

CAMMENGA

CAMMENGA AND ASSOCIATES, LLC

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October 7, 2015

The following package is in response to the NRC's RAI dated 9-21-15 with Mail Control Number **586785**.

A. REQUEST FOR ADDITIONAL INFORMATION REGARDING EXEMPT DISTRIBUTION LICENSE

1. Please refer to the "External Radiation Levels" section of **Attachment 1** for an analysis from MB Microtec on the *Bremsstrahlung* from Tritium encapsulated in glass vials. Given that the sources themselves do not emit any detectable levels of external radiation, Cammenga and Associates has determined that when the sources are glued into the sights, there also is no external radiation level at 5 and 25 centimeters of any sight surface.
2. The probabilities and formulas used to satisfy the conditional criteria of 32.23 will remain constant as well with the new dimensional changes. As some of these formulas refer to the loose glass sources without any protection, we believe they can also be used when glued into protective sight cavities. These formulas with resulting rem levels can be found in **Attachment 2**.
3. **Attachment 2** shows the probabilities that can be used for certain scenarios such as handling, storage, and distribution of these products. The new dimensional changes of the sights will not affect these formulas in any way. The formulas are meant to represent finished sights put into unique accident scenarios.

B. REQUEST FOR ADDITIONAL INFORMATION REGARDING SEALED SOURCE AND DEVICE REGISTRATION CERTIFICATE

1. Cammenga will refrain from using language such as "materials such as" from now on. List of specific materials: Aluminum, Steel, Stainless Steel, and Titanium.

Cammenga's ISO 9001:2008 is a quality standard that sets forth guidelines for various operational processes. In this context, Inventory Control is the important criteria. Simply stated, Cammenga's Inventory Control parameters ensure each material received is stored in proper conditions prior to being used in manufacturing.

2. The glue used for the construction of gun sights is Dow Corning 732. Specifications can be found in **Attachment 3**. This glue does not have any corrosive characteristics. We have used this glue in our products since our company was established in 1992.
3. While the overall max/min dimensions of the sights may have changed, the minimum amount of material around the sources will remain unchanged.

4. Please find a diagram of the labeling locations in **Attachment 4**. Please note that because the dimensions of the sights may vary, so may the labeling dimensions. DH3/DR-H3/DRH3/H3 will be visible while the sights are affixed to the gun. However Cammenga's name or license number 21-26460-03E will be located on the underside of the sights. These items will be visible before the sights are attached to the gun. Regarding the pad printing process, please review **Attachment 5** for letters from Ford Motor Company approving this durable method of labeling on some of our automotive projects.

Best Regards,



Christopher J. Karchon
Director of Strategic Operations

CAMMENGA & ASSOCIATES, LLC

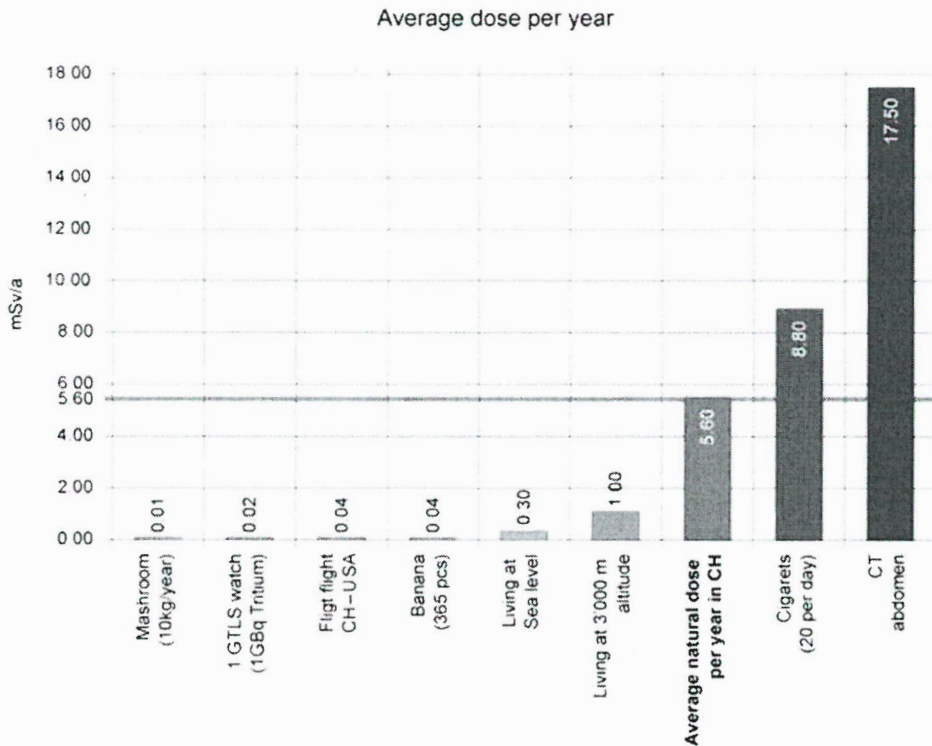
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External Radiation Levels, Transformation, Solubility Concerns

External Radiation Levels:

Cammenga uses Gaseous Tritium Light Sources (GTLS)s from MB Microtec in Bern, Switzerland. According to their executives, there is no relevant dose of external radiation generated by the H-3 Trigelights (MB Microtec brand name) produced by MB Microtec. Section 32.22(a)(2)(vi), 10 CFR 32 requires information about external radiation levels at 5 and 25 centimeters from the external surface of the product. The Tritium in these sources is in gaseous form sealed in borosilicate glass tubes. The Tritium electrons do not exit this glass. The secondary radiation in question, “*Bremsstrahlung*” radiation is dependent on the energy of the primary radiator. In our case this is very low since we use Tritium. To calculate the dose [Sv Sievert] per hour [Sv / h, is the dose rate]. mSv / h or uSv / h is microsieverts per hour] of the radiation in the affected organ (or the whole body in this case) a certain time (which one is exposed to the source) are considered. Please see the below chart of average doses per year of common activities from MB Microtec (<http://www.mbmicrotec.com/en>).



This *bremsstrahlung* effect cannot be measured with a Geiger counter but may be measured with a special ionization chamber monitor for Tritium in the form of gas or a

liquid scintillator for contamination. This is confirmed in NUREG-1717 on page A.4-10, Table A.4.2 footnote b, which states the ^3H "Dose due to *bremsstrahlung* is assumed to be zero (0), because the energies of the *bremsstrahlung* photons are very low and pathways of internal exposure also are assumed to occur."

For further analysis please review NUREG 1717 section 2.13.4.1.3 where the following was taken, "In estimating external dose from routine use of quantities of byproduct material authorized for exempt distribution... External dose is not estimated for radionuclides that emit photons with energies predominantly less than about 0.1 MeV, because the specific gamma-ray dose constant in these cases would substantially overestimate the EDE [Effective Dose Equivalent], especially if any shielding exists between the source and receptor locations. Furthermore, the primary purpose of this part of the assessment is to estimate external dose for those radionuclides for which the quantity was based on the criterion for external exposure, and this is the case only for radionuclides that emit sufficient intensities of higher energy photons."

Through the analysis of MB Microtec and NUREG 1717 along with our own internal measurements, we have determined there are no (zero) external radiation levels at 5 and 25 centimeter distances from any external surface of our products, regardless of raw materials used.

Transformation

Tritium decays to stable Helium-3 (He-3) by emitting a negative beta particle. No direct photon/gamma radiation occurs while undergoing this transformation. The E_{max} energy for this beta particle equals .0186 MeV (18.6 keV) and the E_{av} energy is .005685 MeV (5.69 keV).¹ These are the only changes which will occur in chemical and physical form for the byproduct material in the product during its useful life (Half-Life of 12.32 years).

Solubility in Water:

The Tritium in these sources is in gaseous form sealed in borosilicate glass tubes. Therefore, the Tritium gas does not come into contact directly with water. However, in the event there was a vial breakage, Tritium is an isotope of hydrogen that may bond hydroxyl radicals, forming tritiated water (HTO). Tritium is almost always found naturally in the environment as tritiated water. Everyone is exposed to small amounts of tritium every day, primarily entering the body when people eat or drink food or water containing tritium or absorb it through their skin. Once tritium enters the body, it disperses quickly and is uniformly distributed throughout the soft tissues. Half of the tritium is excreted within approximately 10 days after exposure.²

¹ Kocher, David C. "Radioactive Decay Data Tables." U.S. Department of Energy, DOE/TIC-11026

² The Nuclear Regulatory Commission - <http://www.nrc.gov/reading-rm/doc-collections/fact-sheets/tritium-radiation-fs.html>

People can also inhale tritium as a gas in the air. Inhalation is by far the most important intake mechanism for the user of RL devices (vials). The intake rate of absorption through the skin is between 50%-100% of the intake rate of inhalation. This is why Cammenga chooses to analyze inhalation in its scenario analysis.

Tritiated water distributes itself into all body compartments relatively quickly. The concentration of tritiated water in urine is assumed to be similar to the concentration of tritiated water in the body. This is why Cammenga regularly performs urinalysis of all Clean Room employees. The major factor affecting the biological half-time of tritiated water in the body is the body's rate of water turnover. Because water is itself a diuretic, its increased consumption will speed up its turnover. The faster the water turnover, the briefer the biological half-time of tritiated water. Amount of tritiated water (mg) = Concentration of tritiated water (mg/ml) x Volume of body water (ml).³

³ Pennsylvania Department of Environmental Protection -
(http://www.dep.state.pa.us/brp/Radiation_Control_Division/Tritium.htm)