

SUNSI Review Complete

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Draft Regulatory Guide: Release of Patients Administered Radioactive Material

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

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General Comment

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I believe Proposed Revision 2 to Regulatory Guide 8.39 DG-8061 should not be accepted as written. The calculation method outlined in the guide is overly complex and burdensome. The existing guidance should be maintained and addendums for new radionuclide therapies can be added as needed. An entirely new strategy for calculating potential public dose from radiopharmaceutical therapy patients was unwarranted.