



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

August 24, 2017

mb-microtec, USA, Inc.
ATTN: Roger Siegenthaler
President
P.O. Box 1136
Yarmouth, ME 04096

SUBJECT: MB-MICROTEC, USA, INC., REQUEST FOR ADDITIONAL INFORMATION
REGARDING AMENDMENT REQUEST FOR EXEMPT DISTRIBUTION
LICENSE 18-23712-01E

Dear Mr. Siegenthaler:

This letter refers to your amendment request dated May 30, 2017 (Agencywide Documents Access and Management System [ADAMS] Accession No. ML17152A146) (non-pubic). In reviewing your application, we have determined additional information is required to complete our review. In order to continue our review, please address the issues listed in the enclosure to this letter. This information is required by 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;" and 10 CFR 32.210, "Registration of product information."

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 letter, we will assume that you do not wish to pursue your application.

Please be aware that upon your request, proprietary information submitted to the 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 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 ADAMS. ADAMS is accessible from the NRC Web site at <http://www.nrc.gov/reading-rm/adams.html>.

R. Siegenthaler

2

If you have any questions, you may contact me at (301) 415-7640, or by e-mail at Shirley.Xu@nrc.gov.

Sincerely,

/RA/

Shirley S. Xu
Materials Safety Licensing Branch
Division of Material Safety, State, Tribal
and Rulemaking Program
Office of Nuclear Material Safety
and Safeguards

Docket No. 030-30433
Mail Control No. 599677

Enclosure:
Request for Additional Information

cc: Ms. Yelena Sivaya

MB-MICROTEC, USA, INC., REQUEST FOR ADDITIONAL INFORMATION REGARDING
AMENDMENT REQUEST FOR EXEMPT DISTRIBUTION LICENSE 18-23712-01E

Certified Mailing No. 7015 3010 0000 7901 7250

Date: August 24, 2017

ML17235B113

OFFICE	MSTR/MSLB	MSTR/MSLB	MSTR/MSLB	MSTR/MSLB	MSTR/MSLB
NAME	Shirley Xu	Deborah Weaver	Lymari Sepulveda	Tomas Herrera	Shirley Xu
DATE	08/24/2017	08/24/2017	08/24/2017	08/24/2017	08/24/2017

OFFICIAL RECORD COPY

mb-microtec, USA

Request for Additional Information

General

1. The mb-microtec, USA (mb-microtec) application dated May 30, 2017, identifies a distribution location at 1093 Ridge Road, Windsor, ME. Please describe the function of the company NETCo Services located at the address and their role with mb-microtec.
2. Your mailing address on your current exempt distribution license, 18-23712-01E, as well as your sealed source and device registration certificate NR-0446-D-103-E for timepieces, is 1093 Ridge Road, Windsor, ME 04363; however, on your application you used P.O. Box 1136, Yamouth, ME 04096, as your mailing address. Please clarify whether this is a change of your mailing address.
3. In your application you indicated a commitment to re-distribute the safety markers only via specialized marketplaces whose customers are Army, military, and law enforcement. Please explain in detail how the specialized marketplaces will operate in regards to distributing the safety markers, what type of platform is used, and who would be the distributors you will work with for distributing the device. Additionally, what criteria will mb-microtec use to select the specialized marketplaces, and what commitments must the distributors provide to mb-microtec regarding this device to ensure that it will only be distributed to military and law enforcement customers?
4. Address how mb-microtec will reduce or minimize the use of the safety markers for uses not identified in your application. Please address what methods mb-microtec will use to ensure that only army, military, and law enforcement personnel will be in possession of the safety markers.

Description/Construction

5. Your application states that: "mb-microtec, USA, Inc. requests authorization to distribute any additional safety marker model not listed above provided that the such a model meets the design specifications approved by NRC"; the only differences noted in the application between sub-models is the color of the gaseous tritium light sources. Please describe any other differences between sub-models, if applicable.

Be aware that whenever you decide to distribute any additional models not listed, you must submit an application to the U.S. Nuclear Regulatory Commission to have the new model numbers of the devices added to your exempt distribution license and device registration certificate. The application must include the specification of the new models.

6. Confirm that it is mb-microtec's intent to allow the end user to mount the safety marker. Please provide the instructions that will be provided to the user for mounting the safety marker. Please discuss whether there is an expiration of the thread locker's effectiveness if not locked in a certain period of time after it has been applied by mb-microtec.

Enclosure

7. As described in your cover letter, you stated that the “permanent fix” feature has been introduced with the purpose of mitigating unauthorized repossession/misuse of the device (e.g. by children).” Submit a detailed description of how this “permanent fix” feature works, and how it prevent any misuse of this device. Please discuss whether the end user is able to remove the light container from the braided wire prior to the marker being mounted.
8. Provide the diameter of the braided wire used for the safety markers.
9. Discuss whether there is potential corrosion between any of the materials used in the construction of the safety markers, to include the potential different material used for the light stopper.

Conditions of Use

10. Provide the maximum allowable temperature, vibration, and shock to which the safety markers can be subjected to and still be expected to maintain the integrity of the radioactive material.
11. Indicate if the adhesive Hysol 3430 will withstand the likely conditions of use; specifically the conditions specified in your application which indicate that these devices will be used from +50C to -30C and 100 percent humidity.

Prototype Testing

12. The prototype testing submitted for the safety markers relies on ANSI 43.4-2005, “Classification of Radioactive Self-Luminous Sources.” The safety markers, as indicated in the application, will be used indoors and outdoors by military and law enforcement personnel. The activities of these users could surpass some of the tests performed during the prototype testing. For example, explain how a free fall to a steel plate from one meter is an accurate representation of the environment that the safety markers will be subjected to. Note that for prototype testing an applicant must demonstrate the product’s ability to maintain its integrity when subjected to conditions of normal use and likely accident conditions. Please provide examples of normal use and likely accident conditions, and provide prototype testing results using one of the accepted methods in NUREG-1556, Volume 3, Revision 2, that demonstrate that the safety markers will maintain their integrity during normal use and likely accident conditions.
13. Both of the safety marker series (DRN14001 and DRN14002) use the braided wire and chemical thread locker fastener. The application states that the “chemical thread locking fastener is added on the thread end to make it a one-time lock.” Please describe in detail and provide the testing performed by mb-microtec to demonstrate that the fastener will not open during normal use and likely accident conditions. In your response, include a discussion of the types of evaluations performed by mb-microtec which show that the fastener cannot be opened. In addition, please describe and provide the prototype testing performed to demonstrate that safety marker cannot be separated from the braided wire while the fastener is closed.

14. The application states that the estimated working life of the safety marker is 12.32 years. Please describe what analysis has been performed to determine that the fastener will not become separated during the life of the device.
15. The application states that the device will be glued by using Hysol 3430. Please indicate if testing has been performed to determine that the glue will withstand submersion for long periods of time in water or cleaning solvents.