Region 6 Compliance Assurance and Enforcement Division

INSPECTION REPORT

Inspection Date(s):	01/11-12/2016		
Media:	Air		
Regulatory Program(s)	CAA Section 112(r) & Chemical Accident Prevention Provisions		
Company Name:	**Sterigenics U.S., LLC**		
Facility Name:	**Sterigenics U.S., LLC - Grand Prairie**		
Facility Physical Location:	1302 Avenue T		
(city, state, zip code)	Grand Prairie, TX 75050		
Mailing address:	2015 Spring Road		
(city, state, zip code)	Oak Brook, IL 60523		
County/Parish:	Tarrant County		
Facility Contact:	Christopher Bonilla	General Manager	
	cbonilla@sterigenics.com		
FRS Number:	1100 1532 0543		
Identification/Permit Number:	Air Operating Permit ID: 51907		
Media Number:	RMP ID: 1000 0018 2955		
NAICS:	33999 All Other Miscellaneous Manufacturing		

Personnel participating in inspection:

Christopher Bonilla	Sterigenics U.S., LLC - Grand Prairie	General Manager	972-602-9430
Kevin Pruitt	Sterigenics U.S., LLC - Grand Prairie	Maintenance Supervisor	972-602-9430
Louie Reves	Sterigenics U.S., LLC - Grand Prairie	Operations Manager	972-602-9430
Ron Sharp	Sterigenics U.S., LLC - Grand Prairie	Logistics Supervisor	972-602-9430
Dave Hensley	U.S. EPA / 6EN-AS	Physical Scientist (Environmental)	214-665-6739
Justin McDowell	U.S. EPA / 6EN-AS	Life Scientist (Environmental)	214-665-6557

EPA Lead Inspector Signature/Date	Dave Hensley	2/17/2016
	Dave Hensley	Date
Supervisor Signature/Date	Samuel Tates	2/17/2016
	Samuel Tates	Date

Section I - INTRODUCTION

PURPOSE OF THE INSPECTION

Environmental Protection Agency (EPA), Region Six, Compliance Assurance & Enforcement Division, Air Enforcement Branch, Chemical Accident Prevention Section inspectors Dave Hensley and Justin McDowell arrived at the Sterigenics U.S., LLC - Grand Prairie (Sterigenics) at 9 AM on January 11, 2016, for an announced inspection. We met with Christopher Bonilla, General Manager; Kevin Pruitt, Maintenance Supervisor; Louie Reves, Operations Manager; and Ron Sharp, Logistics Supervisor. I presented my credentials to those present. The scope of the inspection is a partial compliance evaluation (PCE) and includes evaluation of the compliance of the facility with the Clean Air Act (CAA) Section 112(r) and the Chemical Accident Prevention Provisions (40 C.F.R. Part 68). I asked if an employee representative was available to invite to participate in the inspection. Sterigenics is a non-union facility.

FACILITY DESCRIPTION

Sterigenics Grand Prairie operates a contract sterilization facility located in Grand Prairie, Texas. The facility is engaged in the sterilization of medical equipment and spices using ethylene oxide. Ethylene oxide is listed as a regulated toxic substance under U.S. EPA's Chemical Accident Prevention Provisions (40 CFR 68). This facility has 30 full time employees.

Section II - OBSERVATIONS

40 C.F.R. Part 68 – CHEMICAL ACCIDENT PREVENTION PROVISIONS
Subpart A – General
40 C.F.R. § 68.10 Applicability - I observed that Sterigenics is a stationary source that has Air Operating Permit 51907 and more than a threshold quantity of a regulated substances (ethylene oxide) in one process (sterilization process) therefore, these regulations are applicable. Sterigenics submitted a Risk Management Plan (RMP), on June 17, 2013, that describes this process containing a toxic chemical held at more than a threshold quantity. The process is Program three due to the fact that the facility is subject to OSHA's Process Safety Management Standard (29 CFR 1910.119).

40 C.F.R. § 68.12 General requirements – I reviewed the Risk Management Plan (RMP) submitted by Sterigenics, on June 17, 2013, that listed one toxic chemical in one process, ethylene oxide in the sterilization process.

> **40 C.F.R. § 68.160 Registration –** This RMP identifies Sterigenics as having a CAA Title V permit. We discovered on inspection that Sterigenics does not have a CAA Title V permit. The July 1, 2003, RMP submittal identifies the facility as non CAA Title V, the June 19, 2008 RMP submittal identifies the facility at CAA Title V, and the June 17, 2013, identifies the facility at CAA Title V. Sterigenics submitted a change to correct this error the day after this inspection on January 13, 2016.

40 C.F.R. § 68.15 Management – Sterigenics developed a management system to oversee the implementation of the risk management program elements. This system assigned qualified persons or positions overall responsibility for the development, implementation, and integration of the Risk Management Program elements.

Subpart B – Hazard Assessment

40 C.F.R. § 68.20 Applicability - Sterigenics prepared a worst-case release scenario analysis and completed the five-year accident history. Since Sterigenics' process is program three, they must comply with all sections in this subpart.

40 C.F.R. § 68.22 Offsite consequence analysis parameters – I requested to review worst case scenario documentation before the inspection with an announcement email, on December 21, 2015. I reviewed this documentation during the inspection. Upon first review the parameters used to calculate toxic worst-case and alternative case release scenarios were not observed. Sterigenics contacted the person that did the calculations and was able to locate documentation of the required parameters used to calculate toxic worst-case and alternative case release scenarios.

40 C.F.R. § 68.25 Worst-case release scenario analysis – I reviewed documentation and had discussions with Sterigenics during the inspection regarding the worst-case release scenario analysis. It showed that Sterigenics analyzed and reported a worst-case toxic release in its Risk Management Plan. This analysis was done using CHARM® (v9.1) (http://www.charmmodel.com/). The distance to endpoint they calculated was comparable to that generated when we used RMP*Comp.

40 C.F.R. § 68.28 Alternative release scenario analysis – Sterigenics analyzed and reported one alternate release scenarios, for the toxic substance, in their Risk Management Plan.

40 C.F.R. § 68.30 Defining offsite impacts – Population – I talked with Sterigenics about the offsite consequences analysis done. Sterigenics used the Census Bureau population data current at the time of analysis and the distance to endpoints, as specified in these regulations, to calculate the population numbers reported in their Risk Management Plan.

40 C.F.R. § 68.33 Defining offsite impacts – Environment – Discussions with Sterigenics showed me that USGS Data was used to determine the environmental receptors and the distance to endpoints.

40 C.F.R. § 68.36 Review and update – I reviewed Sterigenics' documentation that illustrated reviews and updates regarding the offsite consequences are occurring at least every five years. Sterigenics staff told me that there is a mechanism in the change management system that will flag the need for revisions if the maximum intended inventory of any Risk Management Plan chemical changes.

40 C.F.R. § 68.39 Documentation – I was provided documentation of the offsite consequence analyses. For worst-case and alternative case scenarios, a description of the vessel or pipeline, the substance selected as worst-case, and the rationale for selection was included; likewise, assumptions included use of any administrative controls and any passive mitigation that were assumed to limit the quantity that could be released, estimated quantity released, release rate, and duration of release. The methodology used to determine distance to endpoints was documented by the facility. The data used to estimate population was provided in the form of maps that had the distance to endpoint labeled with a circle from the emissions point. The assumptions and parameters used were not present in the initial

documentation I was provided, however Sterigenics was able to provide documentation of the assumptions and parameters used before the end of the inspection.

40 C.F.R. § 68.42 Five year accident history – Sterigenics had one reported accidental releases in their Risk Management Plan as of June 17, 2013. An accident that occurred on December 3, 2012. I reviewed the National Reporting Center (NRC) and State of Texas Environmental Electronic Reporting System (STEERS) for additional incidents that may have required addition to Sterigenics' five year accident history. I did not locate any additional accidental releases from covered processes that resulted in deaths, injuries, or significant property damage on site, or known offsite deaths, injuries, evacuations, sheltering in place, property damage, or environmental damage.

