IN THE CIRCUIT COURT OF THE 18TH JUDICIAL CIRCUIT
DU PAGE COUNTY, ILLINOIS

PEOPLE OF THE STATE OF ILLINOIS, *ex rel.* KWAME RAOUL, *et al.*,	)	
Plaintiffs,	)	
Vs.	)	No. 2018 CH 001329
STERIGENICS U.S., LLC, a Delaware limited liability company,	)	
Defendant.	)	Honorable Judge Paul M. Fullerton

NOTICE OF FILING

TO: SEE ATTACHED SERVICE LIST

PLEASE TAKE NOTICE that on **August 23, 2019,** I caused to be filed the with the 18th Judicial Circuit Court of DuPage County, Illinois, 505 North County Farm Road, Wheaton, Illinois 60187, via its online filing portal, the foregoing **INTERVENORS' COMMENTS TO CONSENT ORDER**, a copy of which is attached hereto and hereby served upon you.

Respectfully submitted,

By: /s/ Andrew Y. Acker

PROOF OF SERVICE

I, Andrew Y Acker, an attorney, hereby certify that on **August 23, 2019**, I served the foregoing **INTERVENORS' COMMENTS TO CONSENT ORDER** and **NOTICE OF FILING** thereto upon the person(s) listed on the attached Service List via electronic mail and First Class US Mail by depositing same with proper postage before 4:30 p.m. at Rosemont, Illinois. Under penalties of law pursuant to Section 1-109 of the Code of Civil Procedure, the undersigned certifies that the statements set forth in this instrument are true and correct.

Respectfully submitted,

By: /s/ Andrew Y. Acker

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INTERVENORS' COMMENTS TO CONSENT ORDER

Intervenors, VILLAGE OF WILLOWBROOK, CITY OF DARIEN, VILLAGE OF BURR RIDGE, AND VILLAGE OF HINSDALE[1] (collectively "Villages" and/or "Intervenors") submit their COMMENTS TO CONSENT ORDER, supported by the attached affidavit and exhibits:

INTRODUCTION

Since the Court's July 24, 2019 order, the Villages have received approximately forty-five (45) written comments from their residents regarding the Consent Order, many of which are incorporated herein. Almost universally, the residents' comments assert that they object to the Consent Order due to their fear for their health because of continued and cumulative exposure to ethylene oxide ("EtO")[2] if Sterigenics were permitted to resume its operations of one ("Willowbrook I") of its two Willowbrook sterilization facilities.

[1] According to the 2010 U.S. Census, the Village of Willowbrook had 8,540 residents; the City of Darien had 22,086 residents; the Village of Burr Ridge had 10,559 residents; and the Village of Hinsdale had 16,816 residents; total residents for all four municipalities from 2010 U.S. Census were 58,001 residents.

[2] Attached hereto as **Exhibit 1** is the Affidavit of Attorney Acker. Attached to the Affidavit of Attorney Acker as **Affidavit Exhibit A** is a document entitled "Letter Health Consultation" – "Evaluation of Potential Health Impacts from Ethylene Oxide Emissions" – Sterigenics International, Inc. – Willowbrook, Illinois, United States Department of Health and Human Services, Agency for Toxic Substances and Disease Registry ("ATSDR"), Division of Community Health Investigations, Atlanta, Georgia 30333 (August 21, 2018) ("ATSDR – Letter Health

The Villages likewise object to the entry of the Consent Order and echo the concern of their residents that significant public safety issues are presented by this matter such that this Court should exercise its discretion and deny the joint motion for entry of the Consent Order. The Villages believe that prior to the IEPA Director's issuance of a "seal order" on February 15, 2019, Sterigenics's operations using and emitting EtO from Willowbrook I caused a public nuisance that endangered the health, safety and welfare of the Villages' residents and workers. Prior to February 15, 2019, Sterigenics regularly and continuously emitted EtO from its facilities, resulting in significantly elevated ambient air concentrations of EtO to occur in and around the Villages.[3] Because neither Sterigenics nor the IEPA has provided the Villages with an explanation supported by a root cause analysis as to how the operation of Sterigenics' facilities in the Village of Willowbrook prior to February 15, 2019, caused such elevated ambient air concentrations of EtO to occur, there is a legitimate concern that fundamental facts may not have been evaluated fully in order to determine with better certainty the nature and extent of Sterigenics' EtO emissions. It should not be forgotten that when IEPA took the extraordinary step on February 15, 2019, to fully stop the emission of EtO from Willowbrook I (and Sterigenics' other nearby facility, Willowbrook II), it did so because the levels of EtO "present a public health hazard to residents and off-site workers in the Willowbrook community." (February 15, 2019, seal order.) These hazards still exist and the harm caused by years of exposure of EtO cannot be undone. Approval of this Consent Order will obfuscate the basis of

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Consultation"); *see*, **Affidavit Exhibit A**, pp. 2-7, discussing ambient air testing of EtO done by USEPA in May 2018. Also attached to the Affidavit of Acker as **Affidavit Exhibit B** is a document entitled "Cancer Incidence Assessment near Sterigenics in Willowbrook, IL, 1995-2015" – A publication of the Illinois Department of Public Health ("IDPH"), Division of Epidemiological Studies, Springfield, Illinois 62761 (March 29, 2019) ("IDPH Assessment"); *see*, **Affidavit Exhibit B**, pp. 15-23, discussing elevated risk to Villages' residents and workers of certain cancers.

[3] *Id*., **Affidavit Exhibit C** is a document entitled "Risk Assessment Report for the Sterigenics Facility in Willowbrook, Illinois" – United States EPA's Office of Air Quality Planning and Standards, Office of Air and Radiation ("USEPA") (August 14, 2019) ("USEPA Report"); *see*, **Affidavit Exhibit C**, p. 8; Appendix 1, p. 1-8, discussing ambient air testing of EtO done by USEPA for time period between November 2018 and March 2019.

the seal order – to preclude *further* harm to human health and the environment what already had occurred. Without a thorough understanding of the past issues, it is impossible to confirm the proposed corrections and their ability to meet the new standards of Section 5/9.16.

If the Consent Order is entered as presented, it will allow Sterigenics to undertake modifications to Willowbrook I using untested and experimental technology for the control of the emission of EtO in a densely populated area. The Villages have reason to believe that there is a dangerous probability that a threatened or potential injury to our residents and workers could occur should the untested and experimental control technologies fail resulting in renewed and continued exposure to this carcinogen.

The Consent Order (1) does not provide the Village with adequate protections or safeguards from continued and future exposure to EtO; and (2) does not afford the Villages with adequate information or notice regarding whether Sterigenics presently and/or in the future complies with EtO requirements under Illinois law and regulations. The Consent Order should not be approved.

To the extent this Court considers entry of the Consent Order, the Villages submit the following comments to the Consent Order.

COMMENTS TO CONSENT ORDER:

I. Admission of Violations, Lack of Fines, Ambient Air Monitoring Plan.

In order to restore public confidence in this matter, Sterigenics should acknowledge that it committed violations of State law and should not be permitted to deny the same as provided in Paragraph I.C. Likewise, a court-approved order which imposes no fine or penalty against Sterigenics for past conduct as provided in Paragraph III.B sends the wrong message to the public that Sterigenics is not being held accountable for its past conduct. To the extent that

Sterigenics is required to undertake a "Beneficial Project(s)" in the amount of $300,000 pursuant to Paragraph III.A., it is presently unclear how such project will benefit the environment of the Villages.

The provision for ambient air testing provided in Paragraph III.D.3.b. is the one item of the Consent Order that has the potential to provide the Villages with the benefit of objective, quantifiable and scientific information as to the quality of the ambient air its residents and workers are breathing. In addition to the "Air Monitoring Plan" as provided in Paragraph III.D.3.b., the Villages suggest that Sterigenics be required to pay for ambient air testing to occur at sites in each of the Villages for a continuous and ongoing period of time, at least for the five-year period of the Consent Order, and to be performed by a vendor chosen by the Villages, with periodic reporting to the Court.

The "Air Monitoring Plan[4]" as provided in Paragraph III.D.3.b. should be prepared by Sterigenics and submitted to IEPA for approval prior to the entry of the Consent Order so that the specifics of the "Air Monitoring Plan" are known and made a part of the Consent Order. For example, although Paragraph III.5. of the Consent Order provides that Sterigenics is to immediately cease operations in the event the "Stack Testing" (emissions testing of control system at Willowbrook I) demonstrates that the Required Control Efficiency is not being met, there is nothing in the Consent Order defining the consequences of elevated concentrations detected during ambient air testing conducted pursuant the required "Air Monitoring Plan." The Consent Order also does not provide a level of EtO detected during ambient air testing that will be considered safe or acceptable and more importantly, levels that are considered unacceptable or unsafe. It is essential that the Consent Order give meaning to the ambient air testing by setting

[4] Attached to the Affidavit of Attorney Acker as **Affidavit Exhibit D** is a copy of the Villages' comments to the IEPA draft construction permit for Sterigenics dated August 15, 2019, *see*, Sec. 1,ii.c., p. 2, discussing "Ambient Air Monitoring Plan" requirements. The Villages incorporate by reference these comments herein.

a clear standard as to the acceptable or safe level of EtO detected during the ambient air testing, and the operational consequences of detecting levels that exceed that defined standard.

The Villages' request language requiring (i) that ambient air testing take place in appropriate locations within each of the Villages boundaries, and (ii) that the Villages be provided with the funding to retain a consultant of their choosing to independently perform air testing and confirm that Sterigenics is not improperly emitting EtO and the additional capture and control measures provided in Paragraph III.D.2. are properly operating. As discussed above, although Paragraph III.5. of the Consent Order provides that Sterigenics is to immediately cease operations in the event the Stack Testing demonstrates that the Required Control Efficiency is not being met, there are no similar provisions in the Consent Order as to what happens in the event the permanent total enclosure ("PTE") providing negative pressure (so as to prevent fugitive emissions) to Willowbrook I as provided in Paragraph III.D.2. fails or does not operate properly[5].

II. <u>Release of Seal Order, Stack Test, Emergency Temporary Operations.</u>

Although counsel for Plaintiffs and Defendant have orally stated to this Court that Sterigenics is required to comply with the provisions of the newly enacted "Matt Haller Act" (415 ILCS 5/9.16) in addition to the Consent Order, the issues raised in the *amicus* brief filed by State Senator Curran and State Representatives Durkin and Mazzochi as to the applicability of Section 5/9.16(g) to the seal order in this case should be specifically addressed in the Consent Order. Because of the intense public interest in this case, a term should be included that mirrors the language from Section 5/9.16(g) requiring Sterigenics to provide certification[6] by suppliers

[5] *Id*., **Affidavit Exhibit D**, *see*, Sec. 6.ii.b.,c., pp. 5-6, discussing Section 5/9.16 requirements for Sterigenics's permanent total enclosure ("PTE"), and need for clarification in event PTE fails or malfunctions. *See*, Sec. 7., p. 6, discussing events where the pollution control equipment at Willowbrook I is not operating, when elevated ambient air impacts are observed, or when the facility is not capturing 100% of EtO emissions. The Villages incorporate by reference these comments herein.

[6] *Id*., **Affidavit Exhibit D**, *see*, Sec. 2, pp. 2-3, discussing requirement for supplier certifications. The Villages incorporate by reference these comments herein.

of products to be sterilized/fumigated that EtO is the only available method to completely sterilize/fumigate such products, and that the IEPA certify[7] that Sterigenics facility uses technology that produces the greatest reduction of EtO emissions. The IEPA's certification arising from Section 5/9.16(g) can only be obtained after Sterigenics has completed all of the construction to its facility as required by the Consent Order and after IEPA has tested the operation of the facility.

Because Section 5/9.16(g) expressly requires Sterigenics to provide certification from its suppliers and for the IEPA to provide certification as to the facility's use of technology that produces the greatest reduction of EtO emissions before the seal order is lifted, the terms of Paragraph III.J.1. need to be modified to expressly reflect the provisions of Section 5/9.16(g). Because the seal order applies to both of Sterigenics' two facilities ("Willowbrook I" and "Willowbrook II"), and because Sterigenics has not complied with Section 5/9.16(g) as to Willowbrook II, the provisions contained in Paragraph III.J.1. releasing the seal order in its entirety as to both of Sterigenics two facilities, including Willowbrook II, is improper and contrary to the express provisions of Section 5/9.16(g). Paragraph III.D.9. of the Consent Order should be modified to include a date by which Sterigenics must file a construction permit application to the IEPA in order to resume operations of Willowbrook II. If the date is not met, Willowbrook II cannot resume operations.

The Consent Order also fails to take into account any past and cumulative exposure of the Villages' residents to EtO, and instead presupposes a community with zero prior exposure. Because the seal order was entered to protect the public safety, and because the Consent Order seeks to release the seal order, the Villages' submit that this Court should reckon with the fact

[7] *Id*., **Affidavit Exhibit D,** *see*, Sec. 1.i.,ii,iii, p. 2, discussing requirement for certification that pollution controls used has greatest reduction in EtO emissions. The Villages incorporate by reference these comments herein.

that cumulative exposure to EtO is harmful. (S*ee*, **Affidavit Exhibit B**, pp. 15-23) Further, the Consent Order fails to recognize that based upon Sterigenics self-reporting for 1987-1988 and 1995-2016 (omitting reporting of EtO emissions for ten-years, 1984-1986, 1989-1994 and 2017-2018) that it has emitted 465,634 pounds of EtO from its Willowbrook I and II facilities. The Villages submit that this Court should take into account these matters that have been wholly omitted.

Although Paragraph III.D.2.a. provides that Sterigenics has submitted to the IEPA an air dispersion modeling demonstrating that the planned modifications at Willowbrook I will be sufficient to ensure that the maximum long-term average modeled concentrations of EtO will be at or below a level satisfactory to IEPA, the air dispersion modeling[8] submitted by Sterigenics to IEPA is deficient for several reasons. The air dispersion modeling is deficient because it is based upon the premise of Sterigenics constructing a new stack at Willowbrook I to a height of 87 feet. Because the Village of Willowbrook's ordinances do not allow the construction of a stack at Willowbrook I to the height of 87 feet as a matter of right[9], it is speculative as to whether a stack will be constructed at Willowbrook I to a height of 87 feet.

Additionally, the air dispersion modeling did not include or account for EtO emissions from Willowbrook II,[10] which may become operational in the immediate future and emit EtO. As such, the provisions contained in Section III.D.3.a. for the submission of a "Stack Test Protocol" should be modified to reflect that no construction occur until Sterigenics first obtains necessary zoning approvals from Willowbrook, and then submits a new air dispersion model to IEPA based

[8] *Id*., **Affidavit Exhibit D**, *see*, Sec. 9.i.,ii., pp. 7-9, discussing Sterigenics's air dispersion modeling submitted to IEPA. The Villages incorporate by reference these comments herein.
[9] *Id*., **Affidavit Exhibit D**, *see*, Sec. 9.i.a., p. 7, discussing Sterigenics's air dispersion modeling submitted to IEPA based upon a stack height of 87'. The Villages incorporate by reference these comments herein.
[10] *Id*., **Affidavit Exhibit D**, *see*, Sec. 9.ii.a., p. 8, discussing Sterigenics's air dispersion modeling submitted to IEPA did not include or account for EtO emissions from Willowbrook II. The Villages incorporate by reference these comments herein.

upon the actual stack height permitted for Willowbrook I under Village of Willowbrook's ordinances and provide for the emissions from Willowbrook II.

Paragraph III.D.7, providing for emergency temporary operations, does not afford any notice or any protection to the public before allowing Sterigenics to resume operations at Willowbrook I. As drafted, the State in its sole discretion, may approve temporary, limited operations at Willowbrook I. The Consent Order should require that the State provide notice to the Villages if the State obtains information identifying a critical need for sterilization of medical devices necessary to protect public health prior to approving temporary, limited operations. The Consent Order should also require prior approval from this Court of any temporary limited operations at Willowbrook I or II and that Sterigenics be required to post a bond with the Court to secure any damages that may arise from reopening Willowbrook I or II in advance of meeting all requirements in the proposed Consent Order, in advance of completing the work proposed by Sterigenics in its construction application to the IEPA and in advance of meeting the requirements of the Matt Haller Act including IEPA certifying Sterigenics' compliance with Section 5/9.16(g).

III. <u>Best Management Practices, Notice.</u>

Paragraph III.D.6, providing for best management practices ("BMPs"), fails to address Sterigenics's outdoor storage of EtO drums prior to use and also fails to address Sterigenics's storage and disposal of EtO drums after use. Because Paragraph III.D.2.b. mandates the installation of additional capture and control measures at Willowbrook I, including total enclosure providing 100% of all areas containing EtO, the Consent Order should require

Sterigenics's storage of EtO[11] be in an area that is subject to capture and control measures as well as BMPs for proper storage and disposal of used EtO drums.

In order to gain and maintain public confidence, the Villages must be given accurate information regarding IEPA and Sterigenics's performance of the terms of the Consent Order and Section 5/9.16, with full transparency and in real time. As such, the Consent Order must include a clear process for the Villages-or at least the Village of Willowbrook- to receive notice and real time access to documents, plans and reports submitted pursuant to the Order. For example, under Paragraph III.D.1, notice should be given by IEPA that Sterigenics has satisfied the requirements of and obtained written approval from specified in Paragraph III.D.4.(a); notice should be given of Sterigenics's submission of its construction completion report to the IEPA provided in Paragraph III.D.4(a); notice should be given if the negative pressure system fails or does not operate properly; notice should be given if Sterigenics's ambient air testing shows elevated levels of EtO; notice should be given if IEPA is inspecting Sterigenics's operations; notice should be given in the event Sterigenics requests the Consent Order to terminate under Paragraph III.K.1 as well as notice given by the IEPA as to its decision to Sterigenics's request to terminate the Consent Order under Paragraph III.K.1. The Consent Order should also require that the State post publicly all documents, plans and reports submitted pursuant to the Order.

Summary and Conclusion.

This Court should exercise its discretion and deny Plaintiffs' and Defendant's joint motion for entry of Consent Order, because it: (1) does not provide the Villages or their residents and workers with adequate protections or safeguards from continued and future exposure to EtO from Sterigenics' operations; and (2) does not afford the Villages with adequate information or

[11] *Id*., **Affidavit Exhibit D**, *see*, Sec. 5., p. 4, discussing Sterigenics's storage of EtO drums. The Villages incorporate by reference these comments herein.

notice regarding whether Sterigenics presently and/or in the future complies with EtO requirements under Illinois law and regulations.

In the alternative, the Court should ask the parties to consider the comments received and return with a revised proposed Consent Order addressing the Villages' concerns, summarized as follows:

- Require term in Consent Order for Sterigenics to pay for the Villages' ambient air testing for period of five years using independent vendors chosen by Villages;
- Require term in Consent Order setting ambient air standard;
- Require term in Consent Order that Sterigenics immediately cease and desist operations in event ambient air standard exceeded;
- Require term in Consent Order expressly requiring certifications be provided as stated in Section 5/9.16(g) and be provided before Sterigenics reopen;
- Require term in Consent Order requiring air dispersion modeling to be done using both Sterigenics' facilities and using stack height allowed by Village of Willowbrook ordinance;
- Require term in Consent Order requiring Court approval, posting of bond, and notice to Villages before "emergency temporary operations" may occur;
- Require term in Consent Order requiring outdoor storage of EtO be included in area subject to capture and control devices; and
- Require term in Consent Order requiring notice be given to the Villages as to documents, plans and reports given to IEPA.

Respectfully submitted,

By: /s/ Andrew Y. Acker

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Plaintiffs,	)	
Vs.	)	No. 2018 CH 001329
STERIGENICS U.S., LLC, a Delaware limited liability company,	)	
Defendant.	)	Honorable Judge Paul M. Fullerton

AFFIDAVIT OF ATTORNEY ANDREW Y. ACKER

After having been first duly sworn upon oath, your affiant does hereby swear and depose as follows:

1. I am an attorney duly licensed and in good standing to practice law in the State of Illinois since 1993. I have personal knowledge of the facts alleged therein and could competently testify thereto if called upon to do so.
2. At all times relevant, I am an associate attorney with the law firm of Storino, Ramello and Durkin located in Rosemont, Illinois, where my practice is primarily devoted to municipal civil litigation.
3. At all times relevant, Attorney Thomas Bastian, a member of Storino, Ramello and Durkin, is the Village Attorney for the Village of Willowbrook ("Willowbrook").
4. At all times relevant, Attorney Michael K. Durkin, a member of Storino, Ramello and Durkin, is the Village Attorney for the Village of Burr Ridge ("Burr Ridge").
5. In or about September 2018, I was assigned to assist and represent Willowbrook in relation to certain legal issues involving Sterigenics U.S., LLC ("Sterigenics"), a sterilization and fumigation business operating in Willowbrook at two locations: 7775

EXHIBIT 1

South Quincy Street, Willowbrook, DuPage County, Illinois ("Willowbrook I"); and 830 Midway Street, Willowbrook, DuPage County, Illinois ("Willowbrook II").

6. In or about October 2018, I became aware that the Plaintiffs, People *ex rel*. Lisa Madigan (subsequently substituted by Kwame Raoul), Attorney General of the State of Illinois ("State"), and *ex rel.* Robert Berlin, State's Attorney for DuPage County, Illinois ("County") filed a Complaint against Sterigenics in this case seeking to enjoin its operation in Willowbrook for certain violations of State environmental law and for public nuisance arising from Sterigenics emissions of ethylene oxide ("EtO").
7. In or about November 2018, I prepared and filed on behalf of Willowbrook a Petition for Intervention Pursuant to 735 ILCS 5/2-408 with the Clerk of this Court in this case.
8. In or about May 2019, Burr Ridge, by and through its then-attorneys, filed its Petition for Intervention Pursuant to 735 ILCS 5/2-408 with the Clerk of this Court in this case.
9. In or about June 2019, Attorney Durkin became the Village Attorney for Burr Ridge.
10. In or about July 2019, I was assigned to represent Burr Ridge in this case, and therein after this Court granted Burr Ridge leave to substitute counsel wherein I subsequently filed an appearance on behalf of Burr Ridge.
11. In the course of my representation of Willowbrook and Burr Ridge in this matter, I have been made aware of and obtained copies of certain official documents prepared by and issued to the public on behalf of the federal government and on behalf of the State of Illinois relating to EtO emissions from Sterigenics' operations in Willowbrook.
12. Specifically, I am aware of the following official documents and attach hereto true and correct copies of such official documents as exhibits to this Affidavit:

A. "Letter Health Consultation" – "Evaluation of Potential Health Impacts from Ethylene Oxide Emissions" – Sterigenics International, Inc. – Willowbrook, Illinois, United States Department of Health and Human Services, Agency for Toxic Substances and Disease Registry ("ATSDR"), Division of Community Health Investigations, Atlanta, Georgia 30333 (August 21, 2018) ("ATSDR – Letter Health Consultation"); a true and correct copy is attached hereto as **Affidavit Exhibit A**;

B. "Cancer Incidence Assessment near Sterigenics in Willowbrook, IL, 1995-2015" – A publication of the Illinois Department of Public Health ("IDPH"), Division of Epidemiological Studies, Springfield, Illinois 62761 (March 29, 2019) ("IDPH Assessment"); a true and correct copy is attached hereto as **Affidavit Exhibit B**;

C. "Risk Assessment Report for the Sterigenics Facility in Willowbrook, Illinois" – United States EPA's Office of Air Quality Planning and Standards, Office of Air and Radiation ("USEPA") (August 14, 2019) ("USEPA Report"); a true and correct copy is attached hereto as **Affidavit Exhibit C**.

13. At all times relevant, Willowbrook has also retained the legal services of Attorney Renee Cipriano of the law firm Schiff Hardin located in Chicago, Illinois, to assist the Village in certain environmental law issues related to Sterigenics' operations in Willowbrook and emissions of EtO.

14. At all times relevant, Willowbrook has also retained the environmental engineering services of GHD Services, Inc. ("GHD") located in Rosemont, Illinois, to assist the Village in certain environmental engineering issues related to Sterigenics' operations in Willowbrook and emissions of EtO.

15. In or about June 2019, Sterigenics submitted its application for construction permit to the IEPA for Sterigenics' Willowbrook I facility.
16. In or about June 2019, the IEPA issued a draft construction permit, Application No. 19060030, for Sterigenics' Willowbrook I facility.
17. Subsequent thereto, Attorney Cipriano and GHD reviewed and evaluated Sterigenics' application for construction permit submitted to the IEPA as well as the IEPA's draft construction permit for Sterigenics' Willowbrook I facility.
18. On or about August 15, 2019, Attorney Cipriano, with the assistance of GHD, prepared and submitted written comments to the IEPA regarding the draft construction permit for Sterigenics' Willowbrook I facility. A true and correct copy of Attorney Cipriano's August 15, 2019, comments to the IEPA draft construction permit for Sterigenics' Willowbrook I facility is attached hereto as **Affidavit Exhibit D**.

Under penalties as provided by law pursuant to Section 1-109 of the Code of Civil Procedure, the undersigned certifies that the statements set forth in this instrument are true and correct.

/s/ Andrew Y. Acker
Attorney for
Village of Willowbrook and
Village of Burr Ridge

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Letter Health Consultation

"Evaluation of Potential Health Impacts from Ethylene Oxide Emissions"

STERIGENICS INTERNATIONAL, INC.

WILLOWBROOK, ILLINOIS

AUGUST 21, 2018

U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES
Agency for Toxic Substances and Disease Registry
Division of Community Health Investigations
Atlanta, Georgia 30333

Health Consultation: A Note of Explanation

An ATSDR health consultation is a verbal or written response from ATSDR to a specific request for information about health risks related to a specific site, a chemical release, or the presence of hazardous material. In order to prevent or mitigate exposures, a consultation may lead to specific actions, such as restricting use of or replacing water supplies; intensifying environmental sampling; restricting site access; or removing the contaminated material.

In addition, consultations may recommend additional public health actions, such as conducting health surveillance activities to evaluate exposure or trends in adverse health outcomes; conducting biological indicators of exposure studies to assess exposure; and providing health education for health care providers and community members. This concludes the health consultation process for this site, unless additional information is obtained by ATSDR which, in the Agency's opinion, indicates a need to revise or append the conclusions previously issued.

You May Contact ATSDR TOLL FREE at
1-800-CDC-INFO
or
Visit our Home Page at: http://www.atsdr.cdc.gov

LETTER HEALTH CONSULTATION

"Evaluation of Potential Health Impacts from Ethylene Oxide Emissions"

STERIGENICS INTERNATIONAL, INC.

WILLOWBROOK, ILLINOIS

Prepared By:

U.S. Department of Health and Human Services
Agency for Toxic Substances and Disease Registry
Division of Community Health Investigations

DEPARTMENT OF HEALTH & HUMAN SERVICES
Agency for Toxic Substances and Disease Registry, Region 5

Public Health Service
77 W. Jackson Blvd., Room 413
Chicago, IL 60604

July 26, 2018 *

Ed Nam
Director, Air and Radiation Division
United States Environmental Protection Agency, Region 5
77 W. Jackson Blvd., MS A-18J
Chicago, IL 60604

Dear Mr. Nam:

Since February 2018, ATSDR has met with U.S. EPA Region 5 Air and Radiation Division (ARD) staff regarding a change in the cancer risk basis for ethylene oxide (EtO) in the EPA Integrated Risk Information System (IRIS) and how that change affects general population risks estimated from EtO-emitting facilities in the draft 2014 National Air Toxics Assessment (NATA) update[1]. In December 2016, IRIS changed EtO's adult-based inhalation unit risk from 0.0001 per microgram per cubic meter ($\mu g/m^3$) to 0.003 per $\mu g/m^3$, a 30-fold increase in cancer potency. It also changed EtO's cancer weight-of-evidence descriptor from "probably carcinogenic to humans" to "carcinogenic to humans". These changes could result in many census tracts having estimated cancer risks that are greater than 1 in 10,000 from EtO exposure identified through the draft NATA modeling of air emissions across the United States.

Specifically, ARD decided to evaluate the implications of this change at two sites, Sterigenics International, Inc. (referred to in the letter as "*Sterigenics*") in Willowbrook, IL and the Elé Corporation in McCook, IL. This letter addresses EtO emissions from the Sterigenics facility. In June 2018, after the monitoring results were received and reviewed, ARD requested that ATSDR review air measurements of EtO and modeling results of EtO emissions from Sterigenics and specifically answer the question: *If modeled and measured ethylene oxide concentrations represent long term conditions, would they pose a public health problem for people living and working in Willowbrook?*

The air modeling data that U.S. EPA provided to ATSDR estimated potential short-term and long-term concentrations of EtO in ambient air surrounding the Sterigenics Corporation. Follow-up air monitoring data confirm the presence of elevated EtO at concentrations within a similar range to those estimated by the air modeling of Sterigenics emissions. Based on these measured and modeled concentrations and the proximity to residences and other commercial structures, cancer risks higher than 1 in 10,000 people may exist for some community members and workers exposed to airborne EtO in this community. If these measured and estimated concentrations represent chronic exposures

* Minor edits to the reference list have been incorporated into the final posted ATSDR Letter Health Consultation.

[1] The 2014 NATA is expected to be publicly available in the fall of 2018.

in the surrounding community (with higher exposures likely for workers of the facility), EtO emissions from the Sterigenics Corporation poses a public health hazard.

BACKGROUND

Sterigenics provides sterilization processes using gamma, ethylene oxide, Ebeam, and X-ray sterilization and operates 46 facilities in 13 countries (Sterigenics, 2018). The facility stores ethylene oxide that is sprayed into sealed chambers to sterilize medical equipment, pharmaceuticals, and food/spice products contained on 40" x 48" pallets. The sterilization chambers are contained in two buildings. Building 1 has fifteen chambers that can hold 1 to 13 pallets, while Building 2 has four sterilization chambers that can hold 13 to 26 pallets (Illinois EPA, 2017). Building 1 chambers were constructed in 1984, while Building 2 chambers were built in 1999 and 2012. Pollution control technology includes acid water scrubbers and dry bed reactors that convert the ethylene oxide to ethylene glycol after the sterilization process (Illinois EPA, 2015). Although back vents on the units have historically been uncontrolled, Sterigenics is currently in the process of installing pollution controls to control passive releases (ATSDR, 2018).

Figure 1 illustrates the total reported emissions in pounds per year (lbs/yr) of EtO from Sterigenics.

Figure 1. TRI Total Air Emissions Reported (in pounds), by Sterigenics Corporation for Ethylene Oxide, 1995-2016

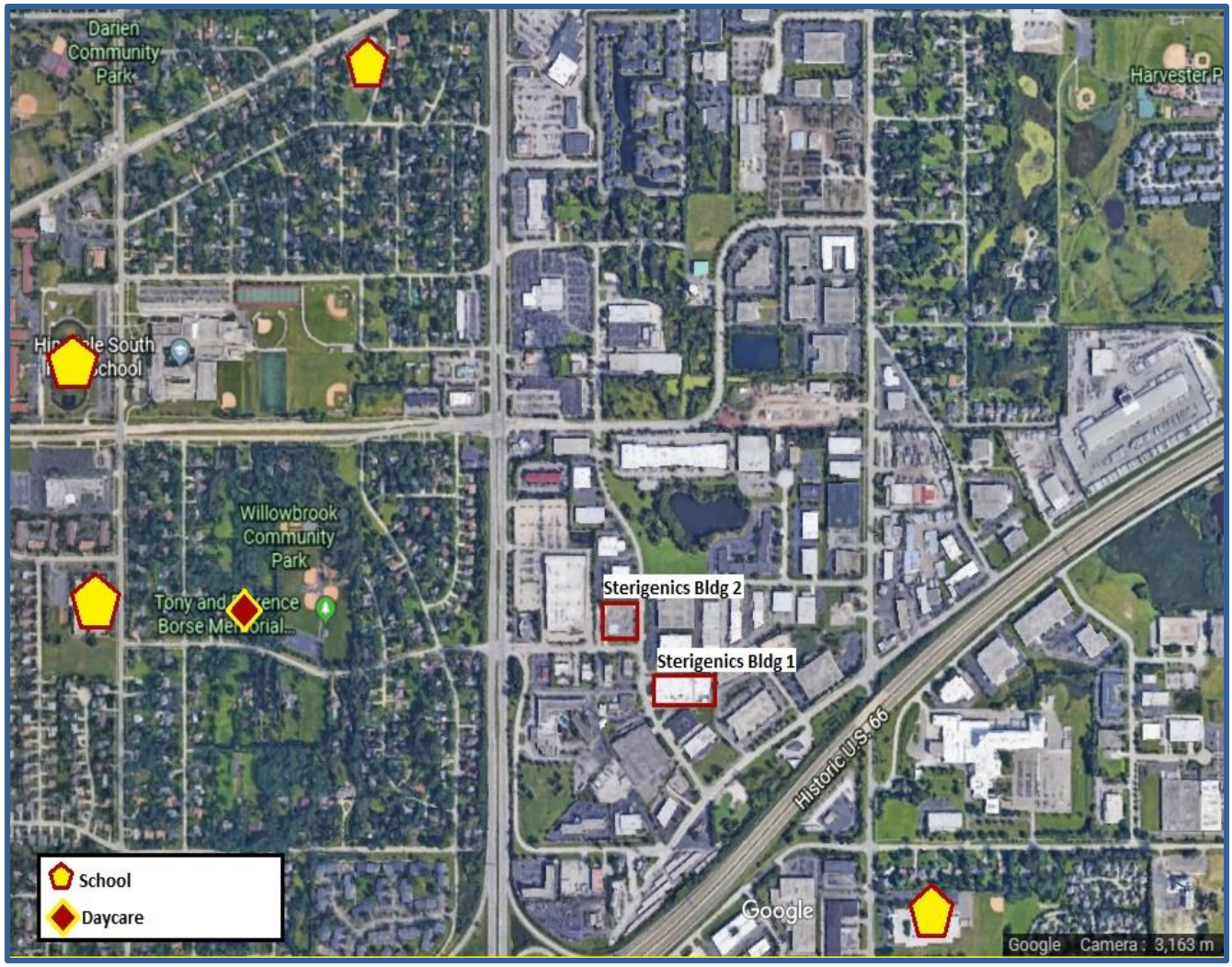
[a]*Source: Toxic Release Inventory (TRI): https://www.epa.gov/enviro/tri-overview*

[b]*Dates for facility constructed and upgrades were identified according to Illinois EPA (2017) DRAFT/PROPOSED Clean Air Act Permit Program (CAAPP) Permit*

The emissions data show a substantial reduction in total air releases after 1998. No data are available before 1995 on ambient air releases, but the available data suggests that substantially higher ambient releases prior to 1995 were likely. The Building 1 sterilization chambers were constructed in 1984, therefore EtO has been emitted over the past 34 years from the Willowbrook facility.

Willowbrook, Illinois is a small suburb of Chicago with approximately 8,500 residents (U.S. Census, 2016). The Willowbrook industrial complex where Sterigenics is located is in a densely populated metropolitan area, with 19,271 people living within 1 mile of the facility boundary. There are four schools and one daycare facility within 1 mile of the facility. According to 2016 Census estimates, Willowbrook residents are predominately white (73.3%), non-Hispanic (66.6%), educated (97.7% graduate high school, and 48.9% graduated with a bachelor's degree or higher), and middle class (median household income was over $67,000 per year). Approximately 18.5% of the population is identified as Asian, and 6.3% as black.

Figure 2. Aerial map of the community surrounding Sterigenics Corporation



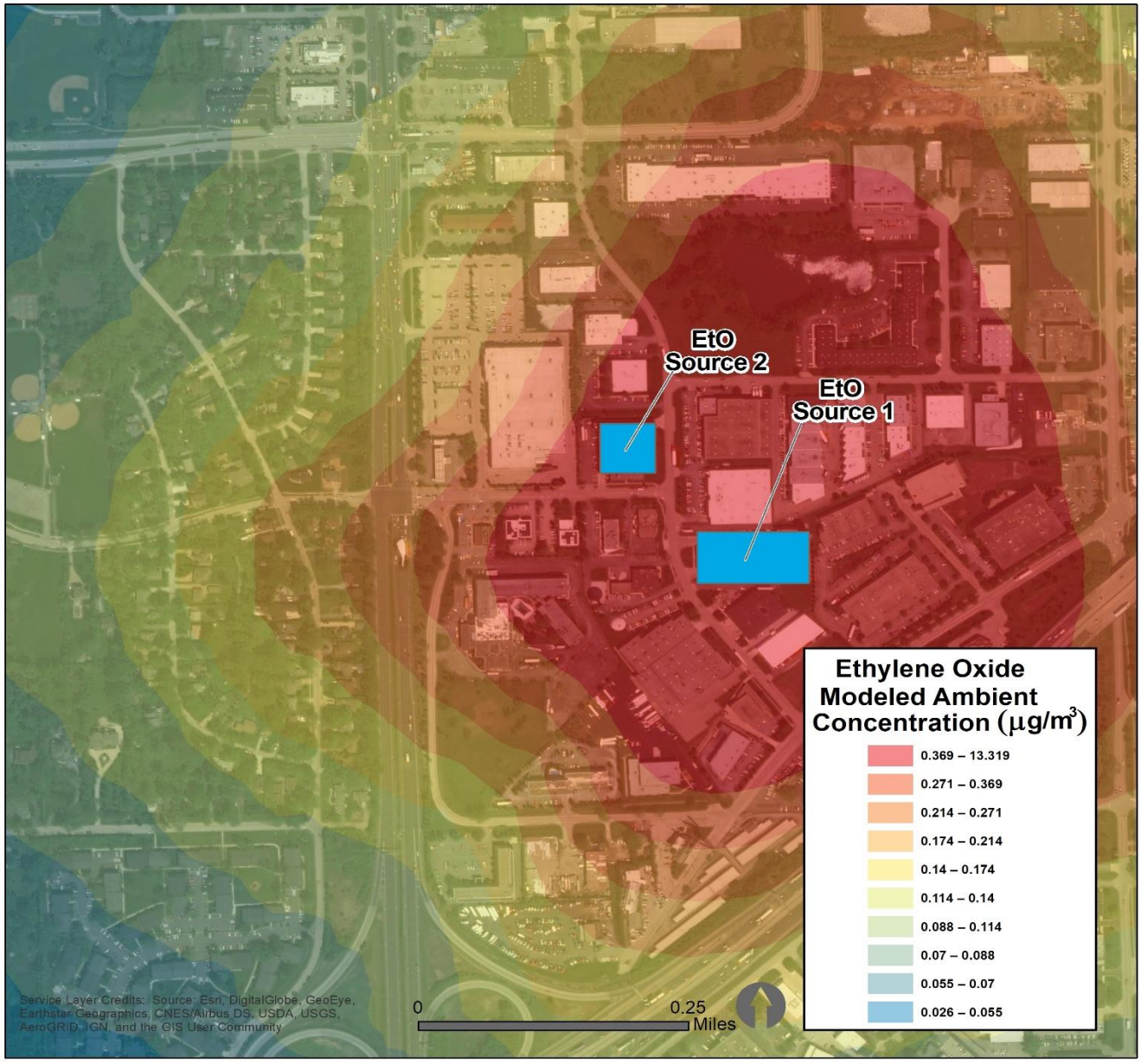
Source: Google Earth

ENVIRONMENTAL DATA

Air Modeling

U.S. EPA modeled short and long-term ambient EtO concentrations (AERMOD version 18081) to evaluate the potential impact of site emissions. These scenarios estimated a 5-year average to represent chronic exposures and maximum 1- and 8-hour averages to represent acute exposures at 882 community receptor points. An overlay of the modeling output is displayed in Figure 3, below. The statistical distributions of the modeled air concentrations are presented in Table 1.

Figure 3. AERMOD modeling output: 5-year average exposure estimates



Source: U.S. EPA Air and Radiation Division, Region 5

Note: Source 1 is Sterigenics Willowbrook Building 1, and Source 2 is Sterigenics Willowbrook Building 2

Table 1. Statistical distribution of EtO modeling*

Statistics	Modeled 1-hour (µg/m³)	Modeled 8-hour (µg/m³)	Modeled 5-year (µg/m³)
Minimum	2.17	1.02	0.03
25th Percentile	4.62	2.26	0.09
50th Percentile	9.72	4.07	0.17
75th Percentile	18.88	7.29	0.31
90th Percentile	33.90	12.62	0.57
95th Percentile	45.22	18.83	0.91
99th Percentile	134.73	61.39	2.97
Maximum	249.77	123.89	13.32
Mean	15.75	6.72	0.32
Geometric Mean	10.13	4.41	0.18

****N= 882 modeled receptors***

Air Measurements

U.S. EPA collected 39 validated samples May 16th and May 17th, 2018. These samples were collected using SUMMA® canisters, and analyzed using U.S. EPA Compendium Method TO-15, Compendium of Methods for the Determination of Toxic Organic Compounds in Ambient Air. A SUMMA® canister is an airtight, stainless-steel container with an inner surface that has been electro-polished and chemically deactivated. The laboratory is required to clean each canister and evacuate it to a high vacuum prior to shipping it to the sampling location. A canister can hold the vacuum for up to 30 days. The air being sampled is "drawn" into the canister by the high vacuum, thus eliminating the need for a pump. While opening the inlet orifice fills the canister in less than a minute, yielding an instantaneous "grab" sample, regulators can be added to the inlet orifice to draw the air into the canister over a designated period, ranging from 1 to 24-hours.

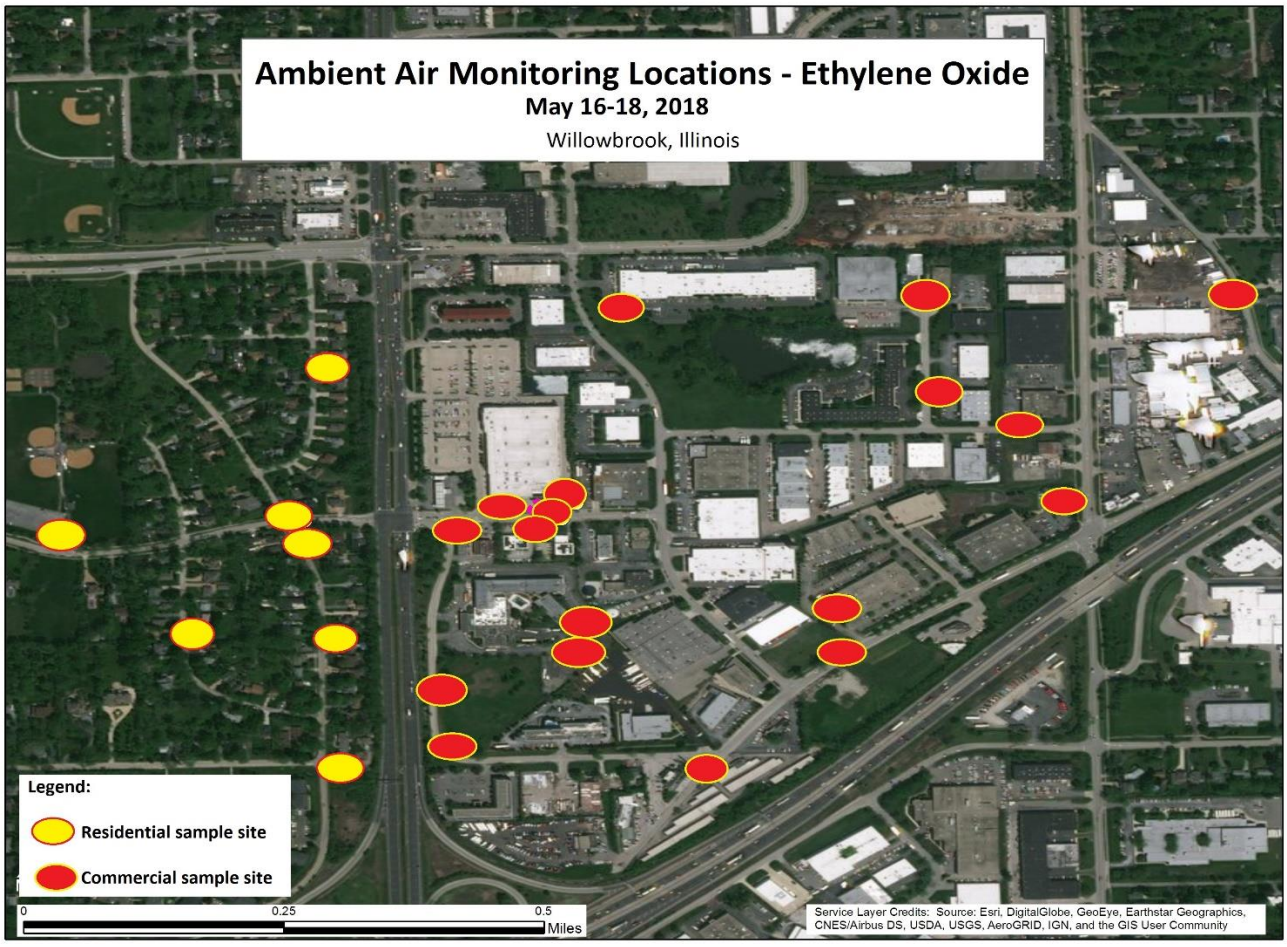
Of the 39 samples collected at 26 discrete locations (Figure 4), 18 were 12-hour samples, and 21 were grab samples (Table 2). Three of the 12-hour samples were collocated duplicates, and three of the grab samples were collocated duplicates. Grab samples generally had lower EtO concentrations than 12-hour averaged samples (U.S. EPA, 2018). However, all grab samples were collected between 10:20 am and 3:05 pm. ARD staff noted that higher EtO concentrations were measured overnight than during the day, and 12-hour samples were collected overnight in some locations. Since Sterigenics is a 24-hour operation, this may be due to calm meteorological conditions overnight with a higher potential for inversions. Given the elevated detections over a limited duration, additional long-term sampling is warranted to better characterize residential exposure to EtO.

Table 2. Statistical distribution of residential and commercial EtO air sampling*

Statistics	Grab samples (µg/m^3)	12-hour samples (µg/m^3)
Min	0.16	0.34
25th Percentile	0.24	0.69
50th Percentile	0.45	1.56
75th Percentile	1.34	4.39
90th Percentile	2.28	8.26
95th Percentile	4.27	8.44
99th Percentile	4.33	8.96
Max	4.34	9.09
Mean	1.07	3.02
Geo Mean	0.62	1.74

N=21 grab samples, 18 12-hour samples

Figure 4. Ambient air samples near the Sterigenics facility, Willowbrook, IL



Source: U.S. EPA, Region 5

Figure 4, shows the location of discrete samples collected in the community. Given limited measured data presented in Table 2, ATSDR used the maximum 12-hour residential sample concentration and the maximum 12-hour commercial sample concentration to represent chronic upper bound residential (2.1 µg/m^3) and occupational (9.1 µg/m^3) exposures in the community. These concentrations represent maximums identified during a very temporally and spatially limited sampling campaign and actual average long-term exposures may be higher or lower.

HEALTH IMPLICATIONS

Overview for identifying contaminants of concern and evaluating risk

To evaluate EtO exposures near Sterigenics, ATSDR considered its own health-based comparison values as well as those published by other agencies. ATSDR uses comparison values for screening purposes to determine whether a pollutant should be evaluated further. A CV was identified for both an intermediate exposure duration (for non-cancer evaluation) as well as for a long-term (chronic) exposure duration (for which we considered both cancer and non-cancer health effects). In this evaluation, the air sampling results were compared to the ATSDR Cancer Risk Evaluation Guide (CREG) and environmental media evaluation guide (EMEG) and California EPA Reference Exposure Level (REL) for EtO.

- ***ATSDR CREGs*** are estimates of the concentrations of a carcinogen at which there is an elevated risk for one additional case of cancer in one million people exposed over a lifetime. ATSDR's CREG for EtO is calculated from the current U.S. EPA's adult-based inhalation unit risk value (0.003 (µg/m^3)$^{-1}$) and is based on U.S. EPA evaluations and assumptions about hypothetical cancer risks at low levels of exposure. ATSDR's CREG for EtO is 0.00021 µg/m^3.
- ***ATSDR inhalation minimal risk levels (MRL)/EMEGs*** are estimates of the concentrations of pollutants calculated that anyone could be exposed to where health effects are unlikely, based on chronic, intermediate, and acute exposures (those occurring longer than 365 days, between 14-365 days, and 14 days of exposure or less, respectively). For EtO, ATSDR only has an intermediate EMEG of 160 µg/m^3 (ATSDR, 1990).
- ***California RELs*** are concentrations that are unlikely to result in adverse non-cancer health effects. The chronic California REL for EtO is 30 µg/m^3 (California EPA, 2008).

All 5-year modeled and 12-hour measured averages exceeded the ATSDR CREG. Only maximum modeled concentrations exceeded intermediate or chronic non-cancer screening values. The following sections evaluate chronic non-cancer and cancer risks further.

Ethylene oxide properties

Ethylene oxide is a highly flammable gas that is highly reactive with nucleophilic substances such as water, alcohols, halides, amines, and sulfhydryl compounds. It is used as an intermediate in the production of ethylene glycol and surfactants as well as a fumigant for sterilizing foods and heat-sensitive medical equipment.

EtO is highly reactive, readily absorbed, and easily distributed in the human body. The absolute odor threshold has been reported in several studies to be about 470 milligrams per cubic meter (mg/m^3)

(or 470,000 µg/m^3), with acute health effects possible in the range of the odor threshold (NRC, 2010). Chronic exposures can result somatic cell damage at much lower concentrations (California EPA, 2008). EtO is mutagenic and causes chromosome damage in many species, including humans. EtO exposure has widely been studied in scientific literature and its adverse health impacts are well understood. The carcinogenic effects of EtO have been documented in human and animal studies (U.S. EPA 2016).

Acute and intermediate exposure and health effects

Acute and intermediate effects have mostly been documented in hospital workers or in other occupational settings that include sterilizing chambers. Short-term exposure (minutes to weeks or months) above the odor threshold of 470 mg/m^3 (into the thousands of mg/m^3) include primarily neurological effects (headache, dizziness, nausea, lethargy, fatigue, muscle weakness, numbness, memory loss, incoordination, etc.), respiratory irritation (irritation of the nasal cavity, sinuses, coughing, shortness of breath, wheezing, and bronchial constriction and hyperreactivity), excessive thirst and dry mouth, and gastrointestinal effects (vomiting, diarrhea, stomach spasms, etc.). Some studies reported skin rashes with short-term exposures (NRC, 2010).

All studies with documented health effects summarized above had substantially higher EtO concentrations than what was observed in measured and modeled data in this assessment. ATSDR does not have an acute health-based comparison value but does have an intermediate-duration health-based comparison value of 160 µg/m^3. No measured data and only the maximum 1-hour modeled concentration of EtO exceeded this value and modeled and measured concentrations of EtO in this investigation were well below the odor threshold. Thus, it is unlikely that the non-cancer health effects noted above would occur in the general or off-site worker populations.

Chronic exposure and health effects

Cancer effects

The U.S. EPA IRIS released an "Evaluation of the Inhalation Carcinogenicity of Ethylene Oxide" in December 2016. This evaluation summarizes the evidence that EtO is "carcinogenic to humans" through a mutagenic mode of action (MOA) and derives an inhalation unit risk value for EtO (U.S. EPA, 2016). Many studies have identified the genotoxic potential and mutagenic mode of action of EtO exposure via inhalation. There is clear evidence from multiple studies that EtO causes chromosomal aberrations, sister chromatic exchanges, and micronuclei in peripheral blood lymphocytes and bone marrow cells. Chromosomal aberrations and micronucleus frequency have been linked to increased risk of cancer in a number of large human studies (Jinot et al., 2017). Mice and rats exposed to EtO demonstrate cancers of the lymphohematopoietic system (cells involved in the production of lymphocytes and cells of blood, bone marrow, spleen, lymph nodes, and thymus), brain, lung, connective tissue, uterus, and mammary gland.

