



Air Quality Bureau
NOTICE OF VIOLATION ("NOV")

TRACKING NUMBER:	STE-0127-2101	ICIS CASE NUMBER:	NM000A200198479
COMPANY NAME:	Sterigenics US, LLC	FACILITY NAME:	Santa Teresa Plant
PERMIT(S):	NSR 0733-M15-R1	SOURCE CLASS:	Minor
INSPECTION DATE:	July 31, 2020 August 3, 2020	EARLIEST DISCOVERY:	July 7, 2020
SELF-REPORTED:	No	*NRV, FRV or HPV:	FRV
FACILITY LOCATION:	2400 Airport Road Santa Teresa, NM 88008	CONTACT PERSON:	Joseph Ulfig (630)-928-1710
MAILING ADDRESS:	2015 Spring Road Suite 650 Oak Brook, IL 60523	COUNTY:	Dona Ana
Electronic Mail:	julfig@sterigenics.com		<i>Via electronic mail</i>

This NOV is a written record of the AIR QUALITY BUREAU'S ("AQB" or "Bureau") finding that a violation of AIR QUALITY CONTROL REGULATIONS OR AIR QUALITY PERMIT CONDITIONS has occurred. An NOV is issued each time a violation is observed or discovered. This NOV may subject you to monetary penalties through administrative, civil, or criminal prosecution.

*Each violation associated with this enforcement case has been evaluated in accordance with EPA's Guidance on Federally-Reportable Violations for Clean Air Act Stationary Sources (September 2014) and Timely and Appropriate Enforcement Response to High Priority Violations (August 2014). The overall assessment of this enforcement case reflects the highest level determined.

NRV: Non-Reportable Violation
FRV: Federally-Reportable Violation
HPV: High Priority Violation

If you have questions or believe any statement in this notice is erroneous, please contact Jeremy Espinoza, Enforcement Specialist, at (505) 629-3404, or at Jeremy.espinoza1@state.nm.us.

Air Quality Bureau Official

Date

Company: Sterigenics US, LLC
Facility: Santa Teresa Plant
NOV #: STE-0127-2101
Permit #: NSR 0733-M15-R1

Inspection By: Margaret Doyle
Date of Discovery: July 7, 2020
NOV Prepared By: Brendan Wyman
NRV, FRV or HPV: FRV

VIOLATION 1: NSR Permit 0733-M15-R1, General Condition B109.A, *General Recordkeeping Requirements*

Number of Claims: 1

Requirement:

NSR Permit 0733-M15-R1, General Condition B109.A states in relevant part, "The Permittee shall maintain records to assure and verify compliance with the terms and conditions of this permit and any other applicable requirements that become effective after permit issuance."

Description:

On June 10, 2020, Bureau staff requested monitoring records from Sterigenics. The request specified that the records were to be submitted via email, by the close of business on June 19, 2020. On July 7, 2020, the records arrived after being sent ground delivery through the mail.

The monitoring records received by the Bureau were incomplete and included numerous errors. The Excel spreadsheet column headers were incomplete, and did not provide the make, model, and serial number for equipment identification. The records lacked identification of whether volumes were totals or averages. The records also lacked units of measure and temperature units. Separate Gas Usage Charge Rates were not included for each sterilization chamber.

Bureau staff requested corrected records by phone on July 30, 2020; Sterigenics personnel refused.

Conclusion:

The failure of Sterigenics to maintain records that assure and verify compliance with the terms and conditions of the permit is in violation of NSR Permit 0733-M15-R1, General Condition B109.A.

Corrective Action Required:

Sterigenics shall identify and submit for Bureau Review and approval the causes of this violation and the actions taken to prevent the recurrence of this violation within 30 days of receipt of this NOV.

The following additional corrective actions are required:

1. Sterigenics shall make the necessary corrections to the monitoring records that meet the requirements of General Condition B109.A, and shall resubmit the corrected electronic records in Excel format by email to the Bureau within 30 days. Corrected records shall include:
 - Appropriate column headers;
 - Identification of volumes as totals or averages;
 - Appropriate units of measure; and
 - Daily Hourly Average Gas Usage Charge Rate report for each unit #S-1 to S-13.
2. Sterigenics shall implement and document a permit compliance training for all employees to include proper recordkeeping. Documentation shall be submitted to the Department within 60 days of receipt of this NOV.

