**UNITED STATES**
**NUCLEAR REGULATORY COMMISSION**
**WASHINGTON, D.C. 20555-0001**

April 23, 2018

Meprolight, Inc.
ATTN: Brad Fisher, President
521 Fifth Avenue
New York, NY 10175

SUBJECT: REQUEST FOR ADDITIONAL INFORMATION, MEPROLIGHT, INC., AMENDMENT REQUEST DATED FEBRUARY 15, 2018

Dear Mr. Fisher:

This letter is in response to your application dated February 15, 2018, requesting amendments to your Exempt Distribution License No. 31-23902-01E and Sealed Source and Device Registration Certificate NR-1119-D-101-E.

We do not have sufficient information to complete the review of your application. In the enclosure to this letter you will find the list of the questions and items not addressed in 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 Title 10 of the *Code of Federal Regulations* (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).

We will continue our review upon receipt of this information. If we do not receive your reply within 30 calendar days from the date of this letter, we will consider your application as having been abandoned by you. This action would be without prejudice to the resubmission of another application with the required information.

In accordance with 10 CFR 2.390 of the NRC's "Agency Rules of Practice and Procedure," a copy of this letter will be available electronically for public inspection in the NRC Public Document Room or from the Publicly Available Records component of NRC's Agencywide Documents Access and Management System (ADAMS). ADAMS is accessible from the NRC Web site at http://www.nrc.gov/reading-rm/adams.html.

Any correspondence regarding your amendment application should reference Control Number 602494.

If you have any questions, please contact Celimar Valentin-Rodriguez at (301) 415-7124, or by e-mail at Celimar.Valentin-Rodriguez@nrc.gov regarding the sealed source and device registration, and Richard Struckmeyer at (301) 415-5477, or by e-mail at Richard.Struckmeyer@nrc.gov regarding the exempt distribution license.

Sincerely,

**/RA/**

Richard K. Struckmeyer
Materials Safety Licensing Branch
Division of Materials Safety, Security, State,
and Tribal Programs
Office of Nuclear Material Safety
and Safeguards

Docket No. 030-36248
License No. 31-23902-01E

Enclosure:
Request for Additional Information

REQUEST FOR ADDITIONAL INFORMATION,

DATE: April 23, 2018

Certified Mail No. 7015 3010 0000 7901 7496

**ML18059A095 (pkg.)** **ML18109A383(Letter)**

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|---|---|---|---|---|
| OFC | NMSS/MSST/MSLB | NMSS/MSST/MSLB | NMSS/MSST/MSLB | NMSS/MSST/MSLB |
| NAME | Richard Struckmeyer | Deborah Weaver | Celimar Valentin-Rodriguez | Tomas Herrera |
| DATE | 04/19/2018 | 04/19/2018 | 04/23/2018 | 04/23/2018 |
| OFC | NMSS/MSST/MSLB | | | |
| NAME | Richard Struckmeyer | | | |
| DATE | 04/23/2018 | | | |

OFFICIAL RECORD COPY

**Meprolight, Inc., Amendment Request**
**Dated February 15, 2018**
**Request for Additional Information**

The U.S. Nuclear Regulatory Commission (NRC) staff has reviewed the Meprolight amendment request dated February 15, 2018, and determined that additional information is needed. In order to continue with our review, please address the issues listed below.

The information related to review of your sealed source and device amendment application is required by Title 10 of the *Code of Federal Regulations* (10 CFR) 32.210 and is described in the relevant guidance document NUREG-1556, Volume 3, Revision 2, titled "Applications for Sealed Source and Device Evaluation and Registration."

The information related to review of your exempt-distribution license amendment application is required by 10 CFR 32.22, 32.23, and 32.24, and is described in the relevant guidance document NUREG-1556, Volume 8, titled "Program-Specific Guidance about Exempt Distribution Licenses."

## A. Information Required for Review of Sealed Source and Device Amendment Application

General

1. In the second section of your letter, you mention that Meprolight is introducing two new models that use components of non-tritium sights. Please confirm that these new models you are referring to are ML-31612 front sight (FSB4) and ML-31612 rear sight (RSA6).

2. In the second section of your letter, you mention that Meprolight is also introducing a small optical sight that falls within the C2 family. Please confirm that this model you are referring to is ML-631/2XX.

