 1 day."

   Same comment as in number 4.

6. **Page U-11,** Instructions Regarding Radiopharmaceutical Administrations "Drink one glass of water each hour..."

---

[3] ICRP Publication 94, "Release of Patients after Therapy with Unsealed Radionuclides", International Commission on Radiological Protection, March 2004 – see paragraph (106), item (v).

The AAPM believes that this instruction on fluid intake should be based on the patient's medical condition and come from the physician Authorized User. While increasing fluid intake will accelerate the excretion of I-131 sodium iodide through the patient's urine, this should not be part of the general radiation safety guidance. We believe that too much fluid intake (especially at a rate of one glass of water each hour) can result in hyponatremia and potential life-threatening consequences.

7. **Page U-11, Lines 1-5,** "Licensees should consider not releasing patients administered I-131, whose living conditions may result in the contamination of infants and young children. The licensee should provide information on the potential consequences, if any, from failure to follow these instructions (e.g., could result in significant doses to the child's thyroid and potentially raise the risk of subsequent radiation-induced thyroid cancer)."

The AAPM asserts that there is no data or study to support the statement that patients administered I-131 present a significant exposure pathway and dose to the thyroid of an infant or child from contamination. These statements are based on ICRP[2] recommendations which used unrealistic assumptions in calculating both the intake of iodine from a released patient and the incidence of radiation induced childhood thyroid cancer. Accordingly, the AAPM suggests the guidance document should emphasize that the licensee assess the radioactive patient's planned living situation upon release, and provide the patient with any additional radiation safety precautions that are appropriate for the living situation.

8. **Page U-17, Lines 18-21,** "In Table U–1 in this Appendix, the activities at which patients could be released were calculated using the physical half-life of the radionuclide and an occupancy factor at 1 meter of either 0.25 (if the radionuclide has a half-life longer than 1 day) or 1.0 (if the radionuclide has a half-life less than or equal to 1 day)."

Same comment as in number 4.

9. **Page U-18, Lines 6-7,** "E = 0.75 when a physical half-life, an effective half-life, or a specific time period under consideration (e.g., bladder holding time) is less than or equal to 1 day."

   Same comment as in number 4.

10. **Page U-20, Lines 6-12,** "However, simple exponential excretion models do not account for (i) the time for the I-131 to be absorbed from the stomach to the blood; and (ii) the holdup of iodine in the urine while in the bladder. Failure to account for these factors could result in an underestimate of the dose to another individual. Therefore, this supplement makes a conservative approximation to account for these factors by assuming that, during the first 8 hours after the administration, about 80% of the iodine administered is removed from the body at a rate determined only by the physical half-life of I-131."

    The AAPM asserts that is no biological or physical basis to support this assumption. We believe this is another example of an unrealistically conservative assumption that results in a gross overestimate of the dose to an exposed individual. Patient-specific calculations should be based on the published literature of the biological retention and excretion models of the radiopharmaceutical being administered to the patient.

11. **Page U-23 B.3** Internal Dose, A fractional transfer of 10-5 is assumed for the internal dose to an individual from exposure to a released patient.

    We believe this is an order of magnitude greater than that stated in the literature of the three references cited in the NUREG. The AAPM suggests that a more realistic assumption in the range of 1x10-6 to 5x10-6 should be used.

12. **The following radionuclides should be added to Tables U-1, U-2, U-3, and U-5, as appropriate: F-18, Ga-68, Ra-223, Lu-177, Cs-131 (sealed sources for implant).**

Conclusion

Thank you for the opportunity to comment on Draft NUREG–1556, Volume 9, Revision 3, "Consolidated Guidance About Materials Licenses: Program-Specific Guidance About Medical Use Licenses." If you have any questions or require additional information, please contact Richard J. Martin, JD, Government Relations Specialist, at 571-298-1227 or Richard@aapm.org

Sincerely,

Melissa C. Martin

Melissa Carol Martin, MS, FAAPM, FACMP
President, AAPM