mb-microtec
self activated illumination

July 3, 2014

Hector Rodriguez-Luccioni
Licensing Branch
Division of Materials Safety and State Agreements
Office of Federal and State Materials
and Environmental Management Programs
United States Nuclear Regulatory Commission
Washington, DC 20555-0001

RE: Docket No. 030-30433

Dear Mr. Rodriguez-Luccioni,

In response to your request for additional information dated May 22, 2014, mb microtec provides the following responses:

(NRC)

1. In our second request for additional information dated April 15, 2014, we requested the estimate external radiation doses and dose commitments relevant to the safety criteria in 32.23 and the basis for such estimates. In your letter dated May 13, 2014, you provided dose assessment for wristwatches model T-27 and T-100. For watch model T-1 00, which contains 100 mCi, you took the dose calculations in NUREG 1717, "Systematic Radiological Assessment of Exemptions for Source and Byproduct Materials," for watches with 25 mCi of tritium gas contained in glass tubes and increased them by a factor of 4.

   Please provide a detailed dose assessment for T-100 model, including calculation examples as shown in NUREG-1717, Appendix A, of the following:
   a. External dose calculation for distribution workers and members of the public who might be exposed during product distribution.
   b. External dose calculation of routine use of wristwatches. Exposure to airborne releases of H-3 from the wristwatches and exposure to skin contact.
   c. External dose calculation during watch repair.
   d. External dose calculation during an accident or misuse of wristwatch.

(mbm) Response:

External dose calculations for the 100 mCi watches are included with this response.

(NRC)

2. In our second request for additional information dated April 15, 2014, we requested the maximum external radiation levels at 5 and 25 centimeters from external surface of product, averaged over an area not to exceed 10 square centimeters, and the method of measurement. In your letter dated May 13, 2014, you stated that the radiation levels at 5 and 25 centimeters form the product are background, and that this was a calculated value as measurement for the low energy beta particles is impractical. Please provide the calculation of the radiation levels at 5 and 25 centimeters.

(mbm) Response:

Since the radiation level is indistinguishable from background, the calculation becomes:

At 5 cm: Measured - Background = radiation level
Background – Background = 0

At 25 cm: Measured - Background = radiation level
Background – Background = 0

(NRC)

3. In our first request for additional information dated January 8,2014 (ADAMS Accession No. ML 14050A184), we requested the procedure of prototype testing and results. In your response letter dated February 14, 2014 (ADAMS Accession No. 14049A327), your provided the prototype testing or the source, which is the primary containment of the radioactive material. In our second request for additional information dated April 15, 2014, we requested the procedure of prototype testing and results of the final product. 10 CFR 32.22(a)(2)(xi) requires the 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. 10 CFR 32.22(a)(2)(xii) requires the 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. In the regulation the word "product" refers to the device(s) that contain the source(s), in your case the products are the watches that will be distribute under 10 CFR 32.22. In your letter dated May 13, 2014, you responded that according to NRC Document 98-88, "NRC Amends Regulations governing Timepieces Containing Tritium," prototype testing is not required for timepieces containing Gaseous Tritium Light Sources (GTLS) and is replaced by detailed engineering drawings, etc. This statement is not correct. The

amendment you referred to is only applicable to timepieces containing GTLS that are licensed under 10 CFR 32.14. Timepieces containing GTLS that are licensed under 10 CFR 32.22, required prototype testing as stated above. You need to provide the procedure and results of prototype testing (e.g. vibration tests, bending of hands or pointers over cylinder, and immersion tests) of each device model under 10 CFR 32.22.

(mbm) Response:

mb microtec commits to performing prototype testing on the 100 mCi watches to meet the classification of T2GC1322222 in accordance with ANSI N43.4. This testing will be performed by December 31, 2014. This date will ensure there is enough time for any testing which may be required to be performed a subsequent time, as well as preparing reports in English.

I trust that this information suffices to address your request.

Sincerely,

Timothy Brandon
RSO, mb microtec

International Radiation Safety Consulting, Inc.

