Viant Medical Inc. (N0795) - Modeling Summary

Prepared by the Michigan Department of Environmental Quality
Air Quality Division, November 5, 2018

Healthcare facilities and commercial sterilization facilities like Viant Medical, Inc. (Viant) use Ethylene Oxide (EtO) to sterilize heat-sensitive medical instruments. In December 2016, the EPA updated EtO from a "probable human carcinogen" to a "human carcinogen" and increased its lifetime inhalation cancer risk estimate. The MDEQ's previous Initial Risk Screening Level (IRSL), 0.03 µg/m^3 was established on September 22, 1982. The updated IRSL (January 17, 2017) for EtO is 0.0002 µg/m^3, 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. Viant's permit (Permit #605-89B) for the sterilization process was issued February 10, 2005 using the previous IRSL of 0.03 µg/m^3.

New ambient air modeling for EtO was conducted for the Viant facility based on information gathered during a site visit on September 14, 2018, involving Jim Haywood and April Lazzaro, MDEQ, Air Quality Division (AQD). The collected site visit information was combined with the most recent actual emissions data, provided by the facility, which included fugitive emissions in addition to scrubber emissions.

The site is located at 520 Watson Street, SW, Grand Rapids. This company has also been known as Medtronic Biomedicus, Inc; Vention Medical; and Medplast Medical, Inc. Summaries of the site visit and emissions data are provided as part of this modeling summary.

September 14, 2018, Site Visit Summary

April Lazzaro and Jim Haywood conducted a site visit early in the afternoon on Friday, September 14, 2018. Site personnel were very accommodating and informative. The first portion of the visit was spent reviewing site plans. It included discussion of the process and that the emissions enter the atmosphere via the scrubber (point source) and various horizontal vents in the building (fugitives). Plant personnel provided the nature of each vent along with flow rates. Fugitive estimates from each vent were based on in-house monitors in areas where those fugitive emissions occur. The MDEQ was not provided with any of the in-house monitor data.

Discussion included traditional methods for reducing ground level impacts (i.e., reduce emissions, control emissions, better dispersion techniques). The company left the opinion that they might be open to other dispersion options like vertical stack release above roof top. The second phase of the site visit was a physical tour of the outside of the plant to observe each vent that emits fugitive emissions.

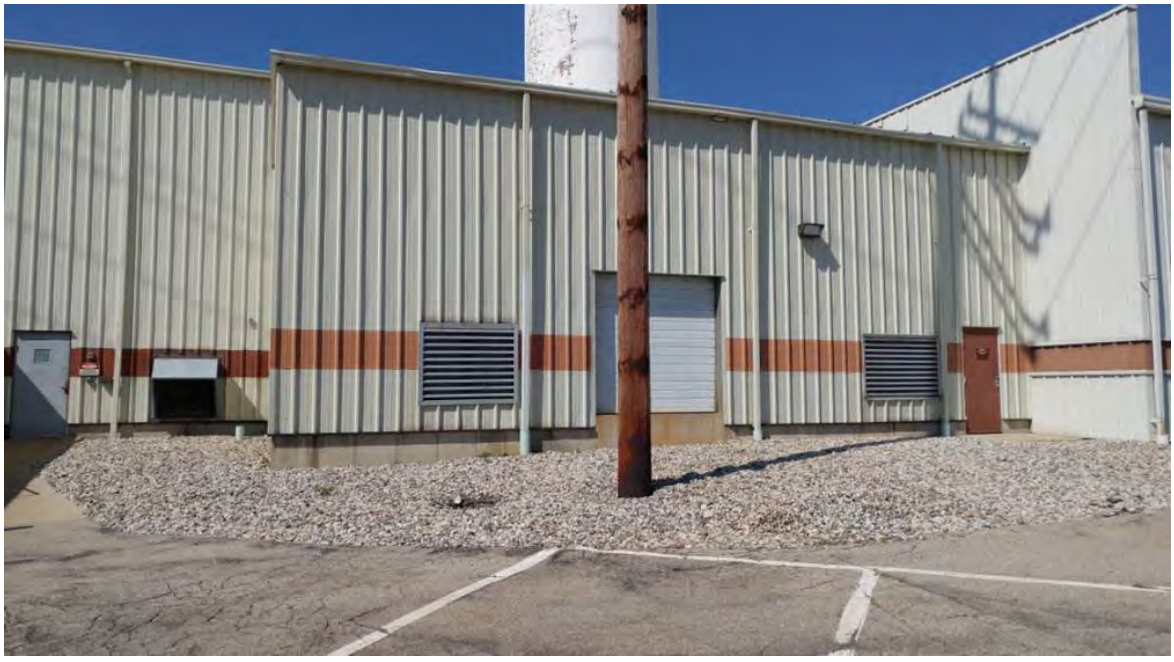
Fugitive Vents

1) Fugitive emissions from hood capture area, floor sweep vents, and vacuum pump room are vented through three closely co-located building side vents (Figure 1). Combined emissions from these three vents account for approximately 30% of all fugitive emissions. There was discussion on whether these emissions could be vented together into a vertical stack for better dispersion.
2) Fugitive emissions from the Drum Room are also vented from a building side vent (Figure 2). Two vents are co-located, with one vent being an intake vent and the other an external vent. Emissions from this vent accounts for approximately 3% of all fugitive emissions.
3) Fugitive emissions from the Scrubber Room and Shipping Area are vented from two vents in the scrubber room and a single vent in the Shipping Area (Figure 3). The vent from the Shipping Area is shut down from November through March. Emissions from these vents account for approximately 67% of all fugitive emissions. Shipping Room emissions were equally split between the two vents. The two Scrubber Room vents are on the right and the part-time Shipping Area hooded vent is to the left. The company noted a stack with a fan near the scrubber/shipping room vents, which is not currently being used. That left open the possibility that if the scrubber/shipping room fugitive emissions could be captured, they might be vented to that stack for better dispersion.

