Source Emission Test Plan

for:

Ethylene Oxide Sterilization

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developed in accordance with:

Michigan Department of Environmental Quality
Air Quality Division
and
40 CFR 63, Subpart O - Ethylene Oxide Emissions Standards for Sterilization Facilities

Viant Sterilization Services
520 Watson SW
Grand Rapids, MI 49504

October 29, 2018

Facility and Process Background

Viant Sterilization Services division of Viant Medical Inc. of in Grand Rapids, Michigan utilizes ethylene oxide (EO) to sterilize medical devices and components. The facility uses greater than 10 tons per year of EO. Sterilization Services emission streams consist of the following:

Sterilization Chamber Vents - The sterilization chamber is a heated vessel in which sterilization treatment takes place. After the items to be sterilized are placed in it, the chamber is closed and sealed. Sterilization involves evacuating a significant portion of the air from the chamber and replacing it with a mixture of steam, EO and Nitrogen. Sterilization occurs by exposing the items to the EO/Nitrogen mix for a specified exposure period. After the exposure period, the chamber is subjected to a series of evacuations (by vacuum pump) followed by injections of Nitrogen or air in order to remove the EO from the chamber atmosphere.

There are five (5) sterilization chambers at the facility. Sterilizer chamber size and average ethylene oxide content are as follows:

2 chambers	1164 cubic feet	Average 53 lb. EO per cycle
2 chambers	1023 cubic feet	Average 53 lb. EO per cycle
1 chamber	130 cubic feet	Average 7 lb. EO per cycle

Chamber Exhaust Vents - After removing the majority of the EO from the chamber using the sterilizer vacuum pump, the chamber door is cracked open which activates the chamber rear exhaust to remove any small amounts of EO from the chamber prior to unloading the chamber. The chamber rear exhaust typically operates for 30 to 45 minutes per cycle.

Aeration Room Vents - After removal from the sterilization chamber, the sterilized products are placed in an aeration room for a specified time to allow further diffusion of residual EO from the products prior to shipment. The aeration room is a heated room that is subject to continuous ventilation. There are seven (7) aeration rooms at the facility.

Emission Controls - In order to comply with EO emission limitations, exhausted gases from the sterilization chamber vent, chamber rear exhaust vent and aeration rooms are directed through an emission control device to remove the EO prior to exhausting the air stream. The emission control device selected for the Viant-Sterilization Services facility is an acid-water scrubber system which hydrolyzes the EO gas to ethylene glycol in an acidic water solution. The sterilization chamber vent exhaust gasses are sent through the Chemrox acid-water pre-scrubber prior to combination with the exhaust gases from the chamber rear exhaust and aeration rooms. The manifolded exhaust gases from the sterilization chamber exhaust vent, chamber rear exhaust vent and the aeration room exhaust are sent through the Deoxx acid-water scrubber. Only the sterilization chamber vents are pre-scrubbed because the Chemrox scrubber was designed to handle only the lower exhaust flow rates associated with the sterilization chamber vents.

Regulatory References

The information and procedures presented in this test plan submittal are proposed in accordance with the requirements of 40 CFR 63, *Subpart O - Ethylene Oxide Emissions Standards for Sterilization*

Facilities as specified in Federal Register, 59 FR 62589, December 6, 1994. Following is a brief summary of those sections of this regulation felt to be of particular significance to this test plan.

Section 63.362 (*Standards*) of this rule specifies the standard for ethylene oxide commercial sterilizers and fumigators to be as specified in the below table (paraphrased):

Existing and new sources	**Source type**	**Sterilization chamber vent**	**Aeration room vent**	**Chamber exhaust vent**
Standard Effective Date		December 6, 1998	December 6, 2000	December 6, 2001
	≥10 tons	99% emission reduction	1 ppmv maximum outlet concentration or 99% emission reduction (whichever is less stringent)	Manifold to a control device used to comply with applicable sterilization chamber vent or aeration room vent standards

Section 63.363 (*Compliance and performance testing*) (b) (1) of this rule specifies that the required performance test for determining control device efficiency for sterilization chamber exhaust be based upon an evaluation of the first evacuation of the sterilization chamber. Section 63.363 (b) (1) (i) further specifies that for facilities with acid-water scrubbers, a site-specific operating parameter shall be established during required testing based upon the maximum ethylene glycol concentration or the maximum scrubber liquor tank level.

