Boaz EtO Reclamation System – TAST Experience

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2025.2.26

List of Participants Selected for Challenge 2

•https://www.fda.gov/medical-devices/general-hospital-devices-and-supplies/fda-innovation-challenge-2-reduce-ethylene-oxide-emissions

List of Participants Selected for Challenge 2

The FDA received 22 applications from companies large and small to this FDA innovation challenge. After careful review using an established set of criteria, the FDA selected eight participants for this challenge.

Company	Alternative Technology Category
Abbott	Enhanced EtO Cycle Design and Processes
Andersen Scientific, Inc.	Use of EtO-Flexible Chamber Technology
Becton, Dickinson and Company (BD)	Enhanced EtO Cycle Design and Processes
DMB Apparatebau GmbH	Reduced Sterilant Concentration
Medtronic plc	Enhanced EtO Cycle Design and Processes
Sterigenics U.S., LLC	Enhanced EtO Cycle Design and Processes
STERIS	Enhanced EtO Cycle Design and Processes
Taiwan Advanced Sterilization Technologies Inc.	Abatement Strategy

TAST

Pursuit of the Ideal Sterilization Process

- Majority of Ethylene Oxide Gas is not used up in sterilization processes
- Incinerating EO or changing EO to ethylene glycol is a waste of valuable resources.
- Environmental agencies are increasingly putting more emphasis on EO emissions.
- It would be ideal to have a sterilization process that recovers most, if not all, the ethylene oxide for reuse. Only a small amount of fresh additional EO is needed to make up for the unrecovered portion.

TAST

Boaz EtO Reclamation System


BOAZ
EtO Reclamation


BOAZ
EtO Reclamation

Design Criteria

- Intrinsically Safe Technology
- Free from possibility of ethylene oxide leakage
- Free from possible explosion hazards
- Removes, collects and purifies ethylene oxide from the sterilizer EO gas stream
- Exhaust gas is virtually free of ethylene oxide, easy to eliminate this small amount left.
- Integrity of validated EO sterilization cycles is maintained, no revalidation is required.

TAST

Principle of Function

- Our BOAZ system collect the EO gas from the ethylene oxide sterilizer using your existing vacuum pumps, the EO gas goes through a series of heat exchangers, progressively cooling the gas to very low temperatures. Nearly all of the ethylene oxide is condensed or froze into liquid or solid phase and can be separated from the inert gas.

TAST

User Safety

- Customer's safety is maintained by requiring no change in current sterilization practices, including equipment, cycle parameters and validation methods. The BOAZ reclaim system for EO is essentially "add-on'' modules that treats sterilizer discharge gas, requiring no changes in the changes in the sterilization equipment and validated processes.

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FDA Master File # MAF3460

- The BOAZ Cryogenic recovery & Abatement plant has already acquired FDA Device Master File number 3460

U.S. FOOD & DRUG ADMINISTRATION

Acknowledgment Letter

5/7/2021

Yashesh Rawal, Regulatory Affairs Specialist
MAE Consulting Group
119 North Road
Deerfield, NH 03037
UNITED STATES

Dear Yashesh Rawal:

The Center for Devices and Radiological Health (CDRH) of the Food and Drug Administration (FDA) has received your submission. This submission has been assigned the unique document control number below. All future correspondence regarding this submission should be identified prominently with the number assigned and should be submitted to the Document Control Center at the address listed below. Failure to do so may result in processing delays. If you believe the information identified below is incorrect, please contact the Office of Product Evaluation and Quality (OPEQ) submission support at (301) 796-5640 or OPEQSubmissionSupport@fda.hhs.gov.

