



UNITED STATES
NUCLEAR REGULATORY COMMISSION
WASHINGTON, D.C. 20555-0001

November 16, 2017

Sig Sauer, Inc.
ATTN: Sean J. Iller
Environmental Health and Safety Manager
72 Pease Boulevard
Newington, NH 03801

SUBJECT: SIG SAUER, INC. REQUEST FOR ADDITIONAL INFORMATION

Dear Mr. Iller:

This letter is in response to your application, U.S. Nuclear Regulatory Commission (NRC) Form 313, dated October 18, 2017, requesting an exempt distribution license and a sealed source and device evaluation.

We do not have sufficient information to complete the review of your application. In the enclosure to this letter you will find the list of the questions and items not addressed in your application.

Please be aware that upon your request, proprietary information submitted to the NRC may be withheld from public disclosure. To do this, you must follow the procedures in Title 10 of the *Code of Federal Regulations* (10 CFR) 2.390(b) including requesting withholding at the time the information is submitted and complying with the document marking and affidavit requirements set forth in 10 CFR 2.390(b)(1).

We will continue our review upon receipt of this information. If we do not receive your reply within 30 calendar days from the date of this letter, we will consider your application as having been abandoned by you. This action would be without prejudice to the resubmission of another application with the required information.

Your application for a distribution license should not contain information concerning the possession and use of radioactive material because that is covered in a separate possession license.

Any correspondence regarding your amendment application should reference Control Number 601547.

In accordance with 10 CFR 2.390 of the NRC's "Agency Rules of Practice and Procedure," a copy of this letter will be available electronically for public inspection in the NRC Public Document Room or from the Publicly Available Records component of NRC's Agencywide Documents Access and Management System (ADAMS). ADAMS is accessible from the NRC Web site at <http://www.nrc.gov/reading-rm/adams.html>.

S. Iller

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If you have any questions, please contact Maria Arribas-Colon at (301) 415-6026, or by e-mail at Maria.Arribas-Colon@nrc.gov regarding the sealed source and device registration, and Richard Struckmeyer at (301) 415-5477, or by e-mail at Richard.Struckmeyer@nrc.gov regarding the exempt distribution license.

Sincerely,

/RA by Maria Arribas-Colon for/

Richard K. Struckmeyer
Materials Safety Licensing Branch
Division of Material Safety, State, Tribal,
and Rulemaking Programs
Office of Nuclear Material Safety
and Safeguards

Docket No. 030-39077

Enclosure:
Request for Additional Information

S. Iller

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LEIDOS, INC. REQUEST FOR ADDITIONAL INFORMATION

Date: November 16, 2017

Certified Mailing No. 7015 3010 0000 7901 7380

ML17311A076 (pkg)

ML17320A109 (Letter)

OFC	NMSS/MSLB	NMSS/MSLB	NMSS/MSLB	NMSS/MSLB	NMSS/MSLB
NAME	MArribas-Colon for RStruckmeyer	DWeaver	MArribas-Colon	THerrera	MArribas-Colon for RStruckmeyer
DATE	11/16/2017	11/16/2017	11/16/2017	11/16/2017	11/16/2017

OFFICIAL RECORD COPY

Sig Sauer, Inc.
Application dated October 18, 2017
Request for Additional Information

The U.S. Nuclear Regulatory Commission (NRC) staff has reviewed the Sig Sauer, Inc. (SIG) application dated October 18, 2017, 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. The SIG application dated October 18, 2017, identifies five model numbers and internal ID numbers for the SIGLITE series of gun sights that SIG has requested to register. For purposes of the device registration certificate please confirm the model numbers that the NRC should use to identify the SIGLITE series of gun sights.
2. Delineate which models in the SIGLITE series are the front sights and the rear sights.

Description/Construction

3. The drawing numbers 1203616, 1203618, 1203629, 1203641, and 1302245 identify variations for the heights of the gun sights as stated in the assembly variants table of each drawing. Our understanding is that the only difference between the gun sights under each model number is the possibility for a difference in height. Please confirm our understanding.
4. Please confirm the different height measurements allowed for the gun sight in drawing number 1302245. We note that the height of the gun sight in drawing number 1301608 appears to be 7.26 mm, while the different heights requested in drawing number 1302245 are 3.82 mm and 4.37 mm.
5. As stated in your application we noted that the gun sights will primarily be mounted to the guns using a dovetail configuration. However, the application identified one alternate mounting style. We noted that in drawing number 1302245 the drawing appears to depict the alternate mounting style. Please clarify whether this will be the only gun sight model that will support the alternate style or whether all of the gun sights in the SIGLIGHT series will include the alternate style. If the other model gun sights may be mounted in the alternate style please indicate whether this will affect the dimensions and if so, the different dimensions for the gun sights.

6. Please provide non-confidential drawings of the gun sights so that they may be added as part of the device registration certificate. The non-confidential versions should include the basic overall dimensions of the gun sights, and their respective labeling.
7. Your application stated that the sights are comprised of a metal housing. Please identify the type of metal that will be used for the housing.
8. Please provide the minimum amount of metal that will surround the sealed sources in the gun sights.
9. Your application stated that adhesive is used to adhere the sources into the sleeve, and that the sleeve is then adhered to the housing with adhesive. Please identify the type of adhesive that will be used to adhere the gaseous tritium light sources into the nylon sleeve and the type of adhesive to adhere the nylon sleeve to the metal housing.
10. Please describe the adhesive curing process stated in the operation procedure included in your application.
11. Your application stated that the SIGLITE series of models will also include a sapphire lens over the source and that epoxy may be used in lieu of the sapphire lens. You also stated "...some models of gunsights contain sapphire "lens" which are glued into the sights..." Furthermore, based on drawing number 1302245 it appears that is the only gun sight model that will not use the sapphire lens. Please clarify the following:
 - a. Whether both methods will be used to secure the source in the gun sights for all the models in the SIGLITE series, or state which models will have the sapphire lens and which models will have epoxy to secure the source.
 - b. Provide the type of adhesive that SIG will use to glue the sapphire lens into the gun sights.
 - c. Provide the type of epoxy that SIG will use to secure the source in the sights for those models that will not have the sapphire lens.
12. The operating procedures included in your application do not delineate the process for those sights containing a sapphire lens. Please provide the operating procedures that includes aspects of the gun sights' construction.
13. Your application identified that SIG will use sealed sources provided by Mb-Microtec USA, Inc.; however the application does not identify the source models that SIG intends to use in the SIGLITE series. Please confirm that SIG will use Mb-Microtec USA, Inc. source model 400/1 as indicated in the exempt distribution license application.

Labeling

14. In your application you stated that the SIGLITE series of gun sights will be marked with "SIG". Drawing numbers 1203629 and 1203641 include SIG's full name "SIG SAUER," however the pictures included in Attachment 5 do not. Please clarify whether only these models in the SIGLITE series of gun sights will include the entire name.

15. In your application you stated that the SIGLITE series of gun sights will be marked with "SIG". Drawing number 1203618 did not include this marking. Please confirm that the model represented in drawing number 1203618 will contain this marking.
16. In your application you stated that the SIGLITE series of gun sights will be marked with "H-3", while the pictures included in Attachment 5 are marked as H3. In addition the marking in drawing numbers 1203616 and 1302245 are "H3" not "H-3". Please clarify whether the marking will be "H3" or H-3".
17. Drawing numbers 1203618, 1203641, and 1203629 did not include the "H-3" or "H3" marking, please confirm that these models will include the H3 (or H-3) marking as required in 10 CFR 32.22(a)(2)(x).
18. Drawing numbers 1203616, 1203618, 1302245, 1203641, and 1203629 contained different type of marking (i.e., XX, 6, 16 and 8), while the pictures included in Attachment 5 have only the following markings "XX" and "8". Please provide the meaning of each marking and clearly state the marking for each model.

Prototype Testing

19. The prototype testing results included in the application identify that the Model "107858, trigalight® sights SIG 50X-08" were tested. Please clarify which models of the SIGLITE series of gun sights were prototype tested, in your response please include the model number by test.
20. Please identify the heights of the model(s) that that were (re) tested and explain the rationale in choosing the specific dimensions to be tested.
21. If only one model of the rear sight was tested, please explain your rationale.
22. Please confirm that the same gunsights were used for each test. If different sights were used, please explain the rationale of using different sights for each test.

Radiation Profiles

23. In the radiation profiles included in Attachment 8 of SIG's application we note that a survey of the gun sights did not include a survey of a gun sight that contains 60 mCi of tritium. SIG has requested that the gun sights have a maximum activity level of 60 mCi. Please either provide an updated radiation profile or explain SIG's rationale for not performing the radiation profile for the gun sights at the maximum activity level.

Quality Assurance

24. The Quality Manual included in the application states that SIG's Quality Management System meets the requirements of ISO 9001. Please provide a copy of SIG's ISO 9001 certificate. In addition please confirm that SIG's quality assurance program for the manufacture and distribution of gun sights will include commitments to verify:

- a. 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).
- b. All units are verified that the radiation levels do not exceed the maximum values stated in the application.

B. Questions Related to the Exempt Distribution License Application

1. 10 CFR 32.22(a)(2)(iii) requires the applicant to submit the chemical and physical form of the byproduct material in the product and changes in chemical and physical form that may occur during the useful life of the product.

Although this information is included on the State possession licenses that you provided as enclosures, you should have explicitly stated this within the body of your application. Please provide this information in your response to this request for additional information (RAI).

2. 10 CFR 32.22(a)(2)(iv) requires the applicant to submit 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.

You provided information on page 8 of your exempt distribution license application about the solubility of tritium; however, this did not explicitly state the degree of solubility. Please provide this information in your response to this RAI.

3. 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 responses to questions A.3 through A.13 will be reviewed to determine whether this requirement is met.

4. 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.

Although you provided radiation profiles in your Application for Device Registration, this requirement specifies that the applicant must provide 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. Please indicate whether the measurements you provided were averaged over an area not to exceed 10 square centimeters. Also to satisfy the requirement for method of measurement, please indicate the detection capability of the detector and probe used for these measurements. As noted in question A.23, you did not provide measurements for a 60 mCi sight. Analogous to that question, either provide the data for this level of activity, or explain the rationale for not doing so.

5. 10 CFR 32.22(a)(2)(vii) requires the applicant to submit information about the degree of access of human beings to the product during normal handling and use.

Please state the design features of the sights that hinder access, and an assessment of the level of difficulty that would be required for a person to gain access to the gaseous tritium light sources.

6. 10 CFR 32.22(a)(2)(viii) requires the applicant to submit the total quantity of byproduct material expected to be distributed in the product annually.

Your application indicated that 1.5 million sights would be distributed in the first year starting on the date of issue of the license. The estimated quantity of tritium distributed will be 135,000 Ci. Please state whether you expect this quantity to remain about the same in succeeding years, or to increase or decrease. Also please explain what is meant by your statement, "This quantity includes only devices manufactured by SIG."

7. 10 CFR 32.22(a)(2)(x) requires the applicant to submit the proposed method of labeling or marking each unit with identification of the manufacturer or initial transferor of the product and the byproduct material in the product.

Your response to this question may be provided in conjunction with A.14 through A.18.