MARATHON
EST. 1939

June 14, 2024

Alessandro Flores Saenz
Material Safety and Licensing Branch
Division of Materials Safety, State, Tribal and Rulemaking Programs
Office of Material Safety and Safeguards
United States Nuclear Regulatory Commission
EMAIL: Alessandro.FloresSaenz@nrc.gov
PHONE: 301-415-4091

RE: MARATHON WATCH COMPANY LTD., REQUEST FOR ADDITIONAL INFORMATION

Dear Alessandro:
Below are the responses for the letter dated May 14th, 2024.
If you require further information after this, please feel free to ask.

Description/Construction

1. Apologies for any inconvenience this may have caused - the absolute maximum activity of each model is as indicated on the label of 26 mCi. The 30 mCi was in keeping with the format of all prior model amendments to our license. Our license lists "Device Model(s)" on Page #2, with the "Maximum Activity" being denoted as 30 mCi. Within each amendment we then denote the actual activity level of each model. However, Marathon ensures the nominal quantity does not exceed 25 mCi on any of our models.

2. The model of each watch is WW194029, WW194030, WW194033, WW194034. The part number for our internal inventory system adds the suffix of SS to indicate that the case is Stainless Steel vs potential future models in other materials. For the sake of consistency, we would like to move forward with the model numbers being WW194029SS, WW194030SS, WW194033SS, WW194034SS. We apologize for any confusion this may have caused.

3. Yes, the comparison of WW194030SS should be to WW194013SS. We apologize for the typo.

4. Models WW194033 and WW194034 are constructed from 316L Stainless Steel. Models WW194003 and WW194004 are constructed from a composite fibreshell.

5. The dials for WW194033 and WW194034 are upsized versions of the WW194003 and WW194004 to accommodate the larger case size.

    a. The WW194003 and WW194004 both have an external case diameter of 34mm (This remains unchanged from original license). The WW194033 and WW194034 both have an external case diameter of 41mm.

    b. The method of attachment of the sealed sources and prototype testing is unchanged compared to all previous models.

6. The date of last distribution from the Pennsylvania location was on December 29th, 2022. We are unable to identify the serial number of the last unit distributed, as it would have been a part of a larger shipment with multiple orders being fulfilled.

7. We do not wish to remove any models from our license at this time.

Labelling

8. There is no change to the location and method of application of labels for the new device models.

To request withhold of proprietary information from the public

1. A revised affidavit, and supplementary documents for the affidavit, will be provided following this submission for additional information.

Compliance with 10 CFR 32.22(a)(2)(v)

2. Shielding of the end user from the tritium is inherent in the design of the device. While the device cannot contain all the tritium escaping from the GTLS's, there is an equilibrium of the tritium level which will naturally occur. Since the betas from this tritium will travel about 6 mm in air, the components of the watch, such as the crystal and case, will shield the end user from these betas. The containment will be maintained under normal use, storage, and handling conditions. Prototype testing demonstrates that the device will also maintain integrity in severe conditions. There are no features that are strictly safety features.

Compliance with 10 CFR 32.22(a)(2)(vi)

3. Performing a survey of the external surfaces of the device would only provide inconclusive evidence that the radiation levels are below the limits. The reasons for this are:

    a. the tritium is contained inside borosilicate vials

    b. the vials are contained within the watch, which is sealed

    c. the betas from the tritium will not travel more than 1 inch (2.5 cm) in air

    d. the betas will not penetrate the window of the survey meter

    e. the estimated doses show that there is negligible dose from the watches, even in doses resulting from accidents

    f. the radiation levels will be indistinguishable from background at 5 and 25 cm

Compliance with 10 CFR 32.22(a)(2)(xiii)

4. Dose calculations are included where the dose commitments in any one year are presented. Please note that 10 CFR 32.23(a) requests estimated external radiation doses OR dose commitments resulting from the intake. Marathon has provided the latter. The assumptions made, (the basis), to perform these calculations are explained in the attached document as well (see Attachment #6.pdf).

