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Submitter Information

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General Comment

Debiopharm acknowledge that dose limit of 5 mSV (500 mrem) prescribed in 10 CFR 35.75 is adequate to protect the public and remains the standard for a licensee to authorize the release of patient that has been administered radioactive material in US.

Debiopharm concurs that the provision of tables outlining an activity threshold and dose rate for patient release, which can be utilized by licensees to meet regulatory requirements, would be beneficial. Such tables would offer a straightforward approach to ensure the safe release of patients, ultimately benefiting the licensee and facilitating the release of patients. The general hypotheses made for calculation in Equation 1 don’t take into consideration patient-specific information, biological half-life (biological loss) and assume an external dose that begins immediately after administration and last through infinity. The introduction of an occupancy factor of 100% (1.0) at one meter doesn’t reflect real-life bystander exposure. Consequently, the revised DG-8061 guidance, which includes this new constraint leads to overly conservative assumptions.

During the ACMUI public meeting on December 21, 2021, physicians and radiation safety officers expressed that it is common practice to provide patients with a consultation and instructions before they are released from a healthcare facility. This aligns with Debiopharm experience.
As highlighted in NUREG-1942, even in complete absence of instructions, the occupancy factor at 1 meter was less than 0.25. This value was supported by empirical measurements as well as professional judgement. Consequently, a factor of 0.25 would already be adequate to minimize the risk of bystander exposure exceeding 5 mSv, even in the worst case scenario of patients not receiving instructions. Importantly an occupancy factor of 0.25 is the value authorized under 10 CFR 35.2075.

By not considering the excretion of the radiopharmaceutical at time of patient release (or effective measured dose rate), as well as by applying an unwarranted restrictive occupancy modifying factor of 1.0 in Equation 1, licensees will be required to perform patient specific dose calculations for patient release in cases when they were not needed previously. Conducting the complex patient specific dose calculation

presented in Equation 7 will add burden to the healthcare facilities (i.e. Geometry factor and attenuation modifying factor determination as well as extended patient behaviour knowledge following release). If the health care facility lacks the necessary resources to carry out Equation 7, the patient will ultimately have to stay hospitalized for unnecessarily longer period (as per Equation 1).

Suggested changes to the guidance:
- To assume a 25% occupancy factor in equation 1 (F0=0.25).
- To update the Table 1 and Table 2 based on this occupancy factor value.
- To add one additional column in Table 1 which would apply a base case scenario for patient release, in line with both theoretical and real-world data which can be referenced by licensee. Assumption should be aligned with ACMUI recommendation from 2017 e.g., F0 =0.25 ± 30% attenuation factor for a 72 kg male patient.