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General Comment

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Attachments

comments on NUREG-1556, Vol. 8

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SUBJECT: NRC-2016-0227; DRAFT NUREG-1556, VOLUME 8

1. 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.

2. 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 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" 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.

3. The introductory language for the checklists that ended up in Appendix E, particularly in the case of page E-4, lines 33-34, 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.

4. As the author of Appendix E and the originator of the broadest class exemption (10 CFR 30.22), I am concerned that 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 Considerations for rulemaking; nor do applicants.)

In earlier drafts, 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"). 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

[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*.

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.

5. 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."

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.

6. Concerning 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.

7. On page 9-11, 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.

8. Page C-1, lines 24-26. Readers should instead be referred to Section 5.6 of this volume, which includes the same guidance as Vol. 16, Section 5.5.

9. Page 3-3, lines 1-2, I do not believe that tritium paint was ever 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.

10. Page 9-7, lines 37-38 mostly need to be deleted as they duplicate lines 34-36.

11. Page 9-17, 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.

Catherine Mattsen