



ETHYLENE OXIDE STERILIZERS

COMPLIANCE INSPECTION CHECKLIST



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

AIRS ID#: 0710274 **DATE:** 09/03/2010 **ARRIVE:** 1:30 p.m. **DEPART:** 2:00 p.m.

FACILITY NAME: FORT MYERS FACILITY

FACILITY LOCATION: 11600 ADELMO LN
FORT MYERS 33966-8398

OWNER/AUTHORIZED REPRESENTATIVE: PHILIP FLEISCHHACKER **PHONE:** (952)926-3515

Email: **Mobile:**
CONTACT NAME: ROBERT COOK **PHONE:**
Email: **Mobile:**

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 $\pm 10^\circ \text{F}$?----

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

09/03/2010

Inspector's Name (Please Print)

Date of Inspection

06/2010

Inspector's Signature

Approximate Date of Next Inspection

COMMENTS: Follow-up inspection to review and obtain copy of records for ethylene oxide usage for last 12 months. Facility started production in June 2010. Ethylene oxide gas use since plant was operational on June 9, 2010 is 305.68 lbs