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MEMORANDUM

DATE: September 20, 2019

TO: File, Construction Permit Application No. 19060030

FROM: Steven King, Modeling Unit, Air Quality Planning Section, Bureau of Air

SUBJECT: Sterigenics US, LLC (ID No. 043110AAC)

Background

Sterigenics US, LLC (Sterigenics) owns a commercial contract sterilization source in Willowbrook, Illinois. The Clean Air Act Permit Program Permit #95120085, issued on June 8, 2015, authorizes Sterigenics to operate two facilities within the village of Willowbrook. One facility is located at 7775 S. Quincy Street and began operation in 1984 (Willowbrook 1). The other facility, located 400 feet away, is located at 830 Midway Drive and began operation in 1999 (Willowbrook 2). At these facilities, Sterigenics primarily sterilizes medical devices and surgical procedure kits using ethylene oxide as the means of sterilization.

In December 2016, the United States Environmental Protection Agency (U.S. EPA) issued a summary report which supported EPA's Integrated Risk and Assessment System (IRIS) upgrade of ethylene oxide from "probably carcinogenic to humans" to "carcinogenic to humans". The adult-based inhalation cancer risk estimate for ethylene oxide, called the "unit risk estimate", was changed from 0.0001 per microgram per cubic meter ($\mu g/m^3$) to 0.003 per $\mu g/m^3$, which equates to a 30-fold cancer potency increase. Per the 2016 report, "*When using the adult-based unit risk estimates to estimate extra cancer risks for a given exposure scenario, the standard age-dependent adjustment factors (ADAFs) should be applied, in accordance with the EPA's Supplemental Guidance (U.S. EPA, 2005b). Applying the ADAFs to obtain a full lifetime total cancer unit risk estimate yields 5.0 × 10^{-3} per $\mu g/m^3$.*" For the modeling demonstration submitted by Sterigenics, the 0.005 per $\mu g/m^3$ lifetime unit risk estimate is the appropriate metric to apply to the dispersion modeling results for residential areas. In commercial, industrial, or off-site adult worker areas, a 0.003 per $\mu g/m^3$ unit risk estimate consistent U.S. EPA's assumption of an 8.5-hour workday, 250 days a year, for 25 years, and an 0.087 exposure factor, is the appropriate method for estimating risk.

U.S. EPA publicly released the 2014 National Air Toxics Assessment (NATA) in August 2018 which identified, in part, areas of the country that may have an increased cancer risk based on 2014 emissions estimates for toxic compounds and via screening level air quality modeling. The NATA assessment estimated that the nationwide average "background" cancer risk from air toxics exposure is approximately 30 in a million. In addition, the NATA report identified census tracts around the country with cancer risk levels that were more than a 1 in 10,000 (100 in a

million) increase in cancer risk. The risk "level" is based on the likelihood that a person could develop cancer if they were to breathe the same air concentration level for 70 years (i.e. "lifetime" risk). The 100 in a million level is considered the upper limit of acceptable lifetime cancer risk for the most exposed person. Although NATA is primarily designed as a screening method to identify where cancer risk may be elevated, it does not pinpoint a specific individual's risk at the local scale. What it does do, is provide a tool for identifying areas that warrant further study on what pollutants and sources may be contributing to the elevated risk.

According to the 2014 NATA, the census track containing Sterigenics and six other adjacent census tracts had overall cancer risk estimates greater than 100 in a million, with ethylene oxide identified as the predominant toxic pollutant driving this estimate. Sterigenics was estimated to emit over 98% of the total ethylene oxide emissions in DuPage county.

The U.S. EPA, in consultation with the Illinois Environmental Protection Agency (Illinois EPA), conducted an ambient air monitoring program in the area around Sterigenics in late 2018 and early part of 2019. These agencies engaged with Sterigenics to further understand ambient impacts and the company's ethylene oxide emissions and operations. The ultimate purpose of this engagement was to require and effectively implement measures to reduce ethylene oxide impact in the surrounding area.

Current Status

When Willowbrook 1 was operating, the ethylene oxide used in the sterilization process was captured and controlled by two systems. A Deoxx scrubber was utilized during chamber operation and evacuations. For the post chamber period, chamber doors were opened, triggering a backvent to operate and capture residual ethylene oxide while sterilized product was removed from the chambers via forklift and placed into an aeration room. This product remained in the aeration room for a prescribed and product specific time-period to allow for "off-gassing" of residual ethylene oxide. The backvent and aeration room ethylene oxide was captured and controlled via a separate control system consisting of a combination wet scrubber system and a dry bed (Advanced Air Technologies control system). Any remaining uncaptured or "fugitive" emissions occurring through work aisles transfer, or in the shipping room area post-aeration, were exhausted through work aisle vents, processing shipping area vents, or shipping doors.

On February 15, 2019, the Illinois EPA issued a seal order on the ethylene oxide storage drums at the Sterigenics facilities in Willowbrook. At the time of the seal order, the company operated sterilization chambers within both Willowbrook 1and Willowbrook 2. The seal order on the ethylene oxide drums effectively "shutdown" the operation of the facilities. On September 6, 2019, a DuPage County court approved a "Consent Order" between the State and Sterigenics that will allow the plant to resume operations if verifiable measures are in place to ensure the company complies with new state legislation. The seal order was lifted on September 10, 2019. Sterilization operations are idled at the time of this memorandum.

Proposed Project

Sterigenics proposes in its construction permit application submitted to Illinois EPA on June 24, 2019, to initiate an improvement plan to reduce ethylene oxide emissions from the Willowbrook 1 facility by installing additional control technology, capturing 100% of emissions (which are in turn ducted to control systems), and to decrease the number of exhaust points to a single new stack. These proposed actions are expected to comply with the new statutory (state legislation) requirements and are anticipated to substantially reduce the amount of ethylene oxide emissions and significantly reduce ambient impacts. These proposed improvements only apply to Willowbrook 1. Willowbrook 2 is not addressed in this application.

Sterigenics has proposed control systems and design improvements that will maintain the Willowbrook 1 facility under permanent total enclosure (100% capture of ethylene oxide emissions), route all ethylene oxide emissions through control equipment, and exhaust the remaining emissions through a single stack (compared to multiple exhaust points pre-seal order) to the atmosphere.

Sterigenics has utilized computer air dispersion modeling to demonstrate that the proposed measures will be effective in reducing impacts on ambient air quality to below the levels that U.S. EPA considers actionable. The remainder of this memorandum summarizes the modeling submitted to Illinois EPA and reviews the appropriateness of the methodology utilized in the air quality analysis.

Illinois EPA Review

For modeling purposes, Sterigenics proposes the following stack design and emissions for Willowbrook 1:

- **Ethylene Oxide Emission Rate:** 84.8 pounds per year (0.0097 pounds per hour)
- **Stack Height:** 87.0 feet above grade (26.5 meters), or 50.0 feet above grade (15.2 meters)
- **Stack Diameter:** 2.8 feet (0.85 meters)
- **Stack Temperature:** 87.0 degrees Fahrenheit (303.7 degrees Kelvin)
- **Stack Exit Velocity:** 96.1 feet per second (29.3 meters per second)

Ramboll Environmental (Ramboll) performed the air quality analysis on behalf of Sterigenics. Sterigenics and Ramboll submitted the technical description, modeling summary, and electronic modeling input/output data for the ethylene oxide air quality impact analysis as part of the permit application on June 24, 2019. On July 10, 2019, U.S. EPA released an updated version of the AERMOD dispersion model. In August 2019, U.S. EPA's Office of Air Quality Planning and Standards (OAQPS) released a report, "*Risk Assessment Report for the Sterigenics Facility in Willowbrook, Illinois*". Because of these two recent actions, Illinois EPA requested Sterigenics and Ramboll to update their modeling to reflect predicted impacts using the new version of AERMOD and add any additional updates to the model inputs to maintain consistency with the

model settings used by OAQPS in their risk analysis. In addition, Sterigenics submitted an alternative modeling analysis to assess modeled impacts should their request to the village of Willowbrook for a proposed stack height at 87 feet be denied. The alternative scenario reflects impacts for a stack height (back at the original AAT stack location) at the current height of the local ordinance, which is 50 feet. The following summary reflects my evaluation regarding the acceptability of the air quality analysis for both scenarios:

- Ramboll performed the dispersion modeling analysis using U.S. EPA's AERMOD model (version 19191) to model impacts from the facility for the proposed project. AERMOD is a state and federally approved regulatory model appropriate for use in an air quality analysis of this nature. This AERMOD version used is the update released in July 2019.
- Ramboll addressed building-induced plume downwash for their proposed stack using U.S. EPA's Building Profile Input Program with PRIME algorithm (BPIPPRM, version 04274) to determine building parameters to model building wake effects. In the updated modeling, the two Sterigenics buildings as well as surrounding buildings were included in the inputs to the BPIPPRM program. The tallest and most influential building for inducing downwash is the Willowbrook 1 building. Modeling inputs utilized Illinois EPA and U.S EPA recommended regulatory options, which simulate phenomena such as atmospheric stability, plume rise, and downwash.
- Ramboll applied five years of locally representative meteorology to the modeling. OAQPS developed this meteorological dataset utilizing AERMET version 19091 and provided Illinois EPA and Sterigenics with 2014-2018 surface meteorological data from Argonne National Laboratory and upper air soundings from Davenport Regional Airport (WBAN No. 94982). AERMET referenced Midway Airport meteorology to provide substitute values for any missing hourly data parameters from the Argonne dataset. OAQPS and Illinois EPA consider this dataset as best representative of meteorological conditions within the modeling domain.
- Illinois EPA provided guidance on the density of the receptor grid both to satisfy statutory requirements and be sufficient to identify the location of the maximum impact area. The receptor network submitted consists of a cartesian grid with 50-meter spacing from the stack to 500-meters, and 100-meter spacing from 500-meters out to 1-kilometer away. The grid contains a total of 879 receptor points. In the 50-foot stack scenario, Illinois EPA requested additional receptors be placed near the area of the predicted maximum impact (since they were predicted to occur very near the stack) to effectively determine the magnitude of maximum concentration.
- U.S. EPA/OAQPS recommended Ramboll utilize the "urban" option in AERMOD since the facility is in the Chicago Metropolitan Area urban heat island influence and surrounded by densely populated areas. To remain consistent with OAQPS risk analysis and to avoid overstating the urban heat island effect, Illinois EPA requested Ramboll update the model to use an urban population input of 50,000 in the model.

- AERMAP (version 18081) was appropriately implemented in conjunction with U.S. Geological Survey National Elevation Dataset data to determine terrain heights for sources, buildings, and receptors.

Ramboll utilized the previously identified models and model settings along with proposed stack parameters and annual emission rate to predict the five-year average concentrations at each receptor point. This timeframe is considered appropriate to reasonably represent long-term (lifetime/70-year) exposures and impacts.

Table 1 presents the maximum predicted five-year average ethylene oxide concentration for the proposed control system improvements, with the hourly emission rate, and proposed stack heights (87' and 50') and exhaust parameter modifications. Illinois EPA has audited the modeling results for the two scenarios and verifies that the correct inputs and procedures were used in the modeling exercise. Illinois EPA also confirms that the area of maximum impact is sufficiently determined in the modeling demonstration.

Table 1
Maximum Predicted Average Ethylene Oxide Concentration

Averaging Period	Stack Height	Receptor Location of Domain Maximum		Maximum Predicted 5-year Average Concentration ($\mu g/m^3$)		
		UTM Easting (m)	UTM Northing (m)	Entire Domain	Off-Property	Entire Domain Highest Residential
5-years	87'	421967.1	4622473.0	0.00101	0.00101	0.00054
5-years	50'	421919.0	4622256.0	0.00719*	0.00649	0.00086

* Maximum predicted concentration for 50' scenario is on Sterigenics property

For the 87' stack height scenario, the maximum predicted five-year average ethylene oxide concentration in the domain is **0.001** micrograms per cubic meter ($\mu g/m^3$). This predicted maximum is off-property in a commercial/industrial area approximately 230 meters north-northeast of the proposed stack at Willowbrook 1. To determine an "in a million" risk factor to this maximum *non-residential impact*, Illinois EPA adhered to calculation procedures outlined in the OAQPS August 2019 risk report. These calculations yield a maximum lifetime risk of **0.3 in a million** for non-residential off-site workers. The maximum predicted *residential* concentration is approximately **0.00054** $\mu g/m^3$, located approximately 800 meters to the northeast of the proposed stack at Willowbrook 1. This impact represents a maximum residential lifetime risk of approximately **3 in a million**.

For the 50' stack height scenario, the maximum predicted five-year average ethylene oxide concentration in the entire modeling domain is **0.00719** $\mu g/m^3$. This predicted maximum is 22

meters east-northeast of the proposed stack and this impact occurs on the Sterigenics property. This maximum concentration represents a *non-residential* lifetime risk of **2 in a million** for off-site workers. The maximum predicted five-year average ethylene oxide concentration off-property is **0.00649 µg/m^3**. This predicted maximum occurs approximately 48 meters northeast of the proposed stack and in a commercial area. This represents a highest off-property *non-residential* lifetime risk of approximately **2 in a million** for off-site workers. The maximum predicted *residential* concentration is approximately **0.00086 µg/m^3**, located about 550 meters southwest of the proposed stack at Willowbrook 1. This impact represents a lifetime risk of **4 in a million.** Table 2 presents a summary of the predicted lifetime risk for both scenarios.

Table 2
Maximum Predicted Lifetime Risk in a Million

Stack Height	Maximum Predicted Lifetime Risk (in a million)		
	Entire Domain Non-Residential	Off-Property Non-Residential	Entire Domain Highest Residential
87'	0.3	0.3	2.8
50'	1.9	1.7	4.4

Recommendation

The area of maximum predicted impact in the 87' proposed stack height and the 50' alternative stack height scenarios are sufficiently determined. All other receptor locations within one-square kilometer of the facility for both scenarios, predict risk considerably below U.S. EPA's upper limit of acceptable lifetime cancer risk for the most exposed person of 100 in a million.
The topography beyond one kilometer of the facility is generally flat to gently rolling. Thus, standard dispersion principles intrinsic in the model gaussian - plume equation will calculate decreasing concentrations and risk beyond the one-kilometer extent of the modeling domain.
Based upon my review and audit of the applicant's dispersion modeling, including associated emission rate, revised stack configuration, modeling procedures, and modeled impacts, I consider the ethylene oxide air quality analysis submitted by Ramboll on behalf of Sterigenics to be acceptable.