

MICHIGAN DEPARTMENT OF ENVIRONMENT, GREAT LAKES, AND ENERGY

INTEROFFICE COMMUNICATION

TO: Centurion Medical Products File

FROM: Amy Robinson, Air Monitoring Unit
Air Quality Division

DATE: September 23, 2021

SUBJECT: Centurion Medical Products Sampling Report

Overview

Healthcare facilities and commercial sterilization facilities like Centurion Medical Products Corporation (Centurion) use Ethylene Oxide (EtO) to sterilize heat-sensitive medical instruments. In December 2016, the United States Environmental Protection Agency (USEPA) updated EtO from a “probable human carcinogen” to a “human carcinogen” and increased its lifetime inhalation cancer risk estimate. EGLE’s previous Initial Risk Screening Level (IRSL), 0.03 µg/m³, was established on September 22, 1982. The updated IRSL (January 17, 2017) for EtO is 0.0002 µg/m³, which is 150 times lower than the previous IRSL. As a result of this change, sterilization facilities have come under new scrutiny even if operating within the limits of their current permit. Centurion’s air permit (Permit to Install No. 24-94B) for the sterilization process was issued by the Air Quality Division (AQD) on August 17, 2017. The permit review relied on the previous IRSL of 0.03 µg/m³ to determine compliance with Michigan’s air toxics rules. Centurion is located at 301 Catrell Drive, Howell, Michigan.

Sampling around the Centurion facility will be carried out in multiple phases. The intent of Phase I sampling was to determine if there were any fugitive emissions coming from the facility. Phase II sampling will be used by the AQD to assess the impact of EtO emissions from Centurion on the surrounding community.

Sampling Event

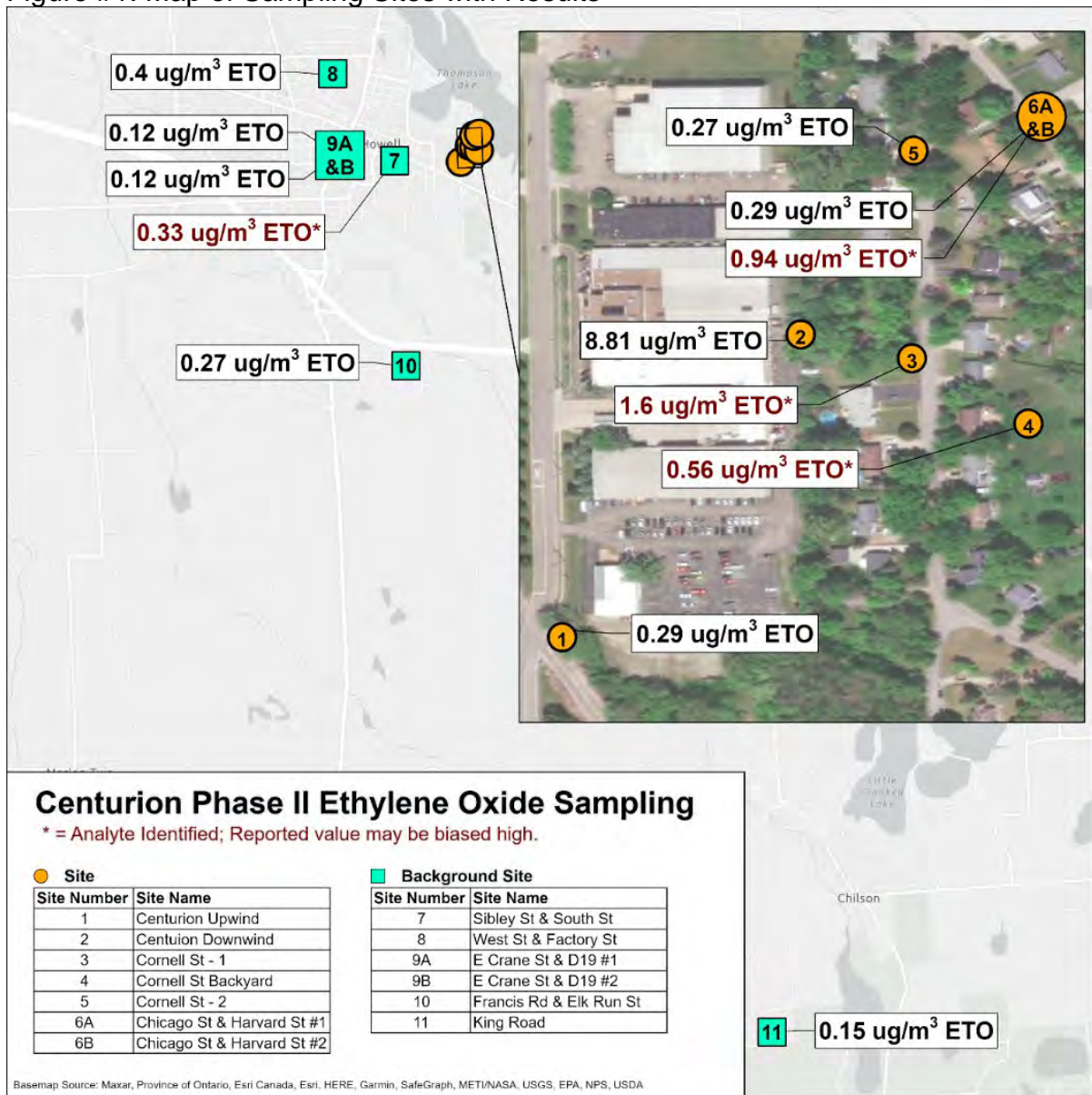
Phase II sampling was conducted for a 24-hour period from August 5 to August 6, 2021. On August 5th, canisters were deployed to the eleven (11) selected sites around the Centurion facility in Howell. There were 2 canisters located on the Centurion property, an additional 4 canisters located at downwind sites, and 5 canisters located at upwind sites. By noon on August 5th, the canisters were fully opened and collecting ambient air. On August 6th, canister takedown started around 10:00 AM.