In humans, an increased incidence and mortality of breast and lymphohematopoietic system cancers have been observed in workers in the EtO manufacturing and in sterilizing facilities (U.S. EPA, 2016). U.S. EPA identified six studies evaluating breast cancer in women, with the largest being a study from the National Institute of Occupational Safety and Health (NIOSH) of over 18,000 workers (45% male, 55% female) in 14 commercial sterilization plants. The NIOSH study reported statistically significant

exposure-response relationships for breast cancer incidence and mortality (Steenland et al., 2003 and Steenland et al., 2004). From assessing these studies, U.S. EPA (2016) determined that there is sufficient evidence of a causal relationship between EtO exposure and breast cancer in women.

U.S. EPA used the cancer incidence data from the NIOSH study, using individual exposure estimates for 17,530 workers from 13 plants, to calculate an inhalation unit risk value. A linear low-dose extrapolation of the lowest effective concentration (LEC; defined here as the lower 95% confidence limit on the EC_{01}, the estimated effective concentration associated with 1% extra risk) for lymphoid cancer was calculated as 2.9 x 10^{-3} per µg/m^3. Using the same approach, the lifetime unit risk for breast cancer was calculated as 8.1 x 10^{-4} per µg/m^3. Combining the risk for lymphoid and breast cancers in females U.S. EPA adopted an inhalation unit risk of 2.99 x 10^{-3} per µg/m^3 (rounded to 3.0 x 10^{-3} per µg/m^3). These adult-exposure only unit risk estimates were then rescaled to a lifetime, using age-dependent adjustment factors (ADAF). ADAFs are used to incorporate the greater risk of early life exposure to chemicals that have a mutagenic MOA. When applying the ADAFs, EPA calculated an inhalation unit risk value over a 70-year lifetime of 5.0 x 10^{-3} per µg/m^3 (U.S. EPA, 2016). Cancer risk from measured and modeled EtO concentrations are estimated by multiplying the IUR by the EtO concentrations.

U.S. EPA Cancer Risk Estimates Reviewed by ATSDR

U.S. EPA Region 5 air modelers estimated cancer risk assuming a 70-year lifetime from measured and modeled data. Based on modeled EtO concentrations at over 882 specific locations around the Sterigenics facility, U.S. EPA used the 5-year average EtO concentrations to calculate lifetime cancer risks between 1.3 x 10^{-4} to 6.7 x 10^{-2}, with a geometric mean risk of 9.1 x 10^{-4}. Even though cancer risks are not generally calculated for short term exposures, the estimated cancer risks associated with the *measured* EtO air concentration (19 samples collected for 12 hours each) were similar (range: 7.9 x 10^{-4} to 4.5 x 10^{-2}, geometric mean: 7.7 x 10^{-3}; Table 3). Note that these cancer risks were calculated using the lifetime ADAF-adjusted IUR of 5.0 x 10^{-3} per µg/m^3.

Table 3. Range of measured and modeled EtO concentrations: U.S. EPA Cancer Risk Estimates

Statistics	Modeled 5-year (µg/m^3)	Modeled cancer risk range	12-hour samples (µg/m^3)	Measured cancer risk range*
Minimum	0.03	1.3E-04	0.16	7.9E-04
Maximum	13.32	6.7E-02	4.34	4.5E-02
Mean	0.32	1.6E-03	1.04	1.4E-02
Geometric Mean	0.18	9.1E-04	0.61	7.7E-03

**Cancer risk was calculated to estimate what long term exposures to the 12-hour concentration could look like if sustained long term and does not represent actual exposures.*

Cancer Risk Estimates Calculated by ATSDR

For ATSDR assessments, the reasonable maximum exposure (RME) scenario for residential exposure duration is 33 years over a lifetime of 78 years, so ATSDR calculated an IUR based on 33-year residential exposure using ADAFs. As mentioned previously, ATSDR's RME exposure point concentration (EPC) of 2.1 µg/m^3 was used as a reasonable estimate of exposure for the most exposed individual in the community. This EPC is the maximum residential sample concentration of EtO in the May 2018 data collection period. Given these assumptions, the cancer risk for this residential sample

location is **6.4×10^{-3}**—an additional lifetime risk of 6.4 cancers in a population of 1,000 residents who could be exposed to EtO emissions from Sterigenics. This cancer risk exceeds U.S. EPA's decision-making cancer risk range of 1.0×10^{-6} to 1.0×10^{-4}, and adds to the lifetime background cancer risk of an average American of 1 in 3 people (American Cancer Society, 2018).

Table 4. Site-specific ADAF calculations for residential exposure*

Age Range	ADAF	U.S. EPA unadjusted IUR	EPC ($\mu g/m^3$)	Duration Adjustment	Partial Risk
0 to <2 yrs	10	2.99×10^{-3}	2.1	2 years/78 years	1.6×10^{-3}
2 to <16 yrs	3	2.99×10^{-3}	2.1	14 years/78 years	3.4×10^{-3}
16 to 33 yrs	3	2.99×10^{-3}	2.1	17 years/78 years	1.4×10^{-3}
				Lifetime Risk	**6.4×10^{-3}**

**Cancer risk was calculated to estimate what long term exposures to the 12-hour concentration could look like if sustained long term and does not represent actual exposures.*

Likewise, ATSDR assumed the maximum commercial 12-hour sample concentration in commercial sample locations of 9.1 $\mu g/m^3$ to represent RME occupational exposures to workers in nearby facilities. Note that workers at the Sterigenics facility would be covered under the Occupational Safety and Health Administration (OSHA) EtO standard (29 CFR 1910.1047). For the off-site worker scenario, ATSDR assumed an 8.5-hour workday, 250 days a year, for 25 years (ATSDR, 2016), yielding an exposure factor (EF) of 0.08.

$$EF_{cancer,\ chronic} = \frac{8.5\frac{hr}{d} x\ 5\frac{d}{wk} x\ 50\frac{wk}{yr} x\ 25\ yr}{24\frac{hr}{d} x\ 7\frac{d}{wk} x\ 52.14\frac{wk}{yr} x\ 78\ yr} = 0.08$$

Cancer risk for workers can be calculated by multiplying the long-term air concentration by the IUR, adjusting the duration of exposure as appropriate using the exposure factor calculation, above:

$$Cancer\ risk = IUR \times EPC\ (\mu g/m^3) \times EF$$

For the maximum commercial concentration of 9.1 $\mu g/m^3$, this risk equation yields a lifetime occupational cancer risk of 2.1×10^{-3}, or an increased risk of cancer for 2.1 people in a population of 1,000 workers from chronic exposures to Sterigenics emissions:

$$Cancer\ risk_{occupational} = 0.00299 \times 9.1\ \mu g/m^3 \times 0.08 = \mathbf{2.1 \times 10^{-3}}$$

While a more complete database from which to characterize exposure is preferable, we used U.S. EPA's limited data for the Sterigenics investigation and applied the standard ATSDR evaluation process. Note that in both ATSDR calculations, we made a very conservative assumption that a 12-hour sample represents long term exposure. We felt this assumption was warranted because the measured and modeled concentrations demonstrated consistency and provided support that this range of exposure is possible in the area surrounding Sterigenics.

Non-cancer effects

Workers exposed to ethylene oxide over a long-term duration experienced similar health effects to those exposed over shorter durations (California EPA, 2008). Workers exposed to levels of EtO at 8,500 µg/m^3 and higher over an average of 5-6.5 years demonstrated cognitive and motor impairment compared to unexposed controls. At lower levels of EtO exposure (145-300 µg/m^3), studies have shown evidence of hemoglobin adducts, DNA damage effects (i.e. sister chromatid exchanges), and hematological effects (i.e. increases in leukocytes and decreases in neutrophil counts; decreases in hematocrit and hemoglobin) (California EPA, 2008). No measured EtO concentrations from the residential or occupational sampling approached or exceeded effect levels in the long-term modeling estimates or the 12-hour samples being used as chronic exposure surrogates, therefore, non-cancer health effects are not expected. However, air sampling in this effort was extremely limited.

LIMITATIONS

ATSDR made several assumptions as part of this assessment that could lead to the over or underestimation of risk. Some limitations of this assessment include:

1. To calculate risks, ATSDR assumed that the concentrations measured during this assessment will continue, unchanged if no actions are taken, over 33 years for residents, and 25 years for workers.
2. ATSDR assumed that the very limited sampling investigation of 26 discrete locations over 2 days throughout the community represents typical exposure conditions from Sterigenics EtO emissions. Only one 12-hour residential sample was collected, and that sample was used to represent the RME residential chronic exposure estimate. EtO concentrations from grab samples at one other residential location were slightly higher than the 12-hour averaged sample collected at this property.
3. ATSDR assumed that the highest EtO concentration in the commercial area surrounding Sterigenics represents worst case off-site worker exposures. This is likely underestimating worker exposures for some employees in this area.
4. Due to a lack of long term sampling, the temporal trends of EtO emissions could not be evaluated. Fluctuations of seasons that affect temperatures, barometric pressure, wind speed and direction, and other potential factors that could influence the transport of EtO into the surrounding community were not assessed.

Despite these limitations, ATSDR acknowledges that the U.S. EPA modeling demonstrates similar concentration ranges to community air measurements. Thus, ATSDR believes the exposure estimates assumed in this assessment are reasonable. Historical emissions were higher before a substantial drop in 1999 with the construction of aeration rooms in Building 1. EtO cancer risks may have been substantially greater for the 14 years the facility operated before these emission controls were implemented, but historical risk cannot be evaluated with available emissions data.

Conclusions:

U.S. EPA asked ATSDR to answer the following question: "*If modeled and measured ethylene oxide concentrations represent long term conditions, would they pose a public health problem for people living and working in Willowbrook?"* U.S. EPA provided modeled and measured data for ATSDR to evaluate and render a health opinion.

It is ATSDR's conclusion that the data U.S. EPA provided suggests that residents and workers are exposed to elevated airborne EtO concentrations from facility emissions. It is difficult to assess long-term public health implications from facility emissions because there has been no historical air monitoring in the community. ATSDR assumed that these data represent long term exposures for area residents and workers. Specifically, ATSDR concludes the following:

1) If measured and modeled data represent typical EtO ambient concentrations in ambient air, *an elevated cancer risk exists* for residents and off-site workers in the Willowbrook community surrounding the Sterigenics facility. These elevated risks *present a public health hazard to these populations*.
2) Measured and modeled ethylene oxide concentrations in ambient air indicate that non-cancer health effects are unlikely for residents and off-site workers in the Willowbrook community surrounding the Sterigenics facility.

Recommendations:

1) ATSDR recommends that Sterigenics take immediate action to reduce EtO emissions at this facility.
2) ATSDR recommends that U.S. EPA work with the Sterigenics facility to initiate long-term air monitoring as soon as possible to measure ambient air levels of EtO. Ongoing air monitoring can demonstrate the effectiveness of actions taken by the company to reduce emissions and subsequent exposures in the community.
3) ATSDR recommends that IDPH investigate whether there are elevated cancers in the population surrounding the Sterigenics facility that are consistent with those associated with chronic EtO exposures.

Please do not hesitate to contact ATSDR Region 5 to discuss this assessment further or to request further public health assistance.

Sincerely,

Michelle A Colledge

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Cancer Incidence Assessment near Sterigenics in Willowbrook, IL, 1995-2015

A publication of the

Illinois Department of Public Health

Division of Epidemiological Studies

Springfield, Illinois 62761

March 29, 2019

EXHIBIT
B to Affidavit

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Cancer Incidence Assessment near Sterigenics in Willowbrook, IL, 1995-2015

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Abstract

Background: The Division of Epidemiologic Studies, Illinois Department of Public Health (IDPH), conducted an assessment to determine if there is elevated cancer incidence in the population surrounding the Sterigenics facility in Willowbrook, Illinois. The facility, operating since 1984, has been emitting ethylene oxide (EtO), a currently known carcinogen.

Methods and Data: Cancer cases were obtained from the Illinois State Cancer Registry (ISCR) for diagnosis years 1995-2015. Two study areas were created based on census tracts and an air sampling/exposure model. Study area 1 included nine census tracts around the Sterigenics facility, and study area 2 included study area 1 and eight additional census tracts. Cases were geocoded into the study areas based on addresses using a combination of GIS software and manual scrutiny. Two groups of cancers were examined. The first group included lymphohematopoietic cancers (non-Hodgkin's lymphoma, Hodgkin's lymphoma, myeloma, and lymphocytic leukemia) and female breast cancer, a group of cancers that have been documented to be associated with EtO exposure. The second group included other common cancer sites. Trends in the lymphohematopoietic and breast cancers were examined, and pediatric cancers were studied separately. Standardized incidence ratios (SIR's) and their 95% confidence intervals (CI) were calculated with comparable county and state populations as references.

Results: Significantly elevated Hodgkin's lymphoma cases in females were observed in study area 1 as compared to county (SIR 1.86, CI 1.12-2.91) and state averages (SIR

1.89, CI 1.14-2.95). Female breast cancer was elevated in both study areas when compared to the state average (Study Area 1: SIR 1.10, CI 1.02-1.18; Study Area 2: SIR 1.07, CI 1.02-1.13). The elevation, however, became non-significant when compared to the county average. Trends in SIR's showed a monotonic increase with time in female non-Hodgkin's lymphoma, with the SIR becoming statistically significant in the most recent time period, 2009-2015 (Study Area 1: SIR 1.61, CI 1.19-2.21; Study Area 2: SIR 1.33, CI 1.07-1.63). Pediatric lymphoma was observed to be elevated over the entire study period in females of both study areas. Other adult cancer sites observed to be elevated include prostate cancer, and female pancreatic, ovarian, and bladder cancers. Also, female leukemia was found to be significantly lower than expected, and lung cancer seemed to be lower in both males and females.

Conclusions: The study's results, when taken as a whole, indicated that some cancers were elevated in populations living near the Sterigenics facility in Willowbrook, Illinois. Many apparent differences and inconsistences, however, existed between genders, across study areas, and among cancer sites. Further studies, preferably with larger populations and multiple facilities, are strongly recommended to confirm this assessment's findings.

Background

In December 2016, the U.S. Environmental Protection Agency (EPA) updated its cancer risk assessment for ethylene oxide (EtO). The new calculations, based on breathing elevated levels of EtO for many decades, resulted in a 30-fold increase in EtO's cancer potency. In response, the Agency for Toxic Substances and Disease Registry (ATSDR) evaluated the implications of the increased cancer risk associated with EtO emissions at a Sterigenics International Inc. facility in Willowbrook, Illinois (referred to in this paper as Sterigenics). The Sterigenics facility has been operating since 1984, releasing between 17,000 and 33,000 pounds of EtO annually before 1999, and about 5,000 pounds of EtO since 1999.

In July of 2018, the ATSDR released an open letter to the EPA regarding ethylene oxide (EtO) emissions at the Sterigenics facility in Willowbrook, Illinois (ATSDR, 2018). In this letter ATSDR concluded that "if modeled and measured data represent typical EtO concentrations in ambient air, an elevated cancer risk exists for residents and off-site workers in the Willowbrook community surrounding the Sterigenics facility. These elevated risks present a public health hazard to these populations." ATSDR then recommended that the Illinois Department of Public Health (IDPH) investigate whether there is elevated cancer incidence in the population surrounding the Sterigenics facility (US DHHS-ATSDR, 2018). Cancer incidence describes how many people were actually diagnosed with cancer.

EtO is a highly reactive gas used in the production of antifreeze, textiles, detergents, and other products, as well as a fumigant for sterilizing foodstuffs and a sterilizing agent for heat sensitive medical equipment. If EtO is inhaled, it is readily absorbed into the human body and easily distributed throughout the body. EtO leaves the body very rapidly (over 2-3 days) through urine and feces or by exhaling it.

The health effects of EtO exposure have been studied since the 1940's. Exposure to EtO can cause difficulty breathing, blurred vision, dizziness, nausea, headache, convulsions, blisters, and vomiting. It is also known to be mutagenic in animals and induce chromosome damage. EtO is known to be carcinogenic in mice and rats. There is evidence of an increased risk of lymphohematopoietic cancers (i.e. non-Hodgkin's lymphoma, myeloma, and lymphocytic leukemia) and of breast cancer in females among people employed in EtO manufacturing and sterilizing facilities (Steenland, Whelan et al 2004 and Steenland, Stayner et al 2003). EtO is identified as a known carcinogen by both the International Agency for Research on Cancer and the U.S. National Toxicology Program (IARC 2009 and NTP 2016).

IDPH has produced the following analysis to answer the following question: Is there evidence of increased cancer incidence in the area surrounding the Sterigenics facility that is consistent with cancers associated with EtO exposure?

Materials and Methods

The U.S. EPA provided the IDPH with modeled 5-year average EtO exposure estimates for the area surrounding the Sterigenics facility. This modeled exposure area was used to define the cancer investigation's first study area, which is comprised

of nine census tracts (Table 1, Map 1). A second, larger study area was created to approximate the zip code 60527, which includes study area 1 and eight additional census tracts (Table 1, Map 2). Zip code areas have typically been used by the Illinois State Cancer Registry (ISCR) to assess cancer incidence. The use of two different study areas helps capture any possible cancer increases in the area around the Sterigenics facility. Also, use of the two study areas assists researchers in determining if results vary between the study areas when the same set of standardizing or reference populations are used. Both study areas were defined using census tracts.

The source for cancer case data was the Illinois State Cancer Registry (ISCR). ISCR abstracts, verifies, and compiles cancer information from medical records. The verified medical information that ISCR collects is much more accurate than alternative information sources such as self reported surveys, which are highly prone to recall bias and errors. The ISCR data , as of November 2017, includes the years 1995 through 2015. This time period was selected for this assessment as it represents the most recent and most complete years of data in the registry that also correlate with the operation of the Sterigenics facility. This choice of time frame also allows for the typical cancer latency period which would be 4 to 10 years for lymphohematopoietic and 10 to 15 years for solid tumors.

Cancer registry data was reviewed to ensure cancer cases were geocoded accurately. Geocoding is a process through which cancer cases are assigned to a geographic location. ISCR, like any other cancer registry in the country, assigns a cancer patient's residential address, at the time of diagnosis, as the patient's

geographic location. The geocoding process was carried out in this study using a series of computer programs (e.g. ArcGIS®, Accurint™, Google® Earth, and Google® Maps), in combination with manual examination of address data to ensure that cancer cases were being placed in the correct census tract. First, cancer cases from 1995-2015 were selected from 10 zip codes surrounding Sterigenics (60480, 60525, 60527, 60521, 60561, 60439, 60559, 60514, 60517, 60558) and prepared for additional examination. One hundred percent of cancer cases in the registry have a valid zip code, so this variable was used to begin the process of assigning cases to census tracts. Of the 24,747 cases examined, 788 cases (3%) did not have a geocode specific enough for a census tract to be assigned. All of the 788 cases had address information reviewed and checked manually for accuracy using Accurint™, a commercial address verification tool, in addition to Google® Earth, to visually identify the residential address. Two cases were found to be residents of other states and were excluded, 33 cases did not fall into the 10 zip code catchment area, and 9 cases contained so little address information that a census tract could not be assigned. As a result, a total of 44 (0.1%) cases were excluded. With this process finished, the selection of cancer cases for the specific census tracts contained in study area 1 (N=4,534) and study area 2 (N=9,416) was completed.

Illinois residents who are diagnosed with cancer do not always get diagnosed in Illinois. In order to capture out-of-state cases, ISCR has standing agreements with other central cancer registries to identify Illinois resident cases that are identified outside the state and to share that data with ISCR. These registries include Arkansas, California, Florida, Indiana, Iowa, Kentucky, Michigan, Mississippi (through August 2004), Missouri,

North Carolina, Washington, Wisconsin, Wyoming (through February 2008), and the Mayo clinic in Minnesota (through October 2005). Completeness of out-of-state reporting depends upon the years of operation of these other central registries, the extent of their identification of out-of-state residents, and their standards of quality. Out-of-state diagnoses among residents of the two study areas accounted for less than one percent (0.5%) of the total number of cases reported, between 1995 and 2015, and were included in the study.

Identification of cancer cases in Illinois is dependent upon reporting by diagnostic and therapeutic facilities as mandated by state law. To benchmark and foster best practices for cancer reporting among population-based cancer registries, the North American Association of Central Cancer Registries (NAACCR) has developed a certification process that reviews registry data for completeness, accuracy, and timeliness of reporting. As of May 2018, ISCR data met the criteria for gold certification for cancer diagnosis years 1996 through 2015. The statewide completeness of case reporting from all reporting sources, assessed using the NAACCR Standard, is estimated to be 100 percent complete for all years between 1995 and 2015. The criteria for silver and gold certification can be found on the NAACCR web site at https://www.naaccr.org/certification-criteria/.

All cancer cases from the study areas were grouped by tumor site, sex, and age. These are referred to as the *observed* cases. Age- and sex-specific rates from comparable populations in Illinois were applied to each age group of the study population (indirect age adjustment) and to each tumor site to obtain an *expected*

number of cases for the study area (Mattson 1986). Two groups of cancer sites were examined in this study. The first group includes female breast, and lymphohematopoietic cancers. The lymphohematopoietic cancers specifically include Hodgkin's lymphoma, non-Hodgkin's lymphoma, myeloma, and lymphocytic leukemia. This group was selected because of their documented associations with EtO exposure in previous studies, almost all of which were conducted in an occupational setting (Steenland, Whelan et al 2004 and Steenland, Stayner et al 2003, Jinot, Fritz et al 2018). The second group includes other tumor sites that ISCR routinely examines when conducting a cancer assessment study, which are oral cavity, esophagus, stomach, colon and rectum, liver, pancreas, lung and bronchus, bone, melanoma, breast, cervix, uterus, ovary, prostate, testis, bladder, kidney, brain, and nervous system, leukemia, thyroid, and all other cancers. This second category of tumor sites was examined to capture other possible cancer increases and generate new hypotheses for future studies. The site recode scheme used in this analysis was the International Classification of Diseases for Oncology version 3 (ICD-O-3) with adjustment for hematopoietic histologies as defined by the Surveillance Epidemiology and End Results Program (SEER) of the National Cancer Institute (NCI) (https://seer.cancer.gov/siterecode/index.html).

In addition to the evaluation of adult cancers, this study also examined pediatric cancer for children ages 0 to 19 years old in both study areas. Tumors diagnosed in children are classified using the SEER site/histology recode based on the International Classification of Childhood Cancer (ICCC), Third Edition and ICD-O-3 (https://seer.cancer.gov/iccc/). Sites examined include leukemia, lymphomas, central

nervous system tumors, neuroblastoma, retinoblastoma, renal tumors, hepatic tumors, bone, soft tissue, germ cell tumors, and all other sites. The category 'all other sites' includes other malignant tumors and those that were unspecified or unclassified by ICCC definitions.

According to the longstanding ISCR practice, cancer incidence in a study area is compared to a population with a similar population density, race distribution, and a large enough size to provide stable estimates (Howe and Keller et al 1993). In addition to state and county geographies, ISCR has defined and maintained four reference groups (urban Cook County, suburban five collar counties, small urban with 13 counties, and rural with 83 counties) for Illinois based on population density, rate of growth, Beale codes, and with a total population of at least two million. The two comparable populations for the study areas of interest were deemed to be the suburban five collar counties (referred to in this report as the state average) and DuPage County (referred to in this report as the county average). The population density and other demographic characteristics of the two comparable populations matched those of the study area better than any other existing county or state level referent group. Table 2 presents race, gender, ethnicity, and age distributions for the two reference populations and the two study areas.

Age-, sex-, and race-specific population counts for census tracts in Illinois for each year between 1995 and 2015 were required in order to compute the observed and expected cases in this cancer assessment. While this level of population information is available for census years, 2000 and 2010, it was not available for intercensal years.

Because of this, intercensal population figures were interpolated/extrapolated based on the population counts from the 2000 and 2010 U.S. Census, the most reliable sources for small area population. Age- and sex-specific population counts for census tracts were created through application of a linear function to stratified counts from the 2000 and 2010 census. These were then aggregated to form age- and sex-specific population figures for both of the study areas.

The observed number of cases was compared with the expected number of cases for all age-, sex-, and site-specific categories. Standardized incidence ratios (SIR) and their 95% confidence intervals (CI) were calculated. An SIR is the ratio of observed cases to the expected number of cases, and an SIR greater than 1.0 or less than 1.0 indicates that observed cases are either higher or lower than the expected cases. The SIR is considered statistically significant when the SIR's confidence interval (CI) does not include 1.0. A statistically significant SIR means that the SIR, as judged by statistical significance, is unlikely to have occurred by chance. More technically, a statistically significant SIR indicates that there is a low probability (less than 5% chance) of getting a result as extreme or more extreme than what is observed, if there is truly no difference between the expected and observed numbers, and all assumptions related to the statistical test are also true. The SIR, CI's, and resulting statistical significance are affected by the strength of the effect, incidence of the disease, the size of the population studied, and many other factors such as quality of the data, choice of the study areas, and changes in cancer reporting, etc. (Aschengrau and Seage 2003, Last 2001). See appendix A for formulas used in the calculation of SIR's.

In addition to examining SIR's for the overall 21-year time period in question (1995-2015), SIR's from three 7-year time periods, 1995-2001, 2002-2008, and 2009-2015, were separately examined for trends in adult EtO related cancer sites. This by time-period analysis was also conducted to detect cancer changes that would otherwise be hidden when only the overall time-period was examined.

Results

Lymphohematopoietic and Female Breast Cancers

No increases in any subgroup of lymphohematopoietic cancers were observed in men of either study area 1 or study area 2 (Table 3). Significantly elevated Hodgkin's lymphoma cases in females, however, were observed in study area 1 when compared to the county and state averages (Table 3). The increase in observed cases in study area 1 was almost 90% higher than expected (SIR 1.86, CI 1.12-2.91). In study area 2, Hodgkin's lymphoma among females was no longer significantly different from either reference group. Significantly elevated SIR's were observed in invasive female breast cancer in both study area 1 and study area 2 when compared to the state average. The observed effect was small with case counts roughly 10% higher than expected in both study areas (Study Area 1: SIR 1.10, CI 1.02-1.18; Study Area 2: SIR 1.07, CI 1.02-1.13). When the study areas were compared to the county average the SIR's in female invasive breast cancer became non-significant.

Lymphohematopoietic and Female Breast Cancer Trends

Figures 1 and 2 display the temporal trends in SIR's for lymphohematopoietic and female breast cancer for study area 1 and study area 2, respectively, by three 7-year time periods; 1995-2001, 2002-2008, and 2009-2015. Since results were similar between the two reference populations, only results relative to the state reference group are shown. Non-Hodgkin's lymphoma in females displayed a consistent and increasing trend in SIR over the time period examined, and its SIR reached statistical significance in the most recent time period, 2009-2015, (SIR: 1.61, 95%CI: 1.19-2.11 for study area 1 and SIR: 1.33, 95%CI: 1.07-1.63 for study area 2). This positive trend and the significant elevation in the last and most recent time period was observed in both study areas. During the earliest time period, 1995-2001, non-Hodgkin's lymphoma among males seemed to be high, although the elevation could only be described as borderline significant (SIR: 1.30, 95%CI: 0.91-1.79 for study area 1 and SIR: 1.27, 95%CI: 1.00-1.59 for study area 2). No other cancer sites showed any clear trends over time or were significantly different from the reference population.

Other Cancer Sites

Males in both study areas had a small but statistically significant increase in prostate cancer when compared to both the state and county averages (Table 4-5). Lung cancer in males, however, was shown to be significantly lower in study area 2. In study area 1, females displayed significantly higher SIR's in the following sites when compared to both the state and county averages: pancreas, ovary, and bladder cancer (Table 4). All of these increases disappeared in study area 2 (Table 5), except for pancreatic cancer, which remained significantly elevated. Leukemia was observed to

be significantly lower in females of study area 1 when compared to both the county and state averages (Table 4). Lung cancer, which was observed to be significantly lower in males for study area 2, seemed to be lower among females, as judged by the value of SIR's and their 95% confidence interval bounds, in both study areas and relative to both county and state averages. However, the decreases only reached a statistical level of significance in study area 2 when compared to the state average (Tables 4 and 5).

Pediatric Cancers

An examination of childhood cancers, utilizing SIR's, showed a significantly higher than expected number of childhood lymphomas in females of both study area 1 and study area 2 (Table 7). Again, results shown are relative to the state reference, as the results relative to the county were similar to those relative to the state reference. No other pediatric cancer sites were observed to have higher or lower incidence relative to either reference group in either study area 1 or study area 2. It should be noted that all of the other individual pediatric sites had SIR's that were based on fewer than 10 cases.

Discussion

This cancer assessment used two study areas, two reference groups, and examined not only lymphohematopoietic and breast cancers, associated with EtO exposure in the literature, but also other cancer sites and pediatric cancers that have not been shown to be related to EtO exposure. While this was done to mainly capture and screen for as many potential cancer elevations as possible and to provide comparisons to assess the stability and robustness of this study's findings, this

approach generated many inconsistencies, which were reflected in differences between genders, between study areas, and even between reference populations.

Despite these inconsistencies, the study's results, when taken as a whole, suggest that some cancers were indeed elevated in populations living in and around the Willowbrook, Illinois area. The main evidence for this came from Hodgkin's lymphoma and, to a lesser extent, breast cancer. Breast cancer was elevated, by about 10%, when comparing the study areas to the state reference group. The elevation became non-significant when the study areas were compared to the county reference group. This change could be plausibly explained by the fact that DuPage County, the county reference group in this study, has consistently displayed higher levels of breast cancer compared to other counties in the state (IDPH-ISCR 2018). Despite the loss of statistical significance, the lower bounds of the 95% confidence intervals were still close to 1.0, suggesting that breast cancer was high even in relation to DuPage County. Some common behavioral risk factors for breast cancer include; drinking alcohol, being overweight or obese, lack of physical activity, not having children, not breastfeeding, use of birth control containing hormones, post-menopausal hormone usage, and breast implants (ACS 2019). In addition, certain genetic mutations can increase the risk of breast cancer, as well as a family or personal history of the disease, certain benign breast conditions, early menstruation, menopause after age 55, having radiation to your chest, and exposure to diethylstilbestrol (ACS 2019).

Hodgkin's lymphoma was observed to be high in females of study area 1. This cancer, which belongs to the lymphohematopoietic group of cancers, has been studied

much less than other sites in that group. Past occupational studies have identified an association between EtO exposure and three lymphohematopoietic cancers, namely non-Hodgkin's lymphoma, myeloma, and lymphocytic leukemia. Similar associations with respect to these three specific sites were not observed in this study. To our knowledge, only one past study observed an elevation of Hodgkin's lymphoma in workers who were exposed to EtO in combination with other chemicals. The sample size in that study was small and the exposure was not limited to EtO (Swaen and Slangen et al. 1996). Many studies only included Hodgkin's lymphoma when lymphohematopoietic cancers, as a group, were used as a single target cancer (US EPA 2016). Because of the lack of specific studies on Hodgkin's lymphoma, the results of this study should be treated with caution and verified in any future examination of this association. The apparent absence of this cancer in males was inconsistent with the finding in females, but it could be the result of some unmeasured difference in exposure or biology. The lack of elevation in females of study area 2 was noticeable, and a simple explanation could be that EtO exposure has been much more concentrated in study area 1 than in study area 2, which is more than twice the size of study area 1 in terms of population and geographical size. Although SIR's failed to reach a significant level in study area 2, their values were relatively large, 1.29 and 1.31, when compared to the state and the county averages, respectively. Current understanding of risk factors for Hodgkin's lymphoma describes that men are slightly more likely to develop the disease; it's most common in early adulthood (20s) and after age 55, and an increased risk exists for those who have had infectious mononucleosis

(Epstein-Barr virus), HIV, those who use immune suppressing drugs, and siblings of a young person with the disease (ACS 2019).

The time period analysis of lymphoid cancer and the examination of pediatric cancer provide further evidence. Although a clear time trend was absent for most lymphohematopoietic cancers and breast cancer, non-Hodgkin's lymphoma in females was observed to be increasing over time and was observed to be significantly elevated for the most recent time period, 2009-2015, and non-Hodgkin's lymphoma in males was borderline significant for the earliest time period, 1995-2001. These patterns were consistent across study areas. Non-Hodgkin's lymphoma has been frequently linked to EtO exposure by prior occupational studies (Steenland, Whelan et al 2004 and Steenland, Stayner et al 2003).

Pediatric lymphoma was observed to be significantly higher than expected in females of both study areas. Known risk factors for pediatric lymphoma are gender (boys), race (white), immune deficiency syndromes at birth, immune suppressing medications, infectious mononucleosis (Epstein-Barr virus), HIV/AIDS, and radiation exposure. Lymphoma has been shown to be associated with EtO exposure in adult occupational studies (Steenland, Whelan et al 2004 and Steenland, Stayner et al 2003). No previous studies have examined this association in children. In this assessment, the elevation was observed only in females, a pattern that seems to be congruent with the adult gender difference found in this study.

In addition to lymphohematopoietic and breast cancers, this study examined a number of other common cancer sites and found increases in several of them. These

results should be viewed with an abundance of caution, as none of these sites have yet been reported by previous studies as having an association with EtO exposure. Likewise, decreases observed in a few cancer sites should not be interpreted as a possible protective effect of EtO. It was observed that increases and decreases were quite consistent across the two reference populations. On the other hand, large and inconsistent changes seemed to exist between study areas, probably reflecting differences in distributions of cancer risk factors and screening practices. A brief review of each of the statistically significant site-specific findings and risk factors is below.

- Prostate cancer was observed to be high in both study areas. Current understanding of the risk of prostate cancer suggest that age, race, geography, and family history are important risk factors in the development of the disease. Screening availability and utilization may also play a role in the differences observed (ACS 2019).
- Pancreatic cancer incidence in females was high in both study areas. Risk factors for the development of pancreatic cancer include: smoking, age (>60), chronic pancreatitis, diabetes, obesity, poor diet, and genetic factors (ACS 2019).

- Females in study area 1 displayed a higher than expected incidence of bladder cancer. Risk factors for bladder cancer include smoking, exposure to aromatic amines, certain medicines and herbal supplements, arsenic in drinking water, not drinking enough fluids, race (white), gender (male), age (>55), chronic bladder irritation or infections, prior bladder or urothelial cancer, bladder birth defects, family history of bladder cancer and chemotherapy or radiation therapy (ACS 2019).
- Ovarian cancer was observed to be higher in study area 1. Ovarian cancer is in association with: age (>65), obesity, not having children or having them after age 35, fertility treatment, post-menopausal hormone therapy, family history, and hereditary genetic mutations and syndromes (ACS 2019).
- Lung cancer incidence was observed to be lower than expected in study area 2 in men and women. In study area 1, lung cancer was also low among females, but the difference was not statistically significant. Lung cancer is strongly associated with tobacco use (ACS 2019). DuPage County has some of the lowest smoking rates in the state (IDPH-BRFSS 2017).
- Females in study area 1 displayed lower than expected incidence of leukemia. This finding was surprising given that EtO exposure has been noted in prior studies to be associated with an increase in lymphocytic leukemia, a sub-set of leukemia. Factors that may increase the risk of developing leukemia include prior cancer treatment, genetic disorders, exposure to certain chemicals (benzene), smoking, and a family history of the disease (ACS 2015).

The present assessment has several significant limitations that need to be considered. First, with more than 400 age, sex, cancer site, study area, and reference group combinations being compared, it is highly likely that the process may produce some 'false significant values' by chance. In statistical terms, this is called the multiple comparison problem. The more comparisons made, the more pronounced the problem is. Clearly, simultaneously examining many cancer sites and employing more than one reference and study area would exacerbate the problem. The potential consequence is that chance occurrences cannot be ruled out in explaining differences between the observed and expected numbers. The confidence interval was set at 95%, which means that there was a one out of 20 chance that a finding could be a false positive. Although the level could be adjusted to potentially reduce false positives, the use of 95% confidence intervals in the study was appropriate as the purpose of the study was to screen as many cancer differences as possible.

Second, due to the lack of annual population data from the Census for both of the study areas, the 2000 and 2010 Census population numbers were used in interpolating and extrapolating population counts for non-census years. These imprecise denominator numbers, when used to derive sex-specific expected numbers, might have introduced errors and biases into the comparison, of which neither the direction nor the magnitude was known.

Third, many potential risk factors for cancer, including occupational exposure, smoking, diet, lifestyle, family history, and other medical conditions, are not collected by the current registry system and, as a result, their inclusion for analysis was not possible.

The Willowbrook community is close to interstate highways and motor vehicle fuel exhaust is a known source of EtO. Living in a study area at the time of diagnosis was used to represent potential exposure to EtO, but it was a very crude proxy because a cancer patient could have either left or moved into the study area right after or before their cancer diagnosis, resulting in either a case under-count or a case over-count. This lack of individual-level information on the history of residence and other risk factors for cases in the study areas and the reference population made more refined analysis and comparison impossible. The EPA air sampling and modeling of EtO exposure in the area provided critical information for the study areas to be appropriately defined, but even with this information, data on actual exposure in individuals was non-existent. There is considerable uncertainty about the length and the level of exposure to EtO that each individual in Willowbrook, and surrounding areas, may have actually experienced in the past. Any observed increase, in and of itself, is insufficient to draw conclusions regarding the potential impact of EtO exposure. Cancers are diseases of complex etiology often with a number of risk factors, and this may particularly be true for common cancers such as female breast cancer.

Finally, small numbers could lead to unstable SIR's and decreased statistical power to detect true differences. The total cancer cases (study area 1 N=4,534 and study area 2 N=9,416) seemed to be adequate for overall analyses in this assessment. However, in by-group analysis, such as with the time-period or pediatric cancer comparisons, some SIR's were based on small numbers that were often less than 10. These SIR's could have large swings in values and should not be given too much weight as a result. The direct consequence of small numbers would be the lack of

statistical power for the study to identify a difference when indeed a true difference existed. The problem could be further amplified by the presence of the study's other limitations (e.g., imprecise measures of EtO exposure and lack of measures on other risk factors), resulting in false negative findings.

In conclusion, this cancer assessment examined a number of cancer sites that included cancers that have a recognized association with EtO (lymphohematopoietic and breast cancers), and other common cancer sites that have no such association with EtO, in both adult and pediatric surrounding the Sterigenics facility in Willowbrook, Illinois, over the years 1995 through 2015. For lymphohematopoietic and breast cancers the study found increases in Hodgkin's lymphoma, and in recent years, non-Hodgkin's lymphoma. Pediatric lymphoma was also elevated during the study period. For other common cancer sites, the study found increased cancer in prostate for males, and increased cancers of the pancreas, ovary, and bladder in females. However, many apparent differences and inconsistences existed between genders, across study areas, and among cancer sites. A number of limitations in methodology and data also exist. Future studies with larger populations and preferably involving multiple EtO emissions sites are strongly recommended to confirm this assessment's findings.

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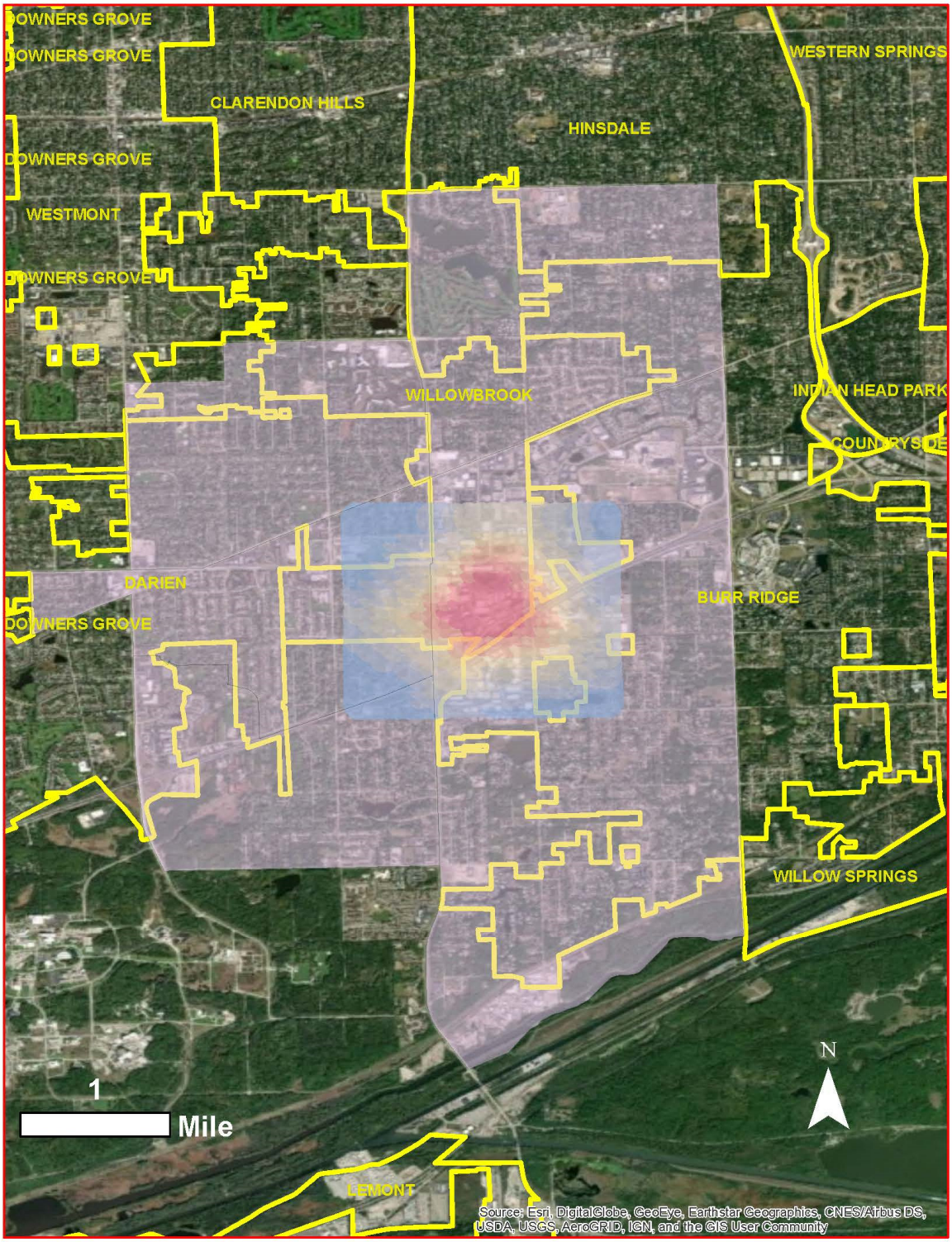
Table 1: 2010 Census Tracts Comprising Study Area 1 and Study Area 2

Study Area 1	**Study Area 2**	
8454.01	8454.01	8455.07
8454.02	8454.02	8455.08
8459.01	8459.01	8458.03
8459.02	8459.02	8458.10
8458.05	8455.02	8458.11
8458.10	8455.10	8458.05
8458.11	8455.09	8202.01
8455.07	8455.06	8201.01
8455.08	8455.05	

Source: U.S. Census Bureau

Map 1: Municipal Boundaries, Study Area 1, and EPA Modeled EtO Exposure



Map 2: Municipal Boundaries, Study Area 2, and EPA Modeled EtO Exposure

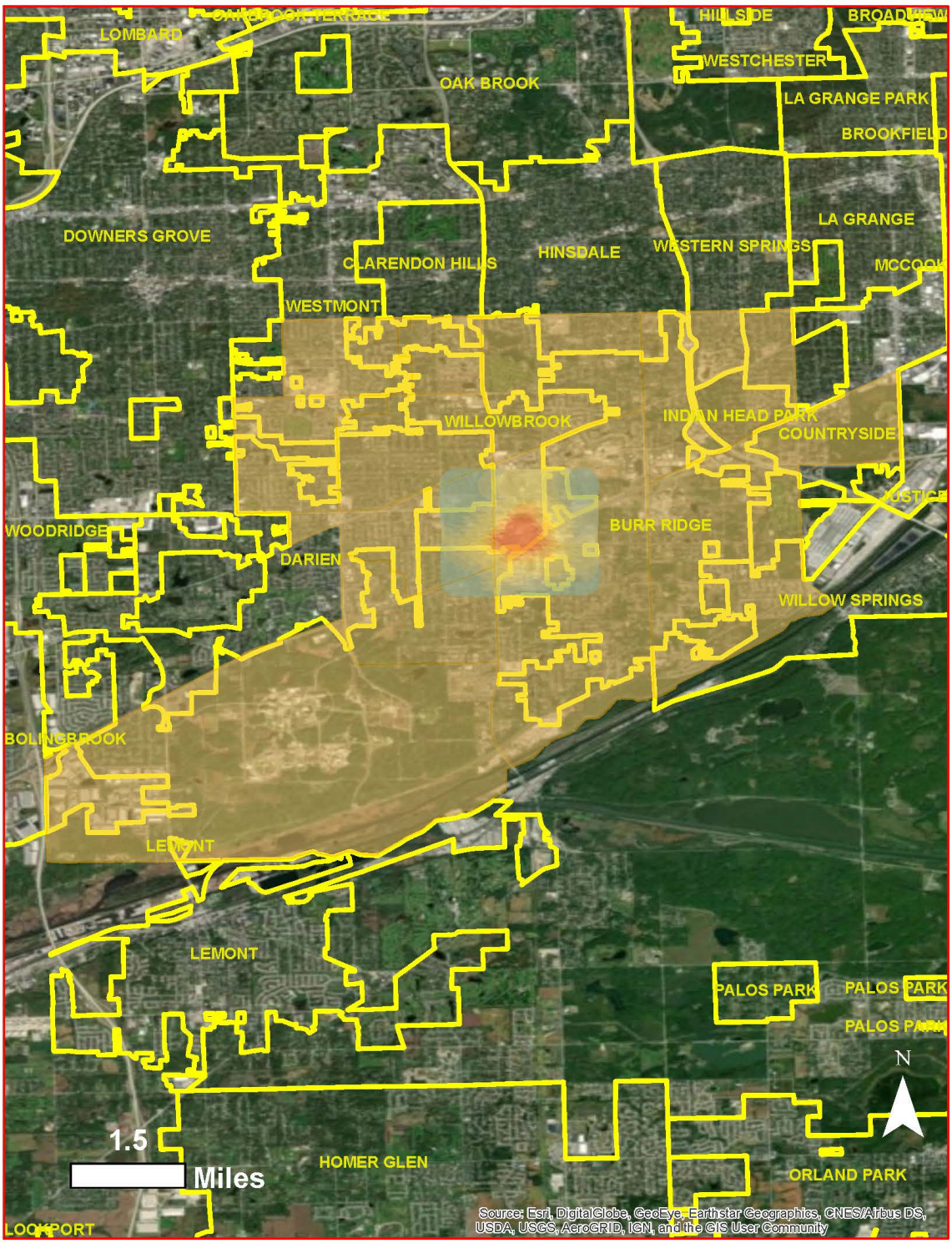


Table 2: Demographic Comparison of Referent Groups and Study Areas, 2010 Census

	Study Area 1	Study Area 2	State* Referent	County** Referent
Total Population	31,808	72,029	3,121,975	916,924
% White	81.0%	78.3%	77.5%	77.9%
% Black	3.4%	6.3%	6.4%	4.6%
% Hispanic	6.2%	7.4%	18.0%	13.3%
% >50	44.7%	41.5%	29.2%	32.1%
Males	47.6%	47.3%	49.6%	49.0%

Source: 2010 Census Summery File 1 accessed through American Fact Finder https://factfinder.census.gov/faces/nav/jsf/pages/index.xhtml

*State referent includes Lake, McHenry, Kane, DuPage and Will counties

**County referent includes DuPage County

Table 3: Standardized Incidence Ratios for Lymphohematopoietic and Female Breast Cancers by Gender, Study Area and Referent Group*, 1995-2015

	County Referent**					State Referent*				
	Obs.	Exp.	SIR	95% LCI	95% UCI	Obs.	Exp.	SIR	95% LCI	95% UCI
STUDY AREA 1										
Males										
Non-Hodgkin's Lymphoma	108	99.63	1.08	0.89	1.31	108	99.63	1.08	0.89	1.31
Hodgkin's Lymphoma	7	11.82	0.59	0.24	1.22	7	11.62	0.60	0.24	1.24
Myeloma	28	28.69	0.98	0.65	1.41	28	28.69	0.98	0.65	1.41
Lymphocytic Leukemia	34	31.52	1.08	0.75	1.51	34	31.52	1.08	0.75	1.51
Females										
Invasive Breast	747	710.76	1.05	0.98	1.13	**747**	**680.60**	**1.10**	**1.02**	**1.18**
Non-Hodgkin's Lymphoma	95	88.87	1.07	0.86	1.31	95	89.16	1.07	0.86	1.30
Hodgkin's Lymphoma	**19**	**10.20**	**1.86**	**1.12**	**2.91**	**19**	**10.06**	**1.89**	**1.14**	**2.95**
Myeloma	23	24.72	0.93	0.59	1.40	23	25.50	0.90	0.57	1.35
Lymphocytic Leukemia	19	24.01	0.79	0.48	1.24	19	22.71	0.84	0.50	1.31
STUDY AREA 2										
Males										
Non-Hodgkin's Lymphoma	222	205.91	1.08	0.94	1.23	222	204.71	1.10	0.95	1.24
Hodgkin's Lymphoma	19	24.90	0.76	0.46	1.19	19	24.45	0.78	0.47	1.21
Myeloma	62	59.08	1.05	0.80	1.35	62	58.89	1.10	0.81	1.35
Lymphocytic Leukemia	69	65.97	1.05	0.81	1.32	69	71.19	1.00	0.75	1.23
Females										
Invasive Breast	1,548	1,507.88	1.03	0.98	1.08	**1,548**	**1,444.64**	**1.07**	**1.02**	**1.13**
Non-Hodgkin's Lymphoma	208	190.61	1.09	0.95	1.25	208	191.11	1.09	0.95	1.25
Hodgkin's Lymphoma	30	23.32	1.29	0.87	1.84	30	22.86	1.31	0.89	1.87
Myeloma	58	52.97	1.09	0.83	1.42	58	54.53	1.06	0.81	1.37
Lymphocytic Leukemia	40	52.06	0.77	0.55	1.05	40	49.24	0.81	0.58	1.11

Note: SIR's in bold indicate statistically significant differences at the $p<0.05$ level

* State Referent group includes Lake, McHenry, Kane, DuPage, and Will counties.

