Rodriguez-Luccioni, Hector

From: Jerry Sirois <jerry@ballwatchusa.com>
Sent: Monday, April 18, 2016 5:59 PM
To: Rodriguez-Luccioni, Hector
Cc: Herrera, Tomas; Gonzalez, Hipolito
Subject: [External_Sender] RE: Request for Additional Information regarding Hess Fine Art renewal application
Attachments: Answers4thRequest.doc

Hello,

Attached is our response to your request for additional information. A hard copy is en route.

Thank you and best regards,

Jerry Sirois

Jerry Sirois
Executive Vice President
BALL Watch USA
1920 Dr MLK St North
Suite D
St Petersburg, FL 33704
727-896-4278
(F) 727-825-0803

From: Rodriguez-Luccioni, Hector [mailto:Hector.Rodriguez-Luccioni@nrc.gov]
Sent: Friday, April 15, 2016 6:40 AM
To: 'Jerry Sirois' (jerry@ballwatchusa.com)
Cc: Herrera, Tomas; Gonzalez, Hipolito
Subject: RE: Request for Additional Information regarding Hess Fine Art renewal application

Mr. Sirois,

This is a reminder that Hess Fine Art due date to respond to our request for additional information is COB, Monday, April 18, 2016. If we have not received complete information by April 18, 2016, we will consider taking regulatory action on your current NRC license no. 09-23920-01E, including termination of your license.

If you have any questions please let me know.

Best regards,

Hector Luis Rodriguez-Luccioni, Ph.D.
U.S. Nuclear Regulatory Commission
Office of Nuclear Material Safety and Safeguards

Division of Material Safety, State, Tribal and Rulemaking Programs
Materials Safety Licensing Branch
(301)415-6004
MS: T-8E18
Hector.Rodriguez-Luccioni@nrc.gov

From: Rodriguez-Luccioni, Hector
Sent: Monday, April 11, 2016 8:52 AM
To: 'Jerry Sirois' (jerry@ballwatchusa.com) <jerry@ballwatchusa.com>
Cc: Herrera, Tomas <Tomas.Herrera@nrc.gov>; Gonzalez, Hipolito <Hipolito.Gonzalez@nrc.gov>
Subject: Request for Additional Information regarding Hess Fine Art renewal application

Mr. Sirois,

This emails refers to your letter dated March 28, 2016, which responds to our third request for additional information dated February 23, 2016. 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.

1. In our letter dated February 23, 2016, we requested the prototype testing procedure and results of the timepieces. In your letter dated March 28, 2016, you provided a review of the operational history of the timepieces to demonstrate the timepieces' ability to maintain its integrity when subjected to conditions of normal use and likely accident conditions. You provided operational history of the timepieces used by explorers of extreme conditions without a reported mishap. Please confirm that the timepieces discussed in your operational history review contain tritium and are of similar constructions of the timepieces distributed under your exempt distribution license no. 09-23920-01E.

2. In our letter dated February 23, 2016, we requested a demonstration of all your calculations and assumptions you made in your dose assessment submitted in your letter dated February 15, 2016. In your letter dated March 28, 2016, you did not submit a response to our request because the efficiency of the detectors was requested but was not received prior to the due date of the submission of your letter dated March 28, 2016. Please provide a complete dose assessment demonstrating all your calculations and include all assumptions you made in your dose assessment submitted in your letter dated February 15, 2016. Please note that you can also 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," as we stated in our letter dated February 23, 2016.

Any correspondence regarding your application should reference the control number 588743. Please submit the requested information by COB, Monday, April 18, 2016. If we have not received complete information by April 18, 2016, we will consider taking regulatory action on your current NRC license no. 09-23920-01E, including termination of your license.

Please note that if the NRC terminates your exempt distribution license, Hess Fine Art will not be able to operate under Exempt Distribution License no. 09-23920-01E, which means Hess Fine Art shall permanently cease licensed activities authorized by the exempt distribution license. If Hess Fine Art wants to resume operations after termination of the license, Hess Fine Art will have to apply for a new exempt distribution license, which includes application fees pursuant to 10 CFR 170.31.

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, please contact me.