Site Locations:

Sites Near Centurion		Background Sites	
Site Number	Site Name	Site Number	Site Name
1	Centurion Upwind	7	Sibley St. & South St.
2	Centurion Downwind	8	West St. & Factory St.
3	Catrell Street #1	9	E. Crane St. & D19
4	Catrell Street Backyard	10	Francis Rd. & Elk Run St.
5	Catrell Street #2	11	King Road
6	Chicago St. & Harvard St.		

Photos of individual sites are available upon request.

Figure #1: Map of Sampling Sites with Results



Results

The table below shows the results for the individual stations. The laboratory reports can be found in Appendix A.

Sites	Latitude	Longitude	EtO ($\mu\text{g}/\text{m}^3$)	Flag	Notes
Centurion Upwind	42.603663	-83.914286	0.29		
Centurion Downwind	42.605315	-83.912983	8.81		
287 Cornell St.	42.605185	-83.912374	1.60	LK	Analyte Identified; Reported value may be biased high.
262 Cornell St. Backyard	42.604829	-83.911737	0.56	LK	Analyte Identified; Reported value may be biased high.
351 Cornell St.	42.606319	-83.912366	0.27		
Chicago St. & Harvard St. #1	42.606506	-83.911665	0.29		
Chicago St. & Harvard St. #2	42.606506	-83.911665	0.94	LK	Analyte Identified; Reported value may be biased high.
Background Sites	Latitude	Longitude	EtO ($\mu\text{g}/\text{m}^3$)	Flag	Notes
Sibley St. & South St.	42.603970	-83.923496	0.33	LK	Analyte Identified; Reported value may be biased high.
West St. & Factory St.	42.613066	-83.931828	0.40		
E. Crane St. & D19 #1	42.604662	-83.931109	0.12		
E. Crane St. & D19 #2	42.604662	-83.931109	0.12		
Francis Rd. & Elk Run St.	42.582857	-83.922653	0.27		
King Road	42.513432	-83.874049	0.15		

The EtO MDL = 0.0261 ppbv or 0.0470 $\mu\text{g}/\text{m}^3$

Appendix A



Eastern Research Group
601 Keystone Park Drive
Suite 700
Morrisville, NC 27560

September 14, 2021

Ms. Amy Robinson
Michigan Department of Environment
PO Box 30260
Lansing, MI 48909
Project Name: MI EtO

Dear Ms. Amy Robinson,

This report contains the analytical results for the sample(s) received under chain(s) of custody by Eastern Research Group on 08/10/21 10:54.