**County Referent is DuPage County

Source: Illinois State Cancer Registry, data as of November 2017

Table 4: Standardized Incidence Ratios for Other Common Cancer Site by Gender and Referent Group*, Study Area 1, 1995-2015

	County Referent**					State Referent*				
	Obs.	Exp.	SIR	95% LCI	95% UCI	Obs.	Exp.	SIR	95% LCI	95% UCI
Males										
Oral Cavity	65	62.57	1.04	0.80	1.32	65	64.53	1.01	0.78	1.28
Esophagus	36	35.03	1.03	0.72	1.42	36	35.90	1.00	0.70	1.39
Stomach	32	40.06	0.80	0.55	1.13	32	39.86	0.80	0.55	1.13
Colorectal	203	221.41	0.92	0.80	1.05	203	227.88	0.89	0.77	1.02
Liver	28	30.76	0.91	0.60	1.32	28	30.90	0.91	0.60	1.31
Pancreas	48	59.81	0.80	0.59	1.06	48	60.46	0.79	0.59	1.05
Lung	273	293.59	0.93	0.82	1.05	273	308.62	0.88	0.78	1.00
Bone	7	3.77	1.86	0.74	3.83	7	3.87	1.81	0.72	3.73
Melanoma	91	83.10	1.10	0.88	1.34	91	86.45	1.05	0.85	1.29
Testis	25	19.46	1.28	0.83	1.90	25	19.09	1.31	0.85	1.93
Prostate	**680**	**629.79**	**1.08**	**1.00**	**1.16**	**680**	**623.24**	**1.09**	**1.01**	**1.18**
Bladder	162	165.97	0.98	0.83	1.14	162	167.31	0.97	0.82	1.13
Kidney	98	84.10	1.17	0.95	1.42	98	88.72	1.10	0.90	1.35
Nervous System	29	33.12	0.88	0.59	1.26	29	31.13	0.93	0.62	1.34
Leukemia	68	66.37	1.02	0.80	1.30	68	70.90	0.96	0.74	1.22
All Other Sites	230	207.43	1.11	0.97	1.26	230	213.22	1.08	0.94	1.23

Note: SIR's in bold indicate significance at the $p<0.05$ level

* State Referent group includes Lake, McHenry, Kane, DuPage, and Will counties.

**County Referent is DuPage County

Source: Illinois State Cancer Registry, data as of November 2017

Table 4 (cont.): Standardized Incidence Ratios for Other Common Cancer Site by Gender and Referent Group*, Study Area 1, 1995-2015

	County Referent**					State Referent*				
	Obs.	Exp.	SIR	95% LCI	95% UCI	Obs.	Exp.	SIR	95% LCI	95% UCI
Females										
Oral Cavity	30	32.03	0.94	0.63	1.34	30	32.01	0.94	0.63	1.34
Esophagus	17	11.91	1.43	0.83	2.28	17	10.91	1.56	0.91	2.50
Stomach	23	25.44	0.90	0.57	1.36	23	25.42	0.90	0.57	1.36
Colorectal	218	215.46	1.01	0.88	1.16	218	221.25	0.99	0.86	1.13
Liver	16	13.37	1.20	0.68	1.94	16	12.79	1.25	0.71	2.03
Pancreas	**77**	**58.74**	**1.31**	**1.03**	**1.64**	**77**	**59.72**	**1.29**	**1.02**	**1.61**
Lung	262	270.36	0.97	0.86	1.09	262	295.00	0.89	0.78	1.00
Bone	1	3.37	0.30	0.00	1.65	1	2.93	0.34	0.00	1.90
Melanoma	57	59.22	0.96	0.73	1.25	57	63.35	0.90	0.68	1.17
Cervix	23	26.66	0.86	0.55	1.29	23	29.96	0.77	0.49	1.15
Uterus	147	149.82	0.98	0.83	1.15	147	145.35	1.01	0.85	1.19
Ovary	**84**	**67.01**	**1.25**	**1.00**	**1.55**	**84**	**65.16**	**1.29**	**1.03**	**1.60**
Bladder	**78**	**56.41**	**1.38**	**1.09**	**1.73**	**78**	**58.62**	**1.33**	**1.05**	**1.66**
Kidney	48	50.93	0.94	0.69	1.25	48	53.31	0.90	0.66	1.19
Nervous System	28	27.33	1.02	0.68	1.48	28	27.20	1.03	0.68	1.49
Leukemia	**38**	**54.80**	**0.69**	**0.49**	**0.95**	**38**	**53.95**	**0.70**	**0.50**	**0.97**
All Other Sites	282	265.95	1.06	0.94	1.19	282	264.54	1.07	0.95	1.20

Note: SIR's in bold indicate significance at the $p<0.05$ level

* State Referent group includes Lake, McHenry, Kane, DuPage, and Will counties.

**County Referent is DuPage County

Source: Illinois State Cancer Registry, data as of November 2017

Table 5: Standardized Incidence Ratios for Other Common Cancer Site by Gender and Referent Group*, Study Area 2, 1995-2015

	County Referent**					State Referent*				
	Obs.	**Exp.**	**SIR**	**95% LCI**	**95% UCI**	**Obs.**	**Exp.**	**SIR**	**95% LCI**	**95% UCI**
Males										
Oral Cavity	120	129.04	0.93	0.77	1.11	120	133.10	0.90	0.75	1.08
Esophagus	74	71.99	1.03	0.81	1.29	74	73.75	1.00	0.79	1.26
Stomach	89	82.54	1.08	0.87	1.33	89	82.20	1.08	0.87	1.33
Colorectal	464	456.83	1.02	0.93	1.11	464	470.03	0.99	0.90	1.08
Liver	71	63.35	1.12	0.88	1.41	71	63.64	1.12	0.87	1.41
Pancreas	115	123.04	0.93	0.77	1.12	115	124.42	0.92	0.76	1.11
Lung	**551**	**603.09**	**0.91**	**0.84**	**0.99**	**551**	**633.77**	**0.87**	**0.80**	**0.95**
Bone	11	7.93	1.39	0.69	2.48	11	8.12	1.36	0.68	2.42
Melanoma	195	172.09	1.13	0.98	1.30	195	178.92	1.09	0.94	1.25
Testis	44	41.58	1.06	0.77	1.42	44	40.73	1.08	0.78	1.45
Prostate	**1,367**	**1,286.83**	**1.06**	**1.01**	**1.12**	**1,367**	**1273.57**	**1.07**	**1.02**	**1.13**
Bladder	335	341.67	0.98	0.88	1.09	335	344.51	0.97	0.87	1.08
Kidney	189	173.30	1.09	0.94	1.26	189	182.82	1.03	0.89	1.19
Nervous System	62	69.21	0.90	0.69	1.15	62	65.03	0.95	0.73	1.22
Leukemia	135	138.30	0.98	0.82	1.16	135	147.47	0.92	0.77	1.08
All Other Sites	467	429.73	1.09	0.99	1.19	467	441.46	1.06	0.96	1.16

Note: SIR's in bold indicate significance at the $p<0.05$ level

* State Referent group includes Lake, McHenry, Kane, DuPage, and Will counties.

**County Referent is DuPage County

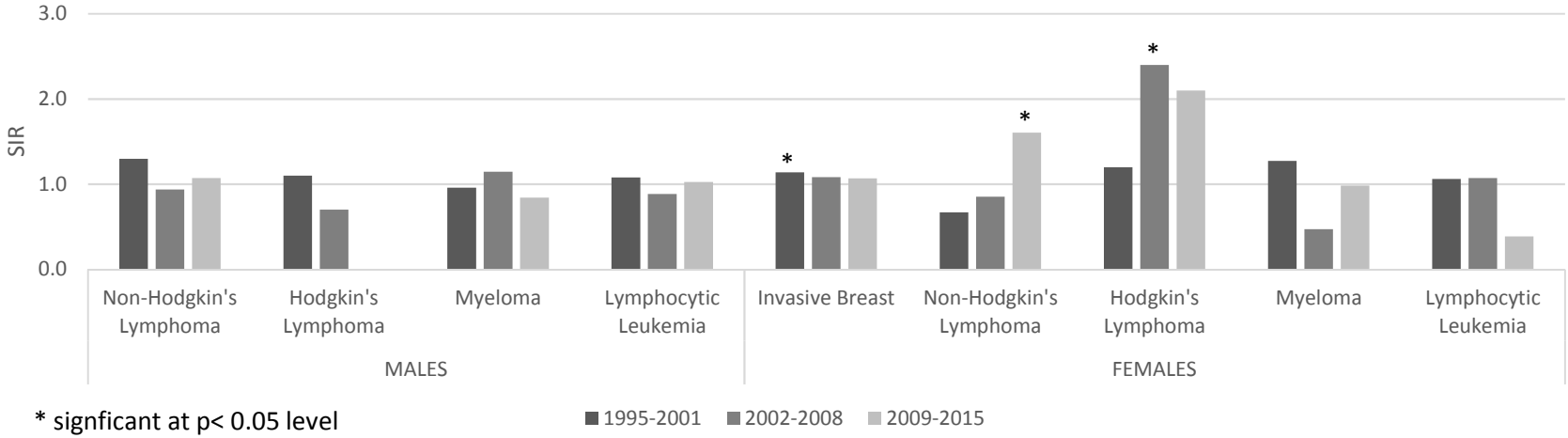
Source: Illinois State Cancer Registry, data as of November 2017

Table 5 (cont.): Standardized Incidence Ratios for Other Common Cancer Sites by Gender and Referent Group, Study Area 2, 1995-2015

	County Referent**					State Referent*				
	Obs.	**Exp.**	**SIR**	**95% LCI**	**95% UCI**	**Obs.**	**Exp.**	**SIR**	**95% LCI**	**95% UCI**
Females										
Oral Cavity	68	68.29	1.00	0.77	1.26	68	68.25	1.00	0.77	1.26
Esophagus	23	25.51	0.90	0.57	1.35	23	23.32	0.99	0.62	1.48
Stomach	61	54.86	1.11	0.85	1.43	61	54.85	1.11	0.85	1.43
Colorectal	483	463.03	1.04	0.95	1.14	483	475.75	1.02	0.93	1.11
Liver	24	28.66	0.84	0.54	1.25	24	27.42	0.88	0.56	1.30
Pancreas	**151**	**126.10**	**1.20**	**1.01**	**1.40**	**151**	**128.22**	**1.18**	**1.00**	**1.38**
Lung	541	575.21	0.94	0.86	1.02	**541**	**627.67**	**0.86**	**0.79**	**0.94**
Bone	3	7.44	0.40	0.08	1.18	3	6.49	0.46	0.09	1.35
Melanoma	114	128.00	0.89	0.73	1.07	114	136.53	0.83	0.69	1.00
Cervix	52	57.62	0.90	0.67	1.18	52	64.93	0.80	0.60	1.05
Uterus	322	315.45	1.02	0.91	1.14	322	306.07	1.05	0.94	1.17
Ovary	152	142.80	1.06	0.90	1.25	152	138.92	1.09	0.93	1.28
Bladder	140	121.13	1.16	0.97	1.36	140	125.64	1.11	0.94	1.31
Kidney	98	108.51	0.90	0.73	1.10	98	113.58	0.86	0.70	1.05
Nervous System	57	58.98	0.97	0.73	1.25	57	58.72	0.97	0.74	1.26
Leukemia	101	118.75	0.85	0.69	1.03	101	116.76	0.87	0.70	1.05
All Other Sites	582	573.88	1.01	0.93	1.10	582	571.07	1.02	0.94	1.11

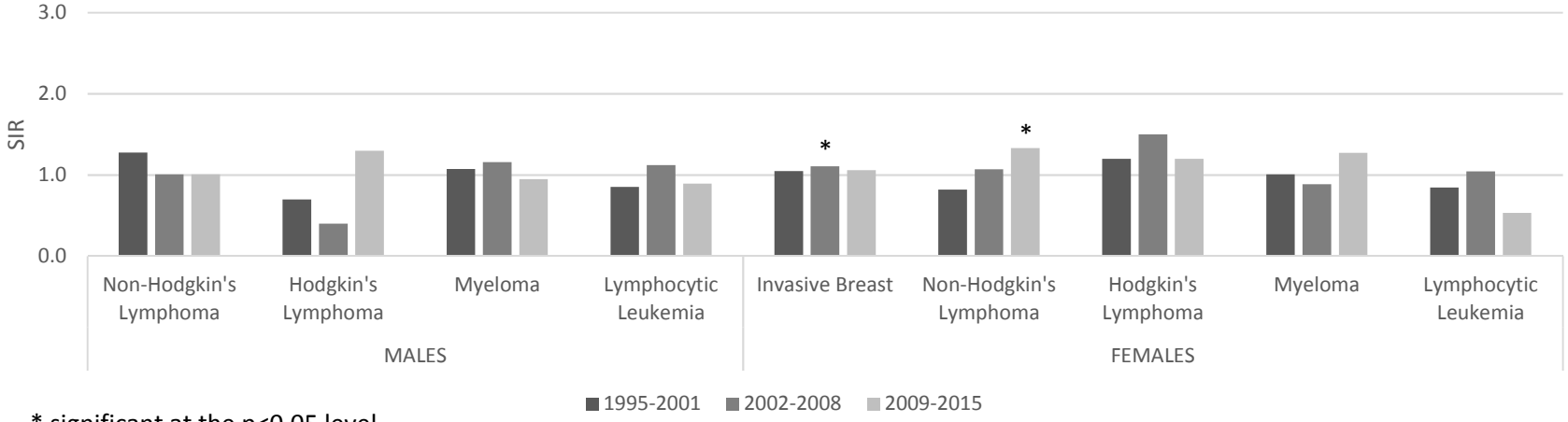
Note: SIR's in bold indicate significance at the p<0.05 level
* State Referent group includes Lake, McHenry, Kane, DuPage, and Will counties.
**County Referent is DuPage County
Source: Illinois State Cancer Registry, data as of November 2017

Figure 1: Temporal Trends in EtO Related SIR's by Gender and Site, Study Area 1, State Referent, 1995-2015



* signficant at p< 0.05 level

Figure 2: Temporal Trends in EtO Related SIR's by Gender and Site, Study Area 2, State Referent, 1995-2015



* significant at the p<0.05 level

Table 7: Pediatric Cancer Standardized Incidence Ratios for Study Area 1 and 2 by Gender, State Referent Group*, <20 years old, 1995-2015

STATE REFERENT	Study Area 1					Study Area 2				
	Obs.	Exp.	SIR	95% LCI	95% UCI	Obs.	Exp.	SIR	95% LCI	95% UCI
Males										
Leukemia	3	4.26	0.70	0.14	2.06	9	9.65	0.93	0.43	1.77
Lymphomas	5	2.69	1.86	0.60	4.34	7	5.69	1.23	0.49	2.54
Central Nervous System	1	2.48	0.40	0.01	2.24	2	5.50	0.36	0.04	1.31
Neuroblastomas	0	0.58	0.00	---	---	2	1.41	1.42	0.16	5.13
Retinoblastoma	0	0.16	0.00	---	---	0	0.41	0.00	---	---
Renal Tumors	0	0.38	0.00	---	---	0	0.91	0.00	---	---
Hepatic Tumors	0	0.17	0.00	---	---	1	0.40	2.50	0.03	13.90
Bone	2	0.93	2.14	0.24	7.73	3	1.95	1.54	0.31	4.50
Soft tissue	0	0.98	0.00	---	---	1	2.18	0.46	0.01	2.56
Germ Cell Tumors	0	1.60	0.00	---	---	1	3.33	0.30	0.00	1.67
Other malignant melanomas	1	1.09	0.92	0.01	5.10	4	2.26	1.77	0.48	4.52
Other unspecified	0	0.03	0.00	---	---	0	0.06	0.00	---	---
Not Classified	0	0.03	0.00	---	---	0	0.07	0.00	---	---
Females										
Leukemia	5	3.20	1.56	0.50	3.64	5	7.29	0.69	0.22	1.60
Lymphomas	**7**	**2.36**	**2.96**	**1.19**	**6.11**	**11**	**4.98**	**2.21**	**1.10**	**3.96**
Central Nervous System	3	2.10	1.43	0.29	4.17	4	4.67	0.86	0.23	2.19
Neuroblastomas	0	0.53	0.00	---	---	0	1.25	0.00	---	---
Retinoblastoma	0	0.18	0.00	---	---	0	0.43	0.00	---	---
Renal Tumors	0	0.65	0.00	---	---	0	1.55	0.00	---	---
Hepatic Tumors	1	0.12	8.42	0.11	46.87	1	0.28	3.59	0.05	19.95
Bone	0	0.82	0.00	---	---	0	1.72	0.00		
Soft tissue	3	0.98	3.07	0.62	8.96	3	2.11	1.42	0.29	4.15
Germ Cell Tumors	1	0.78	1.29	0.02	7.18	3	1.64	1.83	0.37	5.34
Other malignant melanomas	2	2.67	0.75	0.08	2.71	9	5.50	1.64	0.75	3.10
Other unspecified	0	0.03	0.00	---	---	0	0.06	0.00	---	---
Not Classified	0	0.01	0.00	---	---	0	0.02	0.00	---	---

Note: SIR's in bold indicate significance at the p<0.05 level

* State Referent group includes Lake, McHenry, Kane, DuPage, and Will counties.

Source: Illinois State Cancer Registry, data as of November 2017
Site/Histology Recode Based on International Classification of Childhood Cancer, third Edition (ICCC-3) Based on ICD-O-3 / WHO 2008

APPENDIX A: Standardized Incidence Ratio and Confidence Limits

Various authors discuss the standardized mortality ratio (SMR) and provide exact and approximate confidence limits for the true SMR. These results are also applicable to the standardized incidence ratio (SIR). The following sections provide a brief outline of the results and give references to more detailed discussions.

Definition of the SIR

Suppose the person-time from the study group (i.e. cohort) is allocated among *M* cells defined by the cross-classification of various adjustment variables such as gender, race, attained age group, and attained calendar year group. Let *tk* represent the person-time and *Dk* represent the observed events that the cohort subjects contribute to the *k*th cell, and let λ_k^* represent the standard rate for the *k*th cell, where *k* = 1, 2, ..., *M*. Given this notation, the SIR is defined as

$$\mathrm{SIR} = \frac{\sum_{k=1}^{M} D_k}{\sum_{k=1}^{M} t_k \lambda_k^*} = \frac{D}{E^*}$$

where the total number of events observed in the cohort is $D = \sum_{k=1}^{M} D_k$, and the total number of expected events is $E^* = \sum_{k=1}^{M} E_k^* = \sum_{k=1}^{M} t_k \lambda_k^*$ (Breslow and Day,1987; Sahai and Khurshid,1996).

Approximate Confidence Limits for the True SIR

The approximate limits for the true SIR, *Φ*, are $\mathrm{SIR}_{\hat{L}} = \frac{D}{E^*}\left(1 - \frac{1}{9D} + \frac{Z_{\alpha/2}}{3\sqrt{D}}\right)^3$ and

$$\mathrm{SIR}_{\hat{U}} = \frac{D+1}{E^*}\left(1 - \frac{1}{9(D+1)} + \frac{Z_{1-\alpha/2}}{3\sqrt{D+1}}\right)^3$$

where *Zα* is the 100*α* percentile of the standard normal distribution (Rothman and Boice, 1979, 1982;

Breslow and Day, 1987; Sahai and Khurshid, 1993, 1996). Rothman and Boice (1979, 1982) mention that these limits were first proposed by Byar (unpublished).

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STATE OF ILLINOIS UNITED STATES OF AMERICA COUNTY OF DU PAGE

IN THE CIRCUIT COURT OF THE EIGHTEENTH JUDICIAL CIRCUIT

PEOPLE OF THE STATE OF ILLINOIS, ex rel. KWAME RAOUL, et al.,

Plaintiff,

v.

STERIGENICS U.S., LLC, a Delaware limited liability company,

Defendant,

2019 CH 001329

Case Number

File Stamp Here

EXHIBIT COVER SHEET

Local Court Rules 5.06 and 5.09

EXHIBIT NAME: Exhibit C to Exhibit 1-Affidavit of Attorney Andrew Y. Acker

TITLE OF DOCUMENT THIS EXHIBIT BELONGS WITH:

Exhibit 1 to Intervenors' Comments to Consent Order

Document File Date: August 23, 2019

(The file date of the document this exhibit belongs with)

EXHIBIT FILED ON BEHALF OF: Village of Willowbrook and Village of Burr Ridge

(Case Party Name)

Submitted by: Andrew Y. Acker

Name: **Andrew Y. Acker** ☐ Pro Se
DuPage Attorney Number: **7620**
Attorney for: **Villages of Willowbrook and Burr Ridge**
Address: **9501 W. Devon Avenue, Suite 800**
City/State/Zip: **Rosemont, IL 60018**
Telephone Number: **847.318.9500**
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Summary of U.S. EPA's Risk Assessment of Ethylene Oxide Emissions from the Sterigenics Commercial Sterilizer in Willowbrook, Illinois

About U.S. EPA's risk assessment:

U.S. EPA used the same, standard methods that we use when we conduct risk assessments for regulations to assess risk from lifetime exposure to ethylene oxide emissions from the Sterigenics Commercial Sterilizer in Willowbrook, Illinois. The assessment:

- For people living near the facility, assumes people are exposed to ethylene oxide 24 hours a day, 365 days a year for 70 years (to represent lifetime exposure)
- For people working near, but not in, the facility, assumes assumed people were exposed for 8.5 hours a day, five days a week, 50 weeks a year for 25 years.
- Estimates the risk of getting cancer that is *in addition* to people's overall risk of getting cancer for other reasons.
- Focuses on the *risk from ethylene oxide emissions* from the Sterigenics facility; it does not address comprehensive risk from all pollutants and all air pollution sources
- Projects risk going forward. It does not estimate past risk.
- Provides general estimates of risk to *populations*. It cannot predict any one person's risk of developing cancer.
- Is more likely to over-estimate risk than underestimate risk due to what we call 'health-protective assumptions
- The **full risk assessment report is available at** www.epa.gov/il/risk-assessment-report-sterigenics-facility-willowbrook-il

What we assessed

U.S. EPA assessed the risk of getting cancer from lifetime exposure to ethylene oxide emitted from the Sterigenics Willowbrook facility.

We looked at two scenarios:

1. A scenario focused on what risks would be if the facility was operating -- after the back vent was controlled and before the Illinois EPA issued a seal order preventing the facility from using ethylene oxide.
2. An example future scenario, called the "illustrative future case." This scenario looked at what future risks could be if the facility was more highly controlled.

For each scenario, U.S. EPA estimated risk for **people who live in the area,** including communities in Willowbrook, Burr Ridge, Hinsdale, Darien and Indian Head Park. We also estimated risk for **people who work close to the facility** (but not at the facility).

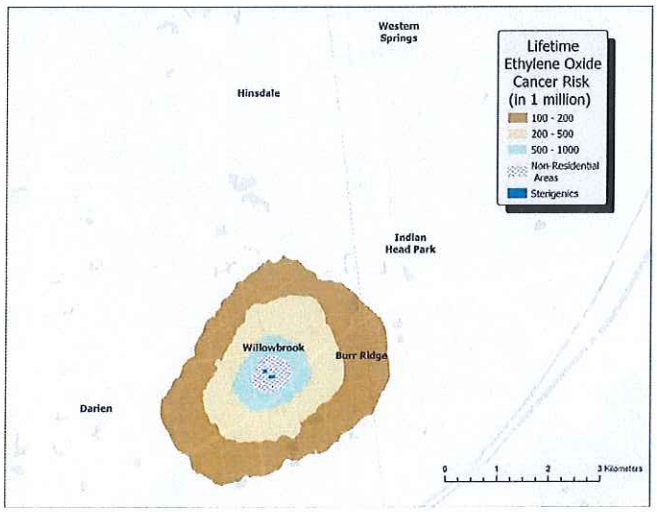
What we found

- **Estimated risks would be below 100 in 1 million – and potentially as low as 1 in 1 million -- if the facility was more highly controlled.**
    - A 1-in-a-million risk means that 1 person out of a million people who were breathed air containing ethylene oxide for a lifetime could develop cancer as a result of that exposure.

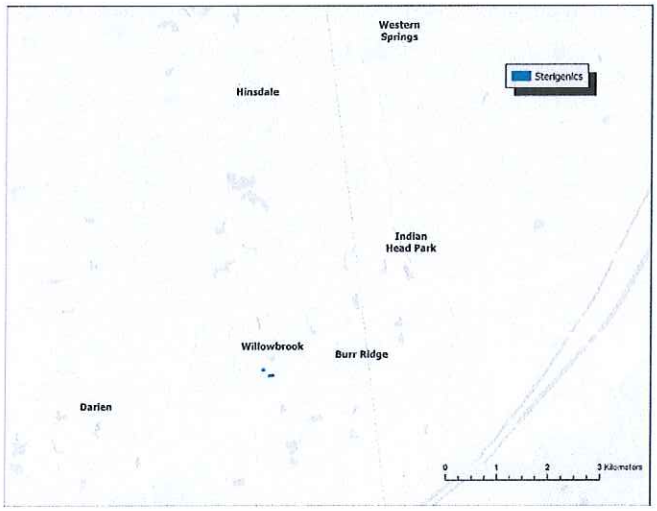
EXHIBIT
C to Affidavit

- For **residential areas,** the estimated risks from lifetime exposure while the facility was operating ranged from less than 100 in 1 million to 1,000 in a million in areas closest to the facility. The assessment estimated that *future* risks would be below 100 in million – and potentially as low as 1 in 1 million -- if the facility was more highly controlled.

Estimated cancer risk in residential areas based on operations before seal order, and reflecting emission controls installed in Summer 2018

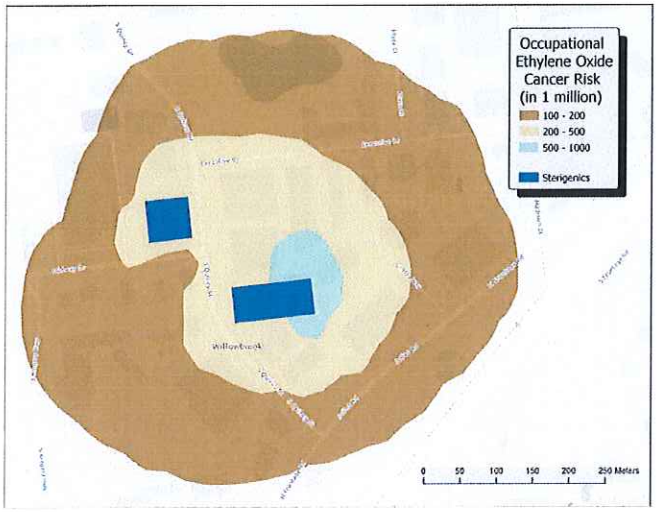


Illustrative future case: estimated cancer risk in residential areas if the facility were highly controlled

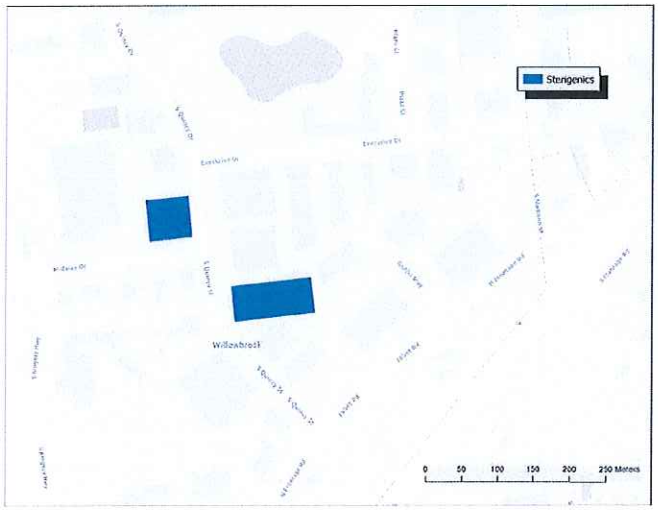


- For **areas where people work near the facility,** the estimated risks while the facility was operating ranged from 200 in 1 million to 1,000 in a million just outside the facility. Estimated *future* risks would be below 100 in million – and potentially as low as 1 in 1 million -- if the facility was more highly controlled.

Estimated cancer risks for people working near the Sterigenics facility, based on operations before seal order, and reflecting emission controls installed in Summer 2018



Illustrative future case: estimated cancer risks for people working near, but not at, the Sterigenics facility if the facility were highly controlled



Risk Assessment Report
for the Sterigenics Facility in Willowbrook, Illinois

EPA's Office of Air Quality Planning and Standards
Office of Air and Radiation
August 2019

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Index of Acronyms

AERMOD	American Meteorological Society/EPA Regulatory Model
AEGL	Acute exposure guideline level
ASTDR	US Agency for Toxic Substances and Disease Registry
CalEPA	California Environmental Agency
ERPG	Emergency Response Planning Guideline
HAP	Hazardous Air Pollutant(s)
HEM	Human Exposure Model
HI	Hazard index
HQ	Hazard quotient
IRIS	Integrated Risk Information System
MACT	Maximum Achievable Control Technology
MIR	Maximum Individual Risk
MOA	Mode of action
NAC	National Advisory Committee
NAAQS	National Ambient Air Quality Standards
NATA	National Air Toxics Assessment
NEI	National Emissions Inventory
PB-HAP	Persistent and Bioaccumulative – HAP
PAH	Polycyclic aromatic hydrocarbon
POM	Polycyclic organic matter
REL	Reference exposure level
RfC	Reference concentration
RfD	Reference dose
RTR	Risk and Technology Review
TOSHI	Target-organ-specific hazard index
URE	Unit risk estimate

Executive Summary

This document describes the risk assessment that the U.S. Environmental Protection Agency (EPA) conducted to assess the human health risks posed by emissions of the hazardous air pollutant (HAP) ethylene oxide (EtO) from the Sterigenics facility in Willowbrook, IL. The facility is a commercial sterilizer subject to the National Emission Standards for Hazardous Air Pollutants (NESHAP) for Ethylene Oxide Commercial Sterilization and Fumigation Operations under 40 CFR part 63, subpart O. Facilities in the commercial EtO sterilization source category, including the Sterigenics facility in Willowbrook, are engaged in commercial sterilization or fumigation using EtO as a sterilant for heat- and moisture-sensitive products and as a fumigant to control microorganisms or insects. Generally, EtO is used to sterilize or fumigate medical equipment (e.g., syringes and surgical gloves), spices, pharmaceuticals, and cosmetics. Emission points included in the assessment are those where EtO can be released during the sterilization cycle, including: sterilization chamber vent(s); sterilization chamber vacuum pump drain; chamber exhaust vent(s) (i.e., the "backvent"); aeration room vent(s); and fugitives.

The EPA conducts risk assessments for regulatory and non-regulatory purposes. The risk assessment described in this document is not part of a regulatory activity, however, the approaches the EPA used in this assessment are similar to those used in the regulatory residual risk and technology review (RTR) program. Typically, the risk assessments we perform are conducted under Section 112 of the Clean Air Act (CAA), which establishes a two-stage regulatory process for addressing emissions of HAP from stationary sources. In the first stage, the EPA must promulgate technology-based NESHAP for categories of sources. For NESHAP that require maximum achievable control technology (MACT) standards, the EPA is required to complete a second stage of the regulatory process eight years after adopting the MACT standards, which is known as the residual risk review. In this second stage, the EPA is required to assess the health and environmental risks that remain after implementation of the technology-based standards. The EPA must also review each of the technology-based standards at least every eight years and revise them, as necessary, taking into account developments in practices, processes and control technologies. For efficiency, the Agency includes the analyses for both reviews in the same regulatory package and calls these rulemakings Risk and Technology Reviews (RTRs). The EPA completed the RTR review for the commercial EtO sterilization NESHAP in 2006.

This risk assessment examined two scenarios: (1) a baseline scenario reflecting operations of the facility prior to a February 2019 Seal Order issued by the State of Illinois (facility emissions under this scenario are approximately 4,000 pounds per year); and (2) an illustrative future scenario in which all emission points are routed to a control device and are released to the atmosphere from a single 26.5 m (87 ft) stack (facility emissions under this scenario are 26 pounds per year). EtO was the only pollutant included in this risk assessment.

We only assessed human health risks from EtO inhalation exposures. EtO is not a persistent and bioaccumulative HAP (PB-HAP), therefore a multipathway risk assessment is not warranted. The EPA evaluates 8 HAP for adverse environmental effects. These

"environmental HAP" were selected by the EPA based on their persistence and bioaccumulation potential, magnitude of emissions, and relative environmental toxicity. Because EtO is not an environmental HAP, an environmental risk screening assessment is not warranted.

Several key points about this risk assessment are worth noting. The assessment:

- Assumes people are exposed to ethylene oxide 24 hours a day, 365 days a year for 70 years to represent lifetime exposures (non-residential exposure[1] durations are lower).
- Estimates the risk of getting cancer that is *in addition* to people's overall risk of getting cancer for other reasons.
- Focuses only on the *risk from ethylene oxide emissions* from the Sterigenics facility (it does not address comprehensive risk from all pollutants and all air pollution sources).
- Projects risk going forward. It does not estimate past risk.
- Provides general estimates of risk to *populations*. It cannot predict any one person's risk of developing cancer.
- Is more likely to over-estimate risk than underestimate risk due to what we call "health-protective" assumptions

The table below summarizes the results of the baseline risk assessment for the facility. The results of the chronic (long-term, i.e., 70-year lifetime) inhalation cancer risk assessment indicate that the maximum lifetime (residential) individual cancer risk is 1,000-in-1 million.[2] The total estimated cancer incidence[3] from this facility is 0.3 excess cancer cases per year, or one excess case in every three years. Approximately 7.7 million people live within 50 kilometers of this facility and 60 people are estimated to have cancer risks equal to 1,000-in-1 million from EtO emitted from this facility. The estimated non-residential maximum cancer risk is also 1,000-in-1 million. It is a coincidence that the risk results for non-residents and residents were the same: the analyses for these two populations were based on different modeled ambient concentrations and different exposure assumptions (see Section 2.3 for details). Population risks are not estimated for the non-resident scenario because there are no data available to estimate with specificity where people would be, or for how long, or how many people there would be at specific locations.

[1] Non-residential locations are where people could spend a significant amount of time, but less than a lifetime (for example, an offsite worker).

[2] Risk results are typically presented by the EPA using one significant figure in light of the uncertainties inherent in these analyses - see, for example, Section 4 of this document.

[3] In this risk assessment context, estimated cancer incidence is the predicted (based on modeling) number of excess cancer cases per year due to emissions of ethylene oxide from Sterigenics. It is not a count of actual cancer cases, which might be provided in other types of studies.

Risk Summary for the Sterigenics Facility in Willowbrook, Illinois
"Baseline" Scenario Reflecting Emissions Prior to Seal Order

	Inhalation Cancer Risk	Population Cancer Risk					Max Chronic Individual Noncancer Risk	Max Acute Noncancer Risk
	Maximum Individual Risk (in 1 million)	Cancer Incidence (cases per year)	Cancer Incidence (years for 1 case)	= 1000 in 1 million	≥ 100 in 1 million	≥ 1 in 1 million	Hazard Index (TOSHI)	Hazard Quotient (HQ)
Residential	1,000	0.3	3	60	11,500	6,500,000	0.01	0.02
Non-Residential	1,000	NA[a]	NA[a]	NA[a]	NA[a]	NA[a]	0.01	0.02

[a] NA = not applicable. Population risks were not estimated for non-residents because there are no data available to estimate with specificity where people would be, or for how long, or how many people there would be at specific locations.

The EPA also examined noncancer risk as part of the assessment, finding the residential maximum chronic noncancer hazard index (neurological) for the facility is 0.01. Of the approximately 7.7 million people living within 50 kilometers of the facility, no one is exposed to noncancer hazard index levels above 1. The non-residential maximum chronic noncancer hazard index for the facility is 0.01. The low hazard index estimates indicate that we do not expect any chronic noncancer effects to occur.

Regarding acute (short-term) noncancer health risks posed by baseline emissions, the highest screening acute hazard quotient is estimated to be 0.02 using the AEGL-2[4] value for EtO. This hazard quotient is based on a 1-hour exposure anywhere off facility property, so there is no distinction made between resident and non-resident. The low hazard quotient estimates indicate that we do not expect any acute noncancer effects to occur.

The table below summarizes the results of the risk assessment for the illustrative future scenario. The maximum lifetime (residential) individual cancer risk is 1-in-1 million, which occurs at a single residential grid receptor. All cancer risks at census blocks are less than 1-in-1 million. The total estimated cancer incidence is 0.002 excess cancer cases per year, or one excess case in every 700 years within the entire modeling domain. Over 70 years, the estimated number of cancer cases is less than 1 (0.1). Approximately 70,000 people are estimated to have cancer risks between 0.1- and 1-in-1 million, so the remaining 7.6 million people within the modeling domain have estimated cancer risk less than 0.1-in-1 million. The maximum chronic noncancer hazard index is 6E-6 (neurological). For non-residential exposures, the maximum cancer risk is 0.08-in-1 million, and the maximum chronic noncancer hazard index is 9E-7 (neurological). The highest screening acute HQ was 4E-6 (based on the 1-hr AEGL-2 value for EtO). These estimates indicate low cancer risk and we do not expect any chronic or acute noncancer effects to occur.

[4] Acute exposure guideline levels (AEGLs) describe the human health effects from once-in-a-lifetime, or rare, exposure to airborne chemicals. The AEGL-2 is the airborne concentration (expressed as ppm or mg/m3) of a substance above which it is predicted that the general population, including susceptible individuals, could experience irreversible or other serious, long-lasting adverse health effects or an impaired ability to escape.

Risk Summary for the Sterigenics Facility in Willowbrook, Illinois
Illustrative Future Scenario

	Inhalation Cancer Risk	Population Cancer Risk					Max Chronic Individual Noncancer Risk	Max Acute Noncancer Risk
	Maximum Individual Risk (in 1 million)	Cancer Incidence (cases per year)	Cancer Incidence (years for 1 case)	= 1000 in 1 million	≥ 100 in 1 million	≥ 1 in 1 million	Hazard Index (TOSHI)	Hazard Quotient (HQ)
Residential	1[a]	0.002	700	0	0	0	6E-6	4E-6
Non-Residential	0.08	NA[b]	NA[b]	NA[b]	NA[b]	NA[b]	9E-7	4E-6

[a] The maximum risk of 1-in-1 million occurs at a single residential receptor. All cancer risk estimates at census blocks are less than 1-in-1 million, so the population estimated to be greater than or equal to 1-in-1 million is zero.

[b] NA = not applicable. Population risks were not estimated for non-residents because there are no data available to estimate with specificity where people would be, or for how long, or how many people there would be at specific locations.

This document summarizes the methods and results of the risk assessment for this facility. Section 1 provides an introduction to the risk assessment, including key questions to be addressed. Methods described in Section 2 include those used by the EPA to develop refined estimates of chronic inhalation exposures and human health risks for cancer and noncancer endpoints, as well as those used to screen for acute health risks. The risk assessment results are presented in Section 3. Section 4 contains a discussion of the uncertainties of the risk assessment, including uncertainties in the exposure assessment and in the dose-response values. The appendices to this risk report contain detailed descriptions of the methods used to develop emissions estimates, process meteorological data, and conduct dispersion modeling.

1 Introduction

The EPA conducts risk assessments for regulatory and non-regulatory purposes. The risk assessment described in this document is non-regulatory, however the approaches the EPA used in this assessment are similar to those used in the regulatory residual risk and technology review (RTR) program. More information on the RTR program, source categories included in the program, the EPA's statutory authorities, and our risk-related framework for decision making can be found on the RTR website at https://www3.epa.gov/ttn/atw/rrisk/rtrpg.html.

The EPA conducted this risk assessment for EtO emissions from the Sterigenics facility in Willowbrook, Illinois to answer several questions:

- What is the estimated maximum cancer risk in the area of highest concentration where people live?
- What is the estimated maximum cancer risk in the area of highest concentration where people work (offsite – not at the facility)?
- How many people have different levels of risk in the neighboring communities?
- What is the estimate of possible cancer cases per year?

The assessment is not designed to predict any individual's risk. Also, it cannot look retrospectively at potential risk experienced in the past, e.g., from the time the facility opened until today. It is designed to assess risks from EtO emissions from this specific facility, not

all risks from EtO exposure that an individual may face. Additional limitations or uncertainties are described in Section 4.

The remaining sections of the document contain the methods we used to conduct the risk assessment (Section 2), the results of the risk assessment (Section 3), and a description of associated uncertainties (Section 4). More detailed information about some of the inputs can be found in the appendices.

2 Methods

A risk assessment consists of four steps: 1) hazard identification, 2) dose-response assessment, 3) exposure assessment, and 4) risk characterization. The first step, hazard identification, determines whether the pollutants of concern can be linked to the health effects in question (cancer and/or noncancer). In our regulatory program, Section 112 of the CAA identifies the HAP to be considered in the risk assessment for a source category. For this facility-specific risk assessment, we are assessing the HAP EtO in the hazard identification step. The second step is the dose-response assessment, which quantifies the relationship between the dose of a pollutant and the resultant health effects. Dose-response assessments are performed by the EPA through the Integrated Risk Information System (IRIS) process as well as by other agencies, such as the Agency for Toxic Substances and Disease Registry (ATSDR). See Section 2.5 of this document for more information on dose-response assessments. The third and fourth steps, the exposure assessment and the risk characterization, respectively, are specific to the facility and are described throughout this report. The exposure assessment includes characterization of HAP emissions, environmental fate and transport, and population exposure for the inhalation pathway. The fourth and final step, risk characterization, integrates all the information from the previous steps and describes the outcome of the assessment. This four-step approach to risk assessment was endorsed by the National Academy of Sciences in its publication "Science and Judgment in Risk Assessment" (NAS, 1994) and subsequently was adopted in the EPA's "Residual Risk Report to Congress" (USEPA, 1999).

The EPA conducts risk assessments that provide estimates of the maximum individual risk (MIR) posed by the HAP emissions from each source, the target-organ-specific hazard index (TOSHI) for chronic exposures to HAP with potential to cause chronic (or long-term) noncancer health effects, and the hazard quotient (HQ) for acute exposures to HAP with the potential to cause acute (or short-term) noncancer health effects. The MIR is defined as the cancer risk associated with a lifetime of exposure at the highest concentration of HAP where people are likely to live. The HQ is the ratio of the potential exposure to the HAP to the level at or below which no adverse effects are expected; the TOSHI is the sum of chronic HQs for HAP that affect the same target organ or organ system. The risk assessment also provides estimates of the distribution of cancer risks within the exposed residential populations as well as cancer incidence. The following sections describe how we estimate HAP emissions and conduct steps three and four of the risk assessment. The methods used to assess risks are consistent with those peer-reviewed by a panel of the EPA's Science Advisory Board (SAB) in 2009 (USEPA, 2009a) and described in their peer review report issued in 2010 (USEPA 2010). In 2017, we submitted updated methodologies to SAB for review. The updated methodologies are described in, "Screening Methodologies to Support Risk and Technology

Reviews (RTR): A Case Study Analysis" (USEPA, 2017a). The SAB's findings for this review, "Review of EPA's draft technical report entitled Screening Methodologies to Support Risk and Technology Reviews (RTR): A Case Study Analysis" (USEPA, 2018a) were submitted to the EPA in September 2018.

2.1 Emissions and source data

The Sterigenics Willowbrook facility consists of two buildings separated by approximately 100 meters (m). To develop baseline emissions estimates and other source data for the facility, we used information provided by Sterigenics regarding their operations and estimated emissions rates and operational parameters from both the controlled and uncontrolled sources. We used this information and derived site-specific emission factors from previous stack testing results for the "controlled" sources and estimated site-specific emission factors for the uncontrolled or "fugitive" emissions. Emissions factors are representative values that attempt to relate the quantity of a pollutant released to the atmosphere with an activity associated with the release of that pollutant and are generally assumed to be representative of long-term averages. Using dispersion modeling, the EPA evaluated the accuracy of these factors and made the necessary adjustments to these factors to better match the observed ambient measurement values at the monitoring sites near the facility with the modeled value. The total EtO baseline emissions from the facility are approximately 2 tons per year and come from the two buildings. Each building has the following sources: sterilizer vacuum pump, aeration room, sterilizer back vent, and fugitives. Details on the development of the source data, emissions, and associated uncertainties for the baseline emissions data for this facility can be found in Appendix 1 (*Development of Ethylene Oxide Emissions Rates Used for Risk Assessment*). We also assessed an illustrative future scenario, where we assumed that all emissions come from one building, and that all remaining emissions come from one stack. We assumed that all fugitives are captured and routed to a control device. Future case emissions are estimated at 26 lbs/yr.[5]

2.2 Dispersion modeling for inhalation exposure assessment

For risk analyses, we estimate both long- and short-term inhalation exposure concentrations and associated health risks from each facility of interest. To do this, we use the Human Exposure Model 3 (HEM-3), which includes the American Meteorological Society/EPA Regulatory Model (AERMOD) for dispersion modeling. HEM-3 performs three main operations: atmospheric dispersion modeling, estimation of individual human exposures and health risks, and estimation of population risks. The approach used in applying this modeling system for the assessment of Sterigenics is outlined below and is similar to the approach used for assessments conducted under the RTR program. Details on the use of HEM-3 for RTR

[5] This scenario was developed considering information available to EPA in April/May 2019, such as a draft permit application for another commercial sterilizer in Illinois and conversations with the state and the company on a possible control scenario. Subsequently, a draft permit for Sterigenics was issued by Illinois EPA on July 15, 2019, based on a permit application submitted by the company on June 24, 2019. The draft permit (and associated permit application) reflect similar, albeit not identical, emissions and operating parameters. For example, allowable emissions in the draft permit, while lower than our estimated baseline emissions, are somewhat higher than our illustrative future emissions. As a result, calculated risks (for these higher future emissions) would be greater than those modeled in this assessment but are still in the range of 1- to 10-in-1 million.

assessments are provided in Appendix 2 to this document (*Technical Support Document for HEM-3 Modeling*). This section focuses on the dispersion modeling component.

The dispersion model in HEM-3, AERMOD version 18081, is a state-of-the-science Gaussian plume dispersion model that is preferred by the EPA for modeling point, area, and volume sources of continuous air emissions from facility applications (USEPA, 2017b). Further details on AERMOD can be found in the AERMOD User's Guide (USEPA, 2018b) and the AERMOD Implementation Guide (USEPA, 2018c). The model is used to estimate annual (or multi-year) average ambient concentrations through the simulation of hour-by-hour dispersion from the emission sources into the surrounding atmosphere. Unless data are available on the hours of operation for a source category, default hourly emission rates used for this simulation are generated by evenly dividing the total annual emission rate from the inventory into the 8,760 hours of the year.

The first step in the application of HEM-3 is to predict ambient concentrations at locations of interest. The AERMOD model options used for this assessment are summarized in Table 2.2-1 and are discussed further below.

Table 2.2 - 1. AERMOD version 18081 Model Options for Risk Assessment Modeling

Modeling Option	*Selected Parameter for chronic exposure*
Type of calculations	Hourly ambient concentration
Source types	Point
Receptor orientation	Polar (13 rings and 16 radials) Discrete (census block centroids, monitor locations, and additional gridded receptors)
Terrain characterization	Actual from USGS 1/3-arc-second DEM data
Building downwash	Included
Plume deposition/depletion	Not included
Urban source option	Urban (population = 50,000)
Meteorology	5-year representative data from nearby sites (Argonne National Lab and Midway Airport) for years 2014-2018

In HEM-3, meteorological data are ordinarily selected from a list of more than 800 National Weather Service (NWS) surface observation stations across the continental United States, Alaska, Hawaii, and Puerto Rico, and HEM-3 defaults to the station closest to each modeled facility. We use data from other stations in special circumstances if we have reason to believe that other data are more representative for certain facilities. The NWS station closest to the Sterigenics facility is Chicago Midway International Airport (approximately 16 km east). While Midway can be considered adequately representative of the facility in the absence of other data, given the proximity of Argonne National Laboratory to the facility (7 km southwest), the EPA concluded that meteorological data collected at Argonne would be more representative of conditions at the facility than data from Midway. The Argonne

meteorological tower had measurements of wind, temperature, and turbulence (standard deviation of wind direction) at 10 m and 60 m vertical levels, making a more robust dataset over standard airport observations which have one level of data without turbulence measurements. Missing data for some parameters in the Argonne data were supplemented with data from Midway. Upper air data were obtained from the nearest NWS site with such data available, which is Davenport Municipal Airport in Davenport, Iowa. We processed 5 years of data for the years 2014 through 2018 (the most recent five full years available) using the AERMET meteorological data preprocessor. In 2016, the Agency released to the public on the EPA's Support Center for Regulatory Atmospheric Modeling (SCRAM) website both AERMET and AERMOD (version 18081). Appendix 3 to this document (*Meteorological Data for HEM-3 Modeling*) provides detailed information on the sources of meteorological data, why we selected the data we used, and how we processed those data for use in AERMOD.

The HEM-3 model estimates ambient concentrations at the geographic centroids of populated census blocks (using the 2010 Census) and at a set of "polar" receptors, which are the intersection points of a set of concentric rings and outward radials that are centered on the facility. Census blocks are the finest resolution data available in the Census, and each block contains approximately 50 people or about 20 households based on national averages. The 50 km (radius) modeling domain centered on the Sterigenics facility is more densely populated than the national average, with the average block in the modeling domain containing about 70 people. We calculate long-term exposure and risk at the census blocks, and we also model short-term concentrations at the blocks. The population data for the census blocks are used to calculate cancer incidence and population risks. The polar receptors are used to estimate long- and short-term exposures at locations that may be closer to the facility than the census blocks (for example, to represent a residence that is closer). The polar receptors are also used to interpolate values for census blocks far from the facility because by default HEM-3 only explicitly models (in AERMOD) block locations within 3 km of the facility. For this assessment, we used polar receptors based on the HEM-3 default of 13 concentric rings and 16 radials (one every 22.5 degrees), but HEM-3 does allow the user to change the number of rings and radials. In addition to the census blocks and polar receptors, we also included a set of nested grid receptors, which were spaced 50 m apart within a 1 km square centered on the facility and spaced 100 m apart within a 2 km square centered on the facility. Using these dense grid receptors near the facility allowed for the estimation of exposures at potential non-residential locations where people could spend a significant amount of time, but less than a lifetime (for example, an offsite worker). Finally, we included as receptors the locations of ambient monitors that collected air samples from mid November 2018 to the end of March 2019. The coordinates of the monitors are given in Table 2.2-2, along with the distance and direction from the facility.

Table 2.2 - 2. Monitor Receptors

Monitor	*Longitude*	*Latitude*	*Distance and Direction from Facility*
EPA warehouse	-87.938738	41.747442	100 m SE
Gower Elementary School	-87.956186	41.748843	1.2 km W
Gower Middle School	-87.933929	41.743473	700 m SE
Hinsdale South High School	-87.948504	41.753694	900 m NW
Village Hall	-87.941100	41.748598	100 m NW
Water tower	-87.939173	41.755373	800 m N
West neighborhood	-87.945561	41.748773	400 m W
Willow pond park	-87.939850	41.763988	1.7 km N

Figure 2.2-1 shows the populated census blocks near the facility, along with the boundaries of those blocks. The monitor locations are also given in this figure. Figure 2.2-2 shows the nested grid of receptors, distinguished by whether they fall in residential areas or non-residential (commercial/industrial) areas. Figure 2.2-3 shows the first five rings of the polar receptors, with the first ring set by default to include all emission points at the facility.

HEM-3 accounts for the effects of multiple facilities when estimating concentration impacts at each block centroid. We typically combine the impacts of all facilities within the same source category and assess chronic exposure and risk for all census blocks with at least one resident (i.e., locations where people may reasonably be assumed to reside rather than receptor points at the fenceline of a facility). For this assessment, we considered only the Sterigenics facility. We calculate long-term ambient concentrations as the annual (or multi-year) average of all estimated short-term (one-hour) concentrations at each receptor. We do not consider possible future residential use of currently uninhabited areas, but this would not impact this assessment because the areas around the facility are already fully developed.

