



UNITED STATES
NUCLEAR REGULATORY COMMISSION
WASHINGTON, D.C. 20555-0001

September 21, 2015

Cammenga and Associates, LLC
ATTN: Christopher Karchon
Director of Strategic Initiatives
2011 Bailey Street
Dearborn, MI 48124

SUBJECT: SECOND REQUEST FOR ADDITIONAL INFORMATION REGARDING
CAMMENGA AND ASSOCIATES, LLC. AMENDMENT REQUEST TO EXEMPT
DISTRIBUTION LICENSE AND SEALED SOURCE AND DEVICE
REGISTRATION CERTIFICATE

Dear Mr. Karchon:

The U.S. Nuclear Regulatory Commission (NRC) staff has reviewed your letter dated August 19, 2015, Agencywide Documents Access and Management System (ADAMS) Accession No. ML15232A165, which responds to our first request for additional information dated July 24, 2015 (ADAMS Accession No. ML15202A187). The staff has determined that additional information is needed. In order to continue with our review, please address the issues listed in the enclosure.

Any correspondence regarding your application should reference the control number specified below. Please submit the requested information within 30 days of the date of this letter. If we have not received complete information within 30 days of the date of this letter, 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,

/RA/

Hector Rodriguez-Luccioni, Ph.D.
Materials Safety Licensing Branch
Division of Material Safety, State, Tribal
and Rulemaking Programs
Office of Nuclear Material Safety
and Safeguards

Docket No. 030-38679
Mail Control No. 586785

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Sincerely,

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Materials Safety Licensing Branch
Division of Material Safety, State, Tribal
and Rulemaking Programs
Office of Nuclear Material Safety
and Safeguards

Docket No. 030-38679
Mail Control No. 586785

SSD Case 15-32
License Numbers: 21-26460-03E and NR-210-D-102-E

ML15254A254 - Certified Mail Tracking Number: 7014 0510 0000 4426 4875

OFC	NMSS/MSTR/MSLB*	NMSS/MSTR/MSLB*	NMSS/MSTR/MSLB*	NMSS/MSTR/MSLB*
NAME	Hector Rodriguez-Luccioni	Shirley Xu	Maria Arribas-Colon	Tomas Herrera
DATE	09/11/2015	09/17/2015	09/17/2015	09/18/2015
OFC	NMSS/MSTR/MSLB	NMSS/MSTR/MSLB		
NAME	Hipolito Gonzalez	Hector Rodriguez-Luccioni		
DATE	09/18/2015	09/18/2015		

OFFICIAL RECORD COPY

Christopher Karchon
Cammenga and Associates, LLC
030-38679

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. In our letter dated July 24, 2015, we requested the maximum external radiation levels at 5 and 25 centimeters from any external surface of the product (gunsights), averaged over an area not to exceed 10 square centimeters, and the method of measurement. In your letter dated August 19, 2015, you stated that through an analysis from mb-microtec and NUREG 1717, "Systematic Radiological Assessment of Exemption of Source and Byproduct Materials," along with your own internal measurements, you determined there are no external radiation levels at 5 and 25 centimeter distances from any external surface of your products. The information you provided is incomplete. Please provide the method you used to get to your conclusion. If you measured the radiation level using an instrument please provide the information of the instrument and the measured values, if you calculated the radiation levels please provide the calculations and analysis.
2. In our letter dated July 24, 2015, we requested the estimated external radiation doses and dose commitments relevant to the safety criteria in 10 CFR 32.23 and the basis for such estimates. In your letter dated August 19, 2015, you provided a discussion of the external dose of the H-3 Trigelights sources manufactured by mb-microtec. Your response is not sufficient and does not satisfy the regulatory requirements. The regulatory requirements under 10 CFR 32.23 shall be pertinent to the product (gunsight) not the sources. Please provide the radiation doses and dose commitments relevant to the safety criteria in 10 CFR 32.23 for the product and the basis for such estimates. You may use NUREG 1717, Section 2.14, "Self-Luminous Products," as a reference.
3. In our letter dated July 24, 2015, we requested a determination that the probabilities with respect to the doses referred to in 10 CFR 32.23(d) meet the criteria of that paragraph. We stated that 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. In your letter dated August 19, 2015, you stated that the probabilities and formulas used to satisfy the conditional criteria of 32.23 will remain constant. In addition you stated that the scenarios presented offer worst-case situations where there are clear breakages of the glass vials containing Tritium and that there are no specifics on how well the outside materials protect the vials from damage. Your response is not sufficient and does not satisfy the regulatory requirements.

Please demonstrate that the product is designed and will be manufactured so that in use and disposal of a single exempt unit, or in handling and storage of the quantities of exempt units

likely to accumulate in one location during marketing, distribution, installation, and servicing of the product, the probability is low that the containment, shielding, or other safety features of the product would fail under such circumstances that a person would receive an external radiation dose or dose commitment in excess of the dose to the appropriate organ as specified in Column III of the table in 10 CFR 32.24, and the probability is negligible that a person would receive an external radiation dose or dose commitment in excess of the dose to the appropriate organ as specified in Column IV of the table in 10 CFR 32.24. You may use NUREG 1717, Section 2.14, "Self-Luminous Products," as a reference.

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

1. In your response to NRC Questions B.1., B.2., and B.3., you stated that Cammenga heavily relies 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. Please provide the following information:
 - A list of the specific materials (e.g. stainless steel, aluminum, titanium) that will be used for the construction of the sites. Please note that statements indicating "materials such as" are not acceptable.
 - Cammenga's standard acceptance criteria for the materials. In addition, confirm that this criteria is included as part of Cammenga's QA/QC Program.
2. In your response to NRC Question B.4., you stated that Cammenga while the aluminum is inserted into the steel (or other material) cavities, the use of silicone glue acts as a barrier to prevent these two different materials from coming into direct contact with one another. Please note that many silicone adhesives release a corrosive entity, such as acetic acid. Please confirm that the silicone glue used for the construction of the gunsights is a non-corrosive formulation.
3. In your response to NRC Question B.5., you stated the overall dimensional changes only help protect the vials even further by adding material around them. Please note, that some of the dimensions you provided in your letter dated May 5, 2015, were significantly less than the ones currently approved in your Registration Certificate and no additional material around them will. For example, for the front gunsight you requested to change the minimum length of the front sight from 15mm to 5mm and the minimum width from 3mm to 2mm. Please clarify the discrepancy.
4. In your response to NRC Question 7, you explained the different types of labeling. Please provide the following information:
 - Please demonstrate that the "durable paint/pad printing" labeling method will be durable under normal use (e.g. rubbing and cleaning with abrasive/chemical products) for the life of the gunsight (10 years).
 - Please delineate which of the labels (DH3, DR-H3, DRH3, H3, 21-26460-03E and CAMMENGA) will be (1) laser engraved/etched, (2) stamped, machined, molded, and casted, and (3) durable paint/pad printed.
 - Please provide a diagram or picture with the specific location and dimensions of the labeling or marking in each gunsight with the identification of the manufacturer or initial transferor (CAMMENGA) and the byproduct material.