Values below the MDL for QC results in this report are recorded as ND, however the actual values are reported in the accompanying Excel report with a "U" flag (Under the detection limit). The actual values are reported in AQS.

This test is accredited under the 2016 TNI Standard for Environmental Laboratories (FL DOH Certification # E87673). All analyses were performed as described in the US EPA-approved QAPP, under the contract for UATMP, NATTS, CSATAM, PAMS and NMOC support (US EPA Contract No. EP-D-14-030). This cover page is an integral part of this report, and any exceptions or comments are noted on the last page.

Release of the data contained in this data package and in the data submitted in the electronic data deliverable, has been authorized by the Program Manager, or the Program Manager's designee as verified by the following signature.

The issuance of the final Certificate of Analysis takes precedence over any previous Report. If you have any questions, please contact me at 919-468-7924.

Sincerely,

Julie Swift
Program Manager
julie.swift@erg.com

The information contained in this report and its attachment(s) are intended only for the use of the individual to whom it is addressed and may contain information that is privileged, confidential, or exempt from disclosure. If the reader of this message is not the intended recipient, you are hereby notified that any dissemination, distribution, or copying of this report is strictly prohibited. If you have received this report in error, please notify julie.swift@erg.com and delete the report without retaining any copies.



CERTIFICATE OF ANALYSIS

U.S. Environmental Protection Agency, Region 5
 PO Box 30260
 Lansing, MI 48909
ATTN: Ms. Amy Robinson
PHONE: (517) 241-2198 **FAX:** (312) 886-5824

FILE #: [none]
REPORTED: 09/14/21 13:31
SUBMITTED: 08/10/21
AQS SITE CODE:
SITE CODE: MI EtO

ANALYTICAL REPORT FOR SAMPLES

<u>SampleName</u>	<u>LabNumber</u>	<u>Matrix</u>	<u>Sampled</u>	<u>Received</u>
Chicago + Harvard #1	1081032-01	Air	08/05/21 14:00	08/10/21 10:54
Chicago + Harvard #2	1081032-02	Air	08/05/21 14:20	08/10/21 10:54
Crane + D19 #1	1081032-03	Air	08/05/21 14:15	08/10/21 10:54
Crane + D19 #2	1081032-04	Air	08/05/21 14:15	08/10/21 10:54
Francis Rd + Elk Run	1081032-05	Air	08/05/21 23:59	08/10/21 10:54
Sibley + South	1081032-06	Air	08/05/21 23:31	08/10/21 10:54
287 Cornell	1081032-07	Air	08/05/21 23:40	08/10/21 10:54
351 Cornell	1081032-08	Air	08/05/21 23:31	08/10/21 10:54
West + Factory	1081032-09	Air	08/05/21 23:55	08/10/21 10:54
262 Cornell Background	1081032-10	Air	08/05/21 23:45	08/10/21 10:54
Centurion Fence	1081032-11	Air	08/05/21 23:45	08/10/21 10:54
Centurion Upwind	1081032-12	Air	08/05/21 23:37	08/10/21 10:54
Background - AR	1081032-13	Air	08/05/21 23:59	08/10/21 10:54



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 PHONE: (517) 241-2198 FAX: (312) 886-5824

FILE #: [none]
 REPORTED: 09/14/21 13:31
 SUBMITTED: 08/10/21
 AQS SITE CODE:
 SITE CODE: MI EtO

Description: Chicago + Harvard #1 **Lab ID:** 1081032-01 **Sampled:** 08/05/21 14:00
Pressure @ Receipt: 6.50 "Hg **Canister #:** 18810 **Received:** 08/10/21 10:54
Comments: Dup 1 **Analyzed:** 08/20/21 19:34

Air Toxics by EPA Compendium Method TO-15

<u>Analyte</u>	<u>Results</u>		<u>Flag</u>	<u>MDL</u>
	<u>ppbv</u>	<u>ug/m³</u>		<u>ppbv</u>
Ethylene oxide	0.160	0.29		0.0261



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FILE #: [none]