We determine census block elevations for HEM-3 nationally from the US Geological Survey 1/3 Arc Second National Elevation Dataset, which has a spatial resolution of about 10 meters. We also used these elevation data to estimate elevations of the nested grid receptors. Each polar receptor is assigned the highest elevation of any census block in its neighborhood (all blocks closer to that polar receptor than any other polar receptor). If an elevation is not provided for an emission source, HEM-3 uses the average elevation of all polar receptors on the innermost polar ring. However, we used the National Elevation Dataset to estimate source elevations. There is very little elevation variance near the facility, with differences less than five meters within several hundred meters of the facility.

We ran AERMOD in urban mode (versus rural mode), which accounts for the dispersive nature of the "convective-like" boundary layer that forms during nighttime conditions due to the urban heat island effect. We concluded the urban mode is most appropriate for modeling the Sterigenics facility. The facility is located within the Chicago-Joliet-Naperville urbanized area, and although Willowbrook is considered suburban and the land use around the facility is mostly low to middle density developed areas, we considered the potential for urban heat island influences across the full modeling domain which includes the nearby large urban area

Figure 2.2 - 1. Census Block and Monitor Location Receptors

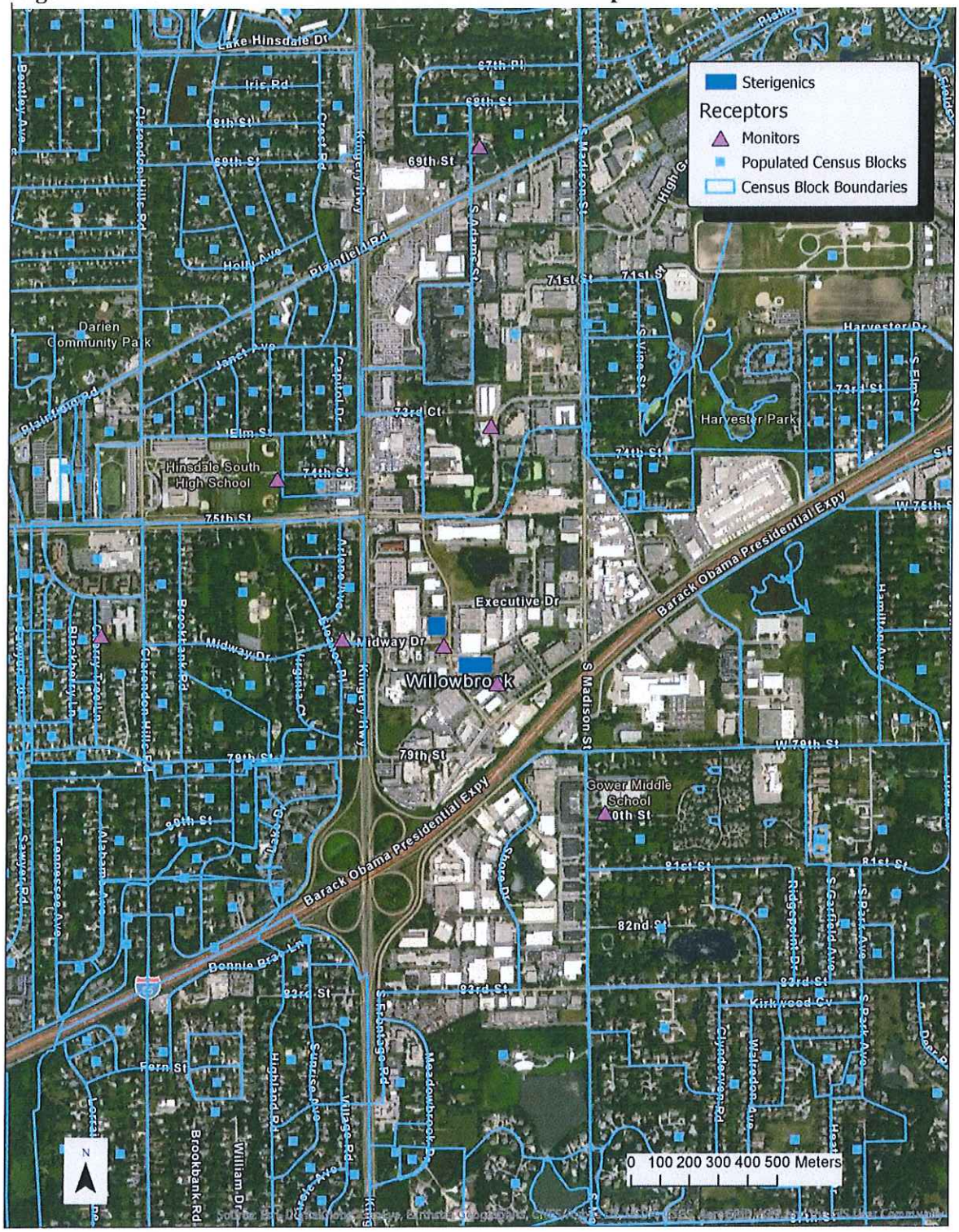


Figure 2.2 – 2. Gridded Residential and Commercial/Industrial Receptors

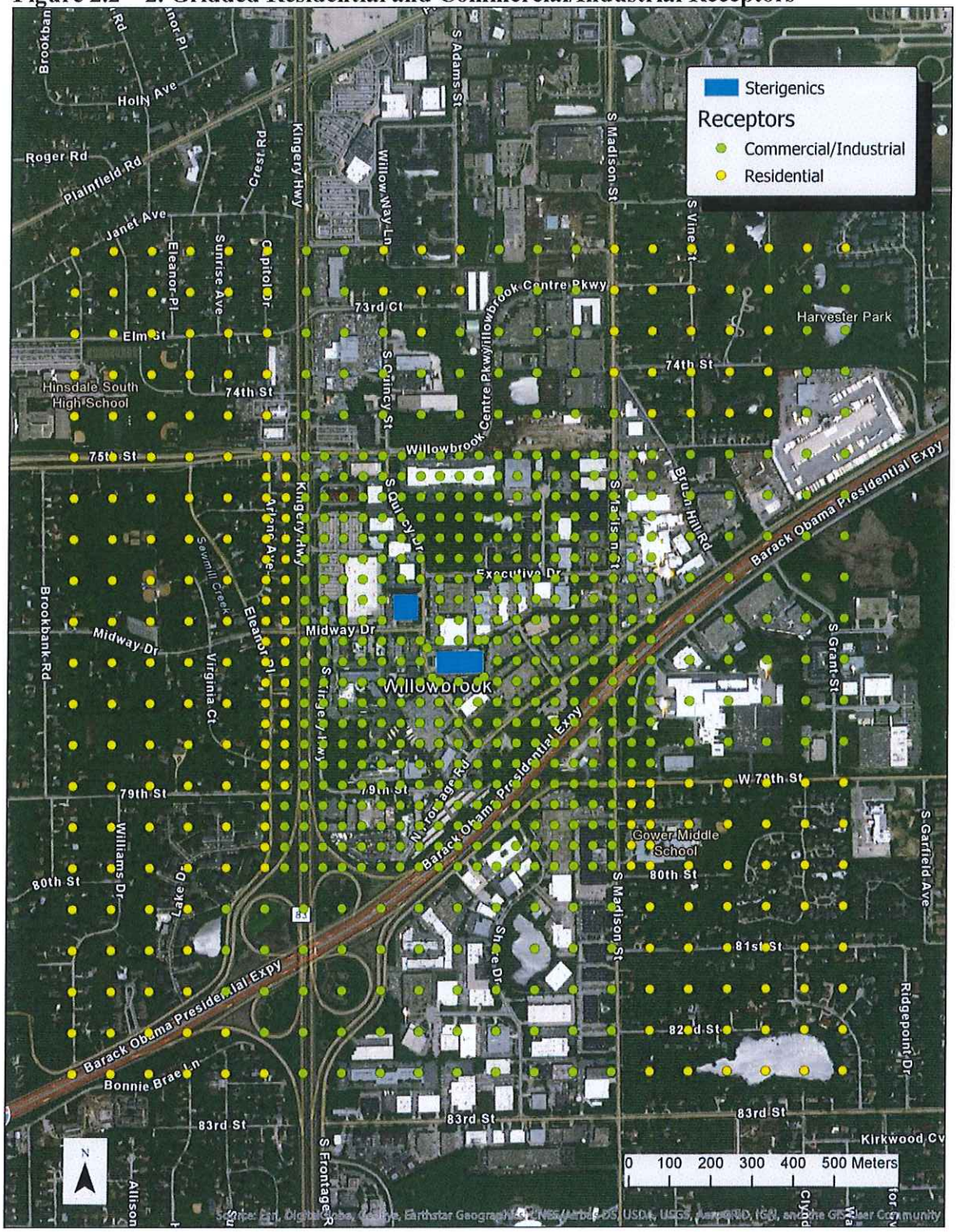
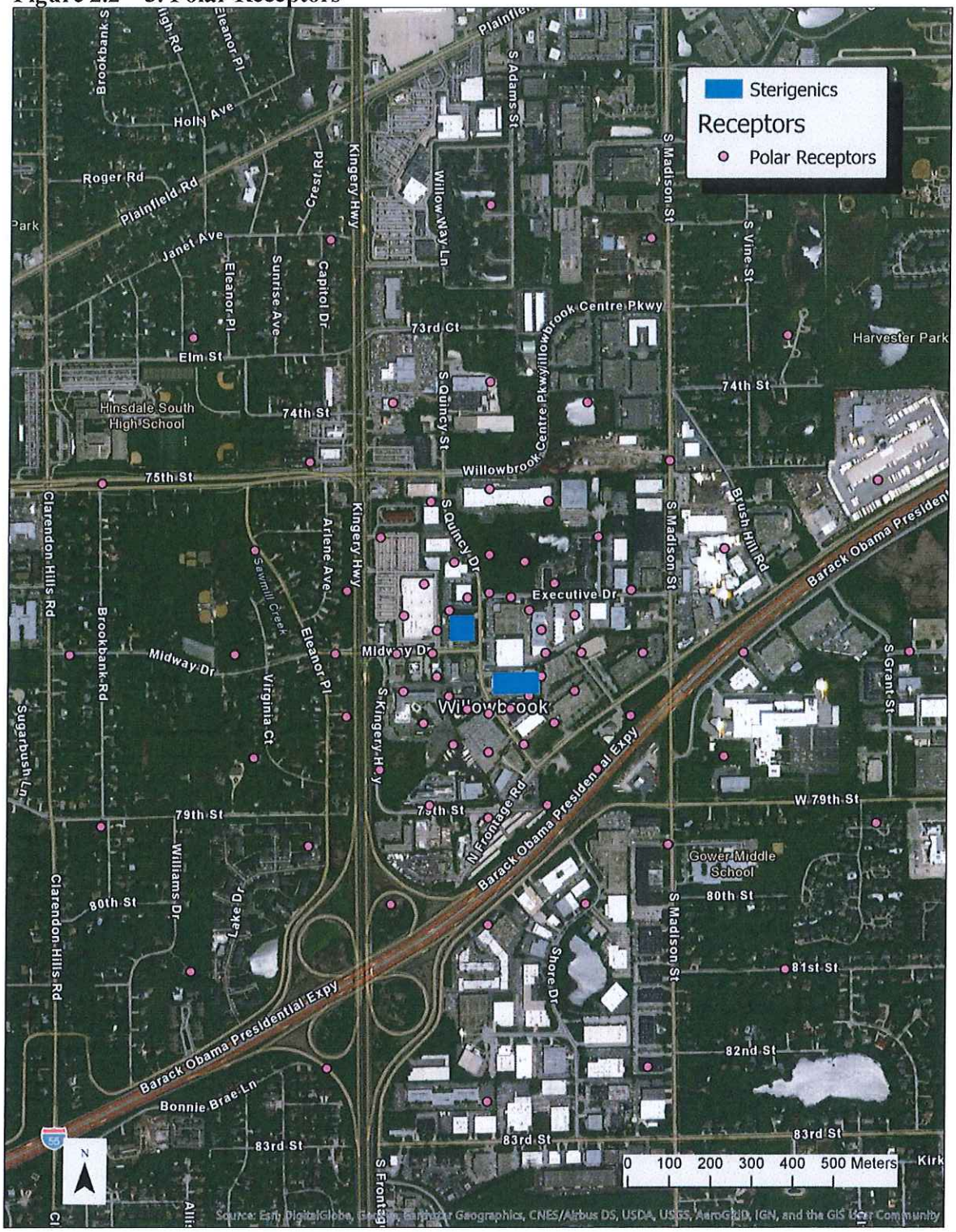


Figure 2.2 – 3. Polar Receptors



of Chicago. Also, most of the areas around the facility have a population density that exceeds the 750 people per square kilometer criteria recommended in the AERMOD Implementation Guide for inclusion as urban. The magnitude of the urban effect in AERMOD is based on an empirical relationship between urban/rural temperature differences and population, and AERMOD requires a population value when in urban mode. Because using the population of the entire metropolitan area (about 9.5 million people) could overstate the urban heat island effect, and to be health protective, we used the minimum population allowed in HEM-3, which is 50,000 people.

To assess the potential impacts from short-term exposures, we estimated worst-case one-hour concentrations at the census block centroids and at points closer to the facility (using either the polar receptors or the grid receptors) where people may be present for short periods. Note that this differs from the estimation of ambient concentrations for evaluating long-term exposures, which we perform only for populated census blocks and residential grid and polar receptors. Because short-term emission rates are needed to screen for the potential hazard from acute exposures, but the emissions data typically contain only annual emission totals, for RTR assessments we generally use the assumption that the maximum one-hour emission rate from each source is ten times the average annual hourly emission rate for that source. Sterilization operations are batch in nature in that individual chambers are charged with EtO, then vented to a control device after sufficient time to sterilize products in the chamber. This batch nature likely leads to some variability in emissions, although with multiple chambers operating simultaneously and at different stages of the sterilization process, we would not expect as much variability as for a truly batch operation. Emissions from aeration room vents and fugitive emissions would not be as variable as those from the chamber. Given these process characteristics, and without process-specific data on hourly emissions variations, we conclude that the short-term emissions factor of ten should be sufficient to estimate hourly emissions. Further discussion of the acute risk assessment can be found in Section 2.4.

2.3 Estimating chronic human inhalation exposure

We considered two chronic human inhalation exposure scenarios: residential and non-residential. For the residential scenario, we use the estimated 5-year average ambient air concentration at each census block centroid as a surrogate for the lifetime inhalation exposure concentration of all the people who reside in the census block. We also use the grid and polar receptors for lifetime inhalation exposure concentration if they fall in residential areas. The residential exposure scenario does not consider either the short-term or long-term behavior (mobility) of the exposed populations and its potential influence on their exposure. For example, we do not reduce exposure durations to reflect that people leave their home census blocks to go to work or school in other blocks. We do not consider that indoor concentrations (of pollutants emitted from outdoor sources) may be higher or lower than outdoor ambient concentrations. However, for gaseous pollutants like EtO, we have no reason to conclude there would be significant differences between indoor and outdoor concentrations caused by outdoor sources.

We do not address long-term migration or population growth or decrease over the 70-year exposure period. Instead, we assume that each person's predicted exposure is constant over the course of their lifetime, which is assumed to be 70 years. The assumption of not

considering short- or long-term population mobility does not bias the estimate of the theoretical MIR (assumes a person stays in one location for 70 years) nor does it affect the estimate of cancer incidence since the total population number remains the same. It does, however, affect the shape of the distribution of individual risks across the affected population, shifting it toward higher estimated individual risks at the upper end and reducing the number of people estimated to be at lower risks, thereby increasing the estimated number of people at higher risk levels.

For the non-residential scenario, we consider all receptors, and we apply an exposure factor to the estimated 5-year average ambient air concentrations to reflect less than lifetime exposure. This scenario is based on an offsite worker as described by ATSDR, which assumes an 8.5-hour workday, 250 days a year, for 25 years (ATSDR, 2016). We use an exposure factor that is slightly different from that used by ATSDR in that the 25-year working time is compared to the EPA's 70-year lifetime assumption rather than ATSDR's 78-year lifetime, resulting in an exposure factor of 0.087. Workers at the Sterigenics facility would be covered under the Occupational Safety and Health Administration (OSHA) EtO standard (29 CFR 1910.1047).

2.4 Acute risk screening and refined assessments

In establishing a scientifically defensible approach for the assessment of potential health risks due to acute exposures to HAP, we follow a similar approach to that for chronic health risk assessments under the residual risk program, in that we begin with a screening assessment and then, if appropriate, perform a refined assessment.

The approach for the acute health risk screening assessment is designed to eliminate from further consideration those facilities for which we have confidence that no acute adverse health effects of concern will occur. For this screening assessment, we use available data and conservative assumptions for emission rates, meteorology, and exposure location that, in combination, approximate a worst-case exposure.

The following are the steps we take and assumptions we make in the acute screening assessment:

- When available, we use peak 1-hour emission data obtained from data collection efforts or estimated based on the operating characteristics and engineering judgement of facility emission sources; otherwise, we use a default emission adjustment factor of 10.
- We assume that the peak emissions occur at all emission points at the same time.
- For facilities with multiple emission points, 1-hour concentrations at each receptor are assumed to be the sum of the maximum concentrations due to each emission point, regardless of whether those maximum concentrations occurred during the same hour.
- Worst-case meteorology (from five years of local meteorology) is assumed to occur at the same time the peak emission rates occur. The recommended EPA local-scale dispersion model, AERMOD, is used for simulating atmospheric dispersion.
- A person is assumed to be located downwind at the point of maximum modeled impact during this same worst-case 1-hour period.

As a result of this screening assessment, the maximum pollutant concentration is compared to multiple acute dose-response values for the HAP being assessed to determine whether a possible acute health risk might exist. The acute dose-response values are described in section 2.5.2 of this report.

A facility will either be found to pose no potential acute health risks (i.e., it will "screen out") or will need to undergo a more refined assessment. When we identify levels of a HAP that exceed its acute health benchmarks, we perform a more refined assessment, if possible. Situations in which we have used engineering judgement to estimate emissions, a refinement may be to obtain facility-specific data on HAP emissions. Other refinements may include the temporal pattern of emissions (number of working hours, batch vs continuous operation), the location of emission points, the boundaries of the facility, and/or the local meteorology. In some cases, all of these site-specific data are used to refine the assessment; in others, lesser amounts of site-specific data may be used to determine that acute exposures are not a concern, and significant additional data collection is not necessary. For the Sterigenics facility, modeled concentrations of EtO are well below the available acute health benchmarks, so we did not perform any refinement of the acute assessment.

2.5 Dose-response assessment

2.5.1 Sources of chronic dose-response information

Dose-response assessments (carcinogenic and non-carcinogenic) for chronic exposure (either by inhalation or ingestion) for the HAP reported in the emissions inventory for this source category are based on the EPA Office of Air Quality Planning and Standards' (OAQPS) existing recommendations for HAP (USEPA, 2018d). This information has been obtained from various sources and prioritized according to (1) conceptual consistency with EPA risk assessment guidelines and (2) level of peer review received. The prioritization process was aimed at incorporating into our assessments the best available science with respect to dose-response information. The recommendations are based on the following sources, in order of priority:

1) **U.S. Environmental Protection Agency (EPA).** The EPA has developed dose-response assessments for chronic exposure for many HAP. These assessments typically provide a qualitative statement regarding the strength of scientific data and specify a reference concentration (RfC, for inhalation) or reference dose (RfD, for ingestion) to protect against effects other than cancer and/or a unit risk estimate (URE, for inhalation) or slope factor (SF, for ingestion) to estimate the probability of developing cancer. The RfC is defined as an "estimate (with uncertainty spanning perhaps an order of magnitude) of a continuous inhalation exposure to the human population (including sensitive subgroups) that is likely to be without an appreciable risk of deleterious effects during a lifetime." The RfD is "an estimate (with uncertainty spanning perhaps an order of magnitude) of a daily oral exposure to the human population (including sensitive subgroups) that is likely to be without an appreciable risk of deleterious effects during a lifetime." The URE is defined as "the

upper-bound excess cancer risk[6] estimated to result from continuous lifetime exposure to an agent at a concentration of 1 $\mu g/m^3$ in air." The SF is "an upper bound, approximating a 95 percent confidence limit, on the increased cancer risk from a lifetime exposure to an agent. This estimate, [is] usually expressed in units of proportion (of a population) affected per mg/kg-day…"

The EPA disseminates dose-response assessment information in several forms, based on the level of review. The Integrated Risk Information System (IRIS) is an EPA database that contains scientific health assessment information, including dose-response information. All IRIS assessments since 1996 have also undergone independent external peer review. The current IRIS process includes review by EPA scientists, interagency reviewers from other federal agencies, and the public, as well as peer review by independent scientists external to the EPA. New IRIS values are developed and old IRIS values are updated as new health effects data become available. Refer to the IRIS Agenda for detailed information on status and scheduling of current individual IRIS assessments and updates. The EPA's science policy approach, under the current carcinogen guidelines, is to use linear low-dose extrapolation as a default option for carcinogens for which the mode of action (MOA) has not been identified. We expect future EPA dose-response assessments to identify nonlinear MOAs where appropriate, and we will use those analyses (once they are peer reviewed) in our risk assessments. At this time, however, there are no available carcinogen dose-response assessments for inhalation exposure that are based on a nonlinear MOA.

2) **U.S. Agency for Toxic Substances and Disease Registry (ATSDR).** ATSDR, which is part of the US Department of Health and Human Services, develops and publishes Minimal Risk Levels (MRLs) for inhalation and oral exposure to many toxic substances. As stated on the ATSDR web site: "Following discussions with scientists within the Department of Health and Human Services (HHS) and the EPA, ATSDR chose to adopt a practice similar to that of the EPA's Reference Dose (RfD) and Reference Concentration (RfC) for deriving substance specific health guidance levels for non-neoplastic endpoints." The MRL is defined as "an estimate of daily human exposure to a substance that is likely to be without an appreciable risk of adverse effects (other than cancer) over a specified duration of exposure." ATSDR describes MRLs as substance-specific estimates to be used by health assessors to select environmental contaminants for further evaluation.

3) **California Environmental Protection Agency (CalEPA).** The CalEPA Office of Environmental Health Hazard Assessment has developed dose-response assessments for many substances, based both on carcinogenicity and health effects other than cancer. The process for developing these assessments is similar to that used by the EPA to develop IRIS values and incorporates significant external scientific peer review. As stated in the CalEPA Technical Support Document for developing their

[6] Upper-bound lifetime cancer risk is a likely upper limit to the true probability that a person will contract cancer over a 70-year lifetime due to a given hazard (such as exposure to a toxic chemical). This risk can be measured or estimated in numerical terms (for example, one chance in a hundred).

chronic assessments (CalEPA, 2008), the guidelines for developing chronic inhalation exposure levels incorporate many recommendations of the U.S. EPA (USEPA, 1994) and NAS (NAS, 1994). The noncancer information includes available inhalation health risk guidance values expressed as chronic inhalation reference exposure levels (RELs). CalEPA defines the REL as "the concentration level at or below which no health effects are anticipated in the general human population." CalEPA's quantitative dose-response information on carcinogenicity by inhalation exposure (CalEPA, 2009) is expressed in terms of the URE, defined similarly to the EPA's URE. The EPA may also look to other state dose-response assessments as appropriate.

For certain HAP, to address data gaps, increase accuracy, and avoid underestimating risk, we make additional changes to some of the chronic inhalation exposure values to take into account their mutagenic mode of action. For carcinogenic chemicals acting via a mutagenic mode of action (i.e., chemicals that cause cancer by damaging genes), we estimate risks to reflect the increased carcinogenicity of such chemicals during childhood. This approach is explained in detail in the Supplemental Guidance for Assessing Susceptibility from Early-Life Exposure to Carcinogens (USEPA, 2005a). Where available data do not support a chemical-specific evaluation of differences between adults and children, the Supplemental Guidance recommends using the following default adjustment factors for early-life exposures: increase the carcinogenic potency by 10-fold for children up to 2 years old and by 3-fold for children 2 to 15 years old. These adjustments have the aggregate effects of increasing by about 60 percent the estimated risk (a 1.6-fold increase) for a lifetime of constant inhalation exposure. The EPA uses these default adjustments only for carcinogens known to be mutagenic for which data to evaluate adult and juvenile differences in toxicity are not available.

In December 2016, the EPA finalized its Evaluation of the Inhalation Carcinogenicity of Ethylene Oxide (USEPA, 2016) in IRIS, which addresses the potential carcinogenicity from long-term inhalation exposure to EtO. The EPA characterizes EtO as "carcinogenic to humans" by the inhalation route of exposure based on the total weight of evidence, in accordance with the EPA's 2005 Guidelines for Carcinogen Risk Assessment (Cancer Guidelines) (U.S. EPA, 2005b). The lines of evidence supporting this characterization include: (1) strong, but less than conclusive on its own, epidemiological evidence of lymphohematopoietic cancers and breast cancer in EtO-exposed workers, (2) extensive evidence of carcinogenicity in laboratory animals, including lymphohematopoietic cancers in rats and mice and mammary carcinomas in mice following inhalation exposure, (3) clear evidence that EtO is genotoxic and sufficient weight of evidence to support a mutagenic mode of action for EtO carcinogenicity, and (4) strong evidence that the key precursor events are anticipated to occur in humans and progress to tumors, including evidence of chromosome damage in humans exposed to EtO. Overall, confidence in the hazard characterization of EtO as "carcinogenic to humans" is high.

In this risk assessment, to estimate lifetime cancer risk from residential exposures we used the IRIS full lifetime cancer unit risk estimate for EtO of 0.005 per $\mu g/m^3$, which includes age-dependent adjustment factors to account for early-life susceptibility. For non-residential exposures, we used the IRIS unit risk estimate (0.003 per $\mu g/m^3$) without age-dependent adjustment factors because those are not relevant for an adult offsite worker. For noncancer

effects, EtO has not been assessed under the IRIS program, nor does ATSDR have a chronic MRL for EtO. Therefore, in this assessment we used the CalEPA chronic REL for EtO, which is 0.03 mg/m^3. In recent and forthcoming rulemakings, the EPA seeks public comment on the use of certain hazard identification and dose-response information for key source categories.

2.5.2 Sources of acute dose-response information

Hazard identification and dose-response assessment information for acute inhalation exposure assessments is based on the existing recommendations of OAQPS for HAP (USEPA, 2018e). When the benchmarks are available, the results from acute screening assessments are compared to both "no effects" reference levels for the general public, such as the California Reference Exposure Levels (RELs), and to emergency response levels, such as Acute Exposure Guideline Levels (AEGLs) and Emergency Response Planning Guidelines (ERPGs), with the recognition that the ultimate interpretation of any potential risks associated with an estimated exceedance of a particular reference level depends on the definition of that level and any limitations expressed therein. Comparisons among different available inhalation health effect reference values (both acute and chronic) for selected HAP can be found in an EPA document of graphical arrays (USEPA, 2009b).

California Acute Reference Exposure Levels (RELs). CalEPA has developed acute dose-response reference values for many substances, expressing the results as acute inhalation RELs. The acute REL is defined by CalEPA (CalEPA, 2016) as "the concentration level at or below which no adverse health effects are anticipated for a specified exposure duration. RELs are based on the most sensitive, relevant, adverse health effect reported in the medical and toxicological literature. RELs are designed to protect the most sensitive individuals in the population by the inclusion of margins of safety. Since margins of safety are incorporated to address data gaps and uncertainties, exceeding the REL does not automatically indicate an adverse health impact." Acute RELs are developed for 1-hour (and 8-hour) exposures. The values incorporate uncertainty factors similar to those used in deriving the EPA's inhalation RfCs for chronic exposures.

Acute Exposure Guideline Levels (AEGLs). AEGLs are developed by the National Advisory Committee on Acute Exposure Guideline Levels (NAC/AEGL) for Hazardous Substances and then reviewed and published by the National Research Council. As described in the Committee's Standing Operating Procedures (NAS, 2001), AEGLs "represent threshold exposure limits for the general public and are applicable to emergency exposures ranging from 10 min to 8 h." Their intended application is "for conducting risk assessments to aid in the development of emergency preparedness and prevention plans, as well as real time emergency response actions, for accidental chemical releases at fixed facilities and from transport carriers." The document states that "the primary purpose of the AEGL program and the NAC/AEGL Committee is to develop guideline levels for once-in-a-lifetime, short-term exposures to airborne concentrations of acutely toxic, high-priority chemicals." In detailing the intended application of AEGL values, the document states, "It is anticipated that the AEGL values will be used for regulatory and nonregulatory purposes by U.S. Federal and State agencies, and possibly the international community in conjunction with chemical emergency response, planning, and prevention programs. More specifically, the AEGL values will be used for conducting various risk assessments to aid in the development of emergency

preparedness and prevention plans, as well as real-time emergency response actions, for accidental chemical releases at fixed facilities and from transport carriers."

The NAC/AEGL defines AEGL-1 and AEGL-2 as:

> "AEGL-1 is the airborne concentration (expressed as ppm or mg/m^3) of a substance above which it is predicted that the general population, including susceptible individuals, could experience notable discomfort, irritation, or certain asymptomatic nonsensory effects. However, the effects are not disabling and are transient and reversible upon cessation of exposure."
>
> "AEGL-2 is the airborne concentration (expressed as ppm or mg/m^3) of a substance above which it is predicted that the general population, including susceptible individuals, could experience irreversible or other serious, long-lasting adverse health effects or an impaired ability to escape."
>
> "Airborne concentrations above AEGL-1 represent exposure levels that can produce mild and progressively increasing but transient and nondisabling odor, taste, and sensory irritation or certain asymptomatic, nonsensory effects. With increasing airborne concentrations above each AEGL, there is a progressive increase in the likelihood of occurrence and the severity of effects described for each corresponding AEGL. Although the AEGL values represent threshold levels for the general public, including susceptible subpopulations, such as infants, children, the elderly, persons with asthma, and those with other illnesses, it is recognized that individuals, subject to unique or idiosyncratic responses, could experience the effects described at concentrations below the corresponding AEGL."

Emergency Response Planning Guidelines (ERPGs). The American Industrial Hygiene Association (AIHA) has developed ERPGs for acute exposures at three different levels of severity. These guidelines represent concentrations for exposure of the general population (but not particularly sensitive persons) for up to 1 hour associated with effects expected to be mild or transient (ERPG-1), irreversible or serious (ERPG-2), and potentially life-threatening (ERPG-3).

ERPG values are described in their supporting documentation as follows: "ERPGs are air concentration guidelines for single exposures to agents and are intended for use as tools to assess the adequacy of accident prevention and emergency response plans, including transportation emergency planning, community emergency response plans, and incident prevention and mitigation."

ERPG-1 and ERPG-2 values are defined by AIHA's Standard Operating Procedures (AIHA, 2018) as follows:

> "ERPG-1 is the maximum airborne concentration below which nearly all individuals could be exposed for up to 1 hour without experiencing more than mild, transient health effects or without perceiving a clearly defined objectionable odor."

"ERPG-2 is the maximum airborne concentration below which nearly all individuals could be exposed for up to 1 hour without experiencing or developing irreversible or other serious adverse health effects or symptoms that could impair an individual's ability to take protective action."

There is no California acute REL available for EtO, nor is there an AEGL-1 or ERPG-1 for EtO. Values for AEGL-1 were not derived because concentrations causing mild sensory irritation are above the AEGL-2 values and would not serve as a warning of potential exposure (NAS, 2010). In this risk assessment, we used the 1-hour AEGL-2 value of 81 mg/m^3.

2.6 Risk characterization

The final product of the risk assessment is the risk characterization, in which the information from the previous steps is integrated and an overall conclusion about risk is synthesized that is complete, informative, and useful for decision makers. In general, the nature of this risk characterization depends on the information available, the application of the risk information and the resources available. In all cases, major issues associated with determining the nature and extent of the risk are identified and discussed. Further, it is the EPA's policy that a risk characterization be prepared in a manner that is clear, transparent, reasonable, and consistent with other risk characterizations of similar scope prepared across programs in the Agency. These principles of transparency and consistency have been reinforced by the Agency's *Risk Characterization Handbook* (USEPA, 2000a), in the Agency's information quality guidelines (USEPA, 2002a), and in the Office of Management and Budget (OMB) Memorandum on Updated Principles for Risk Analysis (OMB, 2007), and they are incorporated in this assessment.

Estimates of health risk are presented in the context of uncertainties and limitations in the data and methodology. We have attempted to reduce both uncertainty and bias to the greatest degree possible in this assessment. We provide summaries of risk metrics (including maximum individual cancer risks and noncancer hazards, as well as cancer incidence estimates) along with a discussion of the major uncertainties associated with their derivation.

For each carcinogenic HAP included in an assessment for which a potency estimate is available, individual and population cancer risks are calculated by multiplying the corresponding lifetime average exposure estimate by the appropriate URE. This calculated cancer risk is defined as the upper-bound probability of developing cancer over a 70-year period (i.e., the assumed human lifespan) at that exposure. Because UREs for most HAP are upper-bound estimates, actual risks at a given exposure level may be lower than predicted.

Increased cancer incidence for the entire population within the area of analysis is estimated by multiplying the estimated lifetime cancer risk for each census block by the number of people residing in that block, then summing the results for the entire modeled domain. This lifetime population incidence estimate is divided by 70 years to obtain an estimate of the number of cancer cases per year. We did not estimate cancer incidence for the non-residential scenario

because we do not have data on where or how many people would be at specific locations, nor how long they would be there. Also, calculating incidence in such cases could double count cases because the same people likely live in a nearby census block for which we are calculating incidence under the residential scenario.

Unlike linear dose-response assessments for cancer, noncancer health hazards generally are not expressed as a probability of an adverse occurrence. Instead, the estimated human health risk for noncancer effects is expressed by comparing an exposure to a reference level as a ratio. The hazard quotient (HQ) is the estimated exposure divided by a reference level (e.g., the RfC). For a given HAP, exposures at or below the reference level ($HQ \leq 1$) are not likely to cause adverse health effects. As exposures increase above the reference level (HQs increasingly greater than 1), the potential for adverse effects increases. For exposures predicted to be above the RfC, the risk characterization includes the degree of confidence ascribed to the RfC values for the compound(s) of concern (i.e., high, medium, or low confidence) and discusses the impact of this on possible health interpretations.

The risk characterization for chronic effects other than cancer is developed using the HQ for inhalation, calculated for each HAP at each census block centroid. As discussed above, RfCs incorporate generally conservative uncertainty factors in the face of uncertain extrapolations, such that an HQ greater than 1 does not necessarily suggest the onset of adverse effects. The target-organ-specific hazard index (TOSHI) is the sum of hazard quotients for substances that affect the same target organ or organ system and approximates the aggregate effect on a specific target organ (e.g., the lungs). The HQ and TOSHI cannot be translated to a probability that adverse effects will occur, and it is unlikely to be proportional to adverse health effect outcomes in a population.

Screening for potentially significant acute inhalation exposures also follows the HQ approach. We divide the maximum estimated acute exposure by each available acute dose-response value to develop an array of HQs. In general, when none of these HQs is greater than one, there is no potential for acute risk. When one or more HQ is above 1, we evaluate additional information (e.g., proximity of the facility to potential exposure locations) to determine whether there is a potential for significant acute risks.

3 Risk results for the Sterigenics facility in Willowbrook, IL

This section presents the results of the risk assessment for the Sterigenics facility in Willowbrook, Illinois based on the modeling methods described in the previous sections. All baseline risk results were developed using the best estimates of actual EtO emissions before the Seal Order issued in February 2019 by the state of Illinois. The basic chronic inhalation risk estimates presented here are the maximum individual lifetime cancer risk, the maximum chronic hazard index, and the cancer incidence. We also present results from our acute inhalation screening assessment in the form of maximum hazard quotients. This section also presents the risk results for the illustrative future scenario.

3.1 Risk assessment results for baseline emissions

Table 3.1-1 summarizes the chronic and acute inhalation risk results for this facility based on baseline emissions. The results of the chronic inhalation cancer risk assessment indicate that the maximum lifetime (residential) individual cancer risk posed by the facility is 1,000-in-1 million. The total estimated cancer incidence is 0.3 excess cancer cases per year, or one excess case in every 3 years within the entire modeling domain. Over 70 years, the estimated number of cancer cases is approximately 20. Estimated maximum lifetime individual cancer risks of 100-in-1 million extend out to about 2 km (1.4 mi) from the facility, cancer risks of 50-in-1 million extend out to about 4 km (2.7 mi) from the facility, cancer risks of 10-in-1 million extend out to about 9 km (6 mi) from the facility, and cancer risks of 1-in-1 million extend out to about 40 km (25 mi) from the facility. Approximately 60 people are estimated to have cancer risks equal to 1,000-in-1 million, 11,500 people are estimated to have cancer risks greater than or equal to 100-in-1 million, 230,000 people are estimated to have cancer risks greater than or equal to 10-in-1 million, and 6.5 million people are estimated to have cancer risks greater than or equal to 1–in-1 million.

The maximum cancer risk from non-residential exposures is also 1,000-in-1 million, but it is only coincidence that this estimate matches the lifetime residential risk estimate. The residential and non-residential risk estimates are based on different exposure concentrations and different cancer unit risk estimates. Estimated maximum non-residential cancer risks of 100-in-1 million extend out to about 400 m (400 yds) from the facility, cancer risks of 50-in-1 million extend out to about 600 m (700 yds) from the facility, cancer risks of 10-in-1 million extend out to about 2 km (1 mi) from the facility, and cancer risks of 1-in-1 million extend out to about 7 km (5 mi) from the facility.

Table 3.1-1. Inhalation Risks for the Sterigenics Willowbrook, Illinois Facility – Baseline Emissions

Result	Residential	Non-Residential
Cancer Risks		
Maximum Individual Lifetime Cancer Risk (in 1 million)	1,000	1,000
Chronic Noncancer Risks		
Maximum Neurological Hazard Index	0.01	0.01
Acute Noncancer Screening Results		
Maximum Acute Hazard Quotient	0.02	0.02
Population Exposure		
Number of People Living Within 50 km of Facility	7,700,000	n/a
Number of People Exposed to Cancer Risk:		
Greater than or equal to 1,000-in-1 million	60	n/a
Greater than or equal to 100-in-1 million	11,500	n/a
Greater than or equal to 1-in-1 million	6,500,000	n/a
Estimated Cancer Incidence (excess cancer cases per year)	0.3	n/a
Estimated number of years for 1 cancer case	3	n/a
Estimated number of cancer cases over 70 years	20	n/a

The maximum chronic noncancer hazard index is 0.01 (neurological) for both residential and non-residential exposures, and no one is exposed to TOSHI levels above 1. Worst-case acute HQs were calculated and are as shown in Table 3.1-1. The highest screening acute HQ was 0.02 (based on the 1-hr AEGL-2 value for EtO). Acute exposures are estimated at all receptors (residential and non-residential) assuming someone could be at the receptor location for an hour, so no distinction is made between residential and non-residential acute exposures. Since the screening HQ was not greater than 1, further refinement of the estimate was not warranted.

Figure 3.1-1 shows the estimated lifetime cancer risk contours near the facility. The figure also shows the commercial/industrial (non-residential) areas adjacent to the facility. The risk contours are not applicable in the non-residential areas because lifetime exposures are relevant only for residential locations. Figure 3.1-2 shows the estimated cancer risk contours for the non-residential scenario. These estimates are based on an offsite worker who is exposed 8.5 hours per day, 250 days per year, for 25 years. Similar maps were presented at a public meeting in Willowbrook, Illinois on May 29, 2019, and are provided in Appendix 4. The risk contours in the maps in Appendix 4 are slightly different than those in Figures 3.1-1 and 3.1-2 because they do not reflect limiting the displayed values to one significant digit. For example, the risk contour in Figure 3.1-1 for the 100- to 200-in-1 million range displays data from 95- to 249-in-1 million, whereas the corresponding risk contour in the Appendix 4 map displays data strictly between 100- and 200-in-1 million.

3.2 Risk assessment results for the illustrative future scenario

In addition to assessing the baseline scenario, we also assessed an illustrative future scenario, where all emission sources at the facility are routed to a control device, and the post-control emissions (26 lb/yr) are released from a single 26.5 m (87 ft) stack. The maximum lifetime (residential) individual cancer risk under this scenario is 1-in-1 million, which occurs at a single residential grid receptor. All cancer risks at census blocks are less than 1-in-1 million. The total estimated cancer incidence is 0.002 excess cancer cases per year, or one excess case in every 700 years within the entire modeling domain. Over 70 years, the estimated number of cancer cases is less than 1 (0.1). Approximately 70,000 people are estimated to have cancer risks between 0.1- and 1–in-1 million, so the remaining 7.6 million people within the modeling domain have estimated cancer risk less than 0.1-in-1 million. The maximum chronic noncancer hazard index is 6E-6 (neurological). For non-residential exposures, the maximum cancer risk is 0.08-in-1 million, and the maximum chronic noncancer hazard index is 9E-7 (neurological). The highest screening acute HQ was 4E-6 (based on the 1-hr AEGL-2 value for EtO).

As discussed in Section 2.1, the emissions and release parameters modeled for the future scenario are similar but not identical to those data in the actual permit application for the Willowbrook facility. The emissions in the permit application are approximately three times higher than the emissions modeled for this assessment, so the calculated risks for these higher future emissions would be greater than those modeled in this assessment but are still in the range of 1- to-10-in-1 million.

Figure 3.1 - 1. Modeled Lifetime Cancer Risks for Sterigenics, Willowbrook, IL

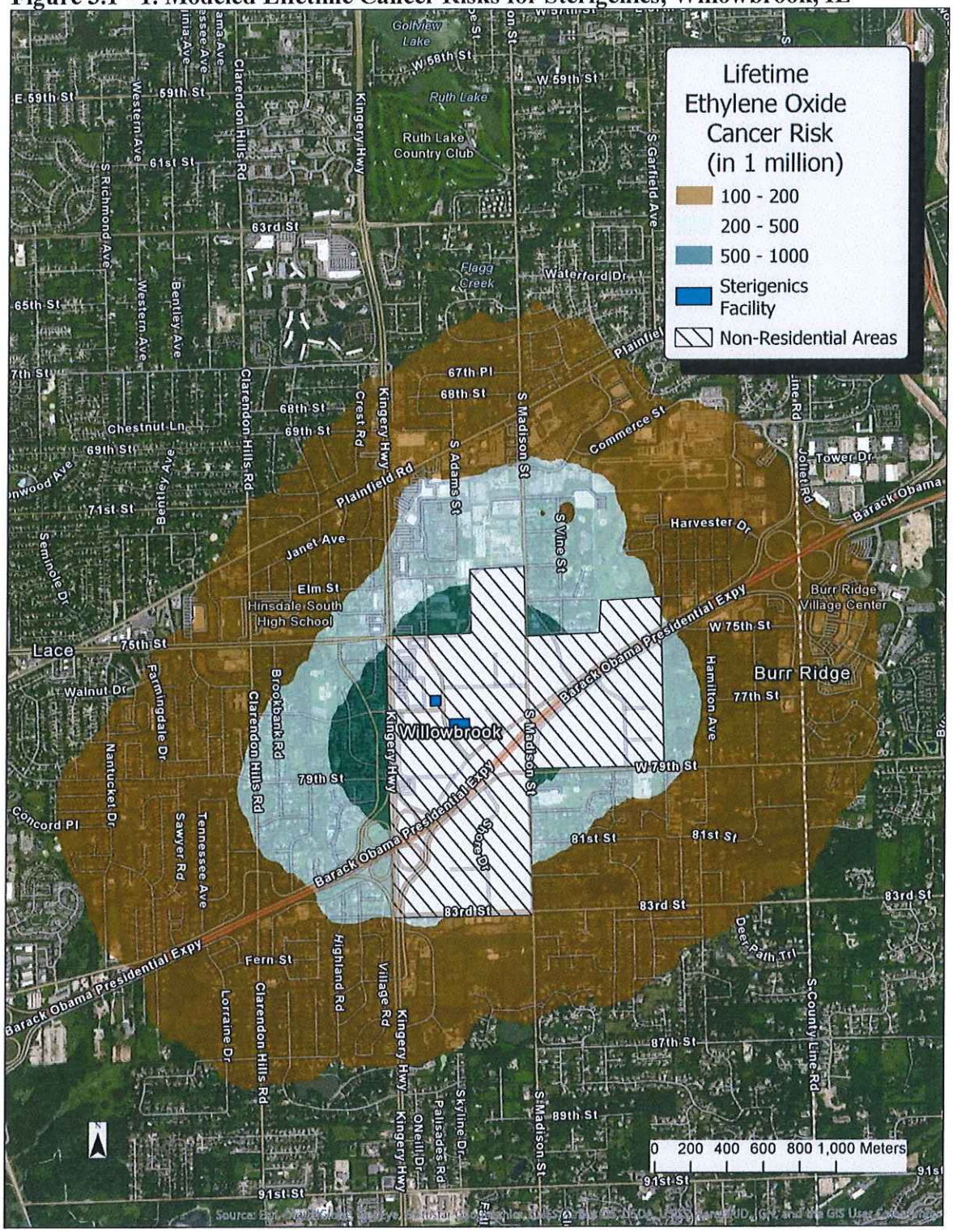
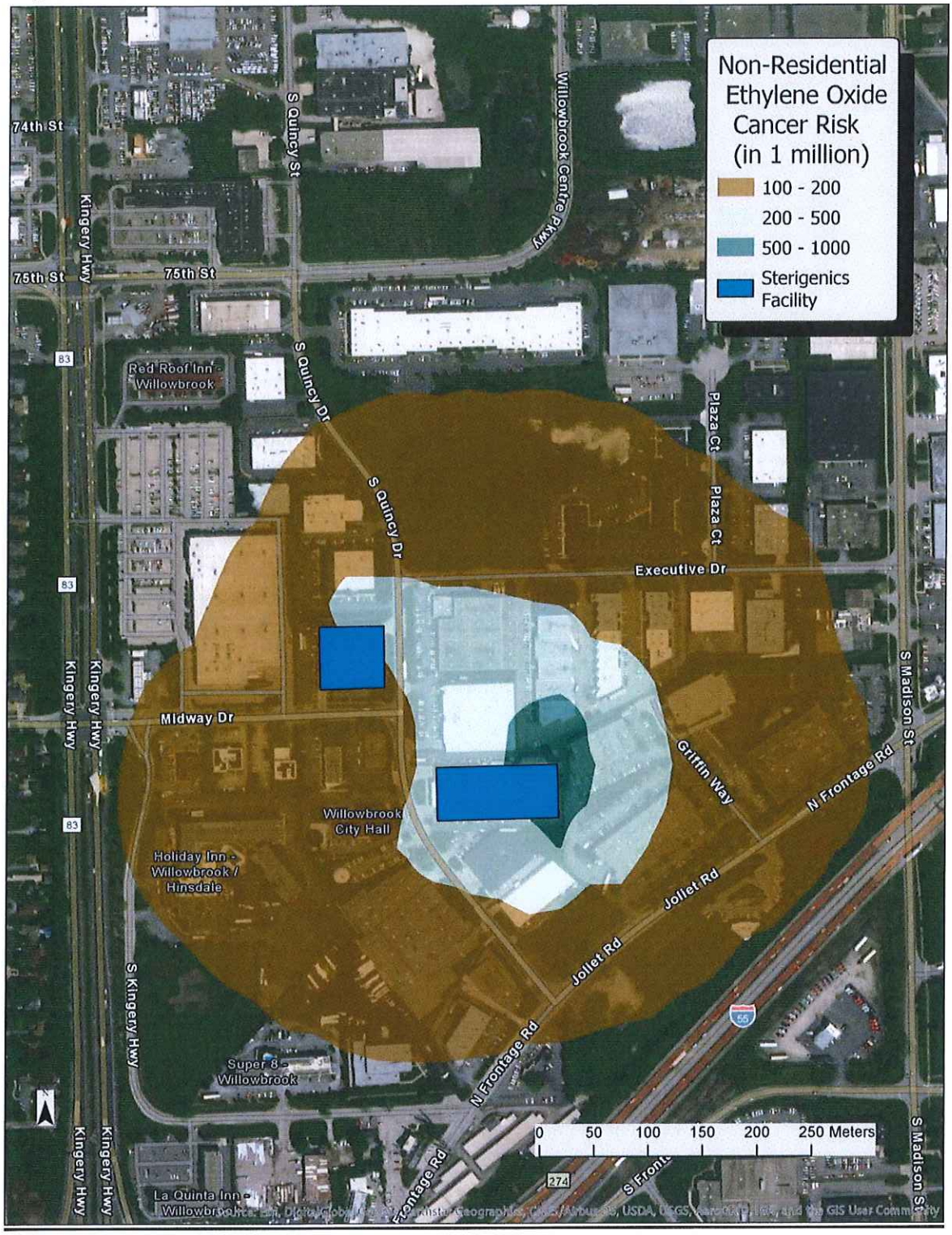


Figure 3.1 - 2. Modeled Non-Residential Cancer Risks for Sterigenics, Willowbrook, IL



4 General discussion of uncertainties in the risk assessment

The uncertainties in virtually all risk assessments can be divided into three areas: 1) uncertainties in the emission data sets, 2) exposure modeling uncertainties, and 3) uncertainties in the dose-response relationships. Uncertainties in the emission estimates and in the air quality models lead to uncertainty in air concentrations. Uncertainty in exposure modeling can arise due to uncertain activity patterns, the locations of individuals within a census block, and the microenvironmental concentrations as reflected in the exposure model. Finally, uncertainty in the shape of the relationship between exposure and effects, the URE and the RfC, also contributes to uncertainties in the risk assessment. These three areas of uncertainty are discussed below.

4.1 Emissions inventory uncertainties

Appendix 1 of this document describes how we developed EtO emission estimates for the Sterigenics facility, starting with information provided to us by Sterigenics regarding their operations and estimated emissions rates and operational parameters for both the controlled and uncontrolled sources. We took this information and derived site-specific emission factors from previous stack testing results for the "controlled" sources and estimated site-specific emission factors for the uncontrolled or "fugitive" emissions. Emission factors are calculated values that relate the quantity of a pollutant released to the atmosphere with an activity associated with the release of that pollutant and are generally assumed to be representative of long-term averages. Using dispersion modeling, we evaluated the accuracy of these site-specific emission factors and made adjustments to these factors so that the modeled results would better correspond with the ambient air values measured at the monitoring sites near the facility. Since the estimated emissions are representative of long-term averages, they do not reflect short-term fluctuations during the course of a year or variations from year to year.

For the acute effects screening assessment, in the absence of available specific estimates or measurements we use estimates of peak hourly emission rates. These estimates typically are calculated by first estimating the average annual hourly emissions rates by evenly dividing the total annual emission rate into the 8,760 hours of the year. An emission adjustment factor that is intended to account for emission fluctuations during normal facility operations is then applied to these average annual hourly emission rates. The adjustment factor can be based on actual fluctuations seen in the available emission data or on engineering judgment; in the absence of such information a default factor is applied, as was done for this assessment.

4.2 Exposure modeling uncertainties

We did not include the effects of human mobility on exposures in the assessment. Specifically, short-term mobility and long-term mobility between census blocks in the modeling domain were not considered. (Short-term mobility is movement from one micro-environment to another over the course of hours or days. Long-term mobility is movement from one residence to another over the course of a lifetime.) The approach of not considering short or long-term population mobility does not bias the estimate of the theoretical MIR (by definition), nor does it affect the estimate of cancer incidence because the total population number remains the same. It does, however, affect the shape of the distribution of individual risks across the affected population, shifting it toward higher estimated individual risks at the

upper end and reducing the number of people estimated to be at lower risks, thereby increasing the estimated number of people at specific high-risk levels (e.g., 1-in-10 thousand or 1-in-1 million).