Compliance with 10 CFR 32.23

5. As stated above, updated dose calculations have been provided (see Attachment #6.pdf) to demonstrate that the watch models meet the safety criteria of 10 CFR 32.23.

If you have questions regarding this additional information, please feel free to contact me. Thank you and have a nice day.

Kindest regards,

Harrison McCrindle
STRATEGIC GOVERNMENT CONTRACTING OFFICER
MARATHON WATCH COMAPANY LTD

DOSE CALCULATIONS FOR MARATHON
EXEMPT DISTRIBUTION & SSD

T. Brandon
tbrandon@diligistics.com

06/13/24

Watches illuminated with GTLS's, (gaseous tritium light sources), have been in use for many years and have an excellent reputation. Thousands of watches have distributed in the US in the past to end users.

Employee dose:

To ensure that the dose to employees from watches stored at Marathon will not exceed the member of public dose, the following dose calculation is provided:

According to the Health Physics Society, (HPS), tritium has an average energy of 6 keV and a maximum energy of 18 keV. (1) The HPS goes on to state that the beta particles emitted from tritium will only travel 6 mm in air, and will not penetrate the dead layer of skin. Since the GTLS's, which contain the gaseous tritium, are made from borosilicate glass, no external dose is expected from the contained tritium.

Marathon expects to have no more than 20,000 watches on hand at any one time. Tritium from the watches is expected to leak at a rate not exceeding 5 nCi/hr. So, with 20,000 watches on hand, the total leakage rate would be:

$L_{total} = L_{piece}$ * Number of pieces

L_{total} = 5 nCi/hr/piece * 20,000 pieces = 100,000 nCi/hr = 100 μCi/hr

To estimate the concentration in the warehouse space where the watches would be stored, the following equation from NUREG 1717 Appendix A.1.2 will be used:

$$C = \frac{Q}{Vkt}\left(1 - e^{-kt}\right)$$

Where:
C = airborne concentration (μCi/m^3)
Q = quantity of radioactive material released (μCi) at t = 0; a conservative estimate is to assume 24 hr of leakage
V = volume of air of the structure (m^3); Typical warehouse is 110' L x 60' W x 10' H
k = ventilation rate (/hr) [assume 1 exchange/hr]
t = time of exposure [assume 8 hour work day]

Q = 100 μCi/hr * 24 hr = 2400 μCi
V = 110' x 60' x 10' = 66,000 ft^3 = 1869 m^3
k = 1 hr^{-1}
t = 8 hr

$$C = \frac{2400\ \mu\text{Ci}}{(1869\ m^3)(1/hr)(8\ hr)}\ (1 - e^{-(1)(8)})$$

C = 0.161 μCi/m^3

The intake from the exposure during an 8-hour workday from inhalation can be calculated from:

$$I = C \times BR \times t$$

Where:
I = inhalation intake (μCi)
C = airborne concentration (μCi/m^3)
BR = breathing rate (m^3/hr)
t = time of exposure (hr)

C = 0.161 (μCi/m^3)
BR = 0.9 (m^3/hr)
t = 8(hr)

$$I = 0.161 \left(\frac{\mu\text{Ci}}{m^3}\right) \times 0.9 \left(\frac{\text{m}^3}{\text{hr}}\right) \times 8\ hr$$

I = 1.16 μCi

Gaseous tritium in itself poses very little risk of dose. But about 1% of tritium inhaled converts to tritiated water (HTO). This is very readily absorbed by the body and provides a much more significant dose than its gaseous form.

So I for HTO is about 0.01 I for gas.

I_{HTO} = 0.1 * 1.16 μCi = 0.116 μCi

The dose from this intake is calculated by using proportions:

$$\frac{5000\ mrem}{80000\ \mu Ci} = \frac{x\ mrem}{0.116\ \mu Ci}$$

x = 0.007 mrem = 7 μrem

This is less than the limit of 2 mrem/hr for members of public.