Sections 63.363 (c) (1) (i) & (ii) specify that performance testing to demonstrate compliance with the aeration room vent standard can be determined by measuring either the ethylene oxide concentration after the control device or by measuring for the efficiency of the control device itself.

Section 63.363 (d) (1) specifies that for chamber exhaust vent emissions that are manifolded to a control device controlling emissions from the sterilization chamber vent and/or the aeration room vent, the facility shall comply with the appropriate compliance provisions for that vent type and control device (i.e., sterilization vent or aeration room vent exhaust).

Section 63.365 (*Test methods and procedures*) specifies the requirement to conduct a performance test and identifies the procedures to be used in determining the efficiency for the control equipment. Section 63.365 (b) specifies the procedures to be followed to determine the control device efficiency for the sterilization chamber vent. Section 63.365 (c) provides the specific procedures to use in determining the concentration from the aeration room and chamber exhaust vents respectively. This section indicates that EO concentration determinations can be obtained utilizing procedures outlined in section 7.2 (Should be section 8.2) of Method 18, 40 CFR Part 60, appendix A.

Air Use Permit No. 605-89A (Special Condition No. 6) specifies that the Sterilization Services shall verify the EO emission rate from the four sterilizers and the control efficiency of the scrubber.

Test Plan

1. Identification and brief description of the source to be tested. The description should include:

a) names, addresses and telephone numbers of the contacts for information regarding the source and the test plan

Name	Address	Telephone number
Thomas Campbell Senior Operations Manager	Viant Medical Inc 520 Watson Street SW Grand Rapids, MI 49504	1-616-643-5563 1-616-643-5292 (fax)
Matthew Kwiatkowski, P.E.	ERM 3352 128th Avenue Holland, MI 49424	1-616-738-7396 1-616-399-3777 (fax)

b) Expected test date(s)

Over two days in November, still to be determined.

c) Type of industrial process or combustion facility

The subject facility conducts sterilization of medical devices and components using ethylene oxide gas. Refer also to the *Facility and Process Background* section above.

d) Type and quantity of raw and finished materials used in the process

The sterilization process uses 100% ethylene oxide gas and nitrogen.

e) Description of any cyclical or batch operations which would tend to produce variable emissions with time

The number of independently operating sterilization chambers and aeration rooms results in a high variability of both the exhaust volume (approximately 4,000 to 12,000 cubic feet per minute (CFM)) and EO concentrations. This variability is due to the many combinations of exhaust flows possible which in turn are dependent upon facility production rates.

In consideration of this highly variable flow and concentration, the facility emission control system has been designed/sized to provide emission control for the range of expected exhaust conditions.

f) Basic operating parameters used to regulate the process

- Sterilization chamber processing is controlled to provide chamber atmosphere temperatures ranging from 100 to 135 °F.

- Sterilization chamber pressures are controlled to range from 1.0"HgA to 35"HgA.

- Aeration room processing is controlled to provide atmosphere temperatures ranging from 80 to 120 °F.

- The aeration rooms operate 24 hours per day, 7 days per week.

- Only one aeration room door may be opened at a time.

g) Rated capacity of the process

- The existing sterilization chamber vacuum pumps are rated at 300 CFM at pressures between 1.5"HgA and 35"HgA. Current cumulative maximum flow is controlled to approximately 200 CFM.

- The existing sterilization chamber rear exhaust blowers are rated at 1500 CFM at pressures between 29"HgA and 35"HgA. Current cumulative maximum flow is 6,000 CFM.

- The existing aeration room vent flows will provide a maximum combined flow from aeration room vents of 5,000 CFM.

- NOTE: An additional 2500 CFM of fresh air flow is added to the aeration room vent flow when an aeration room door is opened. No more than one (1) aeration room door may be opened at one time.

- The air pollution control equipment has an operating capacity of 14,000 CFM for the Deoxx scrubber and of 200 CFM for the Chemrox scrubber.

