MONTROSE
AIR QUALITY SERVICES

March 23, 2020

Medline Industries
3 Lake Drive
Northfield, IL 60093

Attention: Mr. Jasper Titus

Subject: PTE Verification
Sterilization Process
Medline Industries: Waukegan, Illinois
Document No. M928ET-663754-RT-457

Dear Mr. Titus:

Montrose Air Quality Services, LLC (Montrose) was contracted by Medline Industries (Medline) to perform a permanent total enclosure (PTE) verification test at their facility located in Waukegan, Illinois.

The test objective was to determine the ethylene oxide (EtO) capture efficiency (CE) of the sterilization process capture system utilizing USEPA Method 204. The sterilization process and related operations are enclosed in a PTE which was evaluated on March 6, 2020 to determine if it meets the requirements specified in Method 204 to obtain 100% CE.

The PTE areas for shipping, aeration/degassing, and chamber/sterilization were interconnected and treated as a single PTE. The drum room and vacuum pump scrubber room were separate areas and treated as individual PTEs.

The following criteria were checked for PTE compliance:

1. All EtO emissions were captured and contained for discharge through a control device
2. All NDOs were at least 4 equivalent opening diameters from each EtO emitting point
3. The total area of all NDOs did not exceed 5% of the surface area of the enclosure's walls, floor, and ceiling
4. The average facial velocity (FV) of the air through all NDOs was at least 200 fpm or the differential pressure across the PTE was equal to or greater than 0.007 inches of water. The direction of air through all NDOs was into the enclosure.
5. All access doors and windows whose areas were not included in the calculation of FV were closed during routine operation of the process

Montrose performed the following field measurements during the PTE verification:

1. Physical measurements of the PTEs
2. Physical measurements of the NDOs
3. Measurement of the negative static pressure within the PTE while the process was in normal operation and while venting to the control device. A micromanometer was used for the measurements. Inward flow was verified or actual negative pressure readings were taken at 10-minute intervals for 60 minutes.

Mr. Jasper Titus of Medline coordinated the test. Mr. Steve Flaherty of Montrose was the qualified source testing individual who performed the evaluations. Mr. Kevin Mattison of the Illinois Environmental Protection Agency witnessed the test.

The PTE verification results are presented in Table 1. The PTE evaluation field data are included in the attachment. Each PTE met the requirements of USEPA Method 204 demonstrating 100% capture efficiency.

If you have any questions, please do not hesitate to contact me at (847) 487-1580 Ext. 12417 or sflaherty@montrose-env.com.

Respectfully submitted,

Steve Flaherty
Midwest District Manager
Montrose Air Quality Services, LLC

TABLE 1
SUMMARY OF PTE VERIFICATION TEST RESULTS

Date: **3/6/2020**
Time: **10:45 – 11:45**

PTE Criteria	As Measured	Compliance Requirements
NDOs shall be at least 4 equivalent diameters from each EtO emitting point	Yes	≥ 4.0
Total area of all NDOs shall not exceed 5% of the surface area of the enclosure walls, floor, and ceiling		
Shipping, Aeration/Degassing, Chamber/Sterilization Areas	0.047%	≤ 5.0%
Drum Room	0.153%	≤ 5.0%
Vacuum Pump Scrubber Room	0.014%	≤ 5.0%
Pressure differential across the enclosure shall be equal to or greater than 0.007 inches of water	Minimum: 0.013 Maximum: 0.086	≥ 0.007
The direction of air through all NDOs shall be inward or into the PTE	All Inward	All Inward
The access doors and windows whose areas are not included in the calculation of FV shall be closed during operating of the process	All Closed	All Closed

ATTACHMENT
PTE EVALUATION FIELD DATA

Method 204
Procedure T
Criteria For and Verification Of A Permanent of Temporary Total Enclosure
Near Ratio Calculation Worksheet

Client: Medline
Location: Waukegan, IL
Source: PTE Enclosures
Test Date: 3/6/2020

Enclosure Surface Area:

Shipping Area

Section 1

Enclosure Length:	43.667 ft		
Enclosure Width:	49.500 ft	=	9,447.22 ft^2
Enclosure Height:	27.500 ft		

Shipping Area:

Section 2

Enclosure Length:	152.833 ft		
Enclosure Width:	68.500 ft	=	33,111.44 ft^2
Enclosure Height:	27.500 ft		

Aeration/Degassing Room No. 1

Enclosure Length:	118.500 ft		
Enclosure Width:	59.250 ft	=	19,700.74 ft^2
Enclosure Height:	15.917 ft		

Aeration/Degassing Room No. 2

Enclosure Length:	118.500 ft		
Enclosure Width:	56.250 ft	=	19,272.75 ft^2
Enclosure Height:	17.000 ft		

Chamber/Sterilizer Room

Enclosure Length:	116.167 ft		
Enclosure Width:	78.583 ft	=	28,903.71 ft^2
Enclosure Height:	27.333 ft		

Total Enclosure Surface Area (A_t): = 110,435.9 ft^2

Where:

Enclosure Surface Area (A_t): $A_t = 2(L \times W) + 2(W \times H) + 2(L \times H)$

NDO Total Surface Area

NDO Total Area (A_w) = 45.262 ft^2

Near Ratio Calculation

Near ratio $= \frac{A_w}{A_t} = \leq 0.05$ = 0.00041

Method 204

Procedure T

Criteria For and Verification Of A Permanent or Temporary Total Enclosure

NDO Worksheet

Client: Medline
Location: Waukegan, IL
Source: PTE Enclosures
Test Date: 3/6/2020

NDO #	NDO Description/Location	NDO Dimensions,inches (rect/square)	NDO Dimensions, inches (Round)	NDO Area ft2	Eqiv Dia (in.)	NDO Distance from Emission Point (in.)	Meets Distance Criteria	NDO Facial Velocity (fpm)	NDO Inward Flow (Y/N)
1	Shipping Door #4 - Bottom Gap	Length= 94.00 Width= 6.00	Diameter=	3.9167	26.7975	> 107.2	Yes		Y
2	Shipping Door #4 - Right Side Gap	Length= 110.00 Width= 0.50	Diameter=	0.3819	8.3683	> 33.5	Yes		Y
3	Shipping Door #4 - Left Side Gap	Length= 110.00 Width= 0.50	Diameter=	0.3819	8.3683	> 33.5	Yes		Y
4	Shipping Door #5 - Bottom Gap	Length= 94.00 Width= 6.00	Diameter=	3.9167	26.7975	> 107.2	Yes		Y
5	Shipping Door #5 - Right Side Gap	Length= 110.00 Width= 0.50	Diameter=	0.3819	8.3683	> 33.5	Yes		Y
6	Shipping Door #5 - Left Side Gap	Length= 110.00 Width= 0.50	Diameter=	0.3819	8.3683	> 33.5	Yes		Y
7	Shipping Door #6 - Bottom Gap	Length= 94.00 Width= 6.00	Diameter=	3.9167	26.7975	> 107.2	Yes		Y
8	Shipping Door #6 - Right Side Gap	Length= 110.00 Width= 0.50	Diameter=	0.3819	8.3683	> 33.5	Yes		Y
9	Shipping Door #6 - Left Side Gap	Length= 110.00 Width= 0.50	Diameter=	0.3819	8.3683	> 33.5	Yes		Y
10	Shipping Door #7 - Propane/Garbage	Length= 110.00 Width= 0.25	Diameter=	0.1910	5.9173	> 23.7	Yes		Y
11	Shipping Room - Air Makeup No. 1	Length= 33.00 Width= 33.00	Diameter=	7.5625	37.2365	209.0	Yes		Y
12	Shipping Room - Air Makeup No. 2	Length= 33.00 Width= 33.00	Diameter=	7.5625	37.2365	209.0	Yes		Y
13	Sterilizer Fire Door - left side gap	Length= 97.00 Width= 0.25	Diameter=	0.1684	5.5566	190.0	Yes		Y
14	Sterilizer Fire Door - bottom gap	Length= 76.00 Width= 0.75	Diameter=	0.3958	8.5191	190.0	Yes		Y
15	Ster. Fire Door - top/left louvered panel	Length= 23.50 Width= 23.50	Diameter=	3.8351	26.5169	190.0	Yes		Y
16	Ster. Fire Door - top/right louvered panel	Length= 23.50 Width= 23.50	Diameter=	3.8351	26.5169	190.0	Yes		Y
17	Ster. Fire Door - bottom/left louvered panel	Length= 23.50 Width= 23.50	Diameter=	3.8351	26.5169	190.0	Yes		Y
18	Ster. Fire Door - bottom/right louvered panel	Length= 23.50 Width= 23.50	Diameter=	3.8351	26.5169	190.0	Yes		Y

