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March 31, 2017

10/6/2016  
81 FR 87978

Katherine Tapp  
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U. S. Nuclear Regulatory Commission  
Washington, DC 20555

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OPPORTUNITY TO COMMENT ON DRAFT NUREG-1556, VOLUME 9, REVISION 3,  
"CONSOLIDATED GUIDANCE ABOUT MATERIALS LICENSES: PROGRAM-  
SPECIFIC GUIDANCE ABOUT MEDICAL USE LICENSES" (STC-17-010)

Dear Dr. Tapp:

The Organization of Agreement States (OAS) Executive Board (Board) has reviewed the above document and respectfully submits the following comments.

General comments:

1. 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.
2. OAS believes that adding a section explicitly to this guidance for 35.1000 uses would be beneficial. It would be appropriate to have a table of all currently licensed materials under 35.1000 and to indicate that all published guidance documents for 35.1000 uses be adhered to in commensurate means. For example, Radioactive Seed Localization often gets looked over or licensed according to brachytherapy practices, which is inappropriate. There are additional knowledge and training requirements since the sources will be retrieved and handled after implantation.

Specific Comments:

1. The NRC has removed the topic of Appendix G of NUREG-1556, Volume 9, Revision 2, i.e. "Information Needed for Transfer of Control." The draft of Volume 9, Revision 3 simply refers people to NUREG-1556, Volume 15. Unless there are overriding reasons for the removal of the current Appendix G, the topic should be retained in Revision 3. This appendix has proven to be a very convenient summary for licensees, and they have appreciated that such a summary of the information that needs to be

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Add= K. Tapp (KNSA)

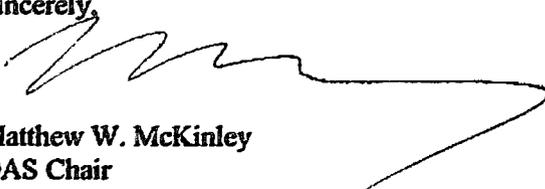
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submitted exists in the same volume that covers other aspects of medical licensing. For those people that want/need more detailed information, the current Appendix G refers them to Volume 15. In summary, the information in Appendix G, as it appears in Volume 9 Revision 2, "Information Needed for Transfer of Control," should be retained in Revision 3.

2. Page 8-85, line 18 and 19 and on page N-5, lines 19 and 20, "explanation" does not appear to be the correct word. Perhaps this should be changed to "explantation."
3. Page 8-86, line 6, only one reference to Subpart K is needed.
4. Page C-8, the last point refers to "AMP," but the rest of the list concerns "AU."
5. Appendix G requires linearity testing annually. This is different from what we typically expect (quarterly).
6. Appendix K should include a statement about instrument selection for alpha-emitting pharmaceuticals.
7. Page R-1, lines 14 and 15, it states that  $0.0025 \text{ mSv/hr} = 2.5 \text{ mrem/hr}$ . This should be  $0.025 \text{ mSv/hr} = 2.5 \text{ mrem/hr}$ .
8. Page R-4: Table R-3 should include a general limit for alpha-emitters. This limit should be determined based on the practicality of standard well counters to detect the limit within a reasonable amount of time. 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.
9. 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?
10. On page V-3, line 27, posting areas where contamination is found as a "radiation area" may not meet the definition of a "Radiation Area" as defined in 10 CFR 20. Different wording may be warranted for this page.

We appreciate the chance to comment on this subject, and stand ready to answer any questions you may have.

Sincerely,



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