

**C**AMMENGA<sup>®</sup>  
CAMMENGA AND ASSOCIATES, LLC

2011 Bailey St.  
Dearborn, MI 48124  
Ph. (313) 914-7160  
Fax (313) 914-7153

August 19, 2015

The following package is in response to the NRC's RAI dated 7-24-15 with Mail Control Number **586785**.

A REQUEST FOR ADDITIONAL INFORMATION REGARDING EXEMPT DISTRIBUTION LICENSE

This information is required by 10 CFR 32.22, "Self-luminous products containing tritium, krypton-85 or promethium-147 : Requirements for license to manufacture, process, produce, or initially transfer."

1. *Please provide the maximum external radiation levels at 5 and 25 centimeters from any external surface of the product, averaged over an area not to exceed 10 square centimeters, and the method of measurement.*

**Response:** Please review Attachment 1 for this information.

2. *Please provide the estimated external radiation doses and dose commitments relevant to the safety criteria in 10 CFR 32.23 and the basis for such estimates. You could also provide a justification of how the new material(s) used will not change the estimated external radiation doses and dose commitments calculated for the AF Series prototypes constructed with carbon steel.*

**Response:** Please review Attachment 1 for this information. The carbon steel does not act to shield the external radiation levels. The Tritium in gaseous form sealed in borosilicate glass tubes. No electrons pass through this glass. The materials used (steel, aluminum, titanium..etc.) shield the vials from physical damage but have no effect on the external radiation doses, as those properties remain constant.

3. *Please provide a determination that the probabilities with respect to the doses referred to in 10 CFR 32.23(d) meet the criteria of that paragraph. You could also provide a justification of how the new material(s) used will not change the probabilities calculated for the AF Series prototypes constructed with carbon steel.*

**Response:** The probabilities and formulas used to satisfy the conditional criteria of 32.23 will remain constant as well. These scenarios presented offer worst-case situations where there are clear breakages of the glass vials containing Tritium. There are no specifics on how well the outside materials protect the vials from damage.

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

The U.S. Nuclear Regulatory Commission (NRC) staff has reviewed the Cammenga and Associates, LLC amendment request dated May 5, 2015, and determined that additional information is needed. In order to continue with our review, please address the issues listed below. This information is required by 10 CFR 32.210 and described in the relevant guidance document NUREG-1556 Volume 3 titled "Applications for Sealed Source and Device Evaluation and Registration."

1. *In your letter dated May 5, 2015, you stated in the materials of construction, you wish to remove the word "carbon" from carbon steel. Please provide the specific kind of steel(s) that will be used for the construction of the AF Series of gun sights. In your response, provide a justification of how this material(s) is equivalent to the material used in the AF Series prototypes (constructed of carbon steel). In your response, provide an analysis how the use of material may affect the product's design and integrity when subjected to conditions of normal use and likely accident conditions.*

**Response:** Cammenga relies heavily on its prototype testing to establish standards on whether a certain material will be able to withstand all required levels of force, various climate conditions, and corrosion. The goal for removal of "carbon" is to allow us to use higher corrosion resistant steels such as Stainless Steel. Using Stainless Steel will remove the need for secondary operations such as the anodizing procedure required for carbon steel. A substitution of steels would not affect the integrity when subjected to conditions of normal use and likely accident conditions.

2. *In your letter dated May 5, 2015, you stated that you wish to add the use of (1) titanium and (2) aluminum for the construction of the AF Series of gun sights. Please provide the specific kind of titanium and aluminum that will be used for the construction of the AF Series of gun sights. In your response, provide a justification of how these materials are equivalent to the material used in the AF Series prototypes (constructed of carbon steel). In your response, provide an analysis how the use of this materials may affect the product's design and integrity when subjected to conditions of normal use and likely accident conditions.*

**Response:** Cammenga relies heavily on its prototype testing to establish standards on whether a certain material will be able to withstand all required levels of force, various climate conditions, and corrosion. A substitution of metals would not affect the integrity when subjected to conditions of normal use and likely accident conditions. There are hundreds of different Titanium and Aluminum alloy options. The goal with selecting a material is to make sure the targeted durability in testing is achieved. In order to guarantee positive results we will stick to a Rockwell minimum hardness when substituting materials. Steels tend to be anywhere from 60 (low carbon) to 88 (stainless) Rockwell. Titanium tends to fall in at about 80 Rockwell (annealed). Aluminum has a wider hardness range, but we will hold a minimum Rockwell hardness to 35 Rockwell (A93004-H34).

- In your letter dated May 5, 2015, you stated that you wish to add the use of "similar materials" for the construction of the AF Series of gun sights. Please provide a list of the "similar materials." In addition, provide a justification of how these materials are equivalent to the material used in the AF Series prototypes (constructed of carbon steel). In your response, provide an analysis how the use of this material may affect the product's design and integrity when subjected to conditions of normal use and likely accident conditions.*

**Response:** Similar Materials refers to materials that will meet the minimum Rockwell hardness of 35 such as Cast Iron (86 Rockwell). Use of this material, for instance, will not affect negatively the product's design and integrity when subjected to normal conditions, however depending on current market demands and availability, may be a needed substitute. Cammenga takes all units through its prototype test procedures found in the original submission.

- In the AF Series of gun sights the sealed source is inserted in an aluminum outer sleeve, which is then secured in the machined cavity of the "carbon steel" with silicone. Please discuss the corrosion compatibility between the materials used in the construction of the gun sights and the aluminum outer sleeve. Provide a discussion for each of the materials you wish to add.*

**Response:** Cammenga's prototype testing includes subjecting the sights to a variety of extreme temperatures (original submission). This effectively simulates how the sights will react in different environments/climates. While the aluminum is inserted into the steel (or other material) cavities, the use of the silicone glue acts as a barrier to prevent these two different materials from coming into direct contact with one another. Further, the glue creates a "seal" to prevent outside moisture from even entering the sight cavity at all.

- In your letter dated May 5, 2015, you requested to change the range of the overall dimensions of the gun sights in the AF Series. Provide an analysis how the change in dimensions may affect the product's design and integrity when subjected to conditions of normal use and likely accident conditions.*

**Response:** The main goal of expanding dimensions was to give us flexibility during manufacturing to certain tolerances. The overall dimensional changes would only help to protect the vials even further by adding more material around them. The maximum levels of Tritium in each sight have not been adjusted. During normal use and accident conditions, the changes to sights would only be superior to their current form.

- In your letter dated May 5, 2015, you provided an updated version of the table for dimensions regions of the AF Series of gun sights. Please describe the components that will be affected by the new dimensions on the front and rear sights and whether they affect the part of the gun sights that contain the tritium sources. Please clarify whether the thickness of the material surrounding the tritium sources will change.*

**Response:** The only dimensional changes will be to the overall lengths and widths of the sights in order to fit different weapons and/or sight angles. Nothing will be changed with regard to thicknesses around the Tritium vials themselves.

- In your letter dated May 5, 2015, you requested to change the labeling from "engraved" to "engraved/etched, stamped, machined, molded, cast, or durable paint." Please provide specific details about each of the following labeling methods: (1) machined, (2) molded, and*

(3) cast.

**Response:** Please refer to Attachment 2 for this information.

8. *In your letter dated May 5, 2015, you requested to change the labeling from "engraved" to "engraved/etched, stamped, machined, molded, cast, or durable paint." Please provide specific details about each of the following labeling methods: (1) stamped and (2) durable paint. In your response address the durability of these labeling methods. Please note that the labeling method used should be sufficiently durable to remain legible for the useful life of the product under normal conditions of use, to be acceptable.*

**Response:** Please refer to Attachment 2 for this information.

9. *In your letter dated May 5, 2015, you requested to add the option of using Cammenga's name/logo in addition to using Cammenga's exempt distribution license. Please provide specific details as well as a diagram or picture that includes "Cammenga's name" and the "Cammenga's logo" that will be used for labeling. For example if the word "Cammenga" will be used for distribution identification purposes, please state so. Please note, if a company logo will be used for identification of the distributor, the company logo must be trademarked and provide a copy of the trademarked logo.*

**Response:** Please refer to Attachment 3 for this information.

**CAMMENGA & ASSOCIATES, LLC**

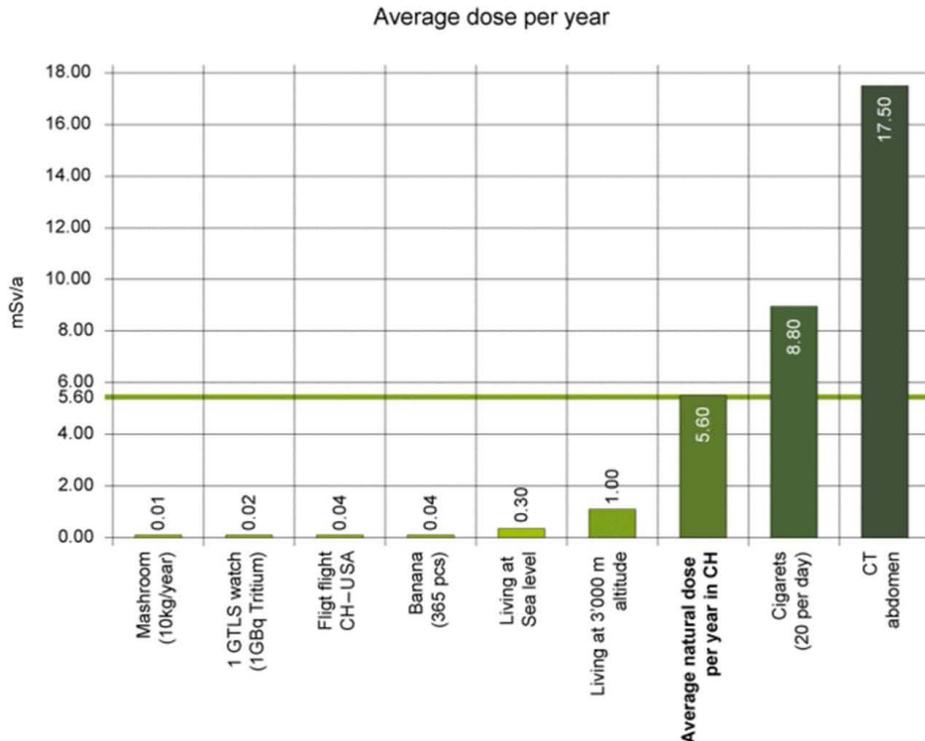
2011 BAILEY ST.  
 DEARBORN, MI 48124  
 Phone: 313.914.7160  
 Fax: 313.914.7153

August 19, 2015

## 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  $^3\text{H}$  “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.”

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  $E_{\text{max}}$  energy for this beta particle equals .0186 MeV (18.6 keV) and the  $E_{\text{av}}$  energy is .005685 MeV (5.69 keV).<sup>1</sup> 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.<sup>2</sup>

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<sup>1</sup> Kocher, David C. “Radioactive Decay Data Tables.” U.S. Department of Energy, DOE/TIC-11026

<sup>2</sup> 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).<sup>3</sup>

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<sup>3</sup> Pennsylvania Department of Environmental Protection -  
([http://www.dep.state.pa.us/brp/Radiation\\_Control\\_Division/Tritium.htm](http://www.dep.state.pa.us/brp/Radiation_Control_Division/Tritium.htm))

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### **Labeling Methods**

#### Laser Engraving:

The sight surface is melted and evaporated with the laser. Consequently, the laser beam removes the material. The thus produced impression in the surface is the engraving.

#### Laser Etching:

Electrochemical Etch is a process that uses a low voltage current to permanently mark the object surface.

#### Stamping, Machining, Molding, and Casting:

These are processes where the labeling is created during the main manufacturing process of the part. There is no ink required, and the impression will be visible even if parts are coated through an anodizing process.

#### Durable Paint/Pad Printing:

Pad printing is a printing process that can transfer a 2-D image onto a 3-D object. This is accomplished using an indirect offset (gravure) printing process that involves an image being transferred from the printing plate (cliché) via a silicone pad onto a substrate (surface to be printed). Pad printing is used for printing on otherwise impossible products in many industries including medical, automotive, apparel, appliances, electronics, sports equipment (ie. golf balls) and children's toys.

The unique properties of the silicone pad enable it to pick the image up from a flat plane and transfer it to a variety of surface (i.e. flat, cylindrical, spherical, compound angles, textures, concave surfaces, convex surfaces).

Pad printing silicone rubber has good printing effect, fine quality, permanent and durable, good resilience, abrasion resistance without any impurities.

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**From:** TMOfficialNotices@USPTO.GOV  
**Sent:** Friday, November 15, 2013 11:01 PM  
**To:** tmmail@patentco.com  
**Subject:** Trademark RN 3345833: Official Notice of Acceptance and Acknowledgement under Sections 8 and 15 of the Trademark Act

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**Serial Number:** 78835663  
**Registration Number:** 3345833  
**Registration Date:** Nov 27, 2007  
**Mark:** CAMMENGA(STANDARD CHARACTER MARK)  
**Owner:** CAMMENGA PRODUCTS

Nov 15, 2013

### **NOTICE OF ACCEPTANCE UNDER SECTION 8**

The declaration of use or excusable nonuse filed for the above-identified registration meets the requirements of Section 8 of the Trademark Act, 15 U.S.C. §1058. **The Section 8 declaration is accepted.**

### **NOTICE OF ACKNOWLEDGEMENT UNDER SECTION 15**

The declaration of incontestability filed for the above-identified registration meets the requirements of Section 15 of the Trademark Act, 15 U.S.C. §1065. **The Section 15 declaration is acknowledged.**

**The registration will remain in force for the class(es) listed below for the remainder of the ten-year period, calculated from the registration date, unless canceled by an order of the Commissioner for Trademarks or a Federal Court.**

**Class(es):**  
013

TRADEMARK SPECIALIST  
POST-REGISTRATION DIVISION  
571-272-9500

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### **REQUIREMENTS FOR MAINTAINING REGISTRATION**

**WARNING: Your registration will be canceled if you do not file the documents below during the specified time periods.**

#### **Requirements in the First Ten Years**

**What and When to File:** You must file a declaration of use (or excusable nonuse) **and** an application for renewal between the 9th and 10th years after the registration date. See 15 U.S.C. §§1058, 1059.

#### **Requirements in Successive Ten-Year Periods**

**What and When to File:** You must file a declaration of use (or excusable nonuse) **and** an application for renewal between every 9th and 10th-year period, calculated from the registration date. See 15 U.S.C. §§1058, 1059.

**Grace Period Filings**

The above documents will be considered as timely if filed within six months after the deadlines listed above with the payment of an additional fee.

**\*\*\*The USPTO WILL NOT SEND ANY FURTHER NOTICE OR REMINDER OF THESE REQUIREMENTS. THE REGISTRANT SHOULD CONTACT THE USPTO ONE YEAR BEFORE THE EXPIRATION OF THE TIME PERIODS SHOWN ABOVE TO DETERMINE APPROPRIATE REQUIREMENTS AND FEES.\*\*\***

To view this notice and other documents for this application on-line, go to <http://tdr.uspto.gov/search.action?sn=78835663>.

NOTE: This notice will only be available on-line the next business day after receipt of this e-mail.

# CAMMENGA