From: Xu, Shirley
To: bradf@meprolight.com
Subject: MEPROLIGHT, INC License renewal
Date: Tuesday, June 01, 2021 2:35:48 PM

Mr. Fisher,

This refers to your license renewal application request dated February 15, 2021. In order to continue our review, we need the following additional information:

1. Please submit a copy of your current State of Pennsylvania license.

2. In accordance with 10 CFR 32.22, your application, February 15, 2021, with NRC Form 313, did not include all required documentation. Please submit:

    1. A description of the product and its intended use or uses.

    2. The type and quantity of byproduct material in each unit.

    3. Chemical and physical form of the byproduct material in the product and changes in chemical and physical form that may occur during the useful life of the product.

    4. Solubility in water and body fluids of the forms of the byproduct material identified in paragraphs (a)(2) (iii) and (xii) of this section.

    5. Details of construction and design of the product as related to containment and shielding of the byproduct material and other safety features under normal and severe conditions of handling, storage, use, and disposal of the product.

    6. Maximum external radiation levels at 5 and 25 centimeters from any external surface of the product, averaged over an area not to exceed 10 square centimeters, and the method of measurement.

    7. Degree of access of human beings to the product during normal handling and use.

    8. Total quantity of byproduct material expected to be distributed in the product annually.

    9. The expected useful life of the product.

    10) The proposed method of labeling or marking each unit with identification of the manufacturer or initial transferor of the product and the byproduct material in the product.

    11) Procedures for prototype testing of the product to demonstrate the effectiveness of the containment, shielding, and other safety features under both normal and severe conditions of handling, storage, use, and disposal of the product.

12) Results of the prototype testing of the product, including any change in the form of the byproduct material contained in the product, the extent to which the byproduct material may be released to the environment, any increase in external radiation levels, and any other changes in safety features.

13) The estimated external radiation doses and dose commitments relevant to the safety criteria in 10 CFR 32.23 and the basis for such estimates.

14) A determination that the probabilities with respect to the doses referred to in 10 CFR 32.23(d) meet the criteria of that paragraph.

15) Quality control procedures to be followed in the fabrication of production lots of the product and the quality control standards the product will be required to meet.

16) Any additional information, including experimental studies and tests, required by the Commission.

We will continue our review upon receipt of this information. If we do not receive a reply from you within 30 calendar days from the date of this email, we will assume that you do not wish to pursue your application.

Please be aware that upon your request, proprietary information submitted to the U.S. Nuclear Regulatory Commission (NRC) may be withheld from public disclosure. To do this, you must follow the procedures in 10 CFR 2.390(b) including requesting withholding at the time the information is submitted and complying with the document marking and affidavit requirements set forth in 10 CFR 2.390 (b)(1).

In accordance with 10 CFR 2.390 of NRC's "Rules of Practice," a copy of this letter will be available electronically for public inspection in NRC's Public Document Room or from the Publicly Available Records (PARS) component of NRC's document system (ADAMS). ADAMS is accessible from the NRC web site at http://www.nrc.gov/NRC/ADAMS/index.html (the Public Electronic Reading Room).

If you have any questions, please feel free to contact me at (301) 415-7640

Sincerely,

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