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Submitter Information

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

General Comment

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See attached file(s)

Attachments

AAPM Comment Patient Release Final

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AMERICAN ASSOCIATION of PHYSICISTS IN MEDICINE

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June 26, 2017

Cindy Bladey
Office of Administration
Mail Stop: TWFN-8-D36M
U.S. Nuclear Regulatory Commission
Washington, DC 20555-0001

RE: Request for Comment Patient Release Program (NRC-2017-0094)

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 its patient release program. The AAPM commends the NRC on its work in addressing whether additional or alternate regulatory criteria are needed or clarification is necessary for the NRC's patient release requirements. The AAPM further commends the NRC for its efforts to engage stakeholders on this issue.

General Remarks

On April 11, 2017, the NRC solicited comments on its patient release program. As stated by the NRC, the purpose of requesting information from the general public was to receive input from the public on whether to clarify NRC's current patient release criteria. The information

[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.

collected will be used to determine whether significant regulatory changes to NRC's patient release program are warranted.

The AAPM believes current rules protect public safety and that no regulatory changes to the NRC's patient release requirements are warranted. We see no scientific basis for changing current patient release requirements and believe it is a practice of medicine issue that is best addressed within the provider community. Moreover, modifications that extend hospital stays, burdening patients with additional hospitalization costs, isolate patients and intensifying patient anxiety, and increase the risk of patients' acquiring hospital-borne infections without strong evidence of improved radiation safety do not serve the patients or their families. Accordingly, the AAPM urges the NRC to refrain from making any modifications to the current requirements for patient release.

Comments Addressing Specific Questions

A. *Development of an Activity-Based Patient Release Threshold* - Question: Should the NRC develop an activity-based patient release threshold?

The AAPM believes the NRC should not revert to an activity-based patient release criterion. A radiation dose-based criterion is the most appropriate metric to use in order to limit risk to public health and safety associated with exposure to a patient administered or implanted with a radionuclide. Recommendations for the management of radionuclide therapy patients from both the ICRP (Publication 94)[2] and NCRP (Report No. 155)[3] are consistent in principle and practice, with current NRC patient release regulations and guidance.

The NRC Advisory Committee on the Medical Uses of Isotopes (ACMUI) extensively evaluated the patient release program in 2010, including petitions to replace the current dose-based release criteria and to re-instate the 1986 10 CFR 35.75 release criteria, widely

[2] ICRP Publication 94, Release of patients after therapy with unsealed radionuclides, Volume 34 No. 2 2004.

[3] NCRP Report No. 155, Management of Radionuclide Patients, December 11, 2006.

known as the "30-mCi" rule. The ACMUI Subcommittee report[4] concluded that there was no scientific merit in returning to such activity-based release criteria, which have no identifiable scientific basis. The Subcommittee maintained, "dose-based release criteria are more scientifically rigorous than activity-based criteria and better protect the public by basing patient releaseability on the quantity, dose, *directly* related to potential radiation hazard rather than on a quantity, activity, *indirectly* related to this potential hazard." Administered activity or dose rate alone, without consideration of the other factors involved in a patient therapy, will not provide a reliable indication of the potential dose to other individuals, even for the same radionuclide.[5]

Most licensees will use the release calculation model in Appendix U of NUREG 1556, Vol. 9, Rev 2, for estimating the dose to other individuals and determining the release of the therapy patient. The Health Physics Society has published a position statement[6] on the NRC patient release dose criteria that maintains release of patients in accordance with 10 CFR 35.75 poses no discernible risk to the public, thus providing ample public health and safety measures, while offering significant benefits to patients, their families, and society. In addition, there are numerous publications that have looked at the radiation exposure to others from I-131 patient therapy which report that doses are unlikely to exceed 1 mSv, as cited by the ACMUI report.

We believe an activity-based patient release criterion would most likely result in excessive economic costs and adverse psychological impact on patients and their families due to the required patient isolation. It would also likely result in the practice of fractionating the patient's therapy dose and reduce the effectiveness of such therapy. Therefore, the AAPM strongly advises against the establishment of an activity- based release criterion.

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[4] U.S. Nuclear Regulatory Commission. Advisory Committee on the Medical Uses of Isotopes (ACMUI): Patient release report. 2010.

[5] Estimated Dose Rates to Members of the Public from External Exposure to Patients with I-131 Thyroid Treatment, S. Dewjia and M. Bellamy, Medical Physics, 42 (4), April 2015.

