NUREG-1556, Volume 8, Revision 1 - External Comments				
Comment No.	**Commenter**	**Location in the Volume**	**Comment**	**Resolution**
1	Jena Rosenbaum	General	List of Bulk Drug Substances That Can Be Used To Compound Drug Products in Accordance With Section 503A of the Federal Food, Drug, and Cosmetic (FD&C) Act: The regulation is identifying an initial list of bulk drug substances that can used to compound drug products in accordance with certain compounding provisions of the FD&C Act. The Agency is proposing to place a six bulk drug substances on the list. I think this regulation is a good addition to 503A(c)(2) of the FD&C Act. It sets criteria to look into the dangerous substances. It requires the physical and chemical characterization of the substance, any potential safety issues raised by the use of the substance, historical use of the substance, and any available information regarding the effectiveness or lack thereof of the drug compound.	Comment acknowledged. This comment is not applicable to this guidance; therefore no change is required.

NUREG-1556, Volume 8, Revision 1 - External Comments				
Comment No.	**Commenter**	**Location in the Volume**	**Comment**	**Resolution**
2	Organization of Agreement States (OAS)	General	General comment: This document is "regulation-centered" and not "application-centered". It would be much more helpful to applicants and license reviewers if the document were "application-centered." For example, it would be easier to follow if page 9-8 said: The information submitted under 10 CFR 32.14(b)(6) on labeling must demonstrate that: • Each unit will be labeled or marked, so that the manufacturer or initial transferor of the product and the byproduct material in the product can be identified. • Each ionization chamber smoke detector will be labeled or marked and its point-of-sale package will contain more detailed information.	Comment not accepted. These exempt-distribution regulations are written in a prescriptive way for all requirements; therefore this document uses the words in the regulations ("regulation-centered") to explain the requirements instead of trying to paraphrase, in order to avoid any misinterpretation of the regulations.
3	OAS	Pages 2-1 – 2-3	The text, map and chart on pages 2-1 through 2-3 are confusing, as this volume is about exempt distribution (which does not authorize possession). Yet Table 2-1 only applies to possession. The information that only applies to possession licenses should not be in this NUREG	Comment not accepted. NRC staff have concluded that the text, map, and chart contain relevant information about regulatory jurisdiction. Also, similar versions of the text, map, and chart are contained in all recently revised NUREG-1556 volumes, as well as the previous version of NUREG-1556, Volume 8.
4	OAS	Page 2-2, Line 2	Add reference to the appropriate volume of NUREG-1556.	Comment accepted.

NUREG-1556, Volume 8, Revision 1 - External Comments				
Comment No.	**Commenter**	**Location in the Volume**	**Comment**	**Resolution**
5	Catherine Mattsen	Page 3-3, Lines 1-2	Tritium paint was never used in radiation measuring instruments. Also, the fact that quality control is required for the manufacture of some products isn't a very good example of positive safety culture, as this would be more related to the licensee's attitude reflected in how well such requirements are followed.	Comment partially accepted. The phrase "radiation measuring instruments" will be removed.
6	OAS	Page 9-1, Lines 26-28; Page 9-6, Lines 9-11, etc.	It is not clear if the intent is about having the possession license before applying for an exempt distribution license. This should be clarified.	Comment accepted. In each instance where this language is used, we will add the following sentence: "An exempt-distribution license will not be issued until a possession license has been obtained."
7	OAS	Page 9-3, Lines 37-39 and for each subsequent section	Eliminate the bullets (just use the checklist immediately below). The first bullet is too general to be useful. The checklist is excellent information for both applicants and license reviewers.	Comment accepted. In Sections 9.1 through 9.4 and 9.8, the bullets were either too general or redundant, as pointed out by this comment; therefore applicable content was revised in those Sections. This comment does not apply to all bullets in Sections 9.5 through 9.7 because most of these bullets add some information not specifically stated in the checklist.
8	Catherine Mattsen	Page 9-4; Pages 9-11 – 9-12; Pages 9-16 –	The headings added to the various checklists in Chapter 9 are inappropriate and unnecessary. In particular, "Suggested Response," is highly inappropriate as that column is a list of the specific requirements; thus, one is suggesting that the	Comment partially accepted. The text "Suggested Response" has been changed to "Response."

