

MB-MICROTEC, USA
APPLICATION DATED JULY 12, 2019
REQUEST FOR ADDITIONAL INFORMATION

The U.S. Nuclear Regulatory Commission (NRC) staff has reviewed the mb-microtec, USA (mb-microtec) application dated July 12, 2019 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) Section 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 application is required by 10 CFR 32.14, 32.15, 32.16, 32.22, 32.23, and 32.24, and is described in the relevant guidance document NUREG-1556, Volume 8, "Program-Specific Guidance About Exempt Distribution Licenses."

A. Questions related to the Sealed Source and Device application

Description/Construction

1. In your amendment request, you indicated that new watch models may contain up to 4 gaseous tritium light sources (GTLS) per hand. Please provide drawings of the watch hands for those watch models that use up to 4 GTLS.
2. Please confirm that only the new Models 101A, 101B, 101C, 101D and 101E will use up to 4 GTLS on the minute and hour hands.
3. In your amendment request, you stated that "In the past several years, mb-microtec has procured new equipment that allows the company to manufacture GTLS's that are smaller in diameter and shorter in length." Please discuss whether these dimensions are in conformance with the dimensions of the registered source models in NY-1271-S-101-S and indicate which source models may be used in the new watch models.

If the sources fall outside of the ranges from the current source registration certificate the sources will need to be registered as part of the timepieces currently registered under NR-0446-D-103-E. In order to register the sources as part of the device you will need to include the sealed source model designation, and a complete description of the sealed source including assembly methods, source dimensions, engineering drawings, prototype testing results, etc.

4. Please discuss any potential for corrosion when using bronze as a new material for the bottom plate.

Prototype Testing

5. In your amendment request, you stated that "mb-microtec claims that the increase in the number of GTLS's per minute and hour hand is an engineering equivalent to the previous 2 GLTS's." Please discuss the specifics of this determination.

Enclosure

As stated in NUREG-1556, Vol. 3, Rev. 2, the NRC accepts one of the following methods of prototype testing: (1) testing of a prototype of a product; (2) engineering analysis; (3) operational history of the product; or (4) comparison to a similar or equivalent model previously reviewed and registered.

B. Questions related to the Exempt-Distribution License application

1. Please provide us with the total quantity of byproduct material expected to be distributed in the devices annually as required by 10 CFR Paragraph 32.30(b)(8).