[6] Health Physics Society. Release of Patients Treated with Therapeutic Quantities of Radiopharmaceuticals and Sealed Sources. HPS Position Statement. McLean, VA: HPS; March 2012.

B. *Clarification of the Time Covered by the Current Dose Limit in 10 CFR 35.75(a) for Releasing Individuals* - Question: Should the NRC amend the regulations to clarify the time frame for the current dose limit in 10 CFR 35.75(a) for releasing Individuals?

The Final Rule statements are very clear that "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). If the NRC wishes to change this to be an annual dose limit, it would require proposed rulemaking as identified in its RIS 2008-07. The primary difficulty of an annual limit is the practicality of licensees tracking all doses to other individuals on an annual basis, potentially including those from multiple therapy administrations to the same patient in a single calendar year. The AAPM believes compliance with an annual dose limit for patient release is both impractical and of dubious benefit to the public welfare. Moreover, if one applies the linear no threshold radiation risk model, there would be no difference in the theoretical risk of radiation dose from exposure to an I-131 therapy patient receiving two therapies in one calendar year, versus the exposure to an I-131 therapy patient receiving two therapies over two calendar years.

C. *Appropriateness of Applying the Same Limit on Dose from Patient Exposure to All Members of the General Public* - Question: Should the NRC continue to apply the same dose criteria of 5 mSv (0.5 rem), to all members of the general public, including family members, young children, pregnant women, caregivers, hotel workers, and other members of the public when considering the release of patients?

The AAPM believes current NRC guidance on patient release calculations overestimate caregiver and public doses because the guidance assumes unrealistically conservative assumptions. In addition, there are numerous publications that have looked at the radiation exposure to others from I-131 patient therapy which report that doses are unlikely to exceed 1 mSv, as cited in the ACMUI report. Since studies have demonstrated that doses to individuals are well below the current release limit of 5 mSv, it is not necessary to establish a different dose criteria for various members of the public,

especially for dose levels comparable to or less than variations in natural background radiation. Therefore, we believe a single release dose limit for all potentially exposed individuals is sufficient to maintain public health and safety.

D. *Requirements for Releasing Individuals Who Are Likely to Expose Young Children and Pregnant Women* - Question: Should the NRC include a specific requirement for the release of a patient who is likely to expose young children or pregnant women to doses above the public dose limit?

The licensee is required to provide written instructions on actions recommended to maintain doses to other individuals ALARA. These instructions should include information on the potential increased risks associated with exposing young children and pregnant women, with instructions to avoid close proximity to those individuals for a few days following treatment. Special consideration for exposing young children and pregnant women is included in the recommendations for the management of radionuclide therapy patients by the NCRP, ICRP, SNMMI, and ATA. It has also been addressed in Appendix U of NUREG 1556 Vol 9, Rev 2 and NRC RIS 2008-11. Therefore, the AAPM believes a separate regulatory requirement to provide this instruction is not necessary.

E. *Requirement for Timely Discussion with the Patient About Patient Isolation to Provide Time for Licensee and Patient Planning* - Question: Should the NRC have a specific requirement for the licensee to have a patient isolation discussion with patients in sufficient time prior to the administration to provide the patient time to make isolation arrangements or the licensee to make plans to hold the patient, if the patient cannot be immediately released?

The AAPM believes there is no need for a prescriptive regulatory requirement on when the safety instruction must be provided to a radionuclide therapy patient or the patient's guardian, as this would not be consistent with the NRC's performance-based regulatory approach. How and when this safety instruction is provided is the responsibility of the

licensee. If a particular licensee is not providing appropriate or timely instructions, this can be addressed by the licensing regulatory agency during the inspection process.

F. *Requirement to Ensure Patients Are Given Instructions Prior to the Procedure* - Question: Should the NRC explicitly include the time frame for providing instructions in the regulations (e.g., the instructions should be given prior to the procedure)?

We believe that there is no need for a prescriptive regulatory requirement on when the safety instruction must be provided to a radionuclide therapy patient or the patient's guardian, as this would not be consistent with the NRC's performance-based regulatory approach. How and when this safety instruction is provided is the responsibility of the licensee. If a particular licensee is not providing appropriate or timely instructions, this can be addressed by the licensing regulatory agency during the inspection process.

Conclusion

The AAPM believes current rules protect public safety and sees no scientific basis for changing current patient release requirements. Accordingly, the AAPM urges the NRC to maintain current requirements, without modification.

Thank you for this opportunity to comment. 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