Figure 1 – Hood, Floor, and Vacuum Room Vents

Figure 2 – Drum Room Vents

Figure 3 – Shipping Room Vents



The locations of the vents at various points of the building are provided on Figure 4:

Figure 4 – Vent and Stack Locations at Facility

Emissions Summary

The first emissions used to set up the modeling was based on the 2017 MAERS submittal. A copy of those emissions is provided in Table 1, below.

Table 1 – 2017 Emissions Inventory:

Month	P1-SterFront lb	P2-VacPumpRm lb	P3-SterRear lb	P4-DrumRm lb	P7-ShipDesk lb	Total
Jan	39.30	22.69	99.50	1.30	39.53	202.32
Feb	23.98	17.43	82.27	0.57	40.95	165.20
Mar	51.29	22.08	136.76	2.17	52.33	264.63
Apr	7.47	5.58	16.93	1.19	65.34	96.51
May	41.97	13.25	90.54	1.23	70.44	217.43
Jun	92.34	19.93	220.32	1.01	69.92	403.53
Jul	59.13	14.50	100.77	0.95	67.06	242.40
Aug	1.99	2.10	5.71	0.81	42.61	53.23
Sep	1.85	2.33	6.20	0.72	39.49	50.59
Oct	2.38	4.01	5.60	0.39	43.10	55.48
Nov	6.45	7.15	12.44	3.77	25.49	55.31
Dec	3.95	5.63	8.82	1.16	18.68	38.24
Annual Total:	332.10	136.69	785.87	15.27	574.93	**1844.86**

After conversations with the district office and the facility, it was determined the January-July 2017 emissions were not representative for typical emissions because equipment and personnel issues lead to leaks measured by the Floor Sweep vent system (i.e., P3-SterRear), which yielded unusually large emissions.

For purposes of determining the fractional percentage of emissions during normal operations, January-July emissions were omitted. Table 2 provides the fractional breakdown of emissions from the remaining months of normal operations.

Table 2 – 2017 Emissions Inventory With Malfunction Data Removed & Percent Breakdown

Month	P1-SterFront lb	P2-VacPumpRm lb	P3-SterRear lb	P4-DrumRm lb	P7-ShipDesk lb	Total
Jan						
Feb						
Mar						
Apr						
May						
Jun						
Jul						
Aug	1.99	2.10	5.71	0.81	42.61	53.23
Sep	1.85	2.33	6.20	0.72	39.49	50.59
Oct	2.38	4.01	5.60	0.39	43.10	55.48
Nov	6.45	7.15	12.44	3.77	25.49	55.31
Dec	3.95	5.63	8.82	1.16	18.68	38.24
Annual Total:	16.62	21.21	38.78	6.86	169.37	**252.84**
% of Total	**6.6%**	**8.4%**	**15.3%**	**2.7%**	**67.0%**	

Following the September 14, 2018 site visit, the facility provided the 2018 emissions, to date, as provided in Table 3.

Table 3 – 2018 Emissions Inventory To Date

Month	Pounds EtO Scale Usage	Stack Pounds EtO Emitted	Fugitive Pounds EtO Emitted
Jan	9274.5	0.461	51.7
Feb	8063.0	0.401	40.5
Mar	8426.0	0.419	45.6
Apr	9063.0	0.449	92.1
May	8226.0	0.409	50.0
Jun	8080.0	0.401	59.2
Jul	9835.5	0.490	33.7
Aug	10562.0	0.528	25.9
Sep			
Oct			
Nov			
Dec			
Totals:	**71530**	**3.56**	**398.75**
Total Treated:	**71131**		

Using the fractional breakdown determined in Table 2, the breakdown of the 398.75 lbs of actual fugitive emissions, from January through August 2018, was determined, as follows in Table 4. The average lbs/hr for each source was determined by the sum of the monthly pounds divided by the sum of the hours over eight months.

Table 4 – 2018 Actual Emissions Breakdown by Vent (398.75 lbs Total Emitted)

