



ADVANCED COMBAT SOLUTIONS

August 10, 2016

Shirley S. Xu
Materials Safety Licensing Branch
Division of Material Safety, State, Tribal and Rulemaking Programs
Office of Nuclear Material Safety and Safeguards
Nuclear Regulatory Commission
Washington, D.C. 20555-0001

RE: Reply to Letter Dated July 20, 2016
Request for Additional Information
Application for Sealed Source and Device Registration Certificate and
Application for Distribution of Exempt Products License
Docket No. 030-38926
Mail Control No. 591166

Dear Sirs,
Enclosed is our response to your letter dated July 20, 2016. For your convenience we have listed your questions with our answers.
If you have any questions, please reach out to me at yelena@advancedcombatsolutions.com or 888.227.1993 ext. 3.

Sincerely,

Yelena Sivaya
Advanced Combat Solutions Inc.
Finance and Regulatory Compliance Officer

ENCLOSURE

Request for Additional Information Regarding Exempt Distribution License

Q#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 materials are possessed. Please submit a copy of your current Florida license that reflects material use authorization information.

A: Please see Attachment 1

Q#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.

A: The measurements are for the products (LEMI and ICSI). The geiger counter was positioned in the nearest proximity to the products, namely where the lamps (GTLs) are installed into the products, with the purpose of measuring maximum external radiation.

Request for Additional Information Regarding Sealed Source and Device Registration Certificate

General

Q#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 6mCi 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.

A: We apologize for confusion. Enclosure C is where correct information is listed: maximum activity per source 6mCi for a device in the LEMI Series and 1.10 mCi for the ICSI device. Form 313 has an outdated activity.

It is possible that one ICSI and one LEMI are both used together (however this is possible only for a Glock firearm). In this case max activity per Glock firearm would be=max activity of one LEMI+max activity of one ICSI= 6+1.1=7.1mCi.

Q#2 Part 1: 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.

A: That is correct. The LEMI provides utility by use in either of the abovementioned weapon-systems, however, in similar as well as slightly different ways (see Answer to Q#2 Part II).

Q#2 Part II: 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.

A: The answer is two parts:

1) The Glock magazines come in various lengths, just like M16/AR15 magazines. Therefore, the same logic applies to the Glock magazines. If the Glock magazine is of a short length (for comparison purposes only let's say 15 rounds, it simply will all be encompassed within the grip of the Glock handgun and not show. However, if of the "extended length" variety (for example purposes let's say 33 rounds), then the LEMI will provide utility to the operator in the same fashion as the M16/AR15 LEMI.

2) Another point to take into consideration pertaining to the LEMI for the Glock handgun: the use of the LEMI in a Glock handgun is primarily intended to be used before it is inserted into the grip of the handgun. The utility derived by use of the LEMI in the Glock handgun is to be fully realized at the time of initial weapon's load, (to insure in low-light or zero-light condition that the magazine the operator is loading into the handgun is in fact a fully loaded one, or at the very least what is the approx. remaining ammunition left in the magazine), or during a magazine change whereby an operator is uninstalling from the handgun a magazine which is not fully depleted, in which case the LEMI provides much needed information in a low-light or zero-light condition as to the approx. round count remaining.

Q#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.

A: Please see below Pic. 1.

Q#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.

A: please kindly see the tables in Attachment 2 (LEMIGLK Series) and Attachment 3 (LEMIM16AR15 Series) that provide min and max dimensions. Method of the installation and location of the source is the same for every model. What differs for every model is the type of the source (the source types are presented in Enclosure C to the Application).

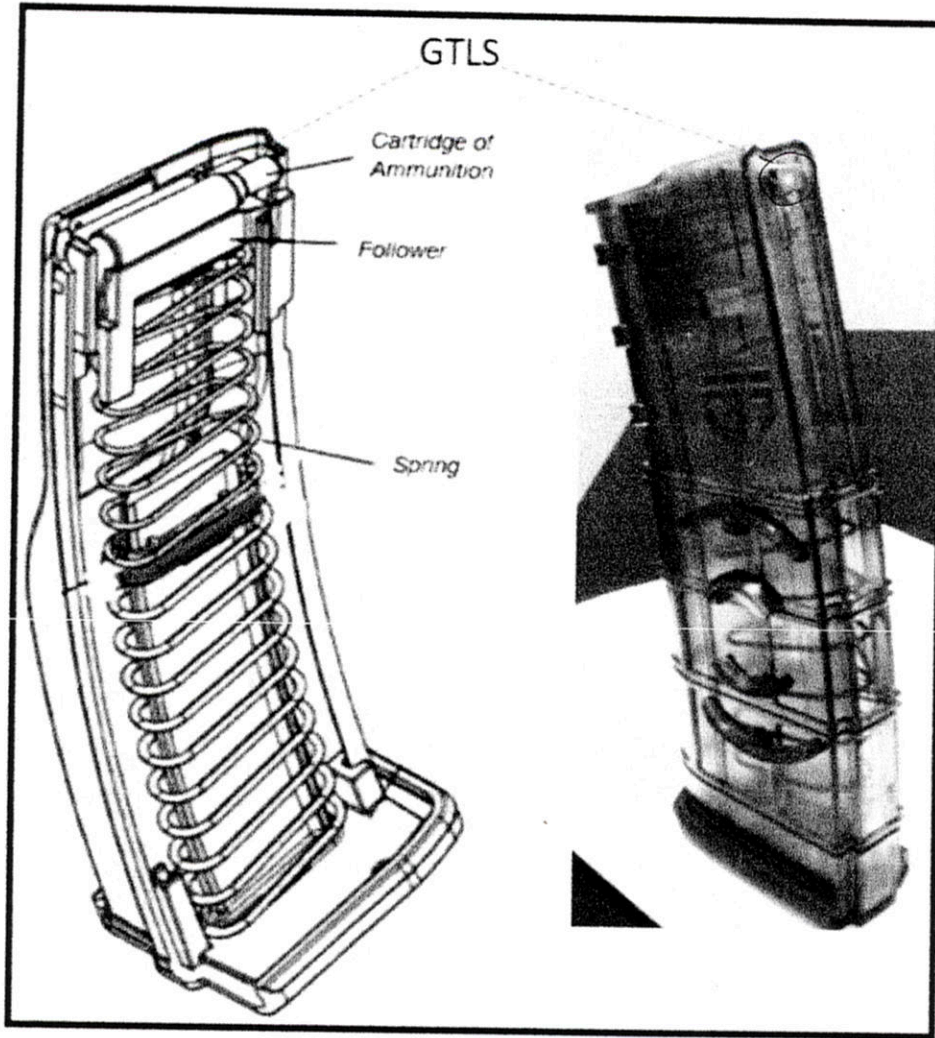
Q#5: Please provide drawings that include the overall dimensions, i.e. length, width, and height of the LEMI Series for the Glock and M16AR15 configurations and the ICSI device.

A: Please see Attachment 2 – 3 for LEMI Series and Attachment 4 for ICSI Series.