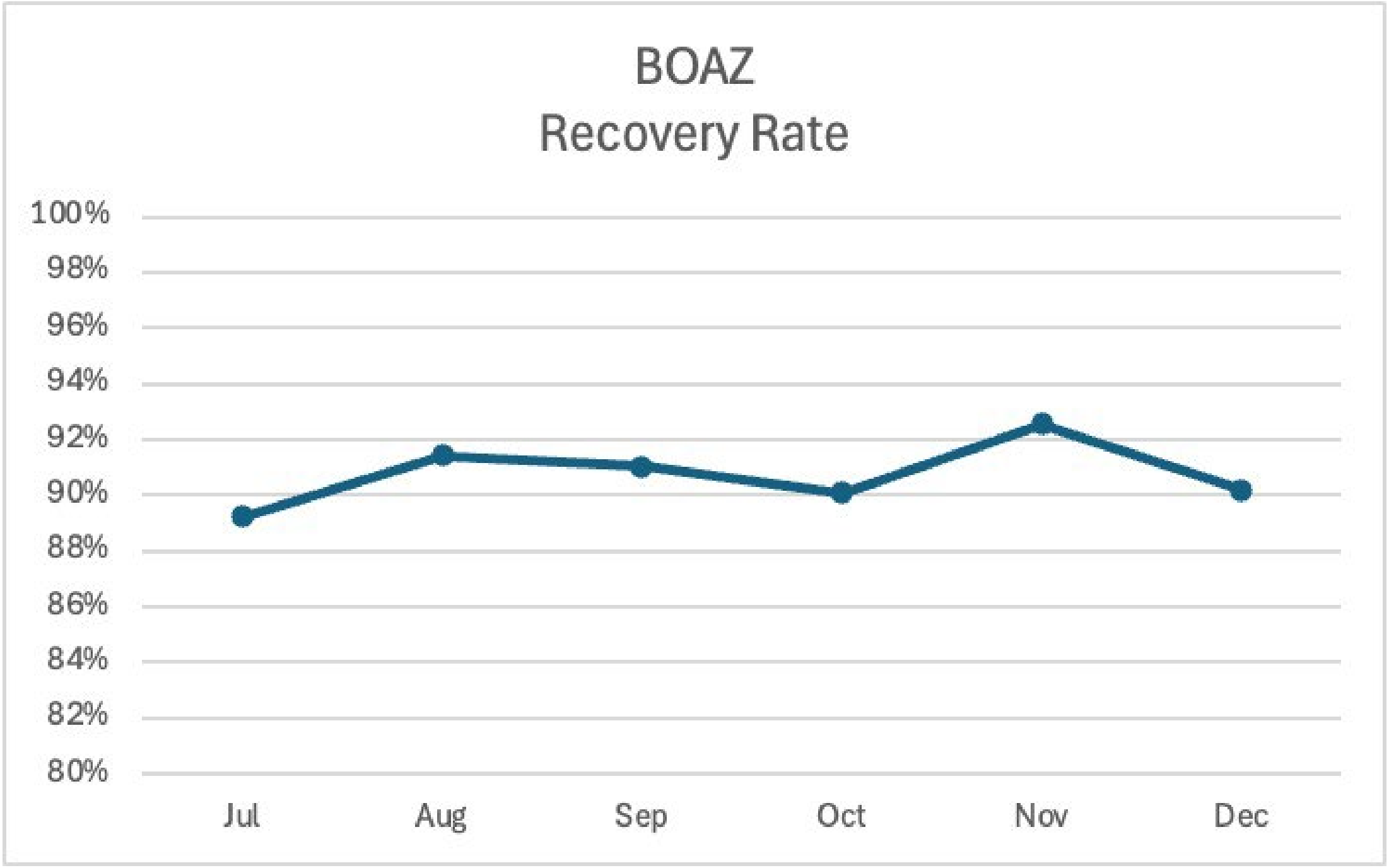
Submission Number: MAF3460
Received: 5/7/2021
Applicant: Taiwan Advanced Sterilization Technology Inc.
Device: BOAZ Clean EtO Emissions and Recovery System