Dose Calculations: Traser T-100 Wristwatch

Doses to Various Critical Groups
Based on NUREG-1717 Methodology

Mb-Microtec USA, Inc.
1093 Ridge Road
Windsor, ME 04363 February 26, 2013

Prepared by:
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19 Pendleton Drive/PO Box 107
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In a letter dated May 22, 2014, the NRC requested external dose calculations for mb-microtec T-100 wristwatches. That information is provided below.

Question a. External dose calculation for distribution workers and members of the public who might be exposed during product distribution.

The worst-credible-case scenario for distribution workers is identified in the last paragraph of NUREG 1717 section 2.3.4.1, last paragraph, which says “The highest calculated individual EDE was approximately 0.09 mSv (9 mrem) to the drivers of large regional delivery trucks that deliver timepieces from the parcel delivery center to truck terminal 1.” This involves the transport of 800,000 timepieces annually. The last paragraph of section 2.3.4 states that the leak rate from timepieces containing ^{3}H in glass tubes is “less than 0.25 nCi/h” (<2.5E-4µCi/h). This is based on each wristwatch containing 25 mCi of ^{3}H.

Given:

> Exposure time = 5 h/trip;
> No structural barrier between driver and cargo (i.e., no shielding);
> Volume of a small delivery truck = 7.1E+6 cm^{3};
> Air exchange rate = 5 ach/h
> Distance from driver to center of cargo = 180 cm.
> Leak rate = 2.4E-4µCi/h from 1 watch
> Number of wristwatches = 800,000 per year

- Calculate Dose to Most-Highly Exposed Distribution Worker
  Following the steps in A.3.3, we get:
  > DF (Dose Factor) for the driver of a small regional delivery truck = 1.2E-11 rem/µCi shipped;
  > 800,000 watches/y x 100 mCi/watch x 1000 µCi/mCi = 8E+10 µCi/y transported in this way;
  > 1.2E-11 rem/µCi x 8E+10 µCi = 0.96 rem = 96 mrem.

Footnote 19 on p. A.3-3 states “An additional step is required for ^{3}H. If the assumed leak rate differs from 1 Pm/h, the DFs for ^{3}H should be multiplied by the assumed leak rate, which must be expressed in units of Pm/h[1].” Since the presumed leak rate for watches containing ^{3}H in glass

[1] Pm/h is interpreted to be “ppm/h.” This was confirmed by J. Stewart Bland, one of the authors of NUREG 1717.

tubes is 10 ppb, we can take the ratio of 1 ppm/10 ppb = 1E+6/10E+9 = 1E-4 and multiply it by the calculated dose above to adjust for the smaller leak rate.

$$960\ mrem\ \times 1E - 4 = 0.096\ mrem.$$

While NUREG 1717 doesn't suggest this, even if the leak rate is quadrupled (100 mCi is 4 times the 25 mCi used in the NUREG examples) the resulting dose would only be 0.4 mrem.
Finally, the assumption that one driver transports all timepieces shipped from one origin facility to a destination facility is very unlikely and is almost certainly overly conservative. Doses to truck drivers would be reduced in direct proportion to the number of drivers involved.

- Calculate Dose to Most-Highly Exposed Member of the Public
  Following the steps in A.3.6, we get:
  Given:
    - The most highly exposed member of the public is a clerk at a small retail store.
    - Volume = 6.4E+8 cm^3 = 640 m^3;
    - Air exchange rate = 4 ach/h;
    - 300 watches/y (section 2.3.4.1)
    - DF (Dose Factor) for a clerk in a small retail store = 6.7E-11 rem/µCi (table A.3.7);
    - 300 watches/y x 100 mCi/watch x 1000 µCi/mCi = 3E+7 µCi/y in a small retail store.

6.7E-11 rem/µCi x 3E+7 µCi = 0.002 rem = **2 mrem**.

