DRAFT

ENGINEERING EVALUATION REPORT

Plant Name:	**SAN FRANCISCO VETERINARY SPECIALISTS**
Application Number:	**21293**
Plant Number:	**19994**

BACKGROUND

The applicant is applying for an Authority to Construct for a new ethylene oxide (ETO) sterilizer. The applicant is requesting an Authority to Construct for the following equipment:

S-1 ETO Sterilizer, Anprolene Model AN74j

PROCESS DESCRIPTION

The Anprolene Ethylene Oxidation Sterilizer is a gas diffusion sterilization system containing an integral dry-bed catalyzed ethylene oxide abatement system. Gas diffusion sterilizers use a permeable bag, usually of low density polyethylene (LDPE) film, to hold the items to be sterilized during the sterilization process. The ethylene oxide sterilizing gas is then diffused into the bag, held for a predetermined amount of time to complete the sterilization process, and then exhausted from the bag over a period of time. Unlike conventional ethylene oxide sterilizers with fixed sterilization chambers and separate fixed aeration chambers, gas diffusions sterilizers perform the sterilization and aeration steps in the same chamber.

The Anprolene AN74j Sterilizer System includes an interior sterilization/aeration chamber surrounded by an exterior cabinet, a cabinet ventilation pump, a purge pump, and the integral ETO abator. The minimum cycle time is 14 hours/day, but – as explained below – the system could operate for up to 24 hours/day. The maximum possible operating time is 626 runs/year, but the site expects to operate this unit no more than three times per week (156 runs/year).

The Anprolene AN74j Sterilizer System includes software and monitors that check all systems for proper operation (including the ETO abator) upon start-up. The system will not allow a new run to begin unless all systems are functioning properly. The system is designed to operate using a specific set of liner bags and ETO ampoules. After the bag containing the parts to be sterilized and the ETO ampoule are loaded into the interior sterilization/aeration chamber, the bag is

connected to the purge pump and evacuated for 2-minutes to remove excess air. The ampoule is broken, the chamber is sealed, and the sterilization cycle begins. The sterilization cycle lasts for a minimum of 12 hours, but the operator can extend the sterilization up to 24 hours. During the sterilization cycle, the ventilation pump maintains a vacuum on the exterior cabinet to ensure worker safety. When the sterilization cycle is complete, the sterilization/aeration chamber is evacuated for 2-hours by the purge pump. Parts may now be removed from the chamber and the unit turned off, or parts may be left in the unit and allowed to aerate for an extended period of time - up to 24 hours/day. During this extended aeration cycle, the cabinet vent pump and purge pump alternate operation every 2-minutes. Both pumps send the vent and purge gases to the integral ETO abatement system, but only one pump operates at any one time.

The Anprolene AN74j Sterilizer System is designed to operate using a pre-packaged ampoule containing 17.5 grams of ethylene oxide. The AN5100 Gas Disposer is designed to achieve at least 99% control of ethylene oxide for a fixed number of cycles per ampoule size. In this case, the gas disposer cartridge must be replaced after 250 sterilization cycles. The typical flow rate from the unit is 1.8 cfm at 72 deg F.

EMISSION CALCULATIONS

This is a new sterilizer, proposed to sterilize miscellaneous veterinary medical operations materials. Since the abatement system destroys more than 99% of the ethylene oxide used, the maximum ethylene oxide emitted per run is:

ETO emissions = 17.5 * 0.01 = 0.175 g/run

It is theoretically possible to run the sterilizer full time, i.e. 24 hours per day, 365 days per year. The minimum sterilization plus aeration time (including post-sterilization purge) is 14 hours, so the maximum number of runs possible is 626 runs per year. The maximum ethylene oxide that could be released to the atmosphere then is:

(0.175 g/run)*(626 runs/year) / (453.59 g/lb) = 0.241 lb/year

Since the theoretical maximum possible ethylene oxide emissions is less than 25 pounds per year, the sterilizer is not subject to the control and compliance requirements of the California Air Resources Board Air Toxic Control Measure for Sterilizers and Aerators.

STERILIZER COMPLIANCE CONSIDERATIONS

The sterilizer does not have a separate fixed aeration chamber. Because the ethylene oxide gas is not exhausted at a single point and time, direct demonstration of abatement efficiency via ARB Test Method 431 (simultaneous measurement of ethylene oxide into and out of the sterilizing compartment using gas chromatography and mass spectroscopy) is not practical.

Compliance with Regulation 2, Rule 5, "New Source Review for Toxic Air Contaminants," can be guaranteed by the imposition of enforceable permit conditions that ensure that total ethylene oxide

emissions do not exceed the Regulation 2, Rule 5, trigger level of 1.2 lbs/year. This can be done by requiring that the maximum ethylene oxide concentration from the sterilizer not exceed a concentration corresponding to 1.2 lbs/year.

One ppm ETO corresponds to approximately 1.8 mg/m^3. Typical gas flow is 1.8 ft^3/minute at 72 deg F. Total exhaust cycle is run over a minimum time period of 14 hours. Under these assumptions, the total amount of ETO emitted per permitted ppm of ETO concentration is:

ETO emitted = 1.8 ft^3 exhaust/min * 60 min/hr * 14 hr * 1 ft^3 ETO/1E6 ft^3 exhaust / 388.5 ft^3 ETO/lbmol ETO * 44.053 lb ETO/lbmol ETO = 0.107 lb/year per permitted ppmv

To ensure that total ETO emissions do not exceed 1.2 lbs/year, ETO emissions must be conditioned to:

Allowable ETO (ppmv) = 1.2 lb/year / 0.107 lb/year = 11 ppmv

Source test requirements to ensure that the sterilizer does not exceed this maximum concentration will need to be incorporated into the source's permit conditions. There are a number of ways that this requirement can be met. One way is to use a continuous monitoring system, such as that used by hospitals for demonstrating OSHA compliance. Another way is for the permit holder to take samples of the sterilizer exhaust using Draeger tubes standardized for ethylene oxide exhaust. Rather than prescribing a specific source test method for demonstrating compliance, it seems preferable to leave the compliance method up to the permit holder, with the testing protocol subject to prior approval of the Manager of the Source Test Section.