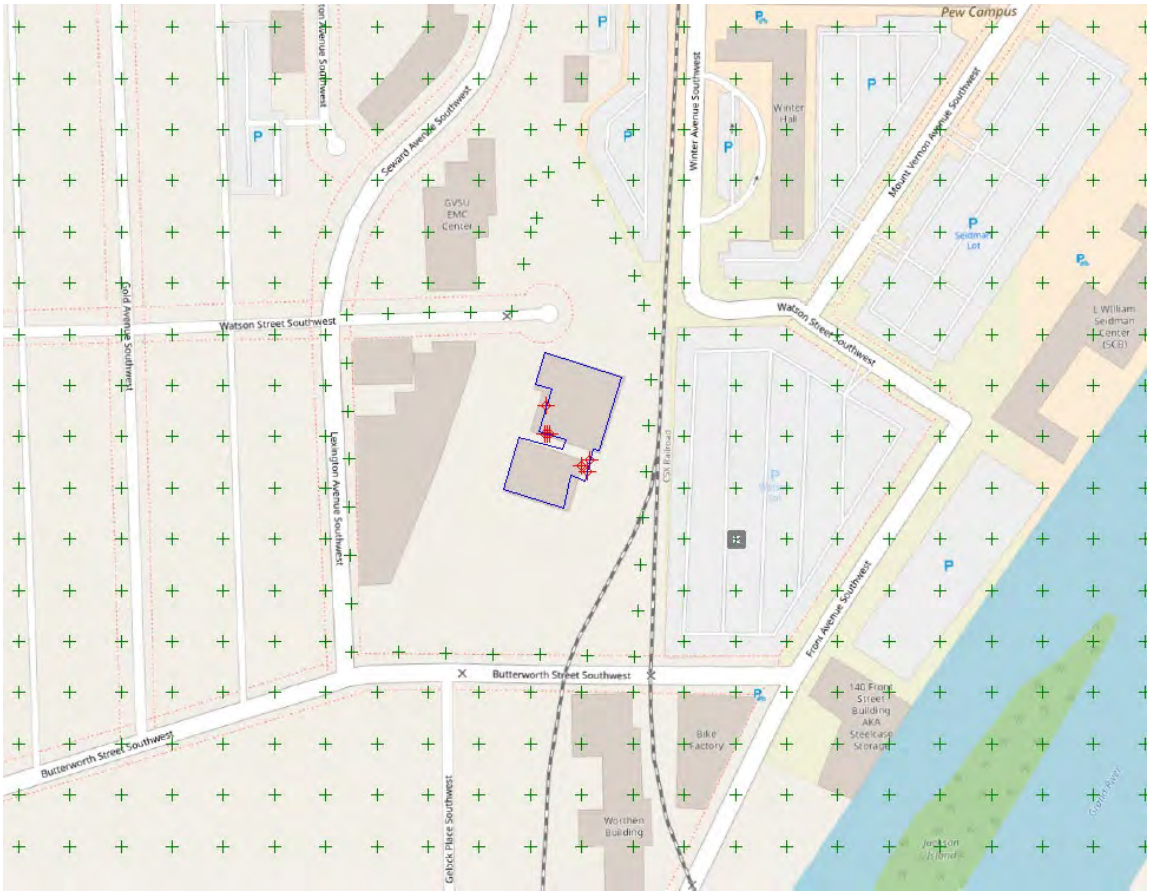
Hoods	Vac Pmp	Sweeps	Drum Rm	Shipping	
6.6%	8.4%	15.3%	2.7%	67.0%	Vent % of total
26.211	33.454	61.162	10.812	267.113	Sum of lbs per vent
0.00440	**0.00562**	**0.01028**	**0.00182**	**0.04488**	Average lbs/hr

The average lbs/hr emissions from the scrubber (3.56 lbs from January through August) was determined in a similar fashion: 3.56 lbs/(8*744 hrs) = 0.0006 lbs/hr.

Modeling Results

With the actual emissions determined, the model was built using the building profile as provided through Google Earth. The scrubber emissions are emitted as a vertical, unobstructed point source. Various fugitive vents were modeled as a horizontal point using AERMOD's POINTHOR option. Flow rates were provided by the facility and indoor ambient temperatures were used. Receptors were placed out to 1,000 meters in each direction from the facility, spaced 25 meters apart. On-site receptors were removed. Additional receptors, spaced at 25 meters, were placed on the property. The meteorology data set was the 2013-2017 Grand Rapids data utilizing 1-minute data and Adjusted Ustar (i.e., varying surface roughness with wind speed for better modeling accuracy with short stacks). The facility building housing the vents and scrubber was determined to be the building of influence and was included for downwash analysis. Figure 5 depicts the center section of the receptor grid with downwash building and source points.

