



Mr. Richard K. Struckmeyer
Materials Licensing Branch
Division of Materials Safety, State, Tribal
and Rulemaking Programs
Office of Nuclear Material Safety and Safeguards
U.S. Nuclear Regulatory Commission
Rockville, MD

RE: Control number 585796 Armson Applications for Exempt Distribution License
and SSD Registration

Dear Mr. Struckmeyer,
In response to your Request for Additional Information dated April 9, 2015, Armson provides
the following answers and attachments. I trust that this information will suffice to answer the
concerns listed. In the event, there are more questions please contact me at (207) 797-8200
or forest@armsonusa.com.

Sincerely,

Forest Hatcher

Cc:
Celimar Valentin-Rodriguez

Enc.:
Replacement Drawings for Attachment G
Label Location Document
Leadership Keyes Documents
Updated Quality Assurance Program
QA Appendices and Forms
Response to Dose-Related Questions from K. Steinmeyer
Revision 3 of Dose Calculations Report

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Enclosure

Armson USA, LLC Application dated January 20, 2015 Applicable Regulations: 10 CFR 32.22, 10 CFR 32.23, 10 CFR 32.210 Applicable Guidance: NUREG-1556, Volumes 3 and 8

A. *Items Regarding Registration Certificate Application Request*

The following issues need to be addressed in accordance with the requirements of the regulations and the information provided in the guidance documents:

General

1. *On Page 2 of your application, you stated that “Armson USA, LLC will be replacing tritium sources in devices previously distributed. The replacement will include disassembly of the gun sights, removal and proper disposal of the tritium sources, and installation of the new tritium sources.” Please provide specifics on this statement and explain what is meant by the term “devices previously distributed.” In your response, include the details about (1) the step-by-step process of the tritium source(s) removal from the gun sight, (2) the process for ensuring that the sight has been decontaminated after removal of the source(s) and after installing the new source, (3) the installation process of the new tritium source(s), and (4) the QA/QC procedures to ensure that the gun sight(s) conform with the specifications of the OEG Series that Armson USA, LLC is requesting to register and the sights originally distributed by Leadership Keys, Inc.*

Please note that the safety evaluation is been conducted on the 11 models of gun sights within the OEG Series you specified in your application. If the “devices previously distributed,” deviate from any of the 11 gun sight models you are trying to register, the devices will not be covered in the safety evaluation. NUREG-1556, Volume 3, Section 10.1, “Summary Information,” states that “Remanufactured products, or products with replacement parts identical to the original, can only be distributed under the registration certificate if they are in conformance with the statements and commitments made in support of the registration certificate.” For example, if any components of the “previously distributed” gun sights are not identical to the components of any of the 11 models within the OEG Series, then the gun sight will not be covered under your registration certificate because it may not be in conformity with the components, materials, and methods of construction.

Armson response: In regard to the term “devices previously distributed,” Armson is referring to Armson branded devices, in particular all OEG and Pro-Dot models. Armson is providing an updated re-sourcing to address the concerns stated in this question (#1) and those in Question #27.

Additionally, Armson confirms its understanding that only the 11 models of gunsights listed in this application will be allowed to be re-sourced. Armson further confirms that it will only re-source sights listed in the registration to be issued.

2. *In your application, you stated that you wish to register 11 models of gun sights: 7 OEG Models (intended for larger arms) and 4 Pro-Dot Models (intended for smaller arms). Based on the information provided in your application, it is our understanding that the 11 models will be in the OEG Series. Please state how these series of models should be listed in the Registration Certificate (e.g. OEG Series, Pro-Dot Series, etc.)*

Armson response: Please list the 11 models as being in OEG Series

3. *In your application, you stated that the OEG Models are the following: 1” OEG, M-16 OEG, M-16 OEG Max Duty, Mini-14 OEG Max Duty, HK OEG Max Duty, UZI OEG Max Duty, and Pic OEG Max Duty. However, the drawings provided in Attachment H referred to these Models as: 1” **O.E.G.**, **M16 O.E.G.**, **M16 O.E.G. Max Duty**, **Mini-14 O.E.G. Max Duty**, **HK O.E.G. Max Duty**, **UZI O.E.G. Max Duty**, and **Picl O.E.G. Max Duty**. Please state how these models should be listed in the Registration Certificate.*

Armson response: Please list models without periods, eg. OEG.

Description/Construction

4. On Page 4 of your application, you stated that the source manufacturer for your products will be mb microtec and that the sealed sources to be used are Model 400 Series, registered under Registration Certificate NY-1271-S-101-S. Please state the exact sealed source model number(s) that will be used in the OEG Series of gun sights. Please note that Registration Certificate NY-1271-S-101-S lists 6 different source models (400/1, 400/2, 400/3, 400/4, 400/5, 400/6). In addition, provide the dimensions of the tritium sealed sources that will be used in the OEG Series of gun sights.

Armson response: The exact model of the sources is 400/2. The dimensions are H 1.50 x W 3.00 x L 7.00 mm.

5. On Page 5 of your application, paragraph 3, you stated that a special "spanner" is required to remove the retaining ring and access the source. Please clarify if "spanner" refers to a wrench or to a screwdriver.

Armson response: The term spanner (short for spanner pliers) refers to specialty pliers.

6. On Page 4 of your application, you stated that the total maximum activity per gun sight is 160 mCi, contained in two 80 mCi sources. In Attachment N, Dose Calculations, Page 1, section B. Radioactive Material Contained, you stated that the isotope will be contained in two 80 mCi sources or four 40 mCi sealed sources per device. Furthermore, the "light source assembly" in the engineering drawings provided in Attachment G appear to indicate that the gun sights will contain four tritium sealed sources. Please provide the total number of sealed sources to be used in the models within the OEG Series of gun sights. If the number of sources varies from model to model, please provide a table indicating: (1) the gun sight model number, (2) model total maximum activity, and (3) the number of sources used in the model.

Armson response: All models of gunsights include two 80 mCi sources.

7. If only two sealed sources will be used in the Armson USA, LLC gun sights, resubmit the drawings in Attachment G to demonstrate that only two tritium sealed sources will be used in the gun sights.

Armson response: Updated drawings are included in this response.

8. On Page 5 of your application, you stated the following: "[t]he sources are placed into and captured in the light source assembly. The plastic components of the light source assembly are glued together using a solvent bond, which ensures that the tritium source is fully retained. This light source assembly is then installed into the protective aluminum housing with an epoxy adhesive, which prevents the source from becoming loose within the sight after shocks [sic] and vibrations." Please provide the following:

- Based on the information provided in Attachment G, the "light source assembly" is composed of 4 components: (1) the "light source pointer", (2) the tritium source(s), (3) the "reticule", and (4) the "reticule holder". Provide a step-by-step process that describes how the 4 tritium sources are affixed within the "light source pointer" and the "reticule" and "reticule holder."
- Please provide step-by-step details about how the "light source assembly" is installed into the "aluminum housing" with epoxy.

Armson response: In regard to the first bullet point:

- a). Light sources are placed into the light source holder. The holes within the holder are

toleranced such that the GTLS's fit snugly.

- b). The reticle is placed into the reticle holder
- c). The reticle holder is glued onto the light source holder to completely contain the sources. Since the light source assembly is glued together, the only way that sources can be accessed is if the light source assembly is broken.

In regard to the second bullet, an error on the part of our consultant incorrectly stated that epoxy was used to affix the light source assembly to the aluminum housing. Epoxy is not used. The light source assembly is contained with the dome and other components by the retaining ring. Just to restate, the retaining ring requires specialty pliers to be removed.

9. In Attachment C of your application, you indicated that the main differences between the models are that (1) in some models the "dome" is external to the sight, while in others the "dome" is enclosed, (2) the mounting of the sights depend on the arm, and (3) the gun sight dimensions. Please confirm that the exploded views of the gun sights provided in Attachment G are a general representation of the components and materials of all the models within the OEG Series and their construction.

Armson response: Armson confirms that the exploded views in Attachment G are a general representation of the components and materials of all the models within the OEG Series and their construction.

10. In Attachment G of your application, the drawing labeled as "Fig. 12" is marked as a draft. NRC cannot accept draft documents. Please provide a final drawing that contains an exploded view of all the components for the Pro-Dot Models.

Armson response: This drawing has been updated and is included as stated in response to Question 7.

11. On Page 5 of your application, you provided the approximate dimensions for the OEG and Pro-Dot models. Please confirm that the only gun sights distributed will be in the dimensions provided in drawings in Attachment H of your application. In addition, please provide the tolerances for all the models.

Armson response: Armson confirms that the gun sights distributed will be within the dimensions provided in drawings in Attachment H. The tolerance for all dimensions in these drawings is ± 2 mm (0.079").

12. Please note that not all the drawings provided in Attachment H contain dimension units. Please confirm that the dimension units in the drawings "HK O.E.G. Max Duty", "UZI O.E.G. Max Duty", and "Pro-Dot ELS-1," are in millimeters (inches).

Armson response: Armson confirms that the dimension units for all dimensions on these drawings are in millimeters (inches).

Labeling

13. Please identify the materials of construction of the labels you described on Page 6 of your application, section Labeling.

Armson response: The material of the label is clear vinyl with 1 mil thick UV protective laminate.

14. On Page 6 of your application, in the Labeling section, you stated that a label with the word "TRITIUM" will be placed on the devices to distinguish the devices that contain tritium lights. Furthermore, in the Commitment section, you state that Armson will apply a label with the term "AUS-R" to the previously distributed devices that have had their sources replaced by Armson. Please provide the locations of these labels on the gun sights.

Armson response: The locations shown in the attached Label Position document.

15. On Page 6 of your application, you state that Armson will apply a label with the term "AUSR" to the previously distributed devices that have had their sources replaced by Armson. However, the copy of the label you provided in Attachment K reads "AUSA-R". Please clarify which will be the text to appear on the label.

Armson response: The text that will appear on the label is "AUSA-R".

16. In Appendix K, on the page titled "Armson Examples of Engraving of OEG Series," Figure 1 "OEG Model Engraving," included the language "EXEMPT TRITIUM." However, on Page 6 of your application it states that the word "TRITIUM" will be on the label. Please clarify whether the models in the OEG series will be engraved with "EXEMPT TRITIUM" or if the sights will use a label with the word "TRITIUM." In addition, clarify the labeling that will be on the Pro-Dot models of gun sights.

Armson response: Armson confirms that labels with the word "TRITIUM" will be used on all OEG and Pro-Dot models.

Prototype Testing

17. Since Armson submitted prototype testing in accordance with NUREG-1556, Volume 8, Appendix O, "Standard Requirements for Gunsights Containing Tritium Gas Sealed in Glass Vials," confirm that the labeling remained legible after being subjected to the prototype testing.

Armson response: Armson confirms that the labeling remained legible after being subjected to prototype testing.

18. In Attachment M of your application, on Page 3 under "H. FIRING PER 3.2.9," you stated that the gun sight was attached to "a Smith & Wesson M&P AR 15-22 .22 caliber rifle." Please discuss whether a larger caliber round like the .223 or 5.56 mm NATO rounds used in AR-15s, would have an adverse impact on the gun sights.

Armson response: Armson used a .22 caliber rifle because the ammunition was the most readily available. The difference between the .22 and .223 or 5.56 mm firearms is the recoil produced by the larger bullets. While the .223 and 5.56 mm rounds are more powerful, the recoil from the firearm is not significantly different. Therefore shock transmitted to the sight is also not significantly more.

19. Please confirm the temperature of the water utilized in the Chemical Test Procedure (Attachment M, Prototype Testing, Page 1, section II.A.1).

Armson response: Armson confirms that the temperature of the water used for the Chemical Test Procedure was room temperature.

20. In Attachment M, Prototype Testing, Pages 4 and 5, sections B, C, D, E, and F, you stated that the water samples were collected from the **cleaning compound tests**. Please confirm that these water samples were collected from the temperature shock, vibration, pressure, and penetration tests, respectively.

Armson response: Armson confirms that Sections B, C, D, E, and F contain a typographical error. Water samples were collected from temperature shock, vibration, pressure, and penetration tests respectively.

21. In your application, you stated that Armson conducted a Prototype Testing in accordance with NUREG-1556, Volume 8, Appendix O, "Standard Requirements for Gunsights Containing Tritium Gas Sealed in Glass Vials." Appendix O stated that at least five gun sights of each model are to be subjected to each of the tests, and that the same gun sights are to be used for each test. Please provide the following:

State the specific gun sight model within the OEG Series that was tested. If only one model was tested, please provide a justification of why the test results apply to all the models you are trying to register.

Please confirm that the same five gun sights were used throughout the tests. If this is not the case, please provide a justification on how using different gun sights for the tests is representative of the likely accident conditions the gun sights may experience during installation, use, handling, maintenance, and transportation.

Armson response: Armson used the 1" OEG model for prototype testing. The 1" OEG is the most susceptible to damage of all models due to the size and shape of the extrusion, and the fact that the dome is unprotected. Therefore Armson chose to test this model, knowing that if this model passed all the tests, all other models would be ensured to pass because they are more structurally sound than the 1" OEG. For example, the size and shape (hexagonal) of the Pro-Dot models allow it to endure more structural stresses. Further, models suffixed with MAX Duty have extended extrusions, which provide protection for the dome. Additionally, the design of the models is significantly the same in regard to materials and mechanical layout.

Armson also confirms that the same five gun sights were used throughout the tests.

Additional Documents

22. Please confirm that the technical drawings you provided in Attachment H of your application can be utilized in the SSD registration certificate. These drawings have not been marked as proprietary information. If you wish to withhold these drawings from public disclosure, please resubmit them with the appropriate statement or watermark, per requirements in 10 CFR 2.390.

Armson response: Armson confirms that the drawings in Attachment H may be used in the SSD registration certificate.

23. Please confirm whether the technical drawing "ARMSON OEG 1" MAXIMUM DUTY SIGHT" in Attachment L is to be considered proprietary. If so, please resubmit the drawing with the appropriate statement or watermark, per requirements in 10 CFR 2.390.

Armson response: Armson confirms that technical drawing "ARMSON OEG 1" MAXIMUM DUTY SIGHT" in Attachment L is to be considered proprietary. This correction is included on the drawing referred to in response to question 7.

24. Armson has stated that it will adhere to the documents referenced in the 1982 registration certificate issued to Leadership Keys. Please provide copies of the documents to determine whether they should be referenced in the new registration certificate.

Armson response: copies of the Leadership Keys documents are included in this response.

Quality Assurance

25. The Quality Assurance Program in Appendix O of your application contained a number of typographical errors and dated information. For example, under "Organization" it identifies "NUREG-1156", when it should be "NUREG-1556." In addition, you make reference to Mr. Bruce Carrico, who is no longer with the U.S. NRC. Please review your Quality Assurance Program document (dated January 20, 2013) for any additional errors and inaccurate information. Please submit a revised final copy.

Armson response: A copy of the updated QA Manual is included with this response.

26. The Quality Assurance Program document in Appendix O of your application made references to Appendices and Forms. Please include the Appendices and Forms with Armson's revised Quality Assurance Program document.

Armson response: Along with the QA Manual, the Appendices and Forms are included.

27. In Appendix L of your application, you provided the Resourcing Procedure for the Armson gun

sights. Please discuss how Armson will ensure that there is no contamination on the gun sights before they are re-distributed. In addition, confirm that Armson will only resource the 11 models of gun sights within the OEG Series that Armson seeks to register.

Armson response: Please see the response to Question 1.

Installation

28. On Page 3 of your application, you stated that "Various mounting methods are incorporated into the designs of the gun sights." Please describe the mounting methods used for the OEG and Pro-Dot models.

Armson response: Armson scopes are intended to be fastened to a mount, which in turn will be fastened to a gun. There are two methods by which the sight is affixed to the mount: by clamp and with fasteners. The method of affixing is dependent upon the mount. Mounts are specific to manufacturer and type of gun. Only the 1" OEG is affixed to the mount with a clamp, all other models are affixed to mounts with fasteners. The mounts are affixed to the gun with either clamps or fasteners.

B. Items Regarding Exempt-Distribution License Application

Your application does not sufficiently address the following requirements in Title 10 of the Code of Federal Regulations, Part 32, Section 32.22 (10 CFR 32.22), "Self-luminous products containing tritium, krypton-85 or promethium-147: Requirements for license to manufacture, process, produce, or initially transfer," and 10 CFR 32.23.

NOTE: Answers to the items below are addressed in the attached letter from K. Paul Steinmeyer dated April 14, 2015 and Revision 3 of the Dose Calculations Report.

Missing Information

- 1. 10 CFR 32.22(a)(2)(iv) requires the applicant to submit information pertaining to the solubility in water and body fluids of the forms of the byproduct material identified in paragraphs (a)(2) (iii) and (xii) of this section.*

The following statement appears in Section 5 on page 4 of the application:

"Tritium is soluble in water, but contact between tritium and water is not anticipated."

Please state the extent to which elemental gaseous tritium is soluble in water and in body fluids.

- 2. 10 CFR 32.23(b) requires the applicant to demonstrate that "In normal handling and storage of the quantities of exempt units likely to accumulate in one location during marketing, distribution, installation, and servicing of the product, 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 product will exceed the dose to the appropriate organ as specified in Column II of the table in § 32.24."*

Attachment I, "Dose Calculations: Gaseous Tritium Light Sources for Gun Sights (Revision 1)," appear to provide sufficient information and calculations to demonstrate that this requirement can be met; however, it appears that no statement to this effect is provided. Please provide this statement or indicate where it can be found in your application.

Accident Scenario Doses

The remaining questions concern the assumptions made in Attachment I.

Section D of Attachment I states that Armson is licensed for 200 Ci of ^3H , which (at 160mCi per set of sights) converts to 1,250 sets, and therefore that this is the maximum number of gun sights that might be in Armson's possession. Dose calculations for accident scenarios are based on the assumption that at any given time they are actually in possession of 80% (i.e., 1,000) of this "maximum number" of sight sets, with 800 sets located in a warehouse, 200 sets in the production area, and 200 sets that might be in transit to sellers in a single vehicle.

You considered six scenarios:

- 1) Dose to a warehouse worker and to a firefighter extinguishing a fire in a manufacturer's warehouse containing 800 sets (assumes that 5% (40) of the sets are destroyed in the fire).*
- 2) Dose to firefighters extinguishing a tractor trailer fire, with the trailer*

containing 200 devices (assumes that 10% (20) of these sets are destroyed in the fire).

- 3) Dose to firefighters extinguishing a fire in an end use facility, assumed to be a private residence and containing 3 gun sights (assumes 100% destroyed).*
 - 4) Catastrophic release from crushing of a set of gun sights in a small repair shop (assumes 100% destroyed).*
 - 5) An accident involving the crushing of a set of gun sights in a home (assumes 100% destroyed).*
 - 6) A shipping accident in a storeroom or cargo-handling area involving the crushing of a shipment of 1000 gun sight sets (assumes 100% destroyed).*
- 3. What is the basis for the assumption that Armson is “actually in possession of 80% of the maximum number” of gun sights (measured in curies) it is licensed to possess at any given time?*
 - 4. What is the basis for the assumption of 5% destroyed in scenario 1 and 10% destroyed in scenario 2? (If these are considered to be upper bounds, please explain why.)*
 - 5. What is the basis for the assumption of an exposure time of 5 minutes, 2 hours, 0.5 hour, and 1 hour in the tables for inhalation intake?*
 - 6. Scenario 6 assumes a much larger number of destroyed gun sights, which presumably was intended to provide an estimate of the upper bound on dose, but it is not clear why this number (1,000) was chosen. (Section 5 on page 4 of the application states that the estimated quantity of radioactive material to be distributed on an annual basis is about 1200 curies (44.4 TBq), which is about 7500 devices.) Given that Armson plans to distribute 7,500 gun sights per year, what is the basis for stating that the number that might accumulate in a storeroom or cargo-handling area is limited to 1,000?*

7. Section H, "Conclusion," of Attachment I, states: "Based on the information provided in this report, scenarios 1 through 5 are judged to have a low probability of occurrence. Scenario 6 is judged to have a negligible probability of occurrence based on the same information." It does not appear that you have provided a basis for the "low" probability (1 in 10,000) or the "negligible" probability (1 in 1,000,000) of occurrence of any of the postulated accident scenarios. Instead, it appears that you have provided estimates of doses, and based on the magnitude of the doses, you concluded that since the maximum calculated dose according to any of the particular scenarios 1 through 5 is less than the value in Column III of the table in § 32.24, therefore the probability is low that the safety features of the product 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 as specified. Likewise, it appears that you concluded that since the maximum calculated dose according to scenarios 6 is less than the value in Column IV of the table in § 32.24, therefore the probability is negligible that the safety features of the product 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 as specified.

Given that the expected inventory of the product is relatively small, a more direct and convincing analysis could be to assume that all of the radioactive material in all of the units is released, and that all available radioactive material will be taken into the body (or explain why it is not). If calculations based on such assumptions result in doses that do not exceed the appropriate values in the table in § 32.24, no further analyses would be necessary.