Since the testing methodology will be new to the District, and it is relatively inexpensive compared to ARB Test Method 431 procedures, it is proposed that the source testing be done quarterly for the first year, and, if the testing is satisfactory to both the applicant and the District, to be done on a yearly basis thereafter.

TOXIC RISK CONSIDERATIONS

An ethylene oxide emissions level of anything greater than 1.2 lb/year of ETO automatically triggers a health risk assessment according to Regulation 2, Rule 5. At a maximum potential to emit, this application will not exceed an ethylene oxide emission level of 1.2 lbs/year and so no health risk assessment is required to be performed under Regulation 2, Rule 5.

BACT/TBACT REVIEW

Under Regulation 2, Rule 2, any new source which results in an increase of 10 lbs/day or more of any criteria pollutant must be evaluated for adherence to BACT/TBACT control technologies. For ethylene oxide sterilizers, BACT is not triggered, as the source does not have the potential to emit more than 10 pounds per day of POC or NPOC (Reg 2-2-301.1). TBACT is not required, as the source does not have the capability of exceeding the trigger level for ethylene oxide as listed in Table 2-5-1 (Reg 2-5-110).

COMPLIANCE DETERMINATION

The sterilizer is covered under ministerial exemption, Chapter 10.2 of the BAAQMD Permit Handbook. CEQA is not triggered for sterilizers under this provision.

The source will be required to meet an ethylene oxide concentration of no more than 11ppmv averaged over an 8-hour time weighted average workday. This will be established by quarterly source tests over the first year of operation of the sterilizer, and by annual source test thereafter.

This is a new source, and no sources are proposed to be closed in connection with this application. The facility does not have the potential to emit more than 10 TPY of precursor organic compounds or nitrogen oxides on a pollutant-specific basis, and so is not subject to offsets under Regulation 2-2-302. The facility is not a Major Facility under Regulation 2-2-220, and so is not subject to PM10 or SO2 emission offset requirements under Regulation 2-2-303.

The proposeed source is within 1,000 feet of two K-12 schools, and will be required to go through public notice under California Health & Safety Code § 42301.6 et seq.

CONDITIONS

Condition #24584, setting out the operating conditions and recordkeeping requirements for operations at Source S-1 shall be made part of the source's Authority To Construct/Permit To Operate.

RECOMMENDATION

I recommend that an Authority to Construct be issued for the following sources:

S-1 ETO Sterilizer, Anprolene Model AN74j

subject to Condition #24584.

By _____ **Date** **7/8/10**

Catherine S. Fortney

COND# 24584 ----------

1. Permitted approval is for the use of ethylene oxide sterilant gas only. The use of any other sterilant gas is expressly prohibited under the terms of the permit unless prior approval and a Change of Condition is obtained in writing from the Bay Area Air Quality Management District. [Basis: Cumulative Increase]

2. Total emissions of ethylene oxide sterilant gas shall not exceed 1.2 pounds per consecutive twelve month period. [Basis: Cumulative Increase; Regulation 2, Rule 5]

3. To ensure compliance with Paragraph 2, the permit holder shall demonstrate that the ethylene oxide concentation in the exhaust stream does not exceed 11 ppmv during the sterilization or aeration cycles, and does not exceed 11 ppmv averaged over the 2-hour purge cycle. [Basis: Cumulative Increase; Regulation 2, Rule 5]

4. In order to demonstrate compliance with Paragraph 2 above, the permit holder shall maintain a log of sterilant gas purchases and the date and time of each sterilization operation cycle. These records shall be retained on site for two years after the date of purchase or entry, and shall be made available for inspection by District staff upon request. [Basis: Cumulative Increase, Regulation 1, Rule 1-543]

5. In order to demonstrate compliance with these permit conditions, the permit holder shall perform a District approved compliance source test within 60 days of sterilizer startup. The source test shall demonstrate that the sterilizer meets the emissions limitations in Paragraph 3. The permit holder shall notify the Manager of the District's Source Test Section and the Director of the Permit Services Division in writing at least seven (7) days prior to the test, to provide District staff the option of observing testing. The protocol for such testing shall be approved in advance in writing by the Manager of the Source Test Section prior to the scheduling of any such source test. Within 30 days of test completion a comprehensive report of the test results shall be submitted to the Manager of the District's Source Test Section for review and disposition. [Basis: Cumulative Increase]

6. In order to demonstrate compliance with these permit conditions, the permit holder also shall perform a District approved compliance source test at least once every three months for the first year of operation. After one year of operation, the continuing compliance source test timing may be extended to once in every twelve months, with the approval of the Director of the District's Director of Permit Services. The permit holder shall notify the Manager of the District's Source Test Section and the Director of the Permit Services Division in writing at least seven (7) days prior to the test, to provide District staff the option of observing testing. The protocol for such testing shall be approved in advance in writing by the Manager of the Source Test Section prior to the scheduling of any such source test. Within 30 days of test completion a comprehensive report of the test results shall be submitted to the Manager of the District's Source Test Section for review and disposition. [Basis: Cumulative Increase]