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

February 27, 2018

AIS Gauging
ATTN: John Young, CEO
5350 N 13th Street
Terre Haute, IN 47805

SUBJECT: DISCONTINUATION OF EVALUATION OF AIS GAUGING APPLICATION FOR SEALED SOURCE AND DEVICE REGISTRATION CERTIFICATE

Dear Mr. Young:

This letter is in response to your application dated January 4, 2018, requesting a sealed source and device (SSD) registration certificate for Apollo Series Model A and B thickness gauges. In reviewing your application, we find that it does not contain sufficient information for us to conduct our review. In the enclosure to this letter, we have summarized the issues not addressed in your application.

Due to incomplete information, the U.S. Nuclear Regulatory Commission (NRC) staff is unable to complete a safety evaluation of your requested device and has discontinued the evaluation of your application (SSD Case No. 18-15). This action is taken without prejudice to submission of the required information. A new action will be opened once the NRC receives a complete application per the requirements in Title 10 of *the Code of Federal Regulations* (10 CFR) 32.210 and the guidance provided in NUREG-1556, Volume 3, Revision 2. If you resubmit the application within 12 months from the date of your original application, you do not need to pay an additional application fee. Please note, when you decide to re-submit your application for registration, ensure that you submit a complete application with sufficient information to allow the NRC staff to evaluate your device.

Proprietary information submitted to the NRC may be withheld from public disclosure, upon your request. To do this, you must follow the procedures in 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).

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.

If you have any questions, please contact me at 301-415-6380, or via e-mail at Samantha.Crane@nrc.gov.

Sincerely,

/RA/

Samantha Crane, Acting Branch Chief
Materials Safety Licensing Branch
Division of Material Safety, Security, State, and Tribal Programs
Office of Nuclear Material Safety and Safeguards

Enclosure:
Issues to be Addressed

DISCONTINUATION OF EVALUATION OF AIS GAUGING APPLICATION FOR SEALED SOURCE AND DEVICE REGISTRATION CERTIFICATE

Date: February 27, 2018

DISTRIBUTION:
SSD 18-15

ADAMS Accession No.: ML18053A780

OFC	NMSS/MSLB	NMSS/MSLB	NMSS/MSLB	NMSS/MSLB
NAME	CValentin-Rodriguez	DWeaver	THerrera	SCrane
DATE	2/23/2018	2/22/2018	2/26/2018	2/27/2018

OFFICIAL RECORD COPY

AIS Gauging Application Dated January 4, 2018

The following issues need to be addressed by AIS Gauging (AIS) in accordance with the requirements of Title 10 of the *Code of Federal Regulations* (10 CFR) Part 32.210 and the information provided in the relevant guidance document NUREG-1556 Volume 3, Revision 2, "Applications for Sealed Source and Device Evaluation and Registration."

General

1. The AIS application refers to 10 CFR 32.14 and 10 CFR 30.15, which are for the distribution of exempt products. However, the application states that the beta gauges are intended to be distributed as generally licensed devices. Furthermore, the "Application and Review Checklist" submitted by AIS indicates that the gauges are for use by both specific and general licensees. Please identify which type of licensee AIS intends to use the beta gauges.

2. Please be aware that in your application you used different designations for the device, such as: Atlas Model A1, Atlas Model B1, Apollo Model A1, and Apollo Model B1. Please identify the designation for the devices you are seeking to register.

Description/Construction

3. Please provide detailed design and construction information for the Models A1 and B1. The information should be sufficient to allow the NRC staff to fully understand the construction and operation of the device. Please see NUREG-1556, Volume 3, Revision 2, Section 10.3 "Construction of the Product" for information that must be included in an application for a sealed source and device. In your response, please make sure you include the following:

    - Provide specific details about the device components and safety features. This should include complete annotated engineering design and/or construction drawings of all safety critical components, such as source holder and shutter assembly. The engineering drawings of safety critical parts and components should be fully dimensioned with tolerances identified, and should indicate the materials of construction.

    - Provide fabrication and assembly methods (e.g., welds, bolts, screws), including size and spacing.

    - Provide engineering drawings and descriptions of non-safety critical components and parts that contribute to safety and/or integrity of the device (e.g., shutter mechanism). These drawings should include sufficient descriptive information to determine how the components contribute to the safety and/or integrity of the device and how the component is integrated with other components of the device, as well as to help determine if the non-safety critical components could degrade the effectiveness or usefulness of safety critical components.

    - If the device construction includes dissimilar materials, or materials that will likely be affected by exposure to radiation, provide an explanation for the choice of material.

- Provide a specific description and location of the device indicators which identify whether the source shielding is in the open or closed position. In addition, please confirm that the indicators clearly state when the shutter is in the open or closed position.

