ETHYLENE OXIDE STERILIZERS

COMPLIANCE INSPECTION CHECKLIST

Environmental Compliance

INSPECTION TYPE: ANNUAL (INS1, INS2) ☒ COMPLAINT/DISCOVERY (CI) ☐
RE-INSPECTION (FUI) ☐ ARMS COMPLAINT NO:

ARMS UPDATED 06/04/12 NB

AIRS ID#: 1050437 **DATE:** 05/30/12 **ARRIVE:** 1015 **DEPART:** 1230

FACILITY NAME: Preferred Medical Sterilization

FACILITY LOCATION: 101 INDUSTRIAL BLVD

WINTER HAVEN 33880-1036

OWNER/AUTHORIZED REPRESENTATIVE: MICHAEL MURPHY **PHONE:** (863)875-6928
Email: mike@etosterile.com **Mobile:**
CONTACT NAME: MICHAEL MURPHY **PHONE:**
Email: mike@etosterile.com **Mobile:** (863)875-6928
ENTITLEMENT PERIOD: 3/18/2011 (effective date) / 3/18/2016 (end date)

PART I: INSPECTION COMPLIANCE STATUS (check ☑ only one box)

☒ IN COMPLIANCE ☐ MINOR Non-COMPLIANCE ☐ SIGNIFICANT Non-COMPLIANCE

PART II: CONTROL TECHNOLOGY – Rule 62-213.300 FAC

Vent type(s) at the facility: Aeration Room--☒ Sterilization Chamber--☒ Chamber Exhaust--☐

Sterilization Chamber Vent

Has one of the following emission control devices been installed? Yes--☒ No--☐

If **yes**, indicate type below.

Acid-Water Scrubber------☒ Thermal Oxidation Unit--☐
Catalytic Oxidation Unit--☐ Other--☐ _____

(Must submit information to DEP for approval)

Chamber Exhaust Vent

No emission control device. *(must use direct measurement in Part III)* ☒
Emissions manifolded to sterilization chamber vent control device. ☐
Dedicated emission control device (indicate type below).---------- ☐

Acid-Water Scrubber------☐ Thermal Oxidation Unit--☐
Catalytic Oxidation Unit--☐ Other --☐_____

(Must submit information to DEP for approval)

PART III: MONITORING REQUIREMENTS – Rule 62-213.300 FAC

Has the facility conducted an initial performance test?
(Existing facilities by 6/8/98;, new sources within 180 days after startup)---------- Yes ☒ No ☐

Acid-Water Scrubbers

What process parameter is the facility monitoring to determine compliance?
ethylene glycol concentration---☐ scrubber liquor tank level--☒

If the facility is monitoring the scrubber liquor tank level, has a liquid level indicator been installed?---------- Yes☐ No☐

Catalytic/Thermal Oxidation Units

Has the facility installed a temperature sensor that is accurate to within ± 10° F?---- Yes☐ No☐
Has the facility verified the accuracy of the temperature sensor?
(must be performed semiannually)---------- Yes☐ No☐

Direct Measurement

Has the facility installed a gas chromatograph?---------- Yes☐ No☐

PART IV: RECORDKEEPING REQUIREMENTS – Rule 62-213.300(3) FAC

Has the facility maintained the following records?

Owner's manuals, designs specifications, and other instructional materials for the sterilization unit and control equipment.---------- Yes☒ No☐

Records of ethylene oxide usage on a 12-month rolling average. ---------- Yes☒ No☐

Records of all initial performance tests, including control efficiency determinations. Yes☐ No☐

Records of all temperature monitoring. *(oxidation units only)* ---------- Yes☐ No☐ N/A☒

Records of all ethylene oxide concentration monitoring. *(direct measurement only)* Yes☐ No☐ N/A☒

Records of gas chromatograph calibration *(direct measurement only)* ---------- Yes☐ No☐ N/A☒

Records of scrubber liquor level. *(acid-water scrubbers only)*---------- Yes☐ No☐ N/A☐

Records of ethylene glycol concentration. *(acid-water scrubbers only)*---------- Yes☐ No☐ N/A☒

Nedin Bahtic	05/30/12
Inspector's Name (Please Print)	Date of Inspection
Nedin Bahtic Digitally signed by Nedin Bahtic Date: 2012.06.04 13:08:35 -04'00'	05/30/17
Inspector's Signature	Approximate Date of Next Inspection

COMMENTS: Note: All items left unanswered do not apply as they were not required at the time of inspection.

Purpose of this visit is to audit the initial ethylene oxide emissions test. The facility is subject to NESHAP Subpart O (Ethylene Oxide Emissions Standards for Sterilization Facilities). Initial startup date (first use of ethylene oxide in a chamber) of Preferred Medical Sterilization was 12/28/11, meaning that the performance testing was required to be completed by 06/25/12 (within 180 days). Only one delivery of ethylene oxide has occurred so far (400 lbs.), so the aeration room did not need to be tested at this time; only sterilization chamber vent (see Table 1 of Section 63.362 in Subpart O). The facility has chosen to install an acid/water scrubber for emissions control. Subpart O requires minimum 99% emission reduction for sterilization chambers. This test was conducted to demonstrate compliance with this standard, and also to establish the maximum allowable scrubber liquor tank level for ongoing operations. With the H2SO4/H2O scrubber, ethylene oxide is converted to ethylene glycol. Over time, the amount of ethylene glycol increases in the scrubber liquor tank. The tank level will be marked at the conclusion of testing (it will be reported in the test report) and will represent the maximum allowable level. Monitoring of the level will need to be done on a weekly basis. Mr. Murphy is well aware of these requirements and has weekly checklists already developed for this purpose.

Test was performed by Mr. Howard Humphreys of EnviroMechanics in accordance with EPA Method 18 (direct interface procedure). Chamber A, with a volume of 531 cu.ft., was charged with ethylene oxide for this test: first run (not observed) with 24 lbs. of ethylene oxide and second run (observed) with 21 lbs. of ethylene oxide. Second run started at 1133 and ended at 1156 (duration of the 1st evacuation). The chamber was empty, as required by Subpart O. Preparation for the second run, which lasted 1-1.5 hours, was also observed. First, the chamber was pressurized, then vacuum was pulled, and then ethylene oxide was introduced into the chamber and chamber re-pressurized. Once set pressure was reached, it was held for 5 minutes, and then test run commenced - the air was pulled from the chamber at a constant rate.

Calibration gases of 0.7 ppm, 9.4 ppm, and 100 ppm were used. Preliminary results show that 99.87% and 99.97% ethylene oxide removal was achieved during Runs 1 and 2, respectively. No testing deficiencies were noted.