Footnote 19 on p. A.3-3 states "An additional step is required for ^{3}H. If the assumed leak rate differs from 1 Pm/h, the DFs for ^{3}H should be multiplied by the assumed leak rate, which must be expressed in units of Pm/h[2]." Since the presumed leak rate for watches containing ^{3}H in glass tubes is 10 ppb, we can take the ratio of 1 ppm/10 ppb = 1E+6/10E+9 = 1E-4 and multiply it by the calculated dose above to adjust for the smaller leak rate.

$$2\ mrem\ \times 1E - 4 = 2E - 4\ \ mrem.$$

[2] Pm/h is interpreted to be "ppm/h." This was confirmed by J. Stewart Bland, one of the authors of NUREG 1717.

Question b. External dose calculation of routine use of wristwatches. Exposure to airborne releases of H-3 from the wristwatches and exposure to skin contact.

Routine Use: Dose Due to Skin Contact

NUREG 1717 (p. 2-201) uses dose calculations based on a watch that contains 50 mCi of ^{3}H. In all the calculations, 100 mCi has been substituted for 50 mCi.

Leak Rate

$$100\ mCi\ \times \frac{1E+3\ \mu Ci}{mCi} \times \frac{1\mathrm{E}+6}{10\mathrm{E}+9} \times 16\frac{h}{d} = \mathbf{0.016\ \mu Ci/d}$$

Where 10 ppb/h is the assumed rate of HTO leakage from the self-luminous watch (see Section 2.14.4).

Intake

$$\frac{0.016\ \mu Ci}{d} \times 0.02 = 3.2E-4\ \mu Ci/d$$

Where 0.02 is the fractional absorption of ^{3}H released from the watch by the skin in contact with the case of the watch.

Annual Dose Equivalent

$$\frac{3.2E-4\ \mu Ci}{d} \times \frac{365\ d}{y} \times \frac{6.7E+3\ mrem-cm2}{\mu Ci} \times \frac{1}{10\ cm^2} = \mathbf{80\ mrem/y}$$

The area of skin in contact with the wristwatch is assumed to be about 10 cm^2.

Annual Dose to Skin of Whole Body (ICRP 23)

$$80\ mrem\ \times \frac{10\ cm^3}{1.8\ E+4\ cm^2} = 0.04\ mrem$$

Where 1.8E+4 cm is the area of the skin of the whole body.

Skin Dose Contribution to EDE

$$0.04\ mrem\ \times 0.01 = 4E-4\ mrem$$

Where 0.01 is the organ weighting factor for skin of the whole body (ICRP 60).

Annual EDE

The annual EDE to the internal organs of the body for the absorption of HTO through the skin in contact with the case of the watch is

$$\frac{3.2\,E-4\ \mu Ci}{d} \times \frac{365\ d}{y} \times \frac{6.4\,E-2\ mrem}{\mu Ci} = 0.008\ mrem/y$$

Where :

- 6.4E-2 mrem/µCi is the dose conversion factor for either absorption through the skin or ingestion of ^{3}H; and
- 3.2E-4 mrem/d is the daily intake of ^{3}H.

Summary

The annual dose equivalent to a small area of skin is estimated to be 80 mrem over an area of 10 cm^{2} in contact with the wristwatch. The skin dose due to the distributed wristwatch source of ^{3}H makes a negligible contribution to the annual EDE, and the total annual EDE to a wearer from skin absorption of ^{3}H in contact with the case of a self-luminous watch is estimated to be 0.008 mrem.

Routine Use: Dose Due to Inhalation/Ingestion

NUREG 1717 (p. 2-202) proposes the following scenario to estimate the potential dose from airborne releases of ^{3}H from self-luminous wristwatches. This scenario is based on a 50 mCi wristwatch, as was the dose due to skin contact above, so the appropriate data in this scenario has been doubled.

- A wearer spends 12 hours at home each day (4380 h/yr) and exposes three other family members to airborne releases of ^{3}H from the wristwatch.
- The home has an enclosed volume of 450 m^{3} and a ventilation rate of 1 volume change per hour.
- The equilibrium concentration of HTO in the air of the home is approximately 2 pCi/m^{3} and
- The breathing rate of the individuals is 0.9 m^{3}/h.

