XS Sight Systems, Inc.
Application dated February 13, 2019
Request for Additional Information

The U.S. Nuclear Regulatory Commission (NRC) staff has reviewed the XS Sight Systems, Inc., application dated February 13, 2019, and determined that additional information is needed. In order to continue with our review, please address the issues listed below.

The information related to review of your Sealed Source and Device amendment application is required by Title 10 of the *Code of Federal Regulations* (10 CFR) 32.210 and is described in the relevant guidance document NUREG-1556, Volume 3, Revision 2, titled "Applications for Sealed Source and Device Evaluation and Registration."

The information related to review of your exempt-distribution license application is required by 10 CFR 32.22, 32.23, and 32.24, and is described in the relevant guidance document NUREG-1556, Volume 8, "Program-Specific Guidance About Exempt Distribution Licenses."

A. Questions related to the sealed source and device application

General

1. In your application, you stated that XS Sight Systems, Inc. has nine product families based on different design features. Please provide the gun sight model number designation(s) that you would like the U.S. NRC to list on your Registration Certificate. If you would like the devices to be listed as a Series, please provide the Series designation(s).

Description/Construction

2. Please indicate the specific source models from the mb-microtec Registration Certificate No. NR-0446-S-102-S that will be used in the construction of the gun sights.

3. Please provide a detailed description of the gun sights' construction and assembly methods. Please include information on which sources will be used in each of the nine families you are looking to register. In your application you stated that XS Sight Systems would use sources from the mb-microtec Tactical series and EcoVial series, as well as bare tritium vials, in the construction of the gun sights. However, you did not indicate which source series and source models would be used in each of the nine families.

4. Please provide a detailed explanation about the differences between the nine families. For example, in your application you stated that the product families are based on the tritium installation (number of vials, positing, and lamp type), but you did not delineate the specific number of sources that are going to be used in a given family.

5. In your application, you stated that pure aluminum or an aluminum alloy, steel, or titanium will be used as housing materials for the gun sights. Please provide the specific types or grades of aluminum, steel, and titanium that will be used in the construction of the gun sights. Also, describe how the materials will be selected to achieve the desired mechanical properties for the gun sights.

6. Please discuss corrosion between unlike materials (e.g., aluminum and steel).

7. On Page 10 of your application, you stated that the overall maximum and minimum dimensions of the sights and corresponding lamps will change depending on the gun requirements. You also stated that the minimum amount of material surrounding the tritium source vials will remain unchanged, 0.38mm (0.15 in). The guidance in NUREG-1556, Volume 3, Rev. 2, Section 10.3 Construction of The Product, Page 10-6, states that drawings of safety-related parts and components should be fully dimensioned with tolerances. Detailed design and construction data should be sufficient to allow the U.S. NRC to fully understand the construction and operation of the product and to evaluate the product's safety and integrity. Please provide a range of dimensions for each of the nine families XS Sight Systems is looking to register.

Labeling

8. In your application, you stated that the labeling methods to be used by XS Sight Systems are engraving, etching, stamping, and pad printing. Please provide specific details about the stamping and pad printing methods. In your response, address the durability of these labeling methods. Please note that the acceptable labeling method will be sufficiently durable for the labeling to remain legible for the useful life of the product under normal conditions of use.

9. In your application, you stated that the labeling will be on the top or on the side and "on the bottom as the last result". The guidance in NUREG-1556, Volume 3, Rev. 2, Section 10.4 Labeling, Page 10-8, states that the labeling should be in a readily visible location. Please discuss the how the labeling will be readily visible when located on the bottom of the gun sight.

10. In Attachment E of your application, you included a sample of the labeling. Due to the quality of the picture, the markings are not clear. Please provide a picture or a drawing that shows a legible example of the labeling.

Prototype Testing/Historical Use

11. In your application, following the prototype testing results, you included photographs of nine gun sights in bright light and in low light. Please confirm if these images correspond to Attachment G, NUREG 5000 Round Test Sight Images. Please discuss the images, specifically if these are before or after pictures, following the 5000 round firing test.

12. On Page 12 of your application, you stated that all samples showed no visible loss of illumination nor leakage. However, three of the gun sights which underwent water immersion testing, Family Class I-1, Family Class I-4, and Family Class I-5, appear to have yielded positive results to contamination. Family Class I-1 yielded 148 Bq (0.004 µCi), Family Class I-4 yielded 80100 Bq (2.16 µCi), and Family Class I-5 yielded 195 Bq (0.0160 µCi). Please explain this discrepancy.

Quality Assurance (QA)

13. Please confirm that your QA program ensures (i) that the materials of construction and the final assembly meet your design specifications; (ii) that the final product is leak tested; that a final radiation profile is performed; (iii) that a test is performed that verifies that the product operates as intended; (iv) and that a visual and mechanical inspection is performed of components that may be susceptible to failure under extreme or unusual conditions.

14. Please confirm that the quality assurance director has the authority to halt production if necessary.

15. In Attachment I of your application, Section I. Organization, you described the roles of the quality assurance manager and the sealed source specialists. These roles, however, are not part of the Organizational Chart you submitted. Please explain this discrepancy.

16. Please state what percent of the sight components and what percent of the completed sites will undergo inspections.

17. Please confirm that XS Sight Systems will conduct periodic physical inventories.

18. In your QA Program, Section XII. Audits, you stated that internal audits will be conducted by a designated member of the XS Leadership Team for procedures associated with handling and inventory of sealed sources. Please confirm that the designated team member will not be responsible for any of the matters being audited.

19. Please confirm that your QA program includes procedures for evaluating deviations and customer complaints.

B. Questions related to the exempt-distribution license application

1. On page 17 of the application, in the last paragraph of section 12, you stated: "The maximum expected dose commitment to workers in the storage area and truck drivers is less than 1mrem/yr. This satisfies the dosage limit in Column 2, § 32.24." However, this conclusion does not appear to follow from the previous paragraph, which states the dose commitments become 178 mrem for the occupant and 356 mrem for the fireman. The dose limit in Column 2, § 32.24, is 10 mrem. Please clarify your statement and/or provide a revised analysis.

2. On page 17 of the application, in the last paragraph on the page (under the subsection "Accidental Release of the Tritium Gas") you stated: "Should an individual ingest an entire source, the estimated dose commitment is 6.3 mrem, also within the limits set in Column IV, §32.24." However, this does not appear to agree with scenario 2 on the previous page, which states: Ingestion or inhalation of a sight with two tritium vials (up to 100mCi); H = 100 mCi x 6.3E-2 rem/mCi = 6.3 rem. Please clarify your statement and/or provide a revised analysis.