Figure 5 – Grid, Source, and Building Depiction

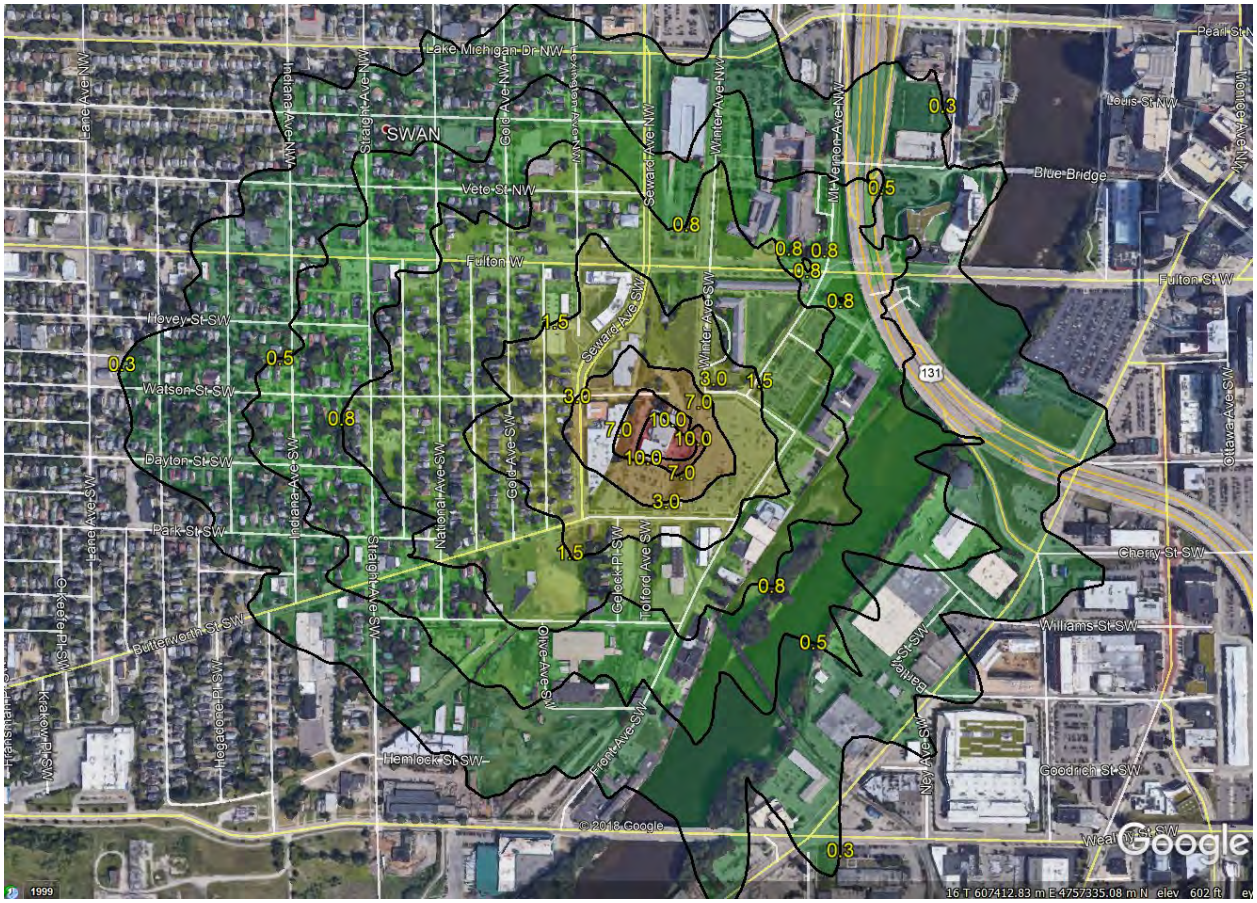


The AERMOD model was run to predict the annual impact using the provided 2018 actual emissions. The IRSL for Ethylene Oxide is 0.0002 µg/m^3. The maximum annual impact was 1.63 µg/m^3, just east of the scrubber/shipping room vents. Of primary concern was the impact to residential areas. The first isopleth to reach residential areas is the 0.3 µg/m^3 isopleth. The impacts diluted by a factor of 10 (e.g., 0.03 µg/m^3) over a distance of 450 meters. Figure 6 provides a graphic depiction of those annual isopleths.

Figure 6 – Annual Impacts (µg/m^3) Resulting from 2018 Actual Emissions

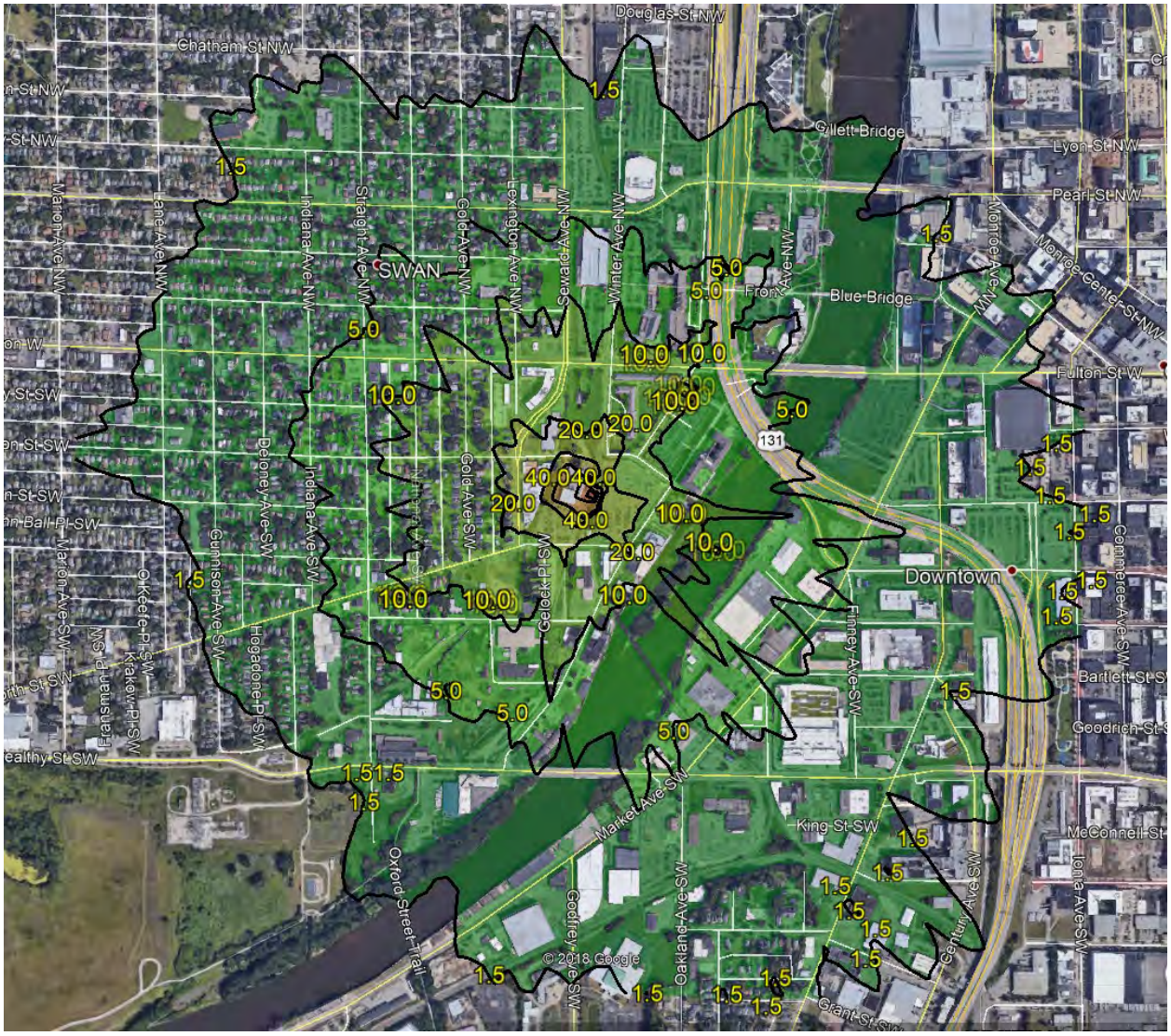
The maximum 24-hour impact was 16.3 µg/m^3, also just east of the scrubber/shipping room vents. The first isopleth to reach residential areas is the 3.0 µg/m^3 isopleth. The impacts diluted by a factor of 10 (e.g., 0.3 µg/m^3) over a distance of 600 meters. Figure 7 provides a graphic depiction of those 24-hour isopleths.

