

June 21, 2006

Department of the Navy
Navel Surface Warfare Center
Dahlgren Division
ATTN: Douglas Ochsenknect
 (Acting) Program Executive
 Counter-Narcoterrorism
 Technology Program Office
17320 Dahlgren Road
Dahlgren, VA 22448-5100

SUBJECT: POTENTIAL LICENSING OF TRITIUM MICROSPHERES

Dear Mr. Ochsenknect:

This refers to your letter, dated January 23, 2006, in which you described a product you have under development and requested the U.S. Nuclear Regulatory Commission's (NRC) views on a proposed licensing approach. Our letter, dated March 30, 2006, responded to your letter and summarized our understanding of your request.

The Navy has been developing the microspheres and, if this project goes forward, the microspheres would be manufactured and initially distributed through a licensed, non-government entity. Once manufactured, the microspheres would then be distributed to the Department of Defense for use as exempt material. It appears that the Navy is requesting that all recipients of the microspheres be exempt from NRC licensing, material accountability, and labeling requirements.

Based on our review, the microspheres, when viewed as a "product," are not envisioned in 10 CFR Part 32.22 and Part 30.19, which cover self-luminous products containing tritium. In addition, the microspheres would not be covered by any of the other "class" exemptions from licensing currently provided in 10 CFR Part 30. However, under 10 CFR Part 30.11 the Commission may issue exemptions from the licensing requirements of Parts 30, 31-36, and 39 on a more specific, case-by-case basis, even where no "class" exemption is provided for under other paragraphs of Part 30. Specifically, 10 CFR Part 30.11 also allows the Commission to, "...upon application of any interested person or upon its own initiative, grant such exemptions from the requirements of the regulations in this Part and Parts 31 through 36 and 39 of this chapter as it determines are authorized by law and will not endanger life or property or the common defense and security and are otherwise in the public interest." The term "authorized by law" in 10 CFR Part 30.11 refers to section 81 of the Atomic Energy Act of 1954, as amended, (AEA), which authorizes the Commission to exempt certain classes, quantities, uses, or users of byproduct material from the requirements for a license when the Commission, "...makes a finding that the exemption of such classes or quantities of such material or such kinds of uses or users will not constitute an unreasonable risk to the common defense and security and to the health and safety of the public." Therefore, the Commission may not issue any exemption to the licensing requirements for byproduct materials unless the requisite finding is made that the microspheres, "...will not constitute an unreasonable risk to the common

defense and security and to the health and safety of the public." In addition, according to Part 30.11, before issuing exemptions on a case-by-case basis the Commission must determine that the exemption, "...will not endanger life or property or the common defense and security and [is] otherwise in the public interest."

Based on the information that you provided, it appears that an exemption from the material accountability and labeling requirements of 10 CFR Part 20 would also be required. 10 CFR Part 20.2301 allows for exemptions to be granted on a case-by-case basis provided the Commission determines that, "...the exemption is authorized by law and would not result in undue hazard to life or property."

Based on the paucity and preliminary nature of the information you have submitted regarding the tritium microsphere product, and the unusually broad nature of the exemptions suggested in that information, we believe it is premature to seek the Commission's views on the feasibility of licensing and the issuance of exemptions at this time. The information provided to date is not sufficient for staff to make any finding that the product would not constitute an unreasonable risk to the health and safety of the public and the environment. Further, the description of the use of the product is vague and does not facilitate understanding of likely exposure scenarios or potential accidents.

Prior to staff consulting with the Commission, you will need to submit additional information. As a minimum, the following information should be included: 1) a more detailed description of product and its intended use; 2) the quantity expected to be distributed annually; 3) any chemical and physical form and changes that may occur during the useful life of the product; 4) the solubility in water and body fluids; 5) the degree of access to human beings during normal use; 6) an expected life of the product; and 7) public dose estimates for normal use and likely accident scenarios. In addition, you should address the basis that would support a determination that the tritium microspheres can safely be distributed as exempt material and will not endanger the common defense and security and is in the public interest.

With respect to licensing, it is envisioned that the manufacture of the product would be specifically licensed by NRC or an Agreement State and that such a license would include a limitation that the product could only be distributed to the Department of Defense. It would be useful to understand which organization in the Department of Defense would control the accumulation of the product prior to use. We understand that the Navy Master Materials program is not interested in incorporating this effort into its program.

D. Ochsenknecht

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Guidance on submitting a more robust exemption request is contained in Section 4.13 of NUREG-1556, Volume 20. If you have any questions, please contact Tim Harris at (301) 415-7218.

Sincerely,

/RA/

Thomas H. Essig, Chief
Materials Safety and Inspection Branch
Division of Industrial and
Medical Nuclear Safety, NMSS

D. Ochsenknect

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Thomas H. Essig, Chief
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