April 15, 2015

Mb-Microtec USA, Inc.
ATTN: Timothy Brandon, RSO
1093 Ridge Road
Windsor, ME 04363

SUBJECT: REQUEST FOR ADDITIONAL INFORMATION

Dear Mr. Brandon:

This letter refers to your application dated August 15, 2013, and letter dated February 14, 2014, for your renewal of the U.S. Nuclear Regulatory Commission (NRC) Exempt Distribution Materials License. In reviewing your application, we find additional information is required to complete our review. In order to continue our review, please address the issues listed below. This information is required by 10 CFR 32.22, "Self-Luminous products containing tritium, krypton-85 or promethium-147: Requirements for license to manufacture, process, produce, or initially transfer," 10 CFR 32.14, "Certain items containing byproduct material; requirements for license to apply or initially transfer," and described in the relevant guidance document NUREG-1556, Volume 8 titled "Program-Specific Guidance about Exempt Distribution Licenses."

1. In your letter dated February 14, 1014, you stated that watch models with less than 25 mCi of activity are distributed under 10 CFR 32.14 and models with 25 mCi or more are distributed under 10 CFR 32.22. Please specify and state the models that will be distributed under 10 CFR 32.14 and the models that will be distributed under 10 CFR 32.22.

2. In your letter dated February 14, 2014, you provided a risk assessment of traser H3 watches over their life cycle dated December 20, 2008. The risk assessment you provided is missing required information, such as:

    a. External dose calculation for distribution workers and members of the public who might be exposed during product distribution.

    b. External dose calculation of routine use of wristwatches. Exposure to airborne releases of H-3 from the wristwatches and exposure to skin contact.

    c. External dose calculation during watch repair.

    d. External dose calculation during an accident or misuse of wristwatch.

10 CFR 32.22(a)(2)(xiii) requires the estimate external radiation doses and dose commitments relevant to the safety criteria in 32.23 and the basis for such estimates. Please provide a dose assessment as described in NUREG-1717, "Systematic Radiological Assessment of Exemptions for Source and Byproduct Materials," Section 2.3, "Timepieces, Hands, and Dials."

3. Please provide the maximum external radiation levels at 5 and 25 centimeters from external surface of product, averaged over an area not to exceed 10 square centimeters, and the method of measurement, as required in 10 CFR 32.22(a)(2)(vi).

4. In our first request for additional information dated January 8, 2014, we requested the procedure of prototype testing and results. In your response letter dated February 14, 2014, you provided the prototype testing of the source, which is the primary containment of the radioactive material. 10 CFR 32.22(a)(2)(xi) requires the 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. 10 CFR 32.22(a)(2)(xii) requires the 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. In the regulation the word "product" refers to the device(s) that contain the source(s), in your case the products are the watches that will be distributed under 10 CFR 32.14 and 32.22. Please provide the procedure and results of prototype testing (e.g., vibration tests, bending of hands or pointers over cylinder, and immersion tests) of each device model.

Any correspondence regarding your application should reference the control number specified below. Please submit the requested information within 30 days of the date of this letter. If we have not received complete information within 30 days of the date of this letter, we will consider taking regulatory action on your current NRC License No. 31-23712-01E, including termination of your license.

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.

If you have any questions, please contact me at (301) 415-6004 or by electronic mail: Hector.Rodriguez-Luccioni@nrc.gov.

Sincerely,

/RA/

Hector Rodriguez-Luccioni, Ph.D.
Licensing Branch
Division of Materials Safety and State Agreements
Office of Federal and State Materials
and Environmental Management Programs

Docket No. 030-30433
Mail Control No. 581716
License No. 31-23712-01E

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DATE	4/ 8 /2014	4/ 8 /2014	4/ 15 /2014	4/ 15 /2014

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