2) A brief description of any air pollution control equipment associated with the process:

a) Type of control device

The DeoxxHF™ Ethylene Oxide Emission Control unit was manufactured by Talos Engineering Company, Inc., 270 D Rowe Avenue, Milford, Connecticut, 06460. The DeoxxHF™ system is an acid-water scrubber which hydrolyzes the EO gas to ethylene glycol in an acidic water solution.

The Chemrox Ethylene Oxide Emission Control unit was manufactured by Chemrox, Inc., 217 Long Hill Crossroads, Shelton, Connecticut, 06484. The Chemrox system is an acid-water scrubber which hydrolyzes the EO gas to ethylene glycol in an acidic water solution.

b) Operating parameters

- Maximum inlet volumetric gas flow rate: DeoxxHF - 14,000 CFM
  Chemrox - _____ CFM

- Maximum inlet gas temperature: 130 °F

- System operating temperature (liquid): 60 to 110 °F

- Operating schedule: 24 hours/day, 365 days/yr

- Maximum scrubber liquor ethylene glycol concentration for the Deoxx scrubber: 40 CFR 63.365 (e) (1) specifies that the scrubber liquor ethylene glycol concentration shall be established based on the average concentration over three sampling runs.

- Maximum scrubber liquor ethylene glycol concentration for the Chemrox scrubber: 40 CFR 63.365 (e) (1) specifies that the scrubber liquor ethylene glycol concentration shall be established based on the average concentration over three sampling runs.

c) Rated capacity and efficiency

Sterilization Services' emissions control system is designed to handle the combined exhaust streams from the sterilizer exhaust vent, aeration rooms and chamber exhaust vent. The system will have an EO removal efficiency of at least 99.5% or reduce the exhaust to less than 1 ppmv, depending on whether sterilization exhaust vent or aeration room gas is being treated.

d) Any maintenance activity on the air pollution control equipment within the last three months

The packing on the DeOxx scrubbers was replaced in June 2018.

3) Applicable permit/license number or designation for the process to be tested.

Sterilization operations are currently conducted under the authority of Michigan Air Use Permit No. 605-89A.

4) Identify all pollutants to be measured.

The measured pollutant will be ethylene oxide (EO).

5) Describe in detail the sampling and analysis procedures, including the applicable standard methods reference. Provide a description of the sampling train(s) to be used, including schematic diagrams if appropriate. Justify any proposed sampling or analytical modifications

The test series will follow USEPA test procedures as detailed in Title 40: Code of Federal Regulations (CFR), Part 60. This test series is a set of three ethylene oxide emissions tests on one scrubber exhaust stack. Testing will be conducted using U.S. EPA Reference Methods 1-4 and 320 (FTIR) for ethylene oxide.

6) The number and length of sampling runs which will constitute a complete test.

1. Three 30 minute sampling runs will be conducted, as specified in 40 CFR 63.365 (b) (1) (vi), for the sterilization vent.

2. Three sampling runs will be conducted, as specified in 40 CFR 63.365 (c) (1), for the aeration room vent. Each run will last for 60 minutes.

7) Dimensioned sketch showing all sampling ports in relation to breeching and to upstream and downstream disturbances or obstructions of gas flow.

Reference Attachment 2.

8) Estimated flue gas conditions such as temperature, moisture and velocity.

Temperature: 65 to 110 °F

% Moisture: 0 to 5%

Gas Velocity: 2,000 to 2,700 feet per minute

9) Projected process operating conditions during which the tests will be run (e.g., production rate). These conditions should match the operating conditions stated in the facility's permit or facility operations shall be at the maximum routine operating conditions during the test. The projected operating conditions should be provided prior to testing to the District Office for review and approval.

Sterilization Chamber Vent and Air Use Permit Compliance Test

This test will establish the worst case maximum hourly emissions from the facility in order to determine compliance with the Air Use Permit (605-89A) and also be used to demonstrate compliance with the sterilization chamber vent standard (40 CFR 63.362 (c)). During each 30 minute sampling run, all five sterilization chamber vents will be exhausted simultaneously while also exhausting the aeration rooms to the control system. The data collected will be used to demonstrate compliance following the spreadsheet layout shown in Attachment 3.

Aeration Room Vent and Air Use Permit Compliance Test

This test will demonstrate compliance with the aeration room vent standard (40 CFR 63.362 (d)). During each 60 minute sampling run, only the aeration rooms will be exhausted to the control system and concentration data will be collected as defined by 40 CFR 63.365 (c) (1).

