AMERIGLO

August 11, 2016

Tomas Herrera
SSD Team Leader
U.S. NRC
NMSS/MSTR/MSLB
301-415-7138

U.S. Nuclear Regulatory Commission
Office of Nuclear Material Safety and Safeguards
Division of Material Safety, State, Tribal, and Rulemaking Programs
Materials Safety Licensing Branch
Mail Stop T-8E18
Two White Flint North
11545 Rockville Pike
Rockville, MD 20852-2738

Dear Sir:

Isolite Corporation has agreed to transfer ownership of SSD NR-1286-D-102-E to Ameriglo, LLC (see attached Isolite letter). The information requested by NUREG-1556 Volume 3, Rev. 2 (reprinted in **bold**) is provided below:

The facility's name and location where the products will be manufactured and distributed:

Ameriglo, LLC
645 Hembree Parkway, Suite K
Atlanta, Ga. 30076

In the SSD, the distributor should be changed from Isolite Corporation to AmeriGlo, LLC, 645 Hembree Parkway, Atlanta, Ga. 30076 and the manufacturer should be changed from Shield Source Incorporated to AmeriGlo, LLC, 645 Hembree Parkway, Atlanta, Ga. 30076.

Specify the serial number of the last unit that was distributed by the old company before the name or address change, and the number of completed units that were transferred by the old company to be distributed by the new company:

The Isolite and AmeriGlo gun sights are not serialized. No devices will be transferred to AmeriGlo from Isolite at the time the SSDR is transferred and AmeriGlo's E-license is granted.

Provide change of ownership information discussing:

Transfer of products: There will be no transfer of finished products. The products are manufactured to specific customer orders. No unsold inventory is present at Isolite.

Records custody: Copies of all prior Isolite distribution records will provided to AmeriGlo who will maintain such records for inspection if necessary.

Servicing arrangements for products previously distributed: Any customer requests to Isolite for product servicing will be forwarded to AmeriGlo. AmeriGlo will service the customer's Isolite product as if it were an AmeriGlo product.

Provide a new label for the devices indicating the new company name and the effective date of the label change:

The markings on the device will remain as written in the present Isolite SSD. AmeriGlo has applied for trademark registration of ZONE 3 and USAH3 (applications attached).

The effective date of label change: not applicable since the labels/markings will remain the same.

Confirm that no changes were made to the product since its initial registration or last amendment: Yes, no changes were or will be made to the product. (We have deleted the sentence from page 6 the E-license application: "Specialty sights may contain more than 2 lamps as long as the safety specification are met as discussed above.") (We have also corrected the application on page 7, indicating that the housing material will have a Brinell Hardness of 100 HB or higher, not 95 HB.)

Verify that previous commitments made by the old company have not changed: We have reviewed the initial Isolite SSD application and the SSDR itself and confirm that previous commitments will be continued by AmeriGlo. All references listed in the Isolite SSD have been obtained by AmeriGlo.

Provide details about the quality assurance program under the new ownership or at the new location. AmeriGlo has used the Isolite Quality Management System Manual as a template for development of its own QMS. A copy is attached. The QMS ensures that:

(1) there is full design conformity in accordance with the statements and commitments submitted in support of the application (including materials of construction, dimensions within stated tolerances, manufacturing methods, assembly methods, and labeling);
(2) all units are leak tested to 185 Bq (0.005 uCi);
(3) all units are tested for proper operation of all safety features; and
(4) all units are verified that radiation levels do not exceed the maximum values stated in the application - not applicable for non-gamma-emitting tritium products.

While the system is designed to meet ISO 9001, we do not wish to join ISO9001 officially at this time. However, the QMS (attached) has procedures to ensure (1) the materials of construction and the final assembly meet design specifications; (2) The final product is leak tested; (3) A final radiation profile is performed (not applicable since tritium does not emit gamma radiation or high-energy beta radiation that would create a radiation field profile); (4) A test is performed that verifies that the product operates as intended; (4) A visual inspection is performed of components that are considered related to safety or are expected to be susceptible to failure under extreme or unusual conditions.

Thank you for your attention to this matter. If you have any questions, please contact the undersigned.

Sincerely,

Richard Callihan,
Vice-President

Attachment 1 – Isolite Letter Agreement to Transfer SSD

isolite

August 11, 2016

Tomas Herrera
SSD Team Leader
U.S. NRC
NMSS/MSTR/MSLB
301-415-7138

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Office of Nuclear Material Safety and Safeguards
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Mail Stop T-8E18
Two White Flint North
11545 Rockville Pike
Rockville, MD 20852-2738

Dear Mr. Herrera,

Isolite Corporation hereby authorizes the transfer of ownership of SSD NR-1286-D-102-E to Ameriglo, LLC and authorizes AmeriGlo to use any and all of Isolite's intellectual property regarding radio-luminous gun sights for the purposes of sales, marketing, manufacturing, licensing and distribution.

Please contact me if you have any questions.

Regards,

William E. Lynch Jr.
President

HEADQUARTERS: 31 Waterloo Avenue • Berwyn, PA 19312 • 800-688-5483 • 610-647-3200 • Fax 610-296-8952
WESTERN OFFICE: 3583 Sueldo, Suite M • San Luis Obispo, CA 93401 • 800-799-5343 • 805-546-9669 • Fax 805-546-9564

Attachment 2 – USTEAS Applications for "USAH3" and "ZONE 3"

From: <TEAS@uspto.gov>
Date: Tuesday, August 02, 2016 10:05 AM
To: "Murphy, Julie C." <Julie.Murphy@sutherland.com>
Subject: 31065 Serial number 87123868: Received Your Trademark/Service Mark Application, Principal Register

1. **YOUR MARK:** USAH3 (Standard Characters, mark.jpg)
   The literal element of the mark consists of USAH3.
   The mark consists of standard characters, without claim to any particular font, style, size, or color.

2. **YOUR SERIAL NUMBER:** We have received your U.S. Trademark Application and assigned serial number '87123868' to your submission. A summary of your application data is provided at the bottom of this message and serves as your official filing receipt. Please keep a copy of this information for your records. All correspondence concerning the application should reference your assigned serial number.

   Please read all of the important information below. Not every mark is registrable with the USPTO and we do not refund the application filing fee(s) if a registration does not ultimately issue.

3. **RECEIVING E-MAIL COMMUNICATIONS/FILING DOCUMENTS ON-LINE:** Because you have authorized receipt of correspondence by e-mail, please make sure that your server will accept USPTO e-mail and not treat it as SPAM. If you must submit correspondence to us, please use the Trademark Electronic Application System (TEAS) forms, available at http://www.uspto.gov/trademarks/teas/index.jsp. Applicants who filed their application online using the lower-fee TEAS RF application form must (1) continue to submit certain documents online using TEAS, including responses to Office actions (see http://www.uspto.gov/trademarks/teas/required_teas_filings.jsp for a complete list of these documents); (2) accept correspondence from the USPTO via e-mail throughout the examination process; and (3) maintain a valid e-mail address. TEAS RF applicants who do not meet these three requirements must submit an additional processing fee of $50 per international class of goods/services. However, in certain situations, authorizing an examiner's amendment by telephone will not incur this additional fee.

4. **KEEP YOUR ADDRESS CURRENT IN USPTO RECORDS:** We do not extend filing deadlines due to a failure to receive USPTO mailings/e-mailings. You must update the correspondence and/or owner's address if a postal address and/or e-mail address changes, using the form(s) available at http://www.uspto.gov/trademarks/teas/correspondence.jsp.

5. **WARNING ABOUT UNSOLICITED COMMUNICATIONS:** You may receive trademark-related communications from private companies not associated with the USPTO. These communications frequently display customer-specific information, including your USPTO serial number or registration number and owner name, and request fees for trademark-related services, such as monitoring, listings in international publications, and document filing. None of the companies offering these services are affiliated with the USPTO or any other federal agency. All official correspondence will be from the "United States Patent and Trademark Office" in Alexandria, VA, and if by e-mail, specifically from the domain "@uspto.gov." Please consult the "Warning" page on the Trademarks section of the USPTO's website for

From: <TEAS@uspto.gov>
Date: Tuesday, August 02, 2016 10:05 AM
To: "Murphy, Julie C." <Julie.Murphy@sutherland.com>
Subject: 31065 Serial number 87123865: Received Your Trademark/Service Mark Application, Principal Register

1. **YOUR MARK:** ZONE 3 (Standard Characters, mark.jpg)
   The literal element of the mark consists of ZONE 3.
   The mark consists of standard characters, without claim to any particular font, style, size, or color.

2. **YOUR SERIAL NUMBER:** We have received your U.S. Trademark Application and assigned serial number '87123865' to your submission. A summary of your application data is provided at the bottom of this message and serves as your official filing receipt. Please keep a copy of this information for your records. All correspondence concerning the application should reference your assigned serial number.

   Please read all of the important information below. Not every mark is registrable with the USPTO and we do not refund the application filing fee(s) if a registration does not ultimately issue.

3. **RECEIVING E-MAIL COMMUNICATIONS/FILING DOCUMENTS ON-LINE:** Because you have authorized receipt of correspondence by e-mail, please make sure that your server will accept USPTO e-mail and not treat it as SPAM. If you must submit correspondence to us, please use the Trademark Electronic Application System (TEAS) forms, available at http://www.uspto.gov/trademarks/teas/index.jsp. Applicants who filed their application online using the lower-fee TEAS RF application form must (1) continue to submit certain documents online using TEAS, including responses to Office actions (see http://www.uspto.gov/trademarks/teas/required_teas_filings.jsp for a complete list of these documents); (2) accept correspondence from the USPTO via e-mail throughout the examination process; and (3) maintain a valid e-mail address. TEAS RF applicants who do not meet these three requirements must submit an additional processing fee of $50 per international class of goods/services. However, in certain situations, authorizing an examiner's amendment by telephone will not incur this additional fee.

4. **KEEP YOUR ADDRESS CURRENT IN USPTO RECORDS:** We do not extend filing deadlines due to a failure to receive USPTO mailings/e-mailings. You must update the correspondence and/or owner's address if a postal address and/or e-mail address changes, using the form(s) available at http://www.uspto.gov/trademarks/teas/correspondence.jsp.

5. **WARNING ABOUT UNSOLICITED COMMUNICATIONS:** You may receive trademark-related communications from private companies not associated with the USPTO. These communications frequently display customer-specific information, including your USPTO serial number or registration number and owner name, and request fees for trademark-related services, such as monitoring, listings in international publications, and document filing. None of the companies offering these services are affiliated with the USPTO or any other federal agency. All official correspondence will be from the "United States Patent and Trademark Office" in Alexandria, VA, and if by e-mail, specifically from the domain "@uspto.gov." Please consult the "Warning" page on the Trademarks section of the USPTO's website for

Attachment 3 – AmeriGlo, LLC Quality Management System Manual

NRC FORM 313 (05-2016) 10 CFR 30, 32, 33, 34 35, 36, 37, 39, and 40

U.S. NUCLEAR REGULATORY COMMISSION

APPLICATION FOR MATERIALS LICENSE

APPROVED BY OMB: NO. 3150-0120 **EXPIRES: 05/31/2016**

Estimated burden per response to comply with this mandatory collection request: 4.3 hours. Submittal of the application is necessary to determine that the applicant is qualified and that adequate procedures exist to protect the public health and safety. Send comments regarding burden estimate to the FOIA, Privacy, and Information Collections Branch (T-5 F53), U.S. Nuclear Regulatory Commission, Washington, DC 20555-0001, or by e-mail to Infocollects.Resource@nrc.gov, and to the Desk Officer, Office of Information and Regulatory Affairs, NEOB-10202, (3150-0120), Office of Management and Budget, Washington, DC 20503. If a means used to impose an information collection does not display a currently valid OMB control number, the NRC may not conduct or sponsor, and a person is not required to respond to, the information collection.

INSTRUCTIONS: SEE THE APPROPRIATE LICENSE APPLICATION GUIDE FOR DETAILED INSTRUCTIONS FOR COMPLETING APPLICATION. SEND TWO COPIES OF THE ENTIRE COMPLETED APPLICATION TO THE NRC OFFICE SPECIFIED BELOW. *AMENDMENTS/RENEWALS THAT INCREASE THE SCOPE OF THE EXISTING LICENSE TO A NEW OR HIGHER FEE CATEGORY WILL REQUIRE A FEE.

APPLICATION FOR DISTRIBUTION OF EXEMPT PRODUCTS FILE APPLICATIONS WITH:

MATERIALS SAFETY LICENSING BRANCH
DIVISION OF MATERIAL SAFETY, STATE, TRIBAL AND RULEMAKING PROGRAMS
OFFICE OF NUCLEAR MATERIALS SAFETY AND SAFEGUARDS
U.S. NUCLEAR REGULATORY COMMISSION
WASHINGTON, DC 20555-0001

ALL OTHER PERSONS FILE APPLICATIONS AS FOLLOWS:

IF YOU ARE LOCATED IN:

ALABAMA, CONNECTICUT, DELAWARE, DISTRICT OF COLUMBIA, FLORIDA, GEORGIA, KENTUCKY, MAINE, MARYLAND, MASSACHUSETTS, NEW HAMPSHIRE, NEW JERSEY, NEW YORK, NORTH CAROLINA, PENNSYLVANIA, PUERTO RICO, RHODE ISLAND, SOUTH CAROLINA, TENNESSEE, VERMONT, VIRGINIA, VIRGIN ISLANDS, OR WEST VIRGINIA,

SEND APPLICATIONS TO:

LICENSING ASSISTANCE TEAM
DIVISION OF NUCLEAR MATERIALS SAFETY
U.S. NUCLEAR REGULATORY COMMISSION, REGION I
2100 RENAISSANCE BOULEVARD, SUITE 100
KING OF PRUSSIA, PA 19406-2713

IF YOU ARE LOCATED IN:

ILLINOIS, INDIANA, IOWA, MICHIGAN, MINNESOTA, MISSOURI, OHIO, OR WISCONSIN, SEND APPLICATIONS TO:

MATERIALS LICENSING BRANCH
U.S. NUCLEAR REGULATORY COMMISSION, REGION III
2443 WARRENVILLE ROAD, SUITE 210
LISLE, IL 60532-4352

ALASKA, ARIZONA, ARKANSAS, CALIFORNIA, COLORADO, HAWAII, IDAHO, KANSAS, LOUISIANA, MISSISSIPPI, MONTANA, NEBRASKA, NEVADA, NEW MEXICO, NORTH DAKOTA, OKLAHOMA, OREGON, PACIFIC TRUST TERRITORIES, SOUTH DAKOTA, TEXAS, UTAH, WASHINGTON, OR WYOMING,

SEND APPLICATIONS TO:

NUCLEAR MATERIALS LICENSING BRANCH
U.S. NUCLEAR REGULATORY COMMISSION, REGION IV
1600 E. LAMAR BOULEVARD
ARLINGTON, TX 76011-4511

PERSONS LOCATED IN AGREEMENT STATES SEND APPLICATIONS TO THE U.S. NUCLEAR REGULATORY COMMISSION ONLY IF THEY WISH TO POSSESS AND USE LICENSED MATERIAL IN STATES SUBJECT TO U.S.NUCLEAR REGULATORY COMMISSION JURISDICTIONS.

1. THIS IS AN APPLICATION FOR *(Check appropriate item)*

- [x] A. NEW LICENSE
- [ ] B. AMENDMENT TO LICENSE NUMBER _____
- [ ] C. RENEWAL OF LICENSE NUMBER _____

2. NAME AND MAILING ADDRESS OF APPLICANT *(Include ZIP code)*

AmeriGlo, LLC
645 Hembree PKWY, STE K
Roswell, GA 30076

3. ADDRESS WHERE LICENSED MATERIAL WILL BE USED OR POSSESSED

AmeriGlo, LLC
645 Hembree PKWY, STE K
Roswell, GA 30076

4. NAME OF PERSON TO BE CONTACTED ABOUT THIS APPLICATION

William E. Lynch, Jr., President

BUSINESS TELEPHONE NUMBER	BUSINESS CELLULAR TELEPHONE NUMBER
7703900554	6102205938

BUSINESS EMAIL ADDRESS

sales@ameriglo.com

SUBMIT ITEMS 5 THROUGH 11 ON 8-1/2 X 11" PAPER. THE TYPE AND SCOPE OF INFORMATION TO BE PROVIDED IS DESCRIBED IN THE LICENSE APPLICATION GUIDE.

5. RADIOACTIVE MATERIAL
   a. Element and mass number; b. chemical and/or physical form; and c. maximum amount which will be possessed at any one time.

6. PURPOSE(S) FOR WHICH LICENSED MATERIAL WILL BE USED.

7. INDIVIDUAL(S) RESPONSIBLE FOR RADIATION SAFETY PROGRAM AND THEIR TRAINING AND EXPERIENCE.

8. TRAINING FOR INDIVIDUALS WORKING IN OR FREQUENTING RESTRICTED AREAS.

9. FACILITIES AND EQUIPMENT.

10. RADIATION SAFETY PROGRAM.

11. WASTE MANAGEMENT.

12. LICENSE FEES (Fees required only for new applications, with few exceptions*) *(See 10 CFR 170 and Section 170.31)*

FEE CATEGORY: 3. H.

AMOUNT ENCLOSED $ 6,400.00

13. CERTIFICATION. *(Must be completed by applicant) THE APPLICANT UNDERSTANDS THAT ALL STATEMENTS AND REPRESENTATIONS MADE IN THIS APPLICATION ARE BINDING UPON THE APPLICANT.*

THE APPLICANT AND ANY OFFICIAL EXECUTING THIS CERTIFICATION ON BEHALF OF THE APPLICANT, NAMED IN ITEM 2, CERTIFY THAT THIS APPLICATION IS PREPARED IN CONFORMITY WITH TITLE 10, CODE OF FEDERAL REGULATIONS, PARTS 30, 32, 33, 34, 35 , 36, 37, 39, AND 40, AND THAT ALL INFORMATION CONTANED HEREIN IS TRUE AND CORRECT TO THE BEST OF THEIR KNOWLEDGE AND BELIEF.

WARNING: 18 U.S.C. SECTION 1001 ACT OF JUNE 25, 1948 62 STAT. 749 MAKES IT A CRIMINAL OFFENSE TO MAKE A WILLFULLY FALSE STATEMENT OR REPRESENTATION TO ANY DEPARTMENT OR AGENCY OF THE UNITED STATES AS TO ANY MATTER WITHIN ITS JURISDICTION.

CERTIFYING OFFICER -- TYPED/PRINTED NAME AND TITLE	SIGNATURE	DATE
Richard Callihan, Vice-President		

FOR NRC USE ONLY

TYPE OF FEE	FEE LOG	FEE CATEGORY	AMOUNT RECEIVED $	CHECK NUMBER	COMMENTS
APPROVED BY				DATE	

Addendum 1 to USNRC FORM 313
Application to Distribute Exempt Products

1. This is an application for: a new license

The purpose of this application is to obtain a license to distribute self-luminous gun sights as exempt products pursuant to 10 CFR 30, §30.19 and §30.33, and 10 CFR 32, §32.22.

Possession of the products will be authorized by AmeriGlo Corporation's radioactive materials license GA-1654 (attached) issued by the State of Georgia. The products will be assembled at our facility in Roswell, Ga. using gaseous tritium light sources imported from our supplier SRB Technologies, Inc. in Canada or MB Microtec in Switzerland.

The radiological assessments of such illuminated sight assemblies performed in NUREG -1717, Section 2.14.5 is the bases for the exemption. This testing data, performed by AmeriGlo, LLC, was submitted to the USNRC as part of SSD NR-1286-D-102-E and is also included herein.

2. Applicant:

AmeriGlo, LLC
645 Hembree PKWY, STE K
Roswell, GA 30076

3. Address from which Licensed Material will be distributed:

a. Address of Licensee: (location of all distribution records):

AmeriGlo, LLC
645 Hembree PKWY, STE K
Roswell, GA 30076

b. Manufacturer of products:

AmeriGlo, LLC
645 Hembree PKWY, STE K
Roswell, GA 30076

c. Physical point of distribution of products

AmeriGlo, LLC
645 Hembree PKWY, STE K
Roswell, GA 30076

4. Contact:

Richard Callihan, Vice-President
770-390-0554

5. Radionuclide Material:

All products to be distributed will be manufactured using gaseous, elemental tritium. The products have as the basic light-producing component, a gaseous tritium light source (GTLS) which consists of a sealed glass tube or other glass shape containing elemental tritium.

A. ELEMENT AND MASS NUMBER

Hydrogen-3 (Tritium)

B. CHEMICAL OR PHYSICAL FORM

Elemental (gas)

in the form of sealed sources

The products to be distributed are manufactured from sources listed in the Registry of Radioactive Sealed Sources and Devices under the following manufacturers / registrants:

- SRB Technologies, Inc. - SSDR# NC-585-S-102-S
- MB-Microtec, AG - SSDR# NR-446-S-102-S

The physical form of tritium in the GTLS (elemental) will slightly change via oxidation over the 12-year useful life of the product. Typically, less than 1% of the tritium will oxidize to tritium oxide (HTO) with a small percentage of intact GTLS's showing 1 to 5% oxidation.[1]

The solubility in water and body fluids of tritium has been well-studied and reported in the scientific literature[2,3]. The literature and this application assume that tritium oxide is 100% soluble in water and body fluids and that elemental tritium is essentially insoluble in water and body fluids (<0.005% in lung fluids). However, for the purposes of conservatism, some of the dose estimates in this application assume that even the elemental form dissolves into body fluids.

C. MAXIMUM AMOUNT THAT WILL BE POSSESSED AT ANY ONE TIME

- 50 mCi per GTLS, 90 mCi per Sight Assembly
- 2000 Ci total possession amount at any one time

6. Purpose for which licensed material will be used:

This Exempt Distribution License is intended to allow the distribution of devices listed herein to persons exempt from licensing pursuant to §30.19, §30.33 and §32.22, or equivalent provisions of the regulations of any Agreement State. See Addendum 1 and the attachments for a

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[1] Werner, J.R., WSRC-TR-95-0311, "Assessment of Commercial Self-Luminous Exit Signs Containing Tritium: Final Report-Task 1 (U)", Westinghouse Savannah River Company, Aiken, SC, 1995.

[2] International Commission on Radiation Protection Publication 30. (1979) *Limits for the Intakes of Radionuclides by Workers*. Oxford: Pergamon Press, ICRP, Part 1; Ann. ICRP.

[3] Environmental Protection Agency. (1988) *Federal Guidance Report No. 11: Limiting Values of Radionuclide Intake and Air Concentrations and Dose Conversions Factors for Inhalation, Submersion, and Ingestion*. Oak Ridge, Tenn. EPA.

discussion of gun sight testing, dose assessment, manufacturing, quality assurance and distribution.

7-11. Not Applicable

12. Fees – see Form 313

13. Certification – see Form 313

Addendum 2

AmeriGlo, LLC Gun Sight E-License Application

Technical Information

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1. DESCRIPTION

Many law enforcement officers, hunters, and recreational shooters of guns use illuminated sight assembly devices. The devices aid the user in visually acquiring the sights in low light conditions.

All models contain a tritiated light source, also called a lamp. The light source is a small cylindrical, sealed glass vial containing tritium gas (H3) and a phosphorescent substance which emits light when energized by the tritium beta particles. The light sources are securely mounted into a metal or plastic sight housing in a way that exposes part of the illuminated cylinder.

In all models, the lamps are mounted inside the housing which is ultimately affixed to the gun. The housings are mounted to the weapon by press fit, screw, dovetail, or clamp connection.

The manner in which the light source is affixed in the housing determines the model series in which the sight is classified. Two series of the device are specified as the L and N series. The differences between the L and N models follow:

- L series: uses a lens made of crystal sapphire; the lamp is mounted in an aluminum sleeve
- N series: no sapphire lens is used; the lamp is mounted in the sight housing and sealed with a polymeric coating.

The L and N series sights may vary in size, shape and number of light sources as long as the key safety specifications are met as discussed in this application.

The sleeve holding the lamp consists of plastic (N series) or metal (L series). The sleeve is secured in the sight housing by a friction fit and with a gluing agent. The gluing agent will operate at a temperature between -30 degrees Fahrenheit or lower and +180 degrees Fahrenheit or higher and has a 1800 pound-per square inch or greater compressive strength.

The sapphire lens in the L series sight fits into the metal sleeve by means of a friction fit. The purpose of the lens is to focus the light from the lamp, not for additional protection of the lamp. However, by nature of its placement, the lens does act as a barrier to prevent access to the lamp and also keeps out dirt. The lens is made from crystal sapphire. The N series does not use a sapphire lens but uses a Mercapto-ester (clear adhesive) coating which also prevents access to the lamp and keeps out dirt.

All series sights use light sources that contain a maximum activity of 50 mCi per tube. There are typically 1 or 2 tubes per device. Typically, the front sight contains 1 lamp and the rear contains 2 lamps. Therefore, there are typically 3 lamps, or 150 mCi per weapon.

The working life of the sights is approximately 12 years based on the half-life of tritium and the resultant luminosity.

Drawings of the devices are shown in Attachment A.

2. DESIGN

The devices are designed to withstand the vibrations from the firearm on which they are mounted. The sights are mounted to the gun by a press fit, screw, dovetail, or clamp connection.

The series of sight models vary in size and shape due to the numerous makes and models of guns to which they fit. Various shapes of device are shown in Attachment A.

Regardless of the shape, the key safety aspects of the devices rely on the following:

1. use of an NRC-approved lamp via the Sealed Source Device Registry,
2. the material used for the housing meets specifications listed herein
3. the length, width and height of the housing meets the specifications listed herein,
4. sleeve materials and gluing agents meet the specifications listed herein, and
5. the wall between the lamp and the exterior of the housing meets a minimum thickness.

The corresponding specifications follow:

1. Lamps:
   - SRB Technologies, Inc. - SSDR# NC-585-S-102-S
   - MB-Microtec, AG - SSDR# NR-446-S-102-S
2. Housing Material: any pure metal or alloy or other material with a Tensile strength of 50,000 PSI or higher and a Brinell Hardness of 100 HB or higher.
3. Dimensions: as listed in the drawings in Attachment A
4. Sleeve material: aluminum (series L); Polymer (series N); Gluing agent must maintain its integrity at a temperature between -30 degrees Fahrenheit or lower and +180 degrees Fahrenheit or higher and have an 1800 pound-per square inch or greater compressive strength.
5. Wall thickness between the lamp and the exterior of the housing: minimum of 0.38 mm (0.015").

3. MANUFACTURING AND DISTRIBUTION

The devices will be assembled at the AmeriGlo Roswell facility using GTLS's imported from various approved manufacturers. The devices will be distributed to persons exempt from the requirements for a license in accordance with Section 30.19 of 10 CFR part 30. Approximately 50,000 sets of gun sights are expected to be distributed annually, totaling 4500 Ci of tritium.

One of the following information cards, or similar, will be included with each order of sights distributed:

AMERIGLO®
Custom Firearm Sights

Important Note: If marked "H3" on metal sight, then the product contains tritium gas and is a 'night sight'. Night Sights are regulated by the US Nuclear Regulatory Commission. The sight shall not be disassembled or exported.

PROFESSIONAL INSTALLATION RECOMMENDED

Exposure to strong organic solvents or ultrasonic cleaning machines may damage painted outlines.

The original owner of this product is entitled to replacement or repair (at our option) if the sight fails (a total loss of illumination) due to defects in material or workmanship during normal use, for a period of 5, 10, or 12 years, depending upon product model.

Visit AmeriGlo.com for return procedures prior to shipping.

Distributed by AmeriGlo, LLC
645 Hembree Parkway, Suite K, Roswell, GA 30076
www.AmeriGlo.com

4. LABELING

Method: Label marking will be performed by an engraving device or by a pad-printing device using Tampapur TPU ink (or equivalent). This ink performs well when extremely high mechanical and chemical resistance is required. Similar inks have been used successfully by other companies in this industry.

Markings: Markings will be placed on the device and will be visible by the end-user upon receipt (see attached drawing). The marking will include the brand name, the symbol "H3", followed by a one, two, or four digit number. This number will designate the manufacturing lot date. The trade names under which these devices will be distributed include Ameriglo, ZONE 3, and USA. One of these names will be marked on each device.

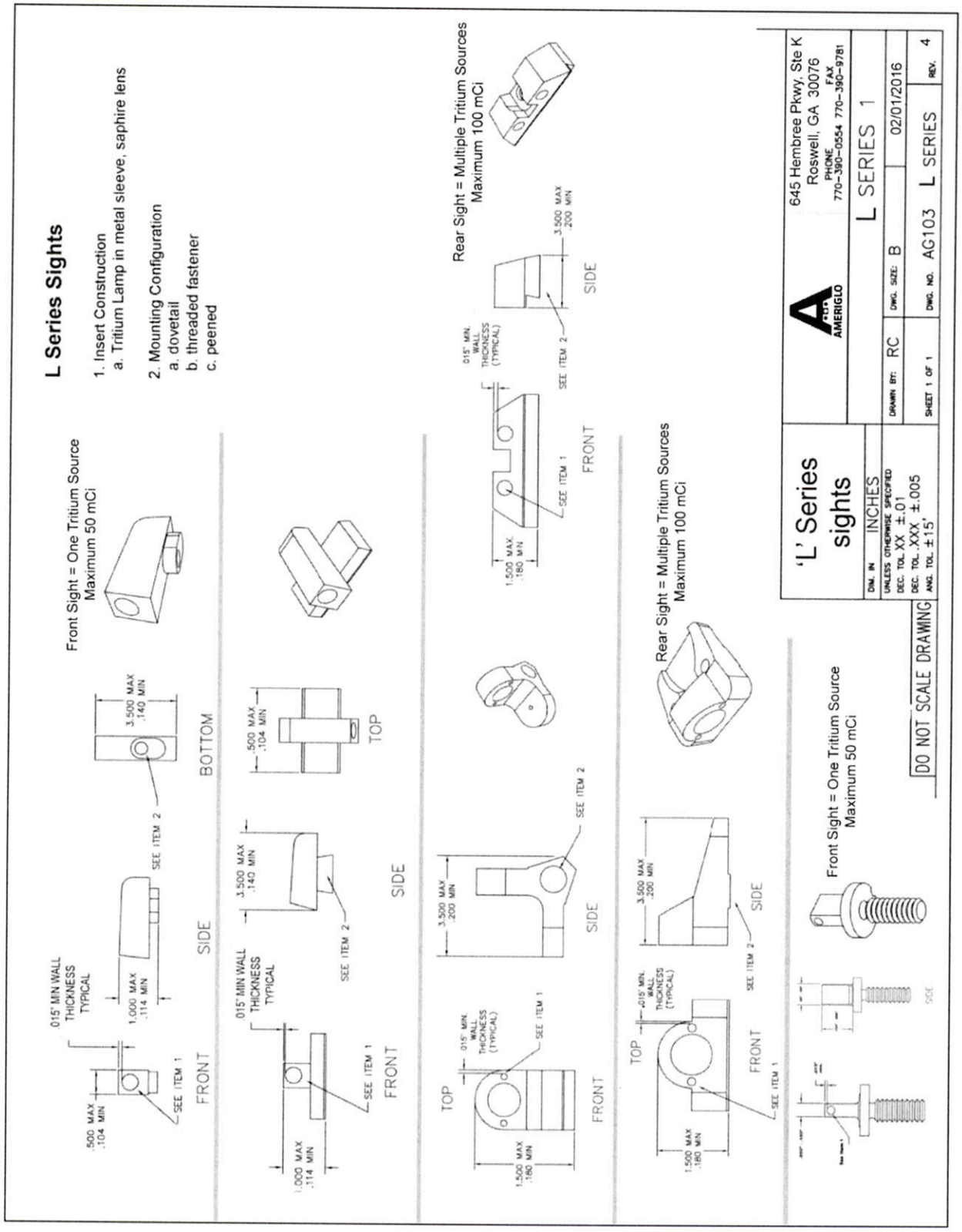
5. QUALITY ASSURANCE AND CONTROL

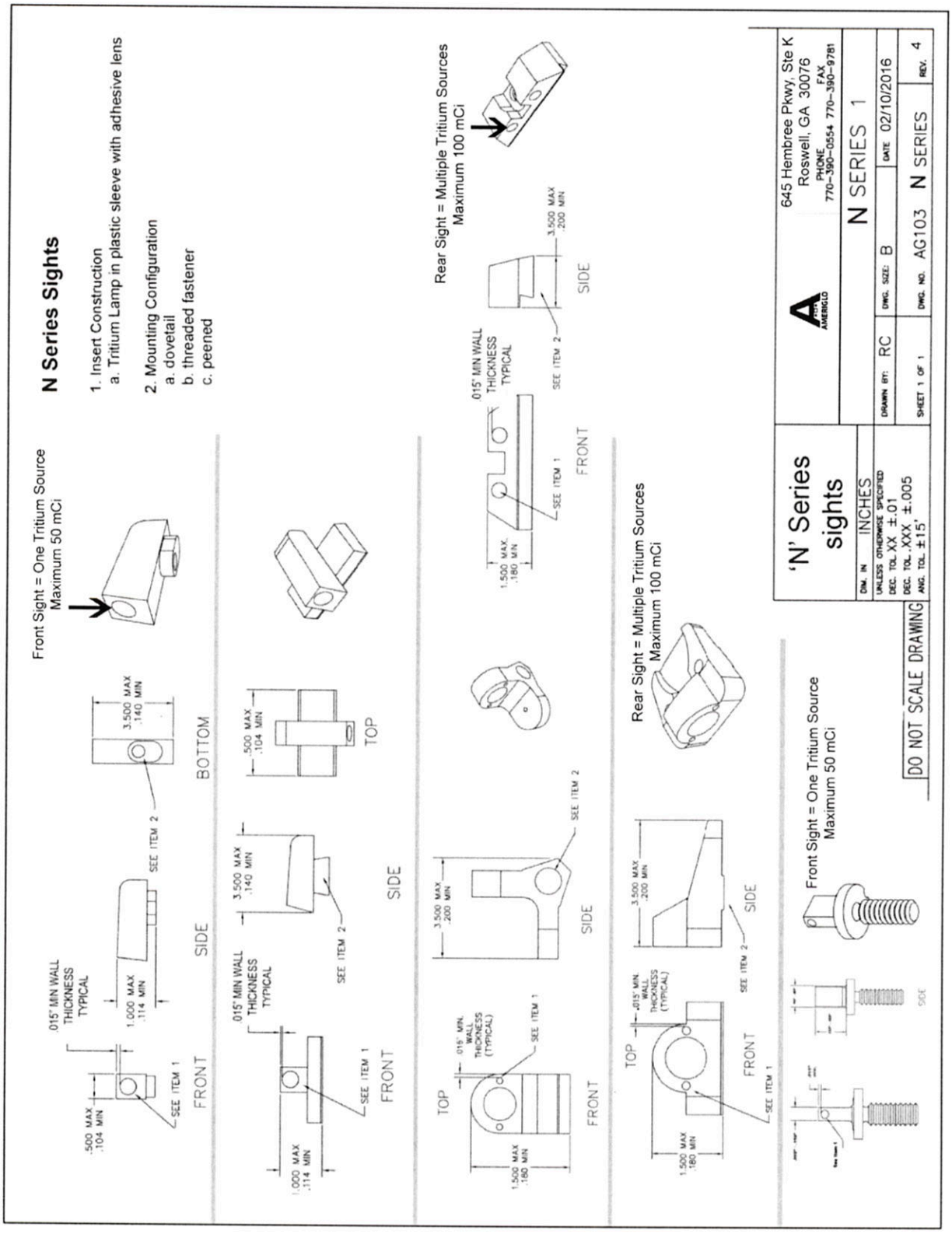
AmeriGlo, LLC will perform quality assurance oversight of the manufacturer via a Quality Assurance Management System (QMS). As holder of the possession and distribution licenses, AmeriGlo, LLC will be responsible for ensuring that all quality assurance and safety requirements are met as specified in their licenses, USNRC and USDOT regulations, and this application. AmeriGlo, LLC conducts annual audits of the supplier's manufacturing and QA functions to ensure all QA specifications are met for applicable radioluminous products. The QMS Manual is shown in Appendix C.

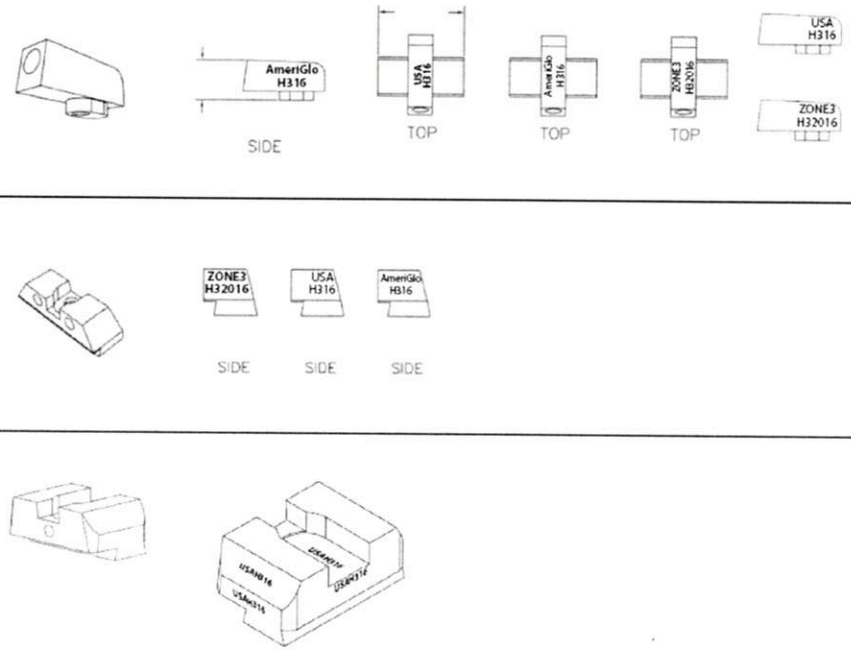
6. TESTING AND ASSESSMENT

Testing of these devices and dose assessment have been performed as specified in NUREG-1556, Vol. 8 Appendix O. The results (in ATTACHMENT B) show that the devices have successfully withstood the tests without exhibiting any damage or leakage and the requirements of 10CFR32.23 have been met.

Attachment A - Sealed Source Device Drawings


L Series Sights
1. Insert Construction
a. Tritium Lamp in metal sleeve, saphire lens
2. Mounting Configuration
a. dovetail
b. threaded fastener
c. peened
Front Sight = One Tritium Source
Maximum 50 mCi
Rear Sight = Multiple Tritium Sources
Maximum 100 mCi
Rear Sight = Multiple Tritium Sources
Maximum 100 mCi
Front Sight = One Tritium Source
Maximum 50 mCi
.015' MIN WALL THICKNESS TYPICAL
.500 MAX .104 MIN
1.000 MAX .114 MIN
3.500 MAX .140 MIN
SEE ITEM 1
SEE ITEM 2
FRONT
SIDE
BOTTOM
TOP
1.500 MAX .180 MIN
3.500 MAX .200 MIN
.015' MIN. WALL THICKNESS (TYPICAL)
'L' Series sights
DO NOT SCALE DRAWING
DIM. IN INCHES
UNLESS OTHERWISE SPECIFIED
DEC. TOL. XX ±.01
DEC. TOL. XXX ±.005
ANG. TOL. ±15'
DRAWN BY: RC
DWG. SIZE: B
02/01/2016
SHEET 1 OF 1
DWG. NO. AG103
L SERIES
REV. 4
AMERIGLO
645 Hembree Pkwy, Ste K
Roswell, GA 30076
PHONE 770-390-0554
FAX 770-390-9781
L SERIES 1


N Series Sights
1. Insert Construction
a. Tritium Lamp in plastic sleeve with adhesive lens
2. Mounting Configuration
a. dovetail
b. threaded fastener
c. peened
Front Sight = One Tritium Source
Maximum 50 mCi
Rear Sight = Multiple Tritium Sources
Maximum 100 mCi
.015" MIN WALL THICKNESS TYPICAL
.500 MAX .104 MIN
1.000 MAX .114 MIN
3.500 MAX .140 MIN
SEE ITEM 1
SEE ITEM 2
FRONT
SIDE
BOTTOM
TOP
.015" MIN. WALL THICKNESS (TYPICAL)
1.500 MAX .180 MIN
3.500 MAX .200 MIN
'N' Series sights
DIM. IN INCHES
UNLESS OTHERWISE SPECIFIED
DEC. TOL. XX ±.01
DEC. TOL. .XXX ±.005
ANG. TOL. ±15'
DO NOT SCALE DRAWING
645 Hembree Pkwy, Ste K
Roswell, GA 30076
PHONE 770-390-0554 FAX 770-390-9781
N SERIES 1
DRAWN BY: RC
DWG. SIZE: B
DATE: 02/10/2016
SHEET 1 OF 1
DWG. NO. AG103 N SERIES
REV. 4



Labeling (Markings on Sights)

1. AmeriGlo H316
2. ZONE3 H32016
3. USA H316

DO NOT SCALE DRAWING

Labeling	AmeriGlo INDEPENDENT LIGHT	645 Hembree Pkwy,Ste K Roswell, GA 30076 PHONE 770-390-0554 FAX 770-390-9781	
DIM. IN INCHES	N & L SERIES 1		
UNLESS OTHERWISE SPECIFIED DEC.TOL. XX ± .01 DEC.TOL. .XXX ± .005 ANG.TOL. ± 15'	DRAWN BY: RC	DWG. SIZE: B	DATE 06/07/2016
	SHEET 1 OF 1	DWG. NO. A108	REV.

Attachment B - Prototype Testing and Dose Assessment

Standard Requirements for Gun Sights Containing Tritium Gas Sealed in Glass Vials

1. INTRODUCTION

The gun sight designs were assessed and tested per the requirements of NUREG-1556, Volume 8, CONSOLIDATED GUIDANCE ABOUT MATERIALS LICENSES, PROGRAM-SPECIFIC GUIDANCE ABOUT EXEMPT DISTRIBUTION LICENSES, Appendix O, *Standard Requirements for Gun Sights Containing Tritium Gas Sealed in Glass Vials.*

Testing was performed by Ameriglo, LLC and Advanced Compliance Solutions, Inc. (ACS).

Nomenclature: At the time of testing, sights were designated as FS (front sight) and RS (rear sight) each with a type A or B suffix. The "A" suffix corresponds to the present "N" series and the "B" suffix corresponds to the "L" series. For example, a test referring to an FS1A is a Series N front sight.

Test Designation:	Series N or L Nomenclature
FS1A -	front sight, series N
FS2A -	front sight, series N
RS1A -	rear sight, series N
RS2B -	rear sight, series L
FS1B -	front sight, series L
RS1B -	rear sight, series L

2. PURPOSE

The purpose of this assessment is to determine if the AmeriGlo tritium-illuminated, night sights, series L and N, meet the integrity and leakage requirements and radiation dose limitations of NUREG-1556, Volume 8, CONSOLIDATED GUIDANCE ABOUT MATERIALS LICENSES, PROGRAM-SPECIFIC GUIDANCE ABOUT EXEMPT DISTRIBUTION LICENSES, Appendix O, *Standard Requirements for Gun Sights Containing Tritium Gas Sealed in Glass Vials.*

3. REQUIREMENTS

The requirements of NUREG-1556, Volume 8, Appendix O are met herein by prototype testing and calculational dose assessments.

3.1 DESIGN

Refer to the drawings in Attachment A showing construction details of the gun sights.

Each gunsight is required to be designed so that:

3.1.1 In normal use and disposal of a single gunsight, it is unlikely the external radiation dose in any one year, or the dose commitment resulting from the intake of radioactive material in any one year, to a suitable sample of the group of individuals expected to be most highly exposed to radiation or radioactive material from the gunsight will exceed the dose to the appropriate organ as specified in Column I of Table O.1.

3.1.2 In normal handling and storage of the quantities of gunsights likely to accumulate in one location during marketing, distribution, installation, and servicing of the gunsights, it is unlikely that the external radiation dose in any one year, or the dose commitment resulting from the intake of radioactive material in any one year, to a suitable sample of the group of individuals expected to be most highly exposed to radiation or radioactive material from the gunsight(s) will exceed the dose to the appropriate organ as specified in Column II of Table O.1.

3.1.3 It is unlikely that there will be a significant reduction in the effectiveness of the containment, shielding, or other safety features of the gunsight from wear and abuse likely to occur in normal handling and use of the gunsight during its useful life.

3.1.4 In use and disposal of a single gunsight, or in handling and storage of the quantities of gunsights likely to accumulate in one location during marketing, distribution, installation, and servicing of the gunsight, the probability is low that the containment, shielding, or other safety features of the gunsight 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 in Column III of Table O.1, 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 in Column IV of Table O.1.

To prove compliance with the above requirements, the example calculation in Appendix O of NUREG 1556 Vol8 r1 is used below after being modified with the physical parameters specific to the use, handling , storage and disposal of AmeriGlo gun sights:

Dose Assessment

A. Estimated Radiation Dose Commitments under Normal Conditions

1. Normal use

   No radiation dose commitment is anticipated during normal use of the gun sights. The external radiation dose rate at 5 and 25 cm is estimated to be less than 0.001 mrem/hr. No inhalation or ingestion of the radioactive material is expected in normal use because the tritium gas is sealed in borosilicate glass which is then mounted in a metal sight housing. In this configuration, there is physically no human access to the radioactive material during normal use and handling.

2. Storage

   The distilled water immersion test on the sights after intense mechanical and environmental testing indicated a leakage rate of < 17 pCi/sight in 24 hours (see test results later in this application). Assuming that 500 units containing three tritium sources each are stored in a 30 ft x 20 ft x 10 ft room with an air exchange rate of 1 air change per hour, the calculated equilibrium concentration of tritium is as follows:

$$C = \frac{I}{\lambda V}$$

where:

I = rate of influx of H-3 gas

V = volume of the room

λ = air exchange rate

$$C = \frac{7.1\ \text{E-4}\ \mu\text{Ci/hr}}{1\ \text{change/hr} \times 1.7\ \text{E8 ml}} = 4.2\ \text{E-12}\ \text{uCi/ml}$$

C = equilibrium H-3 gas concentration

I = 500 sight pairs x 2 sights/pair x 17 E-6 μCi max leakage/sight / 24 hr = 7.1 E-4 μCi/hr

V = 6000 cubic ft x 2.83 E4 ml/cubic foot = 1.7 E8 ml room volume

The concentration limit set in 10 CFR Part 20, Appendix B, Table 2, Column 1 for H-3 in air is 1 E-7 µCi/ml (general public) and the limit set in 10 CFR Part 20, Appendix B, Table 1, Column 3 for occupational exposure to H-3 in air is 2 E-5 µCi/ml (DAC).

The annual dose commitment to an office worker, working in the area for 2000 hours/year is easily calculated from the ratio of the equilibrium concentration to the occupational DAC as follows

H = 4.2 E-12 uCi/ml x 5 rem / 2 E-5 uCi/ml = 1.0 E-6 rem/year

H = 0.000001 rem/year (dose due to normal storage)

In normal handling and storage of exempt units as accumulated in the AmeriGlo Roswell location during marketing and distribution, tests for loose surface contamination on storage shelves containing over one hundred sights for over 4 years have shown no significant levels of tritium (< 100 dpm/100 cm^2).

3. Transportation

Assume a truck driver transports all sights to be delivered to AmeriGlo in a single truckload and spends a total of two hours in the trailer loading and unloading.

V = 2.9 E7 cc (NUREG/CR-0215)

I = 7.1 E-4 µCi/hr

λ = I a ch/hr

$$C = \frac{7.1\ E\text{-}4\ \mu Ci/hr}{1\ change/hr\ \times 2.9\ E7\ ml} = 2.5\ E\text{-}11\ uCi/ml$$

Dose commitment:

H = 2.5 E-11 uCi/ml x 5 rem / 2 E-5 uCi/ml x 2 hours / 2000 hours

H = 6.3 E-9 rem (dose due to normal transportation)

4. All other situations during normal use, storage, and transportation involve smaller quantities of H-3 and/or shorter exposure times thus would result in negligible dose commitment.

5. Disposal

The gunsights are relatively expensive items and are unlikely to be inadvertently removed from the firearm and disposed of. The disposal of an intact firearm to normal trash is unlikely. Instructions accompanying the sights request return of damaged or defective sights to the distributor. Therefore, improper or careless disposal of the sights is unlikely to cause any significant radiation dose.

NUREG/CR-0215 estimates the dose commitment to the maximally exposed individual for burial of 500,000 tritium lighted wristwatches per year in landfills (20,000 in a single location) to be 0.1 mrem/yr. If the sources are burned a potential maximum dose commitment of 17 mrem/yr was estimated.

The total number of gunsights potentially disposed of in a single year would be much lower and the H-3 activity per unit also lower by a factor of seven than that postulated for watches containing H-3. Therefore, disposal of gunsights will not present a radiation hazard to the general public.

B. Accident conditions

1. Use

The maximum credible accident involving the use of a gunsight is rupture of a source and

instantaneous release of the gas during firing. Only the rear sight is of consequence since it is much closer to the breathing zone of the user than the front sight.

Assume:

- Rear sight contains a total of 100 mCi of H-3 gas (2 GTLS)
- Rear sight is 15 cm from the user's face
- Breathing zone can be represented by a cone with apex at the source and base, a 10cm diameter circle at the user's face
- All H-3 is converted to tritiated water instantly
- Effective half-time for tritiated water = 10 days
- Total absorption of inhaled tritium in body fluids
- Mass of soft tissue = 63,000 g (ICRP 30)
- Committed dose equivalent per unit intake of tritiated water is 1.7E - 11 Sv/Bq (6.3 E-2 rem/mCi)

Fraction of gas released in the direction of the breathing zone:

$$F = \frac{\pi \, \mathrm{rXr}}{4\pi \, \mathrm{RXR}}$$

where

r = radius of the base of the cone

R = distance from source to nose

$$F = \frac{3.14 \text{ X } 5 \text{ X } 5 sq\ cm}{4 \text{ X } 3.14 \text{ X } 15 \text{ X } 15\ sq\ cm} = 0.03$$

Maximum estimated dose commitment to user assuming 100% of the H-3 gas is converted to tritiated water

H = 100 mCi X 0.03 X 63 mrem/mCi = 190 mrem (assuming 100% conversion to tritium oxide)

For such an accidental instantaneous release, most of the gas would actually remain as elemental H-3. The dose commitment from H-3 gas would be approximately 1000 times less than that of tritium oxide. The total estimated dose commitment would be 2% of the calculated value since up to 2% of the gas originally in the glass capsule could be in the form of tritium oxide.

H = 50 mCi X 0.03 X 63 mrem/mCi x 0.02 = **3.8 mrem** (assuming 2% conversion to tritium oxide) **(Dose during an accident during use)**

2. Storage

The maximum credible accident involving storage of the units would involve a fire in the storage area which ruptures some of the borosilicate glass capsules. (A massive fire which would rupture all sources would be likely to result in immediate dispersion of the H-3 gas and dilution with outside air, thus reducing the concentrations of H-3 gas in the storage area.

Assume:

- 500 sight pairs in stock, each with 90 mCi H-3
- 50% of the sources ruptured (37.5 Ci released)
- Immediate dispersion of the gas within the storage area
- 1.7 E2 m^3 room volume
- Conversion of all H-3 gas to tritiated water

Total rate of absorption of tritiated water into body fluids (mCi/minute) from inhalation and skin absorption is 3 E-2 C where C is the concentration of tritiated water in air in mCi/cubic meter

(ICRP 30)

$$C = \frac{37.5 \text{ Ci} \times 1E3 \text{ mCi/Ci}}{1.7 \text{ E2 cubic meter}} = 220 \text{ mCi/cubic meter}$$

Dose commitment (due to an accident during storage):

H = 220 mCi/cubic meter x 3 E-2 mCi - cubic meter/mCi-min x 6.3 E-2 rem/mCi

H = 0.42 rem/minute

Dose commitment to personnel leaving the enclosed area without respiratory protection for 1 minute during evacuation = 0.42 rem
Dose commitment to fireman remaining in the enclosed area without respiratory protection for 2 minutes during response to the fire = 0.84 rem

This calculation greatly overestimates the true dose commitments in this situation. Air currents would disperse the gas very rapidly in the case of a fire, particularly one of such severity as to rupture 50% of the sources instantaneously. In addition, only a small fraction of the H-3 gas is likely to be converted to tritiated water before venting to the outside.

A more reasonable estimate of the dose commitment would be obtained using the maximum fraction of tritiated water in the source, 0.02. If this value is used, the dose commitments become **8 mrem for the occupant and 16 mrem for the fireman.**

3. Ingestion or inhalation of the entire H-3 content of the front sight (100 mCi).

   H = 100 mCi x 6.3 E-2 rem/mCi = **6.3 rem (dose due to negligible probability event such as swallowing 2 sources.)**

   The calculation assumes the entire 100 mCi of H-3 gas is converted to tritiated water. H-3 gas is not absorbed readily in body fluids thus produces negligible dose. This postulated accident would require that an individual remove the 2 sources from the front sight without damaging them, swallow them, and have them rupture while in the digestive tract. Each of these conditions is highly improbable. The combination of all three occurring is nearly impossible.

Compliance with 10 CFR 32.23 and 32.24

(Summary of the above calculations)

A. Normal use and storage

   No radiation dose commitment is expected in normal use of the gunsight system. The maximum expected dose commitment to workers in the storage area and during transportation is far less than 0.001 rem/year. This is within the limit set in Column II, Table O.1.

B. Accidental release of the tritium gas

   1. Under maximum credible conditions of use of the equipment, the dose commitment to an individual would not exceed 0.19 rem, within the limits set in Column III, Table O.1. In the highly improbable case where an individual ingested the contents of 2 entire sources, the estimated dose commitment is 6.3 rem. This is within the limits set in Column IV, Table O.1.
   2. Under extreme fire conditions in the storage area, the estimated maximum dose commitment to an occupant of the area is 0.42 rem; to a fireman responding to the fire, 0.84 rem. More reasonable values based on 2% of the H-3 gas being oxidized and remaining in the storage room are 0.008 rem and 0.016 rem respectively. However, even under the extreme conditions the dose commitments would be within the values in Table O.1.

Compliance with 10 CFR 32.22

1. 32.22(a)(1) and 30.33 – AmeriGlo has been issued a possession license, GA-1654-1, by the State of Georgia.

2. 32.22(a)(2)(iii) – The chemical and physical form during the useful life of the product is discussed in the E-license application, paragraph 5.B.

3. 32.22(a)(2)(iv) – The solubility of the physical forms of the radioisotope are described in the E-license application, paragraph 5.B.

4. 32.22(a)(2)(v) – Details and analyses of the design and construction of the product as related to normal use and severe conditions of handling, storage, use and disposal are shown in Attachments A and B of this application.

5. 32.22(a)(2)(vii) – The degree of human access to the GTLS is discussed in Section A.1. in "Dose Assessment" above.

6. 32.22(a)(2)(viii) - An estimate of the total quantity of byproduct material to be distributed annually is 4500 Ci (50,000 sight pairs x 90 mCi per sight pair)

7. 32.22(a)(2)(xiv) – Nominal probabilities and dose estimates per 32.23(d) have been discussed and estimated in the Dose Assessment above. This analysis was performed using the USNRC's example calculation in Appendix O of NUREG 1556 Vol8 r1 after being modified with the physical parameters specific to the use, handling , storage and disposal of AmeriGlo gun sights.

8. 32.22(a)(2)(xv) – Quality Control procedures to be followed in the fabrication of the product are discussed in Attachments D and E.

3.1.5 MARKING/LABELING

The device is marked with "H-3" and the name, trademark, or license number of the manufacturer, processor, producer, or initial transferor of the gun sight. The labeling is applied by engraving, stamping or painting depending on the size, housing material, and application.

Method: Label marking will be performed by an engraving device or by a pad-printing device using Tampapur TPU ink (or equivalent). This ink performs well when extremely high mechanical and chemical resistance is required. Similar inks have been used successfully by other companies in this industry.

Markings: Markings will be placed on the device and will be visible by the end-user (see attached drawing). The marking will include the brand name, or its abbreviated symbol, and the symbol "H3" followed by a one, two, or four digit marking. This marking will designate the manufacturing lot date. The trade names under which these devices will be distributed include AmeriGlo, ZONE 3, and USA. One of these names or its abbreviated symbol will be printed on each device.

3.2 PROTOTYPE TESTING

Testing was performed by AmeriGlo, LLC. Twenty-four (24) of various shapes of L and N series sights were subjected to each of the tests described in this test report. Of the 24 tested devices, 12 were L Series and 10 were N Series devices. Two devices were Type B and are not part of this application. Of the 24 tested devices, 10 were secured by means of a threaded fastener and 14 were secured by means of a friction fit.
Between each test, the gun sights were visually inspected to ensure if any detrimental effects had occurred. The gun sights did not become loosened or detached from the guns (tests 3.2.7 & 3.2.8) and the light sources did not become loosened or detached from the gun sights as a result of any of the tests. Once all of the tests were completed, the gun sights were subjected to leakage evaluation as shown in section 3.2.9.

Models Tested:

# Units tested	Series	Type	Length	Width	Height	# of Lamps
5	L	front	.430",.445", .465", .495", .495"	.140",.140", .140", .125", .125"	.160", .165", .165", .165", .165"	1 each
4	L	rear	.300", .300", .340", .340"	.690", .690", .755", .755"	.220", .220", .256", .256"	2 each
5	N	front	.425", .425", .425", .460", .500"	.140",.140", .140", .140", .140"	.160", .165", .165", .165", .165"	1 each
4	N	rear	.670", .830", .830", .830"	.730", .730", .745", .745"	.270", .435", .256", .256"	2 each

These prototype test devices are representative of the devices to be sold because:

1. They represent standard heights, widths, and lengths seen in the most common applications.
2. They were assembled by using the same materials and techniques specified in this application.
3. They have the same minimum wall thickness (0.015").
4. They utilize lamps that are manufactured under their own SSDR as specified in this application.

3.2.1 CHEMICAL

The gun sights were immersed for 48 hours at room temperature in each of the following:

Kleen Bore No. 10 Solvent

Kleen Bore Formula 3

Aervo Tef-Lube (meets MIL-C-372B)

Results: no damage (See AmeriGlo *Sealed Source Device Safety Evaluation Report*, **Attachment B1.)**

3.2.2 TEMPERATURE

High Temperature: The temperature of the gun sights was raised from ambient to 120°C and held at this temperature for one hour.

Low Temperature: The temperature of the gun sights was lowered from ambient to -46°C and held at this temperature for 48 hours.

Relative Humidity: The gun sights were placed in an environment of 95% relative humidity and a temperature of 42°C and held in this environment for 48 hours.

Results: no damage (See Advanced Compliance Solutions (ACS) *Test Data Summary* **Attachment B2.)**

3.2.3 TEMPERATURE SHOCK

The gun sights were heated to 80°C and held at this temperature for 15 minutes. The gun sights were transferred, within 15 seconds, to a cold chamber having a temperature of -46°C and held in this chamber for 15 minutes.

Results: no damage (See Advanced Compliance Solutions (ACS) *Test Data Summary* **Attachment B2.)**

3.2.4 VIBRATION

The gun sights were subjected to simple harmonic motion having an amplitude of 0.075 cm. The vibration cycle went from 10 Hz to 50 Hz and back again in approximately 1 minute. This was carried out for 10 cycles. Afterwards, the gun sights were subjected to 30 minutes of vibration at resonance frequency.

This test was carried out in each of the three principal axes of the gun sights.

Results: no damage (See Advanced Compliance Solutions (ACS) *Test Data Summary* **Attachment B2.)**

3.2.5 PRESSURE

The gun sights were placed in a test chamber and exposed to 0.25 and 2.0 bars for 4 periods of 15 minutes each, the pressure being returned to atmosphere between each period.

Results: no damage (See Advanced Compliance Solutions (ACS) *Test Data Summary* **Attachment B2.)**

3.2.6 PENETRATION

A hammer with a small point and weighing 10 g was dropped from a height of 1 meter onto the exposed surface of the light sources.

Results: no damage (See AmeriGlo *Sealed Source Device Safety Evaluation Report*, **Attachment B1.)**

3.2.7 MECHANICAL SHOCK

This test was performed with the gun sights attached to a gun which would have the most detrimental effect on the sight. The Mechanical Shock test was conducted using each of the same sights tested as were tested in the Penetration and other tests.

The gun was dropped from 2 meters onto a hard surface (2" thick 85 durometer rubber backed by concrete). The gun was dropped 60 times in such a manner that it struck the surface ten times in each of the following attitudes:

Barrel vertical, muzzle down

Barrel vertical, muzzle up

Barrel horizontal, bottom up

Barrel horizontal, bottom down

Barrel horizontal, left side up

Barrel horizontal, right side up.

Results: no damage (See AmeriGlo *Sealed Source Device Safety Evaluation Report*, **Attachment B1.)**

3.2.8 FIRING

This test was performed with the gun sights attached to the gun which would have the most detrimental effect on the sight. The gun was sequentially fired with 5010 rounds of ammunition with lapses only sufficient to allow reloading and servicing the weapon. The Firing test did not use all of the 24 sights. The Firing test was conducted using only one set of Type L and one set of Type N. Section 3.2.8 of the Testing Requirements states only one of each model needs tested in the Firing test.

Results: no damage (See AmeriGlo *Sealed Source Device Safety Evaluation Report*, **Attachment B1.)**

4 EVALUATION

After the tests were complete, all of the tested gun sights were immersed in 100 ml of water for 24 hours at ambient temperature. The volume of the water was about equal to 10 times that of the volume of an individual gun sight. After sights were removed, the activity of the solution was measured at the Environmental Radiation Branch of the Health and Environmental Systems Laboratory at the Georgia Tech Research Institute. A ten ml aliquot of the solution was measured in a liquid scintillation counter and compared with a standard tritium sample and two background samples. The net activity in the soak solution (sample "A") was less than 17 picocuries, well within the guideline of 50 nanocuries. One other water sample (without sights placed in it) was submitted as a control (sample "B").

See attached Georgia Tech Research Institute report, **Attachment B3 – Radioactivity Leak Testing**

Attachment B1 - Results of Prototype Tests conducted by Ameriglo, LLC

1.0 INTRODUCTION

This is a report of the results of prototype tests performed by AmeriGlo, LLC on self-luminous gunsights, L and N series. All tests were conducted in accordance with the NUREG-1556, Volume 8, CONSOLIDATED GUIDANCE ABOUT MATERIALS LICENSES, PROGRAM-SPECIFIC GUIDANCE ABOUT EXEMPT DISTRIBUTION LICENSES, Appendix O, *Standard Requirements for Gun Sights Containing Tritium Gas Sealed in Glass Vials.*

Twenty-four (24) of various shapes of L and N series sights were subjected to each of the tests described in this test report. Of the 24 tested devices, 12 were L Series and 10 were N Series devices. Two devices were Type B and are not part of this application. Of the 24 tested devices, 10 were secured by means of a threaded fastener and 14 were secured by means of a friction fit.

Sights were tested for the following:

- Chemical
- Penetration
- Mechanical Shock
- Firing

Between each test, the gun sights were visually inspected to ensure that there were no detrimental effects to the gun sights. The gun sights did not become loosened or detached from the guns (tests 3.2.7 & 3.2.8) and the light sources did not become loosened or detached from the gun sights as a result of any of the tests. Once all tests were completed, the gun sights were subjected to leakage evaluation in section 3.2.9.

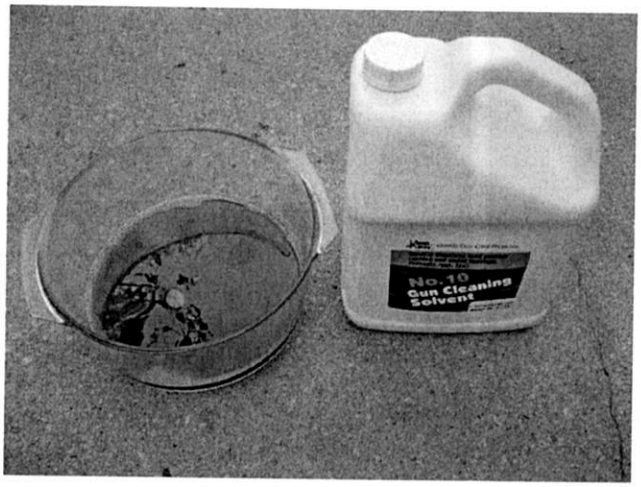
2.0 TESTING

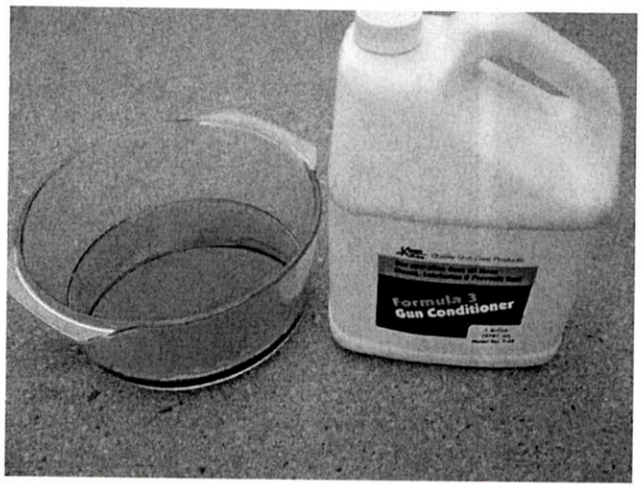
2.1 CHEMICAL TESTS

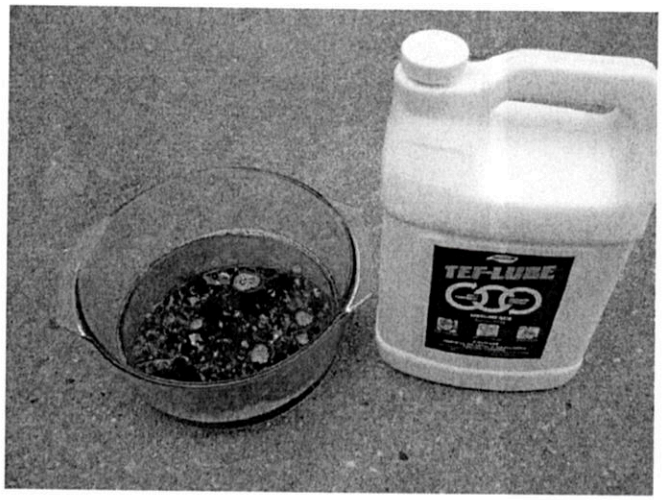
The gun sights were immersed for 48 hours at room temperature in each of the following:

- Gun Cleaning Solvent (Kleen Bore brand, No. 10 Gun Cleaning Solvent brand, commercial grade)
- Gun Cleaning Agent (Kleen Bore Formula 3, commercial gun cleaning agent)
- Tef Lube (commercial gun-cleaning agent equal to MIL-C-372B)

Photos of the tests are shown below. Visual inspection of the sights after the three tests were complete revealed no damage to the lamps or their mountings.


No. 10
Gun Cleaning
Solvent


Formula 3
Gun Conditioner


TEF-LUBE

2.2 PENETRATION TEST

A 10g weight with a point was dropped from a height of 1.0 meter onto the exposed surface of the light source of the sight.

This test was accomplished by placing the sight on a flat surface, with light sources facing upward. A small diameter tube was placed on top of the sight. The tube was 1 meter in length. The 10-gram weight was dropped down the tube, striking the exposed light source area.

The test was repeated for each of the sights.

After completion of the Penetration test the night sights were visually inspected. No damage was done to the tritium lamps or the housings.

2.3 MECHANICAL SHOCK TEST

The sights were mounted on a Remington 870 shotgun. This model shotgun was selected due to its weight, as it weighs 8.25 pounds and would have the most detrimental effect. This shotgun weight exceeds the weight of any gun that could utilize the night sights.

The gun was dropped a total of 60 times (10 times per attitude). The gun was dropped o a hard surface (2" thick, 85 durometer rated surface, backed by concrete). The gun was dropped in such a manner that it struck the surface in each of the following attitudes:

- Barrel vertical, muzzle down
- Barrel vertical, muzzle up
- Barrel horizontal, bottom up
- Barrel horizontal, bottom down
- Barrel horizontal, left side up
- Barrel horizontal, right side up

Upon completion of this test, the sights were inspected and no damage was observed.

2.4 FIRING

The firing test was performed on a Glock model 31, a .357 caliber handgun. The Glock pistol is the most popular brand handgun in the USA. Millions are used by law enforcement, military, target shooters, and defense minded citizens. This gun was chosen due to its high muzzle energy and its quick slide velocity.

To test the sights we selected a cartridge larger than the normal 9mm round (the most popular round used in USA). Corbon 115 grain, jacketed hollow point ammunition was used. This ammunition produces 575 foot pounds of muzzle energy and 1500 feet per second travel.

The sights were mounted to the handgun's slide. When the weapon is fired, the slide (with sights attached) cycles. The cycling of a Glock slide using the Corbon hollow-point ammunition is faster/harder than the popular 9mm and .45 caliber handguns. We did not choose to use a small caliber weapon like a .22 caliber as this would not represent the average use of the sights.

The gun was fired with 5010 rounds of ammunition sequentially. Lapses were made only to reload and service the weapon. The Firing test did not use all of the 24 sights. The Firing test was conducted using only one set of Type L and one set of Type N. Section 3.2.8 of the Testing Requirements states only one of each model needs tested in the Firing test.

Upon completion of this test, the sights were inspected and no damage was observed.

3.0 EVALUATION

After all tests were completed, the gun sights were immersed in water for 24 hours at ambient temperature. The volume of the water was about ten times that of the volume of the sights, or approximately 100 ml. The gun sights were removed and the solution, identified as sample A, was sent to the Georgia Tech Research Institute's Environmental Radiation Branch for liquid scintillation analysis. A control solution, identified as sample B, without exposure to gunsights, was also sent for analysis. The results in **Attachment B3** show that the tritium concentration was undetectable at a minimum detectable concentration of <170 pCi/l or approximately 17 pCi total activity in the entire 100 ml volume of solution. This is well within the 50 nCi guideline for leakage. The control also showed no detectable tritium activity.

4.0 CERTIFICATION

I certify that the following tests were conducted under my supervision on September 14 to 17, 2005:

1. Chemical Test
2. Penetration Test
3. Mechanical Shock Test
4. Firing Test

per NUREG 1556, Vol. 8 Appendix O

_____

Rick Callihan, Director of Operations
AmeriGlo, LLC

Attachment B2 – Mechanical and Environmental Testing Conducted by ACS, Inc.

Note: The following test report by Advanced Compliance Solutions, Inc. was performed for Ameriglo, LLC. The items tested are those that had gone through the firing test performed by Ameriglo. Markups in **red** show the present model designations, Series L and N, as they correspond to the older nomenclature used during the tests (RS and FS series Types A and B). The gun sight designs have not changed since the time of testing, only the models' letter designations have changed as shown.

Note: An error in the page numbering in the original ACS report has been corrected in the submission below.

Advanced Compliance Solutions, Inc.
www.acstestlab.com

Test Data Summary

Manufacturer: Ameriglo Models:		New Series Designation
FS1A	front sight series 1, type A	N
FS1B	front sight series 1, type B	L
FS2A	front sight series 2, type A	N
RS1A	rear sight series 1, type A	N
RS1B	rear sight series 1, type B	L
RS2B	rear sight series 2, type A	N

ACS Report: 05-0315
Revision C

Issue Date: November 7, 2005

This test report shall not be reproduced except in full. This report may be reproduced in part with prior written consent of ACS, Inc. The results contained in this report are representative of the sample(s) submitted for evaluation.

This report contains 7 pages

Table of Contents

1.0 Temperature Shock	3
2.0 Vibration	4
3.0 Pressure	6
4.0 Humidity	7
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1.0 Temperature

Test Details: 120C/-46C for 15 minutes in each temperature. Test Performed: YES

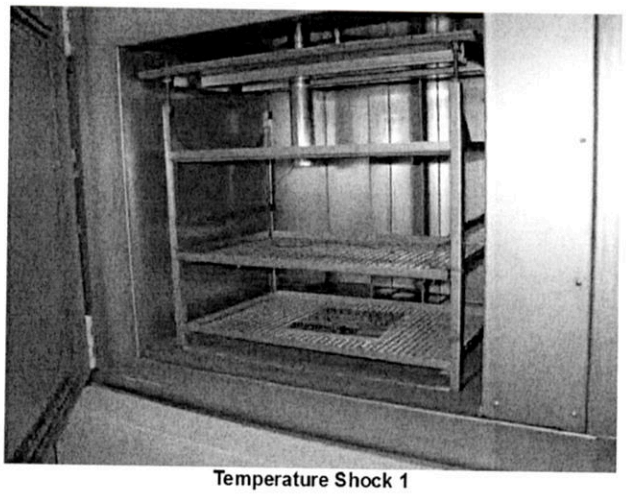
TEMPERATURE

High Temperature: The temperature of the gun sight was raised from ambient to 120C and held at this temperature for one hour.

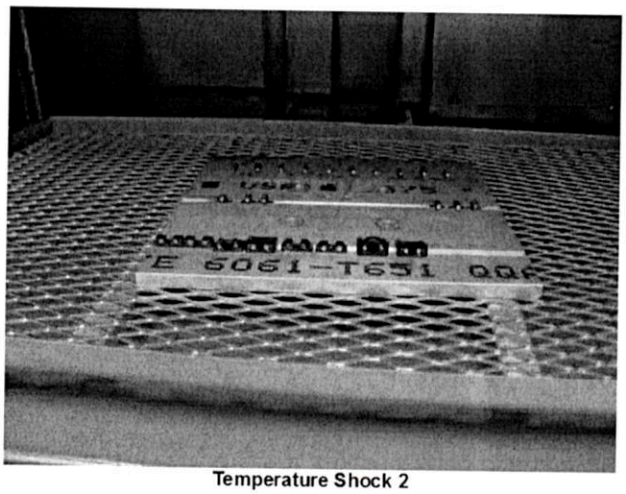
Low Temperature: The temperature of the gun sight was lowered from ambient to -46C and held at this temperature for 48 hours.

TEMPERATURE SHOCK

The gun sight was heated to 80C and held at this temperature for 15 minutes. The gun sight was transferred, within 15 seconds, to a cold chamber having a temperature of -46C and held in this chamber for 15 minutes.



Temperature Shock 1



Temperature Shock 2

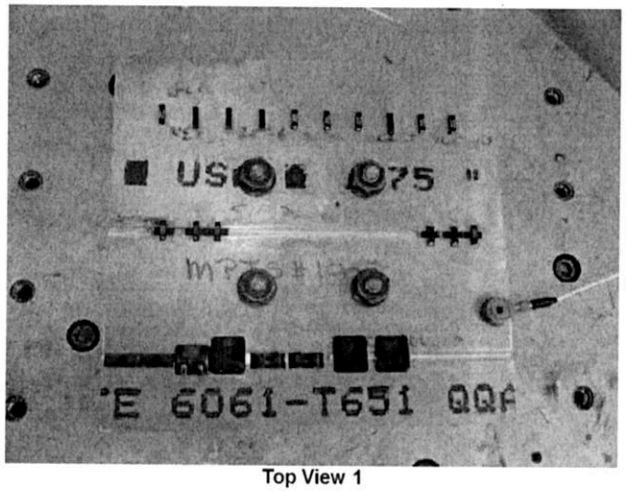
2.0 Vibration

Test Details: Sweep constant acceleration of 0.5g. Test Performed: YES

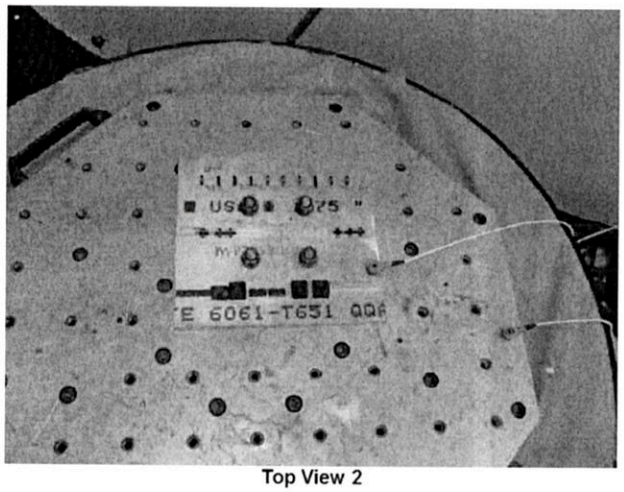
VIBRATION

The gun sight was subjected to simple harmonic motion having an amplitude of 0.075 cm. The vibration cycle went from 10Hz to 50 Hz and back again in approximately 1 minute. This was carried out for 10 cycles. Afterwards, the gun sight is to be subject to 30 minutes of vibration at resonance frequency.

This test was carried out in each of the three principal axes of the gun sight.



Top View 1



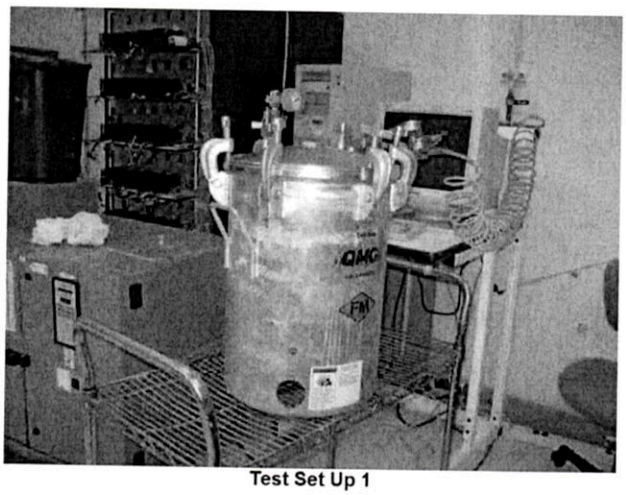
Top View 2

3.0 Pressure

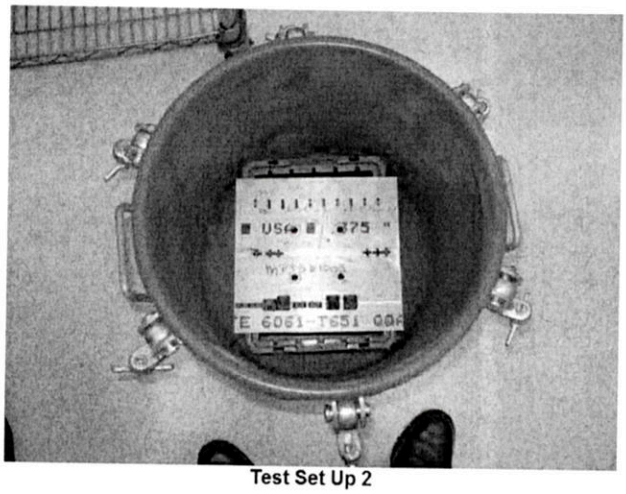
Test Details: 0.25 and 2.0 bars for 4 cycles of 15 minutes each. Test Performed: YES

PRESSURE

The gun sight was placed in a test chamber and exposed to 0.25 and 2.0 bars for 4 periods of 15 minutes each, the pressure being returned to atmosphere between each period.



Test Set Up 1

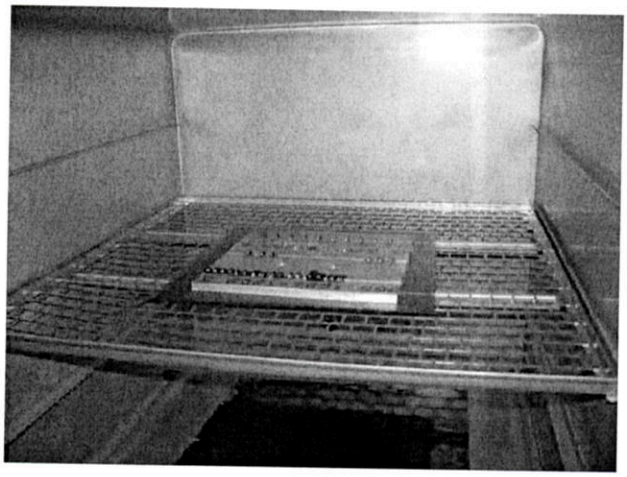


Test Set Up 2

4.0 Humidity

Test Details: 71C for one (1) hour, -46C for 48 hours and 42C at 95%RH for 48 hours. Test performed: YES

Relative Humidity: The gun sight was placed in an environment of 95% relative humidity and a temperature of 42 C and held in this environment for 48 hours.



5.0 Conclusion

After a visual inspection in a dark room, all tritium lamps were visible. Evaluation of the products under test, after testing, was the responsibility of the client.

Attachment B3 – Radioactivity Leak Testing

Note: The following test report by the George Tech Research Institute was performed for Ameriglo, LLC. The devices tested are those that had gone through both the firing test by Ameriglo and vibration / environmental testing by ACS.

All twenty-four test samples were immersed in 100 ml water for 24 hours. The total volume of the 24 parts is approximately 17 ml.

MAR-2-2006 11:36P FROM:AMERIGLO 7703909781 TO:17202941153 P.1/1

Georgia Tech Research Institute

September 27, 2005

Mr. Rick Callihan
Ameriglo
5579b Chamblee Dunwoody Road, Suite 214
Atlanta GA 30338

Dear Mr. Callihan:

In response to your request, we analyzed for tritium content the two water samples marked A and B that you brought to the laboratory on Sept. 23, 2005. The results are as follows, in units of picocurie per liter:

Sample ID	Tritium concentration, pCi/L
A	< 130
B	< 130

Ten-ml samples aliquots of each sample were measured in a liquid scintillation counter and compared with a standard tritium sample and two background samples. The net count rate was below the 3-sitandard deviation uncertainty represented by the "less-than" values shown above.

Please let me know if we can provide any further information.

Sincerely yours,

Bernd Kahn

Bernd Kahn
Head, ERB

Encl.

Environmental Radiation Branch
Health and Environmental Systems Laboratory
Georgia Tech Research Institute
Georgia Institute of Technology
Atlanta, Georgia 30332-0841 U.S.A.

A Unit of the University System of Georgia - An Equal Education and Employment Opportunity Institution

Attachment C – AmeriGlo QMS Manual (see separate file Ameriglo QMS.pdf)

Attachment D – Radioactive Materials License GA-1654-1

Georgia Department of Natural Resources

Environmental Protection Division, Air Protection Branch
4244 International Parkway, Suite 120, Atlanta, Georgia 30354
Judson H. Turner, Director
404-363-7000

RADIOACTIVE MATERIALS PROGRAM

GEORGIA RADIOACTIVE MATERIALS LICENSE

Pursuant to the Georgia Radiation Control Act O.C.G.A. 31-13 (H.B. 947) 1990 and the Georgia Department of Natural Resources Rules and Regulations, designated Chapter 391-3-17, and in reliance on statements and representations heretofore made by the licensee designated below, a license is hereby issued authorizing such licensee to transfer, receive, possess, and use the radioactive material(s) designated below; and to use such radioactive materials for the purpose(s) and at the place(s) designated below. This license is subject to all applicable rules and regulations of the Georgia Department of Natural Resources and orders issued by the Department, now or hereafter in effect, and to any condition specified below.

Amendment No. 1

Licensee	
1.Name AmeriGlo Corporation	3. License Number GA 1654-1
2.Address 5579-B Chamblee Dunwoody RD STE 214 Atlanta, GA 30338	4. Expiration Date December 31, 2018
	5. Telephone Number: (678) 520-5677 Fax Number:

6. Radioactive Material (Element and Mass Number)	7. Chemical and/or Physical Form	8. Maximum Quantity Licensee May Possess at One Time
A. Hydrogen-3 (Tritium)	A. Gas or gas in solution: Gas, contained in self-luminous light sources used to create gun sights.	A. 2000 Curie(s) total. 30 millicuries per source, not to exceed 90 millicuries per device.

CONDITIONS

9. Authorized use.

   A. A. For possession and storage, incidental to distribution to persons exempt from regulation, of gaseous tritium light sources (GTLS's), which are affixed into metal or plastic housings to create illuminated gun sights. This license does not authorize commercial distribution of radioactive material.

10. Radioactive materials shall only be used at the following location(s):

AmeriGlo Corporation, 645 Hembree PKWY STE K
Roswell, GA 30076

Georgia Department of Natural Resources

Radioactive Materials License
Supplementary Sheet

License Number: GA 1654-1
Amendment No. 1

11. The following shall be responsible for the licensee's radiation protection program

Richard Callihan — Radiation Safety Officer

12. Radioactive material listed in Item 6 above is authorized for use by individuals for the materials and uses described as follows:

Radioactive material shall be used by or under the supervision of an individual listed below:

Richard Callihan . — Subitem(s) A

13. In accordance with DNR Board Policy adopted June 25, 2013 the fees associated with this license fee category, C.6.c, are:

Nominal Annual Fee — $1,813.00

Checks for the fees should be made payable to the Department of Natural Resources, Radioactive Materials Program, and mailed to the following address:

Radioactive Materials Fees
P.O. Box 101161
Atlanta, GA 30392

Mail license applications and amendment requests to the following address:

Radioactive Materials Program
4244 International Parkway, Suite 120
Atlanta, Georgia 30354

All license applications, amendments and fee payments should be mailed the same day. Annual fees are billed by the Department at the beginning of each fiscal year.

14. The licensee shall comply with the provisions of Georgia Department of Natural Resources Rule 391-3-17-.03, "Standards for Protection Against Radiation, Amended."; Rule 391-3-17-.06, "Transportation of Radioactive Material, Amended."; Rule 391-3-17-.07, "Notices, Instructions and Reports to Workers: Inspections, Amended."; and Rule 391-3-17-.10, "Administration. Amended."

15. Sealed sources containing radioactive material shall not be opened by the licensee.

16. This license does not authorize commercial distribution of licensed material to persons exempt from licensing pursuant to (3)(b) of Rule 391-3-17-.02.

17. The licensee shall conduct a physical inventory every 6 months to account for all licensed material

Georgia Department of Natural Resources

Radioactive Materials License
Supplementary Sheet

Page 3 of 3
License Number: GA 1654-1
Amendment No. 1

received and possessed under this license. The records of inventories shall be maintained for inspection by the Department and shall include the quantities and kinds of radioactive material, the manufacturer, the model and serial numbers if applicable, the location of radioactive material, the date of the inventory, and the name of the individual performing the inventory.

18. The licensee shall possess and use radioactive material described in Items 6, 7 and 8 of this license according to the most restrictive of the Georgia Radiation Protection Regulations; this license or statements; representations; and procedures contained in the following documents.

    A. The application dated October 27, 2013, signed by Richard Callihan, General Manager, with attachment(s).

    B. **Letter dated October 1, 2014, signed by Rick Callihan.**

    C. **Electronic mail dated November 14, 2014 with attachment dated November 10, 2014.**

The Georgia Department of Natural Resources' Regulations shall govern unless the statements, representations and procedures in the licensee's application and correspondence are more restrictive than the Regulations.

FOR THE DEPARTMENT OF NATURAL RESOURCES

Date November 26, 2014

By: _____

Greg Reese
Environmental Compliance Specialist

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AMERIGLO

Quality Management System (QMS) Manual

This manual describes the Quality Management System format and structure that has been detailed and implemented to meet the ISO 9001 Quality Management Systems – Requirements Standard

The Quality Management System as defined in this document is effective as of December 1, 2015

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1 Scope

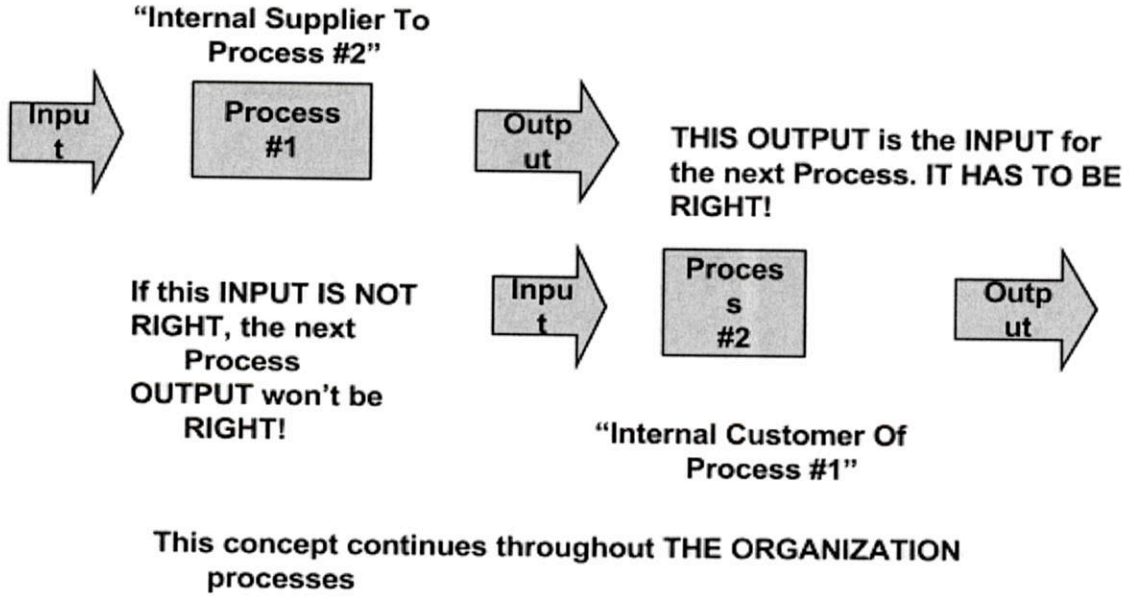
1.1 Scope of Quality Management System

The design, production, processing and distribution of weapons sights and chemluminescent light sticks for the military, law enforcement community, defense minded citizens, recreational shooters and outdoor enthusiasts.

1.2 General

This manual describes the Quality Management System (QMS) format and structure that has been detailed and implemented within the organization in order to meet the ISO 9001:2008 Quality Management Systems. It is developed following the standard numbering system to facilitate the understanding and interaction of the supporting documentation. If there is a conflict between the requirements of the standard and statutory or regulatory requirements the latter takes precedence.

The QMS is based upon the "Process Approach." As such it focuses on the fact that within the organization employees working in a process have "Internal Suppliers" and "Internal Customers." This concept is described in the following diagram;



Each process of the QMS is assigned a Process Owner by Management .The responsibilities of a Process Owner are but not limited to:

a) Making sure the Process is defined,
b) Making sure employees that need to be trained in the Process are trained (training can be delegated) and,
c) Being a contact person for employees if they have questions regarding the process, or have ideas to improve the process,
d) Conduct an annual self-assessment of process.

In the event a Process Owner is not available the Management Representative will fulfill the responsibilities in the interim. This is communicated to those responsible for the implementation of the process requirements.

1.2.1 About Us

The AmeriGlo organization supplies photo-luminescent weapons sights and light sticks to world markets and individual citizens.

1.3 Application

The requirements of the ISO 9001 QMS - Requirements International Standard are implemented within the organization.

2 References

a) ISO 9001:2008 Quality Management Systems ~ Requirements

3 Terms and Definitions

a. Quality Management System – Shown as QMS

b. Product Realization ~ The act or action of bringing our product into effect, from reviewing customer requirements to delivering it to the intended destination.

c. Process ~ A set of interrelated activities that transform “Inputs” into “Outputs.”

d. When the term "includes but not limited to" is used in the QMS it means that as a minimum one of the items listed applies. Other items apply as appropriate to the process.

e. Supplier ~ Any external organization or company that provides AmeriGlo with product or services.

f. Reference Documents - These include but not limited to trade magazines, or training course manuals. These are not considered controlled external documents.

g. Risk ~ Any undesirable situation or circumstance that has both a likelihood of occurring and a potentially negative consequence.

h. Special Requirements ~ Requirements both identified by our customers or internally that have a high risk of being achieved and are therefore included in the risk management process.

i. Critical Items ~ Items that have a significant effect on the product realization and the use of the product that require specific actions to ensure they are adequately managed.

j. Key Characteristics ~ An attribute or feature whose variation has a significant effect on product form, fit, function, producibility, service life or producibility that requires action for controlling variation.

k. Repaired Material/Assemblies ~ Material/assemblies that have been subject to reprocessing to render the item functional, but deviates in form from the drawings, contract, specifications, or applicable product descriptions. Repair may require a customer-approved procedure.

l. Reworked Material/Assemblies ~ Material/assemblies that have been subject to reprocessing to restore the item to the original characteristics in accordance with the requirements of the drawings, contract, specifications, or applicable product descriptions.

m. "Use as is" Material/Assemblies ~ Material/assemblies with minor nonconformance's, accepted by the customer when the material/assemblies are determined to be satisfactory for its intended purpose.

4 Quality Management System

4.1 General Requirements

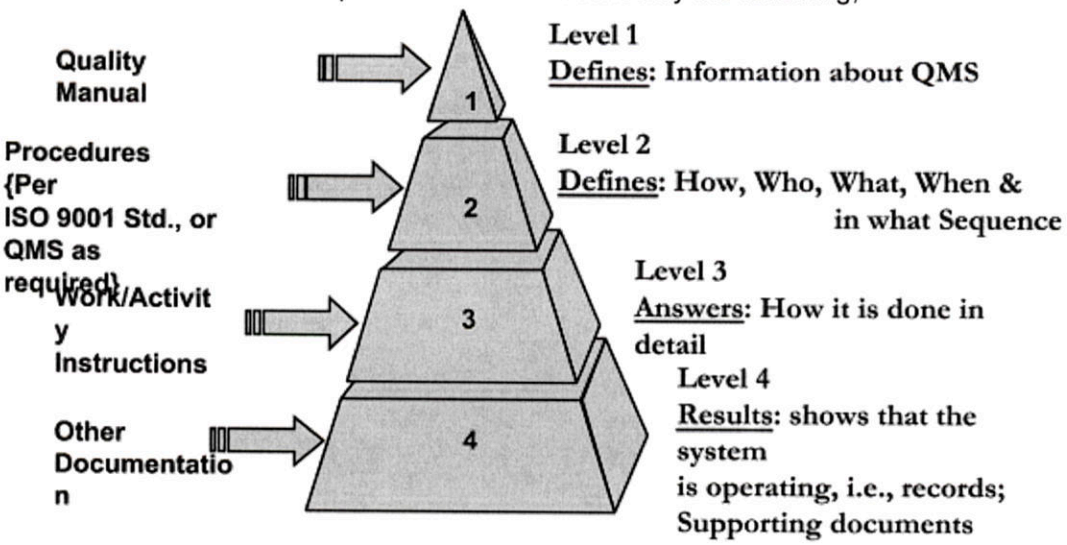
The organization has established documented, implemented and maintains its QMS and continually improves its effectiveness in accordance with the requirements of this Quality Manual, specific industry and any customer related requirements. Activities are performed using the Process Approach.

When the organization chooses to outsource any processes that affect product conformity, controls are in place so that requirements are met. Control of these outsourced processes is defined in the various purchasing documents sent to suppliers.

4.2 Documentation Requirements

4.2.1 General

The structure of the QMS implemented is established by the following;



Source: ANSI/ISO/ASQ Q10013-1995 Guidelines for Developing Quality Manuals

The organization QMS documentation includes:

a) A Quality Policy,
b) Applicable Quality Objectives,
c) This Quality Manual,
d) Documents needed to ensure the effective planning, operation and control of its processes, and
e) Records required by the QMS that are used to prove that requirements have been followed.
f) Quality System Requirements that are imposed by regulatory authorities

Our employees have been trained in the relevant QMS procedures and/or processes that impact the job tasks that they perform and they have access to this documentation.

Customers and regulatory authority personnel have access to the QMS documentation in accordance with their contract or regulatory requirements. They may deal with the Management Representative in matters related to the QMS.

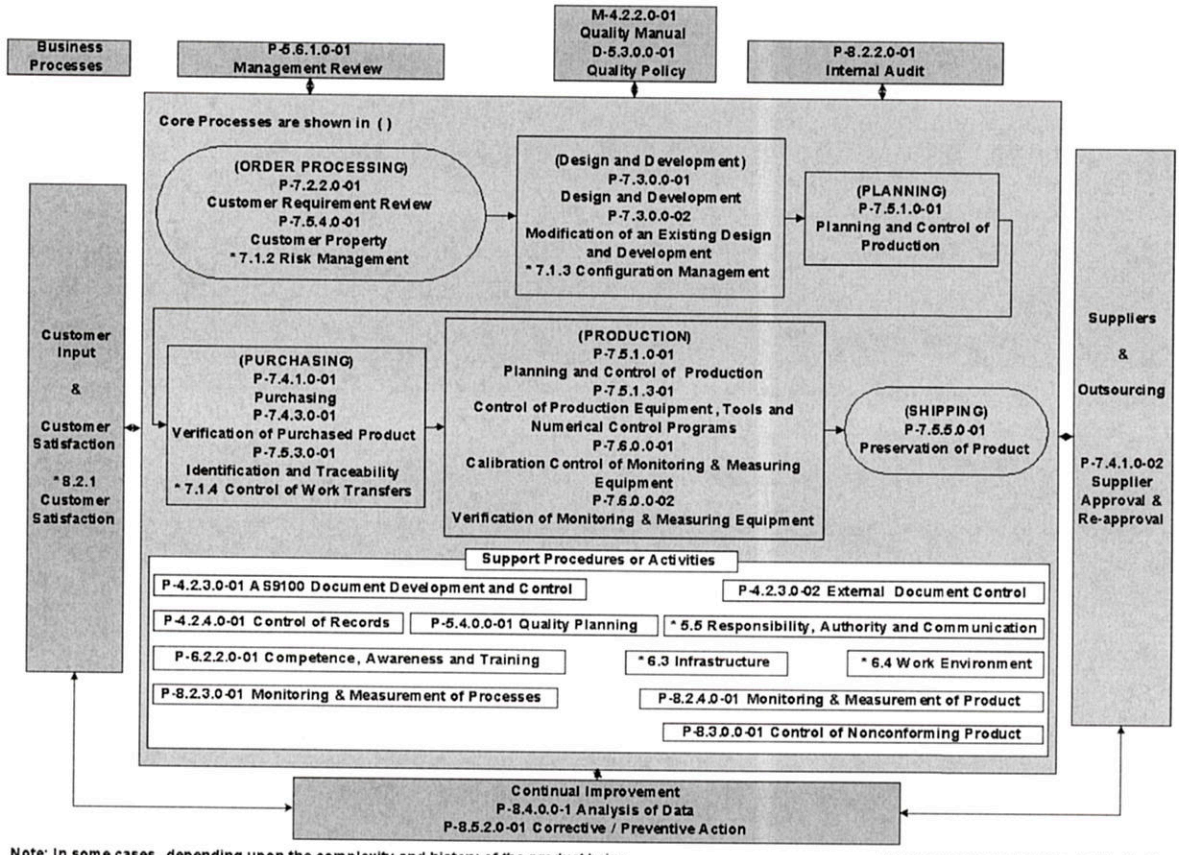
4.2.2 Quality Manual

This Quality Manual includes:

a) The scope of the QMS, including details of and justification for any exclusions,
b) Reference to the documented Level 2 Procedures or forms. Level 2 Procedures are numbered according to the clauses of the standard and are referenced in **bold parenthesis ( )** after the ISO 9001 Clause. If a Level 2 procedure or form is referenced in another clause it is shown in bold print, and
c) A description of the interaction between the processes of the QMS is shown in the following diagram

4.2.2.1 Interaction of Processes

(D-4.2.2.0-01 Interaction of Processes Diagram)



The diagram above depicts the Sequence and Interaction of the Processes that define the QMS. It begins with the input from the customer shown on the left hand side. Once received, the **Core Processes** shown **(in ( ))** are followed. If a procedure exists to define the method of control of that process it is shown in the diagram. The numbering is according to the **P-4.2.3.0-01 ISO 9001 Document Development and Control Procedure**. If a procedure does not exist, the process is defined in the Quality Manual and is shown by an * prefix in the process block. The support processes are shown below the Core Processes and interact with these processes. On the right side is shown the interaction of the Suppliers and Outsourcing activities. At the bottom of the diagram the Continual Improvement Processes are shown. The double-headed arrows indicate that there is input and output from the Continual Improvement Process to the Customer, Suppliers as well as the Organization Core and Support Processes

The Management Review, and Internal Auditing shown at the top of the diagram are the processes in place to assure that the QMS is implemented and effective. If there are action

items to be addressed to improve the QMS they are implemented with the oversight of management.

In some cases all of the processes shown may not be needed based upon the complexity, history of product being purchased/distributed.

4.2.3 Control of Documents

(P-4.2.3.0-01 ISO 9001 Document Development and Control Procedure, P-4.2.3.0-02 External Document Control Procedure) Documents required by the QMS are controlled. Flowcharting Software is used to document the Procedures for the "Core and Support processes." If a procedure does not exist for a given requirement the process used is described in the quality manual.

These procedures are established to ensure that processes have been implemented to assure that the organization's QMS meets the ISO 9001 standard, as well as customer, statutory and regulatory defined requirements as they apply to the product that is supplied.

Process/Procedure Owners determine if Procedures are required other than those required by the standard to control processes. If they are, the QMS has requirements as needed:

a) To approve documents for adequacy prior to issue,
b) To review and update as necessary and re-approve documents,
c) To ensure that changes and the current revision status of documents are identified,
d) To ensure that relevant versions of applicable documents are available at points of use, either in the computer system or hard copies,
e) To ensure that documents remain legible and are identified,
f) To ensure that documents of external origin determined by the organizations to be necessary for the planning and operation of the quality management system including customer and industry standards are identified and their distribution controlled, and
g) To prevent the unintended use of obsolete documents, and to apply suitable identification to them if they are retained for any purpose, such as customers ordering product to previous revisions.

Previous and obsolete versions of documents kept for any reason are identified by a note, stamp or sticker placed on the document or in the computer system specifying why it is being kept. The person putting the identifier dates and initials it.

Document changes are coordinated with customers and/or regulatory authorities when required by contract or regulatory requirements.

Process Owners are also an integral part of the continual improvement process and are consulted by the Management Representative or Supervisor when changes are recommended.

If temporary changes or mistakes are corrected they are noted in pen, the current requirement is crossed out by drawing a line through it and so noted by the initials of the employee making the change and the date. This allows traceability to the person making the change or correcting the mistake.

Any notes for information purposes that are put on a document are so noted with the initials or signature of the person who did it and the date.

4.2.4 Control of Records

(P-4.2.4.0-01 Control of Records Procedure) QMS Records are established and maintained to provide evidence of conformity to requirements and of the effectiveness of the QMS. The identification, storage, the minimum retention time and disposal (how to destroy a record) methods are defined during the development of the QMS. A master record list is maintained. Retention times are determined by but not limited to customer, internal or regulatory requirements. Records are reviewed during the planned internal audits. The procedure defines the method for controlling records that are created by and/or retained by suppliers. This is communicated to the suppliers through purchasing and/or quality when it applies.

5 Management Responsibility

5.1 Management Commitment

The Quality Policy and relevant Quality Objectives are directly a result of Management's commitment to the QMS. The organization management shows its commitment to the development and implementation of the QMS and continually improving its effectiveness by continually keeping a pulse on the business by talking to employees, soliciting their input as well as walking around the facility on a regular basis. In addition the organization management assures that employees are aware of the importance in meeting customer and supporting organizations (federal, state, or local) requirements.

The scheduled Management Reviews are a means of enforcing this commitment to the registrar, customers, employees and stakeholders. The discussion of and identification of

resource needs is an integral part of the Management Review.

5.2 Customer Focus

The organization Management ensures customer requirements are reviewed, determined and met with the aim of enhancing customer satisfaction.

Product conformity and on-time delivery performance are measured. If the performance measures show a need for improvement the appropriate QMS processes are utilized.

5.3 Quality Policy

(D-5.3.0.0-01 QUALITY POLICY)

AmeriGlo is committed to supplying customers with quality firearm accessories and personal and public safety products at competitive prices, while also satisfying customers' delivery and technical support requirements.

We will provide aiming solutions and shooter's accessories for the firearms, law enforcement, Special Forces, military, hunting, and recreational shooter communities.

We will build strong relationships with our independent sales representatives and customers, committing ourselves to their success by supplying quality products, enthusiastic marketing support and exceptional customer service.

To accomplish these goals, we will continue to be an innovative company that is committed to meeting customer requirements while operating in full compliance with all regulatory guidelines and striving for continual improvement of our Quality Management System.

This Quality Policy is evaluated during Management Reviews to determine its continued suitability.

5.4 Planning

(P-5.4.0.0-01 Quality Planning Procedure) This procedure helps define and establish Quality Objectives within the organization.

5.4.1 Quality Objectives

(P-5.6.1.0-01 Management Review Procedure,

P-8.4.0.0-01 Analysis of Data Procedure) the organization determines measurable quality objectives as part of the Management Review process. The quality objectives are communicated to the relevant employees in the workforce via posting of the appropriate metric and goal and discussed at periodic employee meetings. Specific product related quality objectives may be identified at any point within the QMS. These objectives are documented and are reviewed as a minimum at the semi-annual Management Reviews.

5.4.2 Quality Management System Planning

(P-5.6.1.0-01 Management Review Procedure,
P-7.2.2.0-01 Customer Requirement Review Procedure,
P-8.2.3.0-01 Monitoring and Measurement of Processes Procedure,
P-8.4.0.0-01 Analysis of Data Procedure and,
P-8.5.2.0-01 Corrective/Preventive Action Procedure).

QMS planning starts with the Management Review Process. Inputs to the Management Review Process include but are not limited to:

a) The organization Business Strategies from Customer Requirements Review **(P-7.2.2.0-01 Customer Requirement Review Procedure)**
b) Internal and External Audit findings and actions **(P-8.2.2.0-01 Internal Audit Procedure)**
c) Corrective and Preventive Action reviews **(P-8.5.2.0-01 Corrective/Preventive Action Procedure)**
d) Metrics and associated Quality Objectives **(P-5.6.1.0-01 Management Review Procedure and P-8.4.0.0-01 Analysis of Data Procedure)**

Improvements to the QMS are implemented via input from employees, management as well as the use of the Corrective/Preventive action system **(P-8.5.2.0-01 Corrective/Preventive Action Procedure)** and controlled via ISO 9001 Document Control **(P-4.2.3.0-01 ISO 9001 Document Development and Control Procedure)**. Effectiveness of these improvements is monitored on an ongoing basis via the Internal Auditing Process **(P-8.2.2.0-01 Internal Audit Procedure)**

5.5 Responsibility, Authority and Communication

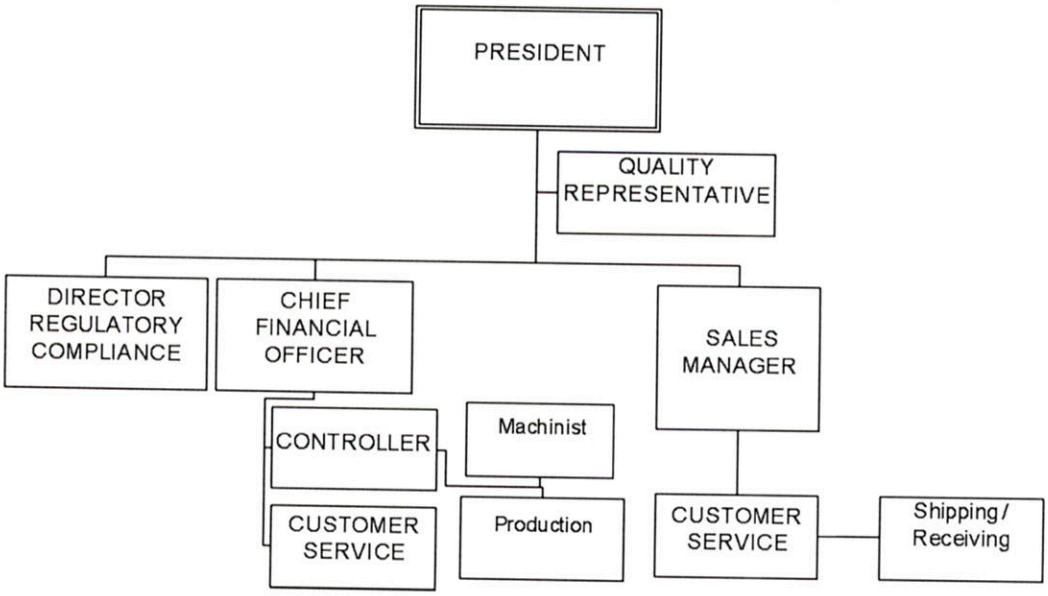
5.5.1 Responsibility and Authority

The Organizational charts below show the departmental reporting hierarchy. Job Duties exist for each position within the organization. When a requirement in the QMS is to be performed by an employee (designated by title, position or name) the responsibility and authority can also be carried out by a management appointed designee.

Top Management is defined by the **President. Chief Financial Officer, General Manager, Radiation Safety Officer (RSO) and the Management Representative.**

5.5.1.1 Organizational Charts

AMERIGLO ORGANIZATIONAL CHART



QMS Responsibilities for all employees include but are not limited to:

a) Knowing the QMS requirements as they relate to them
b) Comply with the organization Policies and Procedures Manual
c) Comply with regulatory and statutory requirements

d) Knowing and explaining the Quality Policy in their own words and how they impact carrying out the requirements of the policy in the job that they do
e) Maintaining a professional atmosphere
f) Performing their essential job functions as defined by job duties and,
g) Upholding the integrity of the organization

QMS Authorities for all employees include but are not limited to:

a) Recommending Corrective/Preventive Actions
b) Stopping processes if they find requirements are not being met
c) Initiating Continual Improvements in customer satisfaction, processes and safety.

5.5.2 Quality Representative

Duties of the Quality Representative include but are not limited to:

a) Ensuring that processes needed for the QMS are established, implemented and maintained,
b) Assuring that the relevant versions of the procedures, documents and forms are available at points of use,
c) Reporting on the performance of the QMS and apparent needs for continual improvement,
d) Ensuring the promotion of awareness of customer requirements throughout the organization,
e) Ensuring employees are trained in the relevant requirements of the QMS and,
f) Having unrestricted access to top management and the organizational freedom to resolve matters pertaining to quality management.

The responsibilities of the Quality Representative may also include liaison with customers or potential customers, regulatory agencies, other interested external parties including the ISO 9001:2008 registrar, on matters relating to the QMS implemented.

5.5.3 Internal Communication

The organization management ensures that adequate communication of the effectiveness of the QMS is essential for the business. Effectiveness of the QMS is included in the agenda for the Management Reviews.

The organization believes that communication is essential in ensuring that the organization operates effectively within the QMS requirements and that we deliver quality products and service to our customers.

Communication is a process for exchanging information effectively and efficiently within the organization. The organization communicates between our employees, in appropriate, professional, respectful, easy to understand and fair methods. These methods of communication include employee meetings, e-mail, postings on bulletin boards and/or departmental meetings.

Examples of topics that are communicated may include but are not limited to: Customer Complaints, Nonconformance's, QMS, Internal audit results, Registrar audit results, Customer audit results, Customer visits, status of Corrective/Preventive actions, customer scorecards, and safety issues.

Corrective Actions and Preventive Actions and QMS enhancements are documented via the **(P-8.5.2-01 Corrective/Preventive Action Procedure, P-5.6.1.0-01 Management Review Procedure).**

5.6 Management Review

5.6.1 General

(P-5.6.1.0-01 Management Review Procedure) Top management, as defined in Clause 5.5.1, conducts a yearly review of the defined and implemented QMS. The review is held in the first quarter. Additional or special management reviews may be held due to business issues. If there are any additional ones, the same format is followed. Participation in these meetings can be in-person or via phone/video conferencing.

As a minimum the attendees include the **President, CFO, RSO, the Quality Representative and others as deemed necessary depending upon the topic being discussed.** The **Quality Representative** facilitates the meeting. The agenda of these meetings, as well as the report for these sessions is documented on form **F-5.6.1.0-01 Management Review Agenda & Minutes Form.** The agenda form is retained as the record of these reviews in accordance with **(P-4.2.4.0-01 Control of Records Procedure).**

5.6.2 Review Input

The inputs to these reviews contain, but are not limited to:

a) Previous Management Review action items,
b) Quality Policy Applicability to changes in our business climate,
c) Status of Quality Objective(s),

d) Status of Internal and/or External Audits,
e) Customer feedback,
f) Process Performance metrics,
g) Product Conformity metrics,
h) Status of Corrective and Preventive Actions,
i) Potential changes to the QMS driven by customer or internal requirements, and
j) Supplier Performance

5.6.3 Review Output

The outputs of the review, documented on the same agenda form, contain, but are not limited to:

a) Changes to improve the effectiveness of the QMS,
b) Continuous improvement actions to improve our products,
c) Resource and training needs and,
d) Action items and assigned responsibilities

6 Resource Management

6.1 Provision of Resources

The organization management reviews, determines and provides the resources needed to:

a) Implement and maintain the QMS and continually improve its effectiveness, and
b) Enhance customer satisfaction by meeting customer requirements.

These resources are determined during the various planning stages of product realization or QMS continual improvement efforts. Modification or changes to resource needs varies depending upon business need.

6.2 Human Resources

6.2.1 Competence, Awareness and Training

(P-6.2.2.0-01 Competence, Awareness and Training Procedure). Trained employees are used to perform the activities required by the processes of the organization QMS. The organization management:

a) Determines the necessary competence for personnel performing work affecting conformity to product requirements. This is determined by but not limited to one or more of the following: Experience, Comprehension, Skills, Reliability and Knowledge,
b) Where applicable provides training or takes other actions to achieve the necessary competence,
c) Evaluates the effectiveness of the appropriate actions taken,
d) Ensures that its personnel are aware of the relevance and importance of their activities and how they contribute to the achievement of the quality objectives, and
e) Maintains appropriate records of education, training, skills and experience.

6.3 Infrastructure

Infrastructure requirements are driven by customer needs or our desire to grow the business for continued success. Employee suggestions for infrastructure improvements are an integral part of this effort and are documented via F-6.3.0.0-01 Work/Improvement /Preventive Request Form.

For the facility, management determines, provides and maintains the infrastructure needed to achieve conformity to product and customer requirements. Infrastructure related items may be part of yearly plans and accounted for in departmental/facility budgets. In some cases, additional approvals for capital spending may require management/financial approval over and above the budget requirements.

Infrastructure includes, as applicable:

a) The building, shelving, aisle ways, office/warehouse space, and associated utilities,
b) Internet service, fax machines, phones, postal equipment, copiers, computer hardware and software, website, , information systems and
c) Trucking companies and common carriers.

Maintenance of buildings, workspace components, communication ~ including phones are the responsibility of the management. These items are repaired on- as needed basis. The supplier work order or invoice is the method of verifying that the maintenance was performed.

Computer systems are considered critical support infrastructure and the data on them is backed up daily to mitigate the potential risk for loss of information.

6.4 Work Environment

The organization management determines and manages the work environment needed to achieve conformity to product requirements. Work environment requirements are established by internal needs as well as regulatory and statutory requirements. These requirements may relate

to building or employee issues. Work environment related items may be part of yearly plans and accounted for in departmental/facility budgets. In some cases, additional approvals for capital spending may require management/financial approval over and above the budget requirements.

Work Environment includes but is not limited to:

a. Workplace Security,
b. Workplace Safety,
c. Internal Work Location,
d. Workplace Amenities,
e. Heating Ventilation & Air Conditioning,
f. Electric, water, lighting, parking, furnishings,
g. Cleanliness

Criteria may be governed by one or more of the following including but not limited to:

a) NRC – Nuclear Regulatory Commission
b) OSHA – Occupational Safety and Health Administration
c) EPA – Environmental Protection Agency
d) DOT – Department of Transportation
e) GaDNR – Georgia Department of Natural Resources
f) Local township requirements

7 Product Realization

7.1 Planning of Product Realization

(P-7.5.1.0-01 Planning and Control of Production Procedure)

Product Quality Planning is performed to assure the production output meet customer and regulatory requirements. This planning addresses core and support processes, procedures, work instructions, inspection/verification, and production requirements. The configuration management that is appropriate to the product is determined. Product Quality Planning is controlled and assured via the

(P-5.6.1.0-01 Management Review Procedure,
P-7.2.2.0-01 Customer Requirement Review Procedure,
P-7.5.1.0-01 Planning and Control of Production Procedure,

P-8.2.3.0-01 Monitoring and Measurement of Processes Procedure,
P-8.4.0.0-01 Analysis of Data Procedure and,
P-8.5.2.0-01 Corrective/Preventive Action Procedure

Records needed to provide evidence that the realization processes and resulting product meet customer or internal requirements are defined and maintained in accordance with (**P-4.2.4.0-01 Control of Records Procedure**).

7.2 Customer-related Processes

7.2.1 Determination of Requirements Related to the Product

(P-7.2.2.0-01 Customer Requirements Review Procedure)

The organization determines:

a) Requirements specified by the customer, including the requirements for delivery and post-delivery activities,
b) Requirements not stated by the customer but necessary for specified or intended use, where known,
c) Statutory and regulatory requirements applicable to the product, and
d) Any additional requirements considered necessary by the organization.

7.2.2 Review of Requirements Related to the Product

(P-7.2.2.0-01 Customer Requirements Review Procedure)

The organization reviews the requirements related to the product requested by our customers. This review is conducted prior to the organization commitment to provide a quote, supply the product to the customer or acceptance of changes to contracts or purchase orders and ensures that:

a) Product requirements are defined,
b) Contract or order requirements differing from those previously quoted are resolved,
c) That the organization has the ability to meet the defined requirements.

Records of the results of these reviews and actions arising from the review are maintained.

Where the customer doesn't provide a documented statement of requirement, the customer requirements are confirmed by the organization before providing a proposal or acceptance of a subsequent order.

Where product requirements are changed either by a request of the customer or the organization, the QMS ensures that relevant documents are amended and that personnel are made aware of the changed requirements.

7.2.3 Customer Communication Process

(P-7.2.2.0-01 Customer Requirements Review Procedure and P-8.5.2.0-01 Corrective/Preventive Action Procedure) The organization has determined and implemented effective arrangements for communicating with customers in relation to:

a) Product information,
b) Inquiries, contracts or order handling, including amendments (changes), and
c) Customer feedback, including customer complaints.

This communication may be written, obtained by accessing the organization's website **www.ameriglo.com,** through email, mail or verbal and can be addressed during customer visits onsite or at their location by the organization employees or as defined in contract documentation.

Any communication with the customer regarding significant changes of scope of work or significant additional cost is coordinated and approved by one or more of the following: President, Vice President and General Manager, Sales Manager or Sales Director.

7.3 Design and Development

7.3.1 Design and Development Planning

(P-7.3.0.0-01 Design and Development Procedure
P-7.3.0.0-02 Modification to an Existing Design and Development Procedure)
This process begins with input from **P-7.2.2.0-01 Customer Requirements Review Procedure**. Understanding the customer requirements is key to achieving a successful Design and Development process. If the organization does not conduct a new design and development during the year, an existing design is reviewed following the requirements of the procedure to determine if improvement needs to be incorporated into the design.

If a new Design and Development program is required, a Team (Note: If a team is one person then the President, General Manager or a Management appointed designee approves the Design and Development Documentation) is assembled and the following tasks are performed as applicable;

a. The statement of work and specification is reviewed against the proposal,
b. Define the D&D stages with respect to;
   i) Organization responsibilities,
   ii) Task sequence,
   iii) Mandatory steps and,
   iv) Significant/distinct stages and methods of configuration control
c. Holding a kickoff meeting and resources are assigned.

These tasks are carried out according to specified safety or functional objectives of the product in accordance with the organization, the customer and/or regulatory authority activities.

The company manages the interaction between different groups involved to ensure effective communication and clear assignment of responsibility.

Where appropriate to the product being designed the design process is divided into distinct activities where resources, responsibilities, and information necessary for the product are defined.

P-7.3.0.0-02 Modification to an Existing Design and Development Procedure is used to satisfy customer requirements for a modification of an existing design. These modifications are managed differently than a full scale new design and the requirements are defined in the procedure.

Planning output is updated, as appropriate, as the design and development progresses. Any changes to USNRC-approved products may not be implemented until SSDR and USNRC license changes are submitted and approved by the appropriate regulatory organization.

7.3.2 Design and Development Inputs

Program Inputs relating to product requirements are determined and records maintained. These inputs include but are not limited to:

a) Statements of work,
b) System requirement specification(s),
c) Military, Regulatory or Commercial standards
d) Technical data package from similar programs,
e) Peculiar test equipment requirements and,
f) Other requirements essential for design and development.

These inputs are reviewed for adequacy before the design and development process starts.

7.3.3 Design and Development Outputs

The outputs of design and development are provided in a form that enables verification against the design and development input and are approved prior to release.

Design and development outputs include but are not limited to:

a) Development tool requirements,
b) Bills of Materials, drawings, functional specifications,
c) Verification and Validation Matrices,
d) Test Plans, test procedures (Developmental, functional, acceptance, and qualification),
e) Engineering review meeting minutes, engineering analyses/reports and,
f) Identification of key characteristics in accordance with design or contract requirements
g) Identifying any critical items including key characteristics and required actions.

In addition requirements for the manufacturing, inspecting and operational requirements are defined.

7.3.4 Design and Development Review

Internal system requirement, Internal preliminary design, Customer preliminary design, Internal critical design and Customer critical design reviews are all part of the of design and

development process. These are performed to assure that the design and development process meets the requirements and that any issues are identified and resolved.

Participants in such reviews include representatives of departments concerned with the design and development stage(s) being reviewed. Authorization to proceed to the next phase is identified.

Records of the results of the reviews and any necessary actions are maintained.

7.3.5 Design and Development Verification

Verification is performed to ensure the design and development outputs have met the design and development input requirements. This verification is complete at the successful completion of the Critical Design Review. Records of the results of verification are maintained.

This may include but not limited to activities such as;

a. Performing calculations
b. Comparing the design with existing or proven designs,
c. Testing, and
d. Reviewing design stage documents before release.

7.3.6 Design and Development Validation

Validation is performed after the assembly and inspection process to make sure the product performs as required by the customer or regulatory specifications. This is normally performed under defined operating conditions and is completed after successful design and/or development verification.

Multiple validations may be performed if there are different intended uses for the product.

Validation includes but not limited to:

a) Developmental, functional, acceptance, qualification, component tests,
b) Engineering analyses,

Records of the results of Validation are maintained.

7.3.6.1 Design and Development Verification and Validation Testing

When tests are required to demonstrate verification and validation they are planned, controlled, reviewed and documented. This assures that;

a. The product being tested is identified as well as objectives and conditions
b. Record requirements are identified

c. The test procedure describes the method of operation and performance of the test,
d. The correct product configuration is submitted for testing
e. The requirements of the test plan and test procedures are observed and,
f. The acceptance criteria are met

7.3.6.2 Design and Development Verification and Validation Documentation

At the completion of the design and development the records such as, reports, calculation, test results demonstrate that the product definition meets the specification requirements for all identified operational conditions as per the contract.

7.3.7 Control of Design and Development Changes

If the product does not meet the requirements the issues are documented. Changes are identified, reviewed, verified and validated as appropriate. When customer and/or regulatory authority approval of changes is required, it is so noted in the documentation. Changes are controlled in accordance with the configuration management process.

Records of the changes including customer and/or regulatory approvals are maintained.

7.4 Purchasing

7.4.1 Purchasing Process
(P-7.4.1.0-02 Supplier Approval and Re-Approval Procedure)

The organization ensures that purchased product conforms to specified purchase requirements. The organization evaluates, re-evaluates and selects suppliers based on their ability to supply product in accordance with requirements. Suppliers are evaluated and re-evaluated. Records of the results of the evaluations and re-evaluation are maintained.

The organization is responsible for the conformity of products purchased from suppliers including customer or regulatory designated sources.

In addition to approving and re-approval of suppliers our process includes but is not limited to;

a. A register of approved supplier with their scope of approval and approval status,
b. Requirements for notifying suppliers of requests for corrective action when they do not conform to requirements,
c. Specify in purchasing documents when suppliers are to use customer-designated special process sources, and
d. Specify in the procedure who has the authority to approve and disapprove suppliers,
e. Possibly using information from accredited/certification bodies or industry specific qualified suppliers in the approval process,

f. Determining and managing risks when selecting and using suppliers. Any risks that are related to suppliers would be noted in the **(P-7.4.1.0-02 Supplier Approval and Re-Approval Procedure)** documentation,

To comply with the NRC Consolidated Guidance About Materials Licenses NUREG – 1556, Volume 3 requirements for the use of a foreign source for the manufacturing of sealed sources or devices the following process applies.

With every lot of product distributed to the U.S. marketplace, the foreign source QA Manager is responsible to ensure that the following reports have been generated and the associated QA results meet requirements:

(a) Leak test results
(b) Final Acceptance Test Results with a certificate of conformance (COC) that the QA/QC commitments made have been met

The records must be reviewed, approved and show authorization to ship by the foreign source QA Manager or designate before the release of each lot. These and other QA/QC records must be forwarded to AmeriGlo. Purchasing by the foreign source monthly and any requested records also must be provided to AmeriGlo in a reasonable time.

These records are to be retained for a minimum of 5 years after each export or import except that byproduct material records must be retained for three years after the date of each export or import shipment.

7.4.2 Purchasing Information

(P-7.4.1.0-01 Purchasing Procedure)
This procedure applies to materials that are used for Safety, Radiation Safety or product realization. Purchasing information describes the product to be purchased and when processes are outsourced (either internally or externally) the requirements are defined in the purchasing documents and may include where appropriate but not limited to:

a) Requirements for approval of product, procedures, processes and equipment,
b) Requirements for qualification of personnel that can perform work,
c) Drawings / sketches including revision number or issue date,
d) Specification designations including revision number (or specifying "latest revision")
e) Any specific Quality Management System Requirements
f) Method of handling nonconforming product or,
g) Any special process requirements and qualification methods
h) Any regulatory requirements related to hazardous or controlled materials
i) Requirements for design, test, examination, inspections/verification and any instructions for acceptance,
j) Requirements for any test specimens,

k) Any requirements related to critical items and key characteristics,
l) Notification requirements for any changes in product and/or process, suppliers, manufacturing facilities and obtain our approval prior to implementing the changes when required,
m) Right of access by our organization personnel, customer and/or regulatory authorities and to records,
n) Requirements for the supplier to flow down to sub-tier suppliers any applicable requirements including key characteristics when required,
o) Records required and retention requirements that may be imposed on the supplier.

The organization ensures the adequacy of specified purchase requirements prior to their communication to the supplier. Requests for quotations and samples are sent to suppliers when pricing is not available through catalogs, on-line websites, supplier pricing sheets or specific contracts.

Requests for purchased items are sent to purchasing. Requests may be verbal, however an e-mail is sent to the buyer as a formal record of the request.

Employees designated by management are provided with company credit cards for purchased items. Should the purchased amount exceed $2,500.00 it requires approval of the General Manager/Finance Department. Purchasing has the authority to purchase up to $5,000.00 of materials and $30,000.00 of Tritium without management approval.

The organization ensures that purchased product conforms to specified purchase requirements. The organization evaluates, re-evaluates and selects suppliers based on their ability to supply product in accordance with requirements. Suppliers are evaluated and re-evaluated. Records of the results of the evaluations and re-evaluation are maintained. The Supplier Approval Process applies to the Manufacturing / Assembly of product only.

7.4.3 Verification of Purchased Material

(P-7.4.3.0-01 Verification of Purchased Product Procedure
P-7.4.3.0-02 Product Receipt Procedure,)
The organization has implemented processes to ensure purchased product meets purchase requirements. In some cases, this involves performing visual or dimensional inspection of product received or the review of certificates of conformance (COC) or certificates of analysis (COA). Onsite source inspection is performed at suppliers if required by contractual requirements.

In addition to these verification controls the organization may include but not limited to;

a. Obtaining test reports, statistical process control records, or process documents,
b. Delegation or verification to a supplier which would involve documentation of this activity, or,

c. Self-certification based upon past performance

If any product is released for production use pending completion of required verification activities it is identified and recorded to allow recall if it is subsequently found not to conform to requirements.

When required by contract if our customer or regulatory authority wants to visit our supplier to verify product conformity we coordinate this with our suppliers.

If a customer verifies the product it is not used as effective control of the quality of product by the supplier. We are responsible for the overall quality of the product including the product supplied by our customer designated suppliers. If our product is rejected by our customer or regulatory agencies we are still responsible for it.

7.5 Production and Service Provision

7.5.1 Control of Production and Service Provision

(P-7.5.1.0-01 Planning and Control of Production Procedure and, P-7.5.1.3-01 Control of Production Equipment, Tools and Production Software Programs Procedure).

The organization plans and carries out production to assure that the customer and/or regulatory requirements are met. Planning considers establishing, implementing and maintaining processes when appropriate to manage critical items including process controls where key characteristics have been identified. This assures that the relevant information and documentation is provided including, as applicable:

a) The availability of information that describes the characteristics of the product,
b) The availability of work instructions, as necessary,
c) The use of suitable equipment or fixtures,
d) The availability and use of monitoring and measuring equipment and carrying out those measurements,
e) Testing requirements and,
f) The implementation of release, delivery and post-delivery activities
g) Accountability for all product during production,
h) Evidence that all production, inspection/verification operations have been performed,
i) Prevention, detection and removal of foreign objects,
j) Monitoring of utilities to the extent they affect conformity to product requirements,
k) Criteria for workmanship standards, samples, illustrations, etc.

Production is performed using documentation and by following planned operations. The documentation contains as necessary;

a) Customer provided drawings,

b) Bill of materials,
c) Process flow charts,
d) Inspection operations,
e) Production and inspection documents,
f) Tooling, and
g) Numerical control (NC) machine programs required as well as any specific instructions associated with their use.

7.5.1.1 Production Process Verification

7.5.1.2 Control of Production Process Changes
(P-7.5.1.0-01 Planning and Control of Production Procedure,
P-7.5.1.3-01 Control of Production Equipment, Tools and Production Software Programs Procedure)

The Management Representative, Process Owners or Supervisors have the authority to make changes to the production documentation.

The organization identifies and obtains acceptance of changes that require customer and/or regulatory authority approval in accordance with contract or regulatory requirements.

Changes affecting processes, production equipment, tools or software programs are documented. The results of changes to production processes are assessed to confirm that the desired effect has been achieved without adversely impacting product conformity.

7.5.1.3 Control of Production Equipment, Tools and Production Software Programs
(P-7.5.1.3-01 Control of Production Equipment, Tools and Production Software Programs Procedure)

The requirements for control of production equipment and tooling including storage are defined in the procedure.

Production equipment, tools and programs are validated prior to use. Tools and production equipment are maintained and inspected periodically. Validation prior to production use includes verification that the first piece produced meets defined requirements.

7.5.2 Validation of Processes for Production Provision

The organization is able to verify all quality requirements before the product is in use; therefore this is excluded from the scope of registration.

7.5.3 Identification and Traceability

(P-7.5.3.0-01 Identification and Traceability Procedure)

The organization identifies the material throughout the product realization process. The identification of the configuration of the product is maintained in order to identify any differences that may come about between the actual configuration and the agreed upon configuration. This includes but is not limited to identification by part number, quantity, item number or sales order number. This allows the configuration of the product to be maintained throughout the production process.

Records of assembly, test and inspection are recorded either by being hand written or stamped on production data package.

If traceability is a contract requirement, controls are in place and the information is recorded according to customer requirements. Records are maintained.

When Quality Assurance inspects material or product, they indicate their approval by initialing and dating the work order next to the appropriate operation.

7.5.4 Customer Property

(7.5.4.0-01-Customer Property Procedure)

Customer property is received; it is identified, inspected/tested, protected and safeguarded while under the organization control. Customer property may include but not limited to packaging materials, fixtures, tooling, gages, raw materials or completed product for testing.

The Internal Auditing process reviews the condition of stored Customer Property to determine compliance with the defined controls. If customer property is lost, damaged or otherwise found to be unsuitable for use the customer is notified and records maintained.

7.5.5 Preservation of Product

(P-7.5.5.0-01 Preservation of Product Procedure)

The conformity of product integrity is preserved during internal processing and delivery to our customers in order to maintain conformity to requirements. This may include statutory and regulatory requirements. As applicable, this preservation may include;

a) The identification, handling, packaging, storage, protection
b) Cleaning
c) Prevention, detection and removal of foreign objects
d) Marking and labeling the product or shipping containers including identified safety warnings
e) Control of shelf life and stock rotation items and,
f) Any hazardous material controls

Wherever possible, material is left in its original as received packaging. When removed from its original packaging it is controlled to prevent damage or deterioration. Product is stored in designated areas throughout the facility.

Documents included with the shipment are protected against loss and deterioration by placing them in externally applied shipping pouches or within the shipping container.

7.6 Control of Monitoring and Measuring Equipment

(P-7.6.0.0-01 Calibration Control of Monitoring and Measuring Equipment Procedure and P-7.6.0.0-02 Verification of Monitoring and Measuring Equipment Procedure.

The organization maintains a register of the monitoring and measuring equipment. It also defines the calibration processes including but not limited to the equipment type, identification, the location of the equipment, frequency of calibration, and the calibration method and acceptance criteria. When any calibration is outsourced the controls are defined in the purchasing documents. Records provided by the outsourced provider are acceptable per this system.

Monitoring and measuring equipment include but are not limited to; Test hardware, test software, automated test equipment (ATE) and any associated plotters used to produce inspection data.

Personally owned and customer provided equipment used to provide evidence of product conformity are included in this system.

Monitoring and/or measuring equipment are:

a) Calibrated or Verified at specified intervals, or prior to use, against measurement standards traceable to international or national measurement standards; where no such standards exist, the basis used for calibration or verification is recorded. Calibration or verification can be performed either in-house or by outside sources;
b) Suitable environmental conditions are controlled during the calibration, inspection, measuring and/or testing of product.
c) Adjusted or readjusted as necessary;

d) Identified either on the equipment or the case (when the environmental conditions are such that the identification indicator does not hold) to enable the calibration status to be determined;
e) Safeguarded from adjustments that would invalidate the measurement result;
f) Protected from damage and deterioration during handling, maintenance and storage; and
g) Recalled by an established method

In addition, **F-7.6.1.0-01 Verification / Calibration Assessment Form** is used to assess and record the validity of previous measuring results when equipment are found not to conform to calibration requirements. The assessment includes appropriate action on the device and any product affected. Records of the results of calibration and/or verification are maintained

h) Calibrated at specified intervals, all calibrations are performed by a certified outside source against measurement standards traceable to international or national measurement standards. Suitable environmental conditions are controlled during the calibration, inspection, measuring and/or testing of product.

i) Identified either on the equipment or the case (when the environmental conditions are such that the identification indicator does not hold) to enable the calibration status to be determined;
j) Safeguarded from adjustments that would invalidate the measurement result;
k) Protected from damage and deterioration during handling, maintenance and storage;

8 Measurement, Analysis and Improvement

8.1 General

The organization management assures the planning and implementation of the monitoring, measurement, analysis and improvement of processes needed:

a) To demonstrate conformity of the product requirements produced,
b) To ensure conformity of the QMS, and
c) To continually improve the effectiveness of the QMS.

This includes determination of applicable methods, including statistical techniques, and the extent of their use. Statistical techniques may include but are not limited to charts, histograms or statistical calculations.

8.2 Monitoring and Measurement

8.2.1 Customer Satisfaction

Customer satisfaction is a benchmark for the organization QMS. The organization strives to ensure that customer's product performance and company performance (responsiveness, on-time delivery and cost) requirements that are agreed to through the customer requirements review process are met. Information monitored includes product conformity, on-time delivery performance, customer complaints and corrective action requests.

The organization conducts internal perception surveys of customers and external surveys every year. The internal perception surveys are evaluated by the organization employees who have had direct contact with customer representatives. These employees have a perception of what the customer thinks about the organization based upon comments, phone calls or on-site visits.

The external surveys are sent to customers for their evaluations as a method of obtaining direct feedback. Customer provided "Scorecards" are considered important feedback information that is reviewed during Management Review.

The organization develops and implements planning for customer satisfaction improvement that is identified by the customer satisfaction information. The effectiveness of the improvement is assessed by the organization.

8.2.2 Internal Audit

(P-8.2.2.0-01 Internal Audit Procedure) The internal audit program is planned, taking into consideration the status and importance of the processes and areas to be audited, as well as the results of previous audits. The audit criteria, scope, frequency and methods are defined. Selection of auditors and conduct of audits ensures objectivity and impartiality of the audit process. Auditors do not audit their own work. The Audit Coordinator assigns auditors for the audits. Potential internal auditors must attend a formal training class as part of their qualification process.

The Audit Coordinator has the authority to train an auditor to audit a specific process without undergoing the full auditor qualification process. The Audit Coordinator determines the extent of the training required.

The responsibilities and requirements for planning and conducting audits, and for reporting results and maintaining records are defined in the documented procedure.

The management responsible for the area being audited ensures that any corrections, corrective or preventive actions are taken to eliminate detected or potential nonconformities and their causes. Follow-up activities include the verification of the actions taken and the reporting of verification results.

8.2.3 Monitoring and Measurement of Processes

(P-8.2.3.0-01 Monitoring and Measurement of Processes Procedure) The organization uses suitable monitoring and where applicable, measurement of the quality management processes to determine conformance to requirements.

If required, corrective or preventive actions are implemented to ensure conformity of the product. Management monitors process data related to the business on a daily basis as part of their job responsibilities. They make daily decisions and assign resources based upon the results of their analysis, business and customer requirements.

Based upon the analysis that a nonconformance has been identified the organization

a) Corrects the nonconformity if possible,
b) Reviews and evaluates if the process nonconformity has led to any product nonconformity,
c) Determines if the nonconformity is an isolated case or if it could have effected any other product or processes, and
d) Identifies and controls any nonconforming product per the **P-8.3.0.0-01 Control of Nonconforming Product Procedure**.

8.2.4 Monitoring and Measurement of Product

(P-8.2.4.0-01 Monitoring and Measurement of Product Procedure) The organization monitors and measures the required characteristics of the product at various production stages to verify that requirements have been met.

Requirements are identified in production documents. QA, production personnel, customer source inspectors, or management personnel have the authority to release product.

Measurement requirements for product include;

a) The criteria for acceptance and/or rejection
b) Where measurements are to be performed during the production process,
c) Recording requirements for the measurement results (as a minimum and indication of whether the measurement was accepted or rejected),

d) Any special measurement instruments and instructions/training for their use.

If critical items including key characteristics are identified they are controlled according to the documentation and processing requirements.

Records indicate the person(s) authorizing release of product at the various stages.

The acceptability of meeting production requirements and inspection results are noted either by an assigned employee stamp or hand written initials on production documentation.

If a customer identifies key characteristics for their product they are included in the production documents required to confirm conformance to requirements.

If customer and or regulatory authorities require the use of the C=0 sampling plan the production lot is rejected when one (1) nonconformity is found in the sample quantity. However, when sampling inspection is performed using an industry/customer/professional society published sampling plan the guidelines specified in the appropriate plan are used. These are considered valid sampling plans.

8.3 Control of Nonconforming Product or Service

(P-8.3.0.0-01 Control of Nonconforming Product Procedure and P-8.3.0.0-02 Control of Nonconforming Process Procedure.)

The organization ensures that product or service that do not conform to requirements are identified and controlled to prevent its unintended use or delivery. Any employee, supplier or customer can identify a nonconformance. Any employee can identify nonconforming processes. The controls define the related responsibilities and authorities for dealing with nonconforming product and are defined in the documented procedure. The process for approving personnel who are authorized to review and disposition nonconforming product is identified in the procedure.

Where applicable, nonconforming product is handled by one or more of the following ways;

a) By reworking it to eliminate the nonconformity;
b) By authorizing its use as is if it does not violate a customer requirement,
c) Release or acceptance by a deviation/waiver granted by a relevant authority and, where applicable, by the customer;
d) By taking action to preclude its original intended use or application;
e) Scrapping it. Product dispositioned for scrap is conspicuously and permanently marked, or positively controlled, until physically rendered unusable.

f) Returning it to the supplier,

Records of the nature of nonconformities and any subsequent actions taken, including any deviations/waivers are maintained.

If nonconforming product is reworked it is re-inspected to assure conformity to the requirements. The organization does not use-as-is or repair unless authorized by the customer if the nonconformance results in a departure of contract requirements.

If nonconforming product is detected after delivery or use by the customer the organization takes action appropriate to the effects, or potential effects, of the nonconformity.

8.4 Analysis of Data

(P-8.4.0.0-01 Analysis of Data Procedure) The organization determines, collects and analyzes appropriate data to demonstrate the suitability and effectiveness of the QMS. In addition this data is used to evaluate where continual improvement of the QMS can be made. This includes data generated as a result of monitoring and measurements of Processes and Product and from other relevant sources.

As a minimum, the analysis of data provides information relating to:

a) Customer satisfaction
b) Conformity to product requirements,
c) Characteristics and trends of processes,
d) Characteristics and trends of products including opportunities for preventive action, and
e) Supplier Performance.

Analysis of data is reviewed during the Management Reviews.

8.5 Improvement

8.5.1 Continual Improvement

(D-5.3.0.0-01 Quality Policy,
P-5.4.0.0-01 Quality Planning Procedure,
P-5.6.1.0-01 Management Review Procedure,
P-8.2.3.0-01 Monitoring and Measurement of Processes Procedure,
P-8.4.0.0-01 Analysis of Data Procedure and,
P-8.5.2.0-01 Corrective/Preventive Action Procedure)

The organization strives to continually improve the effectiveness of the QMS through the use of the Quality Policy, Quality Objectives, Internal and External Audit results, Analysis of data, Customer Satisfaction and Corrective/Preventive actions.

The organization monitors the implementation of improvement activities and evaluates the effectiveness of the results. Continual improvement opportunities may result from lessons learned, problem resolutions, employee communications, customer comments or inquiries, and the benchmarking of best practices.

The information obtained from these key indicators is what the employees and management use to guide and provide priorities for the improvement effort. Top management monitors the continual improvement effort at the Management Reviews.

8.5.2 Corrective Action

(P-8.5.2.0-01 Corrective/Preventive Action Procedure) The organization takes action to eliminate the cause of nonconformities detected in order to prevent recurrence. Corrective actions are appropriate to the effects of the nonconformities encountered. Some of these actions are processed formally while others are processed as part of the normal daily course of business.

The procedure established defines requirements for:

a) Reviewing nonconformities (including customer complaints),
b) Determining the causes of nonconformities,
c) Evaluating the need for action to ensure that nonconformities do not ***Recur,***
d) Determining and implementing action needed,
e) Recording of the results of action taken, and
f) Reviewing the effectiveness of the action.

Suppliers are notified when a corrective/preventive action is required for product or service that they have provided does not conform to requirements.

The process owner or employee that is responsible for determining the corrective action also determines the target date for implementation. Management monitors the status of corrective actions at management review. If there are target dates that are being adjusted management would become aware of this and would address the issues to determine if they need to devote resources to resolving the issues. This includes if the corrective actions are not implemented or effective.

When a request for corrective action is forwarded to the responsible person they have 10 business days to respond with their plan for the corrective action. It does not necessarily mean that the corrective action will be completed in 10 days. The implementation date is determined by their review and it may involve purchasing something that could have a long lead time.

The review determines that the corrective action has been implemented as well as it being effective. In some cases the effectiveness is determined during the next receipt of Supplier product or during the next Supplier production process. If effectiveness has not been verified the issue remains open until the specific actions prevent ***Recurrence***.

8.5.3 Preventive Action

(P-8.5.2.0-01 Corrective/Preventive Action Procedure) The organization determines actions to eliminate the causes of potential nonconformities in order to prevent their *occurrence*. Preventive actions are appropriate to the effects of the potential problems. Some of these actions are processed formally while others are processed as part of the normal daily course of business.

This pertains to all of the organization and can be related to product, paperwork, infrastructure, or the work environment (including employee safety concerns).

The procedure established defines requirements for:

a) Determining potential nonconformities and their causes,
b) Evaluating the need for action to ***Prevent Occurrence*** of nonconformities,
c) Determining and implementing actions needed,
d) Recording of results of actions taken, and
e) Reviewing that the preventive actions identified was both implemented and effective.

The review determines that the Preventive Action has been implemented as well as it being effective. In some cases the effectiveness is determined during the next receipt of product, during the next production process or reviewing records.

9.0 Revision History

INDEX OF CHANGES					
Training Required ?	Doc Rev	Pages or sections affected			Date
		Revised	Added	Removed	
YES☐ NO ☐					

AMERIGLO

Richard K. Struckmeyer
Materials Safety Licensing Branch
Office of Nuclear Material Safety and Safeguards
Nuclear Regulatory Commission
Washington, DC 20555-0001

Re: E-license application

Dear Mr. Struckmeyer:

This letter is in response to your request for additional information dated July 20, 2016 regarding our E-license application.

The request for transfer of the gun sight SSD from Isolite to AmeriGlo is addressed in a separate letter to Mr Herrera (attached).

Your questions are summarized in **bold** below and our answers follow:

B. Items Regarding Exempt Distribution License Application

1. 10 CFR 32.22(a)(2)(vi) requires the applicant to submit information pertaining to the maximum external radiation levels at 5 and 25 cm from any external surface of the product, averaged over an area not to exceed 10 square centimeters, and the method of measurement.

Response: The method of assessment of the external dose at 5 and 25 cm from our gun sights containing tritium, a weak beta emitter, is basic radiological physics, logic, and a USNRC reference which indicate that the external dose is near or essentially zero. The phrase used in the application: "The external radiation dose rate at 5 and 25 cm is estimated to be less than 0.001 mrem/hr" is taken directly from a USNRC reference: Appendix O, Attachment 1 of NUREG 1556 which provides acceptable sample calculations and wording which can be used in such license applications. Also note that the language used in the Ameriglo application is identical in technical details to that in the 2011 Isolite application which was approved by NRC in 2012.

2. … page 15 of your application. The test designation RS2B is stated to be rear sight, series N; however, according to the paragraph on nomenclature, the correct designation would appear to be "series L". Please correct this if it is erroneous.

Response: Thank you for bringing that to our attention. Yes, RS2B was a rear sight, now identified as series L.

The corrected application is attached with that change and various formatting improvements.

Thank you for your attention to this matter.

Sincerely,

Richard Callihan,
Vice-President

encl.