PUBLIC SUBMISSION

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Consolidated Guidance About Material Licenses: Program-Specific Guidance About Medical Use Licenses

Comment On: NRC-2016-0122-0003
Program-Specific Guidance About Medical Use Licenses; Extension of Comment Period

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Submitter Information

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General Comment

See attached file(s)

Attachments

WDE NUREG 1556 Vol Rev 3 comments

SUNSI Review Complete
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Add= *K. Tapp (KnSt)*

I support the addition of the new APPENDIX G (MODEL PROCEDURES FOR DOSE CALIBRATOR CALIBRATION), as it helps to both clarify the NRC's position regarding limits of acceptability of the various performance characteristics, as well as, provide more specific guidance to licensees as to how to perform the measurements. This information was lacking in prior regulatory documents. I also applaud the addition of the introductory paragraphs to APPENDIX U (MODEL PROCEDURES FOR RELEASE OF PATIENTS OR HUMAN RESEARCH SUBJECTS ADMINISTERED RADIOACTIVE MATERIALS), that provide additional guidance for special circumstances (e.g., setting off radiation detectors, consideration of exposures of the same persons from a patient treated more than once within a one-year period, exposure of infants or children). I have the following specific comments:

1. Page G-1, Line 20: In my opinion, a single source (typically Cs-137, due to its conveniently long half-life) is sufficient for assessing the constancy of a dose calibrator over time. Requiring measurement of multiple sources has a time cost associated with it, with no tangible benefit, based on my experience. The wording should clearly indicate that the use of multiple sources is optional.

2. Page G-1, Lines 30-31: It should be explicitly stated what is the expected result, namely, the activity of the reference source decayed to the date of measurement.

3. Page U-2, Line 7: I recommend that the units of specific gamma ray constant ($R\text{-}cm^2/mCi\text{-}h$) be explicitly stated.

4. Tables U-1 and U-2: I recommend adding Lu-177 and Ra-223, which are now commonly used.

5. Table U-5: The numbers for samarium-153 through thallium-201 are incorrect (all shifted up by one row, and those for samarium-153 are missing); and "stontium" is misspelled.

6. Page U-16, Line 8: The whole body clearance of some compounds (e.g., Sm-153 EDTMP, Lu-177 DOTATATE) are better modeled as bi-exponential. It should either be pointed out that such a model is allowed, if not generalizing Equation B-1. I also recommend adding a reference to Zanzonico PB, Siegel JA, St. Germain J. A generalized algorithm for determining the time of release and the duration of post-release radiation precautions following radionuclide therapy. Health Phys 2000;78(6):648-59.

7. Equation B-1: Tp in the exponent for e should be just T, as should Tp on Page U-17, Line 5; and in the description of T, it should be "Physical or effective". If effective, I recommend showing the equation for calculating it from Tp and Tbio, or direct the reader to Equations B-2, 3 and 4. Finally, I recommend adding that $\Gamma \times Q_o / r^2$ could be replaced by measured exposure rate (in Roentgens) at distance r (typically 100 cm or 1 m) and t=0.

8. Page U-18, Line 3: should read "physical half-life of the radionuclide or effective half-life of the radioactive material". Unless, a radionuclide is internally administered in elemental form, it is the compound to which the radionuclide is labeled that dictates the biological clearance.

9. Page U-19, in the equation for D(∞): For clarity, I recommend reformatting the units of 2.2 as "$R\text{-}cm^2/mCi\text{-}h$".

10. Equations B-2, B-3 and B-4: The "=" after T_{eff} is missing; and on Line 21, the description for T_b should be more general, i.e., "Biological half-life of the radioactive material".

11. Equation B-5: It has been suggested that two gamma constants be allowed: one for the activity in the thyroid and the other for the extrathyroidal activity. Also, the equation should support the use of measured exposure rate at r=100 cm (1 m) and t=0 instead of Γ x Qo / 100 cm^2.   It has also been argued that a simple bi-exponential without the circulating component could be employed.   (Siegel JA, Marcus CS, Stabin MG.   Licensee over-reliance on conservatisms in NRC guidance regarding the release of patients treated with I-131. Health Phys 2007;93(6):667-77.)

12. Page U-23, B.3, Internal Dose: Elsewhere, it is stated that internal dose needs to be included if it is 10% or more of the external dose.   A statement to that effect should be added here.