10) A description of any process or control equipment data to be collected during the test period.

During the test period for each test situation, information on the below listed process and control equipment parameters will be collected:

- Inlet EO weights of sterilization chambers
- Sterilization pressure and temperature prior to and after evacuations

- Emission control system (Chemrox) liquor tank ethylene glycol concentration
- Emission control system (Deoxx) liquor tank ethylene glycol concentration

11) A description of any monitoring data to be collected during the test period and subsequently reported (e.g., stationary continuous emission monitor data).

During the test period for each test situation, the below listed monitoring data will be collected and subsequently reported as required:

- Control system outlet air flow (CFM)
- Control system outlet EO concentration (ppmv)
- Emission control system (Chemrox) liquor tank ethylene glycol concentration
- Emission control system (Deoxx) liquor tank ethylene glycol concentration

12) Field quality assurance/quality control (QA/QC) procedures (e.g., field blanks, sample storage, and transport methods) and chain of custody procedures

Chain of custody procedures will be followed.

All the quality assurance and quality control procedures listed in the methods will be incorporated in the sampling and analysis.

13) Laboratory QA/QC procedures utilized as part of the testing (e.g., manner and frequency of blanks, spikes, and standards). This should include analysis of audit samples where required as a component of the approved test method.

Attachment 1

Example Calculations for EO Inlet Mass Test Plan Part 6

Viant-Sterilization Services
520 Watson SW
Grand Rapids, MI 49504

SOURCE: Medtronic - Sterile Systems Chambers + Aeration — Velocity Traverse 11/05/02

STACK DIAMETER= 18 Inch
AREA (SQ.FT) = 1.767146

PITOT (CP) = 0.84

BAR. PRESS. (IN HG 29.05

STATIC (IN H20) = -0.43

AVG TEMP (DEG.F) 74

% MOISTURE = 2.05

%O2 = 20.9 %CO2 = 0 %CO = 0 %N2 = 79.1

EXAMPLE

PORT: POINT	V.PRESS	TEMP	PORT: POINT	V.PRESS	TEMP
	0.37	74	1	0.44	74
	0.51	74	2	0.61	74
	0.7	74	3	0.72	74
	0.71	74	4	0.73	74
	0.65	74	5	0.7	74
	0.52	74	6	0.61	74

AVG SQRT VEL PRESS = 0.774499

% EXCESS AIR = -118750

DENSITY, DRY, @STP (LBS/CU.FT) = 0.074553

DENSITY, WET, @STP (LBS/CU.FT) = 0.073978

DENSITY, WET, @STACK COND (LBS/CU.FT) = 0.071211

MOLECULAR WEIGHT, DRY (LBS/MOLE) 28.84444

AVG. GAS VELOCITY (FPM) = 2672.008

ACFM = 4721.828

SCFM = 4545.234

DSCFM = 4452.057

Attachment 2

Sampling Port Sketch
Test Plan Part 8

Viant-Sterilization Services
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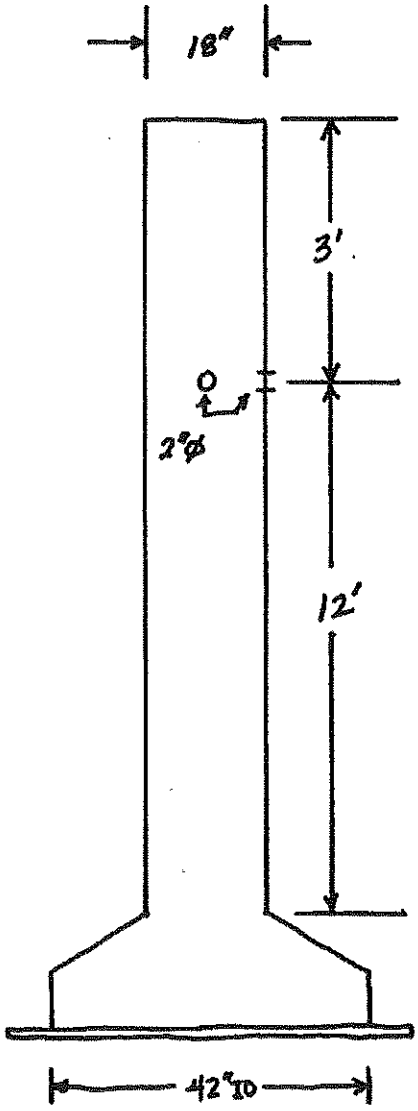