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Inspection By: Margaret Doyle
Date of Discovery: July 31, 2020
NOV Prepared By: Brendan Wyman
NRV, FRV or HPV: FRV

VIOLATION 2: NSR Permit 0733-M15-R1, General Condition B110.C(1), *General Reporting Requirements*

Number of Claims: 4

Requirement:

NSR Permit 0733-M15-R1, General Condition B110.C(1) states in relevant part, “The permittee shall notify the Department’s Permitting Program Manager, in writing of, or provide the Department with (20.2.72.212.C and D): (1) any change of operators or any equipment substitutions within fifteen (15) days of such change ...”

Description:

On July 31, 2020, while conducting an on-site Full Compliance Evaluation of the Sterigenics Santa Teresa Plant, Bureau staff discovered Sterigenics had failed to notify the Bureau in writing of the replacement of four vacuum pumps for the sterilization chamber Units #S-1, #S-5, #S-7, and #S-13.

On August 19, 2020, Sterigenics staff emailed the technical information on the new pumps to Bureau personnel. The information showed that Unit #S-1 had a date of installation of February 29, 2020, #S-5 had a date of installation of February 15, 2019, #S-7 had a date of installation of January 8, 2020, and #S-13 had a date of installation of May 13, 2020. All four (4) units missed the fifteen (15) day period to properly notify the Bureau of the replacement vacuum pumps.

Conclusion:

The failure of Sterigenics to notify the Bureau in writing of the replacement of four vacuum pumps within fifteen (15) days of equipment substitutions is in violation of NSR Permit 0733-M15-R1, General Condition B110.C.

Corrective Action Required:

Sterigenics shall identify and submit for Bureau Review and approval the causes of this violation and the actions taken to prevent the recurrence of this violation within 30 days of receipt of this NOV.

The following additional corrective actions are required:

1. Sterigenics shall implement and document a permit compliance training for all employees to include notifications to the Department. Documentation shall be submitted to the Department within 60 days of receipt of this NOV.
2. Sterigenics shall implement and document an internal system to generate reminders to appropriate staff of notification requirements when regulated equipment is replaced. Documentation of this system shall be submitted to the Department within 30 days of receipt of this NOV.

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Inspection By: Cindy Hollenberg
Date of Discovery: July 7, 2020
NOV Prepared By: Brendan Wyman
NRV, FRV or HPV: FRV

VIOLATION 3: NSR Permit 0733-M15-R1, Specific Condition A800.B, *Oil Seals*

Number of Claims: 2

Requirement:

NSR Permit 0733-M15-R1, Specific Condition A800.B states in relevant part, “Monitoring: The permittee shall inspect the oil seals weekly to ensure proper operations. ... Recordkeeping: The permittee shall keep records of the required monitoring and any maintenance performed for EO or PO pump oil seals.”

Description:

On January 5, 2021, Bureau staff further reviewed the maintenance records received from Sterigenics on July 7, 2020. It was then determined that Sterigenics had not inspected the EO or PO pump oil seals weekly as required. Two calendar weeks in 2019 had no oil seal inspections. Inspections were conducted February 2 and 15, 2019 (13 days apart) and March 2 and 14, 2019 (12 days apart). No oil seal inspections were conducted during calendar weeks February 3 – 9, 2019 and March 3 – 9, 2019.

Conclusion:

The failure of Sterigenics to inspect oil seals weekly for one week in February 2019 and one week in March 2019 is in violation of NSR Permit 0733-M15-R1, Specific Condition A800.B.

Corrective Action Required:

Sterigenics shall identify and submit for Bureau Review and approval the causes of this violation and the actions taken to prevent the recurrence of this violation within 30 days of receipt of this NOV.

The following additional corrective actions are required:

1. Sterigenics shall submit to the Bureau oil seal inspection records from July 1, 2020 to June 30, 2021 within 15 days of receipt of this NOV. Sterigenics shall self-identify all missing oil inspections according to calendar weeks.
2. Sterigenics shall implement and document a system to ensure that oil seal inspections are scheduled on a weekly calendar basis. The system shall include an automatic warning when oil seal inspections are not completed within three (3) days of the scheduled inspection date. Documentation of this system shall be submitted to the Bureau within 30 days of receipt of this NOV.

