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Polymer (Polycarbonate or Polyester) Track Etch (PCTE) Membranes in 10 CFR 30.15

Comment On: NRC-2015-0017-0002
Items Containing Byproduct Material Incidental to Production

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General Comment

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Comments on Proposed New ICBMIP Rules

1) Recommend deleting ", or applied to," in 10 CFR 30.23(e). Including "or applied to" in 30.23(e) would likely require irradiated gemstone licensees to continue to obtain an exemption from the regulations (i.e. 30.23(e)) since the NRC has previously stated that irradiated gemstones are "applied to human beings" (see information provided in NUREG-1556, Volume 8, Revision 1, Appendix C, "Content of Application", Section E (Page C-9)). This will result in additional burden to gemstone (and other ICBMIP) applicants and NRC reviewers without additional safety benefit. The "or applied to" in 30.23 is not needed since an irradiated gemstone (or other ICBMIP) applicant will need to provide sufficient information in their application to show that any external radiation dose and committed dose (including skin dose) meets all of the safety criteria described in 10 CFR 32.34 and this information will be evaluated by the NRC license reviewer before a specific license is issued per 10 CFR 32.33.

2) Change "10 CFR 30.16" to "10 CFR 30.23" in 10 CFR 32.35(c)(2) and (c)(3).

3) Add ", if applicable" after "model number(s) in 10 CFR 32.35(c)(3)(i) and model number in (c)(3)(ii). Not every ICBMIP item/product will have a model number (e.g., gemstones). Also, this will align with the language in the proposed guidance for this rulemaking (see footnote 2 on Page 4 of the proposed guidance).

Comments on "Guidance for the Proposed Rule "Items Containing Byproduct Material Incidental to Production"

1) Delete "or source" in "3. Indicate if no transfers of byproduct or source material..." (see Page 4 of guidance). ICBMIP only includes byproduct material and not source material.

2) Delete "from the unshielded source" in the following sentence, "Specifically, the dose to a person who spends 1,000 hours at 1 meter from the unshielded source..." (see last paragraph on Page 5). ICBMIP should not contain sources.

3) Change "subsection" to "information" and "it" to "NUREG-1717" in the following, "Additional information about the use of NUREG-1717 is provided in the following subsection. Although it provides..." (see paragraph above Note on Page 6). Changes clarify information provided.

4) Delete the following sentence, "Servicing covered by the exemption, however, does not include refurbishment or replacement of a source and redistribution; these activities must take place under an applicable distribution license." (see Note at end of Page 6 and top of Page 7). ICBMIP should not contain a source.

5) Change "distributor" to "applicant or licensee" and add "or licensee" after "applicant" (see first full paragraph on Page 7). Distributors are a subset of potential ICBMIP specific license applicants or licensees.

6) Change "(10 CFR 32.32(b))" to "(10 CFR 32.33(b))" (see end of second full paragraph on Page 7). Incorrect citation.

7) Change "(10 CFR 32.33)" to "(10 CFR 32.34)" (see end of third full paragraph on Page 7). Incorrect citation.

8) Change "above" to "previously and in 10 CFR 32.34" in the following sentence, "Prototype tests are important in demonstrating that the product will meet the criterion noted above and..." (see start of fourth full paragraph on Page 7). Change clarifies information provided.

9) Change "10 CFR 32.23(a) and (b)" to "10 CFR 32.34(a) and (b)" in the following sentence, "...package for each of the scenarios described in 10 CFR 32.23(a) and (b)." (see first sentence in last paragraph on Page 8). Incorrect citation.

10) Add the following rows after "Recycle" (Normal Conditions) in the checklist at the top of Page 9, "Exposure to item 1,000 hours at 1 meter", "Intake of 10-4 of BPM in item (or 10% of tritium)"(make -4 a superscript), and "Skin dose from item in pocket for 80 hours (if possible)". Additions reflect requirements in 10 CFR 32.34(b).

11) Change "this paragraph" to "10 CFR 32.34(a)(3)" in the following, "10 CFR 32.34 stated it is the intent of this paragraph..." (see Note below checklist on Page 9). Change clarifies information provided.

12) Change "product" to "item" in Checklist on Page 10 for Items B1, B3 (only first use of "product"), B7, and B9. Change aligns with language in 10 CFR 32.33(a)(2).

13) Add footnote description for footnote shown in Item B10 in Checklist on Page 10.

14) Change "dose commitment" to "committed dose" and delete "(Use table in Appendix E of this NUREG)" in Item B12 of the Checklist on Page 10. "Committed dose" aligns with language used throughout guidance and there is no Appendix E in this guidance.

15) Delete "Containment, shielding, and other" at the beginning of Item C of the Checklist on Page 10. ICBMIP should not have containments or shielding.

16) Change "(Use table in Appendix E of this NUREG" to "(See Checklist on Pages 8 and 9)" (see Item D in Checklist on Page 10). Aligns with location of applicable checklist.

Additional comments on guidance in followup comment.

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Additional comments on "Guidance for the Proposed Rule "Items Containing Byproduct Material Incidental to Production"

17) Change "(Refer to Section 5.6, Foreign Vendors)" to "(Refer to NUREG-1556, Volume 8, Rev. 1, Section 5.6, "Foreign Vendors)" (see third paragraph in Page A1 of Appendix A). There is no Section 5.6 in the proposed guidance.

18) Delete Section 6.a. and b. on Page A5 of Appendix A. The information regarding identification of radionuclides is not needed since the new proposed rule focuses on dose and not on byproduct material concentrations.

19) Add "or absorption" after "or inhalation" in the following, "... cosmetic, drug, or other commodity or product designed for ingestion or inhalation by a human being." (see first paragraph 3 on Page A7 of Appendix A). Reflects addition of "or absorbed by" in proposed 10 CFR 30.23.

20) Delete "location of work for the importer" in the following, "In this case, the contact organization's identity, mailing address, location of work for the importer, etc., must be..." (see paragraph under Section D, "Information on Quality Assurance (QA) Program" on Page A7 of Appendix A). This is not a good example for what must be provided and would only be applicable for importers of gems.

21) Delete 4.a., "After each irradiation, measurements performed on gemstones are adequate to identify all induced radionuclides" on Page A8 of Appendix A. Sentence 4.b. should address the proposed dose criteria required by the new proposed regulations.

22) Should the following information on Pages E-1 and E-2 of Appendix E of NUREG-1556, Volume 8, Rev. 1 be added to the guidance for the proposed rule, "The type of exemption described in 10 CFR 30.23 is referred to as a "class exemption." Class exemptions are not limited to certain quantities of certain radionuclides as is typical for product-specific exemptions. Issuing a license for distribution of a product for use under exemption 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."

END OF COMMENTS