Subpart D – Program 3 Prevention Program
40 C.F.R. § 68.65 Process safety information – I requested and reviewed a selection of process safety information for Risk Management Plan units at Sterigenics. The process safety information was maintained in an organized manner with binders. I reviewed one of these binders during the inspection and found it met the requirements of this part.

40 C.F.R. § 68.67 Process hazard analysis (PHA) – I requested and reviewed The PHAs for the Risk Management Plan process. I reviewed the two most recent PHAs done at Sterigenics. The PHA start dates were 5.4 years apart, thus was not done within the required five year timeframe. In reviewing the Sterigenics Grand Prairie 2013 PHA Revalidation (CBI Attachment) it was discovered that a list of the recommendations appears on page 49. This list documented a responsible person and estimated end date, but not the date the recommendation was resolved or the actions taken.

40 C.F.R. § 68.69 Operating procedures – I reviewed several operating procedures, which appeared to meet the requirements. 40 C.F.R. 68.69(c) states; "…*The owner or operator shall certify annually that these operating procedures are current and accurate*". Sterigenics provided me with a single certification statement that the operating process are correct and accurate that had been signed by the General Manager for 2013, 2014, and 2015. The dates between these certification documents are more than 365 days.

40 C.F.R. § 68.71 Training – I requested and was provided the training files for an operator. In my review, I found no issues associated with these training files. We discussed the programs in place to insure compliance with the initial training and three year refresher training. Sterigenics has a process in place to ensure initial and three year trainings occur on time.

40 C.F.R. § 68.73 Mechanical integrity – I requested and was provided mechanical integrity records for randomly selected inspections of Risk Management Program covered equipment, and the written procedure for maintaining the integrity of the process. I found no issues with this documentation. I met with the Maintenance Supervisor and discussed how the mechanical integrity program works. I asked if there were any overdue inspections. There were no overdue inspections at the time of this inspection.

40 C.F.R. § 68.75 Management of Change – I asked for and was given a list of the management of changes (MOC) done in Risk Management Plan units at the facility for the last year (January 1, 2014, to January 1, 2015) and the written procedure for MOC. I reviewed the written procedure and two MOC documentation packages for changes occurring in covered processes. All these met the requirements of this section.

40 C.F.R. § 68.77 Pre-startup review – Pre-startup review was included with the MOC documentation that I reviewed, which met the requirements.

40 C.F.R. § 68.79 Compliance audits – I requested the last two Risk Management Program compliance audits. On arrival, I was provided copies of audits that documented the review of all the elements of the Risk Management Program.

40 C.F.R. § 68.81 Incident investigation – Prior to the inspection, I requested the incident investigations for a release, of ethylene oxide, that occurred on December 3, 2012, and reported on Sterigenics RMP five year accident history. I requested a list of Incident Reports/Investigations for all incidents which resulted in, or could reasonably have resulted in, a catastrophic release of a regulated substance over the last three years. I selected, requested, and reviewed an additional incident investigations. The December 9, 2012, incident report did not contain the date the investigation began.

40 C.F.R. § 68.83 Employee participation – I reviewed the employee participation plan during this inspection. It meets the regulation.

40 C.F.R. § 68.85 Hot work permit – While onsite, I reviewed several hot work permits that met the requirements of this regulation.

40 C.F.R. § 68.87 Contractors – I observed that contractors and visitors were required to watch a safety video prior to entering the facility. We discussed contractor selection and training requirements. Sterigenics utilizes a commercial contract selection system that provides initial screening of contractor safety records and training. Sterigenics requires site specific training for all contractors, and job specific training to ensure that all contractors are trained on the potential hazards of the process.

Subpart E – Emergency Response –
40 C.F.R. § 68.90 Applicability – Sterigenics employees are not first responders that respond to fires and releases onsite.