Figure 7 – 24-Hour Impacts (µg/m^3) Resulting from 2018 Actual Emissions



The maximum 1-hour impact was 86.6 µg/m^3, also just east of the scrubber/shipping room vents. The first isopleth to reach residential areas is the 20 µg/m^3 isopleth. At the edge of the grid (1 km), the impacts were in the 1.5 µg/m^3 range. Figure 8 provides a graphic depiction of those 1-hour isopleths.

Figure 8 – 1-Hour Impacts (µg/m^3) Resulting from 2018 Actual Emissions



The AERMOD summary file is provided as Attachment 1.

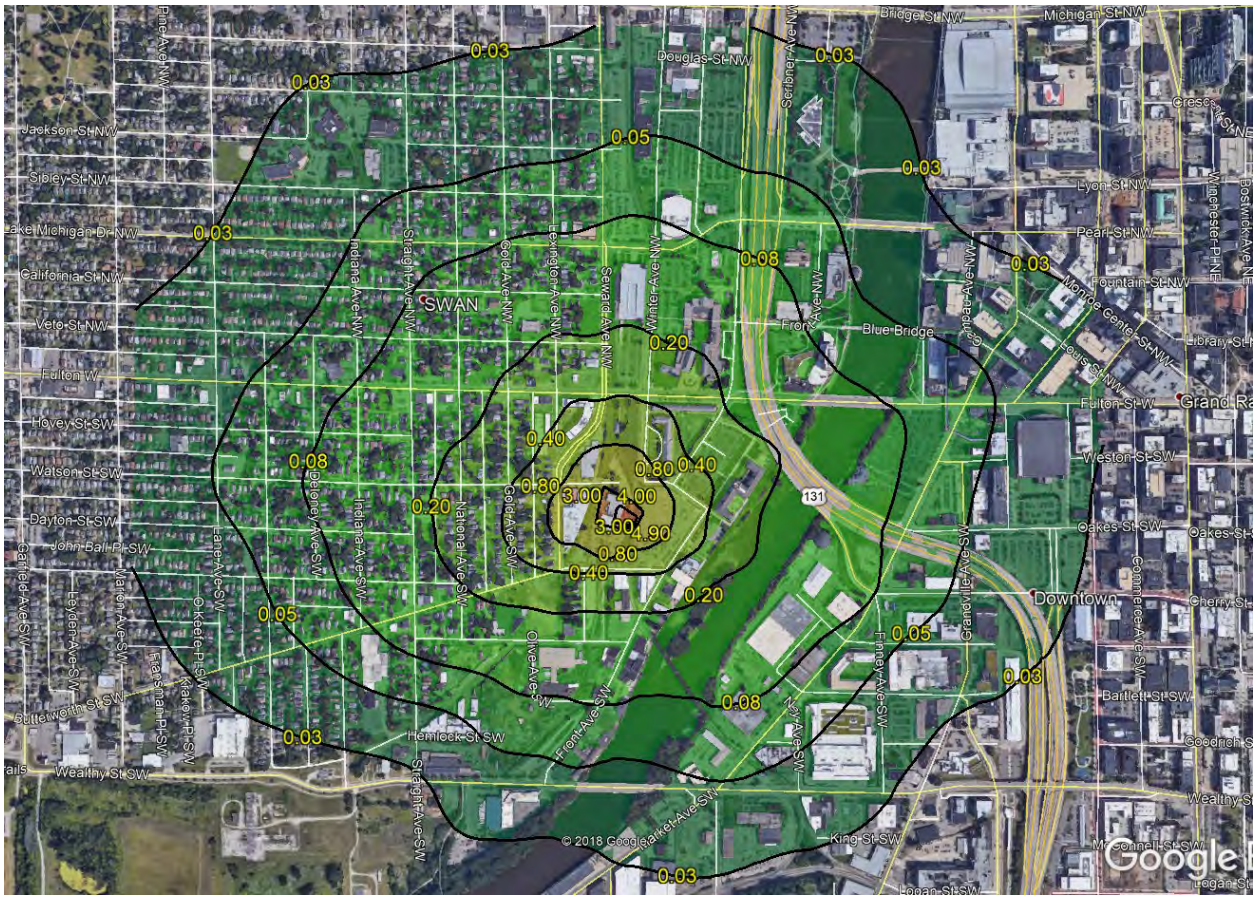
Of additional interest is the predicted impact resulting from allowable or permitted emissions. Total allowed usage of Ethylene Oxide is 360,500 pounds per 12-month rolling average. The permit allows up to 0.5% to be emitted. Applying that ratio to the allowed usage rate of 360,500 lbs yields 1,802.5 lbs, which can be emitted per 12-month rolling average. For purposes of modeling the worst case, it is assumed all is emitted as fugitives. Applying the same vent emissions percentages as provided in Table 4, the allowed vent emissions are as given in Table 5:

Table 5 – Allowed Emissions Breakdown by Vent (1802.5 lbs Total Allowed)

Hoods	Vac Pmp	Sweeps	Drum Rm	Shipping	
6.6%	8.4%	15.3%	2.7%	67.0%	Vent % of total
118.483	151.223	276.475	48.873	1207.445	Sum of lbs per vent
0.01353	**0.01726**	**0.03156**	**0.00558**	**0.13784**	Average lbs/hr

