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May 16, 2013

Response to RAI email received on 5/8/13. Control number 579632.

Mr. Struckmeyer,

In reference to the requirements found in *B.2. Section 32.22(a)(2)(iii), 10 CFR 32*:
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).

Regarding *B.3. Section 32.22(a)(2)(iv), 10 CFR 32* and Tritium's solubility in water and body fluids of the forms:
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]

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 (Attachment 4 of second submission).

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 frequently 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]

In *B.4 Section 32.22(a)(2)(v), 10 CFR 32* it is required to submit information concerning the details of construction and design of product as related to containment and shielding of the byproduct material. Please refer to the General Discussion, Enclosure 5 of our original submission on December 20, 2012 for our various

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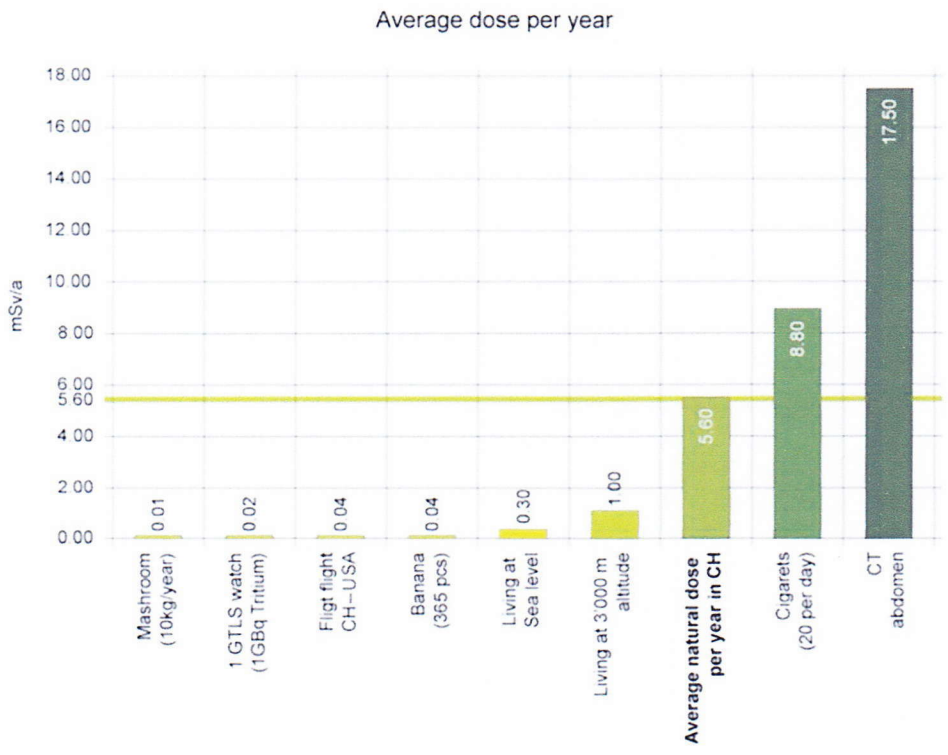
[1] Kocher, David C. "Radioactive Decay Data Tables." U.S. Department of Energy, DOE/TIC-11026
[2] The Nuclear Regulatory Commission - http://www.nrc.gov/reading-rm/doc-collections/fact-sheets/tritium-radiation-fs.html
[3] Pennsylvania Department of Environmental Protection - (http://www.dep.state.pa.us/brp/Radiation_Control_Division/Tritium.htm)

tamper proofing measures. Also, please refer to the drawings in Attachment 3 of the second submission for review of our Tritium Guards. The Tritium Guards, made out of a high impact resistant nylon actively protect the borosilicate glass vials, which contain the Tritium gas. These Tritium Guards are sealed shut with Dow Corning 732 (specs are Attachment 2 of original submission). The Tritium Guards are then locked into the handles of the knives with our custom T-9 screws (Please see answer Conditions and Use answer A.3 from 4/24/13 RAI Response). The Zytel handles that are screwed in place by the T-9 screws further prevent the Tritium Guards (and the vials safely glued within) from ever being impacted directly.

All of these measures were taken with the goal of shielding the byproduct material to withstand the normal and severe conditions of handling, storage, use, and disposal of the product. The normal user will use this knife for approximately 15-20 years. The Tritium gas' half-life is about 12.32 years. By the time the user decides to discard the knife (most likely due to the Tritium illumination degradation), the Tritium will have decayed so much that disposal of the byproduct will not be a concern. If for some reason a user wishes to dispose of a knife earlier than this expected time frame, Cammenga & Associates will offer the service of recycling of byproduct material for them through Cammenga's normal disposal procedures (Attachment 11 of 4/24/13 response to RAI submission).

Users will store the knife in various temperatures depending on their location. We have performed thermal testing at various high and low temperature extremes on the knives with Tritium vials inside (Tests - Enclosure 6, Test #2 of Original Submission; Results – Attachment 6 of 4/24/13 Response to RAI) to simulate different user climates. These tests were based on the military specification for our compasses (Attachment 11 of original 12/20/12 submission). All prototypes passed with no open issues to any of the knife parts/components.

The *B.5. 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. Cammenga uses Gaseous Tritium Light Sources (GTLS)s from MB Microtec in Switzerland. 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). Compare our use of Tritium in this knife product (7.4 GBq) to the 1 GBq found in a Tritium watch in the chart:



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 ^{3}H "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."

Cammenga tested 6 knives with a diffusion test using our scintillation machine (results Attachment 6 of previous submission) immediately after we performed the drop tests (specifications in Attachment 10 of previous submission).

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.

B.6. Section 32.22(a)(2)(vii), 10 CFR 32 requires information regarding the degree of access of human beings to the product during normal handling and use. Attachment 5 of the 12/20/12 submission was meant to explain the normal use and functionality of having a knife use Tritium gas-filled vials for illumination. Attachment 4 of the 4/24/12 response to the NRC RAI submission was meant to show the extreme scenarios for the Safety Criteria from 32.23.

Please refer to Attachment 11 of the original 12/20/12 submission. This is our compass' Military Specification. We used this specification as the base model for the extreme battlefield conditions to simulate soldier and Law Enforcement normal use. We expanded on these test parameters in our prototype test specifications (Attachment 10 of 4/24/13 submission). Also, please refer to the Conditions and Use answer number 3 from the 4/24/13 submission for further detail.

B.12. Section 32.22(a)(2)(xv), 10 CFR 32 refers to quality control procedures to be followed in fabrication of production lots. Attachment 9 of our 4/24/12 submission explains a number of measures Cammenga & Associates takes to ensure the utmost quality is met with regards to Tritium vial assembly. The same guidelines as were tested for the prototype models will be followed for production units (Testing 20 out of every lot of 1,000 knives *and* 100% of Tritium vials). Please review Attachment 6 of 4/24/13 submission and Attachment 10 of 4/24/13 submission for the testing guidelines. These guidelines are based on Attachment 11 of the original 12/20/12 submission, the military specification for our compasses and the background behind the measures listed in the 3H – Tritium Series Knife and Model 3H Series Compass from our license 21-26460-02E.

Cammenga & Associates is ISO 9001:2008 certified (ISO Certificate Attachment 8 of 4/24/12 submission). ISO 9001 is one of the most widely used management and quality tools used worldwide. Please see our ISO Certification in Attachment 8 of 4/24/13 response to RAI.

Best Regards,

Christopher J. Karchon
Cammenga & Associates