Description & Construction

3. Please include a list of materials of construction for all models to be added to your registration certificate.

4. Please confirm that the criteria, parameters, or methods for all models to be added are consistent to those as previously authorized:

    a) assembly methods for each gun sight;
    b) source mounting within each of the gun sights;
    c) features that ensure that each of the gun sights is tamper-proof, regarding access to tritium sources; and
    d) methods of attachment by which the gun sights are to be attached to the corresponding gun.

5. Please confirm that the dimension ranges of the new models will be within the already approved dimension ranges for each family.

6. Please confirm whether the maximum activity for each new model in their corresponding family has changed.

7. Please describe what components, i.e., sleeve, metal body, are included in the protective distance measurement ("P") for the FSB4, RSA6, and C2 gun sights.

8. Please confirm that the dimensions in the drawings for the FSB4 and RSA6 gun sights are in millimeters.

9. The drawing for the RSA6 gun sight indicates that there are two light options: one with two lights on each side and one with four lights (top, bottom, and sides). Please resubmit the drawing and identify the location of all possible light sources.

Labeling

10. Please confirm that each new gun sight will be labeled according to the commitments made in NR-1119-D-101-E.

Prototype Testing

11. One of the weapon sights qualification test reports you attached to your letter makes reference to Model ML-63191. However, this model number is not included in any of the model listings and descriptions included in your letter. Please explain this discrepancy.

12. Please clarify which RSA6 version was tested, the version with two light sources or the version with four light sources. If the version with two light sources was tested, please describe the rationale for testing the two light source version over the one containing four light sources.

13. We note that the firing test submitted for the ML-63191 model only fired 1,000 rounds of ammunition while the firing test for the ML-31612 used 5,000 rounds. Please explain the reason for firing different quantities of ammunition.

**B. Information Required for Review of Exempt Distribution License Amendment Application**

10 CFR 32.22(a)(2) requires the applicant to submit sufficient information relating to the design, manufacture, prototype testing, quality control procedures, labeling or marking, and conditions of handling, storage, use, and disposal of the self-luminous product to demonstrate that the product will meet the safety criteria set forth in Section 32.23. Your application describes new models containing tritium tubes with unspecified activity levels. Therefore you should provide responses to the requirements of Sections 32.22 and 32.23 of 10 CFR Part 32, as stated in the following paragraphs. You may reuse previously submitted information where such information is applicable to specific requirements.

1. 10 CFR 32.22(a)(2)(v) requires the applicant to submit 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. Please confirm that the construction and design of the product provides an equivalent or better degree of 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 as currently authorized by your exempt distribution license.

2. 10 CFR 32.22(a)(2)(vi) requires the applicant to submit the 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. Your application does not appear to contain information pertaining to these external radiation levels. Please provide this information for the new models in your amendment application. Your response to this requirement may be provided in conjunction with question A.6.

3. 10 CFR 32.22(a)(2)(x) requires the applicant to submit 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. Please confirm that the labeling or marking of each unit does not differ from that currently authorized by your exempt distribution license. Your response to this requirement may be provided in conjunction with question A.10.

For the following two requirements (32.22(a)(2)(xi) and 32.22(a)(2)(xii)) it is not necessary to resubmit the procedures and results unless your procedures have changed,

4. 10 CFR 32.22(a)(2)(xi) requires the applicant to submit 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. Please confirm that the procedures for prototype testing do not differ from those currently authorized by your exempt-distribution license.

5. 10 CFR 32.22(a)(2)(xii) requires the applicant to submit 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. If the prototype test results for the products described in this amendment request differ from those described in your original application for a new license, please state 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. Otherwise, please confirm that the prototype test results for the products described in this amendment request do not differ from those currently authorized by your exempt distribution license.

6. 10 CFR 32.22(a)(2)(xv) requires the applicant to submit 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. Unless changes have been made, it is not necessary to resubmit these procedures.

7. 10 CFR 32.22(a)(2)(xiii) requires the applicant to submit the estimated external radiation doses and dose commitments relevant to the safety criteria in Section 32.23 and the basis for such estimates. Please provide these estimates for the new models in your amendment application, or confirm that the estimated external radiation doses and dose commitments do not differ from those currently authorized by your exempt distribution license.

8. 10 CFR 32.22(a)(2)(xiv) requires the applicant to submit a determination that the probabilities with respect to the doses referred to in Section 32.23(d) meet the criteria of that paragraph. Please provide this determination for the new models in your amendment application, or confirm that the probabilities with respect to the doses referred to in Section 32.23(d) do not differ from those currently authorized by your exempt distribution license.