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

The U.S. Nuclear Regulatory Commission (NRC) staff has reviewed the Hess Fine Art, Inc. amendment request dated October 24, 2016, 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

General

1. The application requested to amend the registration certificate NR-1265-D-101-E to increase the activity limits from 95.4 mCi to 150 mCi. However, the application did not specify which watch models will have the increased 150 mCi activity limit. Please identify which specific watch models will have the increased activity limits.

2. Please state if there are any other changes to the watches besides an increase in activity level. If there are any changes, please provide a detailed description of all the changes.

3. Your Exempt Distribution License is under the name "Hess Fine Art, Inc. dba Ball Watch USA." Please confirm that this company name is accurate. If you confirm that the name is correct, the Sealed Source and Device Registration Certificate, NR-1265-D-101-E, will be amended to reflect the correct company name.

4. The application makes references to Attachments A, B, and C. Please note that these attachments were not included with the application package. Please provide copies of the attachments.

Description of the Product/Construction

5. The application includes a Table 1 which lists a watch model identified as NM1092. Please note that Model NM1092 its not currently listed in Registration Certificate NR-1265-D-101-E. Clarify whether Hess Fine Art intends to add a new watch model to the registration certificate. If Hess Fine Art intends to include a new model in the registration certificate, please include all of the relevant information as stated in NUREG-1556, Volume 3, Revision 2, Section 10.3 "Construction of Product."

Enclosure

Labeling

6. Please confirm that there are no changes to the labeling of the watches.

7. Please confirm that the location of the Ball Watch logo is printed on all watches on the face just below the 12 o'clock position.

Conditions of Use

8. Please confirm that the conditions of use will not change for those watch models with increased activity levels.

Prototype Testing

9. The prototype testing section of the application references historical use. However, the purpose of the section is unclear. If it is the intent of Hess Fine Art to use this prototype testing section to register the new watch model NM1092 please state so. If Hess Fine Art intends to register watch Model NM1092, please describe the similarities between Model NM1092 and the Ball Watch timepieces referenced in the prototype testing section. In your description clearly state the specific environments to which the watches have been subjected in order to demonstrate that the products will maintain their integrity during normal use and likely accident conditions. Alternatively, as stated in NUREG-1556, Volume 3, Revision 2, Section 10.5, "Prototype Testing," in lieu of actual prototype testing the NRC may accept comparison to a similar or equivalent Hess Fine Art watch model previously reviewed and registered by the NRC.

Radiation Profiles

10. In the radiation profiles section of the application it states "N/A." Please explain Hess Fine Art's rationale for listing this section as "N/A".

Quality Assurance

11. As noted above, please provide a copy of Attachment C or confirm that there have been no changes to Hess Fine Art's Quality Assurance program since the registration certificate was issued on September 26, 2006.

B. Information required for review of exempt-distribution license amendment application

10 CFR 32.22(a)(2) requires the applicant to submit sufficient information relating to the design, manufacture, prototype testing, quality control procedures, labeling or marking, and conditions of handling, storage, use, and disposal of the self-luminous product to demonstrate that the product will meet the safety criteria set forth in § 32.23. You may reuse previously submitted information where such information is applicable to specific requirements.

1. 10 CFR 32.22(a)(2)(v) requires the applicant to submit information concerning details of construction and design of the product as related to containment and shielding of the byproduct material and other safety features under normal and severe conditions of handling, storage, use, and disposal of the product. This issue may be addressed in conjunction with your response to question A.5.

2. 10 CFR 32.22(a)(2)(vi) requires the applicant to submit 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. This issue may be addressed in conjunction with your response to question A.10.

3. 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.

4. 10 CFR 32.22(a)(2)(viii) requires the applicant to submit the total quantity of byproduct material expected to be distributed in the product annually.

5. 10 CFR 32.22(a)(2)(x) requires the applicant to submit the proposed method of labeling or marking each unit with identification of the manufacturer or initial transferor of the product and the byproduct material in the product. This issue may be addressed in conjunction with your response to question A.6.

6. 10 CFR 32.22(a)(2)(xi) requires the applicant to submit procedures 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. This issue may be addressed in conjunction with your response to question A.9.

7. 10 CFR 32.22(a)(2)(xii) requires the applicant to submit 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. This issue may be addressed in conjunction with your response to question A.9.

8. 10 CFR 32.22(a)(2)(xiii) requires the applicant to submit the estimated external radiation doses and dose commitments relevant to the safety criteria in § 32.23 and the basis for such estimates. This issue may be addressed in conjunction with your response to questions A.10 and B.2.

