

Incident Report

Completed by: John LaMontagne
Date: 27 September 2019
Location of Incident: BD
8195 Industrial Blvd.
Covington GA 30014
Release Point: Vessel 5 vacuum pump exhaust stack.
~ 10 ft. above roof.
Date of Incident: 15-23 September 2019

Description of Incident:

Starting on 15 September 2019 the Covington sterilization operation began experiencing intermittent elevated Ethylene Oxide (EO) levels as reported on the Indoor Ambient Air Monitoring System (Baseline). All elevated instances were investigated and with no root cause initially found, after area inspections and system checks.

On 23 September 2019 it was discovered that the Vacuum Exhaust Valve for the Covington Line 5 Sterilizer was not in the fully closed position. It is believed that the elevated levels were a result of the valve not being fully closed.

The valve was put in the fully closed position and tested to verify it was completely closed. All other vessels were checked, and the correct valve position was verified.

Background:

- 06 September 2019 a Change Control Request (CCR14-19) was initiated to route all vacuum pump exhaust to the Emission Control Device. The current configuration was to route vacuum pump exhaust from the Nitrogen Dilution phases of the cycle to atmosphere via a pipe that extended above the roof. The change involved removing the automated actuator and was made to simplify the system and eliminate a potential point of failure.
- The change was implemented on all Covington Sterilizers on 13 September 2019 via Work Order CV19-168. After the change routine operation resumed on 14 September 19.

On 15 September 2019 the facility started experiencing elevated Baseline readings. Levels were in the 1 to 32 ppm range at various locations inside the building. Elevated levels were intermittent in nature.

- On 23 September the investigation determined that the Vacuum Exhaust Valve was not fully closed. The valve was 180 degrees counterclockwise from the fully closed position. The valve position was immediately corrected.

Root Cause Investigation:

Investigation has determined that elevated levels were a result of the valve not being in the fully closed position. EO was exhausting from the vacuum pump exhaust stack and entering the building through roof mounted ventilation intakes.

The valve actuator had been removed and the technician manually operated the valve to what he believed was the closed position. This valve has no indication to visually determine if it is in the fully closed position. The technician turned the valve so that the flat part of the stem was perpendicular to the pipe. This would typically indicate a closed position. This particular valve design requires that the stem be rotated in the clockwise direction to close. This valve style is unique to Vessel #5. The butterfly valves on the other Covington Vessels can be rotated in either direction to fully closed.

Following correction of the valve position, EO levels inside the facility returned to historical normal levels.

Corrective Action:

The following steps were taken as corrective action:

- The valve was put in the fully closed position and tested to verify on 23 Sept.

The following preventive actions are planned:

- All technicians will be trained on operation of this style valve.
Target date: 30 Sept 19
- Blanks will be installed on the outlet to the Vacuum Exhaust Valve (on all vessels) to prevent flow regardless of valve position or condition.
Target date: 25 Oct 19

Impact of Incident:

Environmental:

Based on the information it is concluded that EO was released to the atmosphere. An estimate of the quantity of EO released, per load, is included below. The data confirms that the release is below the reportable quantity of 10 pounds per 24-hour period. The estimate is based on the technical information from the valve manufacturer and engineering principals. The values expressed are not exact due to the dynamic conditions of the process but are believed to represent worst case.

The following are to support that the actual release was likely less than the calculated values:

- The Scrubber Inlet line is maintained at a negative pressure relative to atmosphere (by the function of the RTO) and therefore the gas would tend to flow to the Scrubber inlet line and be conveyed to the RTO for destruction.
- Line 5 had been experiencing High Separator Pressure warnings just prior to the incident. This indicates that the flame arrester at the outlet of the Vacuum Exhaust line was restricted. This would further indicate the path of least resistance as the line to the RTO.
- Inspection of the subject valve after removal showed a considerable buildup of debris in the area between the valve disc and valve seat which would further restrict flow to the Vacuum Exhaust line/atmosphere.

Tracking Number	Site	Vessel	Total EO Used (lbs.)	EO removed by Vac Pump (lbs.)	To atmosphere (lbs.)	Emission Start	Emission Finish
194822	CV	5	113	112.5	3.0	9/15/19 2:37 PM	9/15/19 7:05 PM
194766	CV	5	142	141.4	3.8	9/16/19 12:30 AM	9/16/19 4:58 AM
194850	CV	5	112	111.5	3.0	9/16/19 11:35 AM	9/16/19 4:03 PM
194774	CV	5	129	128.5	3.4	9/17/19 12:50 AM	9/17/19 5:18 AM
194864	CV	5	121	120.5	3.2	9/17/19 11:12 AM	9/17/19 3:40 PM
194827	CV	5	126	125.5	3.4	9/17/19 8:18 PM	9/18/19 12:47 AM
194702	CV	5	114	113.5	3.0	9/18/19 7:34 AM	9/18/19 12:02 PM
194838	CV	5	123	122.5	3.3	9/18/19 4:58 PM	9/18/19 9:26 PM
194887	CV	5	121	120.5	3.2	9/19/19 3:45 AM	9/19/19 8:13 AM
194699	CV	5	120	119.5	3.2	9/19/19 4:07 PM	9/19/19 8:35 PM
194803	CV	5	117	116.5	3.1	9/20/19 3:27 AM	9/20/19 7:55 AM
194902	CV	5	122	121.5	3.2	9/20/19 1:23 PM	9/20/19 5:51 PM
194882	CV	5	119	118.5	3.2	9/21/19 12:26 AM	9/21/19 4:54 AM
194918	CV	5	113	112.5	3.0	9/21/19 10:12 AM	9/21/19 2:40 PM
194909	CV	5	122	121.5	3.2	9/21/19 8:03 PM	9/22/19 12:32 AM
194890	CV	5	121	120.5	3.2	9/22/19 5:58 AM	9/22/19 10:26 AM
194814	CV	5	115	114.5	3.1	9/22/19 4:06 PM	9/22/19 8:34 PM
		Total	2050		54.5		