DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION

DISTRICT OFFICE ADDRESS AND PHONE NUMBER	DATE(S) OF INSPECTION
Seattle District Office 22215 26th Ave Se, Ste 210 Bothell, WA 98021 425-302-0340 Industry Information: www.fda.gov/oc/industry	4/21 – 4/23/2026
	FEI NUMBER 3017102

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT IS ISSUED

TO: Anneliesa C. Stubb, Plant Manager

FIRM NAME	STREET ADDRESS
Airgas USA, LLC	8008 S 222nd St
CITY, STATE AND ZIP CODE	TYPE OF ESTABLISHMENT INSPECTED
Kent, WA 98032	Medical Gas Manufacturer

THIS DOCUMENT LISTS OBSERVATIONS MADE BY THE FDA REPRESENTATIVE(S) DURING THE INSPECTION OF YOUR FACILITY. THEY ARE INSPECTIONAL OBSERVATIONS; AND DO NOT REPRESENT A FINAL AGENCY DETERMINATION REGARDING YOUR COMPLIANCE. IF YOU HAVE AN OBJECTION REGARDING AN OBSERVATION, OR HAVE IMPLEMENTED, OR PLAN TO IMPLEMENT CORRECTIVE ACTION IN RESPONSE TO AN OBSERVATION, YOU MAY DISCUSS THE OBJECTION OR ACTION WITH THE FDA REPRESENTATIVE(S) DURING THE INSPECTION OR SUBMIT THIS INFORMATION TO FDA AT THE ADDRESS ABOVE. IF YOU HAVE ANY QUESTIONS, PLEASE CONTACT FDA AT THE PHONE NUMBER AND ADDRESS ABOVE.

DURING AN INSPECTION OF YOUR FIRM (I) (WE) OBSERVED:

QUALITY SYSTEM

Observation 1

The responsibilities and procedures applicable to the quality unit shall be in writing; such written procedures shall be followed.

Specifically,

A. Your quality control unit does not have a Standard Operating Procedure (SOP) governing the non-operational status of equipment. On May 4th 2025, multiple pieces of equipment, including the (b) (4) air compressor (b) (4), (b) (4) compressor (b) (4), (b) (4) compressor (b) (4) and Internal (b) (4) which are used in the manufacturing of (b) (4) (b) (4) and (b) (4), were taken out of use due to the implementation of a new (b) (4) Unit.

During a walkthrough of your facility on April 21, 2026, it was observed that there was no consistent use of status tags or out-of-service tags for non-operational equipment. Your firm stated that this equipment was not fully non-operational but "mothballed" and could be used at a later time. However, the equipment still lacks any consistent use of status tags defining its current usage status.

B. On March 4, 2025, March 5, 2025, and March 8, 2025, the firm's (b) (4) Bulk Driver incorrectly documented that a trailer designated for (b) (4) for Industry was filled with (b) (4) medical gas. This error was not discovered until after the trailer was filled with product on all three occasions. This is documented on "Lot and Batch Record Corrections Log" and references the following lots and dates.

- March 4, 2025: Lot (b) (4)
- March 5, 2025: Lot
- March 8, 2025: Lot

Add Continuation Page

SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE	EMPLOYEE(S) NAME AND TITLE (*Print or Type*)	DATE ISSUED
	ARANJEET SINGH -S Digitally signed by ARANJEET SINGH -S Date: 2026.04.23 17:57:39 -07'00' GLORIA E. ANDIA -S Digitally signed by GLORIA E. ANDIA -S Date: 2026.04.23 17:59:55 -07'00'	Aranjeet Singh, Investigator Gloria E. Andia, Investigator	04/23/2026

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NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT IS ISSUED

TO: Anneliesa C. Stubb, Plant Manager

FIRM NAME	STREET ADDRESS
Airgas USA, LLC	8008 S 222nd St
CITY, STATE AND ZIP CODE Kent, WA 98032	TYPE OF ESTABLISHMENT INSPECTED Medical Gas Manufacturer

Your firm was unable to produce documentation that the (b) (4) Bulk Driver received the required Airgas Merchant Gases (AMG) Product Release Specialist (PRS) – ((b) (4) (b) (4) training before March 2025.

C. Your quality control unit failed to adequately investigate Internal Non-conformance #23656, dated June 09, 2025, when the liquid product storage tank for Batch Number (b) (4) and Batch Number (b) (4) (b) (4) were stored past the established limit of (b) (4)

Your firm stated that the root cause was determined to be understaffing. However, Internal Non-conformance #23656 documentation did not contain additional information on how the root cause was identified, batches/lots affected, or dates of occurrence. Your firm acknowledged they did not conduct a thorough investigation. As a result, Internal Non-conformance #24054 was created on 4/22/2026 to address the inadequate investigation in Internal Non-conformance #23656.

LABORATORY CONTROLS

Observation 2

The calibration or verification of calibration for instruments, apparatus, gauges, and recording devices at suitable intervals in accordance with an established written program are not met.

Specifically, during the facility walkthrough on April 21, 2026, it was observed that the Distributed Control System (DCS) used to monitor and control processes in the Air Separation Unit, utilizes two shared login credentials—one for "engineer" and one for "operator"—that are accessed by multiple personnel. Your firm stated that the "operator" login allows for control over valves and adjustments of set points that impact medical gas purity and is used by (b) (4) individuals; and the "engineer" login allows for additional controls such as controls for system shutdown, which is used by two individuals. This practice of using shared login credentials does not allow for maintaining adequate records that identify which specific individual operated the equipment, ensuring accountability for equipment operation and control activities.

Add Continuation Page

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	ARANJEET SINGH -S Digitally signed by ARANJEET SINGH -S Date: 2026.04.23 17:58:18 -07'00' GLORIA E. ANDIA -S Digitally signed by GLORIA E. ANDIA -S Date: 2026.04.23 18:00:31 -07'00'	Aranjeet Singh, Investigator Gloria E. Andia, Investigator	04/23/2026

The observations of objectionable conditions and practices listed on the front of this form are reported:

1. Pursuant to Section 704(b) of the Federal Food, Drug and Cosmetic Act, or

2. To assist firms inspected in complying with the Acts and regulations enforced by the Food and Drug Administration.

Section 704(b) of the Federal Food, Drug, and Cosmetic Act (21 USC 374(b)) provides:

"Upon completion of any such inspection of a factory, warehouse, consulting laboratory, or other establishment, and prior to leaving the premises, the officer or employee making the inspection shall give to the owner, operator, or agent in charge a report in writing setting forth any conditions or practices observed by him which, in his judgement, indicate that any food, drug, device, or cosmetic in such establishment (1) consists in whole or in part of any filthy, putrid, or decomposed substance, or (2) has been prepared, packed, or held under insanitary conditions whereby it may have become contaminated with filth, or whereby it may have been rendered injurious to health. A copy of such report shall be sent promptly to the Secretary."