

NUREG-1556, Volume 13, Revision 2 - External Comments

Comment No.	Commenter	Location in the Volume	Comment	Resolution
1	Wisconsin and Organization of Agreement States (OAS)	Various sections in Chapter 8, "Contents of an Application"	The 10 CFR Part 37 information is very distracting in the various sections in Chapter 8 and should be collected in the back of the document as an appendix. 10 CFR Part 37 applies to very few radiopharmacies.	<p>Comment not accepted:</p> <p>The NRC disagrees with the comment that 10 CFR Part 37 information should be collected in an appendix to NUREG-1556, Vol. 13, Rev. 2. The NRC determined that 10 CFR Part 37 verbiage is appropriate because there is a potential for future medical advances that could result in possession of Category 1 and Category 2 material at radiopharmacies. For this reason, the NRC disagrees with the comment and no change was made as a result.</p>
2	Wisconsin	Page 8-11, Line 5	Recommend deletion of "virtually all" in the sentence that has "...comprises the bulk of virtually all radiopharmacy activities."	<p>Comment accepted:</p> <p>The NRC agrees with the comment that "virtually all" should be removed from text.</p>
3	Washington	Page 8-11, Line 13	Recommend replacing "should" with "shall" in the following, "Radiopharmacies that plan to transfer, distribute, or redistribute licensed material to a mobile medical licensee's mobile van or coach where there is no permanent structure for byproduct material storage should describe procedures to ensure that licensed material is securely and safely provided to the mobile medical licensee." Mobile coaches are usually in high-traffic areas when operating so material security is a concern.	<p>Comment not accepted:</p> <p>The NRC disagrees with the comment that the word "should" should be replaced with "shall" at the articulated location. The word "shall" can only be used when the sentence is compliant with a regulation, which is not the case here. For that reason, the NRC disagrees with the comment and no change was made as a result.</p>

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4	Washington	Page 8-14, Line 1	Recommend replacing “should” with “shall” in the “Response from Applicant” in Section 8.6.2. As stated in the 8.6.2 “Discussion,” radiopharmaceutical preparation makes up the bulk of the activity with radioactive materials.	Comment accepted, in part: The NRC agrees, in part, with this comment about replacing “should” with “shall.” The NRC rewrote the sentence to address the comment.
5	Washington	Page 8-16, Line 13	Recommend adding “didactic training” to the following bullet, “didactic and work experience”	Comment accepted: The NRC agrees with the comment about adding “diadactic training” and added the word “training.”
6	Washington	Page 8-23, Lines 16-17	Is there a more recent document to cite than “NRC Generic Letter (GL) 95-09, “Monitoring and Training of Shippers and Carriers of Radioactive Materials,” dated November 3, 1995”?	Response to question: No. It has been verified that there is not a more recent document to cite than the referenced document.
7	Colorado	Page 8-30, Lines 29-30 and Page 8-31, Figure 8-3	Section 8.9.2, “Facilities and Equipment for PET Radiopharmacies” contains the recommendation that diagrams should be drawn to a specified scale, or dimensions that are indicated. The example given, Figure 8-3, is not drawn to a specified scale, and does not have indicated dimensions.	Comment accepted: The NRC agrees with the comment about Figure 8-3 and added verbiage to Figure 8-3 to indicate it was not drawn to scale.
8	Colorado	Page 8-41, Figure 8-4	Figure 8-4 is missing a parenthesis after 10 CFR 20.1201.	Comment accepted: The NRC agrees with this comment and added a parenthesis.
9	Wisconsin and OAS	Page 8-43, Lines 1-3	Lines 1-3 should be moved directly after Page 8-42, Lines 36-38 and not be separated by Table 8-3	Comment accepted: The NRC agrees with the comment and moved the lines so that the text is not separated by Table 8-3.

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10	Washington	Page 8-52, Lines 36-42; Page 8-53, Lines 1-6 and 35-36; and Page 8-54, Lines 1-2	What about activity measurements for alpha emitters?	<p>Comment accepted:</p> <p>The NRC agrees with the comment regarding activity measurements for alpha emitters. As a result, the NRC revised Section 8.10.8 to add more information on alpha emitters.</p>
11	Washington	Page C-21	In the "Response from Applicant", what about activity measurements for alpha emitters?	<p>Comment accepted:</p> <p>The NRC agrees with the comment regarding activity measurements for alpha emitters. As a result, language was added to the "Response from Applicant" section to address activity measurements for alpha emitters.</p>

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12	Washington	Page D-1, Table D-1	What about training for transportation, shipping and receiving, opening packages, etc. in Table D-1?	<p>Comment not accepted:</p> <p>The NRC disagrees with the comment about adding transportation, shipping and receiving, opening packages, etc. to Table C-1 (formerly Table D-1). Table C-1 is an optional format for documenting the training and experience of an Authorized User (AU) or Radiation Safety Officer (RSO). Transportation activities are usually supplemental to the primary activities of the AUs or RSO. Any individuals involved in transportation responsibilities must have proper transportation training. For these reasons, the NRC disagrees with the comment and no change was made as a result.</p>
13	Wisconsin and OAS	Page J-4	The maximum permissible contamination limits are not correct. In 2014, U.S. Department of Transportation raised the contamination limits to 240 dpm/cm ² for beta/gamma/low toxicity alphas and 24 dpm/ cm ² for other alpha emitters.	<p>Comment accepted:</p> <p>The NRC agrees with the comment regarding the U.S. Department of Transportation's (DOT's) contamination limits. These contamination limits were changed in the updated DOT transportation sheets that were added to Appendix I (formerly Appendix J).</p>

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14	Wisconsin	Page L-1, Lines 12-13	The suggested frequency for dose calibrator linearity testing (quarterly) does not match the suggested frequency in NUREG-1556, Volume 9 (Medical Use Licenses). These NUREG-1556 volumes should have the same frequency for linearity testing.	<p>Comment not accepted:</p> <p>The NRC disagrees with the comment regarding the frequency of dose calibrator linearity testing. Page K-1 (formerly L-1) is dose calibrator testing guidance for radiopharmacies. Radiopharmacies do not conduct medical use. 10 CFR 32.72(c)(1) requires, in part, that radiopharmacies periodically perform linearity tests for each instrument (e.g., dose calibrator). Applicants and licensees can use, Appendix K, "Dose Calibrator Testing Guidance" that includes doing linearity tests at least quarterly. For these reasons, the NRC disagrees with the comment and no change was made as a result.</p>

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15	Wisconsin and OAS	Appendix N	Add guidance for compounding alpha-emitting radioisotopes. This should address contamination control, in particular.	<p>Comment accepted:</p> <p>The NRC agrees with the comment regarding the addition of guidance for compounding alpha-emitters. The following language was added to a “Note” on Page M-1 of Appendix M (formerly Appendix N): “The radiation safety and ALARA guidance (including contamination control) for unsealed radioactive material for compounding alpha-emitters does not significantly differ from gamma or beta emitters; however, particular attention is warranted to prevent intakes of alpha-emitters (e.g., personal protection equipment such as masks, gloves).”</p>
16	Wisconsin and OAS	Page N-1, Lines 10-13	Consider either expanding the item in Lines 10-13 or making it more generic to incorporate other generator systems (e.g., Ga-Ge).	<p>Comment accepted:</p> <p>The NRC agrees with the comment regarding expanding the pertinent language so that it can incorporate other generator systems. The NRC added language to Appendix M (formerly Appendix N) to include other generator systems as a result.</p>

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17	Wisconsin and OAS	Page N-5, Lines 23-25	The minor spill designation should be restricted to no more than five times the lowest annual limit on intake (ALI) for each radionuclide.	<p>Comment accepted:</p> <p>The NRC agrees with the comment regarding minor spill designation restrictions. The section of Appendix M (formerly Appendix N) was modified to make it clearer that, typically, minor spills should be restricted to no more than five times the ALI for each radionuclide. As a result, the language in Appendix N was changed to incorporate the comment.</p> <p>Note: All of the values in the list were checked and verified to be five times the lowest ALI</p>
18	OAS	Page N-5, Lines 26-30	The list of nuclides listed for defining “minor spills” should be expanded to include Ga-68 at a minimum.	<p>Comment accepted:</p> <p>The NRC agrees with the comment and added Ga-68 to the list.</p> <p>In conjunction with comment 17, the five times the lowest ALI value for Gallium-68 (100 mCi) has been added to the list.</p> <p>Note: Gallium-68 has the same ALI as Thallium, so five times for this purpose is up to 100 mCi of Gallium-68.</p>
19	Wisconsin	Page N-5, Lines 41-42	In the following sentence, delete “the requirements in”: “Major spills must be reported to the U.S. Nuclear Regulatory Commission (NRC), if required by the requirements in 10 CFR 30.50.”	<p>Comment accepted:</p> <p>The NRC agrees with the comment and deleted the pertinent language.</p>

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20	Wisconsin and OAS	Appendix O	There is little existing radiopharmacy guidance for alpha surveys, including developing appropriate action levels based on ALARA considerations and the limitations of well counting equipment. Appendix O should provide more guidance specific to alpha surveying. For, example, do the action levels apply to each isotope in a decay chain separately or to the decay chain in total? What types of surveys should be performed in areas where alpha radiopharmaceuticals are compounded and how often? This NUREG should emphasize efficiency determination for performing contamination surveys for daughter isotopes in equilibrium with a parent nuclide.	<p>Comment accepted.</p> <p>The NRC agrees with the comment regarding additional language in Appendix N (formerly Appendix O) regarding alpha surveys. The NRC added information to Appendix N (formerly Appendix O) regarding alpha surveys. The contamination surveys section in this document is now consistent with other NUREG-1556 volumes as a result .</p>
21	Wisconsin and OAS	Page O-2, Lines 36-37	The sentence on Lines 36-37 states, "All areas where radioactive materials are eluted, prepared, assayed, dispensed, or packaged for transport should be surveyed daily." The guidance should specify whether daily surveys are limited to ambient radiation level surveys or whether they should also include contamination surveys.	<p>Comment accepted:</p> <p>The NRC agrees with the comment regarding whether daily surveys should be limited to ambient radiation level surveys or include contamination surveys. As a result, the NRC added verbiage to address the comment. However, the applicant or licensee should determine the type of survey to be conducted.</p>

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22	Wisconsin and OAS	Page O-3, Lines 1-2	The sentences on Lines 1-2 state, "Licensees should establish action levels for the detection of contamination. Typically, licensees establish action levels that are twice the known background radiation level." Table R.1 in NUREG-1556, Volume 13, Revision 1 which contained recommended action levels for removable surface contamination by radiopharmaceuticals should not have been removed from this appendix in the Revision 2 draft. Basing action levels on background that fluctuates with building material and location will complicate compliance determination. A risk-based action level table based on the ALI, containing information similar to the minor/major spill determination ALI information in Appendix N, should be developed for this appendix.	<p>Comment accepted, in part:</p> <p>The NRC agrees, in part, with the comment regarding establishing actions levels for the detection of contamination. As a result, Table N-2 (formerly O-2) was added regarding acceptable surface contamination levels. The guidance provides the licensee with the option of developing other appropriate action levels for the detection of contamination.</p>