Annual Intake

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

Where I = Intake (pCi)

C = average airborne concentration (2 pCi/m^3)

BR = breathing rate (0.9 m^3/h)

t = exposure time (4380 h/y)

$$\frac{2\ pCi}{m^3} \times \frac{0.9\ m^3}{h} \times 4380\ h = 4E + 3\ pCi = 0.004\mu\text{Ci}$$

$$0.004\ \mu Ci \times \frac{6.4E - 2\ mrem}{\mu Ci} = 0.0003\ mrem$$

Where: 6.4E-2 mrem/h is the dose conversion factor for either absorption through skin or ingestion of ^3H.

This can also be done using proportionality with the ALI value for ^3H.
The ALI value for ^3H = 8E+4 µCi; therefore,

$$\frac{0.004\mu\text{Ci}}{\text{x mrem}} = \frac{8\text{E} + 4\ \mu\text{Ci}}{5000\ mrem}$$

$$\frac{0.004\mu\text{Ci} \times 5000\ \text{mrem}}{8\text{E+4}\ \mu\text{Ci}} = x;$$ ***x* = 0.0003 mrem**

Question c. External dose calculations during watch repair.

c.1 A catastrophic release from crushing of a single watch in a small repair shop.

- Calculate concentration.

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

Where C = Airborne concentration

Q = Quantity released (μCi) at t = 0 (1E+5 μCi)

k = ventilation rate (hr^{-1}) (1ach/h)

t = time (h) over which C is averaged (1 h)

V = volume of air (m^3) into which material is released (18 m^3)

$$C = \frac{1E + 5\ \mu Ci}{(18\ m^3)\left(\frac{1}{h}\right)(1\ h)}\left(1 - e^{-\frac{1}{h}\times 1\ h}\right)$$

$$C = \frac{5.6E + 3\ \mu Ci}{(m^3)}\ (0.632)$$

$$\boldsymbol{C = 3.5E + 3\ \mu Ci/m^3}$$

- Calculate intake.

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

Where C = concentration ($3.5E + 3\ \mu Ci/m^3$)

BR = breathing rate (0.9 m^3/h)

t = exposure time (1 h)

$$I = \frac{3.5E + 3\ \mu Ci}{m^3} \times 0.9\frac{m^3}{h} \times 1\ h$$

$$\boldsymbol{I = 3E + 3\ \mu Ci}$$

- Calculate dose

$$Dose = I\ \times DSR$$

Where I = intake (μCi) (3E+3 μCi)

DSR = dose-to-source ratio ($4E - 6\ rem$/μCi, from NUREG 1717, Table A.1.9)

$$Dose = 3E+3 \times \frac{4E-6\ rem}{\mu Ci}$$

$$\boldsymbol{Dose = 0.012\ rem = 12\ mrem}$$

c.2 A catastrophic release from crushing of a single watch in a large repair shop.

- Calculate concentration.

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

Where C = Airborne concentration

Q = Quantity released (µCi) at t = 0 (1E+5 µCi)

k = ventilation rate (hr^{-1}) (1ach/h)

t = time (h) over which C is averaged (1 h)

V = volume of air (m^3) into which material is released (18 m^3)

$$C = \frac{1E + 5\ \mu Ci}{(34\ m^3)\left(\frac{1}{h}\right)(1\ h)}\left(1 - e^{-\frac{1}{h}\times 1\ h}\right)$$

$$C = \frac{2.9E + 3\ \mu Ci}{(m^3)}\ (0.632)$$

$$\boldsymbol{C = 1.9E + 3\ \mu Ci/m^3}$$

- Calculate intake.