Best regards,

Hector Luis Rodriguez-Luccioni, Ph.D.
U.S. Nuclear Regulatory Commission
Office of Nuclear Material Safety and Safeguards
Division of Material Safety, State, Tribal and Rulemaking Programs
Materials Safety Licensing Branch
(301)415-6004
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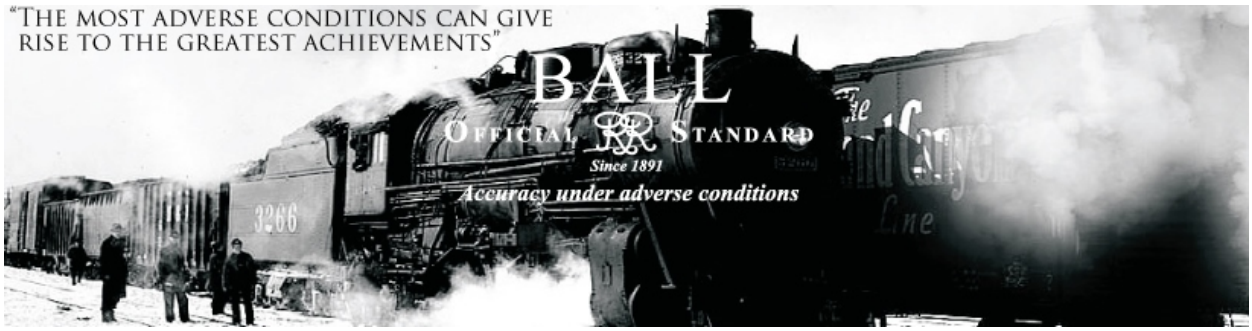
Hector.Rodriguez-Luccioni@nrc.gov



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4/18/16

U.S. Nuclear Regulatory Commission
Attn: 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
Washington, DC 20555-0001

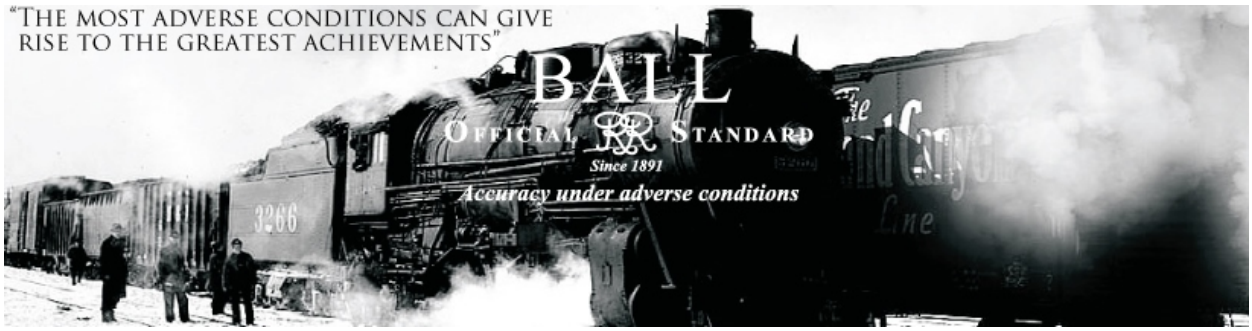
Subject: Docket No. 030-36971
Mail Control No. 58874
Hess Fine Art Exempt Distribution License Renewal Application
License No. 09-23920-01E

Dear Dr. Rodriguez-Luccioni:

The following are answers to your request for additional information sent via email on April 11, 2016. The answers are enumerated in accordance with the questions.

1. In our letter dated February 23, 2016, we requested the prototype testing procedure and results of the timepieces. In your letter dated March 28, 2016, you provided a review of the operational history of the timepieces to demonstrate the timepieces' ability to maintain its integrity when subjected to conditions of normal use and likely accident conditions. You provided operational history of the timepieces used by explorers of extreme conditions without a reported mishap. Please confirm that the timepieces discussed in your operational history review contain tritium and are of similar constructions of the timepieces distributed under your exempt distribution license no. 09-23920-01E.

ANSWER: We confirm that all watches discussed contain the H-3 and there have been no reported failures.



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2. In our letter dated February 23, 2016, we requested a demonstration of all your calculations and assumptions you made in your dose assessment submitted in your letter dated February 15, 2016. In your letter dated March 28, 2016, you did not submit a response to our request because the efficiency of the detectors was requested but was not received prior to the due date of the submission of your letter dated March 28, 2016. Please provide a complete dose assessment demonstrating all your calculations and include all assumptions you made in your dose assessment submitted in your letter dated February 15, 2016. Please note that you can also 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," as we stated in our letter dated February 23, 2016.

ANSWER: The following is a supplement to the test results previously provided. NUREG-1717, Systematic Radiological Assessment of Exemptions for Source and Byproduct Materials, was utilized to further determine the dose to individuals in contact with the Ball Watch timepieces.

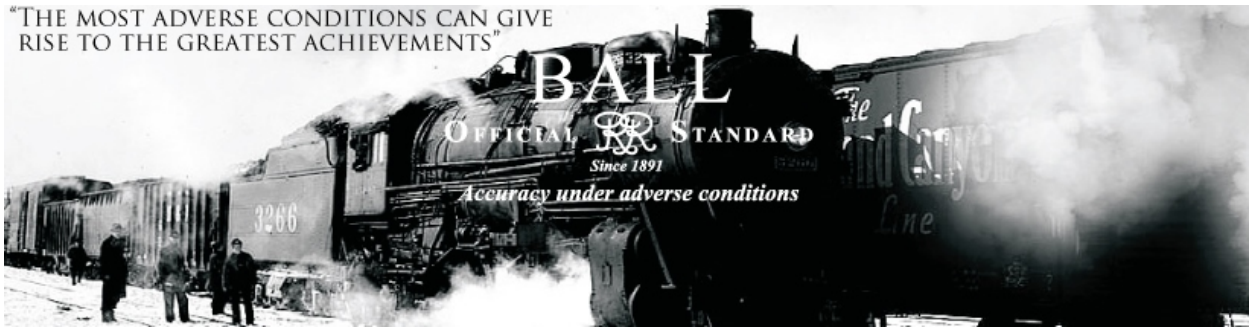
NUREG-1717, Section 2.3, Timepieces, Hands, and Dials was primarily focused on H-3 paint. Ball Watch timepieces do not use H-3 paint but instead uses H-3 gas in sealed tubes. Section 2.3.4 stated the hypothetical doses from timepieces containing H-3 in glass tubes ("GTLS") would be less than those for H-3 in paint due to the assumed lower release rate of 10 ppb/hour for a timepiece containing 25 mCi. This correlation was used in all subsequent calculations. Additionally, another assumption used throughout was the linearity between the activity and the release rate. For instance, if a 25 mCi timepiece releases 10 ppb/hour, a 100 mCi timepiece would release 40 ppb/hour.

Distribution

NUREG-1717, Table 2.3.2 has predicted the highest individual annual Effective Dose Equivalent (EDE) to be 9 mrem for a regional delivery truck driver delivering H-3 timepieces. Ball Watch uses the following assumptions:

1. Ball Watch maintains less than 1,000 timepieces in storage, so the individual annual EDE should be reduced by 1,000.
2. The timepieces reported in the Table 2.3.2 used H-3 paint which was estimated to have a leakage rate of 1 ppm/hour for a timepiece containing 2 mCi of H-3 (or 12.5 ppm/hour for a 25 mCi timepiece). Ball Watch uses GTLS which has an estimated leakage rate of 10 ppb/hr for a 25 mCi timepiece. The difference in leakage rate of H-3 is a factor of 1,250.

Using these assumptions, the highest individual annual EDE for the distribution of Ball Watch timepieces would be $9 \div 1{,}000 \div 1{,}250 = 7.2 \times 10^{-6}$ mrem.



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Routine Use

EDE From Skin Contact

NUREG-1717, Section 2.3.4.2.1 has provided a method for determining the dose from skin contact from routine use of timepieces containing H-3. The method presented in NUREG-1717 was specifically for H-3 paint in timepieces. However, the correlation presented above allows these calculations to determine dose from the routine use of Ball Watch timepieces manufactured with GTLS.

[1] Determine the H-3 leakage from a watch.
Leakage Rate (Bq/hr) = Activity (GBq) X 10 ppb/hr

[2] Determine the intake of tritiated water vapor (HTO) through the skin in contact with the case of the watch.
Intake (Bq/day) = Leakage Rate (Bq/hr) X 16 hr/day X absorbed fraction (0.02)

[3] Determine the annual dose equivalent to the skin in contact with the case.
Annual Dose Equivalent (mSv) = Intake (Bq/day) X 365 days/yr
X dose conversion factor for HTO
$(1.8\times10^{-3}$ mSv-cm^2/Bq)
÷ Exposed Skin Area (10 cm^2)

[4] Determine the average annual dose equivalent to the skin of the whole body from the distributed wristwatch source.
Annual Dose Equivalent (mSv) = Annual Dose Equivalent to contact area (mSv)
X 10 cm^2 contact area / 1.8 m^2 whole body area

[5] Determine the contribution of this skin dose equivalent to the annual EDE.
EDE (mSv) = Annual Dose Equivalent to the whole body (mSv)
X organ weighting factor for skin of the whole body (0.01)

[6] Determine the annual EDE to the internal organs of the body from the absorption of HTO through the skin in contact with the case of the watch.
EDE (mSv) = Intake (Bq/day) X Dose Conversion Factor for absorption through the skin or ingestion of H-3 (1.7E-11 Sv/Bq)

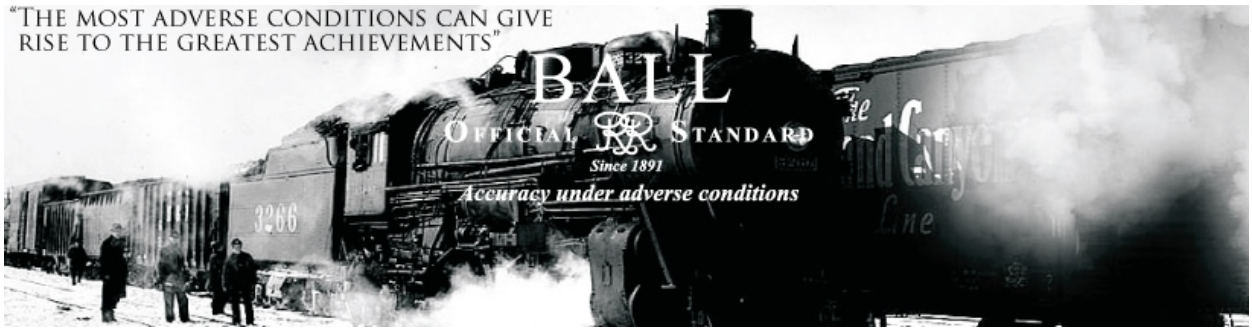

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Table 1 below provides the estimated annual EDE to the skin and also to the organs. Each step above is enumerated in the table. Combining the doses from H-3 on the skin and absorbed by the internal organs, the EDE for timepieces up to 100 mCi are 4.4 X 10^{-6} mSv (4.4 X 10^{-4} mrem).

Table 1. Skin Contact EDE During Routine Use

		[1]	[2]	[3]	[4]	[5]	[6]
		Leakage (10 ppb/h)	HTO intake	Annual Dose Equivalent of contact area	Average annual dose equivalent to skin of whole body	Annual EDE to skin of whole body	Annual EDE to internal organs
mCi	GBq	Bq/h	Bq/day	mSv	mSv	mSv	mSv
100	3.7	37.0	11.8	0.78	4.3 X 10^{-4}	4.3 X 10^{-6}	7.3 X 10^{-8}

EDE From Airborne Releases

NUREG-1717, Section 2.3.4.2.2 has provided a method for determining the dose from airborne releases from routine use of timepieces containing H-3. The method presented in NUREG-1717 was specifically for H-3 paint in timepieces. However, the correlation presented above allows these calculations to determine dose from the routine use of Ball Watch timepieces manufactured with GTLS.

[1] Start with the H-3 leakage rate determined above.

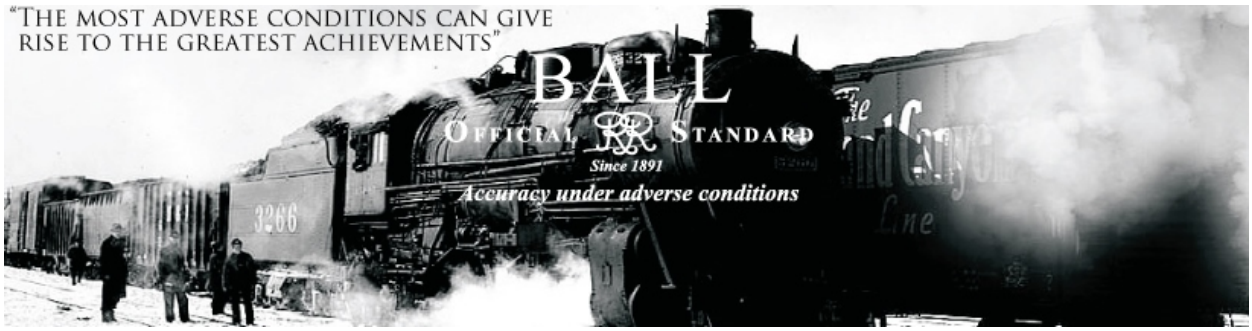
[2] Estimate the concentration of H-3 in the air for an enclosed volume of a 450 m^3 (approximately 2,000 ft^2) home with a recirculation rate of 1 volume air change per hour.

[3] Determine the H-3 breathed in for an estimated 12 hour period.

[4] Determine the EDE from inhalation of H-3 using a dose conversion factor of 1.35 X 10^{-4} mSv/Bq derived from the example contained in NUREG-1717, Section 2.3.4.2.2.

Table 2 provides the annual EDE to the wearer and others in the same house. The annual effective dose equivalent for timepieces up to 100 mCi remains less than 1.2 X 10^{-4} mSv (1.2 X 10^{-2} mrem).

Table 2. EDE from Airborne Released During Routine Use



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		[1] Leakage (10 ppb/h)	[2] HTO in air	Breathing Rate	[3] HTO breathed	[4] Annual EDE from inhalation
mCi	GBq	Bq/h	Bq/m^3	m^3/hr	Bq/hr	mSv
100	3.7	37.0	0.08	0.9	0.89	1.2 X 10^{-4}

Watch Repair

EDE From Skin Contact

NUREG-1717, Section 2.3.4.2.1 has provided a method for determining the dose from skin contact from routine use of timepieces containing H-3. Section 2.3.4.3 provides some modifications to the equations. The method presented in NUREG-1717 was specifically for H-3 paint in timepieces and the correlation previously presented above was used to adjust these calculations to determine dose from the routine use of Ball Watch timepieces manufactured with GTLS.

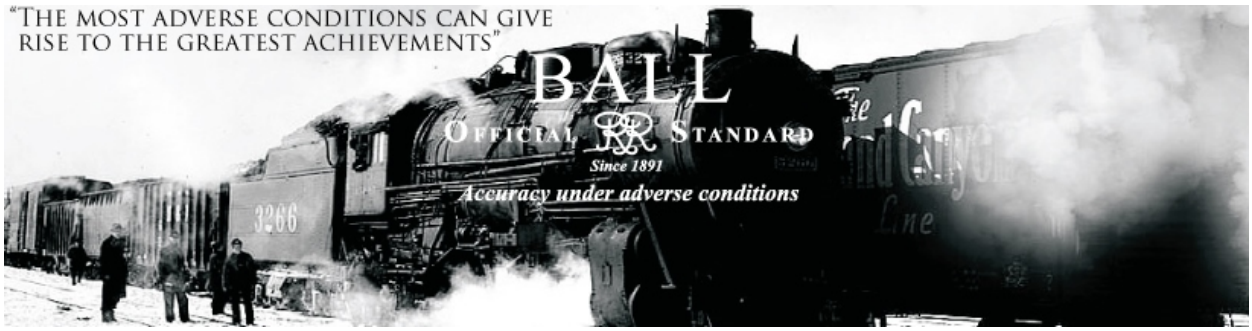
[1] Determine the H-3 leakage from a watch.
Leakage Rate (Bq/hr) = Activity (GBq) X 10 ppb/hr

[2] Determine the intake of tritiated water vapor (HTO) through the skin in contact with the case of the watch.
Intake (Bq/day) = Leakage Rate (Bq/hr) X 8 hr/day X absorbed fraction (0.02)

