

July 20, 2016

Advanced Combat Solutions, Inc.
ATTN: Yelena Sivaya
333 Las Olas Way, CU#1
Fort Lauderdale, FL 33301

SUBJECT: REQUEST FOR ADDITIONAL INFORMATION REGARDING ADVANCED
COMBAT SOLUTIONS, INC., EXEMPT DISTRIBUTION LICENSE
APPLICATION AND SEALED SOURCE AND DEVICE REGISTRATION
CERTIFICATE APPLICATION

Dear Ms. Sivaya:

The U.S. Nuclear Regulatory Commission (NRC) staff has reviewed the Advanced Combat Solutions, Inc. application dated May 6, 2016, for a new Exempt Distribution License and a new Sealed Source and Device Registration Certificate (Agencywide Documents Access and Management System (ADAMS) Accession Nos. ML16175A618 and ML16175A518). 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 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).

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).

Y. Sivaya

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If you have any questions regarding the Sealed Source and Device Registration, you can contact Lymari Sepulveda at (301) 415-5619 or by e-mail at Lymari.Sepulveda@nrc.gov. For questions related to the Exempt Distribution License, please contact me at (301) 415-7640 or by e-mail at Shirley.Xu@nrc.gov.

Sincerely,

/RA/

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

Docket No. 030-38926
Mail Control No. 591166

Enclosure:
Request for Additional Information

Y. Sivaya

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Shirley S. Xu
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Docket No. 030-38926
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Enclosure:
Request for Additional Information

Certified Mail No. 7015 0640 0003 2910 1375

ML16201A320

OFC	NMSS/MSTR/MSLB	NMSS/MSTR/MSLB	NMSS/MSTR/MSLB	NMSS/MSTR/MSLB
NAME	Shirley Xu	Debbie Miller	Lymari Sepulveda	Tomas Herrera
DATE	07/20/2016	07/19/2016	07/20/2016	07/20/2016
OFC	NMSS/MSTR/MSLB	NMSS/MSTR/MSLB		
NAME	Hipolito Gonzalez	Shirley Xu		
DATE	07/20/2016	07/20/2016		

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REQUEST FOR ADDITIONAL INFORMATION REGARDING
EXEMPT DISTRIBUTION LICENSE

This information is required by Title 10 of the *Code of Federal Regulations* (10 CFR) 32.22, “Self-luminous products containing tritium, krypton-85 or promethium-147: Requirements for license to manufacture, process, produce, or initially transfer”; 10 CFR 30.33; and described in the relevant guidance document NUREG-1556, Volume 8 titled, “Program-Specific Guidance about Exempt Distribution Licenses.”

1. 10 CFR 30.33 requires you to apply for and obtain a specific license authorizing possession and use of radioactive materials from the States or NRC Regional Offices wherever licensed material are possessed. Please submit a copy of your current Florida license that reflects all of your radioactive material use authorization information.

2. On page 8 of your application, under item No. 4, “Maximum external radiation levels at 5 and 25 centimeters away from any external surface of the product, averaged over an area not to exceed 10 square centimeters, and the method of measurement (ref. to 10 CFR § 32.22 (a) (2) (vi)),” you stated that “Radiation levels measured right at the surface of the lamps were measured with geiger-counter...” Please clarify whether the measurements are for LEMI and ICSI or the lamps.

Enclosure

REQUEST FOR ADDITIONAL INFORMATION REGARDING SEALED SOURCE AND DEVICE REGISTRATION CERTIFICATE

In order to continue with our review, please address the issues listed below. This information is required by 10 CFR 32.210, 10 CFR 32.22, and described in the relevant guidance document NUREG-1556, Volume 3 titled, "Applications for Sealed Source and Device Evaluation and Registration."