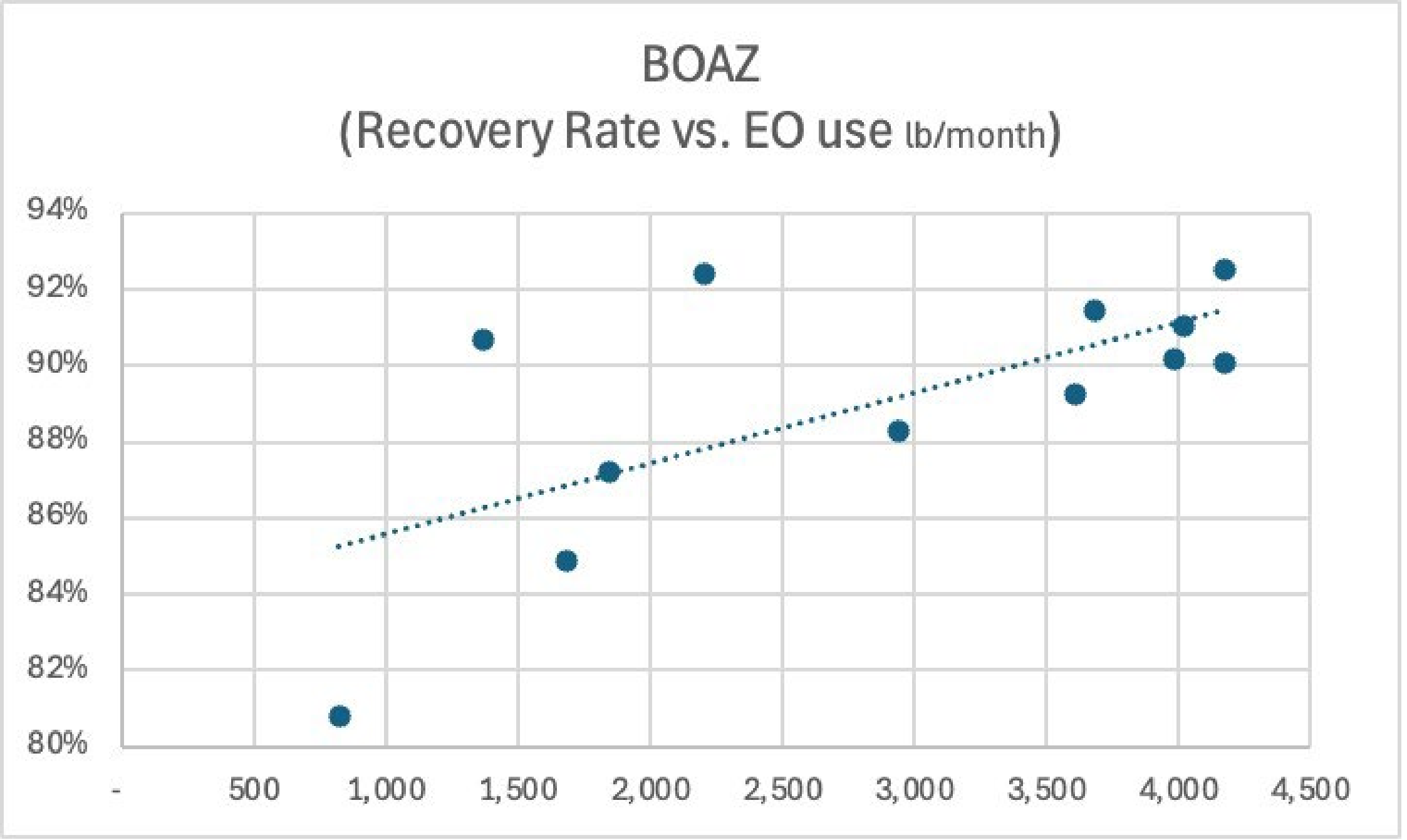
We will notify you when the review of this document has been completed or if any additional information is required. For information about CDRH review regulations and policies, please refer to http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/default.htm.

