

NUCLEAR REGULATORY COMMISSION

10 CFR Part 32

[Docket No. PRM-32-8; NRC-2013-0078]

Commercial Distribution of Tritium Markers

AGENCY: U.S. Nuclear Regulatory Commission.

ACTION: Petition for rulemaking; denial.

SUMMARY: The U.S. Nuclear Regulatory Commission (NRC) is denying a petition for rulemaking (PRM), dated December 2, 2011, which was filed with the NRC by CampCo (the petitioner) and supplemented with additional information on September 18, 2012. The petitioner requests the NRC to amend its regulations that govern the licensing of products containing byproduct material to allow the commercial distribution of tritium markers for use under an exemption from licensing requirements. The NRC is denying the petition because the petitioner fails to demonstrate that a specific exemption is warranted and that the existing regulatory framework for self-luminous products is insufficient.

DATES: The docket for the petition for rulemaking, PRM-32-8, is closed on **[INSERT DATE OF PUBLICATION IN THE *FEDERAL REGISTER*]**.

ADDRESSES: Please refer to Docket ID **NRC–2013–0078** when contacting the NRC about the availability of information regarding this petition. You can obtain publicly-available documents related to the petition using any of the following methods:

- **Federal Rulemaking Web site:** Go to <http://www.regulations.gov> and search on the petition Docket ID **NRC–2013–0078**. Address questions about NRC dockets to Carol Gallagher; telephone: 301-287-3422; e-mail: Carol.Gallagher@nrc.gov. For technical questions, contact the individual listed in the FOR FURTHER INFORMATION CONTACT section of this document.

- **NRC’s Agencywide Documents Access and Management System (ADAMS):** You may obtain publicly-available documents online in the ADAMS Public Documents collection at <http://www.nrc.gov/reading-rm/adams.html>. To begin the search, select “[ADAMS Public Documents](#)” and then select “[Begin Web-based ADAMS Search](#).” For problems with ADAMS, please contact the NRC’s Public Document Room (PDR) reference staff at 1-800-397-4209, 301-415-4737, or by e-mail to pdresource@nrc.gov. The ADAMS accession number for each document referenced in this document (if that document is available in ADAMS) is provided the first time that a document is referenced.

- **NRC’s PDR:** You may examine and purchase copies of public documents at the NRC’s PDR, Room O1-F21, One White Flint North, 11555 Rockville Pike, Rockville, Maryland 20852.

FOR FURTHER INFORMATION CONTACT: Vanessa Cox, Office of Nuclear Material Safety and Safeguards, U.S. Nuclear Regulatory Commission, Washington, DC 20555–0001; telephone: 301-415–8342; e-mail: Vanessa.Cox@nrc.gov.

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I. The Petition.

Section 2.802 of Title 10 of the *Code of Federal Regulations* (10 CFR), “Petition for rulemaking,” provides an opportunity for any interested person to petition the Commission to issue, amend, or rescind any regulation. The NRC received a petition from Motti Slodowitz on behalf of CampCo (the petitioner) dated December 2, 2011 (ADAMS Accession No. ML12132A332). The petition requests that the NRC amend certain regulations concerning exemptions from licensing for products containing byproduct material to include illumination tritium markers.

On July 5, 2012 (ADAMS Accession No. ML121580046), the NRC requested supplemental information to further clarify the request. On September 18, 2012 (ADAMS Accession No. ML13112B010), the petitioner responded to the NRC’s request and submitted supplemental information clarifying that the petitioner is requesting the NRC to amend paragraph (b) of 10 CFR 32.22, “Self-luminous products containing tritium, krypton-85 or promethium-147: Requirements for license to manufacture, process, produce, or initially transfer”; paragraph (c) of 10 CFR 30.19, “Self-luminous products containing tritium, krypton-85,

or promethium-147”; and 10 CFR 30.15, “Certain items containing byproduct material.” The petitioner also provided a dose assessment for the purpose of showing that the tritium markers would result in acceptably low doses.

The petitioner requests that the NRC amend 10 CFR 32.22(b) to include an additional requirement stating that an applicant cannot be denied a device registration or distribution license if they have adequately demonstrated that the criteria in applicable regulations have been met. The petitioner contends that the statement in 10 CFR 32.22(b), that “the Commission may deny an application for a specific license if the end uses of the product cannot be reasonably foreseen,” is a subjective statement without specific criteria and that it is unfair to deny applications based upon subjective statements where the criteria are not codified in the regulations. The petitioner references a Memorandum on Scientific Integrity issued by President Obama on March 9, 2009, which states that “[s]cience and the scientific process must inform and guide decisions of [the] Administration on a wide range of issues, including improvement of public health.” The petitioner notes that the NRC has previously denied approval of products because end uses of the product could not reasonably be foreseen. The petitioner also states that the term “frivolous use,” as used in the NRC’s policy statement on consumer products (March 16, 1965, 30 FR 3462; proposed revision October 14, 2011, 76 FR 63957) and in the NRC’s guidance for materials licenses (NUREG–1556, Volume 3, Revision 1, “Consolidated Guidance About Materials Licenses: Applications for Sealed Source and Device Evaluation and Registration),” (ADAMS Accession No. ML041340618) is not clearly defined and that there are no detailed criteria used to make determinations. The petitioner asserts that the potential misuse of a tritium marker as a toy should not result in the product being banned outright.