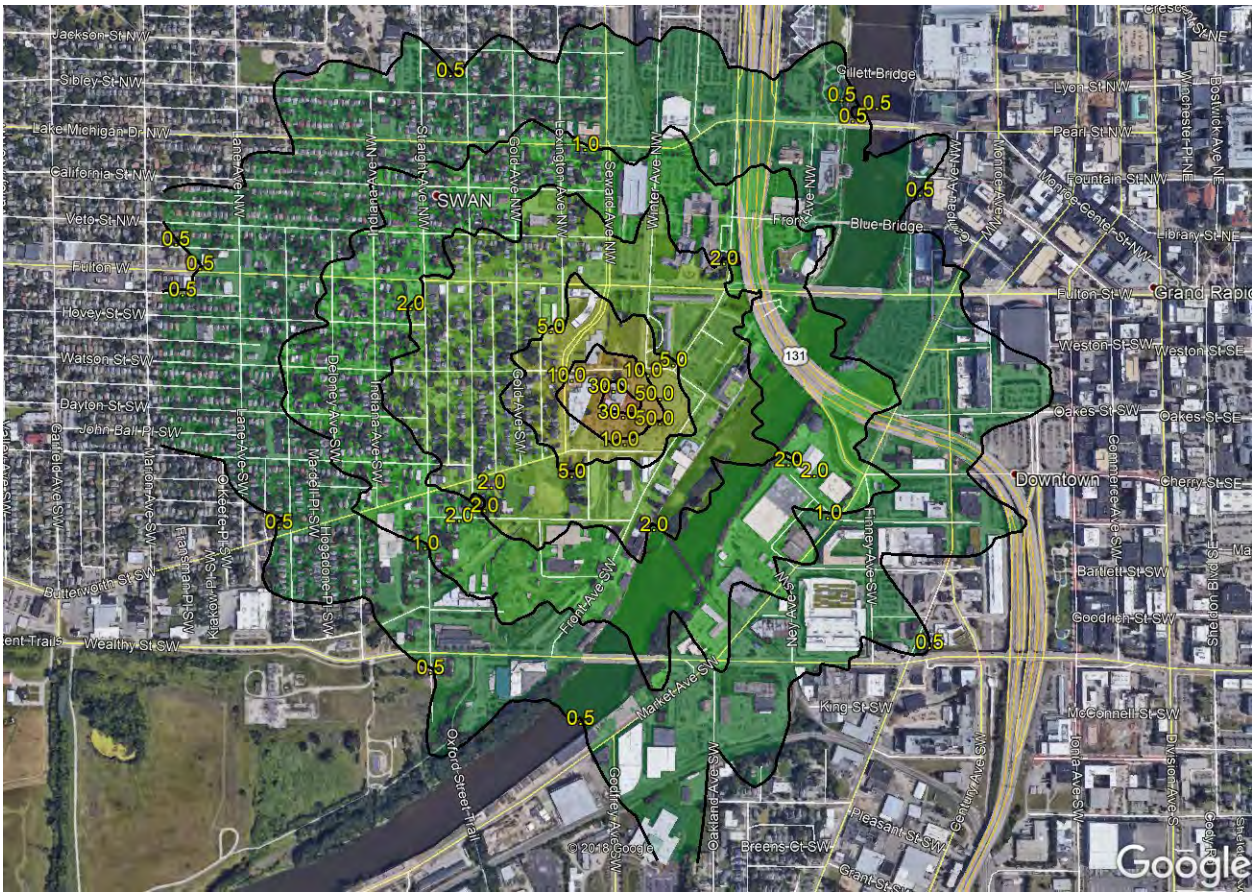
As expected, the predicted impacts using allowed emissions were higher than when assuming actual emissions. The maximum annual impact was 5.0 µg/m^3, just east of the shipping/scrubber room vents. The first isopleth to reach residential areas was the 0.8 µg/m^3 isopleth. At the edge of the grid (1 km), the impacts were in the 0.03 µg/m^3 range. Figure 9 depicts the annual average isopleths using allowed emissions.

Figure 9 – Annual Impacts (µg/m^3) Resulting from Allowed Emissions



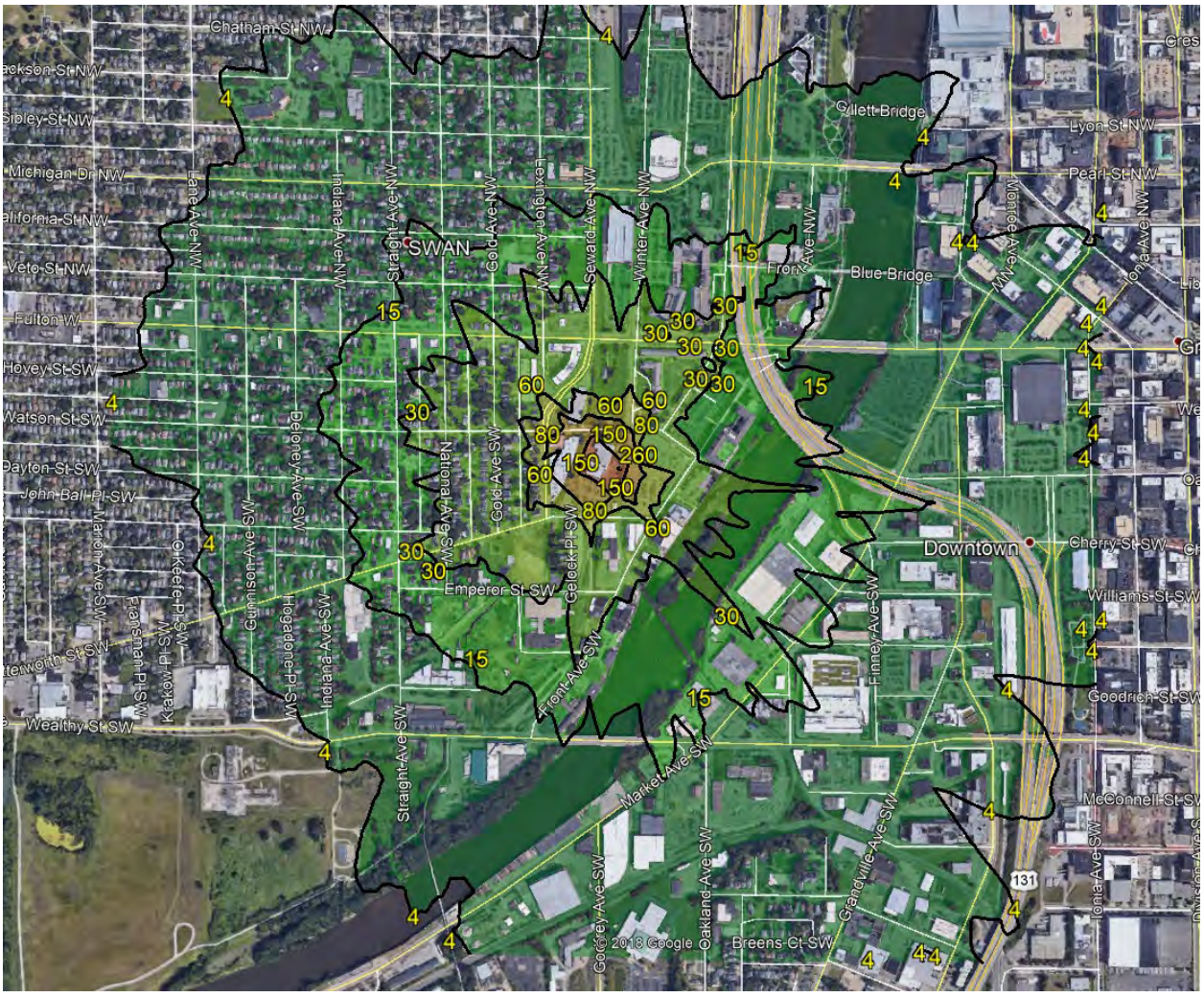
The maximum 24-hour impact was 50.0 µg/m^3, also just east of the shipping/scrubber room vents. The first isopleth to reach residential areas was the 10.0 µg/m^3 isopleth. At the edge of the grid (1 km), the impacts were in the 0.5 µg/m^3 range. Figure 10 depicts the 24-hour average isopleths using allowed emissions.