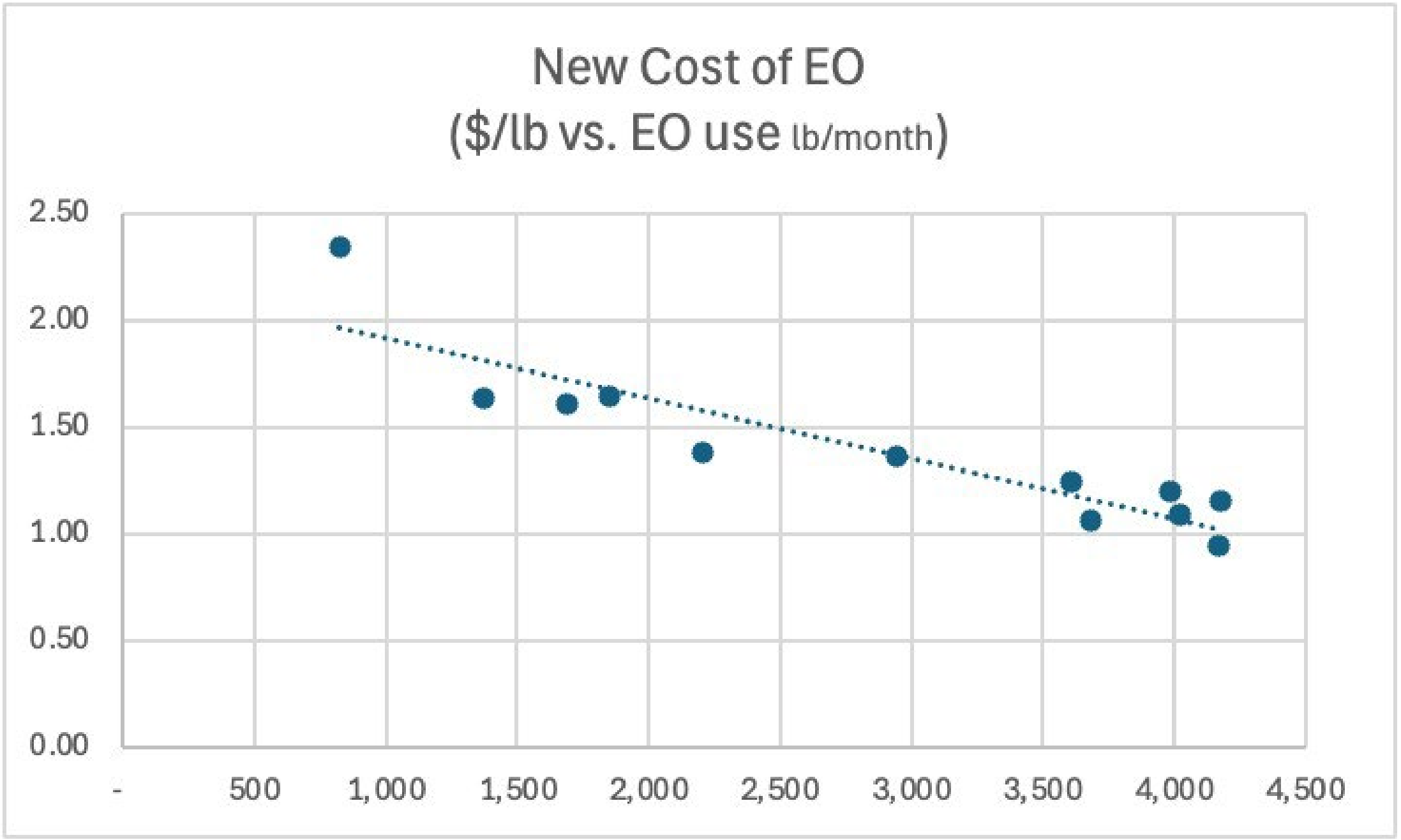
Sincerely yours,