Method 204
Procedure T
Criteria For and Verification Of A Permanent of Temporary Total Enclosure
Near Ratio Calculation Worksheet

Client: Medline
Location: Waukegan, IL
Source: PTE Enclosures
Test Date: 3/6/2020

Enclosure Surface Area:

Drum Room

Enclosure Length:	39.833 ft		
Enclosure Width:	20.250 ft	=	4,947.84 ft^2
Enclosure Height:	27.750 ft		

Total Enclosure Surface Area (A_t): = 4,947.8 ft^2

Where:
Enclosure Surface Area (A_t): $A_t = 2(L \times W) + 2(W \times H) + 2(L \times H)$

NDO Total Surface Area

NDO Total Area (A_w) = 7.569 ft^2

Near Ratio Calculation

$$\text{Near ratio} = \frac{A_w}{A_t} = \leq 0.05 = 0.00153$$

Method 204

Procedure T

Criteria For and Verification Of A Permanent or Temporary Total Enclosure

NDO Worksheet

Client: Medline
Location: Waukegan, IL
Source: PTE Enclosures
Test Date: 3/6/2020

NDO #	NDO Description/Location	NDO Dimensions,inches (rect/square)				NDO Dimensions, inches (Round)	NDO Area ft2	Eqiv Dia (in.)	NDO Distance from Emission Point (in.)	Meets Distance Criteria	NDO Facial Velocity (fpm)	NDO Inward Flow (Y/N)
1	Drum Room Ceiling Makeup Air	Length=	33.00	Width=	33.00	Diameter=	7.5625	37.2365	282.0	Yes		Y
2	Drum Room Garage Door Gap	Length=	4.00	Width=	0.25	Diameter=	0.0069	1.1284	98.0	Yes		Y

Method 204
Procedure T
Criteria For and Verification Of A Permanent of Temporary Total Enclosure
Near Ratio Calculation Worksheet

Client: Medline
Location: Waukegan, IL
Source: PTE Enclosures
Test Date: 3/6/2020

Enclosure Surface Area:

Vaccum Pump Scrubber Room

Enclosure Length:	87.250 ft		
Enclosure Width:	39.667 ft	=	13,944.72 ft^2
Enclosure Height:	27.667 ft		

Total Enclosure Surface Area (A_t): = 13,944.7 ft^2

Where:
Enclosure Surface Area (A_t): $A_t = 2(L \times W) + 2(W \times H) + 2(L \times H)$

NDO Total Surface Area

NDO Total Area (A_w) = 1.929 ft^2

Near Ratio Calculation

$$\text{Near ratio} = \frac{A_w}{A_t} = \leq 0.05 = 0.00014$$

Method 204

Procedure T

Criteria For and Verification Of A Permanent or Temporary Total Enclosure

NDO Worksheet

Client: Medline
Location: Waukegan, IL
Source: PTE Enclosures
Test Date: 3/6/2020

