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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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Comment on FR Doc # 2017-01807

Submitter Information

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81 FR 87978

Name: David Reindl

General Comment

(5)

See attached file(s)

Attachments

Docket ID NRC-2016-0122 Wisconsin Comments

SUNSI Review Complete
Template = ADM – 013
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Add= K. Tapp (KNS1)

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February 9, 2017

Cindy Bladey
Office of Administration
Mail Stop: OWFN-12-H08
U.S. Nuclear Regulatory Commission
Washington, DC 20555-0001

RE: Docket ID NRC-2016-0122, comments on proposed draft NUREG-1556, Volume 9, Revision 3, "Consolidated Guidance About Materials Licenses: Program-Specific Guidance About Medical Use Licenses."

Dear Ms. Bladey,

The State of Wisconsin, Radioactive Materials Program has reviewed the above document and submits the following comments:

1. Page xvi, Line 28: Delete the SLN abbreviation, which is unnecessary. SLN is only used twice in the document, both on page 8-11. The first use of SLN has the term spelled out beforehand, and the second use could be replaced with "the biopsied".

2. Page 8-6, Line 4: Delete "at or".

3. Page 8-6, Line 5: Change "are usually" to "may be". Even if two co-located HDR units have sources exchanged on the same day, they will exceed a Category 2 quantity only for a short period of time.

4. Page 8-6, Line 13: Delete "regulated by the NRC and Agreement States". Are there any Category 1 or 2 sources *not* regulated by NRC or the Agreement States? Also page 8-8, line 12.

5. Page 8-8, Lines 5-12: Delete "The applicant should also review NUREG–2155, "Implementation Guidance for 10 CFR Part 37, 'Physical Protection of Category 1 and Category 2 Quantities of Radioactive Material,'" January 2015 and NUREG–2166, "Physical Security Best Practices for the Protection of Risk-Significant Radioactive Material," May 2014, for additional guidance implementing 10 CFR Part 37 requirements for blood irradiators" and replace with a reference to Section 8.10.24.

6. Page 8-8, Line 12: Move "Category 1 and Category 2 sources regulated by the NRC and Agreement States must be tracked in the NSTS" to Section 8.10.24.

7. Page 8-18, Lines 26-35: Is this new? Why should the licensee commit how many hours per week a consultant RSO will be onsite? Usually it will be 1 day per quarter. Why a description of how the consultant RSO will fulfill duties? This seems above and beyond what is necessary.

8. Page 8-31: The box above line 1 contains too much information. For this NUREG, the important point is that licensees who possess RSRM need to provide initial and annual security training according to 10 CFR 37.43(c). The rest of the text can be deleted.

9. General comment: There is too much specific information about Part 37 requirements. Essentially none of the Part 37 requirements result in submission for licensing. This information would be reviewed during an on-site security review (pre-licensing) or during an inspection. The purpose of NUREG-1556 is to guide applicants in filling out a license application. It is not a guide for how to be a licensee. The attention to Part 37 detail is misplaced and should be removed. There should be a general reference to the Part 37, but not repeated boxes referencing NUREG-2155 and NUREG-2166.

10. General comment: Part 37 information should be consolidated into a separate appendix. Each separate section could then just refer to the appendix, instead of repeating so much information throughout the document.

11. Page 8-82: Lines 9-13 have the same information as in the box just above line 1. This information does not need to be stated twice on the same page.

12. Page R-4: Table R-3 should include a general limit for alpha-emitters. Appendix R should also discuss considerations for performing contamination surveys in areas where alpha-emitters are used. For example, licensees need to verify their counting window to know how many of the daughter products will be counted, as this significantly affects instrument efficiency.

13. Page R-4, Table R-3: Does the note "Where surface contamination by multiple nuclides exists, the limits established for each nuclide should apply independently" apply to daughter products in equilibrium with an isotope?

14. Note: Appendix G requires linearity testing annually. This is different from what we typically expect (quarterly).

15. Appendix H details model procedures which include several "will" steps that are above and beyond what we see at sites with HDRs. For example, sites do not verify intercom systems using two people, and sites do not survey the unit prior to clearing each "interrupt" alarm. We don't think model procedures are necessary for HDRs because the requirements are so explicit in the Rule.

16. Appendix K should include a statement about instrument selection for alpha-emitting pharmaceuticals.

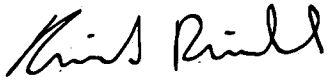
17. Appendix Q, page Q-2: Use an Equation Editor to insert the leak test equations into Appendix Q. The current equations are not lined up correctly. In Microsoft Word, use Alt+=.

18. Appendix U, pages U-6, U-8 and U-15: "stontium-89" is misspelled in Tables U-1, U-2 and U-5.

19. Appendix U, page U-9: "12.6 hours" for Tc-99m MAA is not good guidance. Please use integer numbers.

20. Appendix Z: The contamination limits on page Z-5 are not correct. In 2014, DOT raised the package contamination limits to 240 dpm/cm^2 for beta/gamma/low toxicity alpha and 24 dpm/cm^2 for all other alpha emitters.

Sincerely,



David Reindl
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Radioactive Materials Program
State of Wisconsin