

**POLICY ISSUE**  
**(Notation Vote)**

April 7, 2015

SECY-15-0056

FOR: The Commissioners

FROM: Mark A. Satorius  
Executive Director for Operations

SUBJECT: DENIAL OF PETITION FOR RULEMAKING (PRM-32-8)

PURPOSE:

To obtain Commission approval to publish a *Federal Register* notice (Enclosure 1) denying a petition for rulemaking (PRM) submitted by Motti Slodowitz on behalf of CampCo (the petitioner) (Enclosures 2 and 3). This paper does not address any new commitments or resource implications.

BACKGROUND:

CampCo filed a petition for rulemaking (PRM-32-8) dated December 2, 2011, with the U.S. Nuclear Regulatory Commission (NRC) (Agencywide Documents Access and Management System (ADAMS) Accession No. ML12132A332). The petitioner requests that the NRC amend its regulations to allow the commercial distribution of tritium markers for use under exemption from licensing requirements. On July 5, 2012 (ADAMS Accession No. ML121580046), the NRC requested supplemental information to further clarify the request (Enclosure 3). On September 18, 2012 (ADAMS Accession No. ML13112B010), the petitioner responded to the request and submitted supplemental information that clarified the regulations it requested to be amended. These regulations are: paragraph (b) of Title 10 of the *Code of Federal Regulations* (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)

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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.

A notice of receipt and request for public comments was published in the *Federal Register* on July 11, 2013 (78 FR 41720). The comment period closed on September 24, 2013. The NRC received one comment submission. The commenter raised a concern about the recordkeeping of tritium.

Section 32.22 contains the requirements for an applicant who wishes to obtain a license to distribute a product for use under the exemption in 10 CFR 30.19. Paragraph 32.22(b) allows the Commission to deny an application for a specific license if the end uses of the product cannot be reasonably foreseen. Section 30.19 is a class exemption for self-luminous products containing certain radionuclides that can be used to create light. A class exemption covers a class of products for which a specific product must be approved through the licensing process, which involves providing safety information about the product and demonstrating that the product meets a number of safety criteria. Paragraph (c) in 10 CFR 30.19 restricts the use of the exemption in 10 CFR 30.19(a), indicating that the exemption does not apply to tritium, krypton-85, or promethium-147 used in products primarily for frivolous purposes or in toys or adornments. Section 30.15 is a list of exemptions from licensing requirements for specific products with specific radionuclide quantity limits and, in some cases, other limits.

## DISCUSSION:

### The Petition

The specific actions requested by the petitioner are:

- 1) To amend 10 CFR 32.22(b) to include a statement that an applicant cannot be denied a device registration or license if they have adequately demonstrated that the criteria in the applicable regulations have been met;
- 2) To 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; and
- 3) To amend 10 CFR 30.15 to add a specific exemption for tritium markers with maximum activity of 25 millicuries (925 mBq) of tritium.

The petitioner contends that the statement in 10 CFR 32.22(b), allowing denial of an application if the end use 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 also states that the term "frivolous use" is not clearly defined in the NRC's policy statement on consumer products (March 16, 1965, 30 FR 3462; proposed revision October 14, 2011, 76 FR 63957) or in the NRC's guidance and that there are no detailed criteria used to make determinations. The petitioner states that as long as the product meets the other criteria in 10 CFR 32.22, especially the radiation dose limits, there is no basis to deny an application.

NRC Evaluation of Petition Requests

The staff has considered the petition and its supporting rationale in light of the NRC's revised Consumer Product Policy Statement (CPPS), which was finalized after the submission of the petition and directly applies to any potential rulemaking to add or modify exemptions from licensing regarding consumer products (January 16, 2014; 79 FR 2907). As to the petitioner's request to 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, 10 CFR 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 licenses 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. Such a revision would be inconsistent with the CPPS, which repeatedly stresses the importance of evaluating consumer products containing radioactive material on a case-by-case basis. 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 to 10 CFR 32.22(b) would make the paragraph internally inconsistent and nullify it.

As to the petitioner's request to 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, 10 CFR 30.19(c) already states that the exemption does not cover toys or adornments. The proposed amendment would not further control whether products can be distributed for use as toys or adornments. Additionally, there is no need to define specific products within paragraph 30.19(c) as not being a "toy" or "adornment," in lieu of staff applying the normal dictionary definitions of these terms 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, the staff finds that including a specific 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.

As to the petitioner's request to 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 exempted products listed in 10 CFR 30.15 are designed for specific uses. The Commission has stated in the CPPS responses to public comments that self-luminous products in particular are subject to a wide range of potential applications other than those originally intended if not clearly designed for a specific use. The staff finds that 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) to the extent that the beneficial use is outweighed by the potential for misuse. 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

NRC's CPPS, in particular, paragraph 4 (79 FR 2912; January 16, 2014), which requires that products subject to mishandling, especially by children, must have an unusual degree of safety and utility.

Note also, the petitioner stated that the tritium markers are sold in other countries. As discussed in the CPPS, it is unavoidable that there will be some differences made in judgments concerning justification of practice. The staff reviewed the International Atomic Energy Agency's "Radiation Protection and Safety of Radiation Sources: International Basic Safety Standards, General Safety Requirements Part 3" criteria for exemption. This guidance does not suggest that this product should be exempted; however, individual countries' regulatory bodies make their own judgments.

On June 30, 2014, the staff presented its review and findings to a Petition Review Board (PRB). The staff recommended that the NRC deny the petition because the petitioner failed to demonstrate that a specific exemption was warranted and that the existing regulatory framework for self-luminous products was insufficient. The PRB unanimously agreed to deny the CampCo petition (PRM-32-8) based on the recommendations and findings provided by the staff. For the reasons further set forth in a draft *Federal Register* notice addressing the petitioner's requested actions (Enclosure 1), the staff recommends denial of the petition.

RECOMMENDATIONS:

That the Commission:

1. Approve the denial of the petition for rulemaking and publication of the *Federal Register* notice announcing the denial;
2. Inform appropriate Congressional committees; and
3. Note that a letter is attached for the Secretary's signature (Enclosure 4), informing the petitioner of the Commission's decision on the petition.

COORDINATION:

The Office of the General Counsel has no legal objection to the denial of this petition.

*/RA/*

Mark A. Satorius  
Executive Director  
for Operations

Enclosures:

1. *Federal Register* notice
2. CampCo Petition
3. CampCo Petition – Supplemental Information
4. Letter to the Petitioner

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#### **ML15020A114**

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