We also do not factor in the possibility of a source closure occurring during the 70-year chronic exposure period, leading to a potential upward bias in both the MIR and population risk estimates. Nor do we factor in the possibility of population growth during the 70-year chronic exposure period, which could lead to a potential downward bias in both the MIR and population risk estimates. Finally, we do not factor in time an individual spends indoors. The exposure estimates used in these analyses assume chronic exposures to ambient (outdoor) levels of pollutants. Because people spend most of their time indoors, actual exposures may not be as high, depending on the characteristics of the pollutants modeled. For many HAP, indoor levels are roughly equivalent to ambient levels, but for very reactive pollutants or larger particles, indoor levels are typically lower. This factor has the potential to result in an overestimate of 25 to 30 percent of exposures (USEPA, 2001).

We estimated the chronic exposures at the centroid of each populated census block as surrogates for the exposure concentrations for all people living in that block. Using the census block centroid to predict chronic exposures tends to over-predict exposures for people in the census block who live farther from the facility and under-predict exposures for people in the census block who live closer to the facility. Thus, using the census block centroid to predict chronic exposures may lead to a potential understatement or overstatement of the true maximum impact, but is an unbiased estimate of average risk and incidence. We reduce this uncertainty by analyzing large census blocks near facilities using aerial imagery and adjusting the location of the block centroid to better represent the population in the block, as well as adding additional receptor locations where the block population is not well represented by a single location. In this assessment, we used many additional receptors which cover the areas near the facility, so we likely have not missed the location of maximum exposure.

The assessment evaluates the cancer inhalation risks associated with pollutant exposures over a 70-year period, which is the assumed lifetime of an individual. In reality, both the length of time that modeled emission sources at facilities actually operate (i.e., more or less than 70 years) and the domestic growth or decline of the modeled industry (i.e., the increase or decrease in the number or size of domestic facilities) will influence the future risks posed by a given source or source category. Depending on the characteristics of the industry, these factors will, in most cases, result in an overestimate both in individual risk levels and in the total estimated number of cancer cases. However, in the unlikely scenario where a facility maintains, or even increases, its emissions levels over a period of more than 70 years, residents live beyond 70 years at the same location, and the residents spend more of their days at that location, then the cancer inhalation risks could potentially be underestimated. However, annual cancer incidence estimates from exposures to emissions from these sources would not be affected by the length of time an emissions source operates.

For the acute screening assessment, the results are intentionally biased high, and thus health-protective, by assuming the co-occurrence of independent factors, such as hourly emission rates, meteorology and human activity patterns. Furthermore, in cases where multiple acute

dose-response values for a pollutant are considered scientifically acceptable, we choose the most conservative of these dose-response values, erring on the side of overestimating potential health risks from acute exposures. In cases where these results indicate the potential for exceeding acute HQs, we refine our assessment by developing a better understanding of the geography of the facility relative to potential exposure locations.

Appendix 3 of this document includes the analyses performed to support the use of meteorological data from the Argonne National Laboratory, but there are always uncertainties regarding the spatial and temporal representativeness of any meteorological data. Section 8.4.1 of The Guideline on Air Quality Models states that the meteorological data should be adequately representative of the modeling domain, including proximity of the meteorological station to the source, terrain complexity, exposure of the meteorological tower, and period of time the data were collected relative to the modeled period. While there can be uncertainties in the meteorological data for the modeling domain, such as potential wind direction changes across the domain or surface characteristics of the source versus the meteorological site, these uncertainties are mitigated by the choice of adequately representative meteorological data for the model domain. For example, there will always be variations in winds across a domain especially on an hourly basis, but for the long term the meteorological data selected for this assessment are adequately representative of the model domain.

4.3 Uncertainties in the dose-response relationships

In the sections that follow, separate discussions are provided on uncertainty associated with cancer potency factors and for noncancer reference values. Cancer potency values are derived for chronic (lifetime) exposures. Noncancer dose-response values are generally derived for chronic exposures (up to a lifetime) but may also be derived for acute (less than 24 hours), short-term (from 24 hours up to 30 days), and subchronic (30 days up to 10 percent of lifetime) exposure durations, all of which are derived based on an assumption of continuous exposure throughout the duration specified. For the purposes of assessing all potential health risks associated with the emissions included in an assessment, we rely on both chronic (cancer and noncancer) and acute (noncancer) dose-response values, which are described in more detail below.

Cancer assessment

The discussion of dose-response uncertainties in the estimation of cancer risk below focuses on the uncertainties associated with the specific approach currently used by the EPA to develop cancer potency factors. In general, these same uncertainties attend the development of cancer potency factors by CalEPA, the source of peer-reviewed cancer potency factors used where EPA-developed values are not yet available. According to the EPA's Cancer Guidelines, "The primary goal of EPA actions is protection of human health; accordingly, as an Agency policy, risk assessment procedures, including default options that are used in the absence of scientific data to the contrary, should be health protective." The approach adopted in this document is consistent with this approach as described in the Cancer Guidelines.

For cancer endpoints the EPA usually derives an oral slope factor for ingestion and a unit risk value for inhalation exposures. These values allow estimation of a lifetime probability of developing cancer given long-term exposures to the pollutant. Depending on the pollutant

being evaluated, the EPA relies on both animal bioassay and epidemiological studies to characterize cancer risk. As a science policy approach, consistent with the Cancer Guidelines, the EPA uses animal cancer bioassays as indicators of potential human health risk when other human cancer risk data are unavailable.

Extrapolation of study data to estimate potential risks to human populations is based upon the EPA's assessment of the scientific database for a pollutant using EPA guidance documents and other peer-reviewed methodologies. The EPA Cancer Guidelines describe the Agency's recommendations for methodologies for cancer risk assessment. The EPA believes that cancer risk estimates developed following the procedures described in the Cancer Guidelines and outlined below generally provide an upper bound estimate of risk. That is, the EPA's upper bound estimates represent a plausible upper limit to the true value of a quantity (although this is usually not a true statistical confidence limit). In some circumstances, the true risk could be as low as zero; however, in other circumstances the risk could also be greater.[7] When developing an upper bound estimate of risk and to provide risk values that do not underestimate risk, the EPA generally relies on conservative default approaches.[8] The EPA also uses the upper bound (rather than lower bound or central tendency) estimates in its assessments, although it is noted that this approach can have limitations for some uses (e.g. priority setting, expected benefits analysis).

Such health risk assessments have associated uncertainties, some which may be considered quantitatively, and others which generally are expressed qualitatively. Uncertainties may vary substantially among cancer risk assessments associated with exposures to different pollutants, since the assessments employ different databases with different strengths and limitations and the procedures employed may differ in how well they represent actual biological processes for the assessed substance. Some of the major sources of uncertainty and variability in deriving cancer risk values are described more fully below.

(1) The qualitative similarities or differences between tumor responses observed in experimental animal bioassays and those which would occur in humans are a source of uncertainty in cancer risk assessments. In general, the EPA does not assume that tumor sites observed in an experimental animal bioassay are necessarily predictive of the sites at which

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[7] The exception to this is the URE for benzene, which is considered to cover a range of values, each end of which is considered to be equally plausible, and which is based on maximum likelihood estimates.

[8] According to the NRC report Science and Judgment in Risk Assessment (NRC, 1994) "[Default] options are generic approaches, based on general scientific knowledge and policy judgment, that are applied to various elements of the risk-assessment process when the correct scientific model is unknown or uncertain." The 1983 NRC report Risk Assessment in the Federal Government: Managing the Process defined default option as "the option chosen on the basis of risk assessment policy that appears to be the best choice in the absence of data to the contrary" (NRC, 1983a, p. 63). Therefore, default options are not rules that bind the Agency; rather, the Agency may depart from them in evaluating the risks posed by a specific substance when it believes this to be appropriate. In keeping with EPA's goal of protecting public health and the environment, default assumptions are used to ensure that risk to chemicals is not underestimated (although defaults are not intended to overtly overestimate risk). See EPA 2004 An Examination of EPA Risk Assessment Principles and Practices, EPA/100/B-04/001.

tumors would occur in humans.[9] However, unless scientific support is available to show otherwise, the EPA assumes that tumors in animals are relevant in humans, regardless of target organ concordance. For a specific pollutant, qualitative differences in species responses can lead to either under-estimation or over-estimation of human cancer risks.

(2) Uncertainties regarding the most appropriate dose metric for an assessment can also lead to differences in risk predictions. For example, the measure of dose is commonly expressed in units of mg/kg/d ingested or the inhaled concentration of the pollutant. However, data may support development of a pharmacokinetic model for the absorption, distribution, metabolism and excretion of an agent, which may result in improved dose metrics (e.g., average blood concentration of the pollutant or the quantity of agent metabolized in the body). Quantitative uncertainties result when the appropriate choice of a dose metric is uncertain or when dose metric estimates are themselves uncertain (e.g., as can occur when alternative pharmacokinetic models are available for a compound). Uncertainty in dose estimates may lead to either over or underestimation of risk.

(3) For the quantitative extrapolation of cancer risk estimates from experimental animals to humans, the EPA uses scaling methodologies (relating expected response to differences in physical size of the species), which introduce another source of uncertainty. These methodologies are based on both biological data on differences in rates of process according to species size and empirical comparisons of toxicity between experimental animals and humans. For a particular pollutant, the quantitative difference in cancer potency between experimental animals and humans may be either greater than or less than that estimated by baseline scientific scaling predictions due to uncertainties associated with limitations in the test data and the correctness of scaled estimates.

(4) EPA cancer risk estimates, whether based on epidemiological or experimental animal data, are generally developed using a benchmark dose (BMD) analysis to estimate a dose at which there is a specified excess risk of cancer, which is used as the point of departure (or POD) for the remainder of the calculation. Statistical uncertainty in developing a POD using a benchmark dose (BMD) approach is generally addressed though use of the 95 percent lower confidence limit on the dose at which the specified excess risk occurs (the BMDL), decreasing the likelihood of understating risk. The EPA has generally utilized the multistage model for estimation of the BMDL using cancer bioassay data (see further discussion below).

(5) Extrapolation from high to low doses is an important source of uncertainty in cancer risk assessment. The EPA uses different approaches to low dose risk assessment (i.e., developing estimates of risk for exposures to environmental doses of an agent from observations in experimental or epidemiological studies at higher dose) depending on the available data and understanding of a pollutant's mode of action (i.e., the manner in which a pollutant causes cancer). The EPA's Cancer Guidelines express a preference for the use of reliable, compound-specific, biologically-based risk models when feasible; however, such models are rarely available. The mode of action for a pollutant (i.e., the manner in which a pollutant causes

[9] Per the EPA Cancer Guidelines: "The default option is that positive effects in animal cancer studies indicate that the agent under study can have carcinogenic potential in humans." and "Target organ concordance is not a prerequisite for evaluating the implications of animal study results for humans."

cancer) is a key consideration in determining how risks should be estimated for low-dose exposure. A reference value is calculated when the available mode of action data show the response to be nonlinear (e.g., as in a threshold response). A linear low-dose (straight line from POD) approach is used when available mode of action data support a linear (e.g., nonthreshold) response or as the most common default approach when a compound's mode of action is unknown. Linear extrapolation can be supported by both pollutant-specific data and broader scientific considerations. For example, the EPA's Cancer Guidelines generally consider a linear dose-response to be appropriate for pollutants that interact with DNA and induce mutations. Pollutants whose effects are additive to background biological processes in cancer development can also be predicted to have low-dose linear responses, although the slope of this relationship may not be the same as the slope estimated by the straight line approach.

The EPA most frequently utilizes a linear low-dose extrapolation approach as a baseline science-policy choice (a "default") when available data do not allow a compound-specific determination. This approach is designed to not underestimate risk in the face of uncertainty and variability. The EPA believes that linear dose-response models, when appropriately applied as part of the EPA's cancer risk assessment process, provide an upper bound estimate of risk and generally provide a health protective approach. Note that another source of uncertainty is the characterization of low-dose nonlinear, non-threshold relationships. The National Academy of Sciences (NAS, 1994) has encouraged the exploration of sigmoidal type functions (e.g., log-probit models) in representing dose-response relationships due to the variability in response within human populations. Another National Research Council report (NRC, 2006) suggests that models based on distributions of individual thresholds are likely to lead to sigmoidal-shaped dose-response functions for a population. This report notes sources of variability in the human population: "One might expect these individual tolerances to vary extensively in humans depending on genetics, coincident exposures, nutritional status, and various other susceptibility factors..." Thus, if a distribution of thresholds approach is considered for a carcinogen risk assessment, application would depend on ability of modeling to reflect the degree of variability in response in human populations (as opposed to responses in bioassays with genetically more uniform rodents). Note also that low dose linearity in risk can arise for reasons separate from population variability: due to the nature of a mode of action and additivity of a chemical's effect on top of background chemical exposures and biological processes.

As noted above, the EPA's current approach to cancer risk assessment typically utilizes a straight line approach from the BMDL. This is equivalent to using an upper confidence limit on the slope of the straight line extrapolation. The impact of the choice of the BMDL on bottom line risk estimates can be quantified by comparing risk estimates using the BMDL value to central estimate BMD values, although these differences are generally not a large contributor to uncertainty in risk assessment (Subramaniam et. al., 2006). It is important to note that earlier EPA assessments, including the majority of those for which risk values exist today, were generally developed using the multistage model to extrapolate down to environmental dose levels and did not involve the use of a POD. Subramaniam et. al. (2006) also provide comparisons indicating that slopes based on straight line extrapolation from a

POD do not show large differences from those based on the upper confidence limit of the multistage model.

(6) Cancer risk estimates do not generally make specific adjustments to reflect the variability in response within the human population — resulting in another source of uncertainty in assessments. In the diverse human population, some individuals are likely to be more sensitive to the action of a carcinogen than the typical individual, although compound-specific data to evaluate this variability are generally not available. There may also be important life stage differences in the quantitative potency of carcinogens and, with the exception of the recommendations in the EPA's Supplemental Guidance for carcinogens with a mutagenic mode of action, risk assessments do not generally quantitatively address life stage differences. However, one approach used commonly in EPA assessments that may help address variability in response is to extrapolate human response from results observed in the most sensitive species and sex tested, resulting typically in the highest URE which can be supported by reliable data, thus supporting estimates that are designed not to underestimate risk in the face of uncertainty and variability.

Chronic noncancer assessment

Chronic noncancer reference values represent chronic exposure levels that are intended to be health-protective. That is, the EPA and other organizations, such as the ATSDR, which develop noncancer dose-response values use an approach that is intended not to underestimate risk in the face of uncertainty and variability. When there are gaps in the available information, uncertainty factors (UFs) are applied to derive reference values that are intended to be protective against appreciable risk of deleterious effects. Uncertainty factors are commonly default values[10] (e.g., factors of 10 or 3) used in the absence of compound-specific data; where data are available, uncertainty factors may also be developed using compound-specific information. When data are limited, more assumptions are needed and more default factors are used. Thus, there may be a greater tendency to overestimate risk—in the sense that further study might support development of reference values that are higher (i.e., less potent) because fewer default assumptions are needed. However, for some pollutants it is possible that risks may be underestimated.

For noncancer endpoints related to chronic exposures, the EPA derives a reference dose (RfD) for exposures via ingestion, and a reference concentration (RfC) for inhalation exposures. As stated in the IRIS Glossary, these values provide an estimate (with uncertainty spanning

[10] According to the NRC report *Science and Judgment in Risk Assessment* (NRC, 1994) "[Default] options are generic approaches, based on general scientific knowledge and policy judgment, that are applied to various elements of the risk-assessment process when the correct scientific model is unknown or uncertain." The 1983 NRC report *Risk Assessment in the Federal Government: Managing the Process* defined *default option* as "the option chosen on the basis of risk assessment policy that appears to be the best choice in the absence of data to the contrary" (NRC, 1983a, p. 63). Therefore, default options are not rules that bind the Agency; rather, the Agency may depart from them in evaluating the risks posed by a specific substance when it believes this to be appropriate. In keeping with the EPA's goal of protecting public health and the environment, default assumptions are used to ensure that risk to chemicals is not underestimated (although defaults are not intended to overtly overestimate risk). See EPA 2004 *An examination of EPA Risk Assessment Principles and Practices*, EPA/100/B-04/001.

perhaps an order of magnitude) of daily oral exposure (RfD) or of a continuous inhalation exposure (RfC) to the human population (including sensitive subgroups) that is likely to be without an appreciable risk of deleterious effects during a lifetime. To derive values that are intended to be "without appreciable risk," the EPA's methodology relies upon an uncertainty factor (UF) approach (USEPA, 1994) which includes consideration of both uncertainty and variability.

The EPA begins by evaluating all of the available peer-reviewed literature to determine noncancer endpoints of concern, evaluating the quality, strengths and limitations of the available studies. The EPA typically chooses the relevant endpoint that occurs at the lowest dose, often using statistical modeling of the available data, and then determines the appropriate POD for derivation of the reference value. A POD is determined by (in order of preference): (1) a statistical estimation using the BMD approach; (2) use of the dose or concentration at which the toxic response was not significantly elevated (no observed adverse effect level— NOAEL); or (3) use of the lowest observed adverse effect level (LOAEL).

A series of downward adjustments using default UFs is then applied to the POD to estimate the reference value (USEPA, 2002b). While collectively termed "UFs", these factors account for a number of different quantitative considerations when utilizing observed animal (usually rodent) or human toxicity data in a risk assessment. The UFs are intended to account for: (1) variation in susceptibility among the members of the human population (i.e., inter-individual variability); (2) uncertainty in extrapolating from experimental animal data to humans (i.e., interspecies differences); (3) uncertainty in extrapolating from data obtained in a study with less-than-lifetime exposure (i.e., extrapolating from subchronic to chronic exposure); (4) uncertainty in extrapolating from a LOAEL in the absence of a NOAEL; and (5) uncertainty when the database is incomplete or there are problems with applicability of available studies. When scientifically sound, peer-reviewed assessment-specific data are not available, default adjustment values are selected for the individual UFs. For each type of uncertainty (when relevant to the assessment), the EPA typically applies an UF value of 10 or 3 with the cumulative UF value leading to a downward adjustment of 10-3000 fold from the selected POD. An UF of 3 is used when the data do not support the use of a 10-fold factor. If an extrapolation step or adjustment is not relevant to an assessment (e.g., if applying human toxicity data and an interspecies extrapolation is not required) the associated UF is not used. The major adjustment steps are described more fully below.

1) Heterogeneity among humans is a key source of variability as well as uncertainty. Uncertainty related to human variation is considered in extrapolating doses from a subset or smaller-sized population, often of one sex or of a narrow range of life stages (typical of occupational epidemiologic studies), to a larger, more diverse population. In the absence of pollutant-specific data on human variation, a 10-fold UF is used to account for uncertainty associated with human variation. Human variation may be larger or smaller; however, data to examine the potential magnitude of human variability are often unavailable. In some situations, a smaller UF of 3 may be applied to reflect a known lack of significant variability among humans.

2) Extrapolation from results of studies in experimental animals to humans is a necessary step for the majority of chemical risk assessments. When interpreting animal data, the concentration at the POD (e.g. NOAEL, BMDL) in an animal model (e.g. rodents) is extrapolated to estimate the human response. While there is long-standing scientific support for the use of animal studies as indicators of potential toxicity to humans, there are uncertainties in such extrapolations. In the absence of data to the contrary, the typical approach is to use the most relevant endpoint from the most sensitive species and the most sensitive sex in assessing risks to the average human. Typically, compound specific data to evaluate relative sensitivity in humans versus rodents are lacking, thus leading to uncertainty in this extrapolation. Size-related differences (allometric relationships) indicate that typically humans are more sensitive than rodents when compared on a mg/kg/day basis. The default choice of 10 for the interspecies UF is consistent with these differences. For a specific chemical, differences in species responses may be greater or less than this value.

Pharmacokinetic models are useful to examine species differences in pharmacokinetic processing and associated uncertainties; however, such dosimetric adjustments are not always possible. Information may not be available to quantitatively assess toxicokinetic or toxicodynamic differences between animals and humans, and in many cases a 10-fold UF (with separate factors of 3 for toxicokinetic and toxicodynamic components) is used to account for expected species differences and associated uncertainty in extrapolating from laboratory animals to humans in the derivation of a reference value. If information on one or the other of these components is available and accounted for in the cross-species extrapolation, a UF of 3 may be used for the remaining component.

3) In the case of reference values for chronic exposures where only data from shorter durations are available (e.g., 90-day subchronic studies in rodents) or when such data are judged more appropriate for development of an RfC, an additional UF of 3 or 10-fold is typically applied unless the available scientific information supports use of a different value.

4) Toxicity data are typically limited as to the dose or exposure levels that have been tested in individual studies; in an animal study, for example, treatment groups may differ in exposure by up to an order of magnitude. The preferred approach to arrive at a POD is to use BMD analysis; however, this approach requires adequate quantitative results for a meaningful analysis, which is not always possible. Use of a NOAEL is the next preferred approach after BMD analysis in determining a POD for deriving a health effect reference value. However, many studies lack a dose or exposure level at which an adverse effect is not observed (i.e., a NOAEL is not identified). When using data limited to a LOAEL, a UF of 10 or 3-fold is often applied.

5) The database UF is intended to account for the potential for deriving an underprotective RfD/RfC due to a data gap preventing complete characterization of the chemical's toxicity. In the absence of studies for a known or suspected endpoint of concern, a UF of 10 or 3-fold is typically applied.

Acute noncancer assessment

Many of the UFs used to account for variability and uncertainty in the development of acute reference values are quite similar to those developed for chronic durations. For acute reference values, though, individual UF values may be less than 10. UFs are applied based on chemical- or health effect-specific information or based on the purpose of the reference value. The UFs applied in acute reference value derivation include: 1) heterogeneity among humans; 2) uncertainty in extrapolating from animals to humans; 3) uncertainty in LOAEL to NOAEL adjustments; and 4) uncertainty in accounting for an incomplete database on toxic effects of potential concern. Additional adjustments are often applied to account for uncertainty in extrapolation from observations at one exposure duration (e.g., 4 hours) to arrive at a POD for derivation of an acute reference value at another exposure duration (e.g., 1 hour).

Not all acute dose-response values are developed for the same purpose and care must be taken when interpreting the results of an acute assessment of human health effects relative to the reference value or values being exceeded. Where relevant to the estimated exposures, the lack of dose-response values at different levels of severity should be factored into the risk characterization as potential uncertainties.

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Appendix 1 to the Risk Assessment Report for the Sterigenics Facility in Willowbrook, Illinois:

Development of Ethylene Oxide Emissions Rates Used for Risk Assessment

Introduction

We (the EPA) developed ethylene oxide (EtO) emission estimates for the Sterigenics facility in Willowbrook, Illinois (Willowbrook 1 and Willowbrook 2 buildings), starting with information provided to us by Sterigenics regarding their operations, estimated emissions rates, and operational parameters for both the controlled and uncontrolled sources. We took this information and derived site-specific emission factors from previous stack testing results for the "controlled" sources, and estimated site-specific emission factors for the uncontrolled or "fugitive" emissions. Emission factors are calculated values that relate the quantity of a pollutant released to the atmosphere with an activity associated with the release of that pollutant and are generally assumed to be representative of long-term averages. Using dispersion modeling, we evaluated the accuracy of these site-specific emission factors and made adjustments to the factors so that the modeled results would better correspond with the ambient air concentrations measured at the monitoring sites near the facility. Tables 1 and 2 give the site-specific emission factors for each emission point type used for the risk assessment.

Table 1. Willowbrook 1 and Willowbrook 2 site-specific emission factors used for the risk assessment

Facility	Sterilizer vacuum vent (lbs EtO emitted/ton used)	Aeration room and backvent (lbs EtO emitted/ton used)	Fugitives[11] (lbs EtO emitted/ton used)
Willowbrook 1	0.9	0.5	12.0
Willowbrook 2	9.4	0.5	13.0

The EPA used the site-specific emission factors and annual EtO usage rates for each building to determine the EtO emission rate for each emission point. An emission rate is the mass of a pollutant emitted over a period of time. The emission rate for each emission point was calculated as:

$$E_R = EF * U_D * K$$

Where:

E_R = *Emission Rate (lb/hr)*
U_D = *2017 Facility Usage[12] (ton/year)*
EF = *Emission Factor (lbs EtO emitted/ton used)*
K = *0.000114, conversion from lbs/year to lbs/hr*

The emission rates for all sources at Willowbrook 1 and Willowbrook 2 were combined to yield the emissions estimates in Table 2.

Table 2. Willowbrook 1 and Willowbrook 2 emission estimates used for the risk assessment

	Emission Rate (lbs/hr)
Willowbrook 1	0.28
Willowbrook 2	0.19

Methodology

The emission factors in Table 1 were developed in part based upon ambient sampling that was performed by the EPA in Willowbrook, Illinois, from November 13, 2018 to March 31, 2019.

[11] Combined output for all fugitive emission sources.
[12] 2017 usage rates Willowbrook 1 (142 tons), Willowbrook (70 tons).

Sampling was conducted at eight total locations, two of which are very near the facility (Willowbrook Village Hall and EPA warehouse), and six additional sampling locations in the surrounding community. For the purposes of this analysis, only the sample data for Willowbrook Village Hall and the EPA warehouse were used, and only for the dates on which the facility was actively processing EtO.[13] The EtO samples were collected and analyzed according to EPA Compendium Method TO-15, Determination of Volatile Organic Compounds (VOCs) in Air Collected in Specially Prepared Canisters and Analyzed by Gas Chromatography/Mass Spectrometry (GC/MS),[14] and the Quality Assurance Project Plan (QAPP) for the Field Sampling Plan for Ambient Air Ethylene Oxide Monitoring Near Sterigenics Facility, Willowbrook, IL, dated November 17, 2018.[15] The ambient air samples were collected on a 1-in-3 day schedule[16] throughout the program with the exception of periods in which sampling was collected off-schedule to accommodate holidays or when weather was not conducive to sampling.

Sterigenics provided information to the EPA regarding the locations of expected EtO emissions points for both controlled and fugitive emissions, as well as emission factors for these sources. This information included the exact location, release height above ground, exit velocity, temperature, and other parameters needed for dispersion modeling. In addition to this information, the company also provided daily EtO usage rates[17] for each building for the entire sampling period, which were used to determine the daily emission rates for the individual emission points.

Air dispersion modeling of the emission points[18] was conducted using the latest version of the American Meteorological Society/EPA Regulatory Model (AERMOD) atmospheric dispersion model (version 18081). Meteorological data used for the dispersion modeling came from a temporary weather station located on the roof of the EPA warehouse building. Where meteorological data were not available from this location due to data availability or quality concerns, alternate data were acquired from Midway Airport, located approximately 16 km east of the facility. For each day in which samples were collected, modeling runs were performed using the established modeling parameters (all emission locations), the meteorological data for that day, and calculated daily emission rates (all emission locations combined) to determine the projected impact (i.e., concentrations) of EtO in the areas surrounding the facility. The modeling does not consider any background concentrations of EtO that may be present in the ambient air; it only takes into account EtO emissions from emission points at the facility. To compare the measured ambient values against the modeled values, the EPA corrected the modeling results to include background concentrations[19] of EtO by adding the corresponding background concentration observed at the upwind location for each sampling day. Upwind locations were

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[13] November 13, 2018 – February 11, 2019.

[14] USEPA. 1999. "Air Method, Toxic Organics-15 (TO-15): Compendium of Methods for the Determination of Toxic. Organic Compounds in Ambient Air, Second Edition: Determination of Volatile Organic Compounds (VOCs) in Air Collected in Specially-Prepared Canisters and Analyzed by Gas Chromatography/Mass Spectrometry (GC/MS)." EPA 625/R-96/010b. https://www.epa.gov/homeland-security-research/epa-air-method-toxic-organics-15-15-determination-volatile-organic.

[15] https://www.epa.gov/sites/production/files/2018-11/documents/qapp_eto_willowbrook_v1.4_final_signed.pdf.

[16] See addendum for sampling days and the sample results for all locations (Table A-1).

[17] See addendum for EtO usage for Willowbrook 1 and Willowbrook 2 (Table A-2).

[18] See addendum for emission point details (Table A-3).

[19] See addendum for daily background EtO levels (Table A-4).

identified based on daily meteorology to determine which residential sampling location was not affected by emissions from the facility.

We made a number of assumptions regarding the other sources of EtO emissions in the area of the facility and the emissions from and modeling parameters for the Sterigenics fugitive emission points that could not be verified from previous testing. We evaluated all known sources of EtO in the area and did not identify any significant sources. To confirm this assumption, we used a diagnostic mapping tool called a polarPlot[20] that shows EtO concentrations by wind speed and direction and allows us to identify any potential sources of EtO. This tool identified no sources of EtO other than Sterigenics. Additionally, while there are no test data to verify the exact location of the fugitive sources at the company and their associated modeling parameters, the information provided by the company seemed appropriate based on our understanding of the processes at the facility.

Emission Factor Development and Evaluation

The development of the site-specific emission factors was predicated on the ability to achieve agreement between the modeled values with the observed values from the ambient sampling. To do this, we used an iterative process to evaluate different emission factors and modeling parameters to predict emissions versus the observed ambient values within the accuracy of the model (factor of +/- 2). This was done by determining the impact at the location of the ambient monitoring sites using modeling of each emission point (controlled and fugitive) at the facility. As a starting point, we performed a sensitivity analysis for each of the site-specific emission factors provided by Sterigenics against a "strawman" scenario representing a decrease in the control efficiency of those controlled sources and an increase in fugitives for a number of ambient sampling days.[21] We took the site-specific emission factors combined with the corresponding daily usage rate data for each building to determine the daily EtO emission rate for each emission point. The emission rates for each sampling day were calculated in the same manner as for the risk assessment, but the daily usage rate was used to determine an emission rate specific to the sampling day. Table 3 gives the emission factors used for the sensitivity analysis.

Table 3. Site Specific Emission Factors Used for Sensitivity Analysis

Building	Whole site emission factor (lbs/ton)	Sterilizer vacuum vent (lbs/ton)	Aeration room and backvent (lbs/ton)	Fugitives (lbs/ton)
Sterigenics Emission Factor				
Willowbrook 1	1.4	0.01	0.4	1.0
Willowbrook 2	2.5	1.1	0.4	1.0
Strawman				
Willowbrook 1	5.9	1.9	1.0	3.0
Willowbrook 2	5.9	1.9	1.0	3.0

Table 4 gives the average model-to-monitor comparison for the sensitivity analysis. The results of this analysis indicated that the results of the modeling using the emission factors used for both the Sterigenics and the EPA Strawman were significantly underpredicting the observed values.

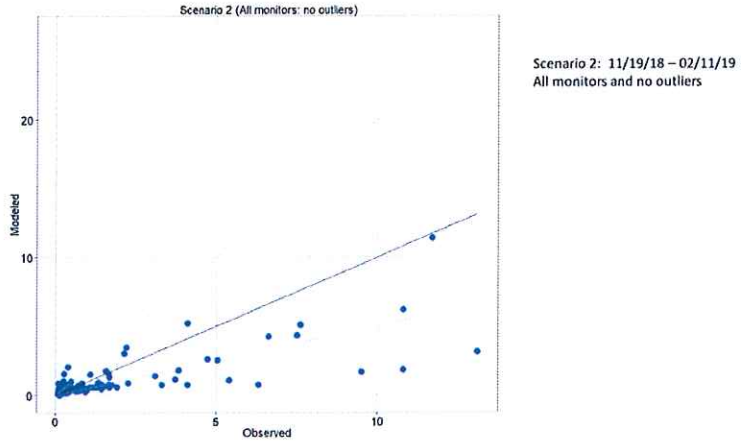
[20] See addendum of polarPlot maps (Figure A-1).
[21] December 6, 13, and 26, 2018; and January 17.

Table 4. Model to Monitor Comparison for the Sensitivity Analysis

Location	Observed ($\mu g/m^3$)	Sterigenics emission factors ($\mu g/m^3$)	Strawman emission factor ($\mu g/m^3$)
Willowbrook Village Hall	4.69	0.13	0.61
EPA Warehouse	8.41	0.49	2.23

Based on these results, we chose to modify the emission factors in Table 3 for the controlled emissions from the EPA strawman to be in-line with manufacturer guarantees for similar pollution control equipment installed at the facility. We also reviewed the modeling parameters and compared them against previous test data at the facility as well as other test data from similar sources. This review yielded some seasonal corrections to the modeling parameters to better reflect the likely exit temperatures of the exhaust points during the winter months. With the controlled emission factors set, we incrementally increased the emission factors for the fugitive sources until the objectives were met for the comparison of the modeled results to the observed values. During this period, we were in contact with the company regarding the modifications being made to the facility air handling system and how these changes would affect the fugitive sources. We made revisions to the modeling parameters as new information was received, and these revisions were used for all modeling going forward. Figure 1 gives the ambient monitoring results (observed) plotted against the values developed from the dispersion modeling (modeled) based on the final emission factors and modeling parameters, for all monitor locations. This plot compares the monitored to the modeled results in a manner consistent with past evaluations of AERMOD[22] by comparing the monitored and modeled results unpaired in time and space, called a Q-Q plot. The monitored and modeled concentration distributions are both sorted and plotted against each other based on rank, so the highest monitored concentration is compared against the highest modeled concentration, regardless of the location and time of occurrence.

Figure 1. Modeled value vs. observed value comparison (11/19/2018 – 02/11/2019)



We did a model-to-monitor comparison using a statistic called the Robust Highest Concentration (RHC) and fractional bias. This comparison focuses on the higher concentrations in the distribution. The RHC coupled with fractional bias is the preferred methodology in the EPA's

[22] USEPA. 2003. "AERMOD: Latest Features and Evaluation Results." EPA-454/R-03-003. https://www3.epa.gov/scram001/7thconf/aermod/aermod_mep.pdf.

Protocol for Determining the Best Performing Model.[23] Normally, the protocol evaluates 1-hour, 3-hour, and 24-hour average concentrations. Since the ambient monitoring data for Sterigenics are only 24-hour averages, we focused only on 24-hour averages. The RHC is calculated at each monitoring location for observed concentrations and modeled concentrations.

The RHC is calculated as:

$$RHC = \mathrm{X}(N) + [\bar{\mathrm{X}} - \mathrm{X}(N)] \times \ln\left[\frac{3N-1}{2}\right]$$

Where X(N) is the Nth highest concentration, and $\bar{\mathrm{X}}$ is the average of N-1 values where N is typically set to 26 values for most model evaluations. However, given the small sample size at each monitor, we started with N=11 and evaluated results up to N=20 (the fewest number of observations across the monitors). As stated above, the RHC is calculated at each monitor for observed concentrations and modeled concentrations. Next a fractional bias is calculated using the maximum observed RHC and maximum modeled RHC as:

$$FB = 2\left[\frac{OB - PR}{OB + PR}\right]$$

Where FB is the fractional bias, OB is the maximum observed RHC, and PR is the maximum modeled RHC. A positive (negative) fractional bias indicates model underprediction (overprediction). Fractional biases within ± 0.67 are not considered statistically different. Also, note that the two RHC values in the fractional bias may not be from the same monitor location. This is done to assess the model's ability to assess concentrations for regulatory purposes, that is, how well the model predicts maximum concentrations regardless of the spatial location. Table 5 gives the fractional biases and monitors used for the calculations for a range of values of N using the meteorology at the EPA warehouse and the estimated emissions factors.

Table 5. Fractional Bias Estimates Using All Monitors

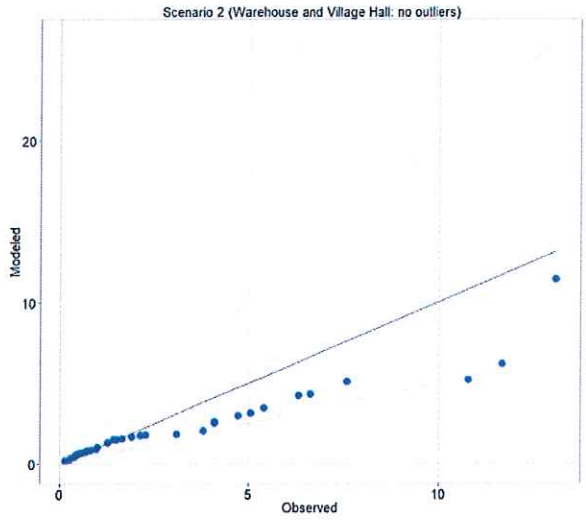
N	Observed RHC	Modeled RHC	Fractional Bias	Observed monitor location	Modeled monitor location
11	20.8	8.0	0.89	EPA Warehouse	EPA Warehouse
12	19.8	7.5	0.90	EPA Warehouse	EPA Warehouse
13	19.0	7.3	0.9	EPA Warehouse	EPA Warehouse
14	17.9	7.0	0.9	EPA Warehouse	EPA Warehouse
15	16.9	6.8	0.8	EPA Warehouse	EPA Warehouse
16	16.7	6.7	0.9	EPA Warehouse	EPA Warehouse
17	16.1	7.0	0.8	EPA Warehouse	EPA Warehouse
18	16.2	6.9	0.8	EPA Warehouse	EPA Warehouse
19	14.4	6.5	0.8	EPA Warehouse	EPA Warehouse
20	13.7	6.3	0.7	EPA Warehouse	EPA Warehouse

We also generated a Q-Q plot of the concentrations at only the Willowbrook Village Hall and the EPA warehouse, shown in Figure 2. The plot indicates good agreement on the low end of the concentration distribution, and underprediction at the middle to high end of the concentration

[23] USEPA. 1992. Protocol for Determining the Best Performing Model. EPA-454/R-92-025.

distribution, but within a factor of 2, which is acceptable performance. At the highest end of the distribution, the model is just slightly underpredicting compared to the observed maximum.

Figure 2. Q-Q plot



In addition to the RHC analysis and Q-Q plots, we also did a direct comparison of the modeled values against the observed values at Willowbrook Village Hall and the EPA warehouse. For this analysis, all data points were included in the comparison unless a sample was invalided, elevated background concentrations were observed, or when a result was considered an outlier. A total of 47 data points was used for this analysis, 26 from sampling events at the Willowbrook Village Hall monitoring location and 21 from the EPA warehouse monitoring location. The modeled value agreed (within a factor of 2) with the observed value for approximately 65 percent of the sampling events, with the model overpredicting 15 percent and underpredicting 20 percent of the time. A comparison of the means of the modeled versus the observed or monitored results, the observed mean was within the accuracy of the model, although the model appears to underpredict. The mean observed value is heavily influenced by the elevated values observed after January 12, 2019, following a maintenance event at Willowbrook 1. Tables 6 and 7 present the results of the model-to-monitor comparison for the entire sampling period and for the period prior to the maintenance event at Willowbrook 1, respectively.

Table 6. Model-to-monitor comparison 11/19/2019 – 02/11/2019

Location	Mean Observed Value ($\mu g/m^3$)	Mean Modeled Value[24] ($\mu g/m^3$)
Willowbrook Village Hall	2.83	1.53
EPA Warehouse	3.14	2.02

[24] Corrected for background.

Table 7. Model-to-monitor comparison 11/19/2019 – 01/09/2019

Location	Mean Observed Value ($\mu g/m^3$)	Mean Modeled Value[25] ($\mu g/m^3$)
Willowbrook Village Hall	2.85	2.05
EPA Warehouse	2.31	2.69

The model-to-monitor comparison showed reasonable results when comparing mean results at the monitor location, but the model had difficulty predicting the elevated results at these locations on a few of the days when samples were collected. Disparities in the modeled versus the observed results can be attributed to the model's sensitivity to errors in the meteorology or to the other activities at the facility or happening in the surrounding area that could affect plume magnitude or dispersion. This could explain the closer relationship observed at the EPA Warehouse sampling location which was near the temporary weather station located on the EPA Warehouse building.

Conclusions

The site-specific estimated emission factors from which the emission rates were derived and modeling parameters developed for the risk assessment appear to adequately predict the expected concentrations surrounding the facility and, while these factors appear to underpredict the emissions from the facility, the results are well within the acceptable performance of the model.

The results of this analysis provide an estimation of the emission of the EtO emissions for the purposes of the risk assessment. These results only provide emission estimates for the period in time when ambient samples were collected and analyzed. A more refined assessment of these emissions was problematic due to the limited number of monitoring locations near the facility and the relatively small sample size. While additional measurements were collected from the residential areas, these were not used for this analysis due to the significant proportion of EtO concentrations present in the ambient air not attributed to the company.

The tools used to perform this analysis were adequate due to the magnitude of the emissions from the facility. Any changes made to the facility or similar facilities which would result in a significant decrease in EtO emissions would result in a need to revise the way emissions are characterized. Any future assessment should incorporate direct measurement of all emission points at the facility during all aspects of operation to more effectively determine emission factors. As these sources become better controlled (e.g., improved capture and control of fugitives), emission characterization using ambient measurements will become more difficult because the contribution from the facility would be less distinguishable from levels found in the ambient air.

[25] Corrected for background.

Addendum to Appendix 1

Table A-1. Ambient monitoring results ($\mu g/m^{3)}$ for Willowbrook village hall and EPA warehouse locations

Sample Start Date	Willowbrook village hall	EPA warehouse	Sample Start Date	Willowbrook village hall	EPA warehouse
11/13/2018	Invalid	2.37	1/27/2019	19.3	1.11
11/16/2018	0.824	1.81	2/1/2019	0.954	0.133
11/19/2018	6.11	6.62	2/2/2019	0.383	0.228
11/23/2018	0.284	0.180	2/5/2019	17.3	26.4
11/25/2018	4.10	Invalid	2/8/2019	0.725	5.04
11/28/2018	1.83	0.248	2/11/2019	3.98	ND
12/1/2018	1.68	0.456	2/14/2019	0.178	0.745
12/6/2018	5.39	11.7	2/19/2019	0.239	0.150
12/7/2018	0.737	2.26	2/20/2019	0.260	0.159
12/10/2018	0.300	0.269	2/21/2019	0.144	ND
12/13/2018	2.04	0.436	2/22/2019	0.123	0.121
12/16/2018	0.871	2.11	2/23/2019	0.128	0.132
12/19/2018	0.521	0.345	2/26/2019	0.166	0.119
12/22/2018	0.981	3.09	3/1/2019	ND	0.103
12/26/2018	10.8	Invalid	3/4/2019	0.161	ND
12/28/2018	0.672	1.42	3/7/2019	0.099	0.096
1/2/2019	0.251	0.237	3/10/2019	Invalid	0.075
1/3/2019	0.372	ND	3/13/2019	0.204	0.122
1/6/2019	7.59	ND	3/16/2019	0.461	0.171
1/9/2019	3.81	Invalid	3/19/2019	0.136	0.056
1/12/2019	1.57	ND	3/22/2019	0.060	0.117
1/15/2019	0.672	14.2	3/25/2019	0.078	0.134
1/17/2019	0.517	13.1	3/28/2019	0.114	0.181
1/22/2019	1.51	4.10	3/31/2019	0.057	ND
1/24/2019	0.262	0.280	-	-	-

Table A-2. Daily ethylene oxide usage rates (lbs) fed to the sterilization chamber

Date	Willowbrook 1	Willowbrook 2	Date	Willowbrook 1	Willowbrook 2
11/13/2018	**755 (820)**	**482 (477)**	12/30/2018	853	0
11/14/2018	753	495	12/31/2018	510	0
11/15/2018	794	258	1/1/2019	622	0
11/16/2018	**864 (935)**	**611 (385)**	**1/2/2019**	**598 (491)**	**0 (0)**
11/17/2018	877	489	**1/3/2019**	**732 (718)**	**0 (0)**
11/18/2018	938	465	1/4/2019	795	151
11/19/2018	**880 (981)**	**517 (529)**	1/5/2019	703.3	420
11/20/2018	1057	413	**1/6/2019**	**110 (517)**	**279 (487)**
11/21/2018	946	694	1/7/2019	0.3	485
11/22/2018	808	339	1/8/2019	0	274
11/23/2018	**827 (1036)**	**690 (593)**	1/9/2019	0	338
11/24/2018	844	538	1/10/2019	0	242
11/25/2018	**665 (729)**	**131 (487)**	1/11/2019	613.9	485
11/26/2018	844	0	**1/12/2019**	**940 (895)**	**315 (468)**
11/27/2018	789	0	1/13/2019	693.7	489
11/28/2018	**851 (864)**	**0 (0)**	1/14/2019	911.4	333
11/29/2018	902	0	**1/15/2019**	**764 (805)**	**318 (336)**
11/30/2018	943	0	1/16/2019	950.7	58
12/1/2018	**793 (908)**	**11 (11)**	**1/17/2019**	**813 (760)**	**344 (128)**
12/2/2018	837	515	1/18/2019	857.7	420
12/3/2018	975	341	1/19/2019	800.2	343
12/4/2018	1035	390	1/20/2019	803.6	484
12/5/2018	972	445	1/21/2019	1068.2	317
12/6/2018	**1054 (1105)**	**347 (317)**	**1/22/2019**	**787 (1003)**	**298 (417)**
12/7/2018	**697 (839)**	**262 (480)**	1/23/2019	862.1	373
12/8/2018	948	447	**1/24/2019**	**653 (859)**	**340 (426)**
12/9/2018	1020	415	1/25/2019	960.9	396
12/10/2018	**852 (892)**	**412 (494)**	1/26/2019	759.7	444
12/11/2018	843	414	**1/27/2019**	**888 (875)**	**286 (313)**
12/12/2018	797	416	1/28/2019	916.1	313
12/13/2018	**1064 (852)**	**476 (441)**	1/29/2019	866.4	358
12/14/2018	671	59	1/30/2019	607.1	289
12/15/2018	574	0	1/31/2019	928.1	357
12/16/2018	**626 (786)**	**293 (222)**	**2/1/2019**	**892**	**345**
12/17/2018	964	470	**2/2/2019**	**829**	**340**
12/18/2018	669	384	2/3/2019	821.5	188
12/19/2018	**826 (988)**	**402 (312)**	2/4/2019	795.1	282
12/20/2018	878	351	**2/5/2019**	**773**	**344**
12/21/2018	784	342	2/6/2019	974.6	131
12/22/2018	**685 (953)**	**0 (283)**	2/7/2019	790.4	312
12/23/2018	797.2	0	**2/8/2019**	**847**	**470**
12/24/2018	736	350	2/9/2019	929.6	352
12/25/2018	893	399	2/10/2019	657.3	553
12/26/2018	**631 (796)**	**471 (471)**	**2/11/2019**	**814**	**260**
12/27/2018	784	360	2/12/2019	69.5	302
12/28/2018	**593 (684)**	**295 (293)**	2/13/2019	818.7	442
12/29/2018	671	228	2/14/2019	852.8	408

Note: BOLD values are days in which ambient sampling was taken. Additionally, the values in (parenthesis) for sample dates from 11/13/2018 – 1/27/2019 are the estimated mass of ethylene oxide sent to the pollution controls.

