



ETHYLENE OXIDE STERILIZERS



COMPLIANCE INSPECTION CHECKLIST

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

AIRS ID#: 0710274 **DATE:** 06/24/2010 **ARRIVE:** 9:30 a.m. **DEPART:** 10:10 a.m.
FACILITY NAME: FORT MYERS FACILITY
FACILITY LOCATION: 11600 ADELMO LN
 FORT MYERS 33966-8398
OWNER/AUTHORIZED REPRESENTATIVE: PHILIP FLEISCHHACKER **PHONE:** (952)926-3515
CONTACT NAME: **PHONE:**
ENTITLEMENT PERIOD: 1/21/2010 / 1/21/2015
 (effective date) (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 $\pm 10^\circ$ 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

ROBERT J. STEWART

06/24/2010

Inspector's Name (Please Print)

Date of Inspection

06/2011



Inspector's Signature

Approximate Date of Next Inspection

COMMENTS: Facility has been in operation since June 9, 2010. Toured plant and observed operations. Facility utilizes an aeration room vent for its sterilization process of which no standards have been established for facilities with this type of vent as per DEP Ethylene Oxide Sterilizers Air General Permit. Facility does have receipts documenting ethylene oxide use at the facility but logs of the usage per month are kept at the main corporate headquarters located in Minnesota. The facility will forward a copy of the usage logs to the Ft. Myers plant with information up to date and will then keep copies of these logs at this facility as per general permit conditions. Facility will be reinspected when informed by management that copies of the logs have been received at the plant and are available for inspection.