



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

July 21, 2025

Dr. Andreas Walte
CEO
AIRSENSE Analytics GmbH
Hagenower Str. 73
19061 Schwerin Germany

**SUBJECT: ACKNOWLEDGEMENT OF RECEIPT AND DISCONTINUATION OF
ACCEPTANCE REVIEW FOR AIRSENSE, SSD 25-25, MCN # 647724**

Dear Dr. Walte:

The NRC staff received your application dated June 4, 2025 (Agencywide Document Access and Management System (ADAMS) Accession No. ML25188A239, requesting registration of the Aerolyzer and Gas Detector Array – Personal (GDA-P) in accordance with 10 CFR Part 32.210, and for an exempt distribution license in accordance with 10 CFR 32.26 and 10 CFR 30.20.

Upon review of your request, the staff has determined that the application does not contain sufficient technical information to enable the staff to complete its detailed review and make an independent determination regarding the satisfaction of regulatory requirements. Moving forward, you may supplement your application and resubmit it for review. If you do so, please ensure that you include the information described in the Enclosure to allow the NRC staff to evaluate your application and make the necessary regulatory findings.

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

If you have any questions regarding the Sealed Source and Device Registry, please contact me at Alessandro.Floressaenz@nrc.gov or (301) 415-4091. If you have any questions regarding Exempt Distribution Licensing, please contact Michelle Hammond at Michelle.Hammond@nrc.gov or (817) 200-1127.

A. Walte

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Sincerely,

X

Booma Venkataraman
Branch Chief

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

Docket No.

Mail Control No.

Enclosure:

Information Needed to Accept Application

SUBJECT: ACKNOWLEDGEMENT OF RECEIPT AND DISCONTINUATION OF
ACCEPTANCE REVIEW FOR AIRSENSE SSD 25-25, MCN # 647724

DATE: July 21, 2025

ADAMS Accession Number: ML25195A178

OFFICE	MSST/MSLB	OGC	MSST/MSLB	MSST/MSLB	MSST/MSLB	MSST/MSLB
NAME	AFloresSaenz	NLO	JRolland	MHammond	BVenkataraman	AFloresSaenz
DATE	07/15/2025	07/17/2025	07/21/2025	07/21/2025	07/21/2025	07/21/2025

OFFICIAL RECORD COPY

AIRSENSE ANALYTICS GMBH
APPLICATION DATED JUNE 4, 2025
INFORMATION NEEDED TO ACCEPT APPLICATION

The U.S. Nuclear Regulatory Commission (NRC) staff has reviewed the Airsense Analytics GmbH application, dated June 4, 2025, and determined that additional information is needed in order for the staff to perform a detailed review. If you would like to resubmit your application, please include the additional information listed below. This information is required by Title 10 of the *Code of Federal Regulations* (10 CFR) Sections [30.32](#), [32.26](#), [32.29](#), and [32.210](#) and described in the relevant guidance documents listed below.

Sealed Source and Device Registration Certificate:

Guidance: NUREG-1556, Volume 3, Revision 2, *Applications for Sealed Source and Device Evaluation and Registration*.

Exempt Distribution License:

Guidance: NUREG-1556, Volume 8, Revision 1, *Program-Specific Guidance About Exempt Distribution Licenses*.

General:

1. In order to issue a distribution license, you must first have a radioactive materials possession license issued by the NRC or Agreement State. Please provide a copy of your possession license.
2. Please provide the information required by [10 CFR 32.29\(b\)\(3\)](#) on labeling of the point-of-sale packaging.
3. As required by [10 CFR 32.26\(b\)\(6\)](#), please provide 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.

Description:

4. Please provide the complete names and addresses of the distributor, manufacturer, and any other companies involved in the manufacture or distribution of the products. Note that the provisions of [10 CFR 110.53\(a\)](#) require a foreign vendor to establish an address in the U.S. to which the NRC can correspond and serve papers, as necessary to accomplish its mission. Typically, this means that the distributor must have a United States address. See NUREG-1556, Vol. 3, Sections 5.5, Foreign Vendors, and 10.1.1, Manufacturer and Distributor.
5. As required in [10 CFR 30.32\(g\)\(1\)](#), please identify the foil source by manufacturer and model number, as registered with the NRC or an Agreement State. Alternatively, provide enough information for the source to be registered as part of the device. See NUREG-1556, Vol. 3, Section 10.1.6 Registration of Sources as Part of a Device.

Labeling:

6. Please provide the information required by [10 CFR 32.29\(b\)\(1\) and \(2\)](#) on labeling of the detectors.

Diagram:

7. Please provide engineering drawings for each model that includes the details as listed in NUREG-1556, Vol. 3, Section 6.3, Engineering Drawings. Note some of the details in the guidance may not apply to your products. At a minimum, drawings should show overall dimensions, list materials of construction, details of safety-related components, and source locations.

Conditions of Normal Use:

8. Please provide the expected working life of the devices and information concerning the conditions of use/likely accident scenarios of the devices including (as applicable) being subjected to corrosive environments, vibration, impact, puncture, compressive loads, explosion, flooding, excessive high or low temperatures, drastic changes in temperature (i.e., thermal cycling), and cycling of the on/off mechanism. See 10 CFR 32.26(b)(5); NUREG-1556, Vol. 3, Section 10.3, Construction of the Product.

Prototype Testing:

9. Provide information that verifies that the product design will maintain its integrity when subjected to conditions of normal use and likely accident conditions. This information can take the form of prototype testing, engineering analysis, operational history of the products, or a detailed comparison to a similar or equivalent model previously registered with the NRC or Agreement States. See 10 CFR 32.26(b)(11); NUREG-1556, Vol. 3, Section 10.5, Prototype Testing.

Quality Assurance and Control:

10. Provide your plan for quality assurance and control for the requested models. See 10 CFR 32.26(b)(15); NUREG-1556, Vol. 3, Section 10.7, Quality Assurance and Control. Note in cases involving foreign manufacturers, if the QA/QC functions for fabrication are to be performed at the foreign 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 110.53\(b\)](#).