Table A-3. Willowbrook 1 and Willowbrook 2 emission points and locations

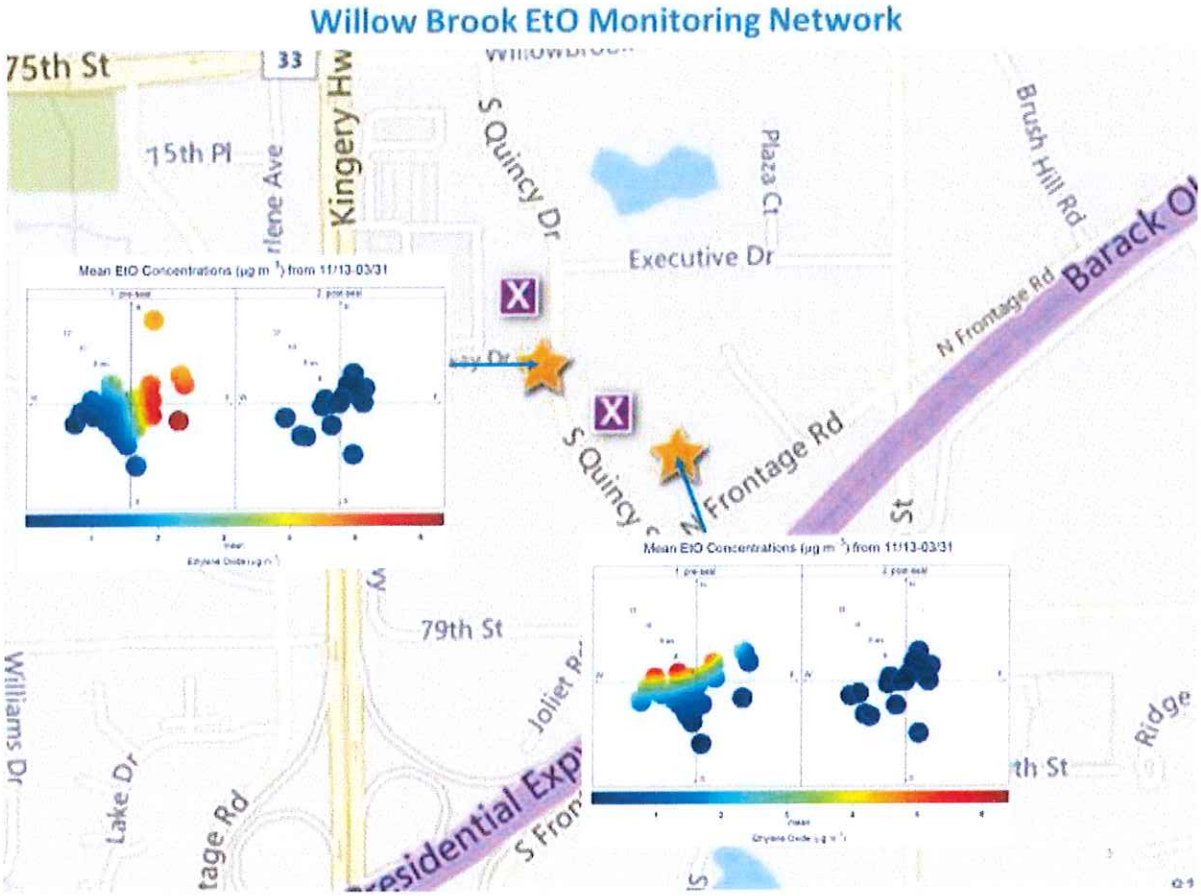
Building	Source ID	Source Description	Easting (X)[26]	Northing (Y)[27]	EtO Emissions (Yes/No)	Emission Type
WB1	STK1	Deoxx	421892.07	4622242.11	Yes	Controlled emissions from the chamber vent
WB1	STK2	AAT Scrubber	421897.15	4622252.27	Yes	Controlled emissions from the aeration rooms and backvent
WB1	1EF11	1-EF-11 Work Aisle	421896.70	4622230.30	Yes	EtO fugitive emission point
WB1	1EF15	1-EF-15 Process Storage/East Aeration	421911.94	4622211.67	No	Former fugitive emission point, exhaust fan has been turned off effective January 2019 (assumed)
WB1	1EF3	1-EF-3 Shipping	421835.32	4622206.80	Yes	EtO fugitive emission point
WB1	1EF4	1-EF-4 Process Storage/Central Aeration	421868.72	4622224.47	Yes	EtO fugitive emission point
WB1	1EF10	1-EF-10 Maintenance Aisle	421897.74	4622213.58	No	Former fugitive emission point
WB1	1EF9	1-EF-9 Work Aisle/Boiler Room	421888.14	4622229.62	Yes	EtO fugitive emission point
WB1	1EF13	1-EF-13 Chamber A or 9	421904.23	4622241.98	No	Former fugitive emission point, exhaust fan has been turned off
WB1	1EF20	1-EF-20 Chamber B Cubical Exhaust	421922.88	4622241.05	No	Former fugitive emission point, exhaust fan has been turned off
WB1	1EF21	1-EF-21 Aat Scrubber Room Exhaust	421925.04	4622249.06	No	No emission expected
WB1	1EF8	1-EF-8 Pump Aisle	421879.63	4622243.03	No	No emission expected
WB1	1EF12	1-EF-12 Chamber A Gassing Room	421908.04	4622241.75	No	Former fugitive emission point, exhaust fan has been turned off
WB1	1EF16	1-EF-16 Chamber A Cubicle	421913.64	4622241.08	No	No emission expected
WB1	1EF19	1-EF-19 Chamber E Cubical Exhaust	421921.00	4622223.31	No	No emission expected
WB1	1EF18	1-EF-18 Chamber C Cubical Exhaust	421916.72	4622238.97	No	No emission expected
WB2	A	AAT Scrubber	421701.70	4622357.89	Yes	Controlled emissions from chamber vent, aeration room, and backvents
WB2	B	3 Chamber Backvent	421708.37	4622378.69	No	Former EtO emission point, routed to AAT scrubber July 2018
WB2	C	1 Chamber Backvent	421709.16	4622354.88	No	Former EtO emission point, routed to AAT scrubber July 2018
WB2	P	Chamber Room Exhaust Fan	421736.89	4622335.04	Yes	EtO fugitive emission point
WB2	Q	Work Aisle Exhaust Fan	421736.30	4622328.70	Yes	EtO fugitive emission point
WB2	T2	North Wall Vent West	421713.72	4622390.70	No	Former fugitive emission point, exhaust fan has been turned off effective January 2019 (assumed)
WB2	T3	North Wall Vent East	421742.29	4622390.70	No	Former fugitive emission point, exhaust fan has been turned off effective January 2019 (assumed)

[26] Coordinates reflect UTM NAD83, Zone 16
[27] Coordinates reflect UTM NAD83, Zone 16

Table A-4. Daily background ethylene oxide levels

Date	Background ($\mu g/m^3$)	Background Location	Modeled Background value ($\mu g/m^3$)	Corrected background value ($\mu g/m^3$)
11/19/2018	0.164	Gower ES	0.016	0.148
11/23/2018	0.197	Gower MS	0.007	0.190
11/25/2018	0.345	Willow Pond Park	0.046	0.299
11/28/2018	0.656	Gower MS	0.064	0.592
12/1/2018	0.211	Willow Pond Park	0.013	0.198
12/6/2018	0.082	Willow Pond Park	0.022	0.060
12/7/2018	0.164	Gower ES	0.030	0.134
12/10/2018	0.138	Gower ES	0.017	0.121
12/13/2018	0.211	Water Tower	0.060	0.151
12/16/2018	0.732	Gower ES	0.011	0.721
12/19/2018	0.360	Gower MS	0.028	0.332
12/22/2018	0.360	Gower ES	0.027	0.333
12/26/2018	0.082	Gower MS	0.084	-0.002
12/28/2018	0.133	Gower ES	0.010	0.123
1/2/2019	0.210	Gower ES	0.004	0.206
1/3/2019	0.082	West Neighborhood	0.040	0.042
1/6/2019	0.082	Willow Pond Park	0.006	0.076
1/9/2019	0.295	Hinsdale South High School	0.027	0.268
1/12/2019	0.082	Gower MS	0.007	0.075
1/15/2019	0.082	Gower ES	0.008	0.074
1/17/2019	0.144	Willow Pond Park	0.008	0.136
1/22/2019	0.349	Hinsdale South High School	0.059	0.290
1/24/2019	0.095	Gower ES	0.005	0.090
1/27/2019	0.155	Gower MS	0.045	0.110
2/1/2019	0.101	Gower MS	0.039	0.062
2/2/2019	0.371	Gower MS	0.016	0.355
2/5/2019	0.174	Willow Pond Park	0.006	0.168
2/8/2019	0.202	Gower ES	0.010	0.192
2/11/2019	0.089	Willow Pond Park	0.001	0.088

Figure A-1. EtO Concentration Plots for the Willowbrook Village Hall and EPA Warehouse Monitors



Appendix 2 to the Risk Assessment Report
for the Sterigenics Facility in Willowbrook, Illinois:

Technical Support Document for HEM-AERMOD Modeling

Modeling for the Residual Risk and Technology Review Using the Human Exposure Model 3 – AERMOD Version

Updated 4/24/2019

Technical Support Document

Prepared for:

U.S. Environmental Protection Agency
Office of Air and Radiation
Office of Air Quality Planning and Standards
Health and Environmental Impacts Division
Air Toxics Assessment Group
Research Triangle Park, NC 27711

Prepared by:

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Disclaimer

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Contents

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1. Introduction

This document describes the general modeling approach used to estimate the risks to human populations in support of the Residual Risk and Technology Review (RTR) currently being carried out by the U.S. Environmental Protection Agency (EPA). It is important to note that risk characterizations of individual source categories under the RTR program may not follow every item/approach noted in this document. The reader is referred to the main body of the risk assessment document for more details on source category specific approaches that may have been included in the analysis.

The model used in these risk assessments is the Human Exposure Model, Version 3 (HEM-3). HEM-3 incorporates AERMOD, a state of the science air dispersion model developed under the direction of the American Meteorological Society / Environmental Protection Agency Regulatory Model Improvement Committee (AERMIC).

Section 2 of this report provides an overview of the HEM-3-AERMOD system; and Section 3 describes inputs and choices made in implementing the model for the RTR program. Quality assurance efforts undertaken in the modeling effort are discussed in Section 4, and uncertainties associated with the modeling effort are discussed in Section 5.

2. Overview of the HEM-3 – AERMOD System

HEM-3 performs three main operations: dispersion modeling, estimation of population exposure, and estimation of human health risks. The state-of-the-art American Meteorological Society (AMS) / EPA Regulatory Model (AERMOD)[1,2] is used for dispersion modeling. AERMOD can handle a wide range of different source types which may be associated with an industrial source complex, including stack (point) sources, area and polygon sources, volume sources, line and buoyant line sources.

To prepare dispersion modeling inputs and carry out risk calculations, HEM-3 draws primarily on three data libraries, which are provided with the model. The first is a library of meteorological data for over 800 stations, which are used for dispersion calculations. A second library of Census block ("centroid") internal point locations and populations provides the basis of human exposure calculations. The Census library also includes the elevations of every Census block, which are used in the dispersion calculations for the RTR assessments. A third library of pollutant unit risk estimates and reference concentrations is used to calculate population risks. These unit risk estimates (URE) and reference concentrations (RfCs) are based on the latest dose response values recommended by EPA for hazardous air pollutants (HAPs) and other toxic air pollutants. A fourth data library, which contains deposition parameters for gaseous pollutants, is also provided with HEM-3 but used only when the user opts to compute gaseous deposition with or without plume depletion. (Note: Deposition has not been computed for the RTR assessments to date).

HEM-3 has been implemented in two versions: a single facility version ("Single HEM-3"), and a multiple facility version ("Multi HEM-3"). Multi HEM-3 is used in the RTR risk assessment modeling. Both versions operate under the same general principles. In essence, Multi HEM-3 provides a platform for running the single facility version multiple times. In both versions, source location and emissions data are input through a set of Excel™ spreadsheets. The main difference is in the user interface for other model inputs. Single HEM-3 includes a graphical user interface (GUI) for the selection of various dispersion modeling options. In Multi HEM-3, a control file replaces many of these GUI inputs.

The model estimates cancer risks and non-cancer adverse health effects due to inhalation exposure at Census block internal point locations (or "centroids"), at concentric rings surrounding the facility center, and at other receptor locations that can be specified by the user. Cancer risks are computed using EPA's recommended unit risk estimates for HAPs and other toxic air pollutants. The resulting estimates reflect the excess cancer risk for an individual breathing the ambient air at a given receptor site 24-hours per day over a 70-year lifetime. The model estimates the numbers of people exposed to various cancer risk levels. In addition, HEM-3 estimates the total incremental cancer risks for people living within different distances of the modeled emission sources.

Potential non-cancer health effects due to chronic exposures are quantified using hazard quotients and hazard indices for various target organs. The "hazard quotient" (HQ) for a given chemical and receptor site is the ratio of the ambient concentration of the chemical to the reference concentration. The "hazard index" (HI) for a given organ is the sum of hazard quotients for substances that affect that organ. HEM-3 computes target-organ-specific hazard

indices (TOSHIs) for HAPs and other toxic air pollutants, and estimates the numbers of people exposed to different hazard index levels. In addition, short term ("acute") concentrations are computed for all pollutants, and concentrations are compared with various threshold levels for acute health effects.

The following sections outline the methodologies used in the HEM-3–AERMOD system. Section 2.1 describes the preparation of dispersion modeling inputs, Section 2.2 describes the running of AERMOD, Section 2.3 describes calculations performed by HEM-3 to calculate risks and exposures, and Section 2.4 details the sources and methods used to produce HEM-3's data libraries. The HEM-3 User's Manuals – for Single HEM-3 and Multi HEM-3 – provide additional details on the input data and algorithms used in the model.[3] Specific model options used in the RTR assessments are discussed in Chapter 3.

2.1 Preparation of Dispersion Modeling Inputs

HEM-3 compiles data that will be needed for dispersion modeling, and prepares an input file suitable for running AERMOD. The dispersion modeling inputs can be divided into three main components: emission source data, information on the modeling domain and receptors for which impacts will be computed, and meteorological data.

2.1.1 Compiling Emission Source Data

A series of Excel™ spreadsheet files are used to specify the emissions and configuration of the facility to be modeled. At a minimum, two files are needed: a HAP emissions file, and an emissions location file. The HAP emissions file includes an emission source identification code for each emission source at the facility, the names of pollutants emitted by each source, and the emission rate for each pollutant. In addition, if the model run is to incorporate deposition or plume depletion, the HAP emissions file must also specify the percentage of each pollutant that is in the form of particulate matter. The balance is assumed to be in gaseous/vapor form.

The emissions location file includes the coordinates of each source, as well as information on the configuration and other characteristics of the source. HEM-3 can analyze point sources, area and polygon sources, volume sources, and line and buoyant line sources - configurations that are described in AERMOD's documentation.[1,2] For stack (point) sources, such as a vertical non-capped, capped or horizontal stacks the emissions location file must provide the stack height, stack diameter, exit velocity, and emission release temperature. The file must also provide dimensions for each area, polygon, volume or line source, as well as the height of the source above the ground. For area sources, the angle of rotation from north can also be specified. The user can also provide the terrain elevation at the base of each source. (The controlling hill height is also used in AERMOD's flow calculations. Calculation of the controlling hill height by HEM-3 is discussed in Section 2.4.2.) If the terrain elevations are not provided by the user, HEM-3 will calculate elevations and controlling hill heights based on elevations and hill heights provided by the Census database for the Census blocks nearest to the facility.

If buoyant line source types are to be considered, particularly when computing building downwash effects, then HEM-3 requires an additional input file to specify the source type's

parameters. For buoyant line sources, the average buoyancy parameter, the average building dimensions (i.e., average building length, height, and width), the average line source width, and the average separation distance between buoyant lines are required inputs for an associated buoyant line parameters input file.

If particulate deposition and plume depletion are to be considered, then HEM-3 requires an input file to specify the particle size distribution. This input file must include the average particle diameter, the mass fraction percentage, and the average particle density for each size range emitted. Another optional file can be used to specify building dimensions if building wake effects are to be modeled.

2.1.2 Defining the Modeling Domain and Receptors

HEM-3 defines a modeling domain for each facility that is analyzed based on parameters specified by the model user or calculated by the model. These parameters are summarized in Table 2-1. The modeling domain is circular, and is centered on the facility, with a radius specified by the user. For the RTR analysis, the radius of the modeling domain is 50 kilometers (km). HEM-3 identifies all of the Census block locations in the modeling domain from its Census database, and divides the blocks into two groups based on their distance from the facility. For the inner group of Census blocks (closest to the facility), each block location is modeled as a separate receptor in AERMOD. The cutoff distance for modeling individual Census blocks is generally set to 3,000 m (3 km) for the RTR assessments, although it can be set differently by the model user. The model user can also provide an Excel™ spreadsheet specifying additional locations to be included as model receptors in AERMOD. These additional discrete "user receptors" may include facility boundary locations, monitoring sites, individual residences, schools, or other locations of interest.

Table 2-1. Parameters Used to Delineate the Modeling Domain in HEM-3

Parameter	Typical value
Modeling domain size – maximum radial distance to be modeled from facility center	50 km
Cutoff distance for modeling of individual blocks[a]	3,000 m
Overlap distance – where receptors are considered on facility property[a]	30 m
Polar receptor network:	
Distance to the innermost ring[b]	≥100 m
Number of concentric rings	13
Number of radial directions	16

[a] Measured from each stack at the facility, and from the edges of each area or volume source.

[b] Generally model-calculated to encompass all emission sources but not less than 100 meters from the facility center.

For Census blocks in the outer group, beyond this modeling cutoff distance, emission impacts are interpolated based on modeling results for a polar receptor network. The user also specifies an

"overlap" distance, within which Census block coordinates will be considered to be on facility property. The following paragraphs provide more details on the treatment of blocks near the facility, on the polar receptor network, and on the determination of receptor elevations and controlling hill heights to be used in AERMOD.

Treatment of Nearby Census Blocks and Screening for Overlapping Blocks

Census block locations near the facility are modeled as separate receptors within AERMOD. The cutoff distance for modeling of individual Census blocks may be chosen by the user, but is typically 3,000 meters for the RTR assessments. This distance is not measured from the center of the facility, but is the minimum distance from any source at the facility. Therefore, any Census block location that is within the cutoff distance from any emission source is treated as a discrete AERMOD receptor.

HEM-3 checks Census blocks that are very close to the facility in order to assess whether they overlap any point, area, volume, line or buoyant line emission sources. In addition, the user can specify an overlap distance, within which receptors will be considered to be on facility property. The default value for the overlap distance is 30 meters, or approximately equal to the width of a narrow buffer and a roadway. HEM-3 tests each nearby receptor to determine whether it is within this distance from any stack or from the perimeter of any area, volume, line or buoyant line source. If a receptor falls within this distance, HEM-3 will not calculate risks based on the location of that receptor, but will instead assume that the risks associated with the receptor are the same as the highest predicted value for any receptor that is not overlapping. The location for calculating the default impact may be either another Census block, one of the polar grid receptors, or one of the additional discrete user-specified receptor locations. [Note: An exception to this occurs when modeling polygon sources. Unlike other sources, when modeling polygons, the overlap function is disabled. This allows the impacts for a census tract modeled as a polygon source (e.g. mobile source emissions modeled uniformly across a census tract) to be calculated within the census tract being modeled.]

Polar receptor network

The polar receptor network used in HEM-3 serves three functions. First, it is used to estimate default impacts if one or more Census locations are inside the overlap cutoff distance used to represent the facility boundary. Second, it is used to evaluate potential acute effects that may occur due to short-term exposures in locations outside the facility boundary. Third, the polar receptor network is used to interpolate long-term and short-term impacts at Census block locations that are outside the cutoff distance for modeling of individual blocks.

Generally, the model calculates the inner radius (or first ring distance) for the polar receptor network to be just outside the emission source locations, but not less than 100 meters from the facility center. However, the user can override the default distance calculated by the model to fit the size and shape of the facility properties to be modeled. Likewise, the model will also use default values for the number of concentric rings to be analyzed (13 rings by default), and the number of radial directions (16 radials by default), although these default values can also be changed by the user to meet the needs of a specific modeling study. The inner radius of the

polar network should be the minimum distance from the facility center that is generally outside of facility property. (For complex facility shapes, it is sometimes useful to specify an inner ring that encroaches on facility property in some directions.) HEM-3 will distribute the radial directions evenly around the facility. For the concentric rings, the model will generate a logarithmic progression of distances starting at the inner ring radium and ending at the outer radium of the modeling domain.

Elevations and hill heights for model receptors

HEM-3 includes terrain elevations by default for the RTR assessments, but the user can choose to exclude terrain effects when running AERMOD. If the default terrain option is used, HEM-3 obtains elevations and controlling hill heights for Census block receptors from its internal Census location library. Section 2.4.2 describes the derivation of these elevations and hill heights.

Elevations and controlling hill heights for the polar grid receptors are also estimated based on values from the Census library. HEM-3 divides the modeling domain into sectors based on the polar receptor network, with each Census block assigned to the sector corresponding to the closest polar grid receptor. Each polar grid receptor is then assigned an elevation based on the highest elevation for any Census block in its sector. The controlling hill height is also set to the maximum hill height within the sector. If a sector does not contain any blocks, the model defaults to the elevation and controlling hill height of the nearest block outside the sector.

2.1.3 Selection of Meteorological Data

In addition to source and receptor information, AERMOD requires surface and upper air meteorological observations in a prescribed format. The model user can select a meteorological station from the HEM-3 meteorological data library, or add new files to the library if site-specific data are available. If the user does not specify a meteorological station, HEM-3 will select the closest station to the center of the modeling domain, as is generally done for the RTR assessments.

2.2 Running of AERMOD

Based on the user input data and other data described in the previous section, HEM-3 produces an input file suitable for AERMOD. HEM-3 then runs AERMOD as a compiled executable program. No changes have been made from the version of AERMOD released to the public by EPA. The following sections give additional information on how AERMOD is used within HEM-3.

2.2.1 AERMOD Dispersion Options Used by HEM-3

AERMOD provides a wide array of options for controlling dispersion modeling calculations. In general, HEM-3 uses the regulatory default options when running AERMOD.[1] These options include the following:

- Use stack-tip downwash (except for Schulman-Scire downwash);
- Use buoyancy-induced dispersion (except for Schulman-Scire downwash);
- Do not use gradual plume rise (except for building downwash);
- Use the "calms processing" routines;
- Use upper-bound concentration estimates for sources influenced by building downwash from super-squat buildings;
- Use default wind profile exponents;
- Use low wind speed threshold;
- Use default vertical potential temperature gradients;
- Use of missing-data processing routines; and
- Consider terrain effects.

The following additional AERMOD options are available to the HEM-3 user:

- Calculation of wet and dry deposition rates for gaseous and particulate pollutants;
- Consideration of plume depletion (due to deposition) when calculating air concentrations;
- Consideration of building wake effects;
- Calculation of short term (acute) impacts;
- Use of the FASTALL option, which conserves model runtime by simplifying the AERMOD algorithms used to represent meander of the pollutant plume; and
- Use of the buoyant line plume option.

As noted in Section 2.1, the calculation of deposition or depletion and the consideration of building wake effects require additional user inputs.

The user can opt to analyze short term impacts on a number of different time scales (i.e., 1 hour, 2 hours, 3 hours, 4 hours, 6 hours, 8 hours, 12 hours, or 24 hours) however only one short term time scale can be selected per run. If the user chooses to analyze short term (acute) impacts, a multiplier must be specified to reflect the ratio between the maximum short term emission rate and the long term average emission rate. If available, acute multipliers specific to source classification codes (SCCs) are used in RTR assessments. If SCC-specific acute multipliers are not available, the default multiplier for short term emissions is a factor of 10. This means that in the default case the maximum short term emission rate is assumed to be 10 times the long term average emission rate. The multiplier can be set to one (1) if emissions from the facility are known to be constant. For RTR assessments, acute impacts are generally included in the modeling and the default multiplier of 10 is used, unless more source-specific information is available upon which to base the acute factor for the source category being modeled.

2.2.2 Use of Dilution Factors

To save computer run time when analyzing the impacts of multiple pollutants, HEM-3 does not model each pollutant separately. Instead, AERMOD is used to compute a series of dilution factors, specific to each emission source and receptor. The dilution factor for a particular emission source and receptor is defined as the predicted ambient impact from the given source and at the given receptor, divided by the emission rate from the given source.

If the user chooses not to analyze deposition (with or without plume depletion), the dilution factor does not vary from pollutant to pollutant. If deposition and/or depletion is chosen as a model option, separate dilution coefficients must be computed for each gaseous pollutant. In addition, separate dilution factors must be computed for different components of particulate matter if the components do not have the same particle size distribution. In the current version of HEM-3, this can be done by creating a separate emission record for each pollutant emitted by from each source. (Common location data and source configurations can be used for different pollutant records representing the same emission source.)

2.3 Postprocessing of AERMOD Results in HEM-3

HEM-3 estimates total excess cancer risks and potential chronic non-cancer health effects for all Census block locations in the modeling domain, all user-defined receptors, and all points in the polar receptor network. Potential chronic non-cancer health effects are expressed in terms of TOSHI. Based on the results for Census blocks and other receptors, HEM-3 estimates the maximum individual risk (MIR) and maximum TOSHI for populated receptors, and determines the locations of these maximum impacts. The model also determines the concentrations of different pollutants at the site(s) of maximum risk and maximum TOSHI, and the contributions of different emission sources to these locations of maximum impact. It should be noted that the locations of maximum impact may differ for the maximum individual cancer risk and for the hazard indices of different target organs.

For acute impacts, HEM-3 calculates the 99^{th} percentile maximum short term concentrations for all pollutants emitted by the facility. These short term concentrations are compared with various threshold levels for acute health effects (e.g., the California EPA reference exposure level [REL] for no adverse effects).

At the option of the model user, HEM-3 will also compute the long term and short term predicted ambient concentrations of all pollutants emitted by the facility at all of the receptors in the modeling domain. In addition, pollutant contributions from each emission source at the facility are computed under this option. In RTR assessments, this option is standard and concentrations are computed for all receptors.

Section 2.3.1 describes methods used to calculate cancer risks and hazard indices for receptors that are explicitly modeled using AERMOD. Section 2.3.2 describes the interpolation approach used to estimate cancer risks and hazard indices at Census blocks that are not explicitly modeled.

2.3.1 Calculation of Impacts at Modeled Receptors

As noted in Section 2.2.2, HEM-3 does not model each pollutant separately unless deposition or depletion is being analyzed. Instead, AERMOD is used to compute a series of dilution factors, specific to each emission source and receptor. The following algorithms are used to compute cancer risks and TOSHI for chronic non-cancer health effects.

For cancer risk:

$$CR_T = \sum_{i,j} CR_{i,j}$$

$$CR_{i,j} = DF_{i,j} \times CF \times \sum_k [E_{i,k} \times URE_k]$$

For TOSHI:

$$TOSHI_T = \sum_{i,j} TOSHI_{i,j}$$

$$TOSHI_{i,j} = DF_{i,j} \times CF \times \sum_k [E_{i,k} / RfC_k]$$

where:

CR_T =	total cancer risk at a given receptor (probability for one person)
$\sum_{i,j}$ =	the sum over all sources i and pollutant types j (particulate or gas)
$CR_{i,j}$ =	cancer risk at the given receptor for source i and pollutant type j
$DF_{i,j}$ =	dilution factor [(μg/m^3) / (g/sec)] at the given receptor for source i and pollutant type j
CF =	conversion factor, 0.02877 [(g/sec) / (ton/year)]
$\sum_k$ =	sum over all pollutants k within pollutant type j (particulate or gas)
$E_{i,k}$ =	emissions of pollutant k from source i and in pollutant type j
URE_k =	cancer unit risk factor for pollutant k
$TOSHI_T$ =	total target-organ-specific hazard index at a given receptor
$TOSHI_{i,j}$ =	target-organ-specific hazard index at the given receptor for source i and pollutant type j
RfC_k =	non-cancer health effect reference concentration for pollutant k

The above equations are equivalent to the following simpler equations:

$$CR_T = \sum_{i,k} AC_{i,k} \times URE_k$$

$$TOSHI_T = \sum_{i,k} AC_{i,k} / RC_k$$

where:

$AC_{i,k}$ =	ambient concentration (μg/m^3) for pollutant k at the given receptor. This is the same as $[E_{i,k} \times DF_{i,j} \times CF]$

However, use of these simpler equations would require modeling all pollutants individually in AERMOD, and performing separate risk calculations for each pollutant.

If the cancer unit risk estimate is not available for a given chemical, then that chemical is not included in the calculation of cancer risk. Likewise, if the non-cancer reference concentration is not available for a given chemical, that chemical is not included in the calculation of hazard indices. Note also that separate reference concentrations are used for acute and chronic hazard indices.

HEM-3 computes short term concentrations and records the highest short term concentration for each pollutant. In addition, the user can opt to compute and record the short term and long concentrations at each receptor. Concentrations are computed as follows.

Long term concentrations:

$$AC_{T,k} = \sum_i AC_{i,k}$$

$$AC_{i,k} = E_{i,k\,x}\, DF_{i,j} \times CF$$

Short term concentrations:

$$AC_T = \sum_i AC_{i,k}$$

$$AC_{i,k} = E_{i,k\,x}\, DF_{i,j} \times CF \times M$$

where:

$AC_{T,k}$ = total estimated ambient concentration for pollutant k at a given receptor
$\sum_i$ = the sum over all sources i ($\mu g/m^3$)
$AC_{i,k}$ = estimated ambient concentration of pollutant k at the given receptor as a result of emissions from source i ($\mu g/m^3$)
M = ratio between the estimated maximum short term emission rate and the long term average emission rate (dimensionless)

2.3.2 Interpolation of Impacts at Outer Census Blocks

For Census blocks outside of the cutoff distance for individual block modeling, HEM-3 estimates cancer risks and hazard indices by interpolation from the polar receptor network. HEM-3 estimates impacts at the polar grid receptors using AERMOD modeling results and the algorithms described in Section 2.3.1. If terrain elevation is part of the modeling, then an elevation is estimated for each polar receptor. HEM-3 estimates elevations and controlling hill heights for the polar grid receptors based on values from the census library. HEM-3 divides the modeling domain into sectors based on the polar grid receptor network, with each census block assigned to the sector corresponding to the closest polar grid receptor.

HEM-3 then assigns each polar grid receptor an elevation based on the highest elevation for any census block in its sector. The controlling hill height is also set to the maximum hill height within the sector. If a sector does not contain any blocks, the model defaults to the elevation and controlling hill height of the nearest block outside the sector.

HEM-3 interpolates the impacts at each outer Census block from the four nearest polar grid receptors. The interpolation is linear in the angular direction, and logarithmic in the radial direction, as summarized in the following equations:

$$I_{a,r} = I_{A1,r} + (I_{A2,r} - I_{A1,r}) \times (a - A1) / (A2 - A1)$$

$$I_{A1,r} = \exp\{(\ln (I_{A1,R1}) + [(\ln (I_{A1,R2}) - \ln (I_{A1,R1})] \times [(\ln r) - \ln(R1)] / [\ln(R2) - \ln(R1)]\}$$
$$I_{A2,r} = \exp\{(\ln (I_{A2,R1}) + [(\ln (I_{A2,R2}) - \ln (I_{A2,R1})] \times [(\ln r) - \ln(R1)] / [\ln(R2) - \ln(R1)]\}$$

where:

$I_{a,r}$ = the impact (cancer risk, hazard index, or concentration) at an angle, a, from north, and radius, r, from the center of the modeling domain

a = the angle of the target receptor, from north

r = the radius of the target receptor, from the center of the modeling domain

A1 = the angle of the polar network receptors immediately counterclockwise from the target receptor

A2 = the angle of the polar network receptors immediately clockwise from the target receptor

R1 = the radius of the polar network receptors immediately inside the target receptor

R2 = the radius of the polar network receptors immediately outside the target receptor

2.3.3 Calculation of Population Exposures and Incidence

Using the predicted impacts for Census blocks, HEM-3 estimates the numbers of people exposed to various cancer risk levels and TOSHI levels. This is done by adding up the populations for receptors that have predicted cancer risks or TOSHI above the given threshold.

The model also estimates the annual excess cancer risk (incidence) for the entire modeling region. The following equation is used:

$$TCR = \sum_m [CR_m \times P_m] / LT$$

where:

TCR = the estimated annual cancer incidence (excess cancers/year) to the population living within the modeling domain

$\sum_m$ = the sum over all Census blocks m within distance the modeling domain

CR_m = the total lifetime cancer risk (from all modeled pollutants and emission sources) at Census block m

P_m = the population at Census block m

LT = the average lifetime used to develop the cancer unit risk factor, 70 years

HEM-3 also estimates the contributions of different chemicals and emission sources to total annual cancer incidence for the overall modeling domain using the following equations:

$$TCR_{i,j} = \sum_m [(\sum_k E_{i,k} \times URE_k) \times DF_{i,j,m} \times CF / LT]$$

$$TCR_{i,k} = TCR_{i\,j} \times E_{i,k} \times URE_k / (\sum_k E_{i,k} \times URE_k)$$

where:

$TCR_{i,j}$ = the estimated total annual cancer incidence (cancers/year) to the population in the modeling domain due to emissions from pollutant type j (1 = particulate, 2 = gas) and emission source i

$\sum_m$ = the sum over all Census blocks m within distance the modeling domain
$\sum_k$ = the sum over all pollutant k, within pollutant type j
$E_{i,k}$ = emissions of pollutant k from source i (tons/year)
URE_k = unit risk factor for pollutant k
$DF_{i,j,m}$ = dilution factor at receptor m, for emissions of pollutant type j (which includes pollutant k), from source i
CF = conversion factor, 0.02877 [(g/sec) / (tons/year)]
$TCR_{i,k}$ = the estimated annual cancer incidence (cancers/year) of the population in the modeling domain due to emissions of pollutant k (in pollutant type j) from emission source i

2.3.4 Model Outputs

The following is a summary of the outputs produced by HEM-3. These are written to a collection of files in Excel™ and dBase™ format (dbf).

- Long term impacts at populated locations
    - maximum long term ambient concentration for each chemical
    - maximum lifetime individual cancer risk (MIR)
    - maximum TOSHI for the following health effects

        - respiratory system effects
        - liver effects
        - neurological system effects
        - developmental effects
        - reproductive system effects
        - kidney effects
        - ocular system effects
        - endocrine system effects
        - hematological system effects
        - immunological system effects
        - skeletal system effects
        - spleen effects
        - thyroid effects
        - whole body effects

    - locations of the maximum cancer risk and maximum TOSHIs
    - Census block identification codes for the maximum concentration, maximum cancer risk and maximum TOSHIs, and number of people in the Census block
    - contributions of different chemicals and emission sources to the maximum risk and TOSHI

- Acute impacts
    - 99^{th} percentile maximum short term ambient concentration for each chemical

- threshold levels for acute health effects of each chemical (compared with the 99th percentile maximum short term concentrations)
- locations of the 99th percentile maximum impacts for different chemicals (often polar receptors)
- Census block identification codes at the locations of 99th percentile maximum concentration, and number of people in the block
- contribution of each emission source at the facility to the 99th percentile maximum short term concentration of each chemical

- Outputs for all receptors
  - maximum individual cancer risk and TOSHI (all target organs) for each Census block and each user-specified discrete receptor (monitoring sites, etc.)
  - maximum individual cancer risk and TOSHI (all target organs) for each polar grid receptor
  - estimated deposition flux (optional)
  - predicted ambient concentration resulting from each emission source at each Census block and polar grid receptor (optional)

- Population exposures and total cancer risk, or incidence
  - estimated numbers of people exposed to different levels of lifetime individual cancer risk (1 in a million, 1 in 100,000, etc.)
  - estimated numbers of people exposed to different levels of TOSHI (1, 2, 10, etc.)
  - total cancer risk, or incidence, in estimated cancer deaths per year, over the entire modeling domain, and for each pollutant and source combination

2.4 Data Libraries Used in HEM-3

2.4.1 Chemical Health Effects Information

HEM-3 includes a library of available health effects data for HAPs. For each pollutant, the library includes the following parameters, where available:

- unit risk estimate (URE) for cancer;
- reference concentration (RfC) for chronic non-cancer health effects;
- reference benchmark concentrations for acute health effects; and
- target organs affected by the chemical for chronic non-cancer health effects.

Unit risk estimates and reference concentrations included in the HEM-3 chemical library have been taken from EPA's database of recommended dose-response factors for HAPs, which is updated periodically, consistent with continued research on these parameters.[4] The URE represents the upper-bound excess lifetime cancer risk estimated to result from continuous exposure to an agent (HAP) at a concentration of 1 microgram per cubic meter ($\mu g/m^3$) in air (e.g., if the URE = 1.5×10^{-6} per $\mu g/m^3$, then 1.5 excess tumors are expected to develop per 1 million people if all 1 million people were exposed daily for a lifetime to 1 microgram of the chemical in 1 cubic meter of air). UREs are considered plausible upper limits to the true value; the true risk is likely to be less but could be greater.[5]

The RfC is a concentration estimate of a continuous inhalation exposure to the human population that is likely to be without an appreciable "risk" of deleterious non-cancer health effects during a lifetime (including to sensitive subgroups such as children, asthmatics and the elderly). No adverse effects are expected as a result of exposure if the ratio of the potential exposure concentration to the RfC, defined as the hazard quotient (HQ), is less than one. Note that the uncertainty of the RfC estimates can span an order of magnitude.[5] Target organs are those organs (e.g., kidney) or organ systems (e.g., respiratory) which may be impacted with chronic non-cancer health effects by exposure to the chemical in question. The hazard index (HI) is the sum of HQs for substances that affect the same target organ or organ system, also known as the target organ specific hazard index (TOSHI).

The reference benchmark concentration for acute health effects, similar to the chronic RfC, is the concentration below which no adverse health effects are anticipated when an individual is exposed to the benchmark concentration for 1 hour (or 8 hours, depending on the specific acute benchmark used and the formulation of that benchmark). A more in-depth discussion of the development and use of these parameters for estimating cancer risk and non-cancer hazard may be found in the EPA's Air Toxics Risk Assessment Library.[6]

The model user can add pollutants and associated health effects to HEM-3's chemical health effects (dose-response and target organ endpoints) library, as needed.

2.4.2 Census Block Locations and Elevation Data

The HEM-3 Census library includes Census block identification codes, locations, populations, elevations, and controlling hill heights for all of the over 6 million Census blocks identified in the 2010 Census and the over 5 million Census blocks identified in the 2000 Census. The model user may choose to use either Census database according to their modeling needs. The location coordinates reflect the internal "centroid" of the block, which is a point

selected by the Census to be roughly in the center of the block. For complex shapes, the internal point may not be in the geographic center of the block. Locations and population data for Census blocks in the 50 states and Puerto Rico were extracted from the LandView® database For the 2000 Census[7] and from the U.S. Census Bureau website for the 2010 Census.[8] Locations and populations for blocks in the Virgin Islands were obtained from the U.S. Census Bureau website.

U.S. Geological Survey data was used to estimate the elevation of each census block in the continental U.S. and Hawaii. The data used for the 2000 Census elevations have a resolution of 3 arc-seconds, or about 90 meters.[9] The data used for the 2010 Census elevations have a resolution of 1/3 of an arc second, or about 10 meters.[10] Using analysis tools (ArcGIS® 9.1 software application for the 2000 Census, and ArcGIS® 10 for the 2010 Census), elevation was estimated for each census block in Alaska and the U.S. Virgin Islands. The point locations of the census blocks in Alaska and the U.S. Virgin Islands were overlaid with a raster layer of North American Digital Elevation Model (DEM) elevations (in meters).[9] An elevation value was assigned to each census block point based on the closest point in the ArcGIS elevation raster file.

An algorithm used in AERMAP, the AERMOD terrain processor, is used to determine controlling hill heights.[11,12] These values are used for flow calculations within AERMOD. To save run time and resources, the HEM-3 census block elevation database is substituted for the DEM data generally used in AERMAP. As noted above, the census block elevations were originally derived from the DEM database. To determine the controlling hill height for each census block, a cone is projected away from the block centroid location, representing a 10% elevation grade. The controlling hill height is selected based on the highest elevation above that 10% grade (in accordance with the AERMAP methodology). The distance cutoff for this calculation is 100 km. (This corresponds to an elevation difference at a 10% grade of 10,000 m, which considerably exceeds the maximum elevation difference in North America.)

2.4.3 Meteorological Data

HEM-3 includes an extensive library of meteorological data to support the AERMOD dispersion model. Currently over 800 meteorological stations have been preprocessed for AERMOD as part of the RTR effort. Section 3.3 includes a depiction of these meteorological stations and Appendix 3 discusses the preparation of meteorological data for the RTR in more detail.

2.4.4 Gaseous Deposition Parameters

HEM-3 provides options to compute the deposition of air pollutants, and to take into account the impacts of plume depletion due to deposition of gaseous and particulate pollutants. If the deposition and depletion option is selected by the model user for gaseous pollutants, a number of pollutant properties are required by AERMOD. (These include the diffusivity of the pollutant in air, the diffusivity of the pollutant in water, the Henry's Law constant, and a parameter reflecting the cuticular resistance to uptake of the pollutant by leaves r_{cl}).[13] HEM-3 includes a library of these parameters for approximately 130 gaseous HAPs. This library is based on a compendium of gaseous deposition parameters developed by Argonne National Laboratories.[14] The HEM-3 user can edit these values, if appropriate, including adding additional

pollutant values available in the literature or calculated based on recommended methodology, as discussed in the Single HEM-3 User's Guide.[3] It should be noted, however, that the deposition and depletion option of HEM-3 and AERMOD have not been used to date for the RTR assessments.

3. Modeling for the Residual Risk Technology Review

This section discusses the general approach used to implement the HEM-3 AERMOD system for the RTR modeling analyses. Separate reports have been prepared for each of the emission source categories analyzed to date. These reports provide information on the emissions inputs and results for specific emission categories.

3.1 Emission Source Inputs

HEM-3 and AERMOD require detailed data on emissions from each emission source included in the modeling analysis. These data include, for example:

- pollutants emitted;
- emission rate for each pollutant;
- emission source coordinates;
- stack height (or emission height for fugitive and other area sources);
- stack diameter (or configuration of fugitive and other area sources);
- emission velocity; and
- emission temperature.

Emissions data for the RTR assessments are compiled from a variety of data sources (e.g., the National Emissions Inventory (NEI)[15], information collection requests). Each source category evaluated under the RTR program utilizes the best available data. These data include HAP emission rates, emission source coordinates, stack heights, stack diameters, flow rates, exit temperatures, and other emission parameters depending on the emission source types modeled. EPA performs an engineering review of the NEI data. In cases where new or better data are known to exist for a particular source category, that information is integrated into the data used in modeling that category. For each source category, the emissions are summarized in the source category specific report. Detailed computer files containing all emission and release characteristics are available in the docket prepared for the specific RTR source category under proposed or final rulemaking.

As noted in the previous section, industrial emission sources can be characterized in AERMOD as point (vertical, capped and horizontal), area, polygon, volume, line or buoyant line

sources. Fugitive emissions are generally characterized as low point sources with minimal exit velocities. For some categories, additional information is available on the configuration of fugitive emission sources. This information is incorporated into the emissions database as part of the engineering review. For example, fugitive emission sources are characterized as area or volume sources when sufficient configuration information is available.

3.2 Pollutant Cross-Referencing

Because the NEI is developed from a number of different data sources, a single chemical may be listed in the inventory under different names (i.e., a "common name" and one or more structure-based names). In addition, pollutant groupings such as polycyclic organic matter (POM), can be listed in the NEI under the names of individual member compounds, and under different synonyms (e.g. polynuclear aromatic hydrocarbons). HEM-3 requires an exact match with the chemical name in order to link emissions to the appropriate dose-response factors. The model will not process any pollutant that is not specifically listed in the chemical library. Therefore, all of the HAP names used in the NEI are linked to the appropriate chemical names in the HEM-3 reference file.

Pollutant-specific dose response values are used in the HEM-3 modeling whenever available, including when modeling POM pollutants and metal compounds. Pollutant groupings, such as POM groupings, are used for POMs without a chemical-specific unit URE's. These POMs are assigned a URE associated with various POM compounds having similar characteristics. The "Technical Support Document – EPA's 2011 National-scale Air Toxics Assessment" 2015 document[16] provides more details regarding POM modeling, including (p. 121):

> [S]ome emissions of POM were reported in [the] NEI as "7-PAH" or "16-PAH," representing subsets of certain POM, or simply as "total PAH" or "polycyclic organic matter." In other cases, individual POM compounds are reported for which no quantitative cancer dose-response value has been published in the sources used for NATA. As a result, simplifying assumptions that characterize emissions reported as POM are applied so that cancer risk can be quantitatively evaluated for these chemicals without substantially under- or overestimating risk (which can occur if all reported emissions of POM are assigned the same URE). To accomplish this, POM emissions as reported in NEI were grouped into categories. EPA assigns dose-response values based on the known or estimated toxicity for POM within each group and on information for the POM speciation of emission sources, such as wood fires and industrial processes involving combustion.

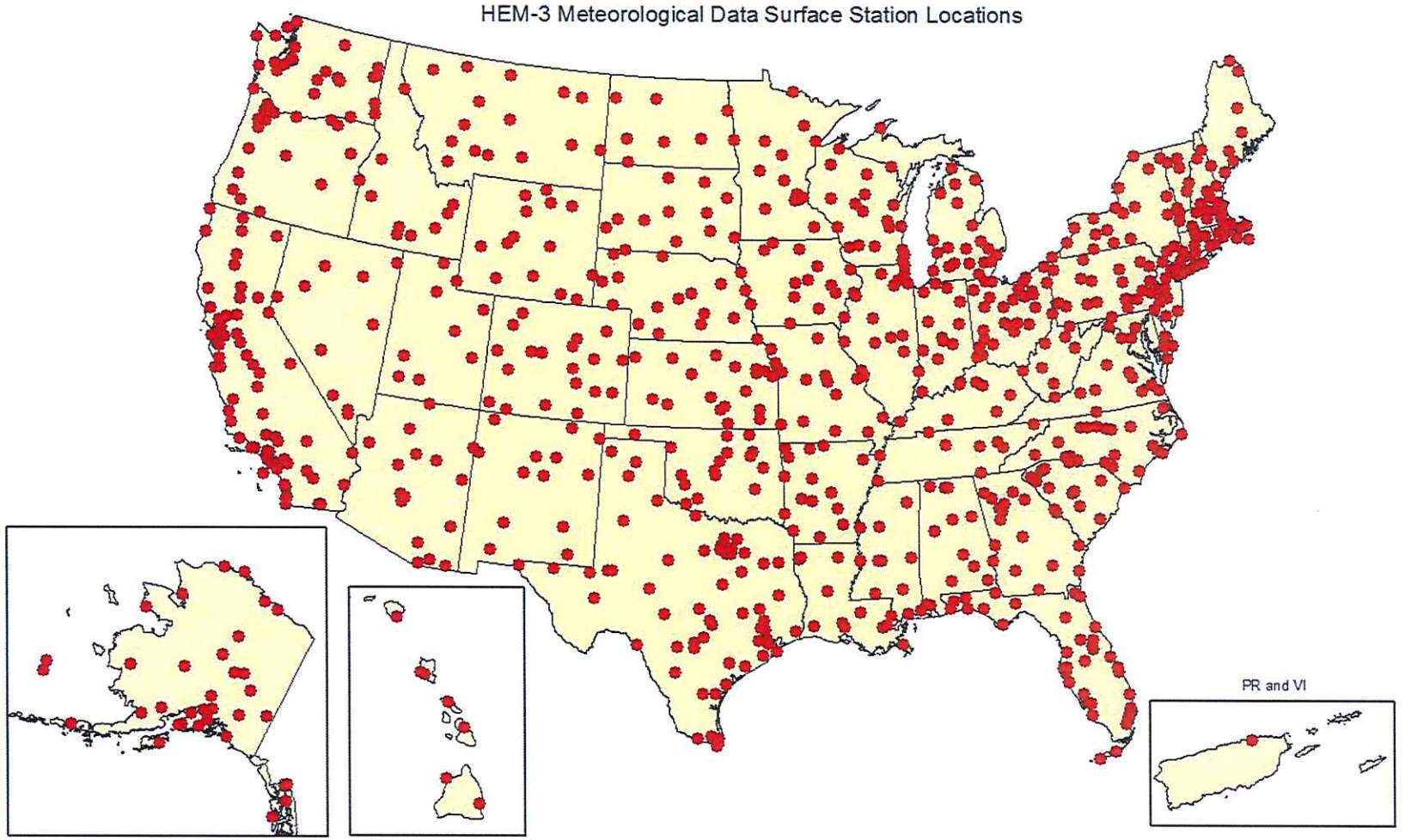
Toxicity values used for metal compounds are also discussed in EPA's 2011 National Air Toxics Assessment Technical Support Document, including the treatment of chromium (VI) compounds, lead and nickel compounds.[16]

3.3 Meteorological Data

Nationwide meteorological data files are accessed by HEM-3 and used for the RTR modeling. The current HEM-3 AERMOD Meteorological Library includes over 800 nationwide

locations, depicted in Figure 3-1. This library contains surface and upper air 2016 meteorological data from National Weather Service (NWS) observation stations, which span the entire U.S. as well as Puerto Rico and the U.S. Virgin Islands. AERMOD requires surface and upper air meteorological data that meet specific format requirements.[17, 18] Appendix 3 discusses the preprocessing performed on the meteorological data used by AERMOD and includes a detailed listing of the 824 meteorological surface and upper air station pairs, including coordinates, ground elevation and anemometer height for each station.

Figure 3-1.


HEM-3 Meteorological Data Surface Station Locations
PR and VI

3.4 Model Options Selected

HEM-3 presents a number of options for characterizing the modeling domain and data sources. As many sources are generally modeled in RTR assessments, established defaults and common practices are relied on to make these choices. The choices available to a HEM-3 user and the selections that are made in most RTR assessments are presented in Table 3-1. Some of the key selections are discussed in more detail in the paragraphs below.

It should be noted that although routine emissions are not expected to vary significantly with time, nonroutine (upset) emissions can be significant relative to routine emissions. Upset emissions occur during periods of startup, shutdown, and malfunction. Upset emissions are not likely for equipment or storage tanks, but do result from malfunctioning control devices and leaks in cooling tower heat exchangers. There is some limited data on upset emissions available,[19] but no facility-specific analyses of these data were performed to characterize short-term emissions from these emission sources, and upset emissions are generally not modeled for the RTR risk assessments.

3.4.1 Urban or Rural Dispersion Characteristics

Current RTR source category assessments which use the 2010 Census are based on either urban or rural dispersion characteristics, depending on the land characteristics surrounding each modeled facility. The EPA provides guidance on whether to select urban or rural dispersion coefficients in its Guideline on Air Quality Models.[20] In general, the urban option is used if (1) the land use is classified as urban for more than 50% of the land within a 3-kilometer radius of the emission source, or (2) the population density within a 3-kilometer radius is greater than 750 people per square kilometer. Of these two criteria, the land use criterion is more definitive.

Using the 2010 Census, the HEM-3 model determines, by default, whether to use rural or urban dispersion characteristics. HEM-3 will find the nearest census block to the facility center and determine whether that census block is in an urban area, as designated by the 2010 Census.[21] The population of the designated urban area will be used to specify the population input for AERMOD's urban mode. (Alternatively, a user may select the rural or urban option to override determination by the model. If a user selects an urban dispersion environment, then the user must provide the urban population as well.)

For the 2008 and prior screening-level RTR assessments of 51 source categories, the rural option was chosen to be most conservative (i.e., more likely to overestimate risk results). The rural option is also chosen by default by the HEM-3 model whenever the 2000 Census is selected by the user.

3.4.2 Deposition and Plume Depletion

The RTR modeling analysis to date has not taken into account the depletion of pollutant concentrations in the plume due to wet or dry deposition, although HEM-3 can model deposition with or without depletion using AERMOD. In addition, reactivity and decay have not been considered. It is possible that this approach may overestimate air concentrations and therefore

risk. However, one of the main metrics used by EPA in the residual risk program is the risk to the individual most exposed (the maximum individual risk, or MIR). Because the maximum risk usually occurs at a receptor very close to the emission source, it is unlikely to be influenced by altered plume dispersion characteristics of this type. For more refined, multipathway assessments, EPA may consider deposition and depletion.

3.4.3 Cutoff Distance for Modeling of Individual Blocks

The cutoff distance for modeling individual Census blocks is initially set to 3 km by default. This distance generally ensures that the maximum individual cancer risk and the maximum TOSHI are modeled explicitly and not interpolated. Following a modeling run, the results for each facility are checked to determine whether the maximum impacts are located inside the modeling cutoff distance. If the maximum impacts are outside the cutoff distance, and if any of the impacts are significant, then HEM-3 is rerun for the facility with a cutoff distance greater than 3 km. In general, this is done if the cancer risk exceeds 1 in 1 million or any TOSHI exceeds one. However, the risks for such facilities are generally very low, since the maximum impacts are in most cases only interpolated when the nearest Census block is more than 3 km from the facility (i.e., in sparsely populated areas).

3.4.4 Facility Boundary Assumptions

The main input mechanisms for incorporating facility boundary information in HEM-3 are the overlap distance, the distance to the innermost polar receptor ring, and user-specified receptor locations. The NEI does not provide information on facility boundaries. However, satellite/aerial images are used to locate residential populations that are closer to a facility than the Census block centroid. User-specified receptor locations are used in such assessments to avoid underestimating risk. Conservative default assumptions are used for the overlap distance and the innermost polar receptor ring. However, these are adjusted for some categories where facility sites are known to be large. In addition, satellite imagery is used to check the facility boundary assumptions for facilities with large projected impacts. These checks are discussed further in the section on Quality Assurance (Section 4).

Table 3-1. HEM-3 Domain and Set-Up Options As Used in the Residual Risk and Technology Review Assessments

Option	Selection
Dispersion model	AERMOD
Census database: 2010 or 2000	2010, unless retrospective analysis
Type of analysis: chronic, acute, or both	Both
Averaging time for short term impacts	1-hour
Multiplier for short term emissions	Source type-specific factors are used if available; a factor of 10 used otherwise
Dispersion characteristics: urban or rural, as determined by model, based on closest 2010 Census block to each facility (when using 2010 Census). Rural by default, when using the 2000 Census.	Urban or Rural based on facility location;
Include terrain impacts	Yes
Include building wake effects	No
Calculate deposition (wet, dry, or both) & include impacts of plume depletion	No[d]
User-specified receptor locations (for residential population locations, facility boundary sites, or other sites of interest)	Yes, for some facilities
Modeling domain size – maximum distance to be modeled	50 km
Cutoff distance for modeling of individual blocks	3 km[a]
Overlap distance where receptors are considered to be on facility property – measured from each source measured from each source	30 m[b]
Polar receptor network specifications:	
Distance from the facility center to the innermost ring	≥ 100 m[c]
Number of rings	13
Number of directions	16
Meteorology data	Closest site

[a] The individual block modeling cutoff is increased for categories and for some facilities to ensure that the maximum individual risk values are not interpolated.

[b] The overlap distance is adjusted for some facilities to avoid modeling locations that are on facility property (see section 4.2).

[c] HEM-3 sets the innermost ring distance to be just outside the emission sources but not < 100 m.

[d] RTR assessments typically do not calculate deposition and/or depletion, although the option to use AERMOD to model deposition with or without depletion is available in HEM-3.

3.5 Modeling of Multiple Facilities

HEM-3 models one facility at a time. However, clusters of nearby facilities may impact the same people, resulting in higher risk to those people. To account for this situation, risks are summed at each Census block for all facilities affecting the Census block.