[3] Determine the annual dose equivalent to the skin in contact with the case (assuming 100 repairs per year and only 3 cm^2 of skin touch the timepiece).
Annual Dose Equivalent (mSv) = Intake (Bq/repair) X 100 repairs/yr
X dose conversion factor for HTO
(1.8×10^{-3} mSv-cm^2/Bq)
÷ Exposed Skin Area (3 cm^2)

[4] Determine the average annual dose equivalent to the skin of the whole body from the distributed wristwatch source.
Annual Dose Equivalent (mSv) = Annual Dose Equivalent to contact area (mSv)
X 3 cm^2 contact area / 1.8 m^2 whole body area

[5] Determine the contribution of this skin dose equivalent to the annual EDE.



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EDE (mSv) = Annual Dose Equivalent to the whole body (mSv)
X organ weighting factor for skin of the whole body (0.01)

[6] Determine the annual EDE to the internal organs of the body from the absorption of HTO through the skin in contact with the case of the watch.
EDE (mSv) = Intake (Bq/day) X Dose Conversion Factor for absorption through the skin or ingestion of H-3 (1.7E-11 Sv/Bq)

Table 3 below provides the estimated annual EDE to the skin and also to the organs. Each step above is enumerated in the table. Combining the doses from H-3 on the skin and absorbed by the internal organs, the EDE for timepieces up to 100 mCi are 2.1 X 10^{-7} mSv (2.1 X 10^{-5} mrem).

Table 3. Skin Contact EDE During Watch Repair

		[1]	[2]	[3]	[4]	[5]	[6]
		Leakage (10 ppb/h)	HTO intake	Annual Dose Equivalent of contact area	Average annual dose equivalent to skin of whole body	Annual EDE to skin of whole body	Annual EDE to internal organs
mCi	GBq	Bq/h	Bq//repair	mSv	mSv	mSv	mSv
100	3.7	37.0	5.9	0.11	1.8 X 10^{-5}	1.8 X 10^{-7}	3.7 X 10^{-8}

EDE From Airborne Releases

NUREG-1717, Section 2.3.4.2.2 has provided a method for determining the dose from airborne releases from routine use of timepieces containing H-3. Section 2.3.4.3 provides some modifications to the equations.

[1] Start with the H-3 leakage rate determined above.

[2] Estimate the concentration of H-3 in the air for an enclosed volume of a 34 m^3 repair shop with a recirculation rate of 1 volume air change per hour.

[3] Determine the H-3 breathed in for an estimated 8 hour work day.

[4] Determine the EDE from inhalation of H-3 using a dose conversion factor of 1.35 X 10^{-4} mSv/Bq derived from the example contained in NUREG-1717, Section 2.3.4.2.2.

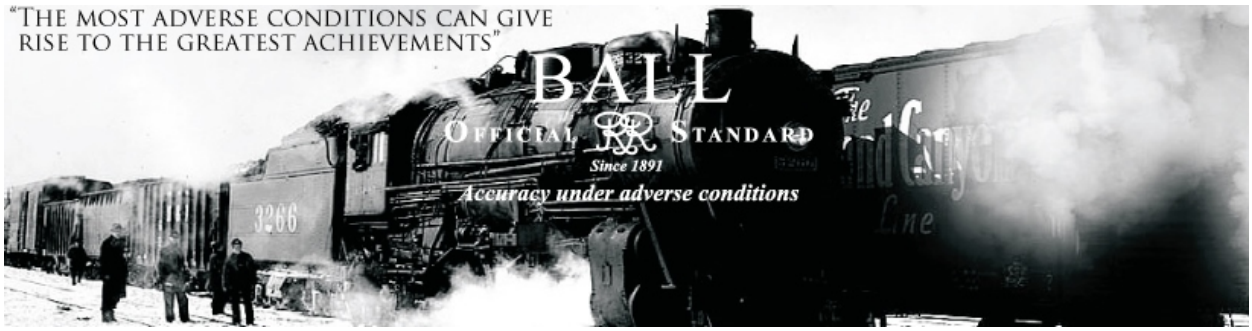

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Table 4 provides the annual EDE to the wearer and others in the same house. The annual effective dose equivalent for timepieces up to 100 mCi remains less than 1.4 X 10^{-3} mSv (0.14 mrem).

