



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

January 29, 2016

Hess Fine Arts, Inc.
ATTN: Jerome Sirois
1131 4th Street North
St. Petersburg, FL 33701

SUBJECT: REQUEST FOR ADDITIONAL INFORMATION REGARDING HESS FINE ARTS, INC. AMENDMENT REQUEST TO EXEMPT DISTRIBUTION LICENSE AND SEALED SOURCE AND DEVICE REGISTRATION CERTIFICATE

Dear Mr. Sirois:

The U.S. Nuclear Regulatory Commission (NRC) staff has reviewed the amendment request dated November 12, 2015, regarding Hess Fine Arts, Inc. exempt distribution license no. 09-23920-01E and Sealed Source and Device (SSD) registration certificate NR-1265-D-101-E. The staff has determined that additional information is needed. In order to continue with our review, please address the issues listed in the enclosure.

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 Title 10 of the *Code of Federal Regulations* (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>.

J. Sirosis

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If you have any questions regarding the Sealed Source and Device Registration you can contact Tomas Herrera at (301) 415-7138 or by e-mail at Tomas.Herrera@nrc.gov. For questions related to the exempt distribution license, please contact me at (301) 415-6004 or e-mail at Hector.Rodriguez-Luccioni@nrc.gov.

Sincerely,

/RA by Tomas Herrera for/

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

Docket No. 030-36971
Mail Control No. 589411

Enclosure:
Request for Additional Information

J. Sirois

-2-

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Hector Rodriguez-Luccioni, Ph.D.
Material Safety Licensing Branch
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Docket No. 030-36971
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Enclosure:
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Certified Mail Tracking Number: 7010 3090 0003 4373 3009

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OFC	NMSS/MSLB	NMSS/MSLB	NMSS/MSLB	NMSS/MSLB
NAME	MArribas-Colon for HRodriguez-Luccioni	Debra Miller	Tomas Herrera	Maria Arribas-Colon
DATE	01/29/2016	01/29/2016	01/29/2016	01/29/2016
OFC	NMSS/MSLB	NMSS/MSLB		
NAME	THerrera for Hipolito Gonzalez	THerrera for Hector Rodriguez-Luccioni		
DATE	01/29/2016	01/ 29/2016		

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REQUEST FOR ADDITIONAL INFORMATION FOR HESS FINE ARTS, INC.
REGARDING EXEMPT DISTRIBUTION LICENSE
AND SEALED SOURCE AND DEVICE REGISTRATION CERTIFICATE

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."

1. In your letter dated November 12, 2015, you stated that Hess Fine Arts, Inc. self-luminous timepieces will use mb-microtec tritium sealed source models 400/1, 400/2, 400/3, 400/4, 400/5 and 400/6. In your letter dated November 2, 2015, which responded to our request for additional information regarding Hess Fine Arts, Inc. renewal application, you provided the Hess Fine Arts, Inc. possession license from the State of Florida. Hess Fine Art, Inc. possession license only authorizes the possession of mb-microtec sealed sources models 400/1 and 400/2. Please provide a copy of Hess Fine Arts, Inc. possession license authorizing the use of mb-microtec sealed sources 400/1, 400/2, 400/3, 400/4, 400/5 and 400/6 and confirm our understanding that it is Hess Fine Arts' intention to distribute watches containing the mb-microtec sealed source models 400/3, 400/4, 400/5, and 400/6.
2. In your letter dated November 12, 2015, you provided a list of Hess Fine Arts, Inc. timepiece models that will contain a maximum of 150 mCi of tritium and that will be distributed under your exempt distribution license in accordance to 10 CFR 32.22. Please confirm and clarify the following:
 - a. The Sealed Source and Device (SSD) registration certificate NR-1265-D-101-E includes models NM1016-SA and NM1038-SEA, which are not included in the list you provided. Please confirm that these two models will be distributed by Hess Fine Arts, Inc. or if they should be removed from the license. If Hess Fine Arts, Inc. will keep distributing these two models, please confirm if the maximum activity in these two models will remain as 66.6 mCi and 72.1 mCi respectively, or if they should be included in the amendment with an increase to a maximum activity of 150 mCi.
 - b. As noted above, Hess Fine Arts, Inc. is requesting an increase in the maximum activity of the watches to 150 mCi. Please provide radiation profiles for the watches at the increased level or provide a justification why new radiation profiles will not be required.
 - c. Please describe the similarities and differences between each of the watch models; this would include the construction of the watches and placement of the sources that Hess Fine Arts, Inc. seeks to add to its SSD registration certificate and exempt distribution license.
 - d. A table was included on page 2 of the SSD registration certificate NR-1265-D-101-E which identified the number of sources and maximum activity for each watch model number. Please provide a table that that includes the model number, number of sources and the maximum activity of each watch that you are requesting to distribute. This list should include any changes in the number of sources and

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maximum activity levels for watches currently listed on the SSD registration certificate.

- e. In the list of models you provided there are models that are duplicates. Please clarify the reason for having two exact same models and what would be the difference between them.
 - f. In your letter under the model list, you stated "...and other watches manufactured by Ball Watch Company SA with H-3 activities less than 150 mCi." In addition, in your letter dated November 2, 2015, which responds to our request for additional information regarding Hess Fine Arts renewal application, you provided a list of models that are distributed under 10 CFR 32.22. There are discrepancies between the two lists of models of your letters dated November 2 and November 12, 2015. Please provide a complete list of all the timepiece models that will be distributed under 10 CFR 32.22. Please note that you can also provide a list of timepiece series, in addition to the models, see NUREG-1556, Volume 3, Revision 2, Section 4.1, for a discussion of models and series.
3. In your letter dated November 12, 2015, you provided engineering drawings for five of Hess Fine Arts, Inc. timepiece models. Please provide an engineering drawing for all new timepiece models that will be distributed under 10 CFR 32.22 that are not included in your current exempt distribution license or SSD registration certificate. The engineering drawings should describe the construction aspects of the product including components of the product, material of construction, dimensions, assembly methods, and source containment and shielding. In addition, these drawings should include the following:
 - a. Tritium sources dimensions (length and width).
 - b. Location of all sources.
 - c. Distance from sources to the edge of dial.
 - d. Distance between sources.
 4. The engineering drawings enclosed in Attachment A in your November 12, 2015, letter included the name "LUEN FUNG WATCH CASE FACTORY LIMITED." Please describe the role of this entity in the manufacturing of the watches.
 5. In your letter dated November 12, 2015, you stated that the timepieces will be labeled with "3H mb microtec illumination" or "3H MBM." As required by 10 CFR 32.22(a)(2)(x), each unit shall be marked with the identification of the manufacturer or initial transferor of the product and the byproduct material in the product. Please confirm that each timepiece will be marked with the initial distributor (i.e. BALL Watch). Please provide a diagram showing the proposed labeling and describe how the labeling is attached to the watches.
 6. In your letter dated November 12, 2015, you stated that the watches are manufactured to military specification ML-PRF-46374G and you provided a copy of the procedure.

For prototype testing, the NRC may accept one of the following methods to demonstrate the product's ability to maintain its integrity when subject to conditions of normal use and likely accident conditions: (1) testing a prototype of the product, (2) performing an engineering

analysis, (3) operational history of the product, or (4) comparison to a similar or equivalent model previously reviewed and registered. Please note that Section 10.5 of Volume 3, Revision 2 of the NUREG-1556 series provide guidance on each of these methods.

Request for Additional Information Regarding Exempt Distribution License

1. As required by 10 CFR 32.22(a)(2)(vi), please provide the maximum external radiation levels at 5 and 25 centimeters from any external surface of the product, averaged over an area not to exceed 10 square centimeters, and the method of measurement.
2. As required by 10 CFR 32.22(a)(2)(vii), please provide the degree of access of human beings to the product during normal handling and use.
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. 10 CFR 32.22(a)(2)(xiii) requires an estimated external radiation doses and dose commitments relevant to the safety criteria in 10 CFR 32.23 and the basis for such estimates. In your letter dated November 12, 2015, you stated that tritium watches of 100 mCi generated a maximum annual dose of 0.02 mrem from use of the wrist watch and that extrapolating this result for 200 mCi wrist watches produces a maximum of 0.04 mrem whole-body dose to the wearer. Your response is insufficient and does not comply with the regulatory requirements. 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."
 - 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.
5. Please provide a determination that the probabilities with respect to the doses referred to in 10 CFR 32.23(d) meet the criteria of that paragraph.

Request for Additional Information Regarding Sealed Source and Device Registration Certificate

In Hess Fine Arts, Inc. letter dated September 15, 2006, you provided a description of BALL Watch USA's Quality Control Procedures. Please confirm that Hess Fine Arts, Inc. continues to use the same procedures for inspecting each watch.