40 C.F.R. § 68.95 Emergency response program – I requested and was provided the Emergency Response Plan for Sterigenics. Sterigenics is included in the community emergency response plan and appropriate mechanisms are in place to notify emergency responders when there is a need for a response.

40 C.F.R. § 68.195 Required corrections – The original Risk Management Plan for this facility was submitted on July 1, 2003. There have been two resubmissions since then, which were all within the five year timeframe. The most recent correction was January 13, 2016, due to correction of the clerical error associated with the CAA Title V status. The next Risk Management Plan submission is due June 17, 2018, unless an update or correction is required by 40 C.F.R. § 68.190 & 195.

Section III – AREAS OF CONCERN

AOC 1 - 40 C.F.R. § 68.67 (f) Process hazard analysis (PHA) not updated and revalidated At least every five years

In reviewing the Sterigenics Grand Prairie 2013 PHA Revalidation and the 2007-Dallas PHA Revalidation (CBI Attachment) it was discovered that start dates were 5.4 years apart, thus not done within the required five year timeframe as per 40 C.F.R. Part 68.67(f).

> "(f) At least every five (5) years after the completion of the initial process hazard analysis, the process hazard analysis shall be updated and revalidated by a team meeting the requirements in paragraph (d) of this section, to assure that the process hazard analysis is consistent with the current process. Updated and revalidated process hazard analyses completed to comply with 29 CFR 1910.119(e) are acceptable to meet the requirements of this paragraph."

AOC 2 - 40 C.F.R. § 68.67 (e) Process hazard analysis (PHA) recommendations resolutions not documented

In reviewing the Sterigenics Grand Prairie 2013 PHA Revalidation (CBI Attachment) it was discovered that a list of the recommendations appears on page 49. This list documented a responsible person and estimated end date, but not the date the recommendation was resolved or the actions taken. Sterigenics did provide PHA Action Sheets (CBI Attachment) for each recommendation. These PHA Action Sheets were signed on January 12, 2016, and that meet the requirements of this regulation.

> "(e) The owner or operator shall establish a system to promptly address the team's findings and recommendations; assure that the recommendations are resolved in a timely manner and that the resolution is documented; document what actions are to be taken; complete actions as soon as possible; develop a written schedule of when these actions are to be completed; communicate the actions to operating, maintenance and other employees whose work assignments are in the process and who may be affected by the recommendations or actions."

AOC 3 - 40 C.F.R. § 68.69 (c) Operating procedures annual certifications more than a year apart

In reviewing the certification statements that the operating process are correct and accurate it was noted that they had been signed by the General Manager for 2013, 2014, and 2015. The dates between these certification documents are more than 365 days (CBI Attachment).

> "(c) The operating procedures shall be reviewed as often as necessary to assure that they reflect current operating practice, including changes that result from changes in process chemicals, technology, and equipment, and changes to stationary sources. The owner or operator shall certify annually that these operating procedures are current and accurate."

AOC 4 - 40 C.F.R. § 68.81 (d) (2) Incident investigation report did not contain the date the investigation began

In review of the December 3, 2012, incident report I discovered it did not contain the date the investigation began.

> "(d) A report shall be prepared at the conclusion of the investigation which includes at a minimum: (1) Date of incident; (2) Date investigation began; (3) A description of the incident; (4) The factors that contributed to the incident; and, (5) Any recommendations resulting from the investigation."

AOC 5 - 40 C.F.R. § 68.160 (b) (12) CAA Title V permit status was incorrect on the registration

The June 17, 2013, RMP identifies Sterigenics as having a Clean Air Act Title V permit. We discovered on inspection that Sterigenics does not have a Clean Air Act Title V permit.

> "(b) The registration shall include the following data: …(12) If the stationary source has a CAA Title V operating permit, the permit number;…"

Section IV – FOLLOW UP

On January 13, 2016, Sterigenics submitted a correction of their RMP due to clerical error associated with the CAA Title V status.

Section V – LIST OF APPENDICES

Appendix Confidential Business Information (not included in published version of the report)