



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

September 29, 2015

mb-microtec  
ATTN: Timothy Brandon  
1093 Ridge Road  
Windsor, ME 04363

SUBJECT: REQUEST FOR ADDITIONAL INFORMATION REGARDING MB-MICROTEC  
AMENDMENT REQUEST TO EXEMPT DISTRIBUTION LICENSE

Dear Mr. Brandon,

The U.S. Nuclear Regulatory Commission (NRC) staff has reviewed the amendment request dated August 21, 2015, regarding mb-microtec exempt distribution license no. 18-23712-01E. The staff has determined that additional information is needed to complete our review.

In order to continue our review, please address the issues listed below. This information is required by 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 August 21, 2015, you stated: "please amend the maximum activities of Models 100/, 100/3, 100/4, and 100/5 from 25 mCi to 100 mCi." It seems that the first model is missing a number, please clarify all the models you want to increase the activity to a 100 mCi.
2. As required by 10 CFR 32.22(a)(2)(xi) and (xii) please provide the procedure and results for prototype testing of the products 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. The guidance in NUREG-1556, Volume 3, Revision 1, Section 10.5, "Prototype Testing," provides the various methods of prototype testing that are acceptable to the NRC. Alternatively, you may provide a copy of the prototype testing dated December 10, 2014 that you provided in your renewal application for model 100/1 and justify how the prototype testing will be the same for the other models by comparing the models in question 1 with the model 100/1.
3. As required by 10 CFR 32.22(a)(2)(viii) please provide the total quantity of byproduct material expected to be distributed in the product annually.
4. Following the NRC's inspection of mb-microtec on August 17 and 18, 2015, it is our understanding that multiple companies manufacture watches using mb-microtec tritium sealed sources (400/1, 400/2 and 400/3) for mb-microtec. The Sealed Source and Device registration certificate NR-0446-D-103-E only lists mb-microtec ag as the manufacturer of

the "Traser®" tritium watch models 100/1, 100/2, 100/3, 100/4 and 100/5. Please address the following questions:

- a. Please provide a list of all the watch manufacturers and watch brands that are being distributed by mb-microtec under exempt distribution license 18-23712-01E. Also please provide the model number for each watch brand.
- b. Please describe the role of each of the watch manufacturers in the manufacturing of the watches.
- c. Please clarify how mb-microtec Quality Assurance (QA)/Quality Control (QC) program maintains oversight of these other manufacturers.
- d. Please confirm that with every lot of the watches, mb-microtec ag must forward to mb-microtec (U.S.) the leak test results and copies of documents certifying that the QA/QC commitments made have been met.

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 your application as having been abandoned by you. This is without prejudice to the submission of a complete 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 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). ADAMS is accessible from the NRC web site at <http://www.nrc.gov/NRC/ADAMS/index.html> (the Public Electronic Reading Room).

T. Brandon

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If you have any questions regarding the exempt distribution license, please contact me at (301) 415-6004 or email at [Hector.Rodriguez-Luccioni@nrc.gov](mailto:Hector.Rodriguez-Luccioni@nrc.gov).

Sincerely,

***/RA/***

Hector Rodriguez-Luccioni, Ph.D.  
Materials Safety Licensing Branch  
Division of Material Safety, State, Tribal  
and Rulemaking Programs  
Office of Nuclear Material Safety  
and Safeguards

Docket No. 030-30433  
Mail Control No. 588781

If you have any questions regarding the exempt distribution license, please contact me at (301) 415-6004 or email at [Hector.Rodriguez-Luccioni@nrc.gov](mailto:Hector.Rodriguez-Luccioni@nrc.gov).

Sincerely,

**/RA/**

Hector Rodriguez-Luccioni, Ph.D.  
Materials Safety Licensing Branch  
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<b>OFC</b>	NMSS/MSTR/MSLB	NMSS/MSTR/MSLB	NMSS/MSTR/MSLB	NMSS/MSTR/MSLB
<b>NAME</b>	Hector Rodriguez-Luccioni	Shirley Xu	Hipolito Gonzalez	Hector Rodriguez-Luccioni
<b>DATE</b>	09/28/2015	09/28/2015	09/28/2015	09/29/2015

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