General

1. U.S. Nuclear Regulatory Commission (NRC) Form 313 lists that the maximum activity for the devices in the LEMI Series is 13.513 mCi and the ICSI is 1.081 mCi per device. Enclosure C of your application indicates that the maximum activity per source is 6 mCi for a device in the LEMI Series and 1.10 mCi for the ICSI device. Please explain the apparent discrepancy. If multiple devices will be used per firearm please indicate how many devices and the activity of each device. Please indicate the maximum activity that will be used for each device.
2. Based on the model numbers provided for the magazine followers for the LEMI series, it is our understanding that Advanced Combat Solutions Inc. (ACS) intends for the LEMI models to be used in magazines for M16/AR15 style rifles and Glock handguns. Please confirm our understanding. In addition, please discuss how the user of the LEMI will be able to see the light emitted by the gaseous tritium light source if the magazine is inserted inside the grip of the handgun.
3. Page 5 of the ACS application includes "Pic 1. Firearm Magazine (Cross-sectional view)." On this drawing or a similar drawing, please identify the location of the gaseous tritium light source.
4. The application requested the evaluation of the LEMI Series. Please provide the maximum and minimum dimensions for the models in the LEMI Series. Please indicate if the installation of the source varies per model.
5. Please provide drawings that include the overall dimensions, i.e., length, width, and height of the LEMI Series for the Glock and M16/AR15 configurations and the ICSI device.
6. Please provide a picture of the LEMI model that will be used for Glock handguns similar to "Pic 2" provided on page 6 of the ACS application.
7. Please indicate if there is a potential for corrosion between unlike materials such as steel and aluminum how it will be prevented.

Prototype Testing

8. The LEMI Series devices will be attached to a spring in a semi-permanent manner and will provide opposite force against the weight of the ammunition being force up and out

of the magazine body. Please explain how the prototype testing performed on the LEMI Series demonstrate that the device will maintain its integrity during normal conditions of use and accidental conditions through the useful life of the devices. Specifically, please explain how the testing is representative of the impact forces and compression the device will receive during its useful working life of 12 years.

9. The design of the ICSI extractor suggests that it is likely to be regularly subjected to friction. Please demonstrate that the source will remain in the device during its useful working life when submitted to repetitive friction.

Labeling

10. Page 9 of the ACS application includes examples of the information that will appear on the LEMI and ICS labels. Please note that the company logo may not be sufficient to meet the requirements for labeling as described in 10 CFR 32.22 as an identification of the manufacturer. In order for a logo to be an acceptable method to identify the manufacturer the logo must be a Registered Trademark. If the logo is trademarked or registered, please provide information to support that the trademark has been registered. If the logo is not registered please provide a new method of identifying the manufacturer; this could include the entire name or the Exempt Distribution License number that will be issued by the NRC.

11. Please provide a picture of the LEMI Series that includes the label.

Drawings

12. Please provide a drawing for the LEMI Series showing the location where the source will be installed.

Quality Assurance

13. Enclosure F of the ACS application includes the ACS Quality Assurance Program. We note the following:

- a. In "Definitions" it states, "NRC Contact – the person identified by the licensee as being responsible for ensuring compliance with NRC regulations."

Please note that it is the licensee's responsibility for ensuring compliance with the NRC's regulations. The licensee's compliance with NRC's regulations will be verified through inspection. Please provide a corrected definition.

- b. In "Definitions" it states, "Specifications – requirements imposed by Advanced Combat Solutions Inc., customer, or NRC that, if not followed, may affect the use or operation of the device."

Please note that the NRC does not impose specifications. ACS must follow the appropriate regulatory requirements and commitments made to the NRC in its application. Please provide a corrected definition.

- c. The Quality Assurance Program provided specific contacts at the NRC. Since there may be turnover in staff, the NRC recommends that this be changed to a more general contact list.

Please resubmit the corrected pages of the Quality Assurance Program.

- 14. Page 5 of the ACS application indicates that a “leak test should be performed before initial distribution.” However, page 127 of the application indicates that “[b]efore packaging at least 1% of the devices will undergo an operational check for illumination and fit, as well as wipe test.” Please confirm that ACS will perform a 100% leak test before the initial distribution of each LEMI and ICSI device.
- 15. Page 127 of the application states that a “final acceptance inspection must be performed by someone other than the person who performed the work being inspected.” Please describe or provide procedures detailing the final acceptance inspection. Please confirm that these tests include full design conformity in accordance with the statements and commitments submitted in the ACS application.