



ETHYLENE OXIDE STERILIZERS



COMPLIANCE INSPECTION CHECKLIST

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

AIRS ID#: 0710274 **DATE:** 6/26/2014 **ARRIVE:** _____ **DEPART:** _____

FACILITY NAME: FORT MYERS FACILITY/AMERICAN CONTRACT SYSTEMS

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:** (813)391-5678
Email: RCook@AMCONSYS.com **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 $\pm 10^\circ$ 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

Laura Comer and Robert Stewart

June 26, 2014

Inspector’s Name (Please Print)

Date of Inspection

Please note all rule references have been changed to 62-210.

Inspector’s Signature

Approximate Date of Next Inspection

COMMENTS: American Contract Systems sterilizes surgical packs which are then distributed by LeeSar. Three injection units are used to vacuum air out and directly inject EtO into the bags containing the surgical equipment. This is performed under a vented exhaust hood. The bag is immediately sealed and multiple packs are boxed before going to one of six aeration rooms. The aeration rooms are heated to 110 degrees F +/- 10 degrees for a minimum of 64 hours. The temperature is monitored and graphed. The aeration rooms are vented to the outside through two vents.

The facility calculates annual EtO usage by tracking the date and number of tanks used (18# EtO used per tank). Assistance was provided to calculate the rolling annual usage. 2010-2012 the facility used less than 1 ton per twelve month period. The rolling annual totals were just over 1 ton in 2013 and 2014 to present. The highest annual usage was 2,358 pounds for the period from August 2012-July 2013.

Alcohol and 409 wipes are used to clean and disinfect. ACS does not generate hazardous waste.