



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

February 1, 2017

Hess Fine Arts, dba Ball Watch USA
ATTN: Jeffry Hess
1131 4th Street North
Saint Petersburg, FL 33701

SUBJECT: SECOND REQUEST FOR ADDITIONAL INFORMATION

Dear Mr. Hess:

This letter refers to your undated letter, postmarked January 19, 2017 (Agencywide Documents Access and Management System (ADAMS) Accession No. ML17024A065), which responded to our first request for additional information dated December 9, 2016 (ADAMS Accession No. ML16343A059). In reviewing your response, we have determined additional information is required to complete our review. In the enclosure to this letter you will find the list of items for which additional information is needed.

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

We will continue our review upon receipt of this information. If we do not receive your reply within 30 calendar days from the date of this letter, we will consider your application as having been abandoned by you. This action would be without prejudice to the resubmission of another application with the required information.

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>.

Any correspondence regarding your amendment application should reference Control Number 592193.

J. Hess

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If you have any questions, please contact Tomas Herrera at (301) 415-5619, or by e-mail at Tomas.Herrera@nrc.gov regarding the Sealed Source Registration, and Richard Struckmeyer at (301) 415-5477, or by e-mail at Richard.Struckmeyer@nrc.gov regarding the Exempt Distribution License.

Sincerely,

/RA/

Richard K. Struckmeyer
Materials Safety Licensing Branch
Division of Material Safety, State, Tribal
and Rulemaking Programs
Office of Nuclear Material Safety
and Safeguards

Docket No. 030-36971
License No. 09-23920-01E

Enclosure:
Request for Additional Information

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Enclosure:
Request for Additional Information

Certified Mailing No. 7015 0640 0003 2910 1566

ML16300A082 (pkg.)		ML17032A053 (Letter)		
OFC	NMSS/MSTR/MSLB	NMSS/MSTR/MSLB	NMSS/MSTR/MSL	NMSS/MSTR/MSLB
NAME	Richard Struckmeyer	Debra Miller	Tomas Herrera	Lymari Sepulveda
DATE	02/1/2017	02/1/2017	02/1/2017	02/1/2017
OFC	NMSS/MSTR/MSLB	NMSS/MSTR/MSLB		
NAME	Hipólito J. González	Richard Struckmeyer		
DATE	02/1/2017	02/1/2017		

OFFICIAL RECORD COPY

Hess Fine Arts Amendment Request dated October 24, 2016
Second Request for Additional Information

The U.S. Nuclear Regulatory Commission (NRC) staff has reviewed the Hess Fine Arts, Inc. amendment request dated October 24, 2016, and the response to our first Request for Additional Information (RAI) postmarked January 19, 2017, and determined that additional information is needed. In order to continue with our review, please address the issues listed below.

The information related to review of your Sealed Source and Device amendment application is required by Title 10 of the *Code of Federal Regulations* (10 CFR) 32.210 and is described in the relevant guidance document NUREG-1556, Volume 3, Revision 2, titled "Applications for Sealed Source and Device Evaluation and Registration."

The information related to review of your Exempt Distribution License amendment application is required by 10 CFR 32.22, 32.23, and 32.24, and is described in the relevant guidance document NUREG-1556, Volume 8, titled "Program-Specific Guidance about Exempt Distribution Licenses."

A. Information Required for Review of Sealed Source and Device Amendment Application

1. In Hess Fine Arts, Inc. dba Ball Watch USA's (Hess Fine Arts) letter postmarked January 19, 2017, there are references to Model NM1092C and Model NM1092; please identify the correct model number for the watch that Hess Fine Arts seeks to add to the registration certificate.
2. In Hess Fine Arts' letter it states that the Model NM1092C will have 63 sources with a total of 102.3 mCi (3.79 GBq) and that Ball will mark the timepieces between 100 mCi and 150 mCi with a "T150" on its face. Please note that the NRC will list the maximum activity level for the watch on the registration certificate. Please state the maximum activity for the Model NM1092C watch.

If the Model NM1092C can potentially be distributed with a maximum activity level of 150 mCi, please provide an updated Attachment A that includes the maximum activity levels for each of the sources inserted into the watch.

3. When providing the updated Attachment A, please indicate in the drawing the location of the "T150" marking.

Enclosure

B. Information Required for Review of Exempt Distribution License Amendment Application

1. Question B.3 in our first RAI stated that 10 CFR 32.22(a)(2)(vii) requires the applicant to submit information relating to the degree of access of human beings to the product during normal handling and use. You responded: "The timepieces are worn by human beings. However, there is no access to the GTLS (gaseous tritium light source) during normal use." This response does not provide information as to why you assert no such access is possible. Please provide your rationale for this statement.
2. Question B.5 in our first RAI stated that 10 CFR 32.22(a)(2)(ix) requires the applicant to submit information relating to the expected useful life of the product. It does not appear that you provided an answer to this question. Please provide the required information, or state where it can be found in your application or in your initial response.
3. Our questions 16, 17, and 18 were concerned with the specific examples you provided in your application. In your responses to these questions, you assumed that damage to a timepiece would result in the crushing of one glass tube (or possibly a combination of tubes) containing a total of no more than 100 millicuries of tritium. However, your calculations and tables must indicate the doses that would result from the crushing of all tubes in any one timepiece, and must assume that any such timepiece contains the maximum activity of 150 millicuries of tritium stated in your application. The alternative to this would be to modify your amendment request to state the actual maximum level of activity that you intend to distribute in a timepiece.