Company: Sterigenics US, LLC
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Permit #: NSR 0733-M15-R1

Inspection By: Cindy Hollenberg
Date of Discovery: January 9, 2021
NOV Prepared By: Brendan Wyman
NRV, FRV or HPV: FRV

VIOLATION 4: NSR Permit 0733-M15-R1, Specific Condition A801.B, *Acid-Water Scrubber (Unit CD-1 and CD-2)*

Number of Claims: 4

Requirement:

NSR Permit 0733-M15-R1, Specific Condition A801.B states in relevant part, "Recordkeeping: Daily, the permittee shall record: For CD-1 and CD-2, the permittee shall record: (1) The gas flow rate; (2) The gas inlet temperature; (3) The liquid temperature; (4) The liquid pH; and (5) The permittee shall record inspections of the scrubber spray atomizers and the results of the inspections."

Description:

On January 5, 2021, Bureau staff further reviewed the maintenance records received from Sterigenics on July 7, 2020. It was then determined that there were errors throughout the Daily PM logs for the Acid-Water Scrubber (Units CD-1 and CD-2). From December 22, 2018 to June 5, 2020, the gas inlet temperatures were recorded in incorrect units; for the week of May 5 – 11, 2018, pH was recorded erroneously as a whole number; on January 12, 2019, an impossible liquid temperature was recorded; and negative gas flow rates were recorded for four (4) weeks in 2020.

On January 7, 2021, these irregularities were included on a questionnaire sent to Sterigenics. On January 9, 2021, the questionnaire responses were received. For each of the irregularities noted above, the response was that the values or units were in error.

Conclusion:

The failure of Sterigenics to accurately record gas inlet temperature, liquid temperature, pH and gas flow rates for the Acid-Water Scrubber (units CD-1 and CD-2) is in violation of NSR Permit 0733-M15-R1, Specific Condition A801.B.

Corrective Action Required:

Sterigenics shall identify and submit for Bureau Review and approval the causes of this violation and the actions taken to prevent the recurrence of this violation within 30 days of receipt of this NOV.

The following additional corrective actions are required:

1. Sterigenics shall implement and document a permit compliance training for all employees to include proper recordkeeping for the Acid-Water Scrubber. Documentation shall be submitted to the Department within 60 days of receipt of this NOV.
2. Sterigenics shall submit Daily PM Logs for July 1, 2020 to June 30, 2021 within 15 days of receipt of this NOV. Sterigenics shall self-identify any inconsistencies or recordkeeping errors in these records.

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Inspection By: Cindy Hollenberg
Date of Discovery: January 9, 2021
NOV Prepared By: Brendan Wyman
NRV, FRV or HPV: FRV

VIOLATION 5: NSR Permit 0733-M15-R1, Condition A802.A, *Operational and Control Requirements for Units AR-08, AR-09, and Units BV1- BV14*

Number of Claims: 2

Requirement:

NSR Permit 0733-M15-R1, Condition A802.A states in relevant part, "Recordkeeping: (1) The permittee shall keep a monthly record of the data from the continuous strip chart recorder or data acquisition system for monitoring the catalytic bed temperature. (2) Monthly, the permittee shall record the pressure drop across the catalyst bed. (3) The permittee shall record the date, start time, and end time of any downtime and/or maintenance of the unit CD-3."

Description:

On January 5, 2021, Bureau staff further reviewed the maintenance records received from Sterigenics on July 7, 2020. It was determined that more information was needed to confirm compliance with NSR Permit 0733-M15-R1, Condition A802.A. On January 7, 2021, Bureau staff requested additional records which included what was needed to determine compliance with Condition A802.A.

On January 9, 2021, the Bureau received records from Sterigenics which included only quarterly readings of pressure drops across the catalyst bed for the entire period of January 1, 2018 to May 31, 2020. The permit requirement is for monthly readings rather than quarterly readings.

Also received on January 9, 2021, were records for the maximum and minimum temperature at the outlet of the catalyst bed. The records for January 1, 2019 to June 2, 2019 included only hourly readings, which is not considered continuous. Continuous readings would be recorded as minute by minute.

Conclusion:

The failure of Sterigenics to record the pressure drop across the catalyst monthly and failure to continuously record the temperature at the outlet of the catalyst bed is in violation of NSR Permit 0733-M15-R1, Specific Condition A802.A.

Corrective Action Required:

Sterigenics shall identify and submit for Bureau Review and approval the causes of this violation and the actions taken to prevent the recurrence of this violation within 30 days of receipt of this NOV.