Table 4. EDE from Airborne Released During Watch Repair

		[1]	[2]		[3]	[4]
		Leakage (10 ppb/h)	HTO in air	Breathing Rate	HTO breathed	Annual EDE from inhalation
mCi	GBq	Bq/h	Bq/m^3	m^3/hr	Bq/hr	mSv
100	3.7	37.0	1.09	1.2	10	1.4 X 10^{-3}

Disposal

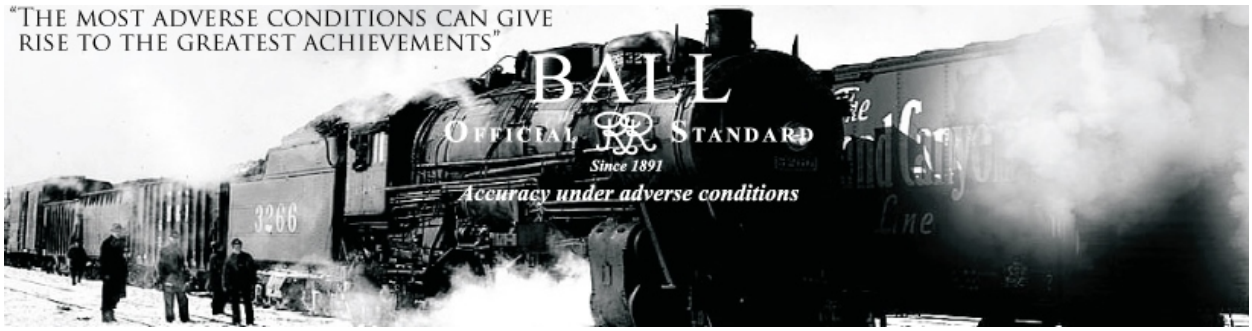
Ball Watch timepieces are expensive items and disposal as waste is remote. Even after the useful life of the GTLS, the timepieces are still state-of-the-art mechanical devices. Each Ball Watch timepiece is registered. To date, all Ball Watch timepieces are accounted for and non have been discarded as refuse. In the event a Ball Watch timepiece is discarded, the dose to the waste collector will not exceed that of the owner of the timepiece previously calculated in Table 2 above. The EDE would be less than 1.2 X 10^{-4} mSv (1.2 X 10^{-2} mrem).

Accident and Misuse

NUREG-1717, Section 2.3.4.5 has provided calculations for several scenarios:

For a watch repairman, the individual EDE from crushing a single watch containing 930 MBq (25 mCi) of H-3 could be 0.02 mSv (2 mrem) at a small repair shop or 0.008 mSv (0.8 mrem) at a large repair shop. Extrapolating this to a 100 mCi timepiece would create an EDE of 3.2 to 8 mrem dose.

For a person at home, the individual EDE from crushing a single watch containing 930 MBq (25 mCi) of 3 H could be 5×10^{-4} mSv (0.05 mrem). Extrapolating this to a 100 mCi timepiece would create an EDE of 0.2 mrem dose.



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For a worker in a storeroom or cargo-handling area, the individual EDE from crushing 200 watches containing a total of 185 GBq (5 Ci) of 3 H could be 0.05 mSv (5 mrem). This value would remain valid for Hess Fine Arts since no more than 50 timepieces are located in each storage container.

For a child that handles the timepiece for 10 minutes per day and sleeps in a closed bedroom for 12 hours per day, NUREG-1717 calculates the dose equivalent to the skin of a 5-year-old child due to absorption of H-3 from the timepiece at 0.1 mrem for a 25 mCi timepiece. That would be extrapolate to 0.4 mrem for a 100 mCi timepiece. The EDE would be estimated at less than 0.004 mrem due to absorption of the H-3 through the skin in contact with the timepiece and 0.004 mrem from inhalation of the airborne H-3.

In each of the scenarios above, the EDE is well below regulatory limits.

Please contact me if you need further clarification on the answer.

Sincerely

/s/Jerry Sirois

Jerry Sirois
Hess Fine Art
1131 4th Street North
St. Petersburg, FL 33701