4. Please indicate if both Models A1 and B1 will be available in the "C" frame and "O" frame configurations.

5. Please describe and identify the location of the on/off indicators on Models A1 and B1.

6. Please indicate if Models A1 and B1 should be listed as a series. If so, please provide the name of the series and also provide the differences and similarities between both models. A table format is preferred.

7. In the application and review checklist page of your application you state that Am-241 will be one of the radionuclides used in the devices. However, you list Sr-90 in the rest of the application. Please confirm that Models A1 and B1 will only use Kr-85 and Sr-90 sealed sources. If AIS plans to use Am-241 in Models A1 and B1, please include information on the maximum activity, as well as information on the associated sealed source.

8. In the section titled *Radionuclides Used in the Product*, you state that the maximum activities for the Kr-85 and Sr-90 sources to be 1 Ci and 200 mCi, respectively. However, in the product brochure included in Attachment A, you state available source strengths of 200, 600 mCi, and 1200 mCi for Kr-85, and 50 mCi for Sr-90. Please confirm the maximum activities for Kr-85 and Sr-90.

Labeling

9. The regulations in 10 CFR 32.51(a)(3) state that in part, "Each device bears a durable, legible, clearly visible label or labels approved by the Commission…".

   We note that the label that includes the general license information appears to be attached to the frame. As indicated in 10 CFR 32.51(a)(3), each device must bear a label. Please identify the location of the label containing the general license information on the source head.

10. Please provide the dimensions for each of the labels used on Models A1 and B1. The labels submitted as part of the application did not include dimensions.

11. Please provide a copy of the label to be used on the devices to be distributed as specifically licensed devices. Provide the materials of construction of the label and the method of attachment for the label to be placed on the source head.

Prototype Testing

12. We note that on page 3 of 68 of the Apollo A1 and B1 Gauge Testing Project, Occupational Services, Inc. stated that they did not assess the source holder, housing, alignment, shutter mechanism, security, warning devices or fire resistance. Please see NUREG-1556, Volume 3, Revision 2, Section 10.5, which states that the applicant must provide information that verifies that the product design will maintain its integrity when subjected to conditions of

normal use and likely accident conditions. Please provide justification as to why the aforementioned tests were not conducted during prototype testing.

Radiation Profiles

13. We note that Model B1 was tested using a Sr-90 source with a maximum activity of 45 mCi. However, the application appears to request a maximum activity of 200 mCi. Please indicate if the radiation profiles submitted as part of the application in the Prototype Testing section were for 45 mCi or for the apparent maximum activity requested of 200 mCi. If the submitted radiation profiles were for 45 mCi, please provide radiation profiles for the maximum activity requested of 200 mCi. As stated in Section 10.6, "Radiation Profiles" in NUREG-1556, Volume 3, Revision 2, measured radiation levels are preferable, but calculated levels are also acceptable.

Conditions of Use

14. Please provide the estimated working life for Models A1 and B1.

15. Describe the actions to be taken when the devices reach the end of their working life.

16. Please provide the maximum allowable conditions of use for Models A1 and B1. Normal use and likely accident conditions should include those experienced during use, handling, storage, and transportation (extremes experienced during accident conditions during transportation need not be considered). Also discuss whether the devices will be subject to extreme conditions of corrosion, vibration, impact, puncture, compressive loads, explosion (i.e., thermal cycling), and cycling of the on/off mechanism.

17. The regulations in 10 CFR 32.51(a)(2)(ii) and (iii) require that design requirements for devices to be used under a general license in 10 CFR 31.5 include dose criteria. Please include dose assessments for both normal use and likely accident conditions. Dose assessments must be consistent with the information submitted about such matters as design, construction, working life, and conditions of use.

Quality Assurance (QA)

18. Please confirm that your QA program ensures that:

    - a final radiation level check is performed on all devices to be distributed, and that

    - a test is performed that verifies that the product operates as intended, including all safety functions.

Accompanying Documentation

19. Please provide a final copy of the AIS Radiation Safety Manual, referenced in the Apollo A/B BW Sensor User Manual.

20. Please be aware that when distributing to general licensees, you must provide them with specific information as required under 10 CFR 32.51a. This information includes:

- a copy of the general license contained in 10 CFR 31.5;
- a copy of 10 CFR 31.2, 30.51, 20.2201, and 20.2202 or a copy of the equivalent Agreement State regulations;
- a list of services that can only be performed by a specific licensee;
- information on acceptable disposal options including estimated costs;
- an indication that NRC's policy is to issue high civil penalties for improper disposal;
- NRC regional information; and
- Agreement States contact information.

Please provide a copy of the information that will be provided to general licensees.