<u>Normal use and disposal of a single exempt unit</u>:
Since the dose from many watches in one location will not provide a dose that exceeds member of public dose, it is evident that a single watch in the possession of an end user will not provide a significant dose. See calculations below:

<u>Normal Use:</u>

L = leakage rate

L = 5 nCi/hr = 0.005 μCi/hr (from source manufacturer)

End users, may use watches for about 12 hours per day. So:

L_{day} = L * hours of use per day

L_{day} = 0.005 μCi/hr * 12 hours = 0.06 μCi (per day)

To estimate the concentration in the breathing zone where the watches would be used, the following equation from NUREG 1717 Appendix A.1.2 will be used:

$$C = \frac{Q}{Vkt}\left(1 - e^{-kt}\right)$$

Where:
C = airborne concentration (μCi/m^3)
Q = quantity of radioactive material released (μCi) at t = 0; assuming that tritium leakage remains within breathing zone
V = volume of air of the structure (m^3); assume 1 m^3 for breathing zone
k = ventilation rate (/hr) [assume 1 exchange/hr]
t = time of exposure [assume 12 hour work day]

Q = 0.06 μCi
V = 1 m^3
k = 1 hr $^{-1}$
t = 12 hr

$$C = \frac{0.06\ \mu\text{Ci}}{(1\ m^3)(1/hr)(12\ hr)}\left(1 - e^{-(1)(12)}\right)$$

C = 0.005 μCi/m^3

The intake from the exposure during an 12-hour workday from inhalation can be calculated from:

$$I = C \times BR \times t$$

Where:
I = inhalation intake (μCi)
C = airborne concentration (μCi/m^3)

BR = breathing rate (m^3/hr)
t = time of exposure (hr)

C = 0.005 (μCi/m^3)
BR = 1.2 (m^3/hr)
t = 12 (hr)

$$I = 0.005 \left(\frac{\mu\text{Ci}}{m^3}\right) \times 1.2 \left(\frac{\text{m}^3}{\text{hr}}\right) \times 12\ hr$$

I = 0.072 μCi

Gaseous tritium in itself poses very little risk of dose. But conservatively less than 1% of tritium inhaled converts to tritiated water (HTO). This is very readily absorbed by the body and provides a much more significant dose than its gaseous form.

So I for HTO is about 0.01 I for gas.

I_{HTO} = 0.1 * 0.072 μCi = 0.007 μCi

The dose from this intake is calculated by using proportions:

$$\frac{5000\ mrem}{80000\ \mu Ci} = \frac{x\ mrem}{0.007\ \mu Ci}$$

x = 0.00045 mrem = 0.45 μrem (per day)

x_{hour} = x/time used

x_{hour} = 0.45 μrem/12 hours = 0.038 μrem/hr

This is less than the limit of 2 mrem/hr for members of public.

Additionally, the use of the device over the course of a year would be:

x_{year} = x * # days
x_{year} = 0.45 μrem/day * 365 days

x_{year} = 164 μrem/year

Disposal:

According to NUREG 1717 Section 2.14.4.4:

> "For exposure to a single exempt unit [watch] used for 10 years before disposal, the individual EDE for waste collectors at either landfills or incinerators would be less than 1×1035 mSv (<0.001 mrem). The individual doses to other workers and members of the public from exposure during disposal of a single exempt unit would be less."

The doses provided in NUREG 1717 are calculated using an activity of 50 mCi per watch. Marathon watches are limited to 26 mCi. Therefore, Marathon confirms that its devices will not provide doses exceeding those in this statement for single devices. In normal use and disposal of a single exempt unit, it is unlikely that the dose commitment resulting from the intake of radioactive material in any one 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 1 mrem of dose to the whole body. There is negligible external dose from tritium.

<u>Normal handling and storage of multiple devices</u>:

Additionally, according to NUREG 1717 Section 2.14.4.4:

> "For disposal at landfills, the annual individual EDE would be about less than 1×1035 mSv (<0.001 mrem) to waste collectors. The annual individual doses to workers at landfills, off-site members of the public, and future on-site residents would be less. The total collective EDE was found to be about 2×1033 person-Sv (0.2 person-rem), due almost entirely to exposure to off-site members of the public from groundwater releases.
>
> For disposal by incineration, the annual EDE would be 4×1035 mSv (0.004 mrem) to waste collectors. The annual individual dose is less to workers at incinerators and off-site members of the public. The total collective EDE is about 3×1033 person-Sv (0.3 person-rem), due mainly to exposures to off-site members of the public from airborne releases during incinerator operations."

The doses provided in NUREG 1717 are calculated using an activity of 50 mCi per watch. Marathon watches are limited to 26 mCi. Therefore, Marathon confirms that its devices will not provide doses exceeding those in this statement for multiple devices. In the normal handling and storage of the quantities of exempt units that are likely to accumulate in one location during marketing and distribution of the product, the location with the greatest likelihood of exposure is distribution. At distribution, the workers will only handle the watches for a brief moment while they are being packaged. This is confirmed in the calculations below:

Assumptions:

a) Preparing watches for shipment takes 10 minutes per week; (the watches are handled multiple times for short intervals)
b) 400 watches would be shipped per week (average of 80 per day)

c) 1 person prepares all watches for shipment
d) breathing area of 7 m^3
e) breathing rate is 1.2 m^3/hr
f) distribution of 20,000 watches/year
g) watches contains 26 mCi
h) Tritium leakage is below 5 nCi/hr/watch

L_{total} = 5 nCi/hr/piece * 80 pieces = 40 nCi/hr = 0.04 µCi/hr

To estimate the concentration in the warehouse space where the watches would be stored, the following equation from NUREG 1717 Appendix A.1.2 will be used:

$$C = \frac{Q}{Vkt}\left(1 - e^{-kt}\right)$$

Where:
C = airborne concentration (µCi/m^3)
Q = quantity of radioactive material released (µCi) in 1 day;
V = volume of air of the structure (m^3); Warehouse is 110' L x 62' W x 13' H
k = ventilation rate (/hr) [assume 1 exchange/hr]
t = time of exposure [assume 8 hour work day]

Q = 0.04 µCi/hr * 8 hrs/day = 0.32 µCi
V = 110' x 60' x 10' = 66,000 ft^3 = 1869 m^3
k = 1 hr^{-1}
t = 8 hr

$$C = \frac{0.32\ \mu\text{Ci}}{(1869\ m^3)(1/hr)(8\ hr)}\left(1 - e^{-(1)(8)}\right)$$

C = 2.1 E-5 µCi/m^3

The intake from the exposure during an 8-hour workday from inhalation can be calculated from:

$$I = C \times BR \times t$$

Where:
I = inhalation intake (µCi)
C = airborne concentration (µCi/m^3)
BR = breathing rate (m^3/hr)
t = time of exposure (hr)

C = 2.1 E-5 (µCi/m^3)
BR = 1.2 (m^3/hr)
t = 8(hr)

$$I = 2.1\ \text{E} - 5\ \left(\frac{\mu\text{Ci}}{m^3}\right) \times 1.2\left(\frac{\text{m}^3}{\text{hr}}\right) \times 8\ hr$$

I = 2.1 E-4 μCi

I_{HTO} = 0.1 * 2.1 E-4 μCi = 2.1 E-5 μCi

The dose from this intake is calculated by using proportions:

$$\frac{5000\ mrem}{80000\ \mu Ci} = \frac{x\ mrem}{2.1\ \text{E} - 5\ \mu Ci}$$

x = 1.3 E-6 mrem = 1.3 E-3 μrem per 8 hours

x = 1.3 E-3 μrem/8 = 1.6 E-4 μrem/hr

This is far less than the limit of 2 mrem/hr for members of public.

