



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

October 17, 2022

Mr. Daniel Spencer
General Counsel & CHRO
CZ-USA
3341 N 7th St Trafficway
Kansas City, KS 66115

SUBJECT: CZ-USA REQUEST FOR ADDITIONAL INFORMATION

Dear Mr. Spencer:

This letter refers to your applications dated May 16, 2022, Agencywide Documents Access and Management System (ADAMS) Accession Nos. ML22195A218 and ML22195A205, concerning your request for an Exempt Distribution Materials License and Sealed Source and Device Registration. In reviewing your applications, we find additional information is required to complete our review. In order to continue our review, we need clarification and additional information. In the enclosure to this letter, we have summarized the issues that need to be addressed.

We will continue our review upon receipt of this information. If we do not receive a reply from you within 30 calendar days from the date of this letter, we will assume that you do not wish to pursue your application. Any correspondence regarding your application should reference the mail control number specified below.

In accordance with Title 10 of the *Code of Federal Regulations* Section 2.390 of the U.S. Nuclear Regulatory Commission's (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 the NRC's ADAMS. ADAMS is accessible from the NRC Web site at <http://www.nrc.gov/reading-rm/adams.html>

If you have any questions regarding the Sealed Source and Device Registration you can contact me at (301) 415-4059 or by email at Joseph.Rolland@nrc.gov. For questions related to the exempt distribution license, please contact Shirley Xu at (301) 415-7640 or email at Shirley.Xu@nrc.gov.

Sincerely,

10/17/2022

X 

Joseph D Rolland
Mechanical Engineer

Signed by: Joseph D. Rolland

Materials Safety and Tribal Liaison Branch
Division of Materials Safety, Security, State,
and Tribal Programs
Office of Nuclear Materials Safety
and Safeguards

Docket No. 030-39314
Mail Control No. 631865
Enclosure: Request for Additional Information

SUBJECT: CZ-USA REQUEST FOR ADDITIONAL INFORMATION

DATE: OCTOBER 17, 2022

**ADAMS Accession Numbers: ML22195A288 (Pkg), ML22195A218, ML22195A205 (Ltrs),
ML22280A003 (RAI)**

OFFICE	MSST/MSTB	MSST/MSTB	DFM/FFLB	MSST/MSTB	MSST/MSTB
NAME	JRolland	THerrera	SPoy	SXu	JRolland
DATE	10/06/2022	10/11/2022	10/13/2022	10/17/2022	10/17/2022

OFFICIAL RECORD COPY

**CZ-USA
SEALED SOURCE AND DEVICE
REGISTRATION CERTIFICATE
APPLICATION DATED MAY 16, 2022
REQUEST FOR ADDITIONAL INFORMATION**

The U.S. Nuclear Regulatory Commission (NRC) staff has reviewed the CZ-USA application, dated May 16, 2022, and determined that additional information is needed. In order to continue with our review, please address the issues listed below. This information is required by Title 10 of the *Code of Federal Regulations* (10 CFR) Section 32.210 and described in the relevant guidance document NUREG-1556, Volume 3, Revision 2, titled "Applications for Sealed Source and Device Evaluation and Registration."

Description/Construction

1. Please confirm our understanding that the only function of Česká zbrojovka a.s. (aka CZUB) is to attach the gun sights to the firearms prior to sending them to CZ-USA for initial distribution.
2. Please confirm the maximum activity of the gun sights and whether there are different maximum activities based on the manufacturer of the gun sights. We note on page 3 of 8 of the CZ-USA submission that CZ-USA is requesting a maximum activity of 25 mCi per source with each gun sight set containing a maximum of 75 mCi of tritium per set. In this same section CZ-USA reports that the Meproflight gun sights will use 15 mCi per front sight and 24 mCi per rear sight for a total of 39 mCi per set. In the information submitted on the Meproflight gun sights later in the application it states that the "rear sight has two sources of 14 mCi each, while the front sight has one source of 15 mCi", this would make a total of 43 mCi.
3. Page 2 of 8 of CZ-USA's application refers to three families of gun sights which will be distributed by CZ-USA. Please provide a table to delineate the below details concerning the gun sights to be included in each family:
 - a. the gun sight models and manufacturers to be included in each family,
 - b. the sealed source manufacturer and specific sealed source model number to be used in each gun sight,
 - c. the dimensions of each gun sight model,
 - d. and the minimum amount of material surrounding the sealed sources.
4. Please describe the design differences between Families 1, 2, and 3.
5. Please discuss whether each Family will have a hole for the addition of a bolt for fastening or whether this is optional depending on the model of firearm that the sight is being mounted on.
6. The CZ-USA application included nine drawings for different gun sights. However, there did not appear to be a discussion of how those drawings fit with the three families that CZ-USA is requesting for evaluation. Please discuss how the drawings correlate with the families. There are two sets of drawings provided by Kummer and Meproflight. Explain the significance of needing these two sets and what the differences are.
7. Please resubmit the Kummer drawings translated into English.

Enclosure

8. Please submit non-proprietary, dimensioned drawings of each gun sight model which may be included as attachments in the sealed source and device registration certificate.
9. Please identify the type of aluminum alloy and steel used for the gun sights for each model used.
10. Please identify the adhesive used to for installing the sources into the gun sight bodies for each model used.
11. In the CZ-USA submission, in the section regarding the Meproflight manufactured gun sights, it states, "It is our understanding that CZ will only be purchasing our TRU-DOT models (but possibly also our Hyper Bright ones)." Please explain what this means and what CZ-USA intends to distribute.

Prototype Testing

12. In your application, you included testing documentation from Meproflight and other companies. Please confirm that CZ-USA understands that it is the sole responsible entity for the gun sights it distributes in the U.S., including the prototype testing provided and performed by the manufacturers of the gun sights.
13. On page 5 of 8 of CZ-USA's application, it is noted that "it became evident that the ECO sleeves did not meet the minimum requirement of testing" and that only sights with Next generation insert (NGI) sleeves passed testing. Please confirm our understanding that only NGI sleeves will be used in sights designed by Kummer to be distributed by CZ-USA.
 - a. If sleeves other than the NGI will be used, please provide a list of all sleeves to be used.
 - b. For each additional sleeve type to be used, please provide prototype testing results, or provide an explanation of the device's acceptability based on the use history with that sleeve installed.
14. We note that tests 7/10 and 8/10 (mechanical shock testing and firing testing, respectively) for the sights designed by Kummer are missing from the package submitted with CZ-USA's application. Please provide documentation for these tests.
15. The CZ-USA submission included the prototype testing for ML-63191 from Meproflight, it is not clear how this test corresponds with the families being requested by CZ-USA. Please discuss the purpose of the Meproflight "WEAPON SIGHTS QUALIFICATION TEST REPORT".
16. For the prototype testing results provided for the Kummer and Meproflight gun sights, please discuss how the tested gun sights correspond to the requested families.
17. Page 5 of 8 also states, "During the first round of testing, there was one sight with NGI sleeves from which one GTLS and sleeve slipped out of the bore that it was in. This appears to be an anomaly, as no others experienced this result." Please discuss the cause of this malfunction and why this is believed to be anomalous.

Labeling

18. On page 4 of 8 we note that CZ-USA is proposing to label the gun sights it distributes with an “M” for Meprolight or “K” for Kummer. Please provide the labeling that will be on the gun sights that will identify CZ-USA as the initial distributor of the gun sights. The NRC will accept the distributor’s name, registered trademark, or license number.
19. We note that on some of the drawings submitted the “H-3” labeling appears to be on the bottom of the gun sight that would not be readily visible when installed. Please note that labeling denoting the presence of tritium should be readily visible when the gun sights are in use. Please resubmit the drawings indicating that the “H-3” will be visible when the gun sight is mounted to the firearm.
20. Please submit images of the labeling to be used on devices distributed by CZ-USA.

Quality Assurance

21. Page 6 of 8 of CZ-USA’s application states that “only certain portions of [CZUB’s quality assurance] policies are applicable to CZ-USA.” Please identify the portions of the QA policy that CZ-USA will adhere to.
22. We further note that page 6 of 8 of the application states that CZ-USA “has controls in place to ensure that removable contamination is below regulatory limits on any device prior to the device leaving the assembly area.” Please describe these controls.
23. We note that CZ-USA did not provide a copy of CZ-USA’s quality assurance program. As the initial distributor of the gun sights in the U.S., CZ-USA must also include a copy of its quality assurance program.

As noted in NUREG-1556, Volume 3, Revision 2, Section 10.7 “Quality Assurance and Quality Control”, it states: “the applicant must provide details of the QA program that will be implemented to ensure that the product is manufactured and distributed in accordance with the representations made in the application and with the statements contained in the registration certificate for the product. At a minimum, the QA program needs to ensure that (i) the materials of construction and the final assembly meet the design specifications; (ii) the final product is leak tested; (iii) a final radiation profile is performed; (iv) a test is performed that verifies that the product operates as intended, including all safety functions; and (v) a visual and mechanical inspection is performed of components that are considered related to safety or are expected to be susceptible to failure under extreme or unusual conditions. Some of these inspections may be performed on a sample basis.”

The CZ-USA quality assurance program must also describe how it assesses the foreign manufacturers QA/QC program. Please see the discussion on page 10-17 in Section 10.7 for more details.

**CZ-USA
EXEMPT DISTRIBUTION
APPLICATION DATED MAY 16, 2022
REQUEST FOR ADDITIONAL INFORMATION**

In reviewing your application, we have determined additional information is required to complete our review. To continue our review, please address the issues listed below. This information is required by 10 CFR 32.22, "Self-luminous products containing tritium, krypton-85 or promethium-147: Requirements for license to manufacture, process, produce, or initially transfer."

1. In your application, it stated that the activity of the sources will be less than 25 mCi per source and less than 75 mCi per gun sight set. In the dose calculation, 65 mCi activity of tritium was used, please submit all dose calculations using 75 mCi tritium activity.
2. Provide 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.