The petitioner requests that the NRC also amend 10 CFR 30.19(c) to add that tritium markers used to label equipment are not considered to be toys or adornments and shall not be sold as such.

The petitioner also requests that the NRC amend 10 CFR 30.15 to add a specific exemption for tritium markers with a maximum activity of 25 millicuries (925 mBq) of tritium. The petitioner believes an exemption is warranted because of the usefulness of the tritium markers and the low dose potential. The petitioner states that the markers would not be a frivolous use of radioactive material, and that “the potential radiation doses to members of the public under normal use and accident conditions...are within regulatory limits.” The petitioner also states that the markers are sold in other countries and have practical benefit such as helping military personnel recover lost items, helping first responders locate tagged equipment at night, assisting hunters in finding lost items, and helping lost campers find their tents.

II. Public Comments on the Petition.

The notice of receipt published in the *Federal Register* (July 11, 2013; 78 FR 41720), invited interested persons to submit comments. The comment period closed on September 24, 2013. The NRC received one public comment opposing the petition. The commenter states:

“An interest in record keeping in the known supply of tritium should be recognized since tritium may, in some cases, be the only useful tracer for a smuggled weapon. An unrecorded presence of legitimately obtained tritium may lead to too many false positives during a crisis.”

Although the NRC is denying the petition, the NRC disagrees with the commenter that the presence of tritium in approved consumer products would negatively affect law enforcement efforts to track illegal weapons.

III. Discussion.

The NRC regulates consumer products containing byproduct material without imposing regulatory controls on the consumer–user. Those who manufacture or distribute products containing byproduct material, including consumer products, must have a license issued under 10 CFR part 32. Exemptions for users of products containing byproduct material appear in 10 CFR part 30. These exemptions are either product-specific or class exemptions.

A class exemption covers a class of products, for which a person who wishes to manufacture or distribute a specific product within that class may submit a license application. An applicant must provide safety information about the product and demonstrate that the product meets a number of safety criteria. Exemption of a product under a class exemption is dependent on approval under the applicable regulations for the distributor.

Section 30.19 is a class exemption for the receipt, possession, use, transfer, ownership, or acquisition of self-luminous products containing certain radionuclides, including tritium. This exemption does not apply to persons who manufacture, process, produce, or initially transfer such products for sale or distribution. Paragraph (c) in 10 CFR 30.19 states that the exemption for products containing tritium, krypton–85, or promethium–147 does not apply to products primarily for frivolous purposes or in toys or adornments. Those who wish to distribute self-luminous products covered by the 10 CFR 30.19 class exemption must first apply for and receive a specific license under 10 CFR 32.22 and must have the product registered under 10 CFR 32.210. Applicants for licenses under 10 CFR 32.22 must also demonstrate that the

product is designed and manufactured in accordance with the safety criteria in 10 CFR 32.23.

Paragraph 32.22(b) further indicates that the Commission may deny an application for a specific license if the end uses of the product cannot be reasonably foreseen.

Section 30.15 provides a list of product-specific exemptions for certain products containing byproduct material, subject to certain limits including specific radionuclide quantity limits. The receipt, possession, use, transfer, ownership, and acquisition of these products, which includes self-luminous timepieces, hands, and dials, are exempt from licensing requirements. Persons wishing to apply or incorporate byproduct material into these products or initially transfer them for sale or distribution must apply for a specific license under 10 CFR 32.14. Unlike products covered by the 10 CFR 30.19 class exemption, specific products listed in 10 CFR 30.15 do not need to be registered under 10 CFR 32.210 in order for one to obtain a specific license for distribution.

NRC's Consumer Product Policy Statement (CPPS or policy) (January 16, 2014; 79 FR 2907) provides the Commission's policy with respect to approval of the use of byproduct, source, and special nuclear material in products intended for use by the general public (consumer products) without the imposition of regulatory controls on the consumer-user. The revision of the consumer product policy statement was finalized after the petition was filed.

Petitioner's Requests

Request 1

The petitioner requests that the NRC amend 10 CFR 32.22(b) to include a statement that an applicant cannot be denied a device registration or distribution license if they have adequately demonstrated that the criteria in the applicable regulations have been met.

Response to Petitioner's Request 1

Paragraph 32.22(b) allows the NRC to exercise its judgment in denying a license application when the end use of a product cannot be reasonably foreseen. The requested amendment would affect all future applications for a license under this section and would revoke the NRC's ability to deny an applicant based on whether a practice (in this case, the distribution of certain products for use by the general public) is justified. Being able to project the likely uses of a product also impacts the ability to fully assess potential exposures of people to radiation and to determine acceptable prototype testing to reflect the conditions of use. If granted, this revision would restrict the NRC's authority. Furthermore, this suggested revision would make 10 CFR 32.22(b) internally inconsistent and essentially would nullify it.

