



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

October 6, 2015

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

SUBJECT: REQUEST FOR ADDITIONAL INFORMATION REGARDING HESS FINE ART
EXEMPT DISTRIBUTION LICENSE RENEWAL APPLICATION

Dear Mr. Sirois,

The U.S. Nuclear Regulatory Commission (NRC) staff has reviewed the renewal application dated September 4, 2015 (Agencywide Documents Access and Management Systems (ADAMS) accession no. ML15254A068), regarding Hess Fine Art exempt distribution license no. 09-23920-01E. The staff has determined that additional information is needed to complete our review.

The intention of this request is to have an up-to-date document that provides all of the information required by the regulations in 10 CFR 32.14, "Certain items containing byproduct material; requirements for license to apply or initially transfer," 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 described in the relevant guidance document NUREG-1556 Volume 8 titled "Program-Specific Guidance about Exempt Distribution Licenses." It is acceptable to reuse previously submitted documents as long as they are provided as attachments to a new document describing your current program. The new document should provide the answers to each of the requested information listed below, either as a statement within the new document itself, or by referring to an attached, previously-submitted document.

A. Information required by 10 CFR 32.14 and 32.22

1. Please provide a copy of your possession license from the state of Florida.
2. Please provide a list of watch models that will be distributed under 10 CFR 32.14 and a list of watch models that will be distributed under 10 CFR 32.22.
3. Please specified the model number of the sources used for each part of the watch (dial, hour hand, minute hand, second hand, etc.), for each watch model.
4. Please provide the chemical and physical form of the byproduct material in the product and changes in chemical and physical form that may occur during the useful life of the product.

5. Please provide the maximum quantity of the byproduct material:
 - a. Per timepiece, per dial and per hand for products under 10 CFR 32.14
 - b. Per timepiece for products under 10 CFR 32.22
 6. Please provide the method of labeling or marking each unit, and its container with the identification of the manufacturer or initial transferor of the product and the byproduct material in the product.
 7. Please provide the method of containment or binding of the byproduct material in the product.
 8. Please provide an engineering drawing (for each watch model) that describes 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.
- B. Information required by 10 CFR 32.22 (NOTE: Please be aware that this request only applies to watch models distributed under this part)
1. Please provide the solubility in water and body fluids of the byproducts material.
 2. 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.
 3. Please provide the degree of access of human beings to the product during normal handling and use.
 4. Please provide the total quantity of byproduct material expected to be distributed in the product annually.
 5. Please provide the expected useful life of the product.
 6. Please provide the procedure 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.
 7. Please provide 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.

8. Please provide the estimated external radiation doses and dose commitments relevant to the safety criteria in 10 CFR 32.23 and the basis for such estimates. You may use NUREG 1717, "Systematic Radiological Assessment of Exemptions for Source and Byproduct Materials," as a reference.
9. 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.
10. Please provide the Quality Control Procedures to be followed in the fabrication of production lots of the product and the quality control standards the product will be required to meet.

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).

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.

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. 030-36971
Mail Control No. 58874

8. Please provide the estimated external radiation doses and dose commitments relevant to the safety criteria in 10 CFR 32.23 and the basis for such estimates. You may use NUREG 1717, "Systematic Radiological Assessment of Exemptions for Source and Byproduct Materials," as a reference.
9. 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.
10. Please provide the Quality Control Procedures to be followed in the fabrication of production lots of the product and the quality control standards the product will be required to meet.

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).

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.

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. 030-36971
 Mail Control No. 588743

ML15274A068 - Certified Mail Tracking Number: 7015 1520 0000 8172 1280

OFC	NMSS/MSTR/MSLB	NMSS/MSTR/MSLB	NMSS/MSTR/MSLB	NMSS/MSTR/MSLB
NAME	Hector Rodriguez-Luccioni	Shirley Xu	Hipolito Gonzalez	Hector Rodriguez-Luccioni
DATE	10/01/2015	10/01/2015	10/ 01/2015	10/06/2015

OFFICIAL RECORD COPY