Comments on the proposed rule of June 27, 2022 [NRC-2015-0017]

1. My most significant issue with the proposed rule is the proposed normal use criterion of 5 mrem/year (§ 32.34(a)(1)). [Pardon my neglect of the Sievert.] This is not consistent with the consumer product policy nor with the considerations behind the other class exemptions. As this is a relatively open ended provision, allowing for unknown future products with potentially limited societal benefits, and which will be applied to irradiated gemstones, the normal use criterion should be the lowest amongst the class exemption provisions.

There is more to the consumer product policy than the general criterion of a small fraction of the public dose limit. There are other considerations mostly involving cost/benefit balancing. Applying a 5 mrem/yr limit to gemstones would be highly inconsistent with the normal use criterion applied to self-luminous products of 1 mrem/year. That exemption also includes § 30.19(c), which excludes frivolous products, and toys and adornments. A normal use criterion applied to gemstones should clearly not exceed 1 mrem/yr, and something lower should be considered. If 1 mrem/yr is chosen (rather than something lower), it would be along the line of a negligible individual risk level or de minimis consideration. Let me also note that 5 mrem/yr is the normal use criterion for gas and aerosol detectors whose benefit is saving lives. Both that provision and the self-luminous product exemption were established when the public dose limit was 500 mrem/yr and the original consumer product policy also said "small fraction" of that. The revision of the policy in 2014 was an update and not a policy shift.

The known application of polycarbonate track edged (PCTE) membranes is not a consumer product and should be covered by a different normal use criterion if the group of individuals likely to be the most exposed during use of the product are at work. The 5 mrem/yr criterion might be appropriate for that. Note, in both of these cases, there are not clearly defined finished products in that the doses after the point of release from the distribution licensee will depend on conditions in the individual license concerning the shape and size of the product (for example will the largest rolls of membranes produced be releasable as is), the amount of time provided for decay prior to release, and required measurements of dose rates to ensure the safety criteria are met. This will introduce uncertainties in the dose analyses. This could be a reason for maintaining the 5 mrem/yr criterion even though the industrial device exemption allows for up to 20 mrem/yr. Also, if it was adequately determined that this is a practical criterion for this application in developing the proposed rule, there would be no reason to raise it. As to allowing more leeway for future products currently unforeseen, the societal benefits may be limited and less than that provided by existing products covered by exemption such as industrial devices.

If criteria for use are split as suggested for members of the public and those occupationally exposed, a criterion similar to § 32.30(c)(2) should be added for

when estimated doses are coming under the higher normal use dose criterion. This would be combined with proposed § 32.33(a)(3).

2. While it is best to follow the pattern in the writing of safety criteria presented by the existing class exemptions to the extent that they are appropriate, more adaptation to the new class of products should be made. The misuse provision in proposed § 32.34(b) seems inappropriate for application to external exposure from gemstones in that an "unlikely" scenario of 1000 hours at an average distance of 1 meter may result in a lower dose than the normal use of gemstones. This is also true of having something in one's pocket for 80 hours. It is not inconceivable that a gemstone would be worn many hours per year close to the skin and even in contact in some situations. (I wear a ring 24/7/365 although the stones are small.) These criteria are to control the maximum dose from unlikely events as opposed to routine exposures from use. It is not mentioned in the proposed rule statement of considerations or the regulatory basis document whether consideration was given to whether the dose criteria are adequate for normal use of gemstones or whether there should be an additional skin dose criterion. Such a possibility should at least be discussed.

The existing safety criteria for the most part apply to discrete sources incorporated into a device. Self-luminous products are the least shielded, but are contained sources. Would one conceive of an item irradiated and incidentally activated during production being incorporated into a device, which then provides containment and shielding, and possibly safety features? This should be considered in deciding whether the misuse criteria are even needed and, if so, the most appropriate criteria.

3. Along this line: because the products being covered are not necessarily distinct units, there are provisions that may or may not be appropriate, such as prototype testing, the use of model numbers. In some cases, discussion recognizes this in the case of prototype testing, but the text does not. For those things that may not apply to all products, the text should include such phrases as, "if applicable" or "if appropriate." Without this, not addressing these things in an application would require an exemption from the particular requirement to be made in the licensing action, rather than just consideration and decision.

Similarly, mention of "safety features" should likely say "any safety features." Are there processes involved in the manufacture of the known products that are not necessary but are important to reducing exposures, such as washing surfaces to remove some of the contamination? That would not be a "safety feature," but could be important to safety. If so, the language should somewhere account for that.

Concerning § 32.33(a)(2)(x): this wording is the same as similar provisions, which, for example, cover the actual individual box in which a smoke detector comes to the individual user (member of the public). Is it envisioned that any individual gemstone or small package of PCTEs will be required to be contained in something

each user would receive. If practical, this would be appropriate, but it may not be. If not, the wording should be different and what is envisioned should be discussed in the SOC.

