

November 14, 2013

Forest Hatcher, Managing Member  
Armson USA, LLC  
28 Stroudwater Street, Suite 10  
Westbrook, ME 04062

Mail Control No. 581174

SUBJECT: DISCONTINUATION OF EVALUATION OF APPLICATION FOR SEALED  
SOURCE AND DEVICE REGISTRATION AND EXEMPT PRODUCT  
DISTRIBUTION LICENSE

Dear Mr. Hatcher:

This letter is in response to your application dated June 12, 2013, requesting the registration of the Model OEG Series gunsights and an exempt product distribution license. In reviewing your application, we find that it is lacking significant amounts of the required information. Specifically, it did not provide adequate responses to our questions in NRC letter dated April 11, 2013. In the enclosure, we have repeated the NRC questions in our letter dated April 11, 2013 and highlighted additional details from which were not addressed in your application dated June 12, 2013.

With incomplete documents and unavailability of adequate information, the NRC Staff is unable to complete a safety evaluation. Therefore, we have discontinued the review of your applications for a sealed source and device registration and an exempt product distribution license. This is without prejudice to re-submission of your application. Please note, when you decide to re-submit your application for registration, ensure that you submit a complete application with sufficient information to allow NRC to evaluate your device.

If you have any questions, please contact Maria Arribas-Colon of my staff at (301) 415-6026, or e-mail [Maria.Arribas-Colon@nrc.gov](mailto:Maria.Arribas-Colon@nrc.gov) regarding the sealed source registration and Dr. Richard Struckmeyer at (301) 415-5477, or email [Richard.Struckmeyer@nrc.gov](mailto:Richard.Struckmeyer@nrc.gov) regarding the exempt product distribution license.

Sincerely,

**/RA/**

Margie Kotzalas, Chief  
Licensing Branch  
Division of Materials Safety and  
State Agreements  
Office of Federal and State Materials and  
Environmental Management Programs

Enclosure:  
As stated

November 14, 2013

Forest Hatcher, Managing Member  
Armson USA, LLC  
28 Stroudwater Street, Suite 10  
Westbrook, ME 04062

Mail Control No. 581174

**SUBJECT: DISCONTINUATION OF EVALUATION OF APPLICATION FOR SEALED  
SOURCE AND DEVICE REGISTRATION AND EXEMPT PRODUCT  
DISTRIBUTION LICENSE**

Dear Mr. Hatcher:

This letter is in response to your application dated June 12, 2013, requesting the registration of the Model OEG Series gunsights and an exempt product distribution license. In reviewing your application, we find that it is lacking significant amounts of the required information. Specifically, it did not provide adequate responses to our questions in NRC letter dated April 11, 2013. In the enclosure, we have repeated the NRC questions in our letter dated April 11, 2013 and highlighted additional details from which were not addressed in your application dated June 12, 2013.

With incomplete documents and unavailability of adequate information, the NRC Staff is unable to complete a safety evaluation. Therefore, we have discontinued the review of your applications for a sealed source and device registration and an exempt product distribution license. This is without prejudice to re-submission of your application. Please note, when you decide to re-submit your application for registration, ensure that you submit a complete application with sufficient information to allow NRC to evaluate your device.

If you have any questions, please contact Maria Arribas-Colon of my staff at (301) 415-6026, or e-mail [Maria.Arribas-Colon@nrc.gov](mailto:Maria.Arribas-Colon@nrc.gov) regarding the sealed source registration and Dr. Richard Struckmeyer at (301) 415-5477, or email [Richard.Struckmeyer@nrc.gov](mailto:Richard.Struckmeyer@nrc.gov) regarding the exempt product distribution license.

Sincerely,  
**/RA/**  
Margie Kotzalas, Chief  
Licensing Branch  
Division of Materials Safety and  
State Agreements  
Office of Federal and State Materials and  
Environmental Management Programs

Enclosure:  
As stated

**DISTRIBUTION:** R. Jones/ARB/DC/CFO SSD 13-28

<b>OFFICE</b>	LB/MSSA	LB/MSSA	LB/MSSA	LB/MSSA	LB/MSSA
<b>NAME</b>	MArribas-Colon	MArribas-Colon for JJankovich	THerrera	RStruckmeyer	MKotzalas
<b>DATE</b>	11/13/13	11/13/13	11/14/13	11/13/13	11/14/13

**OFFICIAL RECORD COPY**

Armson USA, LLC Application dated June 12, 2013  
Applicable regulations: 10 CFR 32.22 and 10 CFR 32.23  
Applicable guidance: NUREG-1556, Volume 3 and Volume 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:

1. [NRC question dated April 11, 2013]: *As per NUREG-1556, Volume 3, Section 10.1, "Summary Information," please note 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." Therefore, if Armson USA, LLC wishes to continue production of the devices which were manufactured and distributed under device certificate NR-418-D-101-G, dated March 31, 1982, please provide a commitment in writing that Armson USA, LLC is making the same commitments as the holder of the 1982 certificate and that Armson USA, LLC retains all records and documentation pertaining to the 1982 certificate. As per NUREG-1556, Volume 3, Section 13.6, "Ownership Change and Corporate Relocations," Item 5, please also delineate the differences between the products which had been registered under NR-418-D-101-G and the products which you wish to register now. If applicable, a table could also be used to summarize the differences.*

Clarification of your second submittal dated June 12, 2013, is needed regarding the following issues:

- The response to this question stated: "Armson will use some new vendors who through technological advances can now produce superior components with higher quality than the original vendor. For example the o-rings now used exceed the quality of the original component." Armson USA, LLC must provide a list that includes each vendor and clearly identify the specific components the vendors will be providing to Armson. Armson USA, LLC future application must explain using technical terms, regarding material properties, and be specific when referring to components. For example, statements such as: "o-rings now used exceed the quality of the original component" are not acceptable.
- The response to this question also stated: "Thus there is a high degree of continuity in the production of the product since it was first introduced." This production was originally in South Africa; please clearly explain how this production applies to operations conducted at your facility in Maine.
- The response to this question stated: "Attachment A which describes the few differences between the original component vendors and the current vendor." Armson USA, LLC must provide a list that clearly delineates a comparison of each product (e.g. model-by-model, component-by-component). Attachment A did not contain this information.

Enclosure

2. [NRC question dated April 11, 2013]: *As per NUREG-1556, Volume 3, Section 10.2, "Conditions of Use," please include information on the likely environments to which the product will be subjected during normal use and likely accident conditions. Normal use and likely accident conditions should include those experienced during use, handling, storage, and transportation (extremes experienced during accident conditions during transportation need not be considered).*

Clarification of your second submittal dated June 12, 2013, is needed regarding the following issues:

- The response to this question stated: (1) "Armson gunsights are designed for battlefield conditions and can withstand various extremes in use conditions", and (2) "Humidity- Gunsights are purged with pure nitrogen and will withstand highest humidity found anywhere in the world." Armson USA, LLC must use quantifiable terms. Statements such as: "designed for battlefield conditions and can withstand various extremes in use conditions", and "will withstand highest humidity found anywhere in the world" are not acceptable.
3. [NRC question dated April 11, 2013]: *As per NUREG-1556, Volume 3, Section 10.3, "Construction of the Product" please include information which describes the construction aspects of the product including components of the product, materials of construction, dimensions, assembly methods, source containment and shielding, and operation of the product and its safety features. This should include a written description of the construction aspects as well as specific, detailed descriptive data such as engineering drawings and product specification sheets. Particularly, please include engineering drawings for each model which show the locations of the sources; provide information on the mounting method and the materials used to retain the sources in the mounting locations.*

Clarification of your second submittal dated June 12, 2013, is needed regarding the following issues:

- Engineering drawings provided in Attachment C are not acceptable for numerous reasons, for example: (1) the component list provided does not match the drawings, (2) the source assembly cannot be identified on the drawings, specifically the components list stated that Item 14 is the source assembly; however, Item 14 in the drawings pointed to the base of the device, and (3) some drawings are marked as "drafts". In addition, your application did not list the different models which you wish to be listed in the registration certificate. Armson USA, LLC must provide a list of all the different models and provide final engineering drawings for each individual model.

4. [NRC question dated April 11, 2013]: *As per NUREG-1556, Volume 3, Section 10.4, "Labeling," please include information on the description of the labeling of the product, including information contained on the label, materials of construction of the label, and how and where the label is attached.*

Clarification of your second submittal dated June 12, 2013, is needed regarding the following issues:

- Based on the response to this question, there are presumably 12 different models in the application. The application stated that engraving will be used, but does not indicate the information that will be engraved. The application also does not specify the information that will be on the adhesive label. Furthermore, the application did not address if the adhesive label will stay in place during the "battlefield conditions." Armson USA, LLC must clearly identify the different models, and clearly address the labeling requirements for each of these models.
5. [NRC question dated April 11, 2013]: *As per NUREG-1556, Volume 3, Section 10.5 "Prototype Testing," please include information that verifies that the product design will maintain its integrity when subjected to conditions of normal use and likely accident conditions. Normal use and likely accident conditions should include those experienced during installation, use, handling, maintenance, storage, and transportation (only normal conditions during transportation need to be considered). Particularly, please address the issue of relevancy of the test protocol, included in the application dated February 11, 2013, which was used for the products in NR-418-D-101-G, since the tests were conducted (a) for generally licensed products, and (b) for the fabrication of new products. The current application is for exempt products and re-furbishing previously manufactured products. The integrity of the re-furbished units should be demonstrated as described in Section 10.5 (referenced above). In your application, please provide the test protocol as well as the test results. Please address how the test results apply to all models that you wish to register. Further guidance on prototype testing of gunsights containing tritium sources is available in Appendix O, NUREG-1556, Vol. 8.*

Clarification of your second submittal dated June 12, 2013, is needed regarding the following issues:

- The response to this question stated: "The original prototype testing data, included in the prior submission, was in the prior submission, was previously adequate by the NRC for exempt version of the device as well as the general license version." Please note, in your application you also stated that original prototype tests were conducted in early 1980's. Armson USA, LLC must submit copies of the prototype test protocol as well as the prototype test results. Please clearly explain the rationale for the following statement in your application: "Since the same components will be used to repair existing devices, all the original prototype testing data is relevant for the refurbished version." Please address how the fabrication process applied to produce new units is equivalent to the refurbishing process of used units.

6. [NRC question dated April 11, 2013]: As per NUREG-1556, Volume 3, Section 10.6, "Radiation Profiles," please include the maximum radiation levels around the product when it contains the maximum allowable quantity of each nuclide, or combination of nuclides for each model. Please include the maximum radiation levels on the surface of the product, at 5 cm, 30 cm, and 100 cm (2.0 in., 11.8 in., and 39.4 in.) from the product and how the levels were measured/determined.

The second submittal, dated June 12, 2013, did not contain a response to this question.

7. The second submittal, dated June 12, 2013, in Section 7.1 you stated "See Appendix E (of the original QA manual) for the Bill of Materials to be used." Please note, NRC letter dated April 11, 2013 stated that the entire application shall be included in the resubmittal, the QA manual was not included as part of your second submittal.
8. The Resourcing Procedure included in your second submittal in TAB E dated June 10, 2013 stated "Place the light source assembly into the body...", please explain if this statement is referring to a new source assembly. In addition, state the name of the supplier of the source assembly, or state if Armson, LLC will make the source assembly by installing new sources.

#### 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.

1. [NRC question dated April 11, 2013]: *10 CFR 32.22(a)(2)(v) requires the applicant to submit details of construction and design of the product as related to containment and shielding of the byproduct material and other safety features under normal and severe conditions of handling, storage, use, and disposal of the product. Your response to this item may be combined with your response to item A.3.*

Item A.3 must be fully addressed in order to satisfy this requirement.

2. [NRC question dated April 11, 2013]: *10 CFR 32.22(a)(2)(vi) requires the applicant to submit the maximum external radiation levels at 5 and 25 centimeters from any external surface of the product, averaged over an area not to exceed 10 square centimeters, and the method of measurement. Your response to this item may be combined with your response to item A.6.*

This item appears to have been adequately addressed by the response to item A.6.

3. [NRC question dated April 11, 2013]: *10 CFR 32.22(a)(2)(xi) requires the applicant to submit procedures for prototype testing of the product to demonstrate the effectiveness of the containment, shielding, and other safety features under both normal and severe conditions of handling, storage, use, and disposal of the product. Your response to this item may be combined with your response to item A.5.*

Item A.5 must be fully addressed in order to satisfy this requirement.

4. [NRC question dated April 11, 2013]: *10 CFR 32.22(a)(2)(xii) requires the applicant to submit results of the prototype testing of the product, including any change in the form of the byproduct material contained in the product, the extent to which the byproduct material may be released to the environment, any increase in external radiation levels, and any other changes in safety features. Your response to this item may be combined with your response to item A.5.*

Item A.5 must be fully addressed in order to satisfy this requirement.

5. [NRC question dated April 11, 2013]: *10 CFR 32.22(a)(2)(xiii) requires the applicant to submit the estimated external radiation doses and dose commitments relevant to the safety criteria in § 32.23 and the basis for such estimates, and 10 CFR 32.22(a)(2)(xiv) requires the applicant to submit a determination that the probabilities with respect to the doses referred to in § 32.23(d) meet the criteria of that paragraph. Appendix L of your Exempt-Distribution License application "Dose Calculations: Gaseous Tritium Light Sources for Gun Sights" provides information relevant to these requirements, but does not provide the basis for the assumptions used in Section D of the appendix. Please state the basis for, and provide references for the assumptions in the three scenarios; i.e.:*

- 1) *5% (15) of the sets are destroyed in the fire;*
- 2) *1% (2) of these sets are destroyed in the fire;*
- 3) *Two gun sights are assumed to be destroyed in the fire.*

*Also, Appendix L discusses only accident scenarios involving fires. NUREG-1717, "Systematic Radiological Assessment of Exemptions for Source and Byproduct Materials," considers other types of accidents for gunsights, such as (1) a catastrophic release from crushing of a rifle scope in a repair shop, (2) an accident involving the crushing of a rifle scope in a home, and (3) a shipping accident in a storeroom or cargo-handling area involving the crushing of a shipment of 1000 handgun sights. Please explain your rationale for considering accidents involving fires but not other types of accidents. Although NUREG-1717 provides analyses only for these three stated scenarios involving gunsights, you should also consider the analyses it provides for other products containing gaseous tritium light sources. You need not provide an analysis of every possible scenario, but you should state why the provided scenarios constitute the worst cases. Unless you are able to provide data to the contrary, your analyses should assume 100% of the available tritium is released in the accident event.*

Although your revised application of June 12, 2013, provided additional information beyond that provided in your initial application of February 11, 2013, it did not fully satisfy the requirements of 10 CFR 32.22(a)(2)(xiii) and 10 CFR 32.22(a)(2)(xiv). In order to satisfy these requirements, please provide the following additional information:

(a) Question 5 asked you to state the basis for, and provide references for the assumptions in the three scenarios:

- 1) 5% (15) of the sets are destroyed in the fire;
- 2) 1% (2) of these sets are destroyed in the fire;
- 3) Two gun sights are assumed to be destroyed in the fire.

However, it does not appear that you stated the basis for, or provided references for the assumptions in these three scenarios. Please provide this information or indicate where it can be found in the application.

(b) Question 5 asked you to explain the rationale for the following statements on page 4 of Appendix G: "This is judged to be an accident with a low probability" and "[t]his is judged to be an accident with a negligible probability." Is it your intention to conclude that the magnitude of the dose defines the probability of its occurrence? If so, please explain why you reached this conclusion.