As described earlier (Section 2.3.4), HEM-3 produces detailed output tables containing the risk and population for every Census block in the modeling domain. These detailed tables are combined for all facilities in a source category and the risk for each Census block is summed, using the RTR Summary Program add-on module to the Multi HEM-3 model, as described in the Multi HEM-3 User's Guide.[3] Thus, the effect of multiple facilities in the same source category on the same receptor are estimated. The resulting "combined facility" or "cluster-effect" census block risks are used to calculate population exposure to different cancer risk levels, non-cancer hazard indices, and source category incidence.

4. Quality Assurance

The National Emissions Inventory (NEI) is subject to an extensive program of quality assurance (QA) and quality control (QC). The QA/QC program for the point source component of the NEI is documented in a separate report, available from the NEI website.[22] This section describes QA activities carried out under the RTR modeling analysis.

4.1 Engineering Review

In addition to the standardized QA steps taken for the entire NEI, EPA performs an engineering review of NEI data for the emission source categories included in the RTR analysis. This engineering review includes two main components. The first component addresses the list of facilities included in each source category. EPA engineers review independent sources of information to identify all sources in the category that are included in the NEI. In addition, EPA reviews the list of sources represented as part of each category in the NEI to ensure that the facilities actually manufacture products characteristic of the source category.

The second component of the engineering review focuses on the appropriateness of facility emissions. EPA reviews the list of HAPs reportedly emitted by each facility to ensure that the pollutants are appropriate to the source category. In addition, EPA engineers review the magnitude of those HAP emissions. In cases where new or better data are known to exist for a particular source category, that information is integrated into the data used in the HEM-3/AERMOD modeling for that category. In these cases, the source category specific documents provide additional details on the emissions inputs used.

4.2 Geographic Pre-Modeling Checks

The NEI QA process includes some basic checks on location data for point sources. The coordinates for each source are checked to ensure that they are in the county that has been specified for the source. If this is not the case, or if no geographic coordinates are available for the emission source, then the coordinates are set to a default location based on the nature of the emission source category.[22] In addition, coordinates for all emission sources at a given facility are checked to ensure that they are within 3 km of one another. These QA checks happen prior to HEM-3 modeling and the results of such checks are reflected in the HEM-3 input files.

Another pre-modeling geographic QA check regards the location of the census block receptors. As noted above, to estimate ambient concentrations for evaluating long-term exposures, the HEM-3 model uses the census block centroids as dispersion model receptors. The census block centroids are often good surrogates for where people live within a census block. A census block generally encompasses about 40 people or 10-15 households. However, in cases where a block centroid is located on industrial facility property, or where a census block is large and the centroid less likely to be representative of the block's residential locations, the block centroid may not be an appropriate surrogate.

Census block centroids that are on facility property can sometimes be identified by their proximity to emission sources. In cases where a census block centroid is within 300 meters of any emission source, aerial images of the facility are reviewed to determine whether the block centroid is likely located on facility property. The selection of the 300-meter distance reflects a compromise between too few and too many blocks identified as being potentially on facility property. Distances smaller than 300 meters would identify only block centroids very near the emission sources and could exclude some block centroids that are still within facility boundaries, particularly for large facilities. Distances significantly larger than 300 meters would identify many block centroids that are outside facility boundaries, particularly for small facilities. Block centroids confirmed to be located on facility property are moved to a location that best represents the residential locations in the block.

In addition, census block centroids for blocks with large areas may not be representative of residential locations. Risk estimates based on such centroids can be understated if there are residences nearer to a facility than the centroid, and overstated if the residences are farther from the facility than the centroid. To avoid understating the maximum individual risk associated with a facility, block centroids are relocated in some cases, or additional user-specified receptors are added to a block. Aerial images of all large census blocks within one kilometer of any emission source are examined. Experience from previous risks characterizations show that in most cases the MIR is generally located within 1 km of the facility boundary. If the block centroid does not represent the residential locations, it is relocated in the HEM-3 input files to better represent them. If residential locations cannot be represented by a single receptor (that is, the residences are spread out over the block), additional user-specified receptors are included in the HEM-3 input files to represent residences nearer to the facility than the centroid.

4.3 Geographic Post-Modeling Checks

As part of the RTR modeling analysis, additional geographical QA checks are made for some facilities, after initial HEM-3 modeling results are reviewed. Facilities subjected to these additional checks include:

- cases where the initial estimates of maximum risks are particularly high
    - maximum individual cancer risk of over 1 in 10,000
    - any maximum TOSHI above 10
- cases where no Census blocks are identified by the model within 3 km of the facility

HEM-3 produces a detailed Google Earth™ map of the modeled point, area, polygon, volume, line and buoyant line emission sources and surrounding receptors (including Census block centroids, polar receptors and user-specified receptors) overlaying Google Earth™'s satellite imagery. This map allows a QA check of the specific source locations, as well as an approximate check of the facility boundaries. The emission source coordinates are reviewed for each of these facilities and compared with the address reported for the facility. If the address and the coordinates represent the same location, then the coordinates are taken to be correct. For

more recent modeling of source categories, the emission coordinates initially modeled by HEM-3 tend to be correct, as they undergo pre-modeling scrutiny and QA checks (as discussed in Section 4.2).

More rarely, the modeled emission coordinates will be determined post initial modeling not to be located on facility property. If the facility and emission coordinate locations are different, then the satellite imagery for the address and the coordinate location are reviewed to determine whether either photograph includes an industrial facility. If emission source coordinates are found to be incorrect, HEM-3 is rerun using corrected coordinates. These changes are described in the source category documents.

For the high-risk facilities, the coordinates used to represent the most impacted Census blocks are also reviewed. This review draws on detailed Census block boundary maps and satellite imagery. Large industrial facilities will frequently occupy one or more entire Census blocks. However, these blocks may also include one or more residences on the periphery of the industrial land. Generally, the centroid coordinates listed for a Census block are near the center of the block. In these cases of mixed industrial and residential blocks, the coordinates may be on facility property.

In general, block coordinates are considered to be on facility property if they are located between the different emission source locations listed for the facility. In these situations, HEM-3 is rerun with an expanded overlap distance, in order to exclude the Census block coordinates that appear to be located on facility property. The distance to the innermost polar receptor ring is also adjusted to ensure that this ring is not on facility property, but as close to the apparent facility boundaries as possible.

5. Uncertainties

The RTR risk assessments using HEM-3 and AERMOD are subject to a number of uncertainties. For instance, model verification studies for AERMOD show predicted maximum annual concentrations ranging from 0.3 to 1.6 times measured values, with an average of 0.9. Predicted maximum short term (1 to 24 hours) concentrations were 0.25 to 2.5 times measured values, with an average of one.[23]

In addition, a number of simplifying assumptions are made in these modeling analyses. First, the coordinates reported by the U.S. Census Bureau for Census block internal points ("centroids") have been used as a surrogate for long-term population exposures. Locations of actual residences have not been modeled. In addition, the current version of HEM-3 does not take into account the movement of people from one Census block to another during the course of their lives, or commuting patterns during a given day. Nor does the model take into account the attenuation of pollutant from outside emission sources in indoor air. Ideally, risks to individuals would be modeled as they move through their communities and undertake different activities. However, such modeling is time-and resource-intensive and can only capture a portion of the uncertainty associated with the full range of human activities. In general, it is expected that long-term exposures will be overstated for high-end estimates (as most individuals will not spend all their time at their highly affected residences), but may understate the total population exposed (as some individuals living outside the modeled area may regularly commute into the area for work or school).

When considering long-term or lifetime exposures, it should be noted that relatively few people in the United States reside in one place for their entire lives. For the purposes of this assessment, cancer risk estimates are based on a lifetime exposure at the Census-identified place of residence. While it is impossible to know how this assumption affects the risk experiences by a particular individual (as people can move into higher- or lower-risk areas), it is likely that this assumption will overstate the exposure to those most exposed (i.e., people already living in high exposure areas are unlikely to move to yet higher exposure areas). However, this assumption will also tend to underestimate the total number of people exposed and population risk (i.e., incidence) because population levels are generally increasing.

In the current analyses, only direct inhalation is modeled. Other pathways such as the deposition of pollutants to drinking water, and to bioaccumulation of deposited pollutants in the food supply may be a significant source of exposure for persistent and bioaccumulative hazardous air pollutants (PB HAP). Screening level evaluations of the potential human health risks associated with emissions of PB HAP from the modeled facilities are used to determine if additional analyses are needed, but these analyses are outside the scope of this document. Because the HEM-3 AERMOD analyses are restricted to the inhalation pathway and depleting the plume would not be a conservative approach to modeling air concentrations, the impacts of plume depletion due to deposition are not taken into account. Thus, inhalation impacts may be overestimated for some pollutants, but exposures through other pathways would be underestimated.

A number of other simplifications are made in the dispersion modeling analyses, as noted in Table 3-1. For instance, building wake effects are not considered. In addition, meteorological observations are based on the closest station in the HEM-3 meteorological library (see Figure 3-1). Alternative meteorological stations may be more appropriate for some facilities. Ideally, facility-specific meteorological observations would be used. A single year of meteorological data (2016) is currently used for AERMOD's dispersion modeling. (The 2008 and prior screening-level RTR assessments of 51 source categories used meteorological data based on the year 1991.) When considering off-site meteorological data most site specific dispersion modeling efforts will employ up to five years of data to capture variability in weather patterns from year to year. However, because of the large number of facilities in the analyses and the extent of the dispersion modeling analysis (national scale), it is not practical to model five years of data. Other national studies such as NATA also consider only a single year of meteorological data. A sensitivity analyses performed by the NATA assessment found that variability attributable to the selection of the meteorology location/time (both temporal and spatial) resulted in a 17-84% variation in predicted concentrations at a given station.[24]

Finally, risk and exposure factors are also subject to uncertainty. Not all individuals experience the same degree of exposure or internal dose of a given pollutant due to individual-specific parameters such as weight, age, and gender. While the health benchmarks used in the analyses crudely account for sensitive populations, a prototypical human (e.g., body weight, ventilation rate) is used to define the benchmark. Because of the variability of these parameters in the population, this factor will result in a degree of uncertainty in the resulting risk estimate.

Table 5-1 summarizes the general sources of uncertainty for the RTR modeling analyses. The table also gives a qualitative indication of the potential direction of bias on risk estimates. The sources of uncertainty in Table 5-1 are divided into four categories, based on the major components of the analyses:

- emissions inventory;
- fate and transport modeling;
- exposure assessment; and
- toxicity assessment.

It must also be noted that individual source categories may be subject to additional uncertainties. These are discussed in separate reports which are prepared for each emission source category included in the RTR assessments.

Table 5-1. Summary of General Uncertainties Associated with Risk and Technology Review Risk Assessments

Parameter	Assumption	Uncertainty/Variability Discussion	Potential Direction of Bias on Risk Estimates
Emissions Inventory			
Individual HAP emissions rates and facility characteristics (stack parameters, property boundaries)	Emissions and facility characteristics from the NEI provide an accurate characterization of actual source emissions.	Our current emissions inventory is based on source category specific ICR and/or the latest NEI, our internal review, and public comments received. The degree to which the data in our inventory represents actual emissions is likely to vary across sources. For the 2008 screening level assessments, nearly half of the sources in a given source category submitted a review of their emissions and facility characteristics data. Some detailed data, such as property boundary information is not available for most facilities. This is an important consideration in determining acute impacts.	Unbiased overall, magnitude variable
Multiplier for short-term emission rates	Generally, maximum short term emission rates are estimated by applying a simple multiplier (a factor of 10) to average annual emissions.	The ratio between short-term and long-term average emission rates may vary among the different emission sources at a facility. In addition, the use of a simple multiplier means that impacts of maximum short term emissions are modeled with the 99th percentile meteorological conditions and assuming these conditions for population exposure.	Potential overestimate due to the fact that worst-case emissions are assumed to occasionally coincide with 99th percentile worst-case meteorology. Overestimate due to lack of actual information on short-term emission rates.
Fate and Transport Modeling			
Atmospheric dispersion model choice	AERMOD is EPA's recommended dispersion model for assessing pollutant concentrations from industrial facilities	Field testing of dispersion models, including AERMOD, have shown results to generally be within a factor of 2 of measured concentrations.	Unbiased overall
Building downwash	Not included in assessments	Use of this algorithm in AERMOD could improve the dispersion calculations at individual facilities. However, data are not readily available to utilize this option.	Potential underestimate of maximum risks near facility. No effect on risks further out.
Plume deposition and depletion	Not included in assessments	Ignoring these impacts for pollutants that deposit minimally, and whose risks derive predominantly from inhalation, should have minimal effect on risk estimates.	Unbiased or minimal overestimate.

Table 5-1. Summary of General Uncertainties Associated with Risk and Technology Review Risk Assessments (continued)

Parameter	Assumption	Uncertainty/Variability Discussion	Potential Direction of Bias on Risk Estimates
Meteorology	One year of meteorological data from the nearest weather station (selected from 824 nationwide) is representative of long-term weather conditions at the facility.	The use of one year of data rather than the five or more adds uncertainty based on whether that year is representative of each location's climatology. Use of weather station data rather than on-site data can add to uncertainty. Additionally, the use of default surface parameters in the generation of the meteorological datasets imparts uncertainty to the results from any individual facility.	Minimal underestimate or overestimate.
Reactivity	Not included in the assessments	Chemical reactions and transformations of individual HAP into other compounds due to solar radiation and reactions with other chemicals happens in the atmosphere. However, in general, the HAP in this assessment do not react quickly enough for these transformations to be important near the sources, where the highest individual risks are estimated. Further, most of the HAP do not react quickly enough for these transformations to be important to risk estimates in the entire modeled domain (i.e., within 50 km of the source).	No impact on maximum risk estimates. Minimal impact on population risks and incidence.
Maximum modeling distance	50 kilometers from center of facility	This distance is considered to be the maximum downwind distance for a Gaussian plume model such as AERMOD. This is because, in general, winds cannot be considered to follow straight line trajectories beyond this distance.	No effect on maximum individual risks. Minimal underestimation of incidence.
Exposure Assessment			
Locations and short-term movements of individuals	Ambient concentration at centroid of each off-site census block is equal to the exposure concentration for all people living in that census block. Effect of human activity patterns on exposures is not included in the assessment.	People live at different areas within block that may have higher or lower exposures than at the centroid. Individuals also move from outdoors to indoors and from home to school/work to recreation, etc., and this can affect their total exposure from these sources.	Unbiased across population for most pollutants and individuals, likely overestimate for most exposed and underestimate for least exposed persons.

Table 5-1. Summary of General Uncertainties Associated with Risk and Technology Review Risk Assessments (continued)

Parameter	Assumption	Uncertainty/Variability Discussion	Potential Direction of Bias on Risk Estimates
Long-term movements of individuals	MIR individual is exposed continuously to the highest exposure concentration for a 70-year lifetime.	Maximum individual risk (MIR) is defined in this way to be a maximum theoretical risk at a point where a person can actually reside.	Unbiased for most individuals, likely overestimate for the actual individual most exposed and likely underestimate for the least exposed. Incidence remains unbiased unless population around facilities increases or decreases over 70 years.
Toxicity Assessment			
Reference concentrations (RfC)	Consistent with EPA guidance, RfCs are developed including uncertainty factors to be protective of sensitive subpopulations. Additionally, RfCs are developed based on the level producing an effect in the most sensitive target organ or system.	While other organ systems may be impacted at concentrations above the RfC, these are not included in the calculation of target organ-specific hazard indices.	In general, EPA derives RfCs using procedures whose goal is to avoid underestimating risks in light of uncertainty and variability. The greater the uncertainties, the greater the potential for overestimating risks.
Unit Risk Estimate (URE)	Use of unit risk estimates developed from dose-response models such as linear low-dose extrapolation.	Uncertainty in extrapolating the impacts from short-duration, high-dose animal or work-related exposures to longer duration, lower-dose environmental impacts.	Overestimate of risks for nonlinear carcinogens and for linear carcinogens with sparse health effects data. In general, EPA derives URE values using procedures aimed at overestimating risks in light of uncertainty and variability.
Toxicity of mixtures	Cancer risks and non-cancer hazard quotients were calculated for each HAP individually and then summed into a total risk or hazard index (assumption of additivity).	Concurrent exposures to multiple chemicals may result in either increased or decreased toxicity due to chemical interactions but the data needed to quantify these effects are generally not available.	Unbiased overall. Some mixtures may have underestimated risks, some overestimated, and some correctly estimated.

Table 5-1. Summary of General Uncertainties Associated with Risk and Technology Review Risk Assessments (continued)

Parameter	Assumption	Uncertainty/Variability Discussion	Potential Direction of Bias on Risk Estimates
Surrogate dose-response values for HAPs without values	In the case of groups of HAPs such as glycol ethers, the most conservative dose-response value of the chemical group was used as a surrogate for missing dose-response values in the group. For others, such as unspeciated metals, we have applied speciation profiles appropriate to the source category to develop a composite dose-response value for the group. For HAP which are not in a group and for which no URE's or RfC's are available from credible sources, no assessment of risk is made.	Rather than neglecting the assessment of risks from some HAPs lacking dose response values, conservative assumptions allow the examination of whether these HAPs may pose an unacceptable risk and require further examination, or whether the conservative level examination with surrogates screens out the HAPs from further assessment.	Overestimate where most conservative values used. Unbiased where category-specific profiles applied. There is the potential to underestimate risks for pollutants which are not included in the assessment.

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Appendix 3 to the Risk Assessment Report for the Sterigenics Facility in Willowbrook, Illinois:

Meteorological Data for HEM-3 Modeling

3.1 Introduction

As part of the risk assessment for Sterigenics, 2014-2018 meteorological data from Argonne National Laboratory were processed in AERMET for subsequent input to AERMOD (USEPA, 2018a). Argonne is approximately 7 km southwest of the Sterigenics facility (Figure 1). The closest National Weather Service (NWS) station, Midway airport, is approximately 16 km east of Sterigenics. While Midway can be considered adequately representative of the Sterigenics facility in the absence of other data, given the proximity of Argonne to the facility, the EPA concluded that meteorological data collected at Argonne would be more representative of conditions at Sterigenics than data from Midway. The Argonne meteorological tower also had measurements of wind, temperature, and turbulence (standard deviation of wind direction, σ_θ) at 10 m and 60 m vertical levels, making a more robust dataset over standard airport observations which only have one level of data without turbulence measurements. Sections 3.4 and 3.5 describe the methodology and results to support the EPA's decision to use Argonne data for the risk assessment.

3.2 Meteorological data processing

Meteorological data for Argonne are available for download at http://www.atmos.anl.gov/ANLMET/. Both hourly averaged data and data in 15-minute intervals are available for download. For the purposes of the risk assessment, the hourly averaged data were used. The following variables from Argonne were input to AERMET (USEPA, 2018b):

- Solar insolation
- Surface pressure
- 10 m wind speed
- 10 m wind direction
- 10 m temperature
- 10 m standard deviation of wind direction (σ_θ)
- 60 m wind speed
- 60 m wind direction
- 60 m temperature
- 60 m standard deviation of wind direction (σ_θ)

The wind speed threshold used in AERMET to define valid wind speeds was set to 0.1 m/s. In accordance with the EPA's Guideline on Air Quality Modeling (USEPA, 2017), since the Argonne data included turbulence data (σ_θ), the adjustment to the surface friction velocity (adjusted u* option) was not utilized.

Figure 1. Locations of Argonne National Laboratory tower and Midway Airport relative to Sterigenics.

Upper air data for Davenport, IA were used as the representative upper air station in AERMET. Additionally, in AERMET, when using site-specific data, a representative NWS station can be used to substitute for missing values in the site-specific data during AERMET processing. Midway Airport was used as the representative NWS station. Hourly observations of wind and temperature were subsituted for missing values of wind and temperature in the Argonne data set, and cloud cover data from Midway were used in AERMET processing. Additionally, the hourly observed winds from Midway were supplemented with the hourly averaged 1-minute winds from Midway, via the AERMINUTE processor (USEPA, 2015). For the period of 2014-2018, 4.3 percent of the hours were substituted with Midway data.

3.3 Surface characteristics

Surface characteristics (albedo, Bowen ratio, and surface roughness) are important components in calculating boundary layer variables. To estimate surface characteristics for both Argonne (primary site) and Midway (secondary site), the new draft 2019 version of AERSURFACE (19039_DRFT)(USEPA, 2019) was used. This version of AERSURFACE, an update of the current 2013 version (13016)(USEPA, 2013), allows for the use of more recent National Land Cover Data (NLCD) to estimate surface characteristics. The current official version of

AERSURFACE is limited to the 1992 NLCD. While the 2019 version is draft, it can be used for regulatory purposes if run with the default 1 km radius for surface roughness estimates, use of landcover, impervious surface data, and tree canopy data for the selected NLCD year, and in consultation with the appropriate reviewing authority (U.S EPA, 2019). For this risk assessment, 2011 data were used. Year-specific monthly surface characteristics were calculated for 2014-2018 because there are two inputs to AERSURFACE that can vary by year: 1) moisture conditions for the year (average, wet, or dry year based on precipitation), and 2) the presence of continuous snow cover during the winter. The assumptions of moisture conditions and winter conditions were assumed to be the same for both Argonne and Midway. These assumptions were based on climatological data for Midway for 1989-2018. The assignments for wet, dry, and average rainfall are based on guidance in the AERSURFACE user's guide (USEPA, 2019). Because the lookup tables used by AERSURFACE are based on seasons, when calculating monthly surface characteristics, each month must be assigned to a season. Table 1 lists the seasonal assignments by month for each modeled year as well as the moisture conditions for each year.

Table 1. Seasonal assignments by month and year for AERSURFACE processing.

	Year				
Season	2014 (wet)	2015 (wet)	2016 (average)	2017 (average)	2018 (average)
Winter (no snow)	November, December, March	November, December, March	November, January, February, March	November, January, February, March	November, December, January, March
Winter (continuous snow)	January, February	January, February	December	December	February
Spring	April, May	April, May	April, May	April, May	April, May
Summer	June, July, August	June, July, August	June, July, August	June, July, August	June, July, August
Autumn	September, October	September, October	September, October	September, October	September, October

Surface roughness was calculated for four sectors for Argonne (Figure 2) and three sectors for Midway (Figure 3). AERSURFACE also allows for different treatment of surface roughness for a sector depending on whether the land use around the site in that sector is more like an airport or non-airport. This choice is used when a sector contains impervious surfaces such as buildings, roads, runways, parking lots, etc. If a sector contains mostly flat impervious surfaces such as roads or parking lots, the sector can be treated as an airport even if the site is not an airport. If the sector contains mostly buildings, then it can be treated as non-airport even if the site is an airport but the sector contains the terminal buildings, for example. All sectors at Argonne were treated as non-airport sectors. Sector 1 at Midway was treated as an airport sector while the other two sectors were treated as non-airport. Sector 1 is treated as an airport sector because most of the land use in that sector is a developed category with large flat developed spaces such as runways. The other two sectors are treated as non-airport because they are developed spaces

Figure 2. Argonne surface roughness sectors.

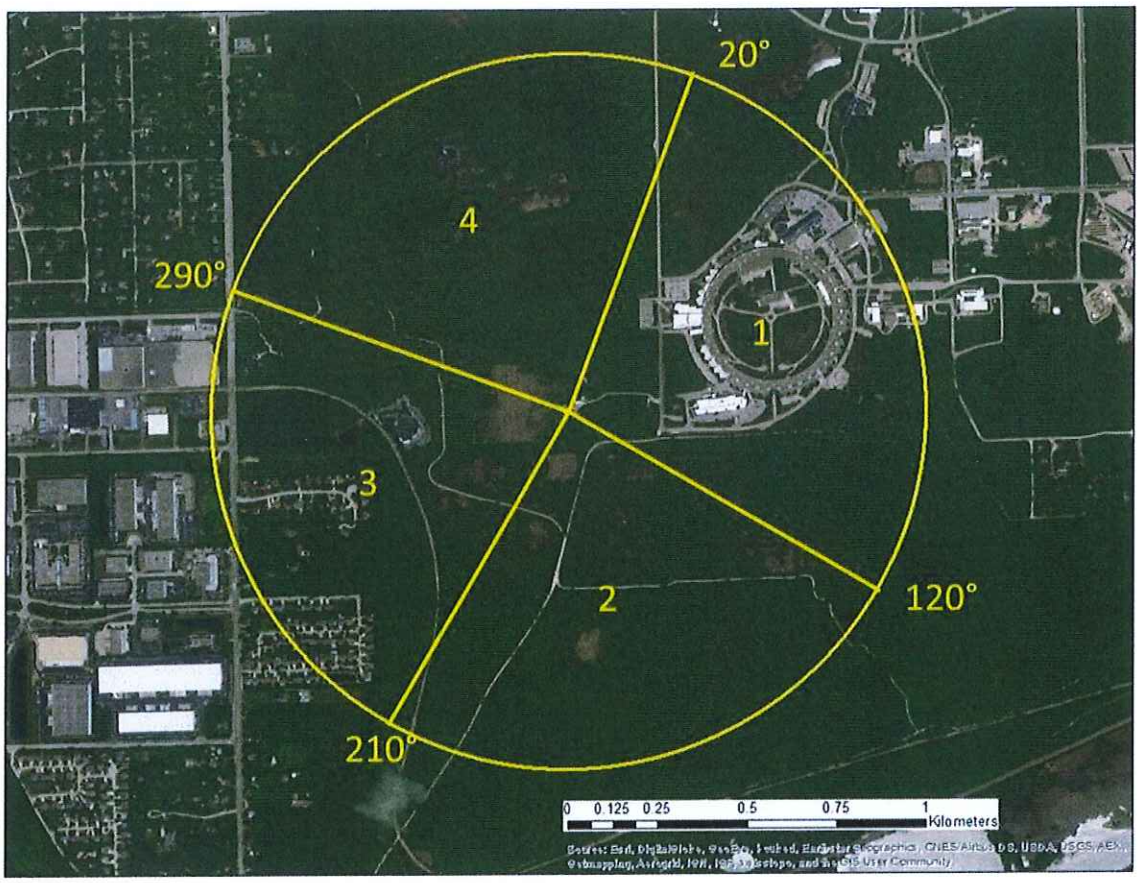


Figure 3. Midway surface roughness sectors.

that are not flat spaces and composed of developed structures such as buildings. See the AERSURFACE guide (USEPA, 2019) for more details on sector treatment.

3.4 Meteorological comparisons for the ethylene oxide sampling period

To determine the representativeness of Argonne for Sterigenics, wind and temperature data from Argonne, Midway, and the meteorological instrument at the EPA warehouse near Sterigenics were compared for the ambient air sampling period of November 13, 2018 through March 31, 2019. Figure 4 shows the location of the EPA warehouse meteorological instrument relative to the two Sterigenics buildings, Willowbrook 1 (WB1) and Willowbrook 2 (WB2). The EPA instrument is located approximately 150 m southwest of WB1 and approximately 300 m from WB2. The height of the EPA instrument is 8.5 m above ground and is indicated by the green triangle in Figure 4. The EPA instrument collected temperature, wind, σ_θ, relative humidity, pressure, and precipitation measurements. The EPA data were processed in AERMET with the inputs listed above except for precipitation, which is only needed for AERMOD simulations involving deposition calculations. The draft 2019 AERSURFACE was run for all three sites for January through March 2019 assuming average moisture conditions, continuous snow for January, and no continuous snow for February and March. For 2018, all three sites used the

moisture conditions and seasonal-month assignments outlined in Table 1 for November and December. AERSURFACE was run for four surface roughness sectors (all non-airport) (Figure 5) for the EPA site. Midway was used as the representative NWS site with surface characteristics as described in the previous section with 5.7 percent of the hours in the data period subsituted with Midway data. As with Argonne, since the EPA warehouse site collected turbulence data, the surface friction velocity adjustment was not performed. AERMET was also run for the sampling period for Midway only to assess how well the representative NWS site performed. Since Midway did not collect turbulence data, the surface friction velocity adjustment was included in the AERMET processing.

Wind roses for the monitoring period are shown for all three locations in Figure 6. The roses indicate that the overall flow pattern among the three sites is similar. However, the EPA site tends to have stronger signals of southerly and northerly flows compared to the other two sites. The differences in flow patterns could be due to building effects near the EPA instrument while the other two sites are in open locations and would represent the more general flow for the area.

Figure 4. Location of EPA meteorological instruments relative to the Sterigenics buildings.

Figure 5. EPA surface roughness sectors.

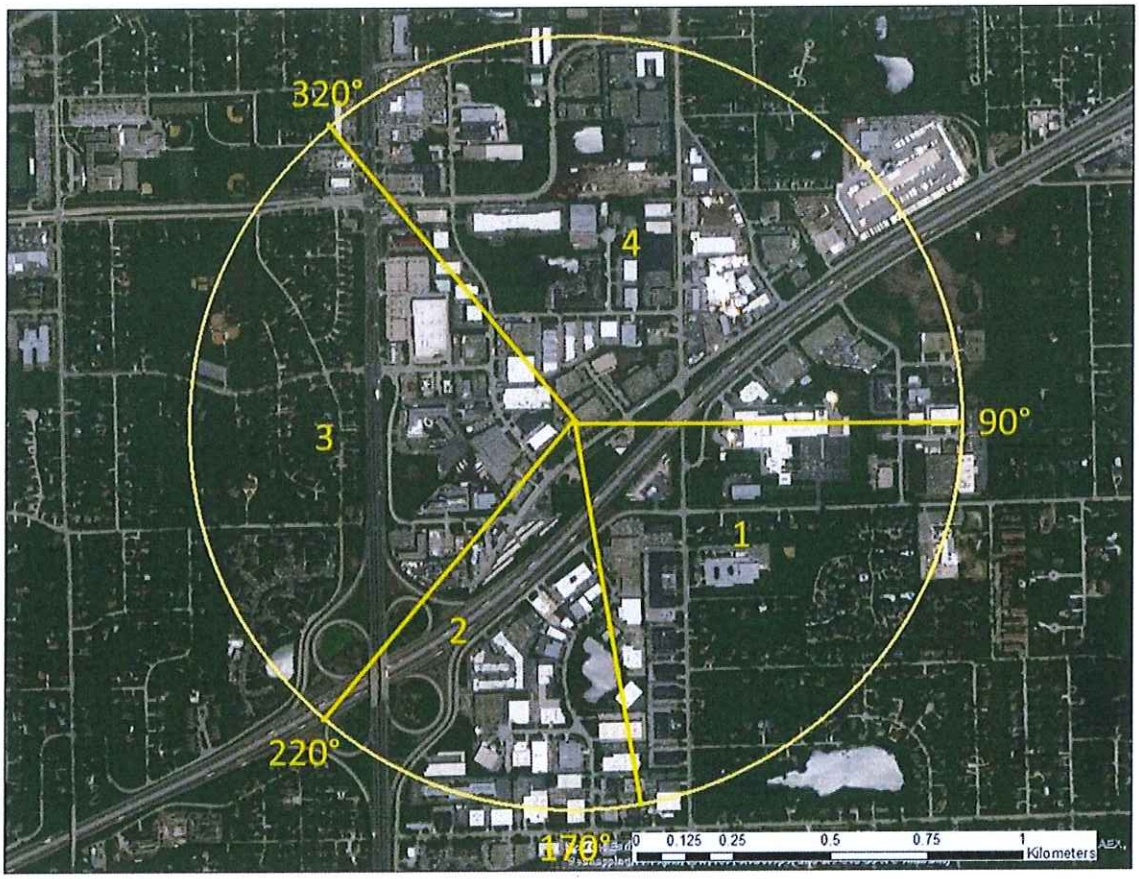
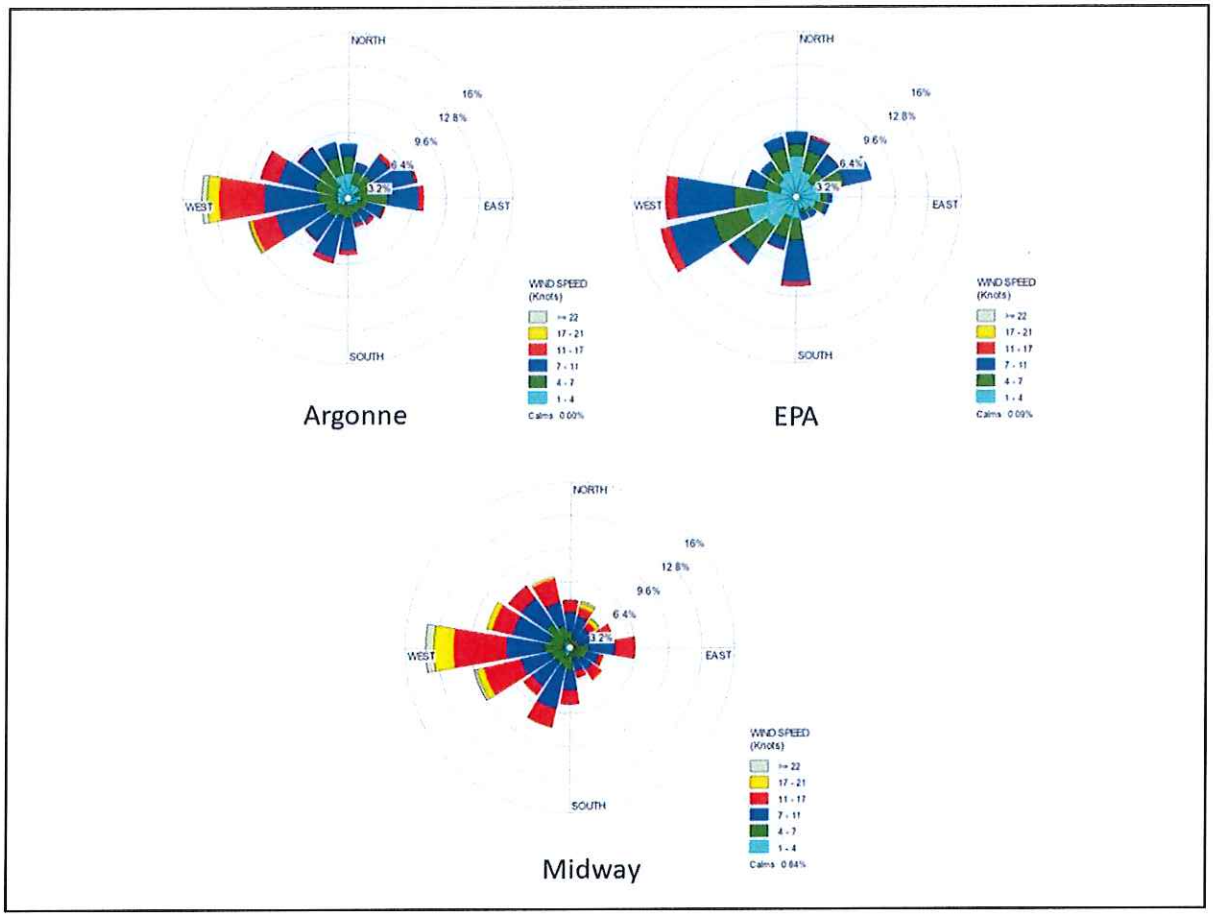


Figure 6. Argonne, EPA, and Midway wind roses for November 13, 2018 - March 31, 2019.



Analyses of wind speeds, directions, and temperatures were conducted among the three sites. Winds and temperatures at the 10 m level for Argonne were compared to the 8.5 m level winds and temperatures for the EPA site, and to the 10 m winds and 2 m temperature for Midway, on an hourly basis. Table 2 lists the minimum, mean, median, and maximum wind speed differences among the three sites. Table 3 lists the minimum, mean, median, and maximum wind direction differences among the three sites[28]. There were 2,920 hours where all three sites had wind data out of a possible 3,300 hours (the EPA instruments started at 13:00 LST on November 13, 2018). The results in Table 2 indicate that Argonne tended to have higher wind speeds than the EPA site. In fact, of the 2,920 hours, there were 2,639 hours where Argonne was higher than the EPA site. Conversely, Argonne tended to have lower wind speeds than Midway (2,537 hours) as did the EPA site when compared to Midway (2,853 hours). When looking at the number of hours where the sites' wind speeds were within 1 m/s of each other, there were 1,515

[28] The maximum difference between two directions is 180°. For example, the difference between a 10° direction and 350° direction is 20. after accounting for the 360° crossover on the compass°, not 340° based on a straight arithmetic difference between 350° and 10°.

hours where Argonne and the EPA site were within ± 1 m/s, 1,388 hours where Argonne and Midway were within ± 1 m/s, and 409 hours where the EPA site and Midway within ± 1 m/s.

Table 2. Hourly wind speed differences among Argonne, EPA site, and Midway.

Difference	Minimum (m/s)	Mean (m/s)	Median (m/s)	Maximum (m/s)
Argonne – EPA	-8.30	1.07	1.00	5.20
Argonne – Midway	-5.34	-1.08	-1.02	3.00
EPA - Midway	-7.38	-2.16	-2.08	8.63

The wind direction differences in Table 3 indicate the wind direction tended to vary within 20° among the three sites, with only a few hours where the winds were in almost opposite directions. There were 1,322 hours where Argonne and the EPA site wind directions were within 10°, 1,573 hours where Argonne and Midway directions were within 10°, and 1,268 hours where the EPA site and Midway directions were within 10°. The number of hours where winds were in almost opposite directions (> 170°) were few. There were only three hours where Argonne and the EPA site direction differences exceeded 170°, one hour where Argonne and Midway direction differences exceeded 170°, and 11 hours where the EPA site and Midway direction differences exceeded 170°.

Table 3. Hourly wind direction differences among Argonne, EPA, and Midway.

Difference	Minimum (°)	Mean (°)	Median (°)	Maximum (°)
Argonne – EPA	0	13	11	178
Argonne – Midway	0	16	9	173
EPA - Midway	0	17	12	180

Table 4 lists the minimum, mean, and maximum hourly temperatures for each site for each month of the sampling period. These statistics were calculated for each site independently of the other two. The results in Table 4 indicate that, on average, the temperatures among the three sites are similar.

Table 4. Monthly minimum, mean, and maximum temperatures for Argonne, EPA site, and Midway.

Temperature (°C)	Site	November	December	January	February	March
Minimum	Argonne	-8.40	-10.20	-31.0	-17.6	-19.9
	EPA	-7.80	-9.90	-30.2	-17.7	-19.5
	Midway	-10.76	-11.26	-32.26	-18.66	-21.96
Mean	Argonne	-0.72	0.51	-6.12	-3.30	1.37
	EPA	-1.20	0.60	-5.63	-2.76	1.66
	Midway	-2.72	-1.92	-8.19	-5.48	-1.01
Maximum	Argonne	9.70	11.50	12.20	10.30	16.90
	EPA	7.90	11.60	12.0	10.60	17.90
	Midway	7.16	9.24	9.74	7.64	15.24

Table 5 lists the minimum, mean, median, and maximum hourly temperature differences among the three sites. There were 3,135 hours where all three sites had temperature data.

Table 5. Hourly temperature differences among Argonne, EPA site, and Midway.

Difference	Minimum (°C)	Mean (°C)	Median (°C)	Maximum (°C)
Argonne – EPA	-4.50	-0.35	-0.3	4.2
Argonne – Midway	-0.74	2.20	2.16	7.96
EPA - Midway	-1.94	2.57	2.46	8.26

While the minimum and maximum hourly differences were greater than 1° for Argonne and the EPA site, the mean and median differences indicated little difference between the two sites. In fact, for the 3,135 hours of temperature data, 2,803 hours had temperature differences within ± 1°C between Argonne and the EPA site. There were larger differences between Midway and the other two sites, with only 111 hours of temperature differences within ± 1°C between Midway and Argonne, and 34 hours of temperature differences within ± 1°C between Midway and the EPA site. These comparisons indicate that the Argonne data seem to better represent the Willowbrook area, supporting the use of the Argonne meteorological data for the risk assessment.

3.5 AERMOD simulations

To further evaluate the representativeness of Argonne, the EPA site, and Midway, AERMOD simulations using day-specific ethylene oxide usage were conducted for 28 of the sampling days. AERMOD performance for the 28 sampling days at the monitors using Argonne, EPA site, and Midway meteorological data was evaluated using methodology from the EPA Protocol for Determining the Best Performing Model (USEPA, 1992) for regulatory application, which focuses on the higher concentrations in the concentration distribution. Normally, the protocol evaluates 1-hour, 3-hour, and 24-hour average concentrations. Since the monitor data for

Sterigenics are only 24-hour averages, the EPA focused only on 24-hour averages. The protocol uses a statistic call Robust Highest Concentration (RHC) and fractional bias for evaluation of model performance. The RHC is calculated at each monitor location for observed concentrations and modeled concentrations. The RHC is calculated as:

$$RHC = X(N) + [\bar{X} - X(N)] \times \ln\left[\frac{3N-1}{2}\right]$$

where X(N) is the Nth highest concentration, $\bar{X}$ is the average of N-1 values, and N is typically set to 26 values for most model evaluations. However, given the small sample size at each monitor, we started with N=5 to determine performance for the higher concentrations and evaluated results up to N=18 (the fewest number of observations across the monitors) to determine performance across the entire concentration distribution. As stated above, the RHC is calculated at each monitor for observed concentrations and modeled concentrations. Next, a fractional bias is calculated using the maximum observed RHC and maximum modeled (predicted) RHC as:

$$FB = 2\left[\frac{OB - PR}{OB + PR}\right]$$

where FB is the fractional bias, OB is the maximum observed RHC, and PR is the maximum modeled RHC. A positive fractional bias indicates model underprediction, and a negative fractional bias indicates model overprediction. Fractional biases within ± 0.67 are not considered statistically different. Also, note that the two RHC values in the fractional bias may not be from the same monitor location. This is done to assess the model's ability to assess concentrations for regulatory purposes, that is, how well the model predicts maximum concentrations regardless of the spatial location. Table 6 lists the fractional biases for three values of N for Argonne, the EPA site and Midway. For all three sample sizes of N, the EPA site performed best, while Argonne outperformed Midway, which supports the use of the Argonne meteorological data for the risk assessment.

Table 6. Fractional biases for N= 5, 10, and 18 for Argonne, Midway, and the EPA site.

N	Argonne fractional bias	Midway fractional bias	EPA fractional bias
5	1.05	1.29	0.98
10	1.05	1.23	0.98
18	0.85	1.10	0.84

3.6 2014-2018 Argonne vs. Midway meteorological data comparisons

Comparisons of winds and temperatures between Argonne and Midway were made for the full period of 2014-2018, with an additional emphasis on the November-March period over all five years, to ensure that the November 2018-March 2019 period was not an outlier relative to other years. Figures 7 and 8 show the wind roses for Argonne and Midway, respectively, for the entire 2014-2018 period. Figures 9 and 10 show the 2014-2018 wind roses for November-March only,

to coincide with the sampling period from November 2018-March 2019. For the entire 5-year period, while there are some differences, the wind roses are similar in the overall pattern of winds. Both stations exhibit a strong northeasterly wind component and south to west

Figure 7. Argonne 2014-2018 wind rose.

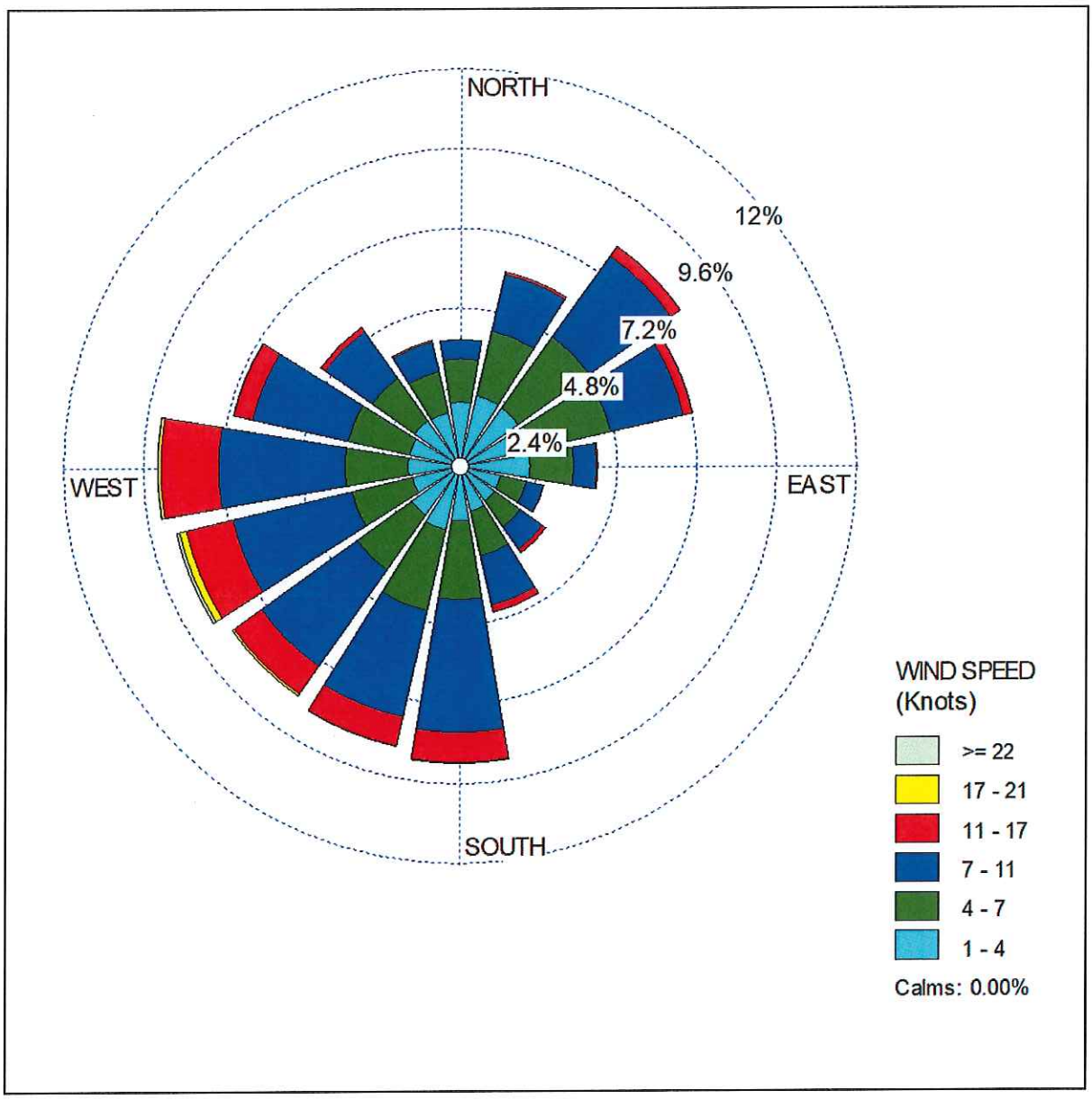


Figure 8. Midway 2014-2018 wind rose.

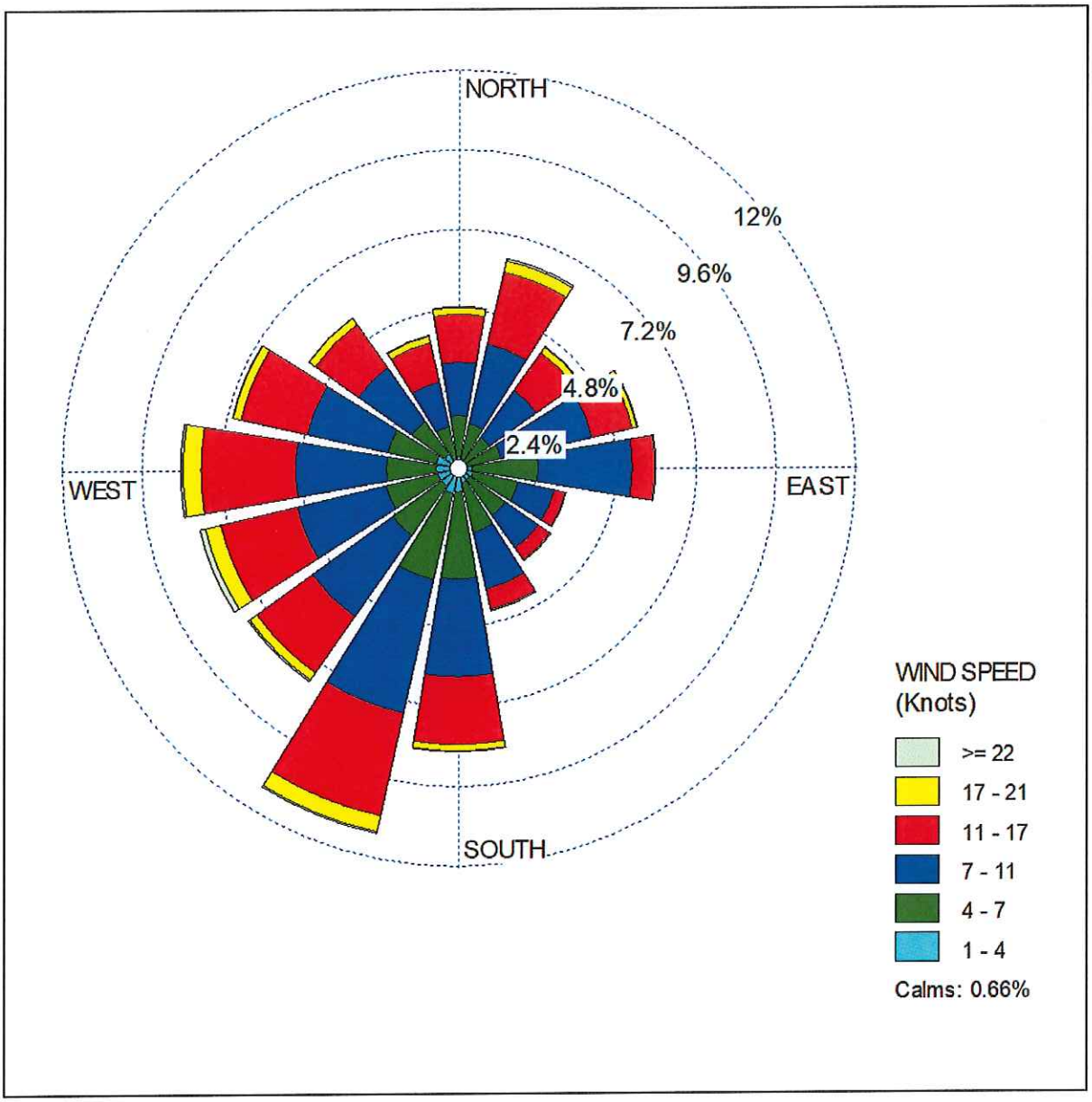


Figure 9. Argonne November-March 2014-2018 wind rose.

