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

April 22, 2019

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

SUBJECT: REQUEST FOR ADDITIONAL INFORMATION

Dear Mr. Karchon:

This letter is in response to your application dated March 7, 2019, requesting amendments to your Exempt Distribution License 21-26460-03E and Sealed Source and Device Registration Certificate NR-0210-D-101-E.

We do not have sufficient information to complete the review of your application. In the enclosure to this letter you will find the list of the questions and items not addressed in your application.

Please be aware that upon your request, proprietary information submitted to the U.S. Nuclear Regulatory Commission (NRC) may be withheld from public disclosure. To do this, you must follow the procedures in Title 10 of the *Code of Federal Regulations* (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).

We will continue our review upon receipt of this information. If we do not receive your reply within 30 calendar days from the date of this letter, we will consider your application as having been abandoned by you. This action would be without prejudice to the resubmission of another application with the required information.

In accordance with 10 CFR 2.390 of the NRC's "Agency Rules of Practice and Procedure," a copy of this letter will be available electronically for public inspection in the NRC Public Document Room or from the Publicly Available Records component of NRC's Agencywide Documents Access and Management System (ADAMS). ADAMS is accessible from the NRC Web site at http://www.nrc.gov/reading-rm/adams.html.

Any correspondence regarding your amendment application should reference control number 611588.

If you have any questions regarding your sealed source and device registration certificate, please contact Tomas Herrera at (301) 415-7138, or by e-mail at Tomas.Herrera@nrc.gov. If you have any questions regarding your exempt distribution license, please contact Richard Struckmeyer at (301) 415-5477, or by e-mail at Richard.Struckmeyer@nrc.gov.

Sincerely,

/RA/

Richard K. Struckmeyer
Materials Safety Licensing Branch
Division of Materials Safety, Security, State,
and Tribal Programs
Office of Nuclear Material Safety
and Safeguards

Docket No. 030-38679
License No. 21-26460-03E

Enclosure:
Request for Additional Information

CAMMENGA AND ASSOCIATES, LLC, REQUEST FOR ADDITIONAL INFORMATION DATED April, 2019

Certified Mail No. 7017 0190 0000 1642 8950

ADAMS ACCESSION NO.: ML19105A842 (pkg.) ML19105B071 (Letter & Enclosure)

OFFICE	MSST/MSTB	MSST/MSTB	MSST/MSTB	MSST/MSTB	MSST/MSTB
NAME	RStruckmeyer	RJackson	THerrera	MArribas-Colon	RStruckmeyer
DATE	4/15/2019	4/15/2019	4/16/2019	4/16/2019	4/22/2019

OFFICIAL RECORD COPY

ENCLOSURE

Cammenga and Associates, LLC Amendment Request dated March 7, 2019
Request for Additional Information

The U.S. Nuclear Regulatory Commission (NRC) staff has reviewed the Cammenga and Associates, LLC (Cammenga) amendment request dated March 7, 2019, and determined that additional information is needed. In order to continue with our review, please address the issues listed below.

The information related to review of your sealed source and device amendment application is required by Title 10 of the *Code of Federal Regulations* (10 CFR) 32.210 and is described in the relevant guidance document NUREG-1556, Volume 3, Revision 2, titled "Applications for Sealed Source and Device Evaluation and Registration."

The information related to review of your exempt distribution license amendment application is required by 10 CFR 32.22, 32.23, and 32.24, and is described in the relevant guidance document NUREG-1556, Volume 8, Revision 1, titled "Program-Specific Guidance about Exempt Distribution Licenses."

A. Information Required for Review of Sealed Source and Device Amendment Application

Description/Construction

1. In Attachment 4, you state that the sources to be used in the additional models for the 3H Tritium Series Knife will not exceed 250 mCi each. However, as noted in on Page 4 and Attachment 9 several knives in the series will only contain one source with a maximum activity listed as 500 mCi (e.g.,knives designated as F-1S-1V, 1S-1V, 1SP, 1SW, and 1TS). Please explain this discrepancy.

2. Please confirm that Cammenga will ensure that the each knife will only be distributed with a maximum amount of 500 mCi, regardless of the number of sources used in each knife.

3. Please confirm that the "durable plastic" you list on Page 1 of Attachment 6, refers to the polycarbonate specifications included in Attachment 16.

4. Please confirm that the only materials of construction for the additional knife models that Cammenga is requesting to be added to NR-0210-D-101-E are listed on Page 1 of Attachment 6 under sub-section titled "B. The materials we wish to use are as follows:"

5. In the drawings submitted by Cammenga for the dimensions of the knives we note that the minimum and maximum range dimensions provided for the A, B, and C dimensions are provided in millimeters. Specifically, based on the dimensions provided in the majority of the drawings a knife can be as small as 4.0 mm long. The range of dimensions varies greatly for the folding and fixed blade knife versions and based on the minimum dimensions provided they appear to be incorrect. Please reassess the submitted dimensions and provide accurate dimension ranges.

6. The overall dimension ranges for the 3H Tritium Series Knife will not be treated as proprietary information and will be included in the registration as a description of the information. Please resubmit non-proprietary versions of the drawings to include the range of dimensions for the knives.

7. Please explain the abbreviations used in the model designations for the 3H Tritium Series Knife and what they represent – to include: F, S, V, SP, SW, and TS.

8. In the drawings titled "ALL FOLDING KNIVES" and "ALL FIXED KNIVES" please explain the following:

    a. Please explain what the dimensions titled A, B, C, and P represent, specifically in the section of the drawing titled "Tritium and Protection Detail".
    b. We noted that the dimensions provided in the "Tritium and Protection Detail" section appear to be those of the recesses used for "V" in the submitted model designations. However, we noted that in other models the drawing includes different locations where the sources will be inserted. Please provide details (including dimensions) and materials if applicable for sources added in the SP, SW, and TS locations.

9. Resubmit a complete drawing of the folding knives that include sources designated in the "TS" position on both sides. We note that the "TS" source is not included in the top view of the drawing for those knives that have them located on both sides.

10. Please describe how the tritium vials are attached and installed in the SP and SW positions.

11. Please describe how the tritium vial is affixed to the TS component and how the component is attached to the knife.

Labeling

12. From the drawings submitted for both the folding knife and fixed blade knife versions, it is unclear what surface will contain the labeling. Please state where the labeling will be located for both the folding and fixed blade knife versions.

Prototype Testing

13. Please discuss the rationale for only testing knives manufactured out of stainless steel. As previously noted Cammenga had tested the polycarbonate versions for other devices because that material presented the highest probability of failure.

14. We noted that the prototype models tested by Cammenga had a maximum of two tritium vials. Please explain why the model containing maximum number of sources (2S-4V-3SP-2SW-2TS) containing 15 sources was not tested. As previously noted Cammenga has tested models which present the highest probability of fail

15. The prototype test results sheets include the following statement: "This certifies that, to the best of my knowledge, the above test was made on --------- and was done accurately." We noted that the date is blank. Please include the date of when the testing was completed for each of the tests.

16. For the Shock and Impact Durability tests, please identify on which surfaces of the knives the impact occurred.

B. Information Required for Review of Exempt Distribution License Amendment Application

1. 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. "Degree of Access to Human Beings" is discussed on page 3 of Attachment 6, which contains the following statement: "These test parameters for our prototype test specifications can be found in Attachment 11." The prototype tests in Attachment 11 provide information that is intended to demonstrate that the method of containment or binding of the byproduct material in the product is such that the radioactive material will not be released or be removed from the product under the most severe conditions that the product is likely to encounter under everyday normal use and handling. However, this is different from the degree of access of human beings to the product during normal handling and use. Therefore, this attachment does not explicitly address the requirement of Section 32.22(a)(2)(vii). Please provide additional information to describe access of human beings to the product during normal handling and use, including (but not necessarily limited to) the degree to which a person could dislodge or damage the byproduct material by mechanical or other means.

   Guidance concerning this regulation can be found in NUREG-1556, Volume 8, Revision 1, Appendix D, "Additional Guidance for Self-Luminous Products," page D-4, "Degree of access of human beings to the product during normal handling and use."

2. 10 CFR 32.22(a)(2)(x) requires the applicant to submit the proposed method of labeling or marking each unit with identification of the manufacturer or initial transferor of the product and the byproduct material in the product. Please provide representative copies of the labels you plan to use on these devices.