NDO #	NDO Description/Location	NDO Dimensions,inches (rect/square)				NDO Dimensions, inches (Round)	NDO Area ft2	Eqiv Dia (in.)	NDO Distance from Emission Point (in.)	Meets Distance Criteria	NDO Facial Velocity (fpm)	NDO Inward Flow (Y/N)
1	Vacuum Pump Man Door Bottom Gap	Length=	35.00	Width=	0.25	Diameter=	0.0608	3.3378	392.0	Yes		Y
2	Vacuum Pump Man Door Top Gap	Length=	96.00	Width=	2.75	Diameter=	1.8333	18.3340	408.0	Yes		Y
3	Vacuum Pump Man Door North Gap	Length=	5.00	Width=	1.00	Diameter=	0.0347	2.5231	433.0	Yes		Y

Company: Medline
Location: Waukegan, IL
Sources: PTE/NDO
Test Date: 3/6/2020
Test Run #: 1 - PTE Verificaiton
Test Time: 10:45-11:45

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Medline NDOs

Time	Elapsed Time	All NDOs demonstrate inward flow	Vacuum/Pump Room		Shipping Garage Doors NDOs				Sterilizer Room	Drum Room
			Man Door NDO	Garage Door NDO	Door #4	Door #5	Door #6	Door #7	Fire Door NDO	Garage Door NDO
10:45	0	Yes	-0.041	-0.042	-0.048	-0.051	-0.047	-0.056	-0.083	-0.046
10:55	10	Yes	Inward	Inward	Inward	Inward	Inward	Inward	Inward	-0.027
11:05	20	Yes	Inward	Inward	Inward	Inward	Inward	Inward	Inward	-0.026
11:15	30	Yes	-0.040	-0.038	-0.037	-0.034	-0.031	-0.034	-0.074	-0.030
11:25	40	Yes	Inward	Inward	Inward	Inward	Inward	Inward	Inward	-0.032
11:35	50	Yes	Inward	Inward	Inward	Inward	Inward	Inward	Inward	-0.025
11:45	60	Yes	-0.033	-0.029	-0.013	-0.031	-0.032	-0.035	-0.086	-0.033

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Company: Medline
Location: Waukegan, IL
Sources: PTE/NDO
Test Date: 3/6/2020
Test Run #: 1 - PTE Verificaiton
Test Time:

Medline NDOs

Time	Elapsed Time	All NDO's demonstrate inward flow	Vacuum/Pump Room Man Door NDO	Vacuum/Pump Room Garage Door NDO	Shipping Garage Doors NDO			
					Door #4	Door #5	Door #6	Door #7
1045	0	Yes	-0.041	-0.042	-0.048	-0.051	-0.047	-0.056
1055	10	Yes	10 - IN	IN	IN	IN	IN	IN
1105	20	Yes	20 - IN	IN	IN	IN	IN	IN
1115	30	Yes	30 - -0.040	-0.038	-0.037	-0.034	-0.031	-0.034
1125	40	Yes	40 - IN	IN	IN	IN	IN	IN
1135	50	Yes	50 - IN	IN	IN	IN	IN	IN
1145	60	Yes	60 - -0.033	-0.029	-0.013	-0.031	-0.032	-0.035

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Company: Medline
Location: Waukegan, IL
Sources: PTE/NDO
Test Date: 3/6/2020
Test Run #: 1 - PTE Verificaiton
Test Time:

Medline NDOs

All fans sealed 100% - No NDO

Time	Elapsed Time	All NDO's demonstrate inward flow	Drum Room Garage Door NDO	Plastic Curtain/Fire Door NDO to Sterilizer Room	Heating fan NDOs upstairs feeding Aeration Room 2		
					North Fan	Middle Fan	South Fan
1045	0	Yes	-0.046	-0.083	NA	NA	NA
1055	10	Yes	-0.027	IN			
1105	20	Yes	-0.026	IN			
1115	30	Yes	-0.030	-0.074			
1125	40	Yes	-0.032	~~IN~~			
1135	50	Yes	-0.025	IN			
1145	60	Yes	-0.033	-0.086			
			~~-0~~ simple				

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If you have any questions, please contact one of the following individuals by email or phone.

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