NUREG-1556, Volume 8, Revision 1 - External Comments				
Comment No.	**Commenter**	**Location in the Volume**	**Comment**	**Resolution**
8 (cont.)		9-17; Page 9-19: Pages 9-24 – 9-25; Page 9-29; Pages 9-35 – 9-36; and Pages 9-43 – 9-44	applicant might meet the requirements. The phrase, "suggested response," should be reserved for presenting an example of details that are expected to meet an actual requirement, rather than a statement of the requirement. It is also inconsistent with the wording used within the checklists, such as "Applicant satisfied..." and "Applicant submitted sufficient..." The phrasing of these suggests that the checklists are intended for NRC reviewers rather than applicants. (The original published document specifically stated that Checklists were for NRC use.) Also, on the checklists, the heading "Description Attached," may seem reasonable if an applicant were using the checklists to simply make sure that their submittal has addressed all of the criteria in the regulations, it gives the wrong impression to NRC reviewers who will also use the Checklists. It is important to understand that a significant amount of judgment is involved in evaluating the information submitted and not simply that the applicant has addressed all of the applicable criteria. While this comment may appear to give little credit to reviewers, all reviewers are inexperienced initially, and only a handful of staff members are ever involved with exempt-distribution licensing. Rather than revise or remove the headings and revise the above-mentioned phrasing, simply removing the checklists would be preferable, as all of the criteria in the lists are copied from the regulations and already included under the "Criteria"	One of the concepts that was considered when the revision of this volume was undertaken was to include checklists for applicants (as well as reviewers) in order to provide greater clarity regarding the requirements in the regulations. The use of the term "Description Attached" is consistent with other volumes of NUREG-1556 (see, for example, Volumes 10, Rev. 1 and Volume 11, Rev. 1).

NUREG-1556, Volume 8, Revision 1 - External Comments				
Comment No.	**Commenter**	**Location in the Volume**	**Comment**	**Resolution**
8 (cont.)			heading. The inclusion of the checklists implies that the processes of applying for a Part 32 license and of approving such applications are more simplistic than they should be.	
9	Catherine Mattsen	Page 9-4; Page 9-12; Page 9-17; Page 9-19; Page 9-25; Page 9-29; Page 9-36 and Page 9-44	Also removed from earlier drafts are statements near the end of each major subsection of Chapter 9, such as: "To confirm your understanding of your responsibilities as a licensee, you should submit the following or substantially similar statements: • "We will transfer only products that are produced consistent with all of the statements in this application as approved by the NRC and referenced in the license." • "We will conduct procedures to control the concentrations of byproduct material as outlined in this application and in accordance with 10 CFR 32.11(b)." • "We will ensure that no more than the specified concentration is introduced into the product or material, as specified in this application." • "We will ensure that the concentrations of byproduct material at the time of transfer will not exceed the concentrations in 10 CFR 30.70." • "We will maintain records and provide annual material transfer reports in accordance with 10 CFR 32.12."	Comment not accepted. These statements were removed because we generally don't ask the applicants to merely repeat the regulations in their responses for an exempt distribution materials license.

NUREG-1556, Volume 8, Revision 1 - External Comments				
Comment No.	**Commenter**	**Location in the Volume**	**Comment**	**Resolution**
9 (cont.)			It is standard licensing practice to request such statements from applicants. There is value to include such guidance here, along with the statement of the reason, i.e., to confirm one's understanding of their responsibilities. Some other volumes include such guidance.	
10	Catherine Mattsen	Pages 9-5 – 9-6, including Lines 1-8	The details of the constraints within the exemptions themselves and example products, such as in Tables 9-1 to 9-6, and on page 9-6, lines 1-8, do not conform to the title/subject of Chapter 9, "INFORMATION REQUIRED FOR SPECIFIC TYPES OF DISTRIBUTION LICENSES", and should be moved back to Chapter 4, "Applicable Regulations," as in earlier drafts of this document, or Chapter 5, as in the original published version. In addition to the fact that they don't fit the subject, their presence interrupts and bogs down the discussion of the applicable Part 32 requirements in each subsection of the chapter. While it is true that without these details in Chapter 9, one can't easily determine which subsection applies to a particular product, it is preferable to expect the potential applicant to review Chapter 4 (as well as other information appearing earlier in the document), before reviewing the details in Chapter 9. You would want the potential applicant to be aware of the other regulations that will apply as a licensee. If consistency with other volumes is a priority, moving the details of the exemption regulations and example products to Chapters 4 and 5 would follow the pattern of Volume 16.	Comments partially accepted. A table has been added to Chapter 4 that is similar to Table 4-1 in NUREG-1556, Vol. 16, Rev. 1 (Draft for Comment). However, NRC staff find this information does not appear to fit within Chapter 5. NRC staff do not agree with the comment that the tables interrupt and bog down the discussion of the applicable Part 32 requirements in each subsection of the chapter; Tables 9-1 to 9-6 were intended to clarify only 10 CFR 30.15 because it includes many different types of products. There are no similar tables in the volume for other sections in 10 CFR 30.

NUREG-1556, Volume 8, Revision 1 - External Comments				
Comment No.	**Commenter**	**Location in the Volume**	**Comment**	**Resolution**
11	Catherine Mattsen	Page 9-7, Lines 37-38	The sentence on Lines 37-38 should be deleted since it is a duplicate of the sentence on Lines 34-36	Comment accepted. NRC staff will remove the duplicate language and move the remaining sentences to the previous paragraph.
12	Catherine Mattsen	Page 9-9, Lines 18-23	This discussion replaced detailed acceptable testing procedures in earlier drafts. Including specifics that are acceptable makes it easier for applicants and staff. These procedures were determined to be acceptable, because they were previously required by the regulations. When the Commission directed the staff to remove prescriptive procedures from the regulations, it also directed the staff to provide the details as an acceptable approach in guidance. Also, when the rule changes were made, this was stated as what would be done.	Comment accepted. The original language was restored, with modifications to the original text.
13	Catherine Mattsen	Page 9-11, Lines 14 and 16	Lines 14 and 16 use the phrase “such fractions” without having established what “such” refers to. Earlier drafts included the term “rule of ratios,” which is a term of art that has apparently fallen out of use. However, the wording that replaced it needs to be clarified.	Comment accepted. “Such” was removed from both sentences.
14	OAS	Page 9-13, Lines 22-30	The discussion of what constitutes “commercial distribution” is confusing. Please clarify.	Comment not accepted. The paragraph explains what is meant by “commercial distribution.” See the sentence beginning on line 27: “The commercial transfer of a product refers to the introduction of a material into the marketplace, whether or not a charge is assessed for that distribution.”

NUREG-1556, Volume 8, Revision 1 - External Comments				
Comment No.	**Commenter**	**Location in the Volume**	**Comment**	**Resolution**
14 (cont.)			For example, if a licensed service provider calibrates survey instruments, do they need an exempt distribution license to attach a check source to the side of a client's instrument? Is this "introducing a material into the marketplace?"	The applicant and/or the reviewer should consult the regulations to determine what is authorized. In this specific case, the check source cannot be redistributed because of the regulation in 10 CFR 30.18(c) which states “This section does not authorize for purposes of commercial distribution the production, packaging, repackaging, or transfer of byproduct material or the incorporation of byproduct material into products intended for commercial distribution.”
15	Catherine Mattsen	Page 9-17, Lines 19, 23, and 25	New paragraphs should be started with the sentences beginning on Lines 19 and 25. Also, in Lines 23 and 25, sentences are not supposed to start with numbers. These should be worded as other references to paragraphs of the regulations that begin a sentence.	Comment accepted. These appear to be mistakes made in editing.
16	Catherine Mattsen	Page C-1, Lines 24-26	Reader should instead be referred to Section 5.6 of this volume, which includes the same guidance as NUREG-1556, Volume 16, Section 5.5.	Comment accepted. The applicable text was revised.
17	Catherine Mattsen	Page E-1, Lines 18-31	In Appendix E, the importance of the safety criteria associated with the class exemptions needs to be fully but concisely explained in a place where it will remain and be seen by those implementing these regulations. (License reviewers don’t routinely review “Statements of Consideration” for rulemaking; nor do applicants.)	Comment accepted. These paragraphs were deleted because of an internal comment; however, upon reconsideration, we believe these paragraphs provide important background information, and do not describe any additional

NUREG-1556, Volume 8, Revision 1 - External Comments				
Comment No.	**Commenter**	**Location in the Volume**	**Comment**	**Resolution**
17 (cont.)			In earlier drafts of Volume 8, the following was included (as the third section, after "Safety criteria" and before "Dose assessments."): "Importance of the safety criteria" For the applicant developing a dose assessment and for a license (or registration certificate) reviewer, a number of questions must be answered appropriately. The process of analyzing whether a product meets the safety criteria for a class exemption is the key step in ensuring that the public health and safety and the environment are adequately protected. Issuing a license for distribution of a product for use under exemption (and the associated registration certificate) comes under the categorical exclusion in 10 CFR 51.22(c)(14)(i), meaning that an environmental assessment is not normally required for this action. This categorical exclusion, when applied to a product to be distributed under a class exemption, relies on the appropriate implementation of the requirements associated with the safety criteria. For comparison, if a manufacturer wanted to develop a product to be used under exemption from licensing that does not come under an existing exemption, the manufacturer would have to prepare a petition for rulemaking (in accordance with 10 CFR 2.802, "Petition for rulemaking") and submit with it an environmental report (in accordance with 10 CFR 51.68, "Environmental report - rulemaking").	requirements. They should be included in the final text. To better represent the intention of including this information, the title of this section will be changed to "Background Information Regarding Criterion for Categorical Exclusion."

NUREG-1556, Volume 8, Revision 1 - External Comments				
Comment No.	**Commenter**	**Location in the Volume**	**Comment**	**Resolution**
17 (cont.)			If the NRC determined that the petitioner made an adequate case for considering the request in rulemaking, the NRC would conduct a notice and comment rulemaking[1]. In accordance with 10 CFR Part 51, "Environmental Protection Regulations for Domestic Licensing and Related Regulatory Functions," the NRC would prepare an environmental assessment and, depending on the findings of that, possibly an environmental impact statement. Rulemaking also involves a careful weighing of costs and benefits as documented in a regulatory analysis. On the other hand, in the case of a product to be approved for use under a class exemption, the safety criteria are intended to ensure that the use of the product represents a justified practice and that the health, safety, and environmental impacts are appropriately controlled. The safety criteria for the various class exemptions are similar but tailored to the particular class of products covered." This explanation should be included in the final revision of Volume 8. 1 i.e., develop and publish a proposed rule for public comment, consider the comments, adjust the provisions proposed as appropriate, respond to the comments in a final rule, which is also published in the *Federal Register*.	

NUREG-1556, Volume 8, Revision 1 - External Comments				
Comment No.	**Commenter**	**Location in the Volume**	**Comment**	**Resolution**
18	Catherine Mattsen	Page E-4, Lines 33-35 and Pages E-5 and E-6	The introductory language for the checklists that ended up in Appendix E, particularly in the case of page E-4, Lines 33-35, is confusing as to how it is envisioned such checklists will be used. This wording suggests that the NRC staff would check the boxes and provide the checklist to the applicant. These checklists may also be misleading as it may be necessary to address more than one accident scenario within a particular category, such as potential accidents during distribution. These might include warehouse fires and truck accidents, for example. However, if the checklists in Chapter 9 are retained, these should be also.	Comments partially accepted. The language as it appears on page E-4, lines 33-34, has been changed for other reasons; namely, “your” has been replaced by “the”; therefore NRC staff find that the sentence no longer suggests that the reviewer will provide the checklists to the applicant (“you”). NRC staff will add a sentence to say: “The applicant should use as many copies of these checklists as necessary to cover all of the accident scenarios.”