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	5/26 – 5/28/2026
	FEI NUMBER 3022691

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT IS ISSUED

TO: Jeffrey A. Mikita, Puyallup Site Manager

FIRM NAME	STREET ADDRESS
Air Products and Chemicals, Inc.	1500 39th Ave SE
CITY, STATE AND ZIP CODE	TYPE OF ESTABLISHMENT INSPECTED
Puyallup, WA 98374	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:

LABORATORY CONTROL SYSTEM

Observation 1

The establishment of test procedures shall be drafted by the appropriate organizational unit and reviewed and approved by the quality unit.

Specifically,

On May 4, 2023, your firm replaced analyzer (b) (4) , (b) (4) , with an identical (b) (4) (b) (4) used to measure (b) (4) content when loading (b) (4) in trailers.

Per SOP 50-0075, Process Validation, Rev. 3, Replacement of Critical Analyzers, a Gage Reliability and Reproducibility Study is the required (b) (4) method for like-for-kind replacements or equivalent model changes. Your firm conducted a Statistical Quality Control - Precision, Quality Assurance - Reliability & Reproducibility/Gage Capability Study ((b) (4) Method) on May 5, 2023 to approve the replacement (b) (4) for use in monitoring trace (b) (4) during the filling of (b) (4) trailers.

However, your firm was unable to provide documentation of a verification method used to conduct the Reliability & Reproducibility/Gage Capability Study, which was used to approve the replacement (b) (4) (b) (4) for use.

Add Continuation Page

SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE	EMPLOYEE(S) NAME AND TITLE (*Print or Type*)	DATE ISSUED
	GLORIA E. ANDIA -S Digitally signed by GLORIA E. ANDIA -S Date: 2026.05.28 12:18:52 -07'00' ARANJEET SINGH -S Digitally signed by ARANJEET SINGH -S Date: 2026.05.28 12:16:55 -07'00'	Gloria E. Andia Investigator Aranjeet Singh, Investigator	05/28/2026

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."