

Rodriguez-Luccioni, Hector

From: Rodriguez-Luccioni, Hector
Sent: Wednesday, October 14, 2015 8:15 AM
To: 'CJ Karchon'
Cc: Arribas-Colon, Maria; Xu, Shirley; Herrera, Tomas
Subject: NRC 3rd Request for Additional Information - Cammenga and Associates, LLC

Mr. Karchon,

The U.S. Nuclear Regulatory Commission (NRC) staff has reviewed your letter dated October 7, 2015, which responds to our second request for additional information dated September 21, 2015, regarding Cammenga and Associates amendment request for the exempt distribution license and the Sealed Source and Device registration certificate. The staff has determined that additional information is needed. In order to continue with our review, please address the issues listed below.

1. In your letter dated October 7, 2015, in Attachment 2, you provided dose calculations as required by 10 CFR 32.23. Please clarify the following:
 - a. Under example A, "Normal use of a Single Unit," you stated that the maximum diffusion rate for each sight is $9.00E-2$ $\mu\text{Ci/hr}$. Under Example B, "Normal Handling/Storage of Quantities of Tritium Vials Likely to Accumulate in One Location," you stated that the maximum tritium diffusion rate in the storage room is $1,200$ $\mu\text{Ci/hr}$. Please provide your basis for these two values.
 - b. Under example C, "Use/Disposal of Quantities of H-3 Vials Likely to Accumulate in One Location," you calculated that the estimated H-3 activity concentration in the storage room is $6.36E-5$ $\mu\text{Ci/ml}$. After reviewing your calculations it seems that the units are incorrect. Please provide a revised calculation for this section.
 - c. Under example D, "Use/Disposal of Quantities of H-3 Vials Likely to Accumulate in One Location during transportation," you calculated that the estimated H-3 activity concentration in affected area is $6.6E-6$ $\mu\text{Ci/ml}$. After reviewing your calculations it seems that the units are incorrect. Please provide a revised calculation for this section.
2. In your response to NRC Question B.1. dated October 7, 2015, you stated the list of specific materials of construction is (1) Aluminum, (2) Steel, (3) Stainless Steel, and (4) Titanium. In addition, you stated that your QA sets the guidelines for various operational processes and that your Inventory Control parameters ensure each material received is stored in proper conditions prior to begin used in manufacturing. Please note that this response does not fully address NRC Question B.1. dated September 21, 2015.

Please note that "Steels" as a material is very broad and cannot be accepted as a specific material for the materials of construction. Steel is a mixture of iron with carbon, usually with other elements. The alloy properties varies (e.g. ductility, corrosion resistance, etc.). The prototype testing you provided for the AF series (which approved by NRC for the construction of the AF Series) was based on the sights made of Carbon Steel 1045 which has a surface Rockwell hardness value of 54-60. Based on the information you provided in letter dated August 19, 2015, and October 7, 2015, its our undestanding that you wish to use the follwing materials for the construction for the gunsights:

- Carbon Steel Alloy with a minimum Rockwell hardness value of 60
- Stainless Steel Alloy with a minimum Rockwell hardness value of 88
- Titanium Alloy with a minimum Rockwell hardness value of 80
- Aluminum Alloy with a minimum Rockwell hardness value of 35

Please confirm and provide the following: (1) Confirm that our understanding of the materials you wish to use for construction is correct, (2) provide the upper ranges for the Rockwell hardness acceptance criteria for each of the bullets stated above, and (3) provide a statement on how these materials are equivalent to the material used for the prototype testing of the AF series of gunsights to ensure that the device will maintain its integrity during normal conditions of use and likely accident conditions. If our understanding is not correct, please provide specifics.

3. In your response to NRC Question B.2. dated October 7, 2014, you stated that the glue used for the construction of the gun sights is Dow Corning 732 and that the glue does not have any corrosive characteristics. In reviewing your original submission to register the AF Series, you also provided a data sheet for Dow Corning 734. Please confirm that both sealants are used and that there are no changes in the gluing process.
4. In your response to NRC question B.3. dated October 7, 2014, you stated that the minimum amount of material around the sources will remain unchanged. Please provide the minimum amount of material around the sources.
5. In your response to NRC question B.4. dated October 7, 2014, you stated that Attachment 5 provides letters from Form Motor Company approving this durable method of labeling on some of your automobile products. The letters you provided point out that this printing method is approved for different types of polymers. Polymers are not metals comparable with the construction materials used for the construction of the AF series of gunsights. In order for us to approve pad printing as an acceptable method of labeling for the gunsights, you have to demonstrate that the labeling method on the gunsight will be durable under normal use (e.g. rubbing and cleaning with abrasive/chemical products) for the life of the gun sight which is 10 years. In our conversation on October 7th, you stated that the compasses distributed by Cammenga use the same labeling process, you may provide Cammenga's experience with using pad printing with other products approved for distribution by the NRC.

Any correspondence regarding your application should reference the control number 586785. Please submit the requested information in an official signed letter within 15 days of the date of this email. If we have not received complete information within 15 days of the date of this email, we will consider your application as having been abandoned by you. This is without prejudice to the submission of a complete application.

Please be aware that upon your request, proprietary information submitted to the NRC may be withheld from public disclosure. To do this, you must follow the procedures in 10 CFR 2.390(b) including requesting withholding at the time the information is submitted and complying with the document marking and affidavit requirements set forth in 10 CFR 2.390 (b)(1).

In accordance with 10 CFR 2.390 a copy of this letter will be available electronically for public inspection in NRC's Public Document Room or from the Publicly Available Records (PARS) component of NRC's document system (ADAMS). ADAMS is accessible from the NRC web site at <http://www.nrc.gov/NRC/ADAMS/index.html> (the Public Electronic Reading Room).

If you have any questions regarding the Sealed Source and Device Registration you can contact Maria Arribas-Colon at (301) 415-6026 or by email at Maria.Arribas-Colon@nrc.gov. For questions related to the exempt distribution license, please contact me at (301) 415-6004 or email at Hector.Rodriguez-Luccioni@nrc.gov.

Sincerely,

Hector Luis Rodríguez-Luccioni, Ph.D.

U.S. Nuclear Regulatory Commission

Office of Nuclear Material Safety and Safeguards

Division of Materials Safety, States, Tribal and Rulemaking Programs

Material Safety Licensing Branch

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