Such a revision would be inconsistent with the NRC's Consumer Product Policy Statement, revised in January 2014. In response to a public comment that discussed the issue of being able to foresee the end uses of products, the Commission explicitly stated the importance of evaluating products "on a case-by-case basis," listing a number of considerations such as likely doses, the probability and severity of accidents and misuse, and the benefits to be obtained from the product, noting that these cannot be reasonably evaluated if the ultimate uses of the product are not known (79 FR 2910). The Commission addressed the importance of this particular regulatory criterion that allows the denial of a distribution license for a product whose end uses cannot be reasonably foreseen, stating "[s]elf-luminous products in particular have a wide range of potential applications and might easily be widely used for purposes other than those originally intended if not clearly designed for a specific use. This criterion also ensures that the uses . . . of radioactive material in products are justified." *Id.* Therefore, the NRC is reserving the right to exercise its judgment in denying a license application when the end use of a product cannot be reasonably foreseen.

Request 2

The petitioner requests that the NRC amend 10 CFR 30.19(c) to add that tritium markers used to label equipment are not considered to be toys or adornments and shall not be sold as such.

Response to Petitioner's Request 2

Paragraph 30.19(c) already states that the exemption does not cover toys or adornments. The requested amendment stating that the tritium markers "shall not be sold" as toys or adornments would not further control whether these products can be distributed as such. Additionally, there is no need to expressly designate products that are or are not "toys or adornments" for purposes of 10 CFR 30.19(c) because NRC staff can apply the normal dictionary definition of such terms to individual products on a case-by-case basis.

Paragraph 30.19(c) also addresses self-luminous products generally, which makes references to specific products inappropriate. Most importantly, including a reference to tritium markers used for labeling purposes would prejudge the product as covered by the exemption, contrary to the intent of the regulatory framework and the CPPS, which stresses the importance of case-by-case determinations.

Request 3

The petitioner requests that the NRC amend 10 CFR 30.15 to add a specific exemption for tritium markers with a maximum activity of 25 millicuries (925 mBq) of tritium.

Response to Petitioner's Request 3

The NRC is choosing to not include a new specific exemption for these tritium markers at this time, consistent with the guiding principles within the CPPS. The exempt products in 10 CFR 30.15, such as timepieces or hands or dials containing specified quantities of byproduct

material including tritium, or marine compasses containing tritium, are designed for specific uses. As previously indicated, the Commission has stated that “[s]elf-luminous products in particular have a wide range of potential applications and might easily be widely used for purposes other than those originally intended if not clearly designed for a specific use” (79 FR 2910). Based on the small size (1.8 cm long by 0.8 cm diameter by 0.2 cm thick) and the design of the tritium markers, the tritium markers have potential uses beyond those intended by the petitioner, including as decorations on zipper pulls on clothing or as jewelry. The lack of a clear design for a specific use creates greater potential for unintended uses (such as the ones specifically excluded from the exemption in 10 CFR 30.19), which outweighs the product’s beneficial uses. Because of the potential for widespread use, careful consideration of justification of practice is important.

Also, the size and glow-in-the-dark nature of the tritium markers would appeal to and be accessible to children. Creating a new specific exemption for these tritium markers would be inconsistent with the CPPS, in particular, paragraph four (79 FR 2912), which requires that products subject to mishandling, especially by children, require an unusual degree of safety and utility. This criterion is unchanged from the original 1965 version of the policy. The tritium markers do not meet this criterion as they do not provide an unusual degree of utility. The unique benefits as compared to other alternatives are considered relatively limited. For example, the uses of the tritium markers asserted by the petitioner can be achieved by other products on the market, such as battery-powered products. While the use of tritium presents a particular benefit by staying illuminated continuously without having to be turned on when needed, the amount of light created using the 25 mCi of tritium suggested for the new exemption is fairly limited. Also, self-luminous products containing tritium light sources incorporated into products with clear end uses can provide some of the same benefits.

The petitioner stated that the tritium markers are sold in other countries. The discussion in the CPPS recognizes that it is unavoidable that there will be some differences made in judgments concerning justification of practice. Generally, international standards, such as the International Atomic Energy Agency's "Radiation Protection and Safety of Radiation Sources: International Basic Safety Standards," would not suggest that this product should be exempted; however, individual countries' regulatory bodies make their own judgments.

IV. Reasons for Denial.

The NRC is denying the petition because the petitioner fails to demonstrate that a specific exemption is warranted and that the existing regulatory framework for self-luminous products is inappropriate. The tritium markers do not meet the regulatory framework for the use of self-luminous products under an exemption from licensing. In addition, the self-luminous product class exemption was set up to eliminate the need to evaluate numerous PRMs for a wide variety of self-luminous products and the need to conduct a separate rulemaking to add individual exemptions for each acceptable one. The NRC confirms that this provision is needed to ensure that the use of radioactive material in a product is justified.

V. Conclusion.

For the reasons cited in this document, the NRC is denying PRM-32-8. The petition fails to present any significant new information or arguments that would warrant the requested amendments.

Dated at Rockville, Maryland, this day of , 2015.

For the U.S. Nuclear Regulatory Commission.

Annette L. Vietti-Cook,
Secretary of the Commission.