Date: 06/29/2015

**Example 5** Ongoing Compliance Status Report

Applicable rule: Subpart O--National Emission Standards for EO Commercial Sterilization and Fumigation Operations

**All sources using 1 ton or more of ethylene oxide (EO) per year are required to submit ongoing status reports once every 6 months (or more frequently if required by the Administrator). See sections 63.366(a) and (c) of subpart O and section 63.10 of subpart A.**

**The source should submit ongoing status reports to the appropriate authority within 30 days after the end of each 6 month reporting period.**

| | Begin | End |
|---|---|---|
| Reporting period dates: | 12/07/2015 | 06/06/2016 |
| | Month/day/yr | Month/day/yr |

Print or type the following for each plant in which commercial sterilization and fumigation operations are performed:

Name of Owner/Operator Covidien LP

Mailing Address 195 McDermott Road

City North Haven State CT Zip Code 06473

Plant Name Surgical Solutions - North Haven

Plant Address (if different than owner/operator's)

Street Address SAME

City _____ State _____ Zip Code _____

Phone Number (203) 492-8240

Plant Contact/Title Jean Paul Marius, Plant EHS Manager

This report contains the following sections (see question 5 to determine whether only Section A must be submitted or whether both Sections A and B must be submitted):

☑ Section A - SUMMARY REPORT

Date: 06/29/2015

☐ Section B - GASEOUS EXCESS EMISSIONS AND CONTINUOUS MONITORING SYSTEM PERFORMANCE

Plant name: Covidien LP
Date: 06/29/2015

Section A SUMMARY REPORT

1. Complete the following table. If additional space is needed, make copies of this page. The first three rows give examples of appropriate entries.

| Vent type[a,b] | Air pollution control technique[c] | Emission reduction or concentration limit requirement | Monitoring: concentration limit or operating parameter limit[d] | Monitoring equipment manufacturer | Monitoring equipment model no. | Date of last monitoring system certification or audit[e] |
|---|---|---|---|---|---|---|
| Example - 2 SCV (30 $m^3$) | catalytic oxidizer (0113B) | 99% reduction | 278°F | Acme Cat-o Inc. | MT061 | July 1998 |
| Example - 1 ARV (280 $m^3$) | catalytic oxidizer (0113B) | 99% reduction | 276°F | Acme Cat-o Inc. | MT061 | July 1998 |
| Example - CEV (30 $m^3$) | manifolded to control device for SCV | 5,300 ppmv | comply with limit from SCV | not applicable | not applicable | not applicable |
| 2 SCV, 2 ARV, 2 CEV (7,100 cfm) | Catalytic Oxidizer | 99.9% Reduction | 150 C Catalyst Bed Outlet Temperature | LESNI | Kjaerulf Pedersen, 25.611 | January 2016 |
| 2 ARV (5,000 cfm) | N/A | 1.0 ppm ETO Conc. | 1.0 ppm ETC Conc. | Baseline | 8900GC Gas Chromatograph | May 2016 |
| | | | | | | |

[a]Attach a brief description of each of the process units (size and number) and the related emission control equipment and emission control configuration. All units vented to the same emission control equipment and subject to the same monitoring parameter must be shown.
[b]SCV = sterilization chamber vent (includes sterilization chamber vacuum pump); ARV = aeration room vent; CEV = chamber exhaust vent (also referred to as back draft or door hood vent).
[c]Provide the equipment numbers the plant uses for identification.

Plant Name: Covidien LP

2. Total process operating hours during the reporting period — 3,264 Hours

3. Check the box that applies:

☐ No **excess emissions** (including concentration limit or parameter limit exceedances) have occurred and **monitoring systems** have not been inoperative, out-of-control, repaired, or adjusted during this reporting period. It is not necessary to complete question 4 or to complete the "Excess Emissions and Continuous Monitoring System Performance" report in Section B.

☑ **Excess emissions** (including concentration limit or parameter limit exceedances) have occurred and/or **monitoring systems** have been inoperative, out-of-control, repaired, or adjusted during this reporting period. Question 4 will be completed.

4. Provide the following:

Total duration (hours) of excess emissions (including concentration limit exceedances or parameter limit exceedances) — 2.5 Hours

**Percent of total duration of excess emissions** (total duration of excess emissions/total process operating hours) — 0.08%

Provide in the following table the total duration of each type of excess emission for the reporting period (including concentration limit or parameter limit exceedances). Include excess emission time periods from all process units/control devices.

| | Total duration of excess emissions | Excess emissions due to control equipment problems | Excess emissions due to process problems | Excess emissions due to other known causes[a] | Excess emis-sions due to unknown causes |
|---|---|---|---|---|---|
| Hours | 2.5 Hours | 0 Hours | 0 Hours | 2.5 Hours | 0 Hours |

[a]Attach a sheet identifying the other known causes.