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

Where C = concentration ($1.9E + 3\ \mu Ci/m^3$)

BR = breathing rate (0.9 m^3/h)

T = exposure time (1 h)

$$I = \frac{1.9E + 3\ \mu Ci}{m^3} \times 0.9\frac{m^3}{h} \times 1\ h$$

$$\boldsymbol{I = 1.7E + 3\ \mu Ci}$$

- Calculate dose

$$Dose = I\ \times DSR$$

Where I = intake (µCi) (1.7E+3 µCi)

DSR = dose-to-source ratio (2.1E-6 rem/µCi, from NUREG 1717, Table A.1.9)

$$Dose = 1.7E + 3 \times \frac{2.1E - 6\,rem}{\mu Ci}$$

$$\boldsymbol{Dose = 0.004\,rem = 4\,mrem}$$

Question d. External dose calculation during an accident or misuse of wristwatch.

Accidents and Misuse

In the case of accidents for timepieces containing ^{3}H in glass tubes, the ^{3}H contained in the watches is assumed to be 99% HT and 1% HTO. Based on this assumptions and the generic accident methodology in Appendix A.1, the potential radiation doses from the crushing of self-luminous watches containing ^{3}H can be calculated as follows:

Accident

d.1. An accident involving the crushing of a single watch (100 mCi) in a home.

- Calculate concentration.

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

Where C = Airborne concentration

Q = Quantity released (µCi) at t = 0 (1E+5 µCi)

k = ventilation rate (hr^{-1}) (1ach/h)

t = time (h) over which C is averaged (1 h)

V = volume of air (m^3) into which material is released (18 m^3)

$$C = \frac{1E + 5\ \mu Ci}{(450\ m^3)\left(\frac{1}{h}\right)(1\ h)}\left(1 - e^{-\frac{1}{h}\times 1\ h}\right)$$

$$C = \frac{222\ \mu Ci}{(m^3)}\ (0.632)$$

$$\boldsymbol{C = 140\ \mu Ci/m^3}$$

- Calculate intake.

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

Where C = concentration (140µCi/m^3)

BR = breathing rate (0.9 m^3/h)

T = exposure time (1 h)

$$I = \frac{140\ \mu Ci}{m^3} \times 0.9\frac{m^3}{h} \times 1\ h$$

$$\boldsymbol{I = 126\ \mu Ci}$$

- Calculate dose

$$Dose = I\ \times DSR$$

Where I = intake (µCi) (126µCi)

DSR = dose-to-source ratio (1.6E-7rem/µCi, from NUREG 1717, Table A.1.9)

$$Dose = 126\ \times \frac{1.6E - 7\ rem}{\mu Ci}$$

$$\boldsymbol{Dose = 2E - 5\ rem = 0.02\ mrem}$$

d.2. A shipping accident in a storeroom or cargo-handling area involving the crushing of a shipment of 200 watches (2E+7µCi)

- Calculate concentration.

$$C = \frac{Q}{Vkt}\ (1 - e^{-kt}) \qquad \text{(Eq. 1)}$$

Where C = Airborne concentration

Q = Quantity released (µCi) at t = 0 (2E+7 µCi)

k = ventilation rate (hr^{-1}) (4ach/h)

t = time (h) over which C is averaged (1 h)

V = volume of air (m^3) into which material is released (300 m^3)

$$C = \frac{2E + 7\ \mu Ci}{(300\ m^3)\ \left(\frac{4}{h}\right)(1\ h)} \left(1 - e^{-\frac{4}{h}\times 1\ h}\right)$$

$$C = \frac{1.7E + 4\ \mu Ci}{(m^3)}\ (0.982)$$

$$\boldsymbol{C = 1.6E + 4\ \mu Ci/m^3}$$

- Calculate intake.

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

Where C = concentration (1.6E+4µCi/m^3)

BR = breathing rate (0.9 m^3/h)

t = exposure time (1 h)

$$I = \frac{1.6E + 4\ \mu Ci}{m^3} \times 0.9 \frac{m^3}{h} \times 1\ h$$

$$\boldsymbol{I = 1.5E + 4\ \mu Ci}$$

- Calculate dose

$$Dose = I\ \times DSR$$

Where I = intake (µCi) (1.5E+4µCi)

DSR = dose-to-source ratio (9.4E-8 rem/µCi, from NUREG 1717, Table A.1.9)

$$Dose = 1.5E + 4\ \mu Ci\ \times \frac{9.4E - 8\ rem}{\mu Ci}$$

$$\boldsymbol{Dose = 0.001\ rem = 1\ mrem}$$

d.3. Misuse

In the case of misuse, this analysis considers the exposure to a 5-year-old child who plays with a self-luminous watch as a "glow-in-the-dark" toy at night while going to sleep during one year.

