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General Comment

See attached file(s)

Attachments

DG-8061-RG8.39Rev2-Comments

Memorial Sloan Kettering Cancer Center

August 19, 2023

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Office of Administration
Mail Stop: TWFN-7-A60M
Unites States Nuclear Regulatory Commission (NRC)
Washington, DC 20555-0111
Attn.: Program Management, Announcements and Editing Staff

Docket ID: NRC-2023-0086

Dear Sir/Madam:

The Medical Health Physics Department of Memorial Sloan Kettering Cancer Center (MSK) thanks the Nuclear Regulatory Commission (NRC) for the opportunity to submit comments on Draft Regulatory Guide DG-8061, Proposed Revision 2 to Regulatory Guide 8.39, which was issued April 2023.

We applaud the NRC's ongoing efforts to revise Regulatory Guide 8.39. The importance of radiopharmaceutical therapies for the safe and effective treatment of a variety of cancers will continue to grow as cancer rates in the population increase and new therapies are researched and developed in the ongoing search for more effective treatments.

General Comment:

Any changes to Regulatory Guide 8.39, Revision 1, should strive to maintain the current balance between any currently scientifically understood potential risk and the benefits of radiopharmaceutical therapies. The proposed occupancy factor of "1" in Tables 1 and 2, a fourfold increase from the current 0.25, for the "First-Tier" does not strike this balance and was determined to not be justified in the January 21, 2022 Final Report by the Advisory Committee on the Medial Use of Isotopes (ACMUI) (ML22021B299) and is not consistent with the current guidance from the National Council on Radiation Protection and Measurements (Report No. 155). DG-8061 does not provide additional rationale or scientific basis to retain the proposed change.

Although licensees can perform their own calculations as part of the "Second-Tier" approach, this may not be feasible for many facilities that do not have on-site physics support. Instead, the unjustified conservatism employed in DG-8061's "First-Tier" could potentially lead to reduced access to care and or increased inpatient admissions for radiopharmaceutical therapies that are predominantly performed on an outpatient basis under the current Regulatory Guide 8.39.

Specific Comments:

1. Occupancy Factors

- *DG-8061, Introduction, Applicable Regulations* (page 2) reads: "10 CFR 35.75(c) and 10 CFR 35.2075(a) require the licensee to maintain a record…if the TEDE…is calculated by…using and occupancy factor less than 0.25 at 1 meter (m)…"

  DG-8061 does not provide examples for thresholds of patient instruction and or release with occupancy factors other than 1 (for radionuclides with half -lives greater than 1-day). There appears to be a lack of harmonization between this DG-8061 and 10 CFR 35 with regards to patient release and occupancy factors.

  If the proposed occupancy factor of 1 in DG-8061 is retained, will 10 CFR 35 be amended to account for the guidance using an occupancy of only 1?

- *DG-8061, Discussion, Reason for Revision* (page 5) reads: "…provides updated guidance based on the available scientific information and data…"

  NUREG 1492 Regulatory Analysis on Criteria for the Release of Patients Administered Radioactive Material, Final Report, US NRC, 1997 provided an occupancy of 25 percent at 1 meter "based on the authors' professional judgement" and "is also supported by empirical data." Three references are provided to support use of the 25 percent occupancy. NUREG 1492 is referenced in NUREG 1556 Vol 9, Appendix U, Rev 0 (US NRC 2002), Rev 1 (US NRC 2005), and Rev 2 (US NRC 2008) and in the initial Regulatory Guide 8.39 (US NRC 1997) and Regulatory Guide 8.39 Rev 1 (US NRC 2020) continuing to support the data included in the literature.

  DG-8061 does not include NUREG 1492 as a reference. DG-8061 instead includes in its First-Tier Approach "an occupancy of 100 percent at 1 m is assumed." The rationale is presented as "overly conservative…by avoiding the underestimating of dose in likely situations." This occupancy factor (to include radionuclides with half-lives greater than 1 day) is then used to generate Tables 1 and 2. Although DG-8061 is purportedly based on available scientific information, no data or peer reviewed references are presented to support the universal use of an occupancy of 100 percent. In fact, the current occupancy factors supported by the scientific review in the current National Council on Radiation Protection and Measurements (Report No. 155) on the subject are all less than 100 percent (ranging from 25-33 percent) (See NCRP-155, Tables A.1 through A.3).

  A literature review should be performed to support this change and or offer continued support of using an occupancy factor of 25 percent for radionuclides with half-lives greater than 1-day.

- *DG-8061, Tables 1 (pages 9-10) and Table 2 (pages 11-12)*

  In addition, DG-8061 continues to refer 10 CFR 35.75(c) and 10 CFR 35.2075(a) and maintaining records if using an occupancy of less than 0.25 at 1 m. Since this occupancy (0.25) continues in the rule and DG-8061, Tables should be included using this factor.

2. References

- DG-8061, Reference 12 (page 35) (RCD Radiation Protection Associates, 2021) has an NRC reference number (ML21348A111). The only available document in the NRC Public Document Room (ADAMS) matching the reference reads as "DRAFT FOR ACMUI REVIEW."

DG-8061 should not be based on unfinalized documents. If document/reference (RCD Radiation Protection Associates, 2021) has been finalized, the final draft should be entered into ADAMS and reference 12 in DG-8061 updated accordingly. If not, the reference should be removed from DG-8061.

3. Appendix B – Patient Specific Modifying Factors and Methods

DG-8061, Section B.2 (page B-8) states “licensees cannot authorize release in accordance with 10 CFR 35.75…if it is possible that dose limits could be exceeded” while 10 CFR 35.75(a) “permits the licensee to authorized release of any individual…” if the “…exposure to the release individual is not likely to exceed 5 millisieverts.”

There seems to be a great difference in the intent of these two phrases. Is it the expectation of the NRC that licensees evaluate every possible exposure scenario, including unreasonable and unlikely ones, to ensure compliance with the 10 CFR 35.75 when committing to the methodologies in this guidance document?

Respectfully submitted,

The MSK Medical Health Physics Department