

## **AmeriGlo, LLC Application dated June 16, 2016**

Applicable Regulations: Title 10 of the *Code of Federal 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 AmeriGlo, LLC application dated June 16, 2016, references a registration issued to the Isolite Corporation (NR-1286-D-102-E). If AmeriGlo, LLC is requesting a transfer of the registration certificate, please provide the following information:

1. Delineate the facility's name and location where the products are manufactured.
2. 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.
3. Provide change of ownership information discussing the transfer of products, records custody, and servicing arrangements for products previously distributed. This includes documentation from the Isolite Corporation regarding the transfer of the registration certificate to AmeriGlo, LLC.
4. Provide a new label for the devices indicating the new company name and the effective date of the label change. Please note that on Page 9 it states that the trade names under which the devices will be distributed include AmeriGlo, ZONE 3, and USA. Your application states that one of the three names will be on the device. In order to determine the entity that is distributing the devices please confirm that ZONE 3 and USA are registered trademarks for AmeriGlo, LLC. If they are not registered trademarks then AmeriGlo, LLC must either label the devices with AmeriGlo or the exempt distribution license number that will be issued to AmeriGlo LLC.
5. Confirm that no changes were made to the product since its initial registration or last amendment. Based on the information provided in the June 16, 2016, application, we noted the following: (1) On Page 6 it states that "Specialty sights may contain more than 2 lamps as long as the safety specifications are met as discussed above." Please note that the registration certificate NR-1286-D-102-E allows a maximum of two sources per gun sights. If the intention is to distribute gun sights with more than two sources, AmeriGlo, LLC must provide the information for the new sources models as outlined in NUREG-1556, Volume 3, Revision 2; and (2) On Page 7 it states that housing material will be "a Brinell Hardness of 95 HB or higher"; however the current registration certificate states a minimum of 100 HB. If the intention is to use housing material with a minimum of 95 HB please discuss what analysis AmeriGlo, LLC performed to ensure that the tritium sources used in the gunsights will maintain their integrity during normal use and likely accidental conditions. Please discuss whether prototype testing was performed using gunsights with the Brinell Hardness of 95 HB.

Enclosure

6. Confirm that previous commitments made by the old company have not changed. Please confirm that AmeriGlo, LLC obtained all of the references included in the registration certificate NR-1286-D-102-E.
7. Provide details about the quality assurance program under the new ownership or at the new location. Please note, the AmeriGlo, LLC application included a copy of the Quality Management System that states it meets the ISO 9001 Quality Management Systems – Requirement Standards. The application did not include a copy of the certification. If AmeriGlo, LLC is ISO 9001 certified, please provide a copy of the certification. In addition, please confirm that your Quality Assurance Program 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  $\mu$ Ci]; (3) all units are tested for proper operation of all safety features, and (4) all units are verified that the radiation levels do not exceed the maximum values stated in the application.

If AmeriGlo, LLC is not ISO 9001 certified, please provide its procedures that ensure the following: (1) The materials of construction and the final assembly meet the design specifications; (2) The final product is leak tested; (3) A final radiation profile is performed; (4) A test is performed that verifies that the product operates as intended; and (5) 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.

#### B. Items Regarding Exempt Distribution License Application

Your application does not sufficiently address the following requirements in 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. 10 CFR 32.22(a)(2)(vi) requires the applicant to submit information pertaining to 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.

Page 16 of your application states: “The external radiation dose rate at 5 and 25 cm is estimated to be less than 0.001 mrem/hr,” but does not provide the method of measurement.

As required by 10 CFR 32.22(a)(2)(vi), please provide the method of measurement.

2. With regard to prototype testing, there appears to be a minor error on 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.