Assumptions:

(1) The watch is a 10-year-old watch containing 57 mCi of ^3H (A_o = 100 mCi),

(2) The child handles the watch for 10 min/day,

(3) The child absorbs 2% of the ^3H released from the watch through a skin area of 10 cm^2 while handling the watch, and

(4) The child sleeps in a closed bedroom with the watch for 12 h/day.

(5) The bedroom has an enclosed volume of 27 m^3 and a ventilation rate of 1 air change per hour (see Appendix A.1),

(6) The child's breathing rate is 0.24 m^3/h while sleeping (ICRP 66),

(7) The dose conversion factors for inhalation and ingestion[3] are about twice those for an adult (ICRP 67; ICRP 71),
(8) The total surface area of the child's skin is approximately 0.8 m^2 (ICRP 23), and
(9) Leak rate is assumed to be 10 ppb.

Misuse: Dose Due to Skin Contact

NUREG 1717 (p. 2-201) uses dose calculations based on a watch that contains 50 mCi of ^3H. In all the calculations, 57 mCi has been substituted for 50 mCi.

Leak Rate

$$57\ mCi \times \frac{1E+3\ \mu Ci}{mCi} \times \frac{1\text{E}+6}{10\text{E}+9} \times 0.17\frac{h}{d} = \mathbf{9.7E-5\ \mu Ci/d}$$

Where 10 ppb/h is the assumed rate of HTO leakage from the self-luminous watch (see Section 2.14.4).

Intake

$$\frac{9.7E-5\ \mu Ci}{d} \times 0.02 = 1.9E-6\ \mu Ci/d$$

Where 0.02 is the fractional absorption of ^3H released from the watch by the skin in contact with the case of the watch.

Annual Dose Equivalent

$$\frac{1.9E-6\ \mu Ci}{d} \times \frac{365\ d}{y} \times \frac{1.3E+4\ mrem-cm^2}{\mu Ci} \times \frac{1}{10\ cm^2} = \mathbf{0.9\ mrem/y}\ \textbf{to 10 cm}^{\mathbf{2}}\ \textbf{of skin}$$

Where:

- The area of skin in contact with the wristwatch is assumed to be about 10 cm^2; and
- The dose conversion factor is twice that given for adults (6.7E+3 mrem-cm^2/µCi) x (2) = 1.3E+4 mrem-cm^2/µCi.

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[3] The dose conversion factors for effective dose equivalent due to ingestion of ^3H or absorption of ^3H through the skin are the same numerically.

Annual Dose to Skin of Whole Body (ICRP 23)

$$0.9\ mrem\ \times \frac{10\ cm^3}{8000\ cm^2} = 0.001\ mrem$$

Where 8000 cm^2 is the area of the skin of the child's whole body.

Skin Dose Contribution to EDE

$$0.001\ mrem\ \times 0.01 = 1E - 5\ mrem$$

Where 0.01 is the organ weighting factor for skin of the whole body (ICRP 60).

Annual EDE

The annual EDE to the internal organs of the body for the absorption of HTO through the skin in contact with the case of the watch is

$$\frac{1.9E - 6\ \mu Ci}{d} \times \frac{365\ d}{y} \times \frac{6.4E - 2\ mrem}{\mu Ci} = 4E - 5\ mrem/y$$

Where 6.4E-2 mrem/µCi is the dose conversion factor for either absorption through the skin or ingestion of ^{3}H.

Conclusion

I believe that these projected radiation doses meet the requirements of 10 CFR 32.23.

K. Paul Steinmeyer, RRPT June 25, 2014