Modified Tower Extension
Sterile Systems
Rec 030300

Attachment 3

Example Calculations for Demonstrating Compliance
Test Plan Part 10

Viant-Sterilization Services
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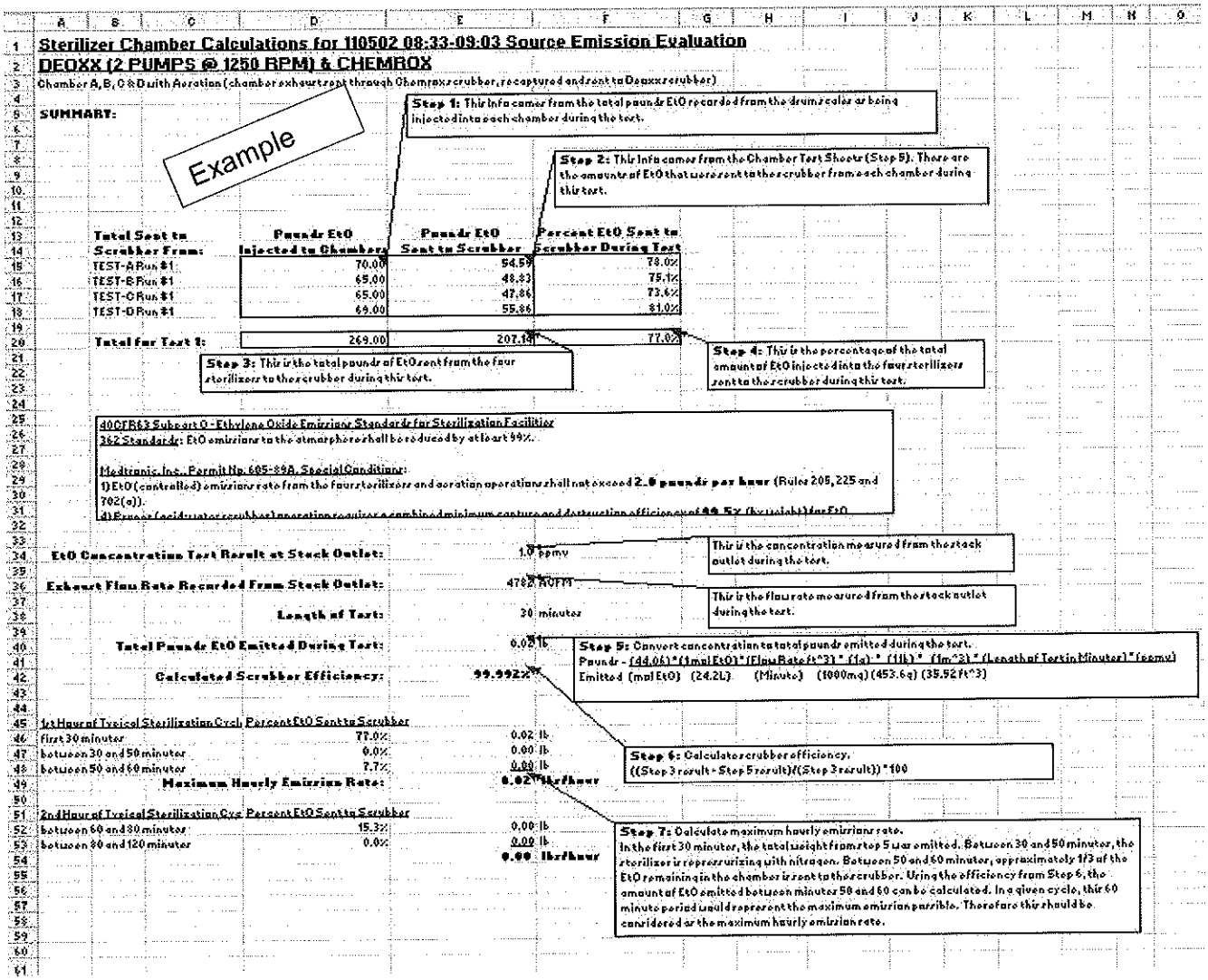
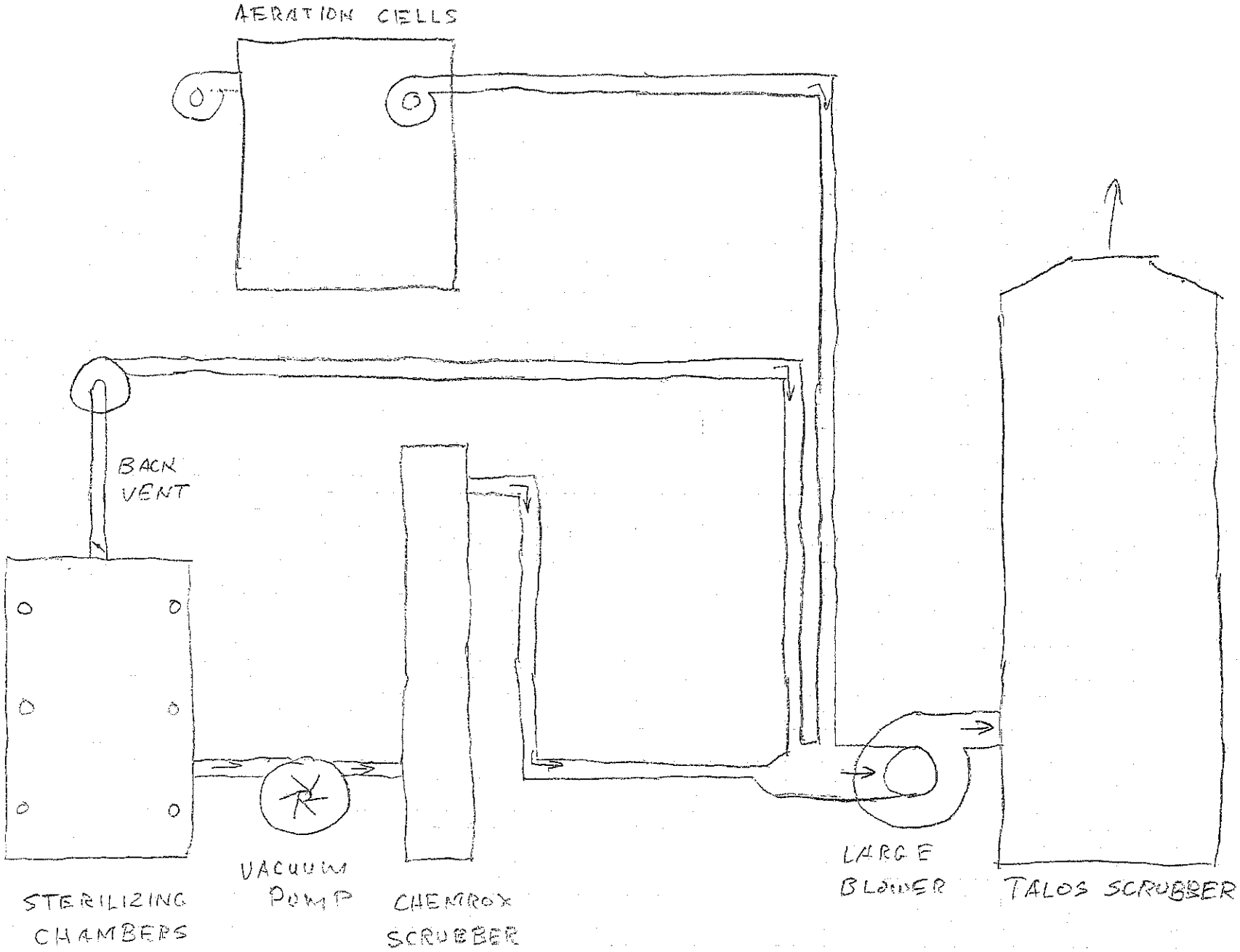
Grand Rapids, MI 49504





SCRUBBER DIAGRAM
RE 19 NOV 2018