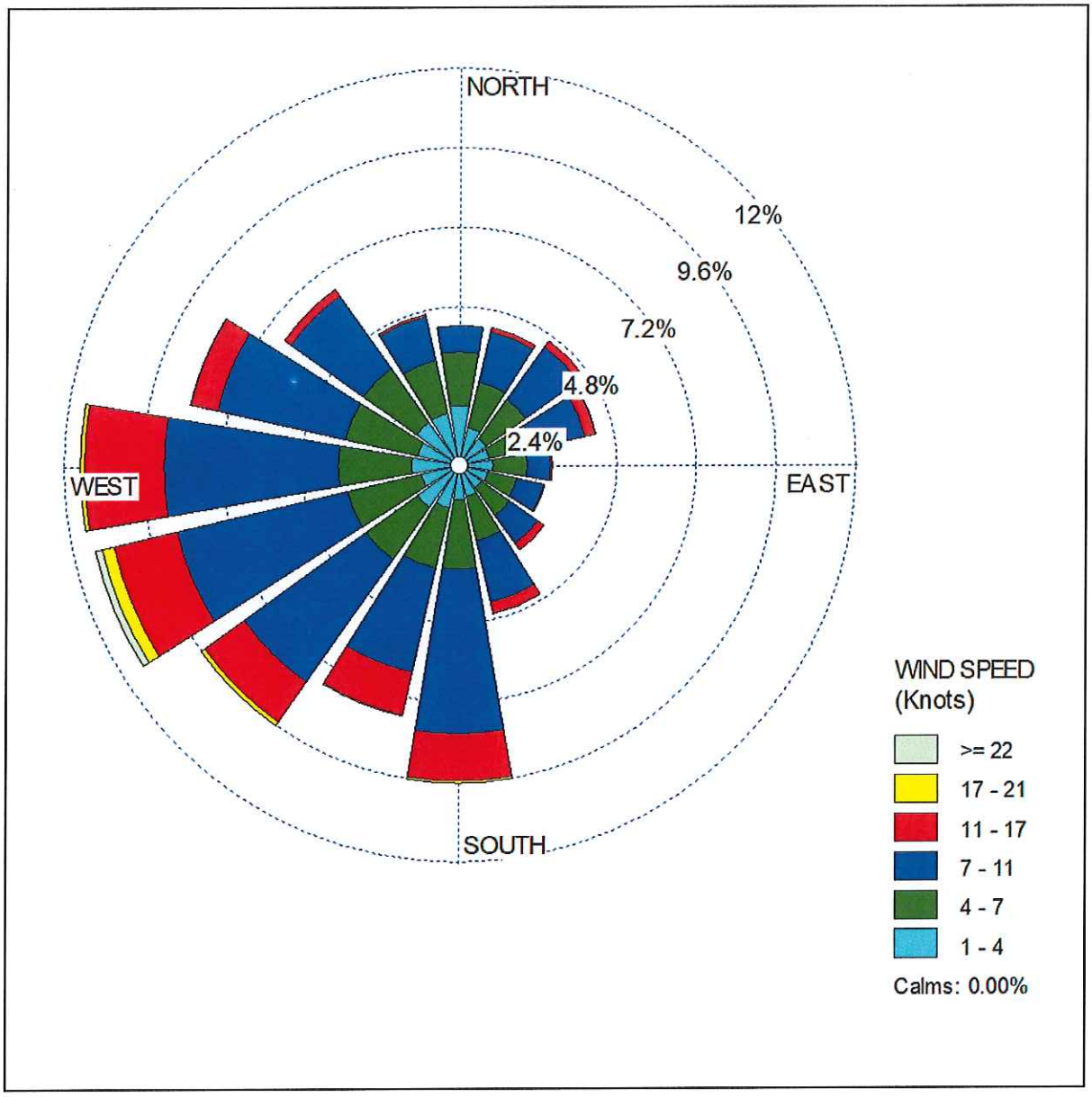
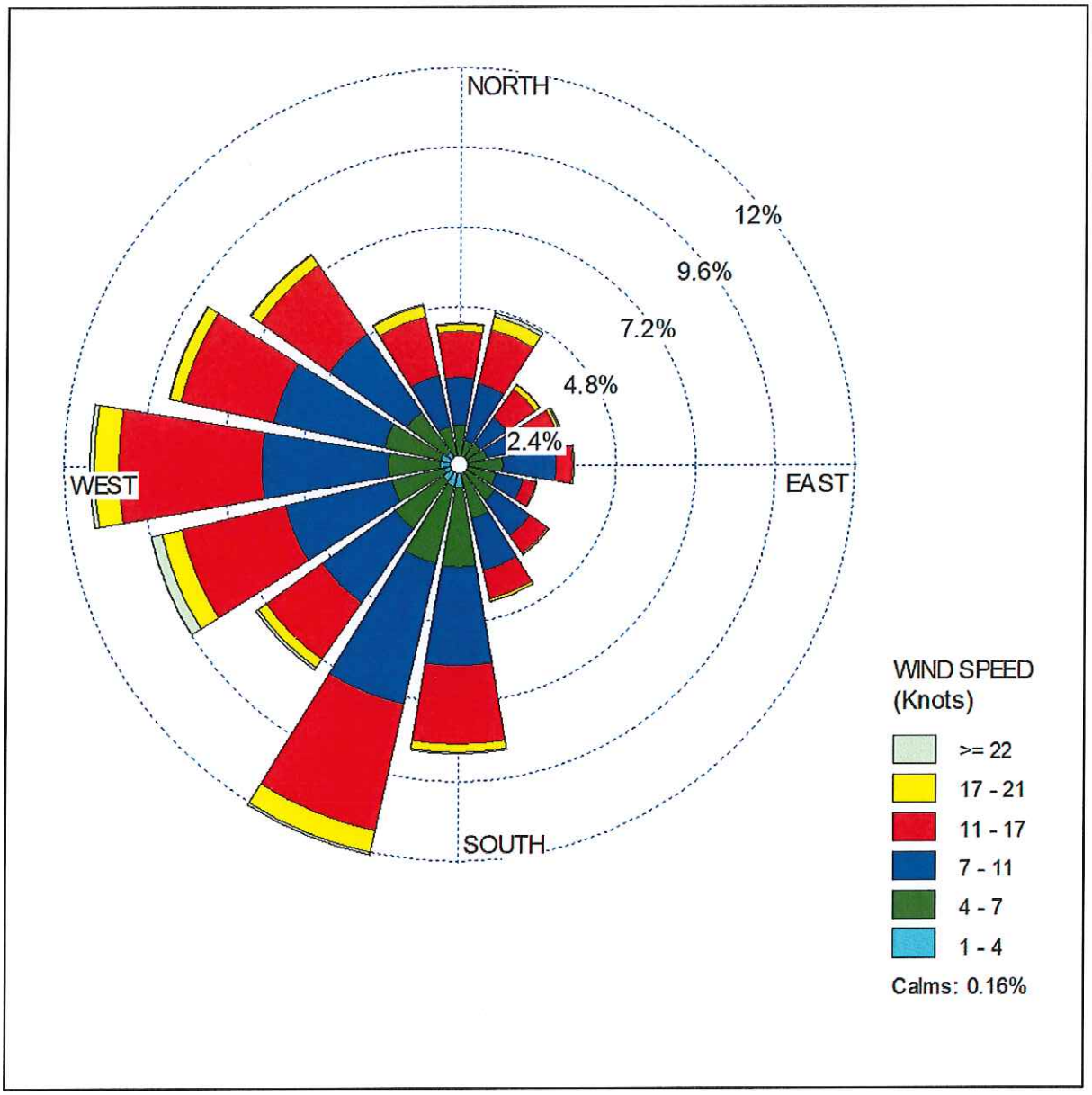


Figure 10. Midway November-March 2014-2018 wind rose.



component (Figures 7 and 8). For November-March periods over the five years, both stations exhibit the same general pattern, with Midway having a higher frequency of mid-range wind speeds (11-17 knots) than Argonne.

Hourly wind difference analyses were conducted between Argonne and Midway for 2014-2018. Table 7 gives the hourly wind speed differences for the entire 5-year period, as well as the November-March period. The distribution of differences for both the entire period and the November to March period were comparable to the distributions in Table 2. Of the 39,043 hours of winds where both sites had data for the full period, 12,937 hours had a wind speed difference within ± 1 m/s. For the November-March months, there were 16,850 hours where both sites had data and 6,417 hours had a wind speed difference within ± 1 m/s. Table 8 lists the wind direction differences between Argonne and Midway, and the distributions of differences in Table 8 compared well with the Table 3 differences. For the wind direction differences, there were 19,144 hours where the wind direction difference was less than 10° for the full 5-year period and 9,566 hours for the November-March period with wind direction differences less than 10°.

Table 7. Hourly wind speed differences between Argonne and Midway for 2014-2018.

Difference	Minimum (m/s)	Mean (m/s)	Median (m/s)	Maximum (m/s)
Argonne – Midway (full period)	-9.05	-1.50	-1.39	4.56
Argonne – Midway (November-March)	-9.05	-1.39	-1.25	3.2

Table 8. Hourly wind direction differences between Argonne and Midway for 2014-2018.

Difference	Minimum (°)	Mean (°)	Median (°)	Maximum (°)
Argonne – Midway (full period)	0	17	10	180
Argonne – Midway (November-March)	0	13	9	179

Table 9 lists the 5-year average minimum, mean, and maximum temperatures by month for Argonne and Midway. As with the November 2018-March 2019 period, the temperatures are similar across all months between the two stations. Also, the statistics for November-March do not indicate that the November 2018-March 2019 differences (Table 4) were unusual when compared to the 5-year averages.

Table 9. 5-year average monthly minimum, mean, and maximum temperatures (°C) for Argonne and Midway.

Month	Argonne			Midway		
	T_{min}	T_{avg}	T_{max}	T_{min}	T_{avg}	T_{max}
January	-23.30	-4.96	10.22	-21.18	-3.74	11.12
February	-18.46	-3.28	14.24	-16.70	-2.17	14.72
March	-12.58	2.75	20.58	-10.90	3.58	21.18
April	-3.60	9.23	26.30	-2.32	9.82	26.92
May	3.70	16.34	31.20	4.60	17.13	32.46
June	12.58	21.85	31.88	11.3	22.47	34.26
July	12.74	22.63	32.10	14.64	24.19	33.72
August	12.38	22.35	31.46	14.12	24.00	33.86
September	7.18	19.6	32.40	8.58	21.00	33.70
October	0.14	12.48	27.26	1.42	13.56	27.96
November	-9.66	4.29	18.24	-8.02	5.48	18.62
December	-16.06	-0.57	13.30	-14.2	0.60	14.44

Table 10 lists the hourly temperature difference statistics between Argonne and Midway. There were 42,291 hours where both sites had data for the entire period and 18,037 hours where both sites had data for the months of November-March. Argonne seems to have slightly cooler temperatures than Midway, possibly due to Midway being in a more urban environment than Argonne. The November-March statistics do vary from the November 2018-March 2019 results in Table 5, especially for the minimum and maximum temperature differences. This would not be unexpected when looking at an individual period (November 2018-March 2019) compared to a longer-term period of 5 years for the same months, but overall the differences for the 5-year period are comparable to the differences for November 2018-March 2019.

Table 10. Hourly temperature differences between Argonne and Midway for 2014-2018.

Difference	Minimum (°C)	Mean (°C)	Median (°C)	Maximum (°C)
Argonne – Midway (full period)	-6.44	-1.14	-1.24	14.86
Argonne – Midway (November-March)	-4.84	-1.10	-1.14	11.16

Based on the analyses in this section, there is nothing to indicate that Argonne would not be representative of Sterigenics for the 2014-2018 period and the analysis of Section 3.5 using November 2018-March 2019 would be valid for the entire period of 2014-2018.

The meteorological analyses presented here indicate that both Midway and Argonne can be considered representative of Sterigenics. A statistical analysis of AERMOD output using

methodology from the EPA's protocol for determining the best performing model shows that Argonne meteorological data outperformed Midway data. These analyses support the conclusion that while both Midway and Argonne are adequately representative meteorological sites for the risk assessment, Argonne would be the most representative of the two sites, given proximity to Sterigenics, available data, and how those data influence model output.

3.7 References

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USEPA. 2013. AERSURFACE User's Guide. U.S. Environmental Protection Agency. EPA 454/B-08-001. Revised January 16, 2013.

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https://www3.epa.gov/ttn/scram/guidance/guide/appw_17.pdf

USEPA. 2018a. User's Guide for the AMS/EPA Regulatory Model – AERMOD. U.S. Environmental Protection Agency. 454/B-18-001.

USEPA. 2018b. User's Guide for the AERMOD Meteorological Processor (AERMET). U.S. Environmental Protection Agency. EPA-454/B-18-002.

USEPA. 2019. User's Guide for Draft AERSURFACE Tool (Version 19039_DRFT). U.S. Environmental Protection Agency. EPA 454/B-19-001.

Appendix 4 to the Risk Assessment Report for the Sterigenics Facility in Willowbrook, Illinois:

U.S. EPA Risk Assessment for Sterigenics-Willowbrook (Slides from May 29, 2019, Public Meeting)

U.S. EPA Risk Assessment for Sterigenics-Willowbrook

Kelly Rimer

Leader, Air Toxics Assessment Group

United States Environmental Protection Agency

What we'll cover

- Key Terms
- EPA's Sterigenics Willowbrook Risk Assessment
  - What the Assessment Examined
  - Areas the Assessment Covered
  - Limitations and Uncertainties
- Review of Results

Two Key Terms

- ***Air toxics*** are pollutants that are known or suspected to cause cancer or other serious health effects
  - Also known as "hazardous air pollutants"
  - Ethylene oxide is an air toxic
- ***Cancer risk*** refers to the chance that breathing in an air toxic will cause people to develop cancer
  - Separate from the risk of developing cancer from other causes
  - EPA describes that chance as a number in 1 million people
    - For example, 1 in 1 million means that 1 person in 1 million people could develop cancer from breathing air toxics

Areas the risk assessment covered

- This risk assessment estimates the risks for several communities including:
  - Willowbrook
  - Burr Ridge
  - Hinsdale
  - Darien
  - Indian Head Park
  - Western Springs

We evaluated two scenarios

1. Potential risks from the Sterigenics-Willowbrook facility that exist after the emission controls that were installed in July 2018
   - Called the "Pre-Seal Order"

2. Potential risks assuming that the emissions from the facility is more highly controlled
   - Called the "Illustrative Future Case"

Assumptions in the scenarios

- For both scenarios the assessment estimates:
  - Risk in areas where people live
  - Risk in areas where people work close to the facility (but not at the facility)
- For areas where people live, we assume continuous 24/7 exposure for 70 years
- For areas where people work close to the facility, we assume people are exposed 8.5 hours a day, 5 days a week, 50 weeks a year for 25 years

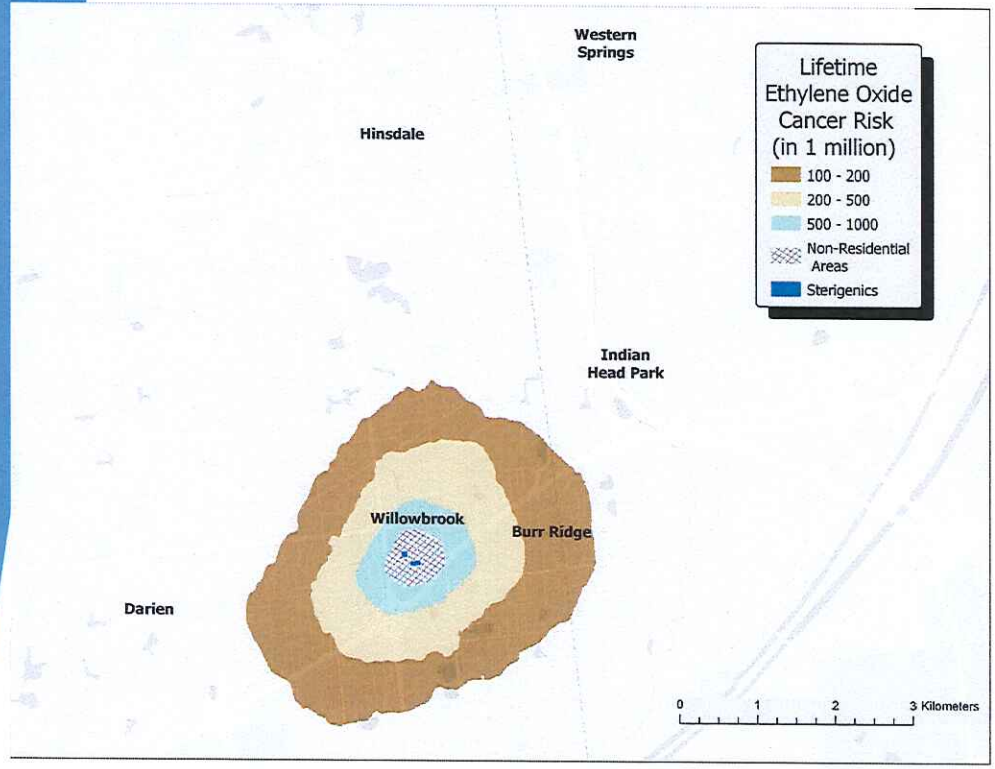
Limitations and Uncertainties

This risk assessment:

- Focuses on risks from the Sterigenics facility only
  - Does not assess comprehensive risk from all air pollution sources
- Provides *general* estimates of a population's risk of getting cancer due to EtO emissions from the Sterigenics-Willowbrook plant
  - Cannot be used predict an individual's chance of getting cancer
- Is more likely to over-estimate risk than underestimate risk due to what we call 'health-protective assumptions'

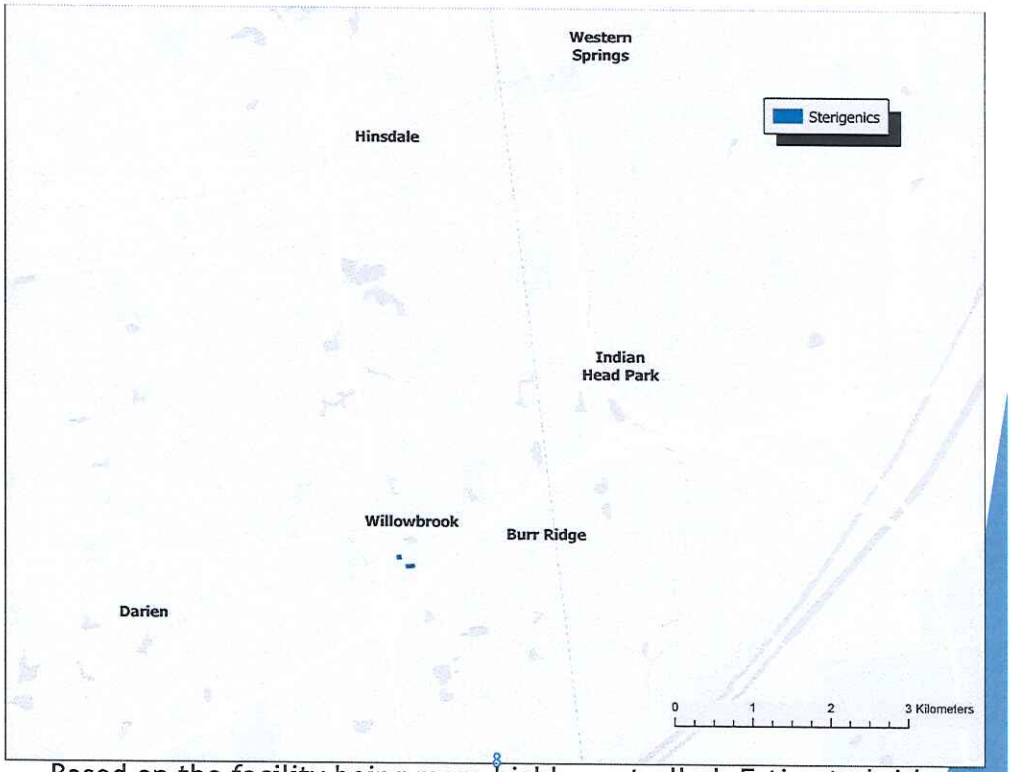
Estimated *Residential* Lifetime Cancer Risk from ethylene oxide emissions from Sterigenics Willowbrook

Pre-Seal Order Conditions



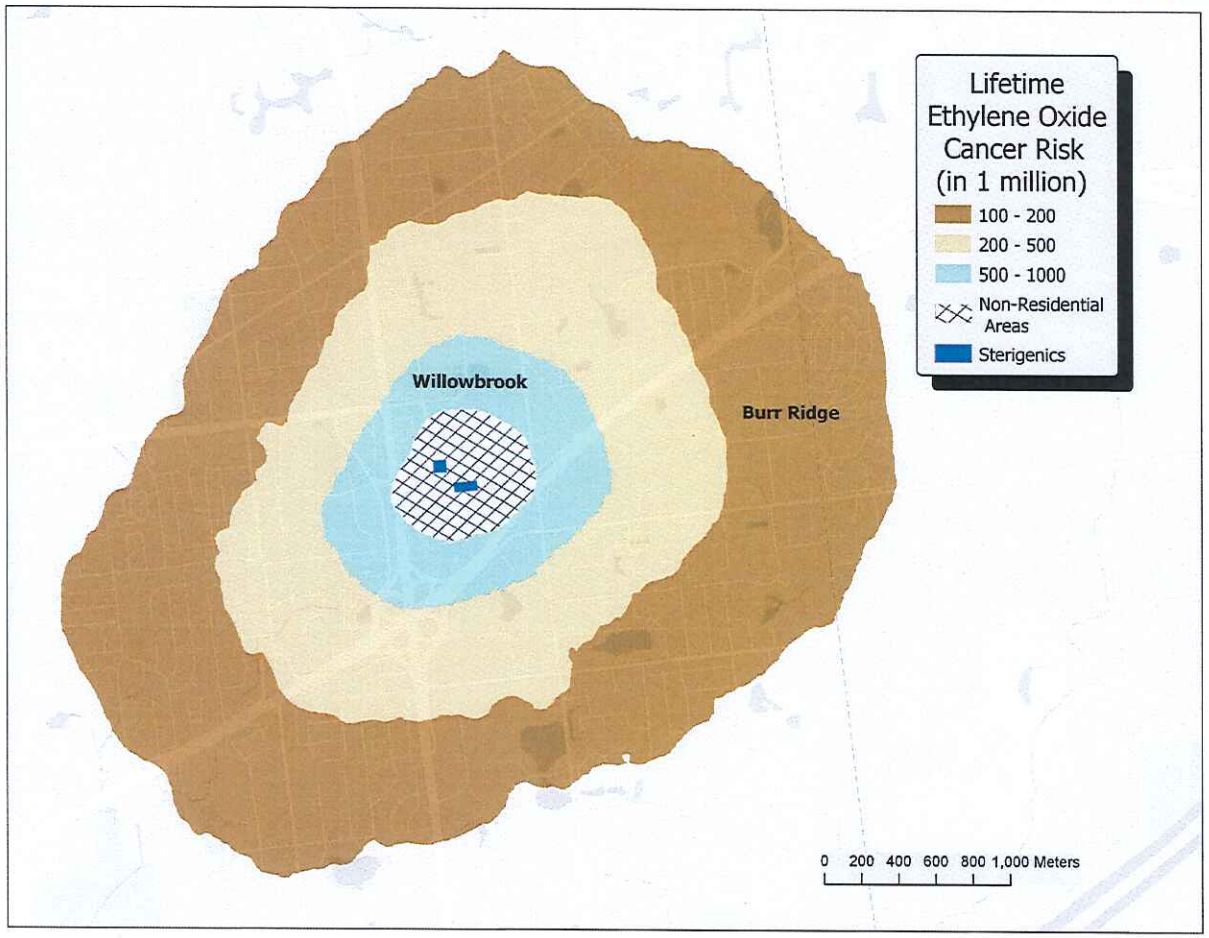
Based on operations before seal order (Reflects emissions reductions from controls installed in Summer 2018)

Illustrative Future Case



Based on the facility being more highly controlled. Estimated risks would be below 100 in 1 million - and potentially as low as 1 in 1 million.

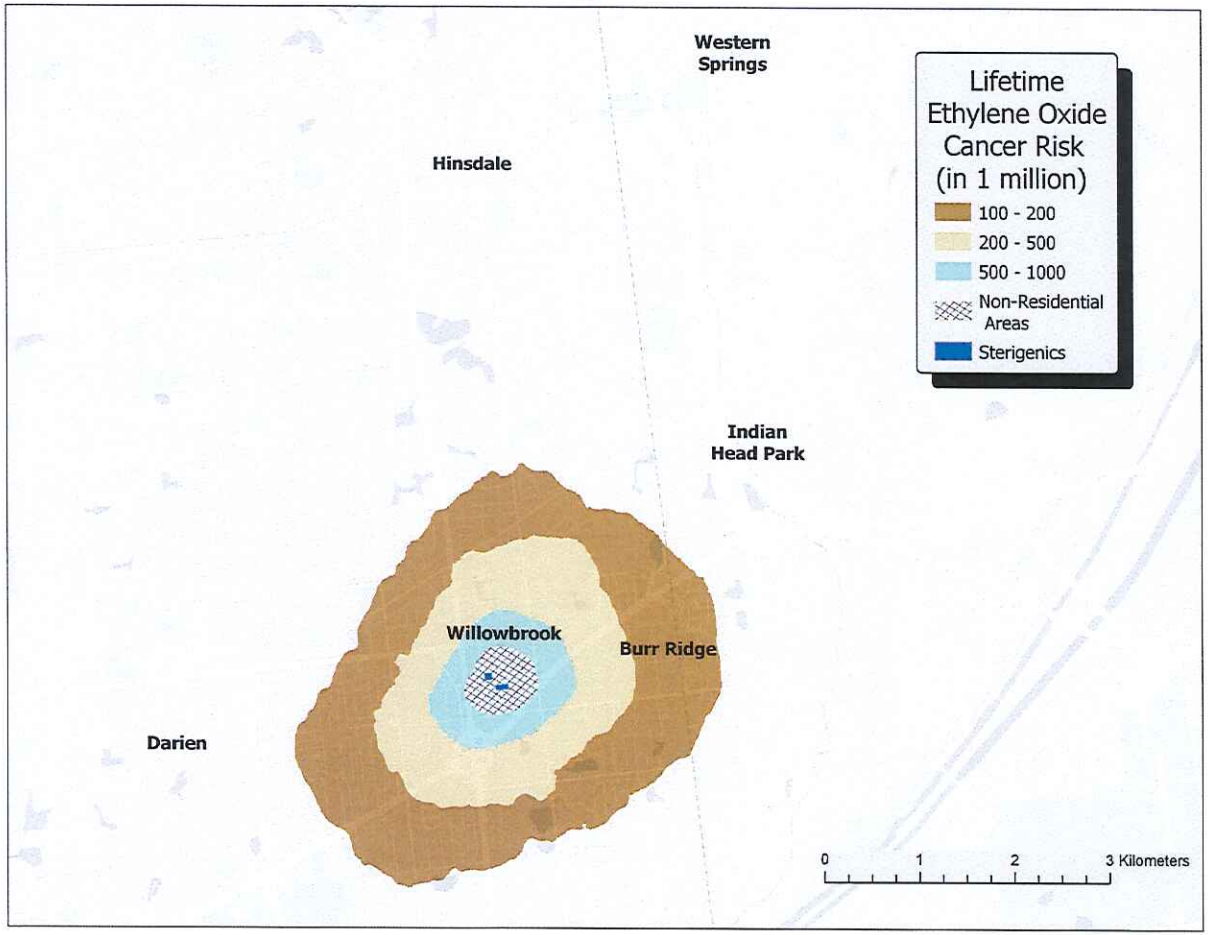
Zooming in:
Estimated *Residential* Lifetime Cancer Risk



Pre-Seal Order Conditions

Based on operations before seal order (Reflects emissions reductions from controls installed in Summer 2018)

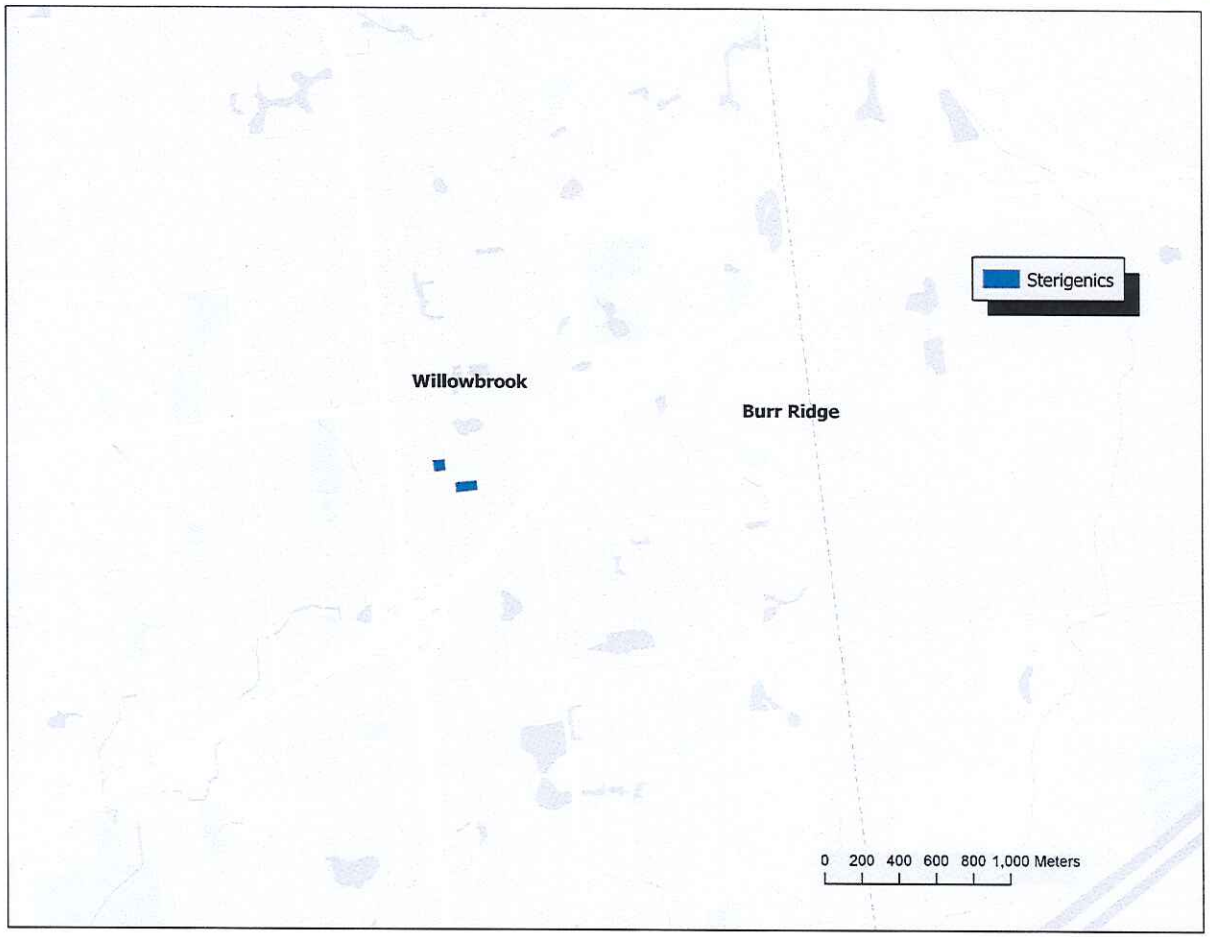
Estimated *Residential* Lifetime Cancer Risk from ethylene oxide emissions from Sterigenics Willowbrook



Pre-Seal Order Conditions

Based on operations before seal order (Reflects emissions reductions from controls installed in Summer 2018)

Zooming in:
Estimated *Residential* Lifetime Cancer Risk

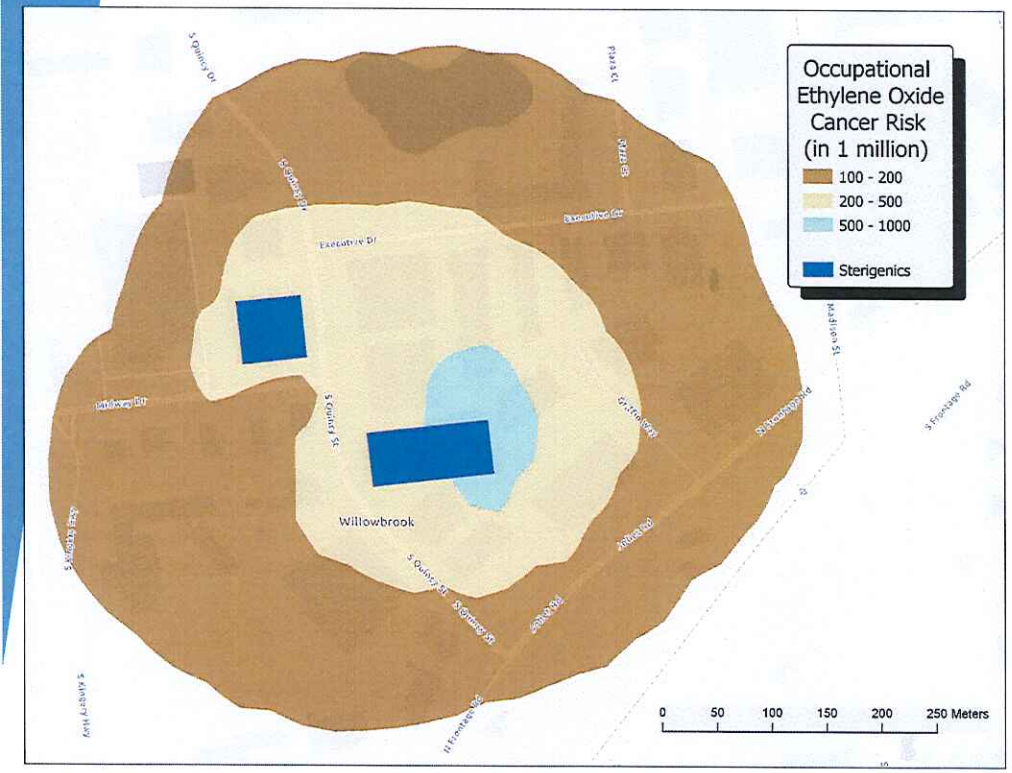


Illustrative Future Case

Based on the facility being more highly controlled. Estimated risks would be below 100 in 1 million - and potentially as low as 1 in 1 million

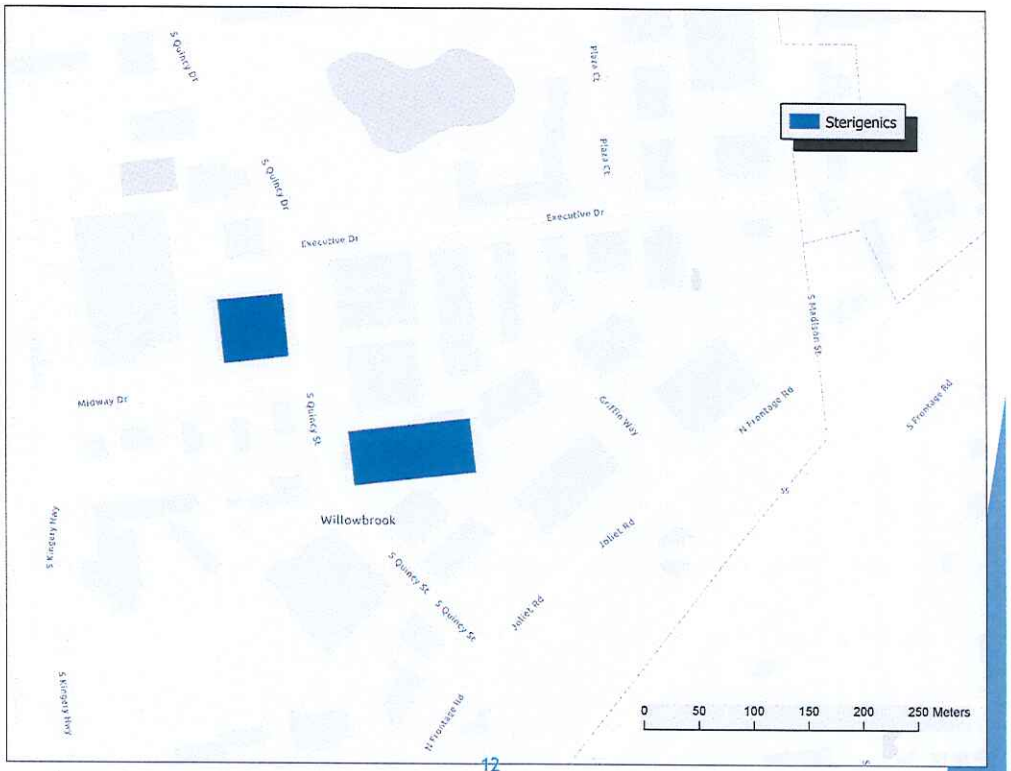
Estimated *Occupational* Lifetime Ethylene Oxide Cancer Risk from Sterigenics Willowbrook

Pre-Seal Order Conditions



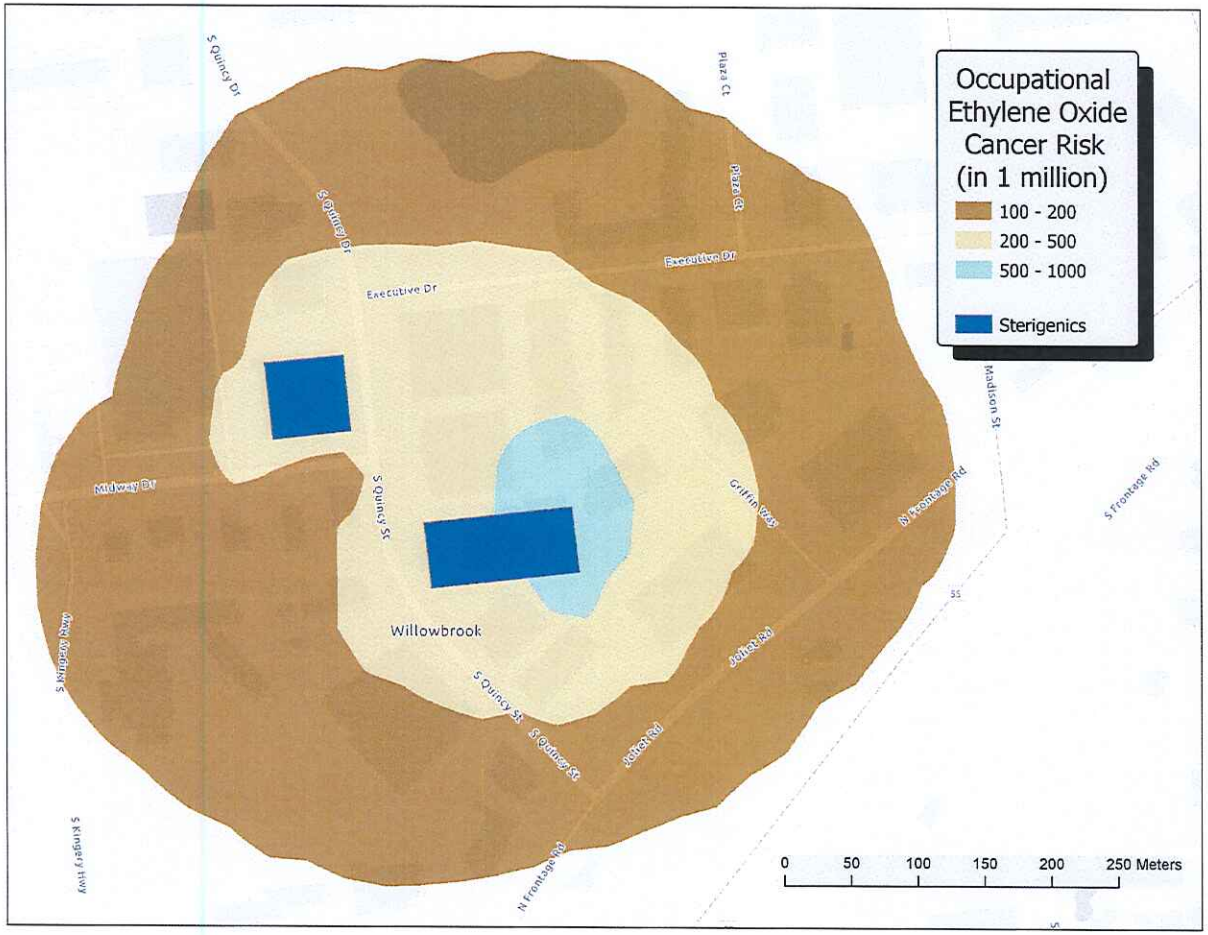
Based on operations before seal order (Reflects emissions reductions from controls installed in Summer 2018)

Illustrative Future Case



Based on the facility being more highly controlled. Estimated risks would be below 100 in 1 million - and potentially as low as 1 in 1 million.

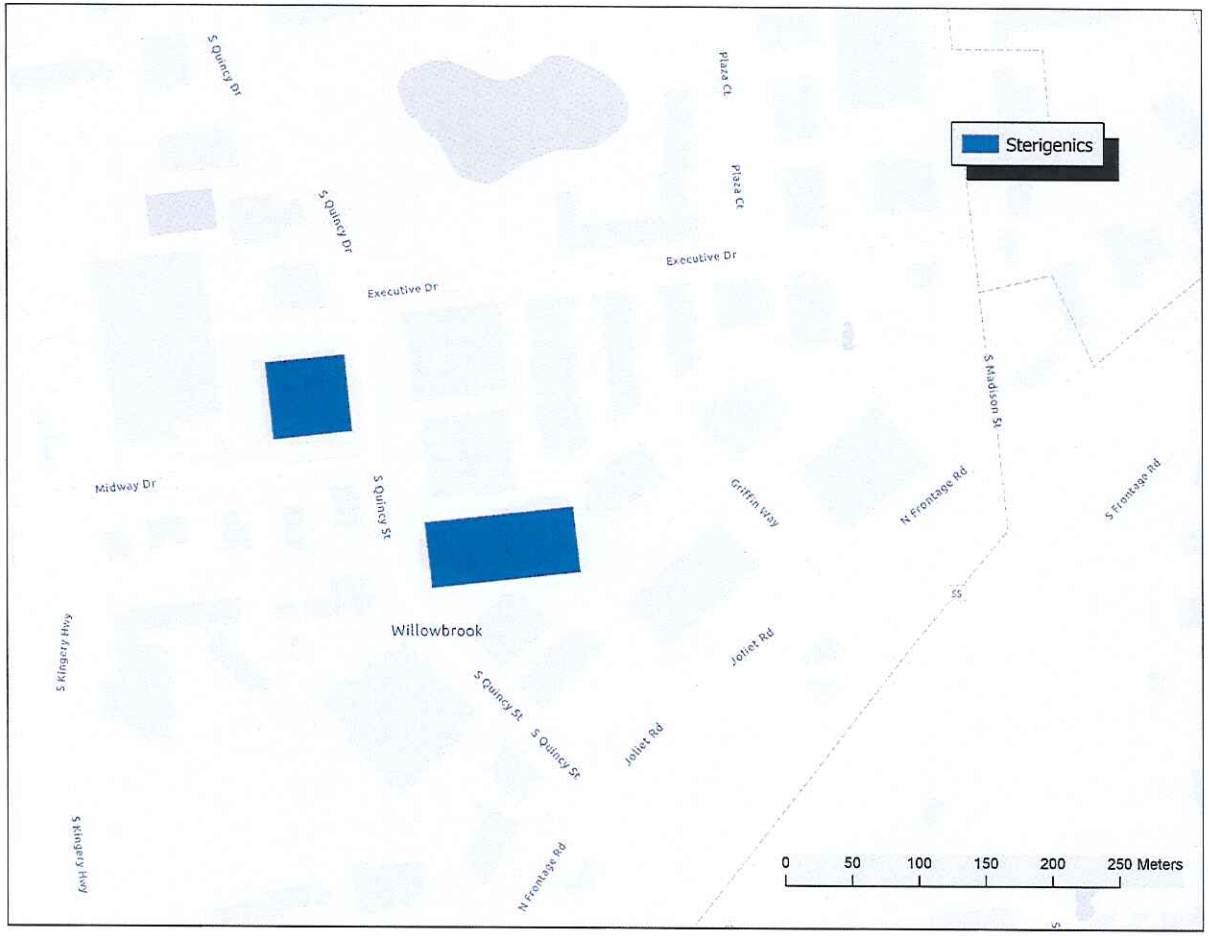
Estimated *Occupational* Lifetime Ethylene Oxide Cancer Risk from Sterigenics Willowbrook



Pre-Seal Order Conditions

Based on operations before seal order (Reflects emissions reductions from controls installed in Summer 2018)

Estimated *Occupational* Lifetime Ethylene Oxide Cancer Risk from Sterigenics Willowbrook



Illustrative Future Case

Based on the facility being more highly controlled. Estimated risks would be below 100 in 1 million - and potentially as low as 1 in 1 million

Thank You

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August 15, 2019

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VIA E-MAIL EPA.STERIGENICS@ILLINOIS.GOV

Illinois Environmental Protection Agency

Re: Public Comment on behalf of the Village of Willowbrook and Village of Burr Ridge re: Illinois Environmental Protection Agency Draft Construction Permit to Sterigenics US, LLC Willowbrook I facility (Application No. 19060030)

Dear Illinois Environmental Protection Agency:

On behalf of the Village of Willowbrook and the Village of Burr Ridge (the "Villages")[1], we submit the following comments on the Illinois Environmental Protection Agency's ("IEPA" or the "Agency") draft Construction Permit, Application No. 19060030, issued for Sterigenics US, LLC's Willowbrook I facility (the "Facility") on June 25, 2019 (the "CP"). These comments were prepared with the assistance of GHD, which has assisted the Villages in evaluating the impact of EO emissions from the Facility.

While the Villages appreciate this opportunity to provide comment on the draft CP, the Villages strongly object to IEPA's issuance of the CP. On February 15, 2019, the Agency took the necessary and appropriate measure to prevent the continued release of harmful emissions of EO from the Facility. IEPA's decision to now permit the Facility to recommence operation undermines this critical action to protect public health and the environment. The CP is premature. Based on the deficiencies in the CP discussed below, the CP (and the information relied upon by IEPA to develop and substantiate issuance of the draft CP) is inadequate to ensure that the Facility will comply with Illinois EO legislation (415 ILCS 9.16) and ensure protection of human health and the environment. As such, Illinois EPA must not allow the Facility to reopen.

For the following reasons IEPA should not issue the draft CP. In the event the Agency does elect to issue the permit, then the following deficiencies in the draft CP must be addressed prior to issuance:

[1] The Village of Hinsdale and the City of Darien support these comments.

EXHIBIT
D to Affidavit

1. **Certification that Pollution Controls Use the Greatest Reduction in EO Emissions Available**

   i. Provision 1.c of the draft CP includes a conclusory and deficient statement that IEPA has determined that the Facility's pollution controls produce "the greatest reduction in [EO] emissions currently available."

   ii. Section 9.16(g) of the Illinois Environmental Protection Act (the "Act") prohibits the emission of EO until, among other requirements, IEPA has "certified" that the controls use the greatest reduction currently available.

      a. No such certification is provided with the draft CP, nor does the permit contain any condition verifying that such certification has occurred. The Agency has not shared how it certified that Sterigenics' proposed pollution controls represent the greatest reduction in EO emissions currently available, as the statute requires.

      b. The certification cannot be made until the Facility has demonstrated, through an emissions test, that the Facility is in compliance with the emission limits contained in the CP and under 415 ILCS 5/9.16. The CP application does not contain sufficient information for IEPA to certify that the Facility's emission control system uses technology that produces the greatest reduction in ethylene oxide emissions currently available.

      c. In addition, the Ambient Air Monitoring Plan (required under 415 ILCS 5/9.16(e)(1)) should be submitted and reviewed by the Agency and interested parties before the Agency can certify that the Facility's emission control system uses technology that produces the greatest reduction in ethylene oxide emissions currently available.

   iii. The public should have an opportunity to review the information supporting any such certification before the Agency issues the permit and before the Facility resumes operation. IEPA should create a publicly accessible database that contains all of this information (as well as all data, reports and submissions that the CP requires the Facility to submit).

2. **Supplier Certifications**

   Neither the CP application nor the draft CP provides any evidence that the Facility has obtained and provided to IEPA certifications from their customers that EO sterilization or fumigation is the "only available method to completely sterilize or fumigate the[ir] product" as required under 415 ILCS 5/9.16(g). In fact, in IEPA's August 5, 2019, response to a Freedom of

Information Request dated July 24, 2019 submitted to IEPA on behalf of the Villages (No. 109478) (the "FOIA"), IEPA identified no records of supplier certifications. IEPA should not issue the CP until and unless such certifications are provided.

3. <u>Continuous Emissions Monitoring (CEMS)</u>

i. Neither the draft CP nor Sterigenics' CP application provides sufficient assurances or details, respectively, that the CEMS is capable of accurately measuring EO emissions to determine compliance with applicable permit limits. By law, IEPA cannot permit the Facility to operate unless the Facility can "demonstrate[] that it...reduces [EO] emissions to the atmosphere from each exhaust point...by at least 99.9%." 415 ILCS 5/9.16(b). While proposed Condition 7-1(d) requires the Facility to submit an Emissions Monitoring Plan that prescribe the CEMS operating parameters, that requirement does nothing to assure that the CEMS itself is capable of accurately measuring point source EO emissions. To our knowledge, apart from the recent construction permit issued to Medline Industries (Application No. 19020013) ("Medline Permit"), neither IEPA nor U.S. EPA have approved the use of a CEMS to monitor emissions of EO.[2]

ii. If IEPA does authorize use of a CEMS to measure EO, the CP should require the following:

   a. The CEMS are designed and operated to maintain a limit of quantification that is no greater than 10 parts per billion by volume (ppbv) (IEPA has included a similar requirement in the Medline Permit).

   b. The CEMS must comply with all applicable quality assurance and quality control requirements (i.e., reliability, calibration, linearity checks, and relative accuracy test audits (RATA)), and specifically those monitoring requirements found under 40 CFR 63.8 and 63.10 (monitoring and reporting requirements applicable to hazardous air pollutants) and 40 CFR Part 75.

   c. Electronic and field auditing of the CEMS must occur to verify the overall integrity of the emissions monitoring data, including, but not limited to: (i) semi-annual on-site audits to verify the Facility's CEMS performance and compliance with monitoring requirements; (ii) automatic screening of reported CEMS data with

[2] In a separate public comment submitted by P. Farber & Associates, LLC, Mr. Farber conducted a survey of manufacturers and distributors of emissions monitoring equipment that confirmed that no known, reliable, monitors are commercially available to continuously and accurately monitor emissions of EO. The Villages support the comments and deficiencies identified by Mr. Farber in his public comment.

electronic QA checks; and (iii) review and QA checks/audits of the reported CEMS data from the Facility.

iii. As further discussed below, the draft CP requires installation of a new stack, but does not specify the height or dimensions of the stack other than to authorize installation of an 87-foot stack if approved by the Village of Willowbrook. Neither the draft CP nor the CP application addresses or evaluates whether a change in stack parameters will affect the reliability of the CEMS and, therefore, the assurance that the required pollution controls are achieving the 99.9% reduction in EO emissions required by the CP and the Act (a process typically achieved through RATA). Because CEMS have not been demonstrated effective at measuring EO emissions, IEPA must perform additional evaluation of the CEMS to assure that the monitored data will be accurate and reliable based on the actual physical parameters of the Facility (including the to-be-constructed stack).

4. Annual Emission Testing

The draft CP proposed that all required emissions testing be conducted "under operating conditions that are representative of maximum emissions...." Condition 8-2.a. It is unclear what IEPA means by the phrase "representative of maximum emissions". Does IEPA mean maximum *potential* emissions from the Facility during which time all sterilization chambers are in operation? To clarify and ensure that "maximum emissions" are tested, the CP should require that any emissions test be performed when the Facility is operating at no less than 90% of maximum capacity (i.e., at least 13 sterilization chambers in operation).

5. Storage of EO

The CP should not allow Sterigenics to store new or used/spent drums of EO outside of the Facility. More specifically, at all times – including during delivery and removal – the new or spent drums should be maintained with a permanent total enclosure or other structure to reduce to the greatest extent possible the likelihood that emissions of EO can escape from the drums, including during an unforeseen emergency such as a spill. Absent total enclosure and monitoring of fugitive leaks from the drums, the CP does not provide any mechanism to ensure that harm emissions of EO