Figure 10 – 24-Hour Impacts (µg/m^3) Resulting from Allowed Emissions



The maximum 1-hour impact was 266.0 µg/m^3, also just east of the shipping/scrubber room vents. The first isopleth to reach residential areas is the 60 µg/m^3 isopleth. At the edge of the grid (1 km), the impacts were in the 4 µg/m^3 range. Figure 11 provides a graphic depiction of those 1-hour isopleths.

Figure 11 – 1-Hour Impacts (µg/m^3) Resulting from Allowed Emissions



The AERMOD summary file is provided as Attachment 2.

Dated: November 5, 2018
Completed by: Jim Haywood, MDEQ
SIP Development Unit
Air Quality Division

Attachment 1 – AERMOD Summary File for Actual Emissions

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*** AERMOD - VERSION  18081 ***   *** C:\Lakes\AERMOD View\Vention_Medical\Vention_Medical.isc            ***        10/15/18
*** AERMET - VERSION  16216 ***   ***                                                                    ***        11:09:25
                                                                                                                   PAGE   1
*** MODELOPTs:    RegDFAULT  CONC  ELEV  RURAL  ADJ_U*


                                                *** POINT SOURCE DATA ***

             NUMBER EMISSION RATE                        BASE     STACK   STACK    STACK     STACK    BLDG   URBAN  CAP/  EMIS RATE
   SOURCE     PART.  (GRAMS/SEC)      X         Y       ELEV.    HEIGHT  TEMP.    EXIT VEL. DIAMETER EXISTS SOURCE HOR   SCALAR
    ID        CATS.                (METERS)  (METERS) (METERS) (METERS) (DEG.K)  (M/SEC)  (METERS)                       VARY BY
- - - - - - - - - - - - - - - - - - - - - - - - - - - - - - - - - - - - - - - - - - - - - - - - - - - - - - - - - - - - - - - - -

STCK1            0   0.75314E-04  607474.9 4757335.8   186.0    15.24   297.59     2.54     1.07    YES     NO    NO
STCK2            0   0.12947E-02  607456.8 4757351.6   186.2     4.57   294.26     5.66     1.22    YES     NO   HOR
STCK3            0   0.70819E-03  607458.4 4757351.5   186.2     3.05   294.26     1.29     1.22    YES     NO   HOR
STCK4            0   0.55486E-03  607459.6 4757351.2   186.2     4.57   294.26     2.47     1.22    YES     NO   HOR
STCK5            0   0.22888E-03  607457.4 4757364.9   186.3     4.57   294.26     0.22     0.91    YES     NO   HOR
STCK6            0   0.28273E-02  607477.8 4757332.7   186.0     1.83   294.26     2.31     1.22    YES     NO   HOR
STCK7            0   0.28273E-02  607479.0 4757338.5   186.0     1.83   294.26     2.31     1.22    YES     NO   HOR


                                        *** SOURCE IDs DEFINING SOURCE GROUPS ***

SRCGROUP ID                                          SOURCE IDs
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 ALL        STCK1       , STCK2       , STCK3       , STCK4       , STCK5       , STCK6       , STCK7       ,


                          *** THE SUMMARY OF MAXIMUM ANNUAL RESULTS AVERAGED OVER   5 YEARS ***

                           ** CONC OF OTHER    IN MICROGRAMS/M**3                        **

                                                                                                  NETWORK
GROUP ID                        AVERAGE CONC              RECEPTOR  (XR, YR, ZELEV, ZHILL, ZFLAG)  OF TYPE  GRID-ID
- - - - - - - - - - - - - - - - - - - - - - - - - - - - - - - - - - - - - - - - - - - - - - - - - - - - - - - - - - - - - - - - -

ALL       1ST HIGHEST VALUE IS       1.62965 AT (  607506.31,  4757332.84,   185.60,   185.60,    0.00)  DC


                                        *** THE SUMMARY OF HIGHEST  1-HR RESULTS ***

                           ** CONC OF OTHER    IN MICROGRAMS/M**3                        **

                                                    DATE                                                                  NET
GROUP ID                        AVERAGE CONC     (YYMMDDHH)            RECEPTOR  (XR, YR, ZELEV, ZHILL, ZFLAG)    OF TYPE  GRI
- - - - - - - - - - - - - - - - - - - - - - - - - - - - - - - - - - - - - - - - - - - - - - - - - - - - - - - - - - - - - - - - -

