

May 22, 2014

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 response letter dated May 13, 2014, Agencywide Documents Access and Management System (ADAMS) Accession No. ML14135A305, which responds to our second request for additional information dated April 15, 2014 (ADAMS Accession No. ML14098A377). In reviewing your response letter, 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," and 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 our second request for additional information dated April 15, 2014, we requested the estimate external radiation doses and dose commitments relevant to the safety criteria in 32.23 and the basis for such estimates. In your letter dated May 13, 2014, you provided dose assessment for wrist watches model T-27 and T-100. For watch model T-100, which contains 100 mCi, you took the dose calculations in NUREG 1717, "Systematic Radiological Assessment of Exemptions for Source and Byproduct Materials," for watches with 25 mCi of tritium gas contained in glass tubes and increased them by a factor of 4. Please provide a detailed dose assessment for T-100 model, including calculation examples as shown in NUREG-1717, Appendix A, of the following:
 - 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.

2. In our second request for additional information dated April 15, 2014, we requested 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. In your letter dated May 13, 2014, you stated that the radiation levels at 5 and 25 centimeters from the product are background, and that this was a calculated value as measurement for the low energy beta particles is impractical. Please provide the calculation of the radiation levels at 5 and 25 centimeters.

3. In our first request for additional information dated January 8, 2014 (ADAMS Accession No. ML14050A184), we requested the procedure of prototype testing and results. In your response letter dated February 14, 2014 (ADAMS Accession No. 14049A327), you provided the prototype testing of the source, which is the primary containment of the radioactive material. In our second request for additional information dated April 15, 2014, we requested the procedure of prototype testing and results of the final product. 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 32.22. In your letter dated May 13, 2014, you responded that according to NRC Document 98-88, "NRC Amends Regulations governing Timepieces Containing Tritium," prototype testing is not required for timepieces containing Gaseous Tritium Light Sources (GTLS) and is replaced by detailed engineering drawings, etc. This statement is not correct. The amendment you referred to is only applicable to timepieces containing GTLS that are licensed under 10 CFR 32.14. Timepieces containing GTLS that are licensed under 10 CFR 32.22, required prototype testing as stated above. You need to 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 under 10 CFR 32.22.

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 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).

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T. Brandon

-3-

If you have any questions, please contact me at (301) 415-6004 or 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
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-4-

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