The following additional corrective actions are required:

1. Sterigenics shall submit to the Bureau within 15 days of receipt of this NOV records of the monthly pressure drop measurements for July 1, 2020 to June 30, 2021. Sterigenics shall self-identify all months when a pressure drop measurement has not been recorded.
2. Sterigenics shall submit to the Bureau within 15 days of receipt of this NOV records of continuous monitoring for the catalyst bed temperature. Sterigenics shall self-identify all gaps within the continuous data.

3. Sterigenics shall submit to the Bureau records of the monthly pressure drop measurements across the catalyst bed for the next six (6) months within 15 days of each month's end, beginning with July 2021.

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Inspection By: Margaret Doyle, Cindy Hollenberg
Earliest Date of Discovery: July 7, 2020
NOV Prepared By: Brendan Wyman
NRV, FRV or HPV: FRV

CORRECTIVE ACTION VERIFICATION

This form must be completed and signed by the facility’s Responsible Official or other designee and returned within 30 days of the receipt of this Notice of Violation (“NOV”). All corrective actions must be completed according to each violation’s corrective action instructions. Documentation for corrective actions (in addition to this form) must be submitted electronically no later than the dates specified for each violation. Submit this form and all required documentation to:

Jeremy Espinoza, Enforcement Specialist
Jeremy.Espinoza1@state.nm.us

I hereby verify that Sterigenics has initiated the required corrective actions outlined in this NOV. The following corrective actions have been taken or will be taken by the dates indicated below for each violation. All required documentation will be submitted electronically by the due dates specified for each corrective action requirement.

Signature

Date

Printed Name:
Title:

Company: Sterigenics US, LLC
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Inspection By: Margaret Doyle
Date of Discovery: July 7, 2020
NOV Prepared By: Brendan Wyman
NRV, FRV or HPV: FRV

VIOLATION 1: Failure to maintain records that assure and verify compliance with the terms and conditions of their permit

Corrective Action Required:

Sterigenics shall identify and submit for Bureau Review and approval the causes of this violation and the actions taken to prevent the recurrence of this violation within 30 days of receipt of this NOV.

The following additional corrective actions are required:

1. Sterigenics shall also make the necessary corrections to the monitoring records that meet the requirements of General Condition B109.A, and shall resubmit the corrected electronic records in Excel format by email to the Bureau within 30 days. Corrected records shall include:
 - Appropriate column headers;
 - Identification of volumes as totals or averages;
 - Appropriate units of measure; and
 - Daily Hourly Average Gas Usage Charge Rate report for each unit #S-1 to S-13.
2. Sterigenics shall implement and document a permit compliance training for all employees to include proper recordkeeping. Documentation shall be submitted to the Department within 60 days of receipt of this NOV.

Cause(s) of violation:

Required Corrective Action taken to date:

- 1.
- 2.

Documentation submitted with this report:

Required Corrective Action planned (include date action will be completed):

- 1.
- 2.

Documentation to be submitted by the dates indicated above:

Additional corrective actions taken or planned to prevent recurrence of this violation:

Company: Sterigenics US, LLC
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Inspection By: Margaret Doyle
Date of Discovery: July 31, 2020
NOV Prepared By: Brendan Wyman
NRV, FRV or HPV: FRV

VIOLATION 2: Failure to notify the Bureau in writing about the replacement of four vacuum pumps within fifteen (15) days of equipment substitutions

Corrective Action Required:

Sterigenics shall identify and submit for Bureau Review and approval the causes of this violation and the actions taken to prevent the recurrence of this violation within 30 days of receipt of this NOV.

The following additional corrective actions are required:

1. Sterigenics shall implement and document a permit compliance training for all employees to include notifications to the Department. Documentation shall be submitted to the Department within 60 days of receipt of this NOV.
2. Sterigenics shall implement and document an internal system to generate reminders to appropriate staff of notification requirements when regulated equipment is replaced. Documentation of this system shall be submitted to the Department within 30 days of receipt of this NOV.

Cause(s) of violation:

Required Corrective Action taken to date:

- 1.
- 2.

Documentation submitted with this report:

Required Corrective Action planned (include date action will be completed):

- 1.
- 2.

Documentation to be submitted by the dates indicated above:

Additional corrective actions taken or planned to prevent recurrence of this violation:

Company: Sterigenics US, LLC
Facility: Santa Teresa Plant
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Inspection By: Cindy Hollenberg
Date of Discovery: July 7, 2020
NOV Prepared By: Brendan Wyman
NRV, FRV or HPV: FRV

VIOLATION 3: Failure to inspect oil seals weekly for one week in February 2019 and one week in March 2019

Corrective Action Required:

Sterigenics shall identify and submit for Bureau Review and approval the causes of this violation and the actions taken to prevent the recurrence of this violation within 30 days of receipt of this NOV.

The following additional corrective actions are required:

1. Sterigenics shall submit to the Bureau oil seal inspection records from July 1, 2020 to June 30, 2021 within 15 days of receipt of this NOV. Sterigenics shall self-identify all missing oil inspections according to calendar weeks.
2. Sterigenics shall implement and document a system to ensure that oil seal inspections are scheduled on a weekly calendar basis. The system shall include an automatic warning when oil seal inspections are not completed within three (3) days of the scheduled inspection date. Documentation of this system shall be submitted to the Bureau within 30 days of receipt of this NOV.

Cause(s) of violation:

Required Corrective Action taken to date:

- 1.
- 2.

Documentation submitted with this report:

Required Corrective Action planned (include date action will be completed):

- 1.
- 2.

Documentation to be submitted by the dates indicated above:

Additional corrective actions taken or planned to prevent recurrence of this violation:

Company: Sterigenics US, LLC
Facility: Santa Teresa Plant
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Permit #: NSR 0733-M15-R1

Inspection By: Cindy Hollenberg
Date of Discovery: January 9, 2021
NOV Prepared By: Brendan Wyman
NRV, FRV or HPV: FRV

VIOLATION 4: Failure to accurately record gas inlet temperature, liquid temperature and liquid pH for the Acid-Water Scrubber (units CD-1 and CD-2)

Corrective Action Required:

Sterigenics shall identify and submit for Bureau Review and approval the causes of this violation and the actions taken to prevent the recurrence of this violation within 30 days of receipt of this NOV.

The following additional corrective actions are required:

1. Sterigenics shall implement and document a permit compliance training for all employees to include proper recordkeeping for the Acid-Water Scrubber. Documentation shall be submitted to the Department within 60 days of receipt of this NOV.
2. Sterigenics shall submit Daily PM Logs for July 1, 2020 to June 30, 2021 within 15 days of receipt of this NOV. Sterigenics shall self-identify any inconsistencies or recordkeeping errors in these records.

Cause(s) of violation:

Required Corrective Action taken to date:

- 1.
- 2.

Documentation submitted with this report:

Required Corrective Action planned (include date action will be completed):

- 1.
- 2.

Documentation to be submitted by the dates indicated above:

Additional corrective actions taken or planned to prevent recurrence of this violation:

Company: Sterigenics US, LLC
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Inspection By: Cindy Hollenberg
Date of Discovery: January 9, 2020
NOV Prepared By: Brendan Wyman
NRV, FRV or HPV: FRV

VIOLATION 5: Failure to record the pressure drop across the catalyst monthly and failure to continuously record the temperature at the outlet of the catalyst bed

Corrective Action Required:

Sterigenics shall identify and submit for Bureau Review and approval the causes of this violation and the actions taken to prevent the recurrence of this violation within 30 days of receipt of this NOV.

The following additional corrective actions are required:

1. Sterigenics shall submit to the Bureau within 15 days of receipt of this NOV records of the monthly pressure drop measurements for July 1, 2020 to June 30, 2021. Sterigenics shall self-identify all months when a pressure drop measurement has not been recorded.
2. Sterigenics shall submit to the Bureau within 15 days of receipt of this NOV records of continuous monitoring for the catalyst bed temperature. Sterigenics shall self-identify all gaps within the continuous data.
3. Sterigenics shall submit to the Bureau records of the monthly pressure drop measurements across the catalyst bed for the next six (6) months within 15 days of each month's end, beginning with the month ending July 31, 2021.

Cause(s) of violation:

Required Corrective Action taken to date:

- 1.
- 2.

Documentation submitted with this report:

Required Corrective Action planned (include date action will be completed):

- 1.
- 2.

Documentation to be submitted by the dates indicated above:

Additional corrective actions taken or planned to prevent recurrence of this violation: