

NUREG-1556, Volume 16, Revision 1 - External Comments

Comment No.	Commenter	Location in the Volume	Comment	Resolution
1	John N Gillespie, MD	General	Physician supervision was at the heart of the original approval for the position for Nurse Practitioners and Physician assistants. The current shortage of health providers for patients cannot be solved by simply up credentialing current providers, thus taking away their various regulatory boards' credentialing process. I cannot support this, while expedient may not be prudent where the care of our veterans may suffer as a result.	<p>Comment not accepted:</p> <p>This comment does not apply to Volume 16 because requirements for medical use of isotopes are set in 10 CFR Part 35, not this licensing guide.</p>
2	Virginia	General	The format for bulleted items is not consistent throughout the document. These should have a semicolon for each, an "and" on the second to last item and a period on the last bulleted item.	<p>Comment not accepted:</p> <p>The format followed NRC's style guide and the NRC's Office of Administration (ADM) guidance.</p>
3	Virginia	General	This document contains extensive information regarding the SSD process and related guidance. Recommend this information be removed and references made to NUREG-1556, Vol. 3.	<p>Comment not accepted</p> <p>The sealed source and device (SSD) guidance in this volume describes the specific requirements for generally licensed products, including, but not limited to, testing, labeling, dose, and installation. The purpose of NUREG-1556, Vol. 3 is to provide guidance on how to submit an application in order to obtain an SSD registration certificate. Therefore, the SSD information currently provided in this volume is supplemental to the other licensing information and is needed to provide complete information regarding</p>

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3 (cont.)				the general guidance for the distribution of generally licensed products.
4	Virginia	General	The title to this document is "Guidance about Licenses Authorizing Distribution to General Licensees" which leads to the assumption that it is written to the specific licensees who are distributing to general licensees but the document contains specific information to the general licensees possessing the devices. OAS recommends that either the title be changed to "Guidance on General Licensed Devices" or the information regarding the general licensees be removed and placed in a separate guidance document.	Comment not accepted: Volume 16 does address licensing for distribution starting in Section 6.1. The other information is included as background information. The name change would not fully describe the entire document.
5	Virginia	Page 2-2	Lines 4-12 are identical to the first paragraph on page 2-1. Delete on page 2-2.	Comment accepted: Revision made.
6	Virginia	Page 4-4	The note under Table 4-1 is not a sentence and is confusing. Either clarify or delete.	Comment accepted: Revise Note under Table 4-1 to read: " Note: If an Agreement State license authorizes the manufacture or installation of 10 CFR 31.5 generally licensed devices, the Agreement State licensee is granted a 10 CFR 31.6 general license to install and service the devices in NRC jurisdiction without filing for reciprocity. Other applicants who wish to install and service 10 CFR 31.5 generally licensed

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6 (cont.)				devices in NRC jurisdiction must apply for a specific license. NUREG-1556, Volume 18, "Consolidated Guidance About Materials Licenses: Program-Specific Guidance About Service Provider Licenses," provides NRC guidance to obtain a license to perform these activities."
7	Virginia	Page 5-2	Line 13 says, "The applicants will perform an SSD safety evaluation." The applicant does not perform an SSD safety evaluation, they submit the required information such that an SSD can be reviewed and approved. Rephrase the sentence.	Comment accepted: Revise Section 5.2, page 5-2, second paragraph to read: "The NRC or an Agreement State will perform an SSD safety evaluation on the devices authorized for use under 10 CFR 31.5, 10 CFR 31.7, and 10 CFR 31.10 that the applicant proposes to distribute to general licensees."
8	Virginia	Page 5-7	Line 4 uses depleted uranium as shielding in an accelerator as an example of a "small quantity of source material." Shielding in an accelerator would likely exceed the "small quantity" limit for DU. Replace with another example (e.g., thorium used for coating optical lenses.	Comment accepted: Section 5.3 on page 5-7, the example under 10 CFR 40.22 revised to read: "Example: thorium used for coating optical lenses"

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9	Wisconsin	Page 5-7	Line 4 should use a better example of a “small quantity of source material.” Shielding an accelerator would exceed the “small quantity” limit for depleted uranium. More appropriate examples could be using small amounts of depleted uranium for research and development or optical lenses containing thorium.	Comment accepted: Section 5.3 on page 5-7, the example under 10 CFR 40.22 revised to read: “Example: thorium used for coating optical lenses” (Same as Comment #8)
10	Virginia	Page 5-8	Move lines 37-40 to page 5-7 in the paragraph covering lines 12-16.	Comment not accepted: This language regarding 10 CFR 2.390 in the “Identifying and Protecting Sensitive Information” section of this NUREG is listed in this same location in the other NUREG-1556 volumes. The language is accurate and understandable where it is currently located.
11	Virginia	Page 5-9	Line 1 change “personal privacy information” to “personally identifiable information”.	Comment not accepted: This is the language used in 10 CFR 2.390 and the other NUREG-1556 volumes.
12	Wisconsin	General and Chapter 9	The revision sometimes presents information in a way that makes it difficult to follow. Specifically, in Chapter 9 the language mostly makes references to sections of 10 CFR. We think it would be more beneficial to present concise lists of the required information contained in these references so that it is more useful as a guide. This would be advantageous to both licensees and license reviewers.	Comment not accepted: Chapter 9 provides other helpful information besides the regulation references and required information which is beneficial to a license applicant and license reviewer.

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13	Washington	Page 9-2 of Section 9.1	No mention of lock-out tag-out procedures for generally licensed fixed gauges. This information should be included in the licensee's application to be able to service generally licensed fixed gauges in their possession.	<p>Comment accepted:</p> <p>For Section 9.1, third paragraph on line 26 of page 9-2: "lock-out/tag-out the device" added to the list of tasks on.</p>
14	Virginia	Page 9-8, lines 24-28	This paragraph should be removed because this information does not pertain to the GL distribution license (it pertains to the SSD application)	<p>Comment not accepted:</p> <p>Most of the relevant sections of 9.2 and 9.4 contain information related to 10 CFR Part 32, which contain the regulations for the distributor who manufactures (or imports) a device for use under the general license. Most of that information does not pertain to the general license (GL) distribution licensee but rather, to the manufacturer/distributor possession licensee. The GL distribution license does not authorize 'possession' of material; therefore all those tests etc. must be done under the possession (manufacturing/distribution) license. All of these regulatory requirements for manufacture, including registration in the sealed source and device (SSD), must be met prior to the item being allowed to be distributed.</p>

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14 (cont.)				When a GL license is issued, often the license will contain a list of the authorized devices as "Model XYZ Series" rather than a list of each of the individual sub-model numbers. Therefore, it is acceptable to state that devices can be registered as a series along with all the specific information required to be provided during the SSD review.
15	Virginia	Page 9-18, lines 23-27	This paragraph should be removed because this information does not pertain to the GL distribution license (it pertains to the SSD application)	Comment not accepted: See previous response (Comment 14).
16	Virginia	Page 9-26	On line 25, delete "industrial products and devices for use".	Comment accepted: Section 9.7, page 9-26, second paragraph: Revision: "A specific license under 10 CFR 40.54 must be obtained, in order to initially transfer source material for use under the general license in 10 CFR 40.25."
17	Virginia	Page 9-28	On line 9, delete "as approved by NRC". This is generally understood.	Comment accepted: Section 9-7, page 9-28, the second bullet: delete "as approved by NRC".

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18	Washington	Sections 11.1 and 11.2 (Revised to Sections 10.1 and 10.2)	Why not apply the thirty day notification timeline to amendment requests for change of control or bankruptcy? Specifying a time frame would help prevent loss of control of generally licensed devices during changes in control or administration of licensees.	<p>Comment not accepted:</p> <p>As noted in Section 10.2, a licensee must make an immediate notification to the appropriate NRC Regional Administrator following the filing of a voluntary or involuntary petition for bankruptcy for or against a licensee. Also, Section 10.2 does state the following: "The NRC must be notified when licensees are in bankruptcy proceedings in order to determine whether all licensed material is accounted for and adequately controlled and whether there are any public health and safety (e.g., contaminated facility) and security concerns. The NRC shares the results of its determinations with other involved entities (e.g., trustee) so that health and safety and security issues can be resolved before bankruptcy actions are completed and may request that the U.S. Department of Justice (DOJ) represent the NRC's interests in the bankruptcy proceeding." Additionally, NRC Regulatory Issue Summary (RIS) 2014-08, Rev. 1 (Referenced in</p>

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18 (cont.)				Section 10.1) notes that for most licenses and transactions, information on a proposed transfer of control should be submitted to the NRC no less than 90 days prior to the proposed transfer, not 30 days.
19	Virginia	Appendix A	Include NUREG-1556, Vol. 3 as a reference document.	Comment not accepted: Appendix A (References) was deleted from this NUREG.
20	Virginia	Page E-1 (Revised to Page D-1)	On line 9, change to "...jurisdiction who have a GL..."	Comment not accepted: Sentence completely rewritten so that "who have a" isn't needed.
21	Virginia	Page E-1 (Revised to Page D-1)	On line 35, delete "easy-to-read".	Comment accepted: Deleted the words "an easy-to-read".
22	Virginia	Page E-3 (Revised to Page D-3)	On line 10, delete "easy-to-read".	Comment accepted: Deleted the words "an easy-to-read".
23	Virginia	Appendix F (Revised to Appendix E)	Include web links to the NMSS and OAS webpage for reference	Comment partially accepted: A link to the Webpage for NRC forms is included for those wishing to electronically obtain NRC Form 653, Form 653A, and Form 653B. No Webpage was listed for the Organization of Agreement States (OAS) since no specific OAS documents are noted in Appendix E.

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24	Virginia	Appendix G (Revised to Appendix F)	Revise the regulation reference to 31.5(c)(15).	Comment not accepted: 10 CFR 31.5(c)(15) states in part, that any person who acquires, receives, possesses, uses or transfers byproduct material in a device pursuant to the general license in paragraph (a) of this section: may not hold devices that are not in use for longer than 2 years. Therefore, no revision is needed.
25	Virginia	Appendix G (Revised to Appendix F)	Remove G-3 as Appendix H is for Tritium exit signs.	Comment not accepted: Exit signs are also part of 10 CFR 31.5 GLs.
26	Virginia	Appendix K (Revised to Appendix I)	The answer to #18 should be revised to remove "The preference would be for" and state that no contamination shall be left behind by licensees.	Comment not accepted: The commenter's proposed revisions would not be in accordance with the language in the 10 CFR 40.22 regulations.
27	Virginia	Appendix L	This appendix should be removed from this NUREG, as it is not referenced by the document. The two places in the appendices that reference NRC Form 664 do not indicate that the form is included in Appendix L. NRC Form 664 does not directly pertain to distributors of GL devices.	Comment accepted: Appendix L deleted from this NUREG.