Provide the following:

Total duration of monitoring system downtime, hours 2.5 Hours

**Percent of monitoring system downtime** (total monitoring downtime/total process operating time) 0.08%

Provide in the following table the total duration of each type of monitoring system downtime for the reporting period. Include downtime periods from all monitoring systems.

| | Total duration of monitoring system downtime | Monitoring system downtime due to monitoring equipment malfunctions | Monitoring system downtime not due to monitoring equipment malfunctions | Monitoring system downtime due to QA/QC calibrations | Monitoring system downtime due to other known causes[a] | Monitoring system downtime due to unknown causes |
|---|---|---|---|---|---|---|
| Hours | 2.5 Hours | 0 Hours | 0 Hours | 2.5 Hours | 0 Hours | 0 Hours |

[a]Attach a sheet identifying the other known causes.

Plant Name: Covidien LP

Plant Name: Covidien LP

5. If the percentage of total duration of excess emissions (calculated above) is **less than 1%** of the operating time for the reporting period **and** the percentage of total monitoring system downtime (calculated above) is **less than 5%** of the operating time for the reporting period, the source is required to complete and submit **only Section A** for this reporting period.

   If the percentage of total duration of excess emissions (calculated above) is **greater than or equal to 1%** of the operating time for the reporting period **or** the total monitoring system downtime (calculated above) is **greater than or equal to 5%** of the operating time for the reporting period, the source is required to complete and submit **Sections A and B** for this reporting period.

6. If the source has made any changes since the last reporting period regarding the process, air pollution control techniques or equipment, or the monitoring systems, attach a description of these changes.

7. Print or type the name and title of the Responsible Official for the plant:

| Jean Paul Marius | Plant EHS Manager |
|---|---|
| Name | Title |

A Responsible Official can be:

- The president, vice-president, secretary, or treasurer of the company that owns the plant;
- The owner of the plant;
- The plant engineer or supervisor; or
- A government official if the plant is owned by the Federal, State, City, or County government.

The Responsible Official must certify below that all of the information presented in this report is accurate and true.

I certify that this facility has complied with all of the applicable provisions in subpart O and that the information contained in this report is accurate and true to the best of my knowledge.

Signature of Responsible Official Date

Plant name: Covidien LP
Date: 06/29/2015

Section B GASEOUS EXCESS EMISSIONS AND CONTINUOUS MONITORING SYSTEM PERFORMANCE

**See question 5 of Section A to determine whether Section B must be completed for this reporting period.**

8. Provide in the following table the date and time for each period of excess emissions (concentration limit and parameter limit exceedances). If additional space is needed, make copies of this page. **OR** Attach copies of the monitoring data recordkeeping sheets that indicate date and time of excess periods for the reporting period.

| Date (beginning to end) | Time (beginning to end) | Date (beginning to end) | Time (beginning to end) |
|---|---|---|---|
| N/A | N/A | | |
| | | | |
| | | | |
| | | | |
| | | | |
| | | | |
| | | | |

Plant Name: Covidien LP

9. Identify in the following table the date and time for each period when the monitoring system was inoperative or out-of-control (not to include zero checks or high checks).[a] If additional space is needed, make copies of this page. **OR** Attach an additional page describing the repairs and adjustments made to the monitoring system.

| | Date (beginning to end) | Time (beginning to end) | Repairs or adjustments made to the monitoring system when inoperative or out-of-control |
|---|---|---|---|
| Periods when monitoring system was inoperative or out-of-control | N/A | N/A | N/A |
| | | | |
| | | | |
| | | | |
| | | | |
| | | | |
| | | | |
| | | | |

[a]Out-of-control periods refer to periods when monitoring calibrations, audits, or verifications (i.e., according to performance specification 9 or temperature accuracy verification) reveal the monitoring systems are not operating properly. Inoperative periods refer to periods when the monitoring system is offline or not functioning (other than zero checks or high checks).

Plant Name: Covidien LP

10. Complete the following table regarding malfunctions of the monitoring system during this reporting period. If additional space is needed, make copies of this page, or attach a discussion of the malfunction incident.

| Malfunctions of the monitoring system that have occurred | Nature of the malfunction | Cause of the malfunction | Corrective action or preventive measures adopted to deal with the malfunction |
|---|---|---|---|
| | | | |
| | | | |
| | | | |
| | | | |

11. Print or type the name and title of the Responsible Official for the plant:

Jean Paul Marius — Plant EHS Manager

Name — Title

A Responsible Official can be:

- The president, vice-president, secretary, or treasurer of the company that owns the plant;
- The owner of the plant;
- The plant engineer or supervisor; or
- A government official if the plant is owned by the Federal, State, City, or County government.

The Responsible Official <u>must</u> certify below that all of the information presented in this report is accurate and true.

I certify that this facility has complied with all of the applicable provisions in subpart O and that information contained in this report is accurate and true to the best of my knowledge.

Signature of Responsible Official — Date