REPORTED: 09/14/21 13:31

SUBMITTED: 08/10/21

AQS SITE CODE:

SITE CODE: MI EtO

Description: Chicago + Harvard #2	Lab ID: 1081032-02	Sampled: 08/05/21 14:20
Pressure @ Receipt: 6.00 "Hg	Canister #: SAT139	Received: 08/10/21 10:54
Comments: Dup 2		Analyzed: 08/20/21 20:35

Air Toxics by EPA Compendium Method TO-15

<u>Analyte</u>	<u>Results</u>		<u>Flag</u>	<u>MDL</u>
	<u>ppbv</u>	<u>ug/m³</u>		<u>ppbv</u>
Ethylene oxide	0.518	0.94	LK	0.0261



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FILE #: [none]

REPORTED: 09/14/21 13:31

SUBMITTED: 08/10/21

AQS SITE CODE:

SITE CODE: MI EtO

Description: Crane + D19 #1	Lab ID: 1081032-03	Sampled: 08/05/21 14:15
Pressure @ Receipt: 6.00 "Hg	Canister #: 18880	Received: 08/10/21 10:54
Comments: Col 1 (modified analysis list)		Analyzed: 08/17/21 01:15

Air Toxics by EPA Compendium Method TO-15

<u>Analyte</u>	<u>Results</u>		<u>Flag</u>	<u>MDL</u>
	<u>ppbv</u>	<u>ug/m³</u>		<u>ppbv</u>
Ethylene oxide	0.0664	0.12		0.0261
trans-1,2-Dichloroethylene	0.0651	0.26		0.00708
Trichloroethylene	0.00450	0.02	U	0.0146



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FILE #: [none]

REPORTED: 09/14/21 13:31

SUBMITTED: 08/10/21

AQS SITE CODE:

SITE CODE: MI EtO

Description: Crane + D19 #2

Lab ID: 1081032-04

Sampled: 08/05/21 14:15

Pressure @ Receipt: 8.00 "Hg

Canister #: 18889

Received: 08/10/21 10:54

Comments: Col 2 (modified analysis list)

Analyzed: 08/17/21 02:15

Air Toxics by EPA Compendium Method TO-15

<u>Analyte</u>	<u>Results</u>		<u>Flag</u>	<u>MDL</u>
	<u>ppbv</u>	<u>ug/m³</u>		<u>ppbv</u>
Ethylene oxide	0.0639	0.12		0.0261
trans-1,2-Dichloroethylene	0.0671	0.27		0.00708
Trichloroethylene	0.00430	0.02	U	0.0146



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FILE #: [none]
 REPORTED: 09/14/21 13:31
 SUBMITTED: 08/10/21
 AQS SITE CODE:
 SITE CODE: MI EtO

Description: Francis Rd + Elk Run **Lab ID:** 1081032-05 **Sampled:** 08/05/21 23:59
Pressure @ Receipt: 6.50" Hg **Canister #:** SAT031 **Received:** 08/10/21 10:54
Comments: **Analyzed:** 08/20/21 21:35

Air Toxics by EPA Compendium Method TO-15

<u>Analyte</u>	<u>Results</u>		<u>Flag</u>	<u>MDL</u>
	<u>ppbv</u>	<u>ug/m³</u>		<u>ppbv</u>
Ethylene oxide	0.152	0.27		0.0261



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FILE #: [none]
 REPORTED: 09/14/21 13:31
 SUBMITTED: 08/10/21
 AQS SITE CODE:
 SITE CODE: MI EtO

Description: Sibley + South	Lab ID: 1081032-06	Sampled: 08/05/21 23:31
Pressure @ Receipt: 7.00" Hg	Canister #: SAT005	Received: 08/10/21 10:54
Comments:		Analyzed: 08/20/21 22:36

Air Toxics by EPA Compendium Method TO-15

<u>Analyte</u>	<u>Results</u>		<u>Flag</u>	<u>MDL</u>
	<u>ppbv</u>	<u>ug/m³</u>		<u>ppbv</u>
Ethylene oxide	0.183	0.33	LK	0.0261



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FILE #: [none]

REPORTED: 09/14/21 13:31

SUBMITTED: 08/10/21

AQS SITE CODE:

SITE CODE: MI EtO

Description: 287 Cornell

Lab ID: 1081032-07

Sampled: 08/05/21 23:40

Pressure @ Receipt: 7.50" Hg

Canister #: SAT014

Received: 08/10/21 10:54

Comments:

Analyzed: 08/20/21 23:36

Air Toxics by EPA Compendium Method TO-15

<u>Analyte</u>	<u>Results</u>		<u>Flag</u>	<u>MDL</u>
	<u>ppbv</u>	<u>ug/m³</u>		<u>ppbv</u>
Ethylene oxide	0.888	1.60	LK	0.0261



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FILE #: [none]
 REPORTED: 09/14/21 13:31
 SUBMITTED: 08/10/21
 AQS SITE CODE:
 SITE CODE: MI EtO

Description: 351 Cornell	Lab ID: 1081032-08	Sampled: 08/05/21 23:31
Pressure @ Receipt: 7.50" Hg	Canister #: 18818	Received: 08/10/21 10:54
Comments:		Analyzed: 08/21/21 00:37

Air Toxics by EPA Compendium Method TO-15

<u>Analyte</u>	<u>Results</u>		<u>Flag</u>	<u>MDL</u>
	<u>ppbv</u>	<u>ug/m³</u>		<u>ppbv</u>
Ethylene oxide	0.147	0.27		0.0261



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FILE #: [none]
 REPORTED: 09/14/21 13:31
 SUBMITTED: 08/10/21
 AQS SITE CODE:
 SITE CODE: MI EtO

Description: West + Factory **Lab ID:** 1081032-09 **Sampled:** 08/05/21 23:55
Pressure @ Receipt: 6.00" Hg **Canister #:** 35141 **Received:** 08/10/21 10:54
Comments: **Analyzed:** 08/21/21 01:38

Air Toxics by EPA Compendium Method TO-15

<u>Analyte</u>	<u>Results</u>		<u>Flag</u>	<u>MDL</u>
	<u>ppbv</u>	<u>ug/m³</u>		<u>ppbv</u>
Ethylene oxide	0.222	0.40		0.0261



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FILE #: [none]
 REPORTED: 09/14/21 13:31
 SUBMITTED: 08/10/21
 AQS SITE CODE:
 SITE CODE: MI EtO

Description: 262 Cornell Background **Lab ID:** 1081032-10 **Sampled:** 08/05/21 23:45
Pressure @ Receipt: 5.50" Hg **Canister #:** SAT018 **Received:** 08/10/21 10:54
Comments: **Analyzed:** 08/21/21 02:38

Air Toxics by EPA Compendium Method TO-15

<u>Analyte</u>	<u>Results</u>		<u>Flag</u>	<u>MDL</u>
	<u>ppbv</u>	<u>ug/m³</u>		<u>ppbv</u>
Ethylene oxide	0.308	0.56	LK	0.0261



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FILE #: [none]
 REPORTED: 09/14/21 13:31
 SUBMITTED: 08/10/21
 AQS SITE CODE:
 SITE CODE: MI EtO

Description: Centurion Fence **Lab ID:** 1081032-11 **Sampled:** 08/05/21 23:45
Pressure @ Receipt: 7.00" Hg **Canister #:** SAT061 **Received:** 08/10/21 10:54
Comments: **Analyzed:** 08/21/21 03:39

Air Toxics by EPA Compendium Method TO-15

<u>Analyte</u>	<u>Results</u>		<u>Flag</u>	<u>MDL</u>
	<u>ppbv</u>	<u>ug/m³</u>		<u>ppbv</u>
Ethylene oxide	4.88	8.81		0.0261



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FILE #: [none]

REPORTED: 09/14/21 13:31

SUBMITTED: 08/10/21

AQS SITE CODE:

SITE CODE: MI EtO

Description: Centurion Upwind

Lab ID: 1081032-12

Sampled: 08/05/21 23:37

Pressure @ Receipt: 7.50" Hg

Canister #: 35125

Received: 08/10/21 10:54

Comments:

Analyzed: 08/21/21 05:40

Air Toxics by EPA Compendium Method TO-15

<u>Analyte</u>	<u>Results</u>		<u>Flag</u>	<u>MDL</u>
	<u>ppbv</u>	<u>ug/m³</u>		<u>ppbv</u>
Ethylene oxide	0.162	0.29		0.0261



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FILE #: [none]
 REPORTED: 09/14/21 13:31
 SUBMITTED: 08/10/21
 AQS SITE CODE:
 SITE CODE: MI EtO

Description: Background - AR	Lab ID: 1081032-13	Sampled: 08/05/21 23:59
Pressure @ Receipt: 8.00" Hg	Canister #: 33243	Received: 08/10/21 10:54
Comments:		Analyzed: 08/21/21 06:41

Air Toxics by EPA Compendium Method TO-15

<u>Analyte</u>	<u>Results</u>		<u>Flag</u>	<u>MDL</u>
	<u>ppbv</u>	<u>ug/m³</u>		<u>ppbv</u>
Ethylene oxide	0.0837	0.15		0.0261



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FILE #: [none]
 REPORTED: 09/14/21 13:31
 SUBMITTED: 08/10/21
 AQS SITE CODE:
 SITE CODE: MI EtO

Analyte	Result	Units	Source Result	RPD	RPD Limit	Notes
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Air Toxics by EPA Compendium Method TO-15 - Quality Control

Batch B1H1612 - Summa Canister Prep

Blank (B1H1612-BLK1)

Prepared: 07/23/21 Analyzed: 08/16/21

Ethylene oxide	ND	ppbv				U
trans-1,2-Dichloroethylene	ND	ppbv				U
Trichloroethylene	ND	ppbv				U

Duplicate (B1H1612-DUP3)**Source: 1081032-03**

Prepared: 08/05/21 Analyzed: 08/17/21

Ethylene oxide	0.0698	ppbv	0.07	4.99	25	
trans-1,2-Dichloroethylene	0.0639	ppbv	0.07	1.86	25	
Trichloroethylene	ND	ppbv	ND		25	U

Duplicate (B1H1612-DUP4)**Source: 1081032-04**

Prepared: 08/05/21 Analyzed: 08/17/21

Ethylene oxide	0.0589	ppbv	0.06	8.14	25	
trans-1,2-Dichloroethylene	0.0666	ppbv	0.07	0.748	25	
Trichloroethylene	ND	ppbv	ND		25	U

Batch B1H2003 - Summa Canister Prep

Blank (B1H2003-BLK1)

Prepared & Analyzed: 08/20/21

Ethylene oxide	ND	ppbv				U
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Duplicate (B1H2003-DUP1)**Source: 1081032-11**

Prepared: 08/05/21 Analyzed: 08/21/21

Ethylene oxide	4.87	ppbv	4.88	0.277	25	
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FILE #: [none]
 REPORTED: 09/14/21 13:31
 SUBMITTED: 08/10/21
 AQS SITE CODE:
 SITE CODE: MI EtO

Analyte	Result	Units	% Difference	Limit (%)	Notes
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Air Toxics by EPA Compendium Method TO-15 - Quality Control

Sequence 2108047

Calibration Check (2108047-CCV1)

Prepared & Analyzed: 08/16/21

Ethylene oxide	2.28	ppbv	-8.6	30.00	
trans-1,2-Dichloroethylene	2.73	ppbv	9.2	30.00	
Trichloroethylene	3.04	ppbv	20.2	30.00	

Sequence 2108062

Calibration Check (2108062-CCV1)

Prepared & Analyzed: 08/20/21

Ethylene oxide	2.46	ppbv	1.8	30.00	
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FILE #: [none]
REPORTED: 09/14/21 13:31
SUBMITTED: 08/10/21
AQS SITE CODE:
SITE CODE: MI EtO

Notes and Definitions

U Under Detection Limit
LK Analyte identified; Reported value may be biased high.
ND Analyte NOT DETECTED
NR Not Reported
MDL Method Detection Limit
RPD Relative Percent Difference

Note: This test is accredited under the 2016 TNI Standard; however the following analytes are not accredited: acetylene, bromodichloroethane, dichlorotetrafluoromethane, ethyl tert butyl ether, n-octane, tert amyl methyl ether, trichlorofluoroethane, and bromochloromethane.