



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

March 20, 2026

Ms. Patty Ugalde,
President
Tooling.Aero, LLC
7863 SW 162nd PI
Miami, FL 33193

SUBJECT: REQUEST FOR ADDITIONAL INFORMATION FOR TOOLING.AERO, LIMITED LIABILITY COMPANY IN RESPONSE TO APPLICATION REQUEST TO APPLY FOR A NEW REGISTRATION CERTIFICATE AND EXEMPT DISTRIBUTION LICENSE FOR DEVICE MODEL GDA-P AND AEROLYZER

Dear Ms. Ugalde:

This letter is in response to your application dated December 10, 2025, requesting a new registration certificate and exempt distribution license for ion mobility spectrometer device models GDA-P and Aerolyzer. In reviewing the application, we find that additional information is required to complete our evaluation. In the enclosure to this letter, we have summarized the issues not addressed in your request.

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.

If you have any questions regarding the exempt distribution license, please contact Vanessa Cox at (301) 415-8342 or by email at Vanessa.Cox@nrc.gov. For questions related to the sealed source and device registration certificate, please contact me at (301) 415-4091, or by e-mail at Alessandro.FloresSaenz@nrc.gov.

Sincerely,

3/20/2026

X 

Vanessa Cox

Project Manager

Signed by: Nuclear Regulatory Commission

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

Enclosure:
Request for Additional Information

**REQUEST FOR ADDITIONAL INFORMATION
NEW REGISTRATION CERTIFICATE AND EXEMPT DISTRIBUTION LICENSE REQUEST
DATED DECEMBER 10, 2025**

The U.S. Nuclear Regulatory Commission (NRC) staff has reviewed the Tooling.Aero, LLC application dated December 10, 2025, 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” and NUREG-1556, Volume 8, Revision 1, titled “Program-Specific Guidance About Exempt Distribution Licenses.”

Device Registration Certificate

General

1. Upon reviewing your application, we noted that documents “*Radioactive Source in Device*” and “*Device and Source Engineering Drawing Requirements and Description*” submitted in your application request on December 10, 2025, includes a label on top of the images indicating the image ‘*Contains proprietary information – not for public release.*’ Please confirm whether this information is proprietary and whether Tooling.Aero, LLC requests that it be withheld in accordance with 10 CFR 2.390. If so, please provide an affidavit supporting your request for withholding with proper letter head of Tooling.Aero, LLC. Proprietary information submitted to the NRC may be withheld from public disclosure if you follow the procedures outlined in 10 CFR 2.390. This includes requesting withholding at the time of submission and complying with the document marking and affidavit requirements specified in 10 CFR 2.390(b)(1).
2. Please confirm our understanding of the following:
 - a. 7863 SW 162nd PI, Miami FL 33193-3438 should be recorded on the SSD Registration Certificate as Tooling.Aero’s mailing address, and
 - b. 1845 NW 112th Avenue Suite 210, Miami 33172 should be recorded as Tooling.Aero’s distribution location.

Description/Construction

3. In your application request dated December 10, 2025, the maximum activity provided throughout the application is 2.6 mCi (95 MBq) for both device models GDA-P and Aerolyzer. However, the possession license provided in your application lists the maximum allowable activity as 2.57 mCi. Please specify whether the maximum activity is 2.57 mCi (95.09 MBq) or 2.60 mCi (96.20 MBq). Please note that the possession license and SSD Registration certificate must be in agreement.
4. In your application dated December 10, 2025, it states, “an additional sealing material ensures a hermetically sealing housing (class IP65).” Please state what material the seal referenced here will be constructed from.

Enclosure

5. In order to register the foil source as part of the device, the source must have an ANSI N43.6/ISO 2919 classification of at least C32211 for this type and use of source. Please provide testing or documentation to show what the source's classification is.

Conditions of Use

6. In your application, it states, "the estimated working life...is approximately 20 years, assuming routine preventive maintenance is performed as recommended." Please address by whom maintenance will be performed in the US.

Labeling

7. Please note that both device labels provided in your application request dated December 10, 2026, in the document '*Labeling and Visibility Description*' are not in compliance with 10 CFR 32.29(b). Specifically, there are missing the following required language:
 - (i) The following statement: "CONTAINS RADIOACTIVE MATERIAL"
 - (ii) The name of the radionuclide and quantity of activity
 - (iii) An identification of the person licensed under 10 CFR Part 32.26 to transfer the detector for use pursuant to 10 CFR Part 30.20."
8. Please note that in the labels submitted with your application request dated December 10, 2025, the maximum activity has been rounded up to the nearest 10th, and it must display the maximum allowable activity as registered which we believe will be 2.57 mCi based on the possession license provided in your request (reference question 3 above).

Engineering Drawings

9. Please provide a diagram of device models GDA-P and AeroLyzer that may be used in the registration certificate or provide permission to use the drawing submitted (*Radioactive Source in Device and Device and Source Engineering Drawing Requirements and Description*), despite being marked proprietary.

Radiation Profiles

10. In your submission named *Source-to-Surface Distance Description*, we note that there appears to be tape on the detector. Please confirm our understanding that this tape was not covering the detector window when the measurements were taken.
11. Please confirm that the radiation profiles provided in the *Source-to-Surface Distance Description* submission will be the same even when the valves are opened and/or after installation.

Quality Assurance and Quality Control

12. We note that Airsense GmbH provided an ISO 9001 QA/QC certificate. Please also provide Airsense's QA/QC procedures.
13. Please note that in cases where the QA/QC functions for fabrication are performed at a foreign manufacturing facility, the U.S. distributor periodically must audit the foreign facility. Copies of all records must be maintained in the U.S., as specified by the provisions of 10 CFR Part 110.53(b). With every lot of the product, the foreign manufacturer must forward to the U.S. distributor (i) the leak test results and (ii) copies of documents certifying that the QA/QC made in the application have been met. Additionally, please provide the frequency with which Tooling.Aero, LLC will perform these audits.

Exempt Distribution License

1. As required by 10CFR32.26 (a)(8), provide the total quantity of byproduct material expected to be distributed in the product annually.
2. As required by 10 CFR 32.26 (a)(10), provide the proposed methods of labeling or marking the detector and its point-of-sale package to satisfy the requirements of 10 CFR 32.29(b). On the label provided referenced 10 CFR 30.15(a)(8), provide the correct reference.