Additionally, the use of the device over the course of a year would be:

x_{year} = x * # days
x_{year} = 1.3 E-3 μrem/day * 365 days

x_{year} = 0.475 μrem/year

In normal handling and storage of the quantities of exempt units likely to accumulate in one location during marketing and distribution of the product, it is unlikely that the dose commitment resulting from the intake of radioactive material in any one 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 10 mrem. There is negligible external dose from tritium.

Probability of receiving dose:

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 or distribution of the product, the most likely occurrence of dose would be that of distribution. With the assumption that 20,000 watches would be distributed annually and that weekly distributions would be consistent, Marathon estimates that about 400 watches would be distributed weekly. As shown above, the estimated dose for an employee distributing watches, would be 0.475 μrem/year. With the exception of accidents, there is a very low probability that any of the watches would have a failure of containment or shielding in which a vial would rupture and the dose received would exceed the committed dose of 0.5 rem to whole body or 7.5 rem to the extremities or skin. Subsequently, the probability that a dose would exceed 15 rem to the whole body and 200 rem to the extremities is negligible. There is negligible external dose from tritium.

Accidental Doses:

The most likely accident scenario where vials might have the opportunity to rupture and dose received is more concentrated, is during a facility fire. It is assumed that about 800 watches would be present in the facility at the time of a fire. This assumption is based on 2 weeks worth of production would be present at any time. It is also assumed that 10% of the watches (80) would be damaged in the fire. This assumption considers that 1) the fire suppression systems would function quickly and adequately, 2) that the fire would be in close proximity to the sights, and 3) firefighters would also act quickly in quenching the fire.

The amount of tritium released in this scenario is:

(percentage of devices damaged) x (total quantity of devices) x (activity per device) = activity of material released

0.10 * 800 * .026 Ci = 2.08 Ci.

The instantaneous concentration

$$C = \frac{Q}{Vkt}\,(1 - e^{-kt})$$

Where:
C = airborne concentration (µCi/m^3)
Q = quantity of radioactive material released (µCi) at t = 0
V = volume of air of the structure (m^3)
k = ventilation rate (/hr)
t = time of exposure (hr)

Q = 2.08 Ci = 2.08 E6 µCi
V = 3000 m^3 (NUREG 1717 Table A.1.2)
k = 1 hr^{-1}
t = 2 hr [estimated time to fight the fire]

$$C = \frac{2.08\,E6\ \mu\text{Ci}}{(3000\,m^3)(1/hr)(2\,hr)}\,(1 - e^{-(1)(2)})$$

C = 273 µCi/m^3

The dose from the exposure of 80 watches being damaged in a fire is given by the equation for inhalation dose found in NUREG 1717 A.1.5:

$$I = C \times BR \times t$$

Where:
I = inhalation intake (µCi)
C = airborne concentration (µCi/m^3)
BR = breathing rate (m^3/hr)
t = time of exposure (hr)

C = 273 (µCi/m^3)
BR = 1.2 (m^3/hr)
t = 2 (hr)

$$I = 273\left(\frac{\mu\text{Ci}}{m^3}\right) \times 1.2\left(\frac{\text{m}^3}{\text{hr}}\right) \times 2hr$$

I = 655 µCi

So I for HTO is about 0.01 I for gas.

I_{HTO} = 65.5 µCi

The dose from this intake is calculated by using proportions:

$$\frac{5000\ mrem}{80000\ \mu Ci} = \frac{x}{65.5\ \mu Ci}$$

x = 4.09 mrem

This is less than the limit of 1 rem as required by 10 CFR 32.23. This is far less than that 20 rem as well. The probability of a person receiving doses in excess of 1 rem to the whole body and 20 rem to the skin and extremities is negligible.

Conclusion:

Because doses from the watches are below the criteria listed in 10 CFR 32.23, the watches meet the requirements for use by users exempt from regulatory requirements.