



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

April 26, 2021

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

SUBJECT: CAMMENGA AND ASSOCIATES, LLC, REQUEST FOR ADDITIONAL
INFORMATION

Dear Mr. Karchon:

This letter is in response to your application dated December 30, 2020, requesting amendments to your Exempt Distribution License (E-License) 21-26460-03E and Sealed Source and Device (SSD) 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) Paragraph 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 Section 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 mail control number 621046.

If you have any questions regarding your SSD Registration Certificate, please contact Lymari Sepulveda at (301) 415-5619, or by e-mail at Lymari.Sepulveda@nrc.gov. If you have any questions regarding your E-License, please contact Shirley Xu at (301) 415-7641, or by e-mail at Shirley.Xu@nrc.gov.

Sincerely,

4/26/2021

X



Lymari Sepulveda

Mechanical Engineer

Signed by: Lymari Sepulveda

Lymari Sepulveda
Materials Safety Tribal and Liaison 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

SUBJECT: CAMMENGA AND ASSOCIATES, LLC, REQUEST FOR ADDITIONAL
INFORMATION

DATED: April 26, 2021

ADAMS ACCESSION NO.: ML21111A171 (Letter & Enclosure)

***Concurrence Via email**

OFFICE	MSST/MSTB	MSST/MSTB	MSST/MSTB	MSST/MSTB	MSST/MSTB
NAME	LSepulveda	TBrockington	THerrera*	SXu*	LSepulveda
DATE	4/21/2021	4/21/2021	4/26/2021	4/26/2021	4/26/2021

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CAMMENG AND ASSOCIATES, LLC
APPLICATION DATED DECEMBER 30, 2020
REQUEST FOR ADDITIONAL INFORMATION

The U.S. Nuclear Regulatory Commission (NRC) staff has reviewed the Cammenga and Associates, LLC (Cammenga) application dated December 30, 2020, 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 Title 10 of the *Code of Federal Regulations* (10 CFR) Section 32.210 and described in the relevant guidance document NUREG-1556, Volume 3, Revision 2, titled "Applications for Sealed Source and Device Evaluation and Registration."

Description/Construction

1. The NRC's Consumer Product Safety Policy (CPSC) states that "products proposed for distribution will be useful to some degree." Also, in the Principal Considerations with Respect to Evaluation of Product of the CPSC, Item (d), states that "The societal benefit that will accrue to or be denied because of the usefulness of the product by approval or disapproval of a specific product." Contrary to the NRC's policy your application to amend your sealed source and device registration certificate and your exempt distribution license does not address the intended use of the products or provide a clear description of the product.

Please provide a clear statement of the intended use for these products.

2. In the table shown below, please note the minimum and maximum dimensions. The minimum and maximum dimensions do not appear to be accurate or representative of the final product.

DIMENSIONS	MIN	MAX	NOMINAL
A	20	200	114
B	3	26	6
C	3	51	25

Please submit actual dimensions for the devices, for example, it is not clear what the intended use for a product measuring 20 mm in length will serve. Dimensions should show the distances between sources and distance between the source and the edge of the side. Please note that this table is one example of all Tables under the Engineering Drawings, your response must address all the devices in your application.

3. Please also identify the dimensions of the sources that will be used in the device. We note that dimension for "C" will need to accommodate a source and maintain the source protection. Based on the information in the table listing all the models in the new series,

Enclosure

the sealed source has a nominal diameter of 1.5 mm and Nominal Length of 7.0 mm. Based on your drawings and picture of tested devices, it appears that all the sources will have the same dimensions.

4. In the pictures of the tested devices it shows an unpolished surface. Please indicate whether the devices will be polished or finished after the source is install, if so, please indicate whether the finishing will have a detrimental effect in the installed source.
5. Please indicate whether Cammenga will be manufacturing all the pieces or if Cammenga will only be handling the source installation.
6. Please confirm our understanding that none of the models requested will include a source on the "T" or tool side of the devices.
7. For model MJ-S1.4-S2.4-S3.4-S4.4-T0-B1, please address how the design of the device with the range of dimensions as requested will accommodate a sealed source in position B, and ensure that the minimum source protection is achieved.

Conditions of Use

8. Please provide the intended temperature ranges that the VERSA Series models.

Prototype Testing

9. It appears that the device models that were tested will contain a source in in the B position, specifically model GR-S1.4-S2.4-S3.4-S4.4-T0-B1, MJ-S1.4-S2.4-S3.4-S4.4-T0-B1, and SP-S1.4-S2.4-S3.4-S4.4-T0-B1. The picture of devices that were tested do not show the source in position B. Please confirm that the model tested did include a source in the B position and provide a picture of that position.