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Draft Regulatory Guide: Release of Patients Administered Radioactive Material; Extension of Comment Period

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## General Comment

See attached file

## Attachments

University of Pennsylvania EHRS comments on Reg Guide 4.39 Rev 2

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The University of Pennsylvania has reviewed Draft Reg Guide 8.29 Rev 2 as well as the Final Report of the USNRC Advisory Committee on the Medical Use of Isotopes (ACMUI). We agree with the recommendations stated in the ACMUI Final Report submitted January 21, 2022 relating to dosimetric equations, methodologies, and tables used to calculate dose to members of the public from released patients.

The University of Pennsylvania has a Medical Broad Scope license and is comprised of 6 Hospitals and 30 ambulatory care facilities. We perform approximately 350 radioactive material therapeutic administrations each year. In many cases dose exposure measurements at a meter are used to determine release, but in all cases the current system of justifying patient releases already includes reviewing the patient's medical and home living conditions. If modifying the standard release conditions is appropriate, those cases are documented. Requiring additional record keeping for all patients will not result in greater safety for the patient, the patient's family, or other members of the public. Using overly conservative assumptions is unnecessary to provide reasonable assurance of adequate protection of public health and safety.

In summary, we agree with the ACMUI recommendation 2 that the standard use of a 1.0 occupancy factor is unrealistic and should not be used in Equation 1.

1. The proposed Tier 1 assumption of an occupancy factor of 1.0 at 1 m from a patient and the associated table of releasable activities and dose rates are unrealistic. The proposal to change the default occupancy factor from 0.25 to 1.0 cannot be justified and is overly conservative.

   The proposal's goal to achieve bystanders being "highly unlikely" to exceed the limits in 10 CFR 35.75 is inconsistent with the requirements of 10 CFR 35.75. It also contradicts the associated regulation for record keeping. 10 CFR 35.2075(a) states: "A licensee shall retain a record of the basis for authorizing the release of an individual in accordance with 10 CFR 35.75, if the total effective dose equivalent is calculated by (2) Using an occupancy factor less than 0.25 at 1 meter." Enacting the proposed default occupancy factor in Rev 2 would result in no record of this factor for most releases which are reasonably based on an occupancy factor of 0.25.

2. Not only is release based on a default occupancy factor of 1.0 unrealistic, but it will also cause an unnecessary logistical and financial burden on licensees, including hospitals which often have a shortage of available inpatient beds. NRC attempts to implement guidance and effectively regulate patient release using overly conservative methods would be intrusive and would affect patient care by potentially requiring longer hospital stays than are necessary or reasonable. The challenge of generating bed availability is constant throughout the Penn Medicine enterprise. Requiring patients to remain in-house any longer than necessary may create significant financial hurdles for both the hospital and the patient, and may result in patients not being able to obtain necessary care. In cases when patients are sedated for treatment, it poses an increased risk to the patient's health as longer sedation periods increase the risk of patients experiencing withdrawal effects. Longer hospital stays also lead to additional stress for patients and family members. Reasonable in ALARA should not require patients whose release is not likely to result in doses exceeding 5 mSv to any other individual to continue to occupy hospital beds that are greatly needed for other patients, thus directly negatively impacting patient care. We believe 0.25

should be maintained as the standard value in calculations/the table values for releasable activity and dose rates.

3. The proposal to have modifying factors defined with a default value of 1, and documenting values used that are different from 1 based on patient specific information, is not unreasonable. However, the proposed methods and calculations to determine them are overly complicated and unnecessary. We agree with ACMUI Recommendation 4. As patients can be released based on measured dose rates at 1 m from the patient, similar measurements can be performed to determine doses to bystanders at different distances rather than using a complicated series of calculations proscribed in a regulatory guide. Other methods can also achieve the same goal, while being far simpler. Any new standard should allow licensees flexibility to demonstrate compliance with applicable regulations by appropriate and reasonable methods, not restrict them to unnecessarily and overly complicated methods and calculations that are proscribed in a regulatory guide.

We agree with ACMUI Recommendation 5 that material from the patient should not be included for meeting dose limits, with the exception of temporary implants.

We also agree with ACMUI Recommendation 6. We agree that additional information on how to deal with deceased bodies still containing radioactivity, particularly if cremation is chosen, would be welcome.

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