

From: Elizabeth Hackley
To: Seung Lee
Date: 06/29/2001 7:23:24 AM
Subject: 6/28 response from M. Schwartz - OGC

June 28, 2001

NOTE TO: Seung Lee
Material Safety Branch
Nuclear Materials Safety and Safeguards

FROM: Maria E. Schwartz /MES/
Attorney for Rulemaking and Fuel Cycle
Office of the General Counsel

SUBJECT: WHETHER A PARTICULAR FLASHLIGHT DESIGN PREVENTS IT FROM
BEING LICENSED FOR DISTRIBUTION AS AN EXEMPT PRODUCT

You have asked the Office of the General Counsel (OGC) whether, because of its design, flashlights containing tritium markers which allow individuals to locate the flashlights under circumstances where there is no light, including loss of power, emergency situations, etc., can be licensed for distribution to persons exempt from NRC regulation under 10 CFR 30.19. We have concluded that if the staff finds that the product meets the general criteria for a specific license in 10 CFR 32.22 and the safety criteria in 10 CFR 32.23, the design of these flashlights would not prevent this product from being distributed as an "exempt product."

The applicant discussed its application with the staff and made a presentation in which the applicant described the usefulness of the product. The staff, in consultation with OGC, concluded that the product is not "frivolous". Thus, the remaining consideration was whether the product meets the general criteria in section 32.22 and the safety criteria in section 32.23. In its examination of these criteria, the staff asked OGC to consider whether the design of the flashlight would prevent it from licensing the product for distribution to persons exempt from NRC regulation. The proposed design allows the end user to unscrew the end of the flashlight containing the light source and tritium markers from the body of the flashlight in order to replace batteries as needed.

The Statement of Consideration (SOC) for the exemption of tritium, krypton-85 and promethium-147 in self-luminous products (34 FR 9025, June 6, 1969), does not indicate that such a design in and of itself would affect whether or not the product could be distributed as an exempt product, placing this determination more squarely on whether the product meets the safety criteria in section 32.23(a) which limits the average dose, or dose commitment, in any one year to members of the group expected to receive the highest dose from normal use, and, in section 32.23(b), which limits the dose or dose commitment received by persons engaged in marketing, distributing, and servicing of exempt products, as a result of exposure to the quantities of exempt units likely to accumulate in one location. The SOC provides clarity on this issue, pointing out that servicing an exempt product was envisioned when the exemption was enacted.

Based on this rationale, a 1978 internal ELD memorandum from Jane R. Mapes to Wayne Kerr, regarding the redistribution of backlighted dials containing tritium, concludes that repairs which

do not involve removal of the tritium source, such as replacement batteries, do not present radiological health and safety issues, and therefore, constitute the kind of repairs “which properly fall within the scope of the exemption in 10 CFR 30.19.” In other words, the end user or a repair person could replace batteries in these watches without requiring an NRC license to do so. In addition, the product itself would not lose its exempt status in the process.

That memorandum points out that “the Commission’s regulations implementing section 81 of the Act now provide that once a product has qualified for a section 30.19 exemption by virtue of having been manufactured, processed or produced or initially transferred for sale or distribution in accordance with a specific license issued pursuant to section 32.22, or in the case of manufacturer, equivalent regulations of an Agreement State, it is no longer necessary for any person, including a person engaged in repair of the product, to obtain a license authorizing the receipt, possession, use or transfer of the product.”

Therefore, OGC believes that if the staff can make a determination based on the criteria in sections 32.22 and 32.23 that the flashlight does not constitute an unreasonable risk to the common defense and security and to the health and safety of the public, this design, which allows the end user to replace batteries as needed, should be approved for distribution to persons exempt from licensing under section 30.19. The staff should ascertain whether the applicant has any plans for replacing the tritium sources themselves in the flashlights at some future point. If that is its intention, the staff should advise the applicant that repairing or replacing the tritium source itself requires a specific license, and a specific license is also necessary for the repair/replacement entity to “redistribute” the flashlights to the owner.

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Mail Envelope Properties (3B3C6529.C8D : 11 : 51419)

Subject: 6/28 response from M. Schwartz - OGC
Creation Date: 06/29/2001 7:23:21 AM
From: Elizabeth Hackley
Created By: EFH1@nrc.gov

Recipients

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Flashlight.wpd

Size

13193

Date & Time

7:22:48 AM 06/29/2001

Options

Expiration Date: None
Priority: Standard
Reply Requested: No
Return Notification: None

Concealed Subject: No
Security: Standard