HESS FINE ART
FINE & DECORATIVE ARTS
ESTATE JEWELERY • WATCHES
DIAMONDS • ANTIQUES

HESSFINEART.COM
1131 4TH STREET NORTH
ST. PETERSBURG, FL 33701

JEFFREY P. HESS, CEO
KATRINA HESS, G.G, V.P.
727.896.0622
FAX 727.822.8899

October 24, 2016

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
Mail Stop: T8E18
Attn: Tomas Herrera
Two White Flint North
11545 Rockville Pike
Rockville, MD 20852-2738

Subject: Registry of Radioactive Sealed Sources and Devices, Safety Evaluation of Device NR-1265-D-101-E

Dear Dr. Herrera:

The following is a request to amend the above named Registry to increase the activity limits from 95.4 mCi to 150 mCi. The following information applies:

DEVICE TYPE: Wrist Watches

MODEL: See Table 1 below.

DISTRIBUTOR: Hess Fine Arts, Inc.
1131 4th Street north
St. Petersburg, FL 33701

MANUFACTURER: Ball Watch Company SA
41 A Route de Chene in
CH-1208 Geneva
Switzerland

SEALED SOURCE MODEL DESIGNATION: mb-microtec Model 400/1
mb-microtec Model 400/2
mb-microtec Model 400/3
mb-microtec Model 400/4
mb-microtec Model 400/5
mb-microtec Model 400/6

ISOTOPE	**MAXIMUM ACTIVITY**
Hydrogen-3	150 mCi (5.55 GBq)

LEAK TEST FREQUENCY: Not Required

PRINCIPAL USE: (W) Self-Luminous Light Source

CUSTOM DEVICE: No

DESCRIPTION:

The timepieces will be distributed by the name Ball Watch USA, under the Hess Fine Arts, Inc. exempt distribution license. The watch models listed use gaseous tritium light sources to enable the wearer to read the watch dial in low or no light situations. The light sources are located on the hour, minutes, and seconds hands and on some models, on the dial to indicate the number or the hour position and below the bezel to provide backlight to other functions of the watch.

DESCRIPTION/CONSTRUCTION

1. If the registration certificate holder is requesting to register more than one source/device on a certificate, are designs similar enough to do so?

   Yes. The tritium light sources (GTLS) are manufactured by mb-microtec ag under Registry of Radioactive Sealed Source and Devices Safety Evaluation of Devices number NY-1271-S-101-S (superseding NR-446-S-102-S). The manufacturer address is Freigurgstrasse 634, CH-3172 Niederwangen, Switzerland. The complete timepieces are manufactured by Ball Watch Company SA with address Rue du Châtelot 21, 2300 La Chaux-de-Fonds, Switzerland. The individual sources from mb-microtec are mounted on the face and hands of the wrist watch, to be described later.

2. Provide Device/Source design with complete engineering drawings (dimensions, tolerances, list of materials) for timepieces greater than 25 mCi H-3.

See Attachment A for drawings and specification sheets on the following timepieces:

Table 1. Timepieces with H-3 activity greater than 100 mCi but less than 150 mCi.

	Number of Sources	Activity (mCi)	Activity (GBq)
NM1092	63	102.3	3.79

Assembly Methods

The timepieces are manufactured to military specification MIL-PRF-46374G. All of the watch cases are made of 316L stainless steel.

Source Mounting and Security

Gaseous Tritium List Source (GTLS) are manufactured by mb-microtec ag. The longer GTLSs are bonded to the minute and hours hands using elastomeric adhesives applied in a double layer. The shorter GTLSs are placed on the watch dial and held in place by clamping pressure created when a plastic holder ring having U-shaped channels for the GTLSs is press-fitted into the back of the dial. The ring is then adhesively bonded to the dial. Each model number has a specific number of GTLSs at a specific length and specific configuration.

LABELING

The label is either engraved or permanently stamped on the rear of the 316L steel watch housing and contains the watch model number, a consecutive serial number, and "3^H mb microtec illumination" or "3H MBM". All timepieces containing tritium greater than 25 mCi will have "T SWISS" or "T" printed on the lower left of the dial face. All timepieces containing tritium greater than 25 mCi but less than 100 mCi will have "T100" printed on the lower left of the dial face. All timepieces containing tritium greater than 100 mCi and less than 150 mCi will have "T150" printed on the lower left of the dial face.

CONDITIONS OF USE

The estimated working life of the wrist watch is indefinite. The working life of the GTLS is approximately 10 years for timepieces containing less than 25 mCi H-3. The estimated life of the GTLS for timepieces with activities greater than 25 mCi H-3 should be proportional.

No action is required when the GTLS reaches the end of its working life. The timepieces will still function properly but lack the capacity of visibility in the dark.

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
(1.8×10^{-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)

Table 2 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 2. 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 3 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 3. EDE from Airborne Released During Routine Use

		[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	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.
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 4 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 2.1×10^{-7} mSv (2.1×10^{-5} mrem).

Table 4. 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
150	5.6	55.5	8.9	0.58	9.7×10^{-5}	9.7×10^{-7}	5.5×10^{-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 1.35×10^{-4} mSv/Bq derived from the example contained in NUREG-1717, Section 2.3.4.2.2.

Table 5 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 1.4×10^{-3} mSv (0.14 mrem).

Table 5. EDE from Airborne Released During Watch Repair

		[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
150	5.6	55.5	1.63	1.2	16	2.1×10^{-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 1.2×10^{-4} mSv (1.2×10^{-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.

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.
In the article "*Estimated Radiation Dose From Timepieces Containing Tritium*", L.M. McDowell-Boyer, Health and safety Research Division, Oak Ridge National Laboratory, January 1, 1980, testing indicated tritium timepieces of 100 mCi generated a maximum annual dose of 0.02 mrem from use of the wrist watch. Extrapolating this result for 200 mCi wrist timepieces produces a maximum of 0.04 mrem whole-body dose to the wearer. This is below the 1 mrem annual whole body dose requirement pursuant to 10 CFR 32.24.

Dose is linearly related to activity. Therefore if a wrist watch containing 200 mCi of H-3 produces a maximum of 0.04 mrem whole-body dose to the wearer, then a wrist watch with 5,000 mCi would produce a whole-body dose to the wearer of 1 mrem.

PROTOTYPE TESTING/HISTORICAL USE

The timepieces are manufactured to military specification MIL-PRF-46374G. A copy is included in Attachment B. Results of prototype testing in accordance with NUREG 1556, Volume 3, Revision 2, Section 10.5 can be shown through a review of the operational history of timepieces to demonstrate the timepiece's ability to maintain its integrity when subjected to conditions of normal use and likely accident conditions. The following examples used timepieces identical to those being distributed by Ball Watch USA.

All timepieces are constructed with Swiss manufactured movements. The movements are encased in 316L stainless steel. The crystal hardness must be 500 Vickers for mineral crystals and 1700 Vickers for sapphire crystals.

H-3 has been used as a light source in timepieces for approximately 25 years. Not all Ball Watch timepieces contain H-3. Only select models have been enhanced with H-3. The construction of those timepieces does not vary from non-H-3 timepieces.

All H-3 sources are fixed in the timepieces in the same fashion. The longer sources are bonded to the minute and hours hands using elastomeric adhesives applied in a double layer. The shorter sources are placed on the watch dial and held in place by clamping pressure created when a plastic holder ring having U-shaped channels for the sources is press-fitted into the back of the

dial. The ring is then adhesively bonded to the dial. Since its inception, no H-3 sources have breached the binding process.

The Ball Watch timepieces were originally constructed in the late 1800's. Over that period, the construction of the timepieces has evolved to meet extreme needs. The Ball Watch timepieces are routinely used today by explorers of extreme conditions without a reported mishap.

1. Specially blended Swiss watch oils used on a selection of ultimate watches expand the operating temperature range from -40°C to 60°C (-40 to 140°F).
    a. Anthony Powell has been working in Antarctica with his wife Christine for many years. After over 10 years (9 winters) of filming, his documentary "Antarctica: A Year on Ice" is now complete.
    b. Edurne Pasaban is a Spanish professional mountaineer that has lead over 20 expeditions to the Himalayas and is the first woman in history to conquer the 14 eight-thousander peaks found on the planet.
    c. Hervé Barmasse is the only climber to have soloed the 1,500m South Face of the Matterhorn. He also conquered unclimbed and what were considered as unscalable routes such as his first ascent of 6,970m Beka Brakai Chhok in Pakistan and the smooth granite walls of Cerro Piergiorgio in Patagonia.

2. Ball Watch timepieces have shock resistance up to 5,000Gs. The shock resistance test is conducted according to the International Standard ISO 1413 using a pendulum impact-testing machine. The mechanism sets off a circular movement that brings the weighted pendulum to hit the watch from one meter.
    a. On October 4, 2004, former U.S. Navy aviator Brian Binnie piloted the private rocket SpaceShipOne to an altitude of 69.6 miles, winning the US$10 million Ansari X Prize and opening a new era in space exploration.
    b. John "Mad Cow" Hembel was among the first Americans to break 150mph on skis. In 2003, he took the overall World Cup Championship.
    c. Dr. Josh Wurman chases one of the most destructive forces on Earth, tornadoes, for a living. As the president of the Center for Severe Weather Research, he has pioneered techniques for tracking and analyzing tornadoes.

3. Water resistance is tested by immersing the watch completely in distilled water containing a wetting agent of 1% by weight and under the prescribed atmospheric pressure for at least five minutes. To be qualified, the watch must not show any evidence of water leakage.
    a. Guillaume Néry is a French free-diving champion, specialized in deep diving with a single breath to depths of 125 meters.
    b. Richard Limeburner is currently working as a Senior Research Specialist in the Physical Oceanography Department at Woods Hole Oceanographic Institution with a wide range of research projects. He works on the dynamics of the coastal ocean such as the general circulation, buoyancy and wind forcing, tidal rectification, sea ice annual cycles, mixing, LaGrangian (drifter) trajectories, circulation under Antarctic ice shelves, and climate change.

Performance of the timepieces in these extremes sufficiently demonstrates the timepiece's ability to operate when subjected to conditions of normal use and likely accident conditions.

RADIATION PROFILES

N/A

QUALITY ASSURANCE

Distributor not involved in manufacturing. However, manufacturing quality procedure is included in Attachment C.

INSTALLATION

N/A

ACCOMPANYING DOCUMENTATION

None

Sincerely

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