ALL      HIGH   1ST HIGH VALUE IS      86.62687  ON 13070904: AT (  607506.31,  4757332.84,   185.60,   185.60,    0.00)  DC


                                        *** THE SUMMARY OF HIGHEST 24-HR RESULTS ***

                           ** CONC OF OTHER    IN MICROGRAMS/M**3                        **

                                                    DATE                                                                  NET
GROUP ID                        AVERAGE CONC     (YYMMDDHH)            RECEPTOR  (XR, YR, ZELEV, ZHILL, ZFLAG)    OF TYPE  GRI
- - - - - - - - - - - - - - - - - - - - - - - - - - - - - - - - - - - - - - - - - - - - - - - - - - - - - - - - - - - - - - - - -

ALL      HIGH   1ST HIGH VALUE IS      16.30633  ON 17083024: AT (  607506.31,  4757332.84,   185.60,   185.60,    0.00)  DC
```

Attachment 2 – AERMOD Summary File for Allowed Emissions

```
*** AERMOD - VERSION  18081 ***   *** C:\Lakes\AERMOD View\Vention_Medical\Vention_Medical.isc            ***        10/15/18
*** AERMET - VERSION  16216 ***   ***                                                                   ***        13:46:37
                                                                                                                  PAGE   1
*** MODELOPTs:    RegDFAULT  CONC  ELEV  RURAL  ADJ_U*


                                                *** POINT SOURCE DATA ***

                NUMBER EMISSION RATE                          BASE     STACK   STACK    STACK     STACK    BLDG   URBAN  CAP/  EMIS RATE
   SOURCE        PART.  (GRAMS/SEC)      X          Y        ELEV.    HEIGHT  TEMP.   EXIT VEL. DIAMETER  EXISTS SOURCE HOR   SCALAR
     ID          CATS.                (METERS)   (METERS)  (METERS)  (METERS) (DEG.K)  (M/SEC)  (METERS)                       VARY BY
- - - - - - - - - - - - - - - - - - - - - - - - - - - - - - - - - - - - - - - - - - - - - - - - - - - - - - - - - - - - - - - - - -

STCK1            0   0.00000E+00  607474.9 4757335.8   186.0     15.24   297.59     2.54     1.07    YES     NO    NO
STCK2            0   0.39765E-02  607456.8 4757351.6   186.2      4.57   294.26     5.66     1.22    YES     NO   HOR
STCK3            0   0.21747E-02  607458.4 4757351.5   186.2      3.05   294.26     1.29     1.22    YES     NO   HOR
STCK4            0   0.17048E-02  607459.6 4757351.2   186.2      4.57   294.26     2.47     1.22    YES     NO   HOR
STCK5            0   0.70307E-03  607457.4 4757364.9   186.3      4.57   294.26     0.22     0.91    YES     NO   HOR
STCK6            0   0.86838E-02  607477.8 4757332.7   186.0      1.83   294.26     2.31     1.22    YES     NO   HOR
STCK7            0   0.86838E-02  607479.0 4757338.5   186.0      1.83   294.26     2.31     1.22    YES     NO   HOR


                                        *** SOURCE IDs DEFINING SOURCE GROUPS ***

 SRCGROUP ID                                          SOURCE IDs
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  ALL        STCK1       , STCK2       , STCK3       , STCK4       , STCK5       , STCK6       , STCK7       ,


                                    *** THE SUMMARY OF MAXIMUM ANNUAL RESULTS AVERAGED OVER   5 YEARS ***

                                     ** CONC OF OTHER    IN MICROGRAMS/M**3                          **

                                                                                                      NETWORK
GROUP ID                        AVERAGE CONC              RECEPTOR  (XR, YR, ZELEV, ZHILL, ZFLAG)  OF TYPE  GRID-ID
- - - - - - - - - - - - - - - - - - - - - - - - - - - - - - - - - - - - - - - - - - - - - - - - - - - - - - - - - - - - - - - - - -

ALL       1ST HIGHEST VALUE IS       4.99249 AT (  607506.31,  4757332.84,   185.60,   185.60,    0.00)  DC


                                              *** THE SUMMARY OF HIGHEST  1-HR RESULTS ***

                                     ** CONC OF OTHER    IN MICROGRAMS/M**3                          **

                                                        DATE                                                          NET
GROUP ID                        AVERAGE CONC     (YYMMDDHH)            RECEPTOR  (XR, YR, ZELEV, ZHILL, ZFLAG)    OF TYPE  GRI
- - - - - - - - - - - - - - - - - - - - - - - - - - - - - - - - - - - - - - - - - - - - - - - - - - - - - - - - - - - - - - - - - -

ALL      HIGH   1ST HIGH VALUE IS     265.96091  ON 13070904: AT (  607506.31,  4757332.84,   185.60,   185.60,    0.00)  DC


                                              *** THE SUMMARY OF HIGHEST 24-HR RESULTS ***

                                     ** CONC OF OTHER    IN MICROGRAMS/M**3                          **

                                                        DATE                                                          NET
GROUP ID                        AVERAGE CONC     (YYMMDDHH)            RECEPTOR  (XR, YR, ZELEV, ZHILL, ZFLAG)    OF TYPE  GRI
- - - - - - - - - - - - - - - - - - - - - - - - - - - - - - - - - - - - - - - - - - - - - - - - - - - - - - - - - - - - - - - - - -

ALL      HIGH   1ST HIGH VALUE IS      50.02192  ON 17083024: AT (  607506.31,  4757332.84,   185.60,   185.60,    0.00)  DC
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