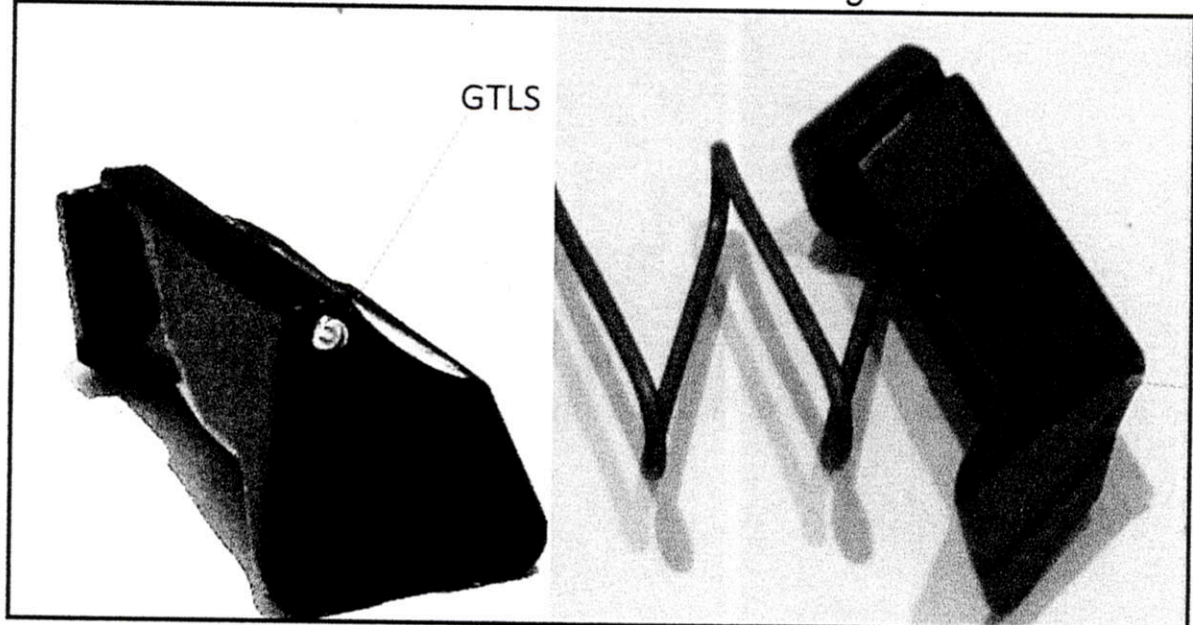
Q#6: Please provide a picture of the LEMI model that will be used for Glock handguns similar to "Pic. 2" provided on page 6 of the ACS application.

A: Please see below Pic.2

Pic. 1. M16AR15 magazine and location of GTLS



Pic. 2. LEMI Model to be used for Glock handguns



Q#7: Please indicate if there is a potential for corrosion between unlike materials such as steel and aluminum how it will be prevented.

A:

ICSI:

The potential for rust forming on the ICSI and the slide of the weapon-system and subsequent corrosion is negligible since the ICSI comes from the ACS factory coated in an anti-rust coating of MIL-SPEC zinc phosphate.

The slide of the weapon-system is coated by the Glock factory in much the same coating, or an alternative rust protection coating that even further exceeds the rust prevention capabilities of the ICSI's zinc phosphate.

Lastly, it is important to note the ICSI and Glock factory slide are made of the Same material, 4140 steel.

Therefore, they are not dissimilar materials.

Please also note that for ICSI we do not use aluminum-sleeved GTLSs (please see Enclosure C to the Application).

LEMI:

No. There is zero chance of corrosion that would affect either the LEMI assembly, or the magazine body by which the LEMI is contained and operates within.

All components of the overall magazine assembly are some form of plastic, with the exception of the spring. However, although the magazine spring and LEMI assembly make contact inside of the magazine body, the LEMI assembly is made from an acetyl-copolymer and incapable of rusting.

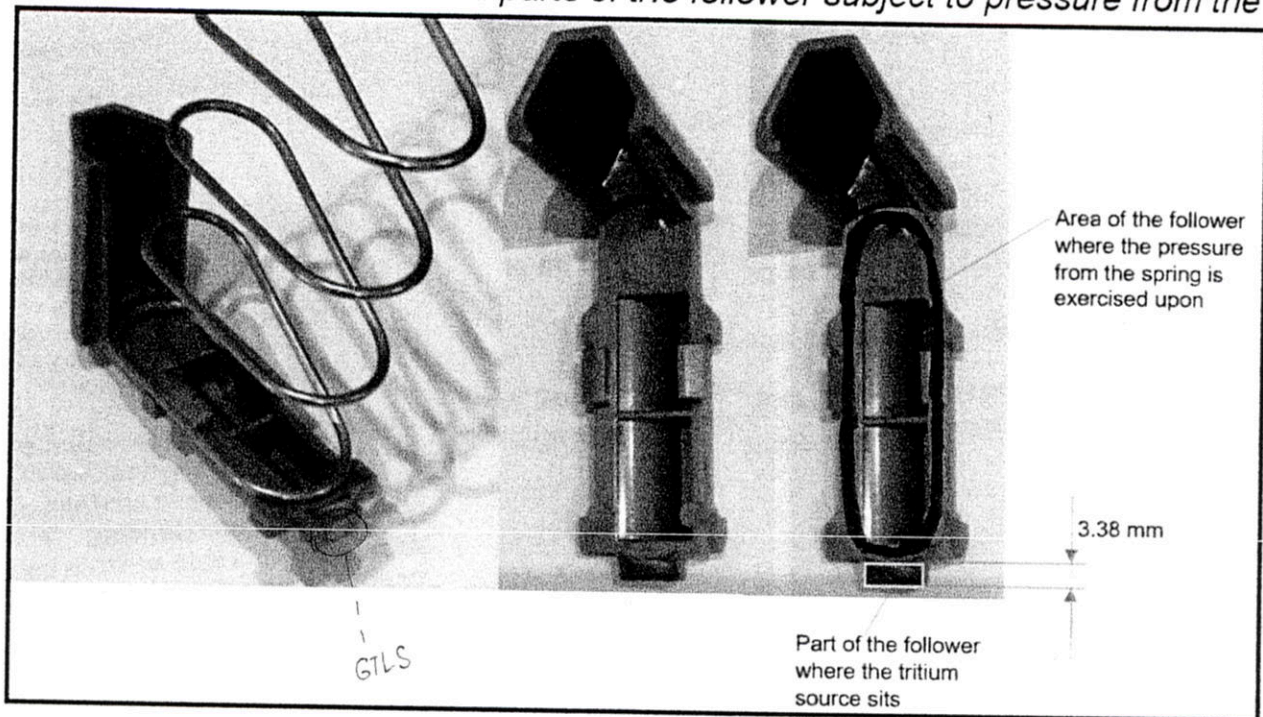
The spring and GTLS (that might be wrapped in an aluminum sleeve) never come into contact.

Prototype Testing

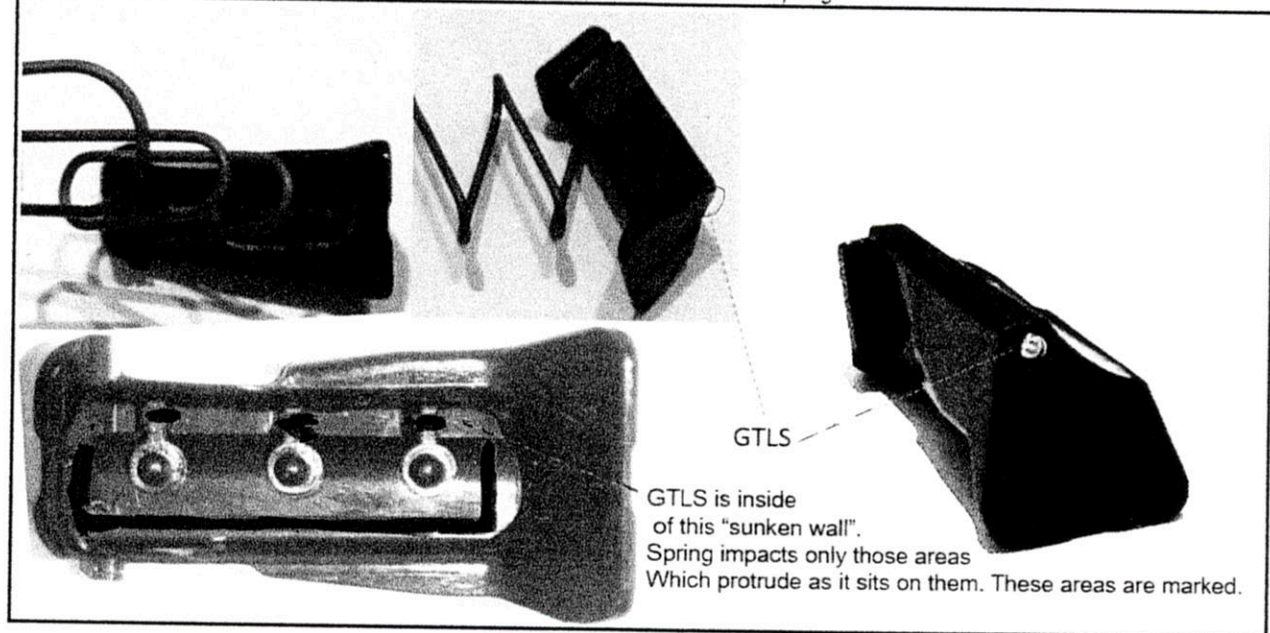
Q#8: The LEMI Series devices will be attached to a spring in a semi-permanent manner and will provide opposite force against the weight of the ammunition being forced up and out of the magazine body. Please explain how the prototype testing performed on the LEMI Series demonstrate that the device will 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.

A: Opposite force coming from the spring pressing the follower against ammunition is applied at its maximum to the area of the follower marked below (Pic. 4 – Pic. 5).

Pic.4. M16AR15 Follower and parts of the follower subject to pressure from the spring

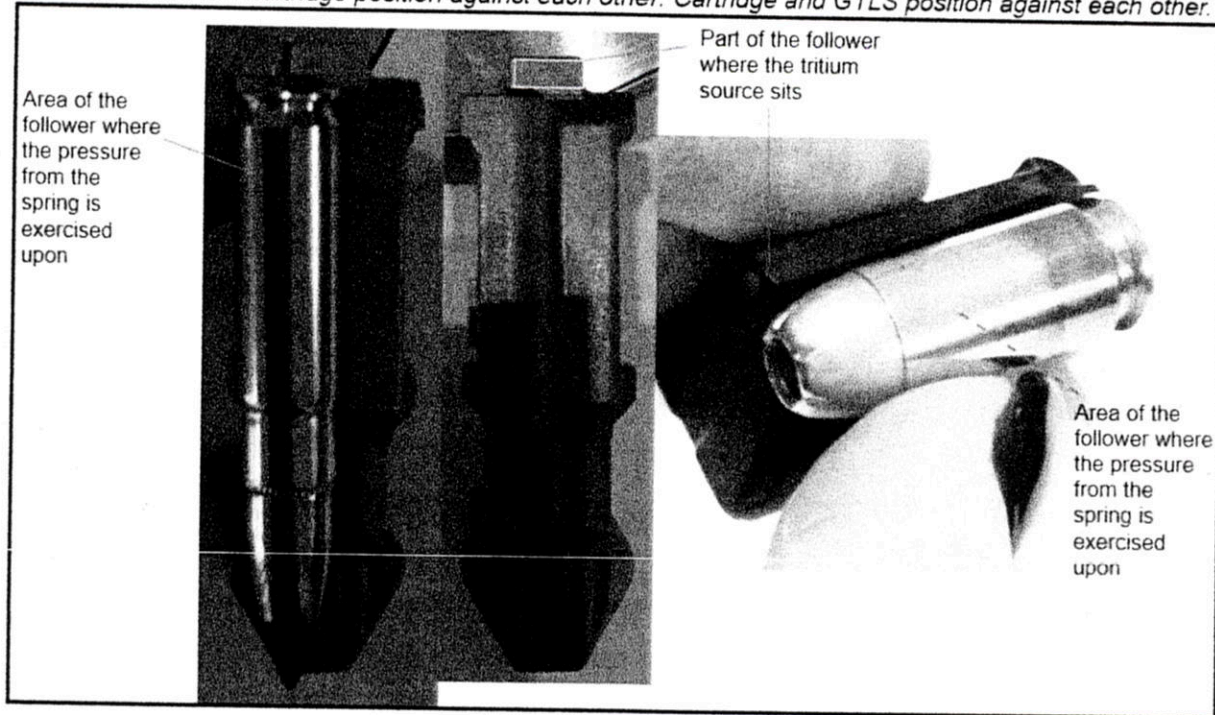


Pic.5. Glock follower and parts of the follower subject to pressure from the spring



Pics. 4 - 5 above prove that the tritium source is not under direct compression and impact effects from the spring.

Pic. 6. Follower and cartridge position against each other. Cartridge and GTLS position against each other.



Pic. 6 provides graphic representation of which area of the follower is subject to pressure coming from the weight of the ammunition. Again, the part of the follower where the tritium source sits is not subject to the direct effect from compression and impact.

Maximum pressure exercised by a brand new spring in its fully compressed position against any surface (in our case, the follower followed by a stack of cartridges) is on the area of contact with the follower (marked on Pics.4-5), and is approx.20 psi for M16AR15 magazine spring (and circa 12 psi for Glock magazine spring) (measured with the scale "Mini crane scale. Model: OCS-L). It is important to note that the spring's energy potential decreases over time and is inversely proportional to its increased use. Therefore, with continual use the spring's ability to exert opposing force against the captive weight of cartridges contained within the magazine body lessens over time.

For prototype testing of the extended pressure coming from spring compression the follower (5 M15AR16 followers and 5 GLK followers in total) was subjected to a much higher pressure: weight bar of 80 psi was placed onto each follower for the period of 21 days. After it the follower and tritium source were examined for their integrity. By visual inspection no damage was observed. The follower was subjected to immersion test afterwards (After the test the device is to be immersed in water for 24 hours at ambient temperature. The volume of the water is to be about equal to 10 times that of the volume of the device. After the device is removed, the activity of the solution is to be measured. The activity of the solution is to be less than or equal 50 nanocuries.) and the result of immersion test indicated that the activity of the solution is less than 50 nanocuries. Labelling maintained legible. No luminosity loss observed during and after test.

Maximum impact that a follower (M16AR15 and Glock types) might be subjected to as a result of a cartridge discharge is 0.5 psi (measured with the scale "Mini crane scale. Model: OCS-L). Again, as with the pressure from the compression, the impact effect affects the parts of the follower where the spring and cartridges touch the follower and not where the GTLS is installed. Hence, the effect of discharge impact on the area where GTLS is located is much lesser and the integrity of the device after impact was successfully tested as a part of initial prototype tests (Enclosure E, Penetration Test).

Conclusion:

Since

- a) the followers, made of acetal copolymer, were able to withstand pressure equal to 80 psi during extended period of time (21 days) and
 - b) the real day-to-day pressure at its maximum that the follower is going to experience during its useful life (12 years) is much less (20psi at its max) and
 - c) this much lesser pressure (20psi) is exercised onto the area of the follower different from where the GTLS is installed and
 - d) the history of use of the acetal copolymers shows no complaints regarding deformation of the followers during their use and
 - e) mechanical properties of acetal copolymers are such that they are able to withstand 2,760 -16,000 psi (compressive strength, 73°F*) as well as impact of much more than 0.5 psi*
- we may conclude the LEMI is able to maintain its integrity as a result of compression and impact forces that it will experience during useful life (normal and accidental conditions of use).

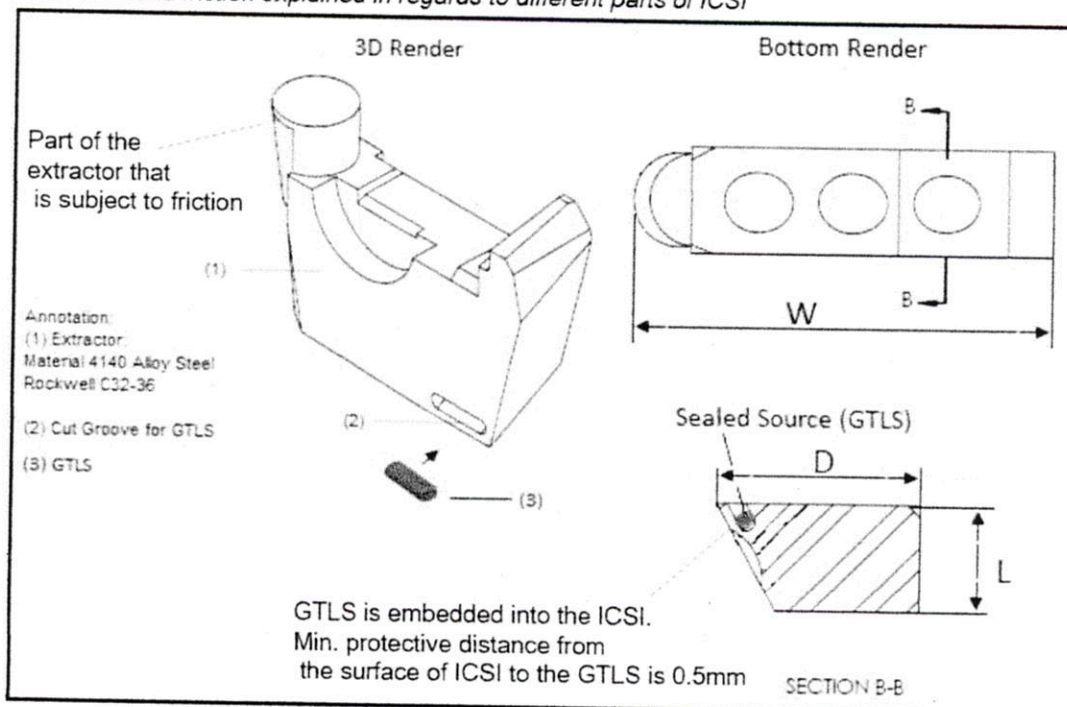
*<https://plastics.ulprospector.com/generics/2/c/t/acetal-properties-processing>

Q#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.

A: The ICSI extractor may visually appear to be a component within the firearm that is under constant frictional forces. However, this is true only to a small part of the ICSI: the area of the ICSI extractor that undergoes any friction is the pivot-arm looking part of the ICSI extractor assembly. It is easily recognizable in the drawings as it has a conical shape. Furthermore, the area in which the tritium lamp is located in the ICSI assembly is at the diagonally opposite end, so at the furthest distance from where the source of friction is occurring. Moreover, the tritium source is located below the surface and embedded into the ICSI extractor which then literally encapsulates and protects it from any direct contact, including any friction. Due to the design and materials used in the construction of the ICSI, the tritium source will persist in a condition that is fully removed from any friction or direct contact of any kind while in use for the full life of the weapon.

Please also see Pic.3 for a visual representation of what is explained above.

Pic.3. ICSI and friction explained in regards to different parts of ICSI



Labeling

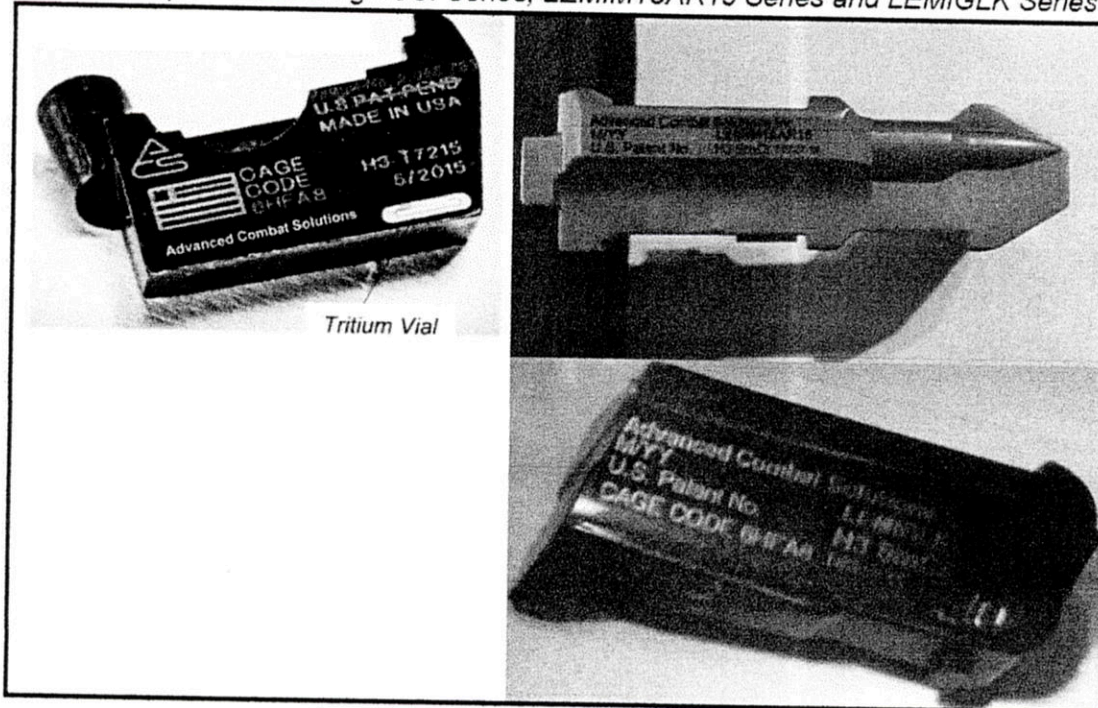
Q#10: Page 9 of the ACS application includes examples of the information that will appear on the LEMI and ICSI labels. Please note that the company logo may not be sufficient to meet the requirements for labeling as described in 10 CFR 32.22 as an identification of the manufacturer. In order for a logo 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 of the Exempt Distribution License number that will be issued by the NRC.

A: Thank you. Well noted. We will laser etch the complete name of the company then ("Advanced Combat Solutions" as in the Pic. 7 below).

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

A: Please see the Pic. 7 below.

Pic.7. Examples of Labeling: ICSI Series, LEMIM16AR15 Series and LEMIGLK Series



Drawings

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

A: Please see Attachments 2-3.

Quality Assurance

Q#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 licenses 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.

A: The corrected definition is: "ACS' Point of Contact with NRC - the person identified by the licensee as being responsible for ensuring compliance with NRC regulations".

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.

A: The corrected definition is: "Specifications - requirements imposed by Advanced Combat Solutions Inc., customer, and the requirements stipulated by appropriate regulatory acts and legislation as well as by the commitments made to the NRC, that if not followed, may affect the use or operation of the device".

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

Please resubmit the corrected pages of the Quality Assurance Program.

A: Please see Attachment 5.

Q#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 "before 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.

A: We apologize for confusion. 100% leak test commitment refers to the test of tritium sources and is performed by the tritium supplier (MB-Microtec, soaking test as per ANSI N540, section 8.3.2.) before selling the tritium source to ACS.

ACS intends to subject at least 1% of the devices (LEMI and ICSI) to an operational check for illumination and fit, as well as wipe test. Any failure will trigger 100% inspection of the lot for the defect.

Q#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.

A: Final acceptance inspection is performed by the CEO and includes the following:

- 1. All finished devices are subjected to**
 - a 100% visual inspection for missing, dislodged or dim light sources;
 - a visual inspection of the labelling (to make sure ACS's name and H3 on each device);
- 2. In addition, a random sample (at least 1% of the devices) is subjected to**
 - the drop (impact) test from 3.27 feet (1m) to a steel plate,
 - then a visual inspection for missing, dislodged, damaged or dim light black sources and

- the leak test.

The leak test involves the following: the device is to be immersed in water for 24 hours at ambient temperature. The volume of the water is to be about equal to 10 times that of the volume of the device. After the device is removed, the activity of the solution is to be measured. The activity of the solution is to be less than or equal 50 nanocuries.)

Any failure will trigger a 100% inspection of the lot for the defect.

ACS confirms that full design conformity and compliance with the statements and commitments submitted in the ACS application is checked during the final acceptance inspection.

Mission:

To protect, promote & improve the health of all people in Florida through integrated state, county & community efforts.



Rick Scott
Governor

Celeste Philip, MD, MPH
Interim State Surgeon General

Vision: To be the Healthiest State in the Nation

May 13, 2016

Yelena Sivaya, Finance and Regulatory Compliance Officer
ADVANCED COMBAT SOLUTIONS, INC.
333 Las Olas Way, CU#1
Fort Lauderdale, FL 33301

Dear Ms. Sivaya:

Re: State of Florida Radioactive Materials License Number 4520-1

Enclosed is State of Florida Radioactive Material License Number 4520-1, along with your invoice for the annual and reclamation fees, which are due within 60 days of the issuance date on the license. This action closes control number 20160329-0612.

Please review the enclosed license carefully and be sure that you understand its terms and conditions. You are responsible for verifying the accuracy of the license and to notify us immediately if you find anything you consider to be in error. Below are some of the requirements that you are responsible for as the holder of a radioactive materials license.

- Conduct your program involving radioactive materials in accordance with the conditions of your Florida license, representations made in your license application, and Florida regulations "Florida Control of Radiation Hazards," Chapter 64E-5, *Florida Administrative Code* (F.A.C.)
- Post "Notice to Employees 3/01" and other documents in accordance with Section 64E-5.901, F.A.C.
- Possess radioactive material only in the quantity and form indicated in your license and use radioactive materials only for the purposes indicated in your license.
- Notify this bureau in writing of any change in mailing address.
- Notify this bureau in writing immediately if there is a change in ownership or controlling interest in the organization or if the legal entity listed in item 1 of the license changes.
- Request and obtain an appropriate amendment prior to a change in location of radioactive material, or any other changes in your facility or program which are contrary to your license conditions or representations made in your license application and any subsequent correspondence with this bureau.
- Submit a complete renewal application or termination request at least 30 days before the expiration date on your license. Possession of radioactive material after your license expires is a violation of Florida regulations.
- Request termination of your license if you plan to permanently discontinue activities involving radioactive material prior to your expiration date.

Florida Department of Health
Division of Emergency Preparedness and Community Support •
Bureau of Radiation Control • Radioactive Materials Section
4052 Bald Cypress Way, Bin C-21 • Tallahassee, FL 32399-1741
PHONE: 850/245-4545 • FAX 850/921-6364

www.FloridaHealth.gov
TWITTER: HealthyFLA
FACEBOOK: FLDepartmentofHealth
YOUTUBE: fldoh
FLICKR: HealthyFla
PINTEREST: HealthyFla

STATE OF FLORIDA
DEPARTMENT OF HEALTH
BUREAU OF RADIATION CONTROL

RADIOACTIVE MATERIALS LICENSE

Pursuant to Chapter 404, Florida Statutes, and Chapter 64E-5, Florida Administrative Code (F.A.C.), and in reliance on statements and representations heretofore made by the licensee designated below, a license is hereby issued authorizing such licensee to receive, acquire, possess and transfer the radioactive material(s) designated below and to use such radioactive material(s) for the purpose(s) and at the place(s) designated below. This license is subject to all applicable rules, regulations and orders of the state of Florida, Department of Health now or hereafter in effect and to any conditions specified below.

<p style="text-align: center;">Licensee</p> <p>1. Name: ADVANCED COMBAT SOLUTIONS, INC.</p>	<p>3. License Number: 4520-1</p> <p>is hereby issued with reference to application dated March 22, 2016, and April 21, 2016.</p>
<p>2. Address: 333 Las Olas Way, CU#1 Fort Lauderdale, FL 33301</p>	<p>4. Expiration Date: 5/31/2021</p> <p>5. Category: 3L(V)</p>

6. Radioactive Material (element and mass number)	7. Chemical And/Or Physical Form	8. Maximum Quantity Licensee May Possess At Any One Time
A. Hydrogen 3	A. Sealed source (mb-microtec ag Model 400/1)	A. 50 sources; not to exceed 1.1 millicuries each
B. Hydrogen 3	B. Sealed source (mb-microtec ag Model 400/1)	B. 100 sources; not to exceed 6 millicuries each
C. Hydrogen 3	C. Sealed source (mb-microtec ag Model 400/1)	C. 100 sources; not to exceed 1.4 millicuries each

- 9. Authorized Use**
- A. To be used as a gaseous tritium light source designated as Advanced Combat Solutions, Inc., Model T7215-1/I in an Advanced Combat Solutions, Inc., Model ICSI4140GLK40LEMIL, Illuminated Chamber Status Indicator (ICSI) source holder, for assembly onto a firearm shell extractor.
 - B. To be used as gaseous tritium light sources designated as Advanced Combat Solutions, Inc., Models T8327-1/I and T8327-2/I in Advanced Combat Solutions, Inc., Models LEMIM16AR158327-1/I, LEMIM16AR168327-2/I, LEMIGLK8327-1/I, and LEMIGLK8327-2/I Light Emitting Magazine Indicator (LEMI), source holders, for assembly into a firearm magazine.

STATE OF FLORIDA
DEPARTMENT OF HEALTH
BUREAU OF RADIATION CONTROL

9. Authorized Use Continued:

- C. To be used as a gaseous tritium light source designated as Advanced Combat Solutions, Inc., Models T8328-1/I and T8328-2/1 in Advanced Combat Solutions, Inc., Models LEMIM16AR158328-1/I, LEMIM16AR168328-2/I, LEMIGLK8328-1/I, and LEMIGLK8328-2/I Light Emitting Magazine Indicator (LEMI), source holders, for assembly into a firearm magazine.

CONDITIONS

10. The authorized place of use is the licensee's facility located at 13290 West State Road 84, Davie, Florida 33325.
11. Failure to comply with the provisions of this license is a felony of the third degree pursuant to section 404.161, Florida Statutes. Also, violations may warrant an administrative fine of up to \$1,000.00 per violation per day, pursuant to section 404.162, Florida Statutes.
12. A. Licensed materials shall be used by, or under the supervision of Gavin Palmer.
B. The radiation safety officer is Michael Ball.
13. The licensee shall comply with the provisions of Chapter 64E-5, F.A.C., Part IX, "Notices, Instructions and Reports to Workers; Inspections" and Part III, "Standards for Protection Against Radiation."
14. The licensee shall not transfer possession or control of radioactive material, or products containing radioactive material as a contaminant except:
A. By transfer to a specifically licensed recipient; or
B. As provided otherwise by specific provision of this license pursuant to the requirements of Chapter 64E-5, F.A.C.
15. Radioactive material transported on public thoroughfares shall be packaged, prepared for shipment and transported in accordance with Title 49, Code of Federal Regulations and Chapter 64E-5, F.A.C.
16. This license does not authorize the distribution of radioactive material to the public.

License Number: 4520-1
Amendment No.: 0
Control Number: 20160329-0612

HQ COPY

Page 2 of 3 Page(s)

Category: [3L(V)]

Expiration Date: 5/31/2021

STATE OF FLORIDA
DEPARTMENT OF HEALTH
BUREAU OF RADIATION CONTROL

17. The licensee shall conduct a physical inventory and inspection at least every 6 months to account for all sealed sources received and possessed under this license as required by section 64E-5.1304, F.A.C. Inventory records shall be maintained for 3 years from the date of the inventory for inspection by the department, and shall include the manufacturer's name, model and serial numbers of each sealed source, the identity of each sealed source radionuclide and its estimated activity, the location of each sealed source, the date of the inventory and the signature of the radiation safety officer or designee.
18. The licensee shall notify the Bureau of Radiation Control at least 48 hours in advance of shipping its low-level radioactive waste to a commercial treatment, storage or disposal facility. Notification shall consist of either calling (407) 297-2095 or writing the Bureau of Radiation Control, Department of Health, Post Office Box 680069, Orlando, Florida 32868-0069.
19. A. Except as specifically provided otherwise by this license, the licensee shall possess and use licensed material described in Items 6, 7, 8 and 9 of this license in accordance with statements, representations and procedures contained in the licensee's application dated March 22, 2016, signed by Yelena Sivaya, Finance and Regulatory Compliance Officer (made certifying official by Michael Ball, Director), and correspondence dated: April 21, 2016 (inventory, various commitments, and parts diagram), also signed by Yelena Sivaya, Finance and Regulatory Compliance Officer
- B. The licensee shall comply with all applicable requirements of Chapter 64E-5, Florida Administrative Code, and these regulations shall supersede the licensee's statements in applications or correspondence, unless the statements are more restrictive than the regulations.

For the Bureau of Radiation Control:

ORIGINAL SIGNED BY:
JOY STEPHENSON

Issuance Date: MAY 13 2016

Joy Stephenson
Environmental Specialist III
4052 Bald Cypress Way – Bin C21
Tallahassee, FL 32399-1741
(850) 245-4545

A party whose substantial interest is affected by this order may petition for an administrative hearing pursuant to sections 120.569 and 120.57, Florida Statutes. Such proceedings are governed by Rule 28-106, Florida Administrative Code. A petition for administrative hearing must be in writing and must be received by the Agency Clerk for the Department, within twenty-one (21) days from the receipt of this order. The address of the Agency Clerk is: Agency Clerk, 4052 Bald Cypress Way, BIN # A02, Tallahassee, Florida 32399-1703. The Agency Clerk's facsimile number is 850-410-1448. A copy of the petition should also be sent to Bureau Chief, Bureau of Radiation Control, 4052 Bald Cypress Way, BIN # C21, Tallahassee, FL 32399-1741. The Bureau Chief's facsimile number is 850-487-0435. Mediation is not available as an alternative remedy. Your failure to submit a petition for hearing within 21 days from receipt of this order will constitute a waiver of your right to an administrative hearing, and this order shall become a "final order." Should this order become a final order, a party who is adversely affected by it is entitled to judicial review pursuant to Section 120.68, Florida Statutes. Review proceedings are governed by the Florida Rules of Appellate Procedure. Such proceedings may be commenced by filing one copy of a Notice of Appeal with the Agency Clerk of the Department of Health and a second copy, accompanied by the filing fees required by law, with the Court of Appeal in the appropriate District Court. The notice must be filed within 30 days of rendition of the final order.

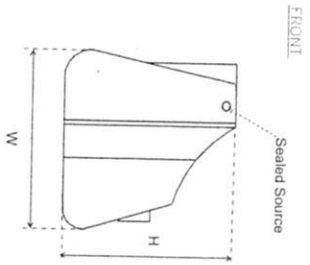
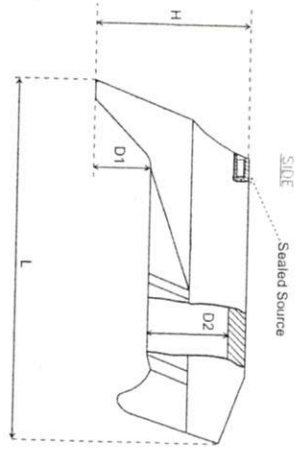
License Number: 4520-1
Amendment No.: 0
Control Number: 20160329-0612

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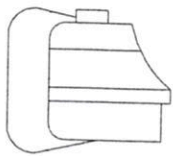
Page 3 of 3 Page(s)

Category: [3L(V)]

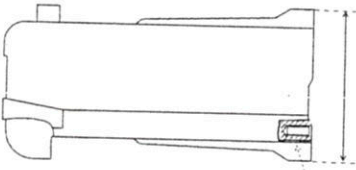
Expiration Date: 5/31/2021



REAR



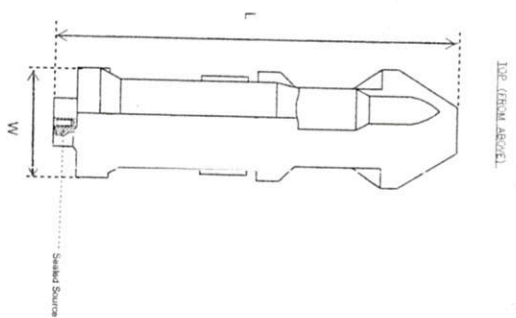
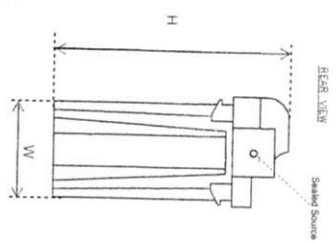
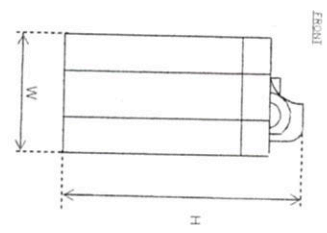
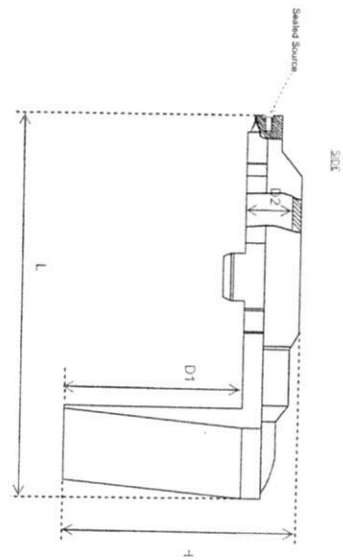
TOP RENDER



Dimensions are in mm	Version 1.0	LEMGLK	
Tolerances:		Date: 1 Aug 2016	Drawing # ACS-0011
Fractions: +/- 1/32		Sheet: 1 of 1	
.xx +/- 0.05		Title	Comprehensive View
.xxx +/- 0.005			Render
Angles: +/- 1 Deg.			

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Type LEMGLK			
	Min	Max	Nominal
L, mm	33	40	35.0
W, mm	16	20	17.3
H, mm	15	20	16.7
D1, mm	5.9	9	6.9
D2, mm	5.4	8.4	6.4



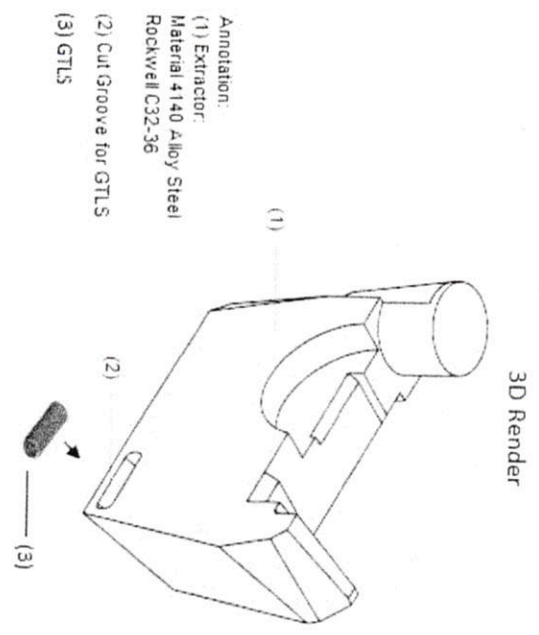
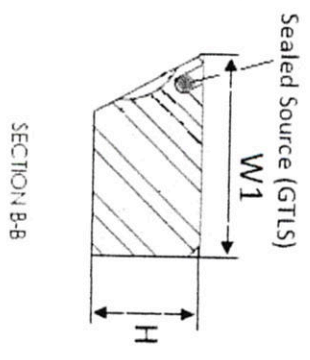
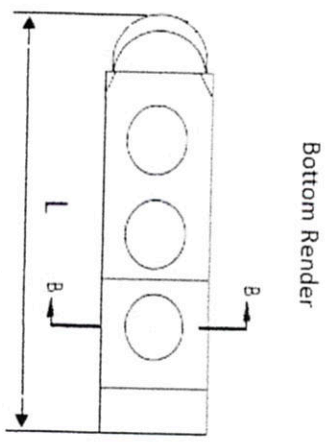
Dimensions are in mm
 Tolerances:
 Fractions: +/- 1/32
 xx +/- 0.05
 xxx +/- 0.005
 Angles: +/- 1 Deg.

Version 1.0 LEMIM16AR15 Series
 Date: 1 Aug 2016 Drawing #: ACS-00010
 Sheet: 1 of 1
 Title Comprehensive View Render

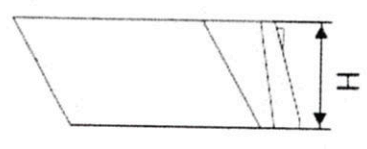
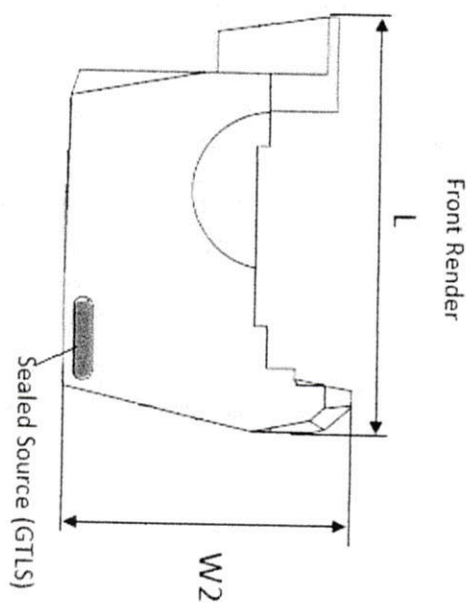
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Type LEMIM15AR16			
	Min	Max	Nominal
L, mm	53	65	58.0
W, mm	14.9	19	15.9
H, mm	32.7	39.7	34.7
D1, mm	25	28	26.0
D2, mm	5	8	6.0

Dimensions are in inches
 Tolerances:
 Fractions +/- 1/32
 .xx +/- 0.05
 .xxx +/- 0.005
 Angles +/- 1 Deg.



Annotation:
 (1) Extractor
 Material 4140 Alloy Steel
 Rockwell C32-36
 (2) Cut Groove for GTLS
 (3) GTLS



Type ICSI Series			
	Min	Max	Nominal
L, inches	0.2	0.9	0.7
W1, inches	0.2	0.5	0.3
W2, inches	0.1	0.5	0.4
H, inches	0.1	0.4	0.2

MATERIAL: 4140 ALLOY STEEL
 HARDNESS: ROCKWELL C32-36
 The information contained in this drawing is the clear sole property of Advanced Combat Solutions Inc. Any reproduction in part or as a whole without the written permission of Advanced Combat Solutions Inc. is prohibited.

Version 1.0	ICSI4140GLK40LEMIL	DATE	Aug 2 2016	SCALE	3:1
		DESIGNED BY	ACS-0002	DRAWN BY	5-REV 1

Attachment 5



ADVANCED COMBAT SOLUTIONS

Quality Assurance Program

April 2016

Revision 2.0

Master Copy

Approvals:

<u>CEO</u>	<u>Aug 10 2016</u>	_____	_____
Title	Date	Title	Date
<u>Fin & Reg. Compliance Officer</u>	<u>Aug 10 2016</u>	_____	_____
Title	Date	Title	Date
_____	_____	_____	_____
Title	Date	Title	Date
_____	_____	_____	_____
Title	Date	Title	Date
_____	_____	_____	_____
Title	Date	Title	Date

Rev	Description of Changes	Release
1	Initial Release	4/4/2016
2	Corrected definitions and NRC contact information	10 Aug 2016

Description of changes Since Last Revision:

1. Corrected definition of "NRC Contact" (changed into "ACS' Point of Contact with NRC")
2. Corrected definition of "Specifications"
3. NRC contact information changed to a more general contact list

Revision 2.0

Initial release

Definitions

ACS' Point of Contact with NRC - the person identified by the licensee as being responsible for ensuring compliance with NRC regulations.

Assembly Manager - a person who performs assembly and inspection of products (devices).

Deviation - a departure from the specifications for a device, or a departure from the information supplied to NRC pertaining to the device.

Device - a product to be registered in accordance with 10 CFR 32.210, that is manufactured and distributed by Advanced Combat Solutions Inc.

Document - any drawing, procedure, instruction, or record pertaining to the production of the device.

Material - any item that is raw material, subassembly, or a component used in the production of the device.

Operational Check - a test or set of tests performed on a completed device to ensure that the device operates in its intended manner and to its intended specifications. This includes verification of device safety features.

Production - the process of assembling or fabricating a device or any part of a device. Production includes all operations associated with a device or any part of a device from the time it is received from a supplier until it is distributed to the customer.

QA Director - person in upper management who does not have direct responsibility for production of a device but is responsible for ensuring that the QA program is established and maintained.

QA Manager - person responsible for ensuring that an appropriate QA program is running properly and verifying that the activities affecting device quality have been correctly performed.

QA Program - planned and systematic actions necessary to provide confidence that a firm or product will meet the required specifications. The program must provide a means to control and measure characteristics of an item, process, or facility to the established requirements of the program.

Quality Control - actions taken to prevent or detect product deficiencies.

Radiation Safety Officer - person designated for maintaining the radiation safety program. The radiation safety program is conducted according to the radiation safety manual, which is a separate document from the QA program. The radiation safety officer may be an Advanced Combat Solutions Inc. employee or a consultant.

Sample - one or more units of product drawn from a lot or batch, the units of the sample being drawn without regard to their quality.

Sample Size - the number of units of product in the sample selected for inspection.

Service - any operation pertaining to production of the device or operation performed on any part of the device.

Supply Chain Manager - person designated for shipping and or receiving packages.

Specifications - requirements imposed by Advanced Combat Solutions Inc., customer, and the requirements stipulated by appropriate regulatory acts and legislation as well as by the commitments made to the NRC, that if not followed, may affect the use or operation of the device.

Supplier - any person, persons, or company that supplies material, equipment, or service to Advanced Combat Solutions Inc.

1. ORGANIZATION

This is the quality assurance program for Advanced Combat Solutions Inc. for the purpose of assembling products (devices). This QA program has been developed in order to comply with the QA requirements for products containing radioactive material as specified in Appendix G of US NRC Regulatory Guide NUREG 1556, Vol 3. The structure of this QA manual is based on the suggested format of NRC Regulatory Guide 6.9, Revision 0.

The organizational structure, functional responsibilities, and levels of authority are documented in this manual, starting with the Chief Executive Officer down to each employee position. Tasks shall be designated by position and not by individual employee. For example, the duties of an Assembly Manager shall be spelled out as opposed to duties of an individual person identified by Name and Last Name.

The radioactive materials possession and manufacturing license (Radioactive Material License) is to be issued by the Florida Department of Health, Bureau of Radiation Control. The exempt device registration and distribution license shall be issued by the US NRC.

Contact information for the state of Florida:

FL Bureau Of Radiation Control
Division of Emergency Preparedness and Community Support
4052 Bald Cypress Way, Bin C21
Tallahassee, FL 32399-1741
Phone 850-245-4545 FAX 850-921-6364

Contact information for US NRC:

Mailing Address - U.S. Nuclear Regulatory Commission
Washington, DC 20555-0001
1-800-368-5642, 301-415-7000
TTD: 301-415-5575
24-Hour Ops Ctr for Emergencies 301-816-5100
NRC Waste, Fraud or Abuse 1-800-233-3497 (OIG hotline)
Safety or Security Concern - 1-800-695-7403
General Help or Information - 301-415-8200, Fax: 301-415-3716

At Advanced Combat Solutions Inc. the QA Manager and QA Director positions are combined since the Company is a small business. The QA Director/QA Manager is continually involved in ensuring that the QA program is properly implemented. The QA Manager/Director has the authority to access to work areas, and the organizational freedom to identify quality problems, recommend or initiate solutions, verify implementation of solutions, and halt production at any time to ensure that the device or production procedures conform to all regulations and specifications. The QA Director/QA Manager is empowered to issue a halt order.

The organizational structure is documented in the form of an organizational chart, with a brief explanation of each key position and the responsibilities associated with the position. Position titles are used in the organizational chart in lieu of the names of the persons occupying the positions. A separate list shall be maintained as to who occupies these positions, including the date of hire. There are currently 6 employees.

Appendix A- Organizational chart

Appendix B- List of Advanced Combat Solutions Inc. personnel

The following positions are recognized:

- CEO, QA Manager/QA Director/ RSO