9. 10 CFR 32.22(a)(2)(xiv) requires the applicant to submit a determination that the probabilities with respect to the doses referred to in § 32.23(d) meet the criteria of that paragraph. Although your application contains a paragraph with the heading “Disposal,” you did not specify whether this requirement is met. Please submit a determination that the probabilities with respect to the doses referred to in § 32.23(d) meet the criteria of that paragraph.

10. 10 CFR 32.22(a)(2)(xv) requires the applicant to submit 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. This issue may be addressed in conjunction with your response to question A.11.

11. 10 CFR 32.23(a) requires the applicant for a license under § 32.22 to demonstrate that in normal use and disposal of a single exempt unit, it is unlikely that the external radiation dose in any 1 year, or the dose commitment resulting from the intake of radioactive material in any 1 year, to a suitable sample of the group of individuals expected to be most highly exposed to radiation or radioactive material from the product will exceed the dose to the appropriate organ as specified in Column I of the table in § 32.24 of this part.

12. 10 CFR 32.23(b) requires the applicant for a license under § 32.22 to demonstrate that in normal handling and storage of the quantities of exempt units likely to accumulate in one location during marketing, distribution, installation, and servicing of the product, it is unlikely that the external radiation dose in any 1 year, or the dose commitment resulting from the intake of radioactive material in any 1 year, to a suitable sample of the group of individuals expected to be most highly exposed to radiation or radioactive material from the product will exceed the dose to the appropriate organ as specified in Column II of the table in § 32.24.

13. 10 CFR 32.23(c) requires the applicant for a license under § 32.22 to demonstrate that it is unlikely that there will be a significant reduction in the effectiveness of the containment, shielding, or other safety features of the product from wear and abuse likely to occur in normal handling and use of the product during its useful life.

14. 10 CFR 32.23(d) requires the applicant for a license under § 32.22 to demonstrate that in use and disposal of a single exempt unit, or in handling and storage of the quantities of exempt units likely to accumulate in one location during marketing, distribution, installation, and servicing of the product, the probability is low that the containment, shielding, or other safety features of the product would fail under such circumstances that a person would receive an external radiation dose or dose commitment in excess of the dose to the appropriate organ as specified in Column III of the table in § 32.24, and the probability is negligible that a person would receive an external radiation dose or dose commitment in excess of the dose to the appropriate organ as specified in Column IV of the table in § 32.24.

The following items are concerned with the specific examples you provided in your application:

15. Calculation of Skin Contact EDE during Routine Use (Table 2)

    The number in column [6] of Table 2 (“Annual EDE to internal organs”) is shown as 7.3×10^{-8} mSv. However, in step 6 of the calculations above the table, it appears that using the intake of 11.8 Bq/day (from step 2) and multiplying by the Dose Conversion Factor (1.7×10^{11} Sv/Bq) would result in an annual EDE to internal organs of 2×10^{-7} mSv.

    Please provide an explanation for the apparent discrepancy, or revise your calculations.

16. Skin Contact EDE during Watch Repair (Table 4)

    The number in column [3] of Table 2 (“Annual Dose Equivalent of contact area”) is shown as 0.58 mSv. However, in step 3 of the calculations above the table, it appears

that using the intake of 8.9 Bq/day (from step 2), then multiplying by the Dose Conversion Factor (1.8 X 10^{-3} mSv-cm^2/Bq) and dividing by the exposed skin area of 3 cm^2 would result in an annual dose equivalent to the contact area of 0.534 mSv. Therefore, in step 4, multiplying by 3 cm^2 and dividing by 1.8 m^2 (1.8 X 10^4 cm^2) should produce a result of 8.9 X 10^{-5} mSv. Furthermore, in step 5, using the organ weighting factor for skin of the whole body (0.01) should produce a result of 8.9 X 10^{-7} mSv. Finally, in step 6, multiplying by the Dose Conversion Factor (1.7 X 10^{-11} Sv/Bq) should produce a result of 1.5 X 10^{-10} mSv.

Please provide an explanation for these apparent discrepancies, or revise your calculations.

17. Accident and Misuse

Your application requests to increase the activity limits from 95.4 mCi to 150 mCi, but in this section you provide examples for timepieces containing 100 mCi. Your examples should conform to this upper limit. In addition, you have not explicitly satisfied the requirements of 10 CFR 32.23, as described above in items 11 through 14. Please specify how you will meet these requirements.