



ILLINOIS ENVIRONMENTAL PROTECTION AGENCY

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JB PRITZKER, GOVERNOR

JOHN J. KIM, DIRECTOR

MEMORANDUM

DATE: August 2, 2019

TO: File, Construction Permit Application No. 19020013

FROM: Steven King, ^{SK} Modeling Unit, Air Quality Planning Section Bureau of Air

SUBJECT: Medline Industries, Inc. (ID No. 097190AFG)

Background

Medline Industries Inc. (Medline) owns and operates a commercial ethylene oxide sterilization source in northeastern Lake County. The facility operates at 1160 South Northpoint Boulevard, within the Waukegan city limits. At this facility, Medline primarily sterilizes medical devices, surgical kits, pharmaceutical, and laboratory equipment 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 ($\mu\text{g}/\text{m}^3$) to 0.003 per $\mu\text{g}/\text{m}^3$, 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 $\mu\text{g}/\text{m}^3$."* For the modeling demonstration submitted by Medline, the 0.005 per $\mu\text{g}/\text{m}^3$ lifetime unit risk estimate is the appropriate metric to apply to the dispersion modeling results.

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 30 in a million. In addition, the NATA report identified census tracts around the country with potential risk levels that may have 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 specific risk on the local scale. What it

August 2, 2019 MEMORANDUM



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 NATA, the census tract containing Medline and three other adjacent census tracts had overall cancer risk estimates greater than 100 in a million, with ethylene oxide identified as the predominant toxic pollutant of concern driving this estimate. Medline was estimated to emit over 80% of the total ethylene oxide emissions in the county.

In early 2019, Illinois Environmental Protection Agency (Illinois EPA) engaged with Medline 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

Currently, ethylene oxide used during the chamber process at Medline is controlled via a wet scrubber system which uses acid in a water solution to convert ethylene oxide to ethylene glycol. For the post chamber period, sterilized product is placed in an Aeration room to allow "off-gassing" of residual ethylene oxide escaping the product. Ethylene oxide emissions from the post-chamber period are controlled through use of a catalytic oxidizer and two packed tower wet scrubbers. The remaining uncaptured ethylene oxide emissions are exhausted to the atmosphere via five stacks and other "fugitive" emissions may escape via openings such as vents or shipping doors.

Proposed Project

Medline, in consultation with Illinois EPA, proposed to initiate an improvement plan to reduce ethylene oxide emissions facility-wide by installing additional control technology, capturing 100% of emissions (which are in turn ducted to control systems), and to decrease the exhaust points to the atmosphere 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.

Medline 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 consider significant. The remainder of this memorandum summarizes the modeling submitted by Medline to Illinois EPA and reviews the appropriateness of the methodologies utilized in the air quality analysis.

Illinois EPA Review

For modeling purposes, Medline proposes the following stack design and emissions for their facility:

August 2, 2019 MEMORANDUM



- **Ethylene Oxide Emission Rate:** 150.9 pounds per year (0.00172 pounds per hour)
- **Stack Height:** 85.3 feet above grade (26 meters)
- **Stack Diameter:** 4.6 feet (1.41 meters)
- **Stack Temperature:** 89.3 degrees Fahrenheit (305 degrees Kelvin)
- **Exit Velocity:** 60.0 feet per second (18.3 meters per second)

On behalf of Medline, the air quality analysis was performed by TRC Companies, Inc. (TRC) out of Connecticut. Medline and TRC submitted the technical description, modeling summary, and electronic input/output data for the ethylene oxide air quality impact analysis as part of the permit application on April 30, 2019. The following summary reflects my evaluation regarding the acceptability of the air quality analysis:

- TRC performed the dispersion modeling analysis using U.S. EPA's AERMOD model (version 18081) 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.
- TRC 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. The coordinates and building dimensions for the two buildings owned by Medline; the chamber process building, and the larger office building to the east are the only two structures considered nearby enough to impact model downwash calculations.
- Modeling inputs utilized Illinois EPA and U.S. EPA recommended regulatory options, which simulate phenomena such as atmospheric stability, plume rise, and downwash.
- TRC applied five years of locally representative meteorology to the modeling. Illinois EPA provided Medline 2014-2018 surface meteorological data from Waukegan Regional Airport (WBAN No. 14880) and upper air from Davenport Regional Airport (WBAN No. 94982). The 5-year hourly meteorological dataset was developed in accordance with the United States Environmental Protection Agency Region V and States Meteorological Data Processing Protocol (May 2018). Illinois EPA considers this dataset representative of meteorological conditions within the modeling domain.
- Illinois EPA provided guidance on the density of the receptor grid to sufficiently determine the location of the maximum impact area. The receptor network is comprised of a grid with 50-meter fine spacing from the stack to 500-meters and 100-meter spacing from 500-meters to 1 kilometer from the stack. This grid contains a total of 750 receptor points.
- Illinois EPA accepts the running of AERMOD in rural dispersion mode based on an analysis of land use within a 3-kilometer radius of the facility. This analysis indicated that land use is greater than 50% rural.

August 2, 2019 MEMORANDUM



ILLINOIS ENVIRONMENTAL
PROTECTION AGENCY

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

TRC utilized the proposed stack parameters, annual emissions, models, and model settings to predict the five-year average concentrations at each receptor point. Illinois EPA considers this timeframe appropriate to reasonably represent long-term (lifetime/70-year) exposures and impacts.

The table below presents the maximum predicted five-year average ethylene oxide concentration for the proposed control system improvements, with the specified hourly emission rate, and proposed stack height and exhaust parameter modifications. Illinois EPA has audited the results 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 adequately resolved in the modeling demonstration.

Maximum Predicted 5-Year Average Ethylene Oxide Concentration

Averaging Period	Data Period	Receptor Location (meters)		Maximum Predicted 5-year Average Concentration ($\mu\text{g}/\text{m}^3$)
		Easting (m)	Northing (m)	
5-Years	2014-2018	426735	4687795	0.00539

The predicted maximum 5-year average ethylene oxide concentration is $0.00539 \mu\text{g}/\text{m}^3$. This predicted maximum is located on the Medline property at the north side of the parking lot of the main office building. Upon applying the 0.005 per $\mu\text{g}/\text{m}^3$ unit risk factor to the maximum predicted receptor location, this yields a lifetime risk of 1 in 27 million. The maximum predicted off-property concentration is $0.00458 \mu\text{g}/\text{m}^3$, located east of the Medline facility on Route 41. This impact represents a 1 in 23 million risk. The maximum predicted residential concentration is approximately $0.00147 \mu\text{g}/\text{m}^3$, located about one-fifth of a mile to the southwest of the proposed stack at Medline. This impact represents a 1 in 7 million risk. Both on-property and off-property maximum predicted impacts and all other locations within a 1-kilometer radius of the facility 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.

Based upon my review and audit of the applicant's dispersion modeling, including associated emission levels, revised stack configuration, modeling procedures, and modeled impacts, I consider the ethylene oxide air quality analysis acceptable.