

# UNITED STATES NUCLEAR REGULATORY COMMISSION

WASHINGTON, D.C. 20555-0001

September 9, 2021

Mr. John B. Young President/Radiation Safety Officer AIS Gauging 934 E Innovative Dr. Terre Haute, IN 47802

SUBJECT: AIS GAUGING REQUEST FOR ADDITIONAL INFORMATION

Dear Mr. Young:

This letter is in response to your application dated June 16, 2021, requesting an amendment to your Sealed Source and Device Registration Certificate NR-1494-D-101-B to add two additional models.

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 questions and items not addressed in your application.

Please be aware that upon your request, proprietary information submitted to the U.S. Nuclear Regulatory Commission (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) Paragraph 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.

In accordance with 10 CFR Section 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 <a href="http://www.nrc.gov/reading-rm/adams.html">http://www.nrc.gov/reading-rm/adams.html</a>.

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If you have any questions, please contact me at (301) 415-5619, or by e-mail at Lymari.Sepulveda@nrc.gov.

Sincerely,

9/9/2021

Lymari Sepulveda

Mechanical Engineer

Signed by: Lymari Sepulveda

Lymari Sepulveda, Mechanical Engineer Materials Safety Tribal and Liaison Branch Division of Materials Safety, Security, State, and Tribal Programs Office of Nuclear Material Safety and Safeguards

Enclosure:

Request for Additional Information

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SUBJECT: AIS GAUGING REQUEST FOR ADDITIONAL INFORMATION

DATED: September 9, 2021

ADAMS ACCESSION NO.: ML21168A264 \*Concurrence Via email

OFFICE	MSST/MSTB	MSST/MSTB	MSST/MSTB
NAME	MPringle	LSepulveda	THerrera
DATE	9/08/21	9/9/21	9/9/21

OFFICIAL RECORD COPY

# AIS GAUGING APPLICATION DATED JUNE 16, 2021 REQUEST FOR ADDITIONAL INFORMATION

The U.S. Nuclear Regulatory Commission (NRC) staff has reviewed the AIS Gauging application dated June 16, 2021 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. We note that the address submitted with your request and the address in your registration certificate are different. Please clarify the apparent discrepancy.
- 2. Please indicate if the models A1-M and B1-M will be registered for use as both a specifically and generally licensed device. If generally licensed, please confirm that the dose requirements for generally licensed user remain the same.
- 3. Please provide the location of the shutter indicator lights or confirm that the location of the lights is the same as the other models in the Apollo Series.

#### Labeling

- 4. Please confirm that there are no changes to the labels.
- 5. Please provide the location of the labels for the new devices.

# Conditions of Use

- 6. Please confirm that the conditions of use for the A1-M and B1-M models will remain the same as the other models in the Apollo Series or identify any changes.
- 7. Please confirm that the working life will remain at 20 years.
- 8. Please confirm if the A1-M and B1-M will be mounted to the "O" and "C" frames in the same manner as the other models in the Apollo series or identify any differences

# Prototype Testing

9. Please provide the procedures and results of the prototype testing. You can use any of the methods identified in NUREG-1556, Volume 3, Rev 2., Section 10.5, "Prototype Testing", to demonstrate that the product will maintain its integrity when subjected to normal conditions of use or likely accidents conditions. The methods are the following: testing a prototype of the device, an engineering analysis, operational history, or comparison to a similar or equivalent model previously reviewed and registered.

# Quality Assurance (QA)

10. Please confirm there are no changes to the Quality Assurance and Control program.