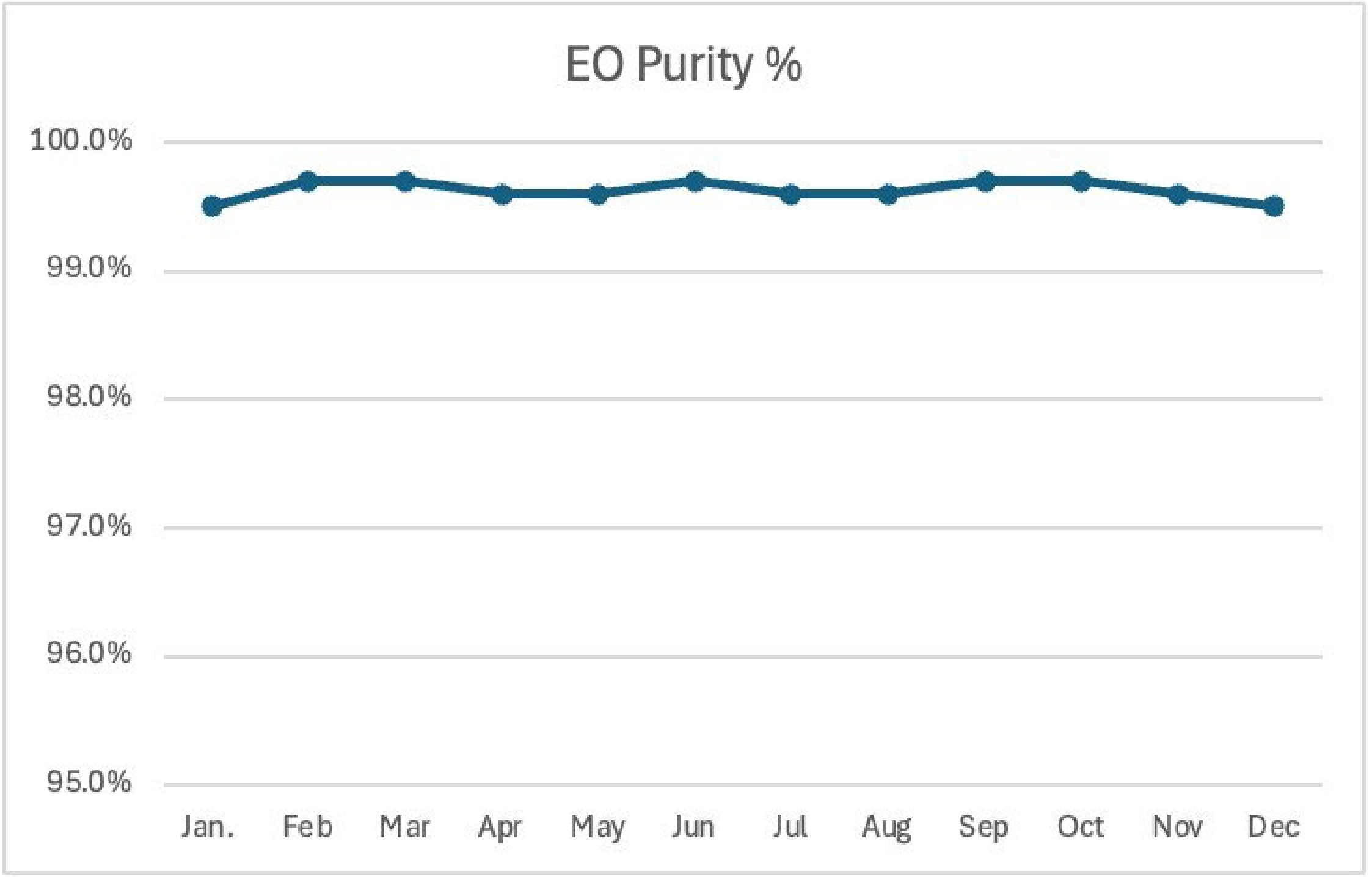
Center for Devices and Radiological Health