Are the criteria in § 32.23(a)(2)(vi) the most appropriate for an product like gemstones, which are routinely closer than 5 cm from the skin when worn or handled?

There are probably more appropriate words than "construction and design" in § 32.33(a)(2)(v) to describe what is needed here. Maybe "processing" could address the point made in the second paragraph in this comment.

4. Throughout the package for the rulemaking, including the Regulatory Analysis and the Environmental Impact Assessment, the alternative to not taking the proposed action is that products (except gemstones) would be covered by future product specific exemptions. Doing so allows for the analyses to say that there are no impacts on the public or on public health. (Although assuming that a product becomes exempt one way or another doesn't really ensure that doses would be the same, only that they would be acceptable.) It also allows for costs and benefits to more easily be turned into dollar amounts, no matter how uncertain.

It needs to be recognized that without this exemption, some potential future products for which use under exemption is the only practical approach will not be realized, which means that the public (and industry) would not experience any associated potential benefits, nor would there be resulting exposures (albeit ones that would be limited and acceptable under the regulatory provisions). Such impacts cannot be quantified, but should be recognized.

The cost/benefit balancing for establishing an exemption (for a product that would otherwise not be manufactured and used) is primarily about the benefits to society from use of the product vs. the resultant exposures. The Statement of Considerations, as well as the rest of the package, is lacking adequate discussion of such considerations. Maybe many readers are so bogged down with the vast amount of boilerplate, that they miss this fact. Also, the desire to follow guidance about ridiculously detailed cost analyses no matter the nature of the issue at hand leads the agency to avoid discussing factors that are difficult to quantify.

Note that even if something had previously been allowed through a licensing action, the level of justification for rulemaking is not diminished; establishing standards in the regulations, which then apply across the board, should be provided with the most robust analysis. Important considerations should not be glossed over because they may be difficult or impossible to quantify.

5. The proposed text of the rule should be more consistent with respect to the use of the terms "item," "product," and "unit," although not necessarily using just one of these throughout. For the types of product envisioned, "unit" may be inappropriate;

"product" would seem most appropriate in most cases. PCTE membranes are manufactured in large rolls and cut to varying degrees for use. Gemstones may be cut or divided after irradiation.

Also, "10 CFR" is used in some places, the section symbol in others. The section symbol should be used throughout consistent with the rest of Part 32. (As all of NRC's regulations are in Title 10, there is no need to clarify this by writing it out.)

6. It was totally inappropriate that gemstones and silicon chips were not mentioned in the Summary of the proposed rule. The Summary serves to put the reader on notice as to what this rule is about so that they can decide whether to read on. Clearly, gemstones would be of more interest to the public than PCTEs.

7. In proposed § 30.23(e), the words "applied to a human being," could be interpreted so as to restrict the use of gemstones. The intent of this paragraph otherwise seems to be to prevent intakes. Is the restriction against application to human beings also for that purpose? Should it be taken to mean implants? If so, clarification would be helpful. The SOC notes that when allowing gemstones to be distributed under § 32.11, the Commission had used an exemption from essentially these same words contained in paragraph (c). This should not be necessary.

8. In the Regulatory Analysis, page 9, 6.3, and maybe elsewhere in the package, it says that the industry "prefers" membranes made through irradiation. It should instead be pointed out that the more uniform pore size and distribution present significant benefit to the industries that use these membranes.

9. There should not be editorial differences in the Part 32 requirements applicable to the other distribution provisions for use under class exemptions that do not represent actual differences appropriate for the different types of products covered. This might suggest differences in meaning where there are none intended. For example, § 32.33 (a) (introductory paragraph) should say, "….for sale or distribution such products **for use** under…" This is actually an important clarification.

Also, the words of § 32.31(a)(1), "In normal use, handling, and storage…" are well understood without the repeating of "normal." (§ 32.34(a)(1))

In § 32.33(a)(1), "provided that" is not an improvement over, "However." It is more commonly used for a restriction rather than an exception.

10. A comparable paragraph to § 32.32(b)(3) should be included in § 32.35(b) even though nothing additional is envisioned at this time. If so, § 32.33(a)(2)(x) should reference it, such as in § 32.30(b)(10).

11. In SOC, II. Background, A., it says, "The incidental radioactivity of these products presents a small fraction, less than a few hundredths, of the public dose limits." Is this true immediately after the irradiation or at some point when the product is

assumed to be released? The Regulatory Analyses, I believe, talks more generally about the products covered by the proposed exemption containing a minor amount of residual radiation incidental to the production process. In the case of irradiated, activated products, at least, the level of radioactivity is not necessarily small when initially irradiated, but must be held to allow for decay prior to release for use without further regulatory control. Care should be taken when describing the low levels expected to be in subject products when there are procedures that will be required under the license to ensure that the levels are appropriately low when transferred from under the license.

12. In § 32.35(c)(2) and (3), "30.16" should be "30.23."

In spite of my significant number of comments, I do believe that this rulemaking should proceed in a timely way and that the overall approach is optimal.

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