Armson USA, LLC Application dated February 11, 2013 Applicable regulations: 10 CFR 32.22 and 10 CFR 32.23 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:

- 1. 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.
- 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).
- 3. 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.
- 4. 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.

- 5. 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 refurbishing 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.
- 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.

Please note that no further information is needed on the following subjects at this time:

- Quality Assurance and Quality Control,
- Installation, Servicing, and Instructions to Users
- 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.

- 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.
- 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.

- 3. 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.
- 4. 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.
- 5. 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.