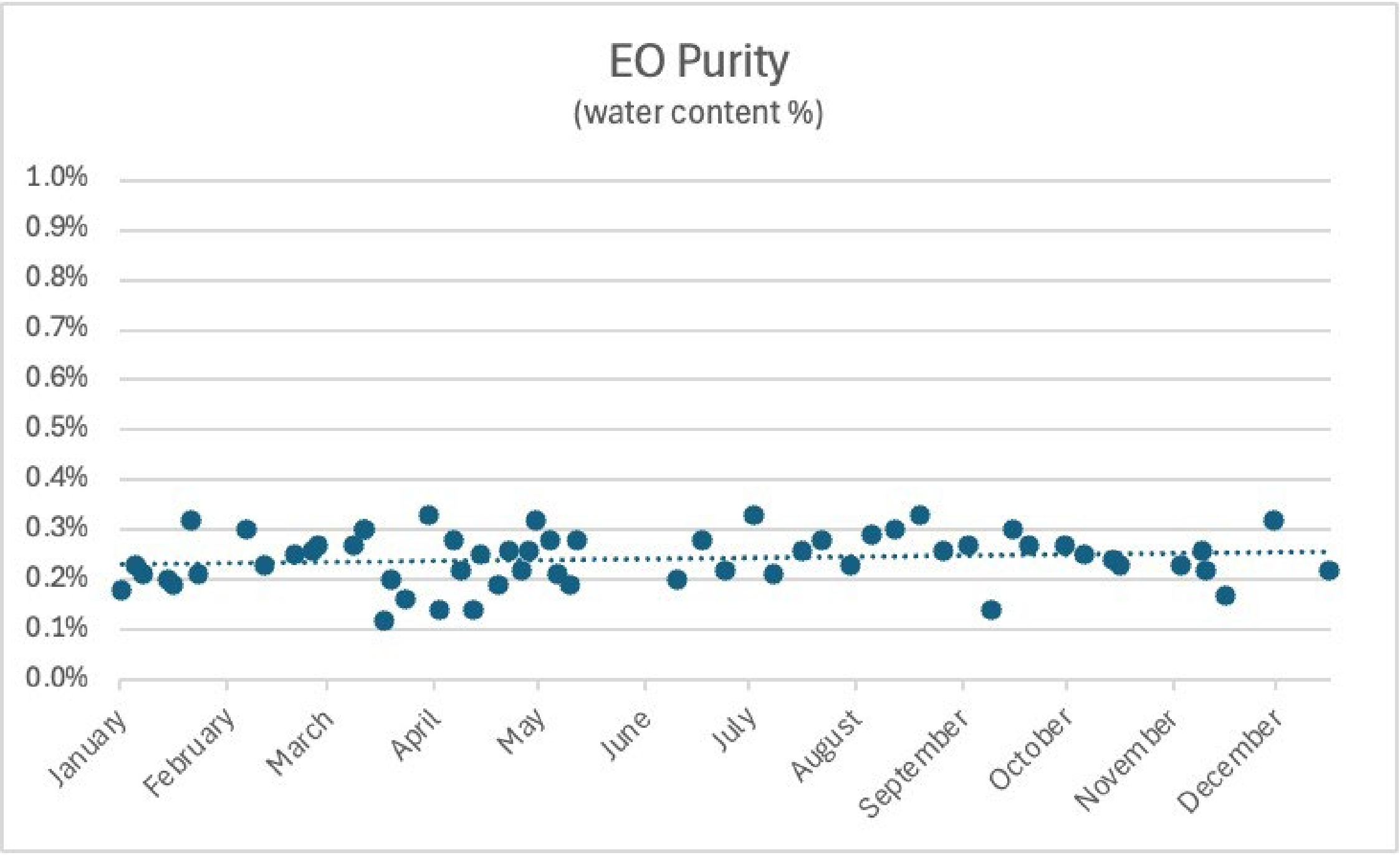
TAST


BOAZ
Recovery Rate
100%
98%
96%
94%
92%
90%
88%
86%
84%
82%
80%
Jul
Aug
Sep
Oct
Nov
Dec


BOAZ
(Recovery Rate vs. EO use lb/month)
94%
92%
90%
88%
86%
84%
82%
80%
-
500
1,000
1,500
2,000
2,500
3,000
3,500
4,000
4,500


New Cost of EO
($/lb vs. EO use lb/month)
2.50
2.00
1.50
1.00
0.50
0.00
-
500
1,000
1,500
2,000
2,500
3,000
3,500
4,000
4,500


EO Purity %
100.0%
99.0%
98.0%
97.0%
96.0%
95.0%
Jan.
Feb
Mar
Apr
May
Jun
Jul
Aug
Sep
Oct
Nov
Dec


EO Purity
(water content %)
1.0%
0.9%
0.8%
0.7%
0.6%
0.5%
0.4%
0.3%
0.2%
0.1%
0.0%
January
February
March
April
May
June
July
August
September
October
November
December

Q&A