



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

February 23, 2016

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

SUBJECT: THIRD REQUEST FOR ADDITIONAL INFORMATION REGARDING HESS
FINE ARTS, INC., EXEMPT DISTRIBUTION LICENSE RENEWAL
APPLICATION

Dear Mr. Sirois,

This letter refers to your letter dated February 15, 2016, Agencywide Documents Access and Management System (ADAMS) Accession No. ML16050A426, which responded to our first request for additional information dated November 5, 2015 (ADAMS Accession No. ML15307A689). In reviewing your letter, we have determined additional information is required to complete our review. In order to continue our review please address the issues listed below.

The intention of this request is to have an up-to-date document that provides all of the information required by the regulations in Title 10 of the *Code of Federal Regulations* (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 information contained 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. In our letter dated November 5, 2015, we requested a clarification of the relationship of the timepiece model numbers you provided in Attachment B of your letter dated November 2, 2015, and the model numbers in the sealed source and device (SSD). In Attachment B of your letter dated February 15, 2015, you provided a description of the Ball Watch USA model number breakdown, and in addition you provided a table with model numbers for the timepieces that will be distributed under 10 CFR 32.14 and for the timepieces that will be distributed under 10 CFR 32.22. You have provided multiple tables with model numbers in different correspondences to the NRC. All of the tables that have been submitted identify different model numbers.

In Attachment B of your letter dated February 15, 2016, "Ball Watch USA Model Number Breakdown" description, you state that there are up to three groupings of alphanumeric characters separated by hyphens (XX1234X-YYYY-ZZ), but that only the left-most six alphanumeric characters indicate if every version of the particular model contains tritium.

Our understanding from this description is that XX1234 is the actual model of the watch. Every watch with the same XX1234 will be constructed in the same manner with regard to the tritium sources. The other alphanumeric characters represent features that are not related to the byproduct material. Please confirm that our understanding of the model breakdown is correct. If this is the case please provide a complete and final list of all the timepiece models that will be distributed under 10 CFR 32.14 and 10 CFR 32.22, only using the alphanumeric characters that describe the timepiece construction regarding the byproduct material.

The complete and final list of the timepiece models requested above should include the following:

- a. 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.
 - b. The total activity per timepiece, the activity per dial and per hand (i.e. second, minute and hour) for each watch model under 10 CFR 32.14.
 2. In our letter dated November 5, 2015, we requested 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, we requested that these drawings include Tritium sources dimensions (length and width), location of all sources, distance from sources to the edge of dial, and distance between sources. In Attachment E of your letter dated February 15, 2016, you provided CAD Drawings for timepieces subject to 10 CFR 32.14 and 10 CFR 32.22. The CAD Drawings are missing the location of tritium sources in each watch model. In addition the drawings have information in a foreign language. Please provide the following for all timepiece models (models you will provide as an answer to question #1):
 - a. Please identify the location all tritium sources in all engineering drawing for each watch model.
 - b. Please make sure all information provided in the drawings is included in English.
- 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. In your letter dated November 2, 2015, you stated that the watches are manufactured to military specification MIL-PRF-46374G. You also stated that if the prototype testing is unsuccessful, the watch model is discarded. All prototype testing is performed in a laboratory in Switzerland under controlled testing procedures. In our letter dated November 5, 2015, we stated that your response was insufficient and to please provide the procedures for the prototype testing and results of this prototype testing.

In your letter dated February, 15, 2016, you stated that Ball Watch Co. receives gaseous tritium light source from mb-microtec and that mb-microtec performs leak testing on their sources pursuant to their SSD Registration certificate NY-1271-S-101-S. Please note that the prototype testing procedures and results required by 10 CFR 32.22 are the prototype testing procedures and results of the final product (self-luminous timepieces), not the tritium sources.

Please provide the prototype testing procedure and results of the timepieces. Note that for prototype testing, the U.S. Nuclear Regulatory Commission (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.

2. In our letter dated November 5, 2015, we requested the estimated external radiation doses and dose commitments relevant to the safety criteria in 10 CFR 32.23 and the basis for such estimates. We also requested a determination that the probabilities with respect to the doses referred to in 10 CFR 32.23(d) meet the criteria of that paragraph. The calculations you provided as a response in your letter dated November 5, 2015, are not clear. George Chabot exposure rate equation uses the activity of the isotope in Becquerel (Bq) and by reviewing your calculations it seems you used fluence rate (cps).

Please demonstrate all your calculations and include all assumptions you made in your dose assessment. 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.

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 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 ADAMS. ADAMS is accessible from the NRC Web site at <http://www.nrc.gov/reading-rm/adams.html>.

If you have any questions regarding the exempt distribution license, please contact me at (301) 415-6004, or by e-mail 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

J. Sirois

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If you have any questions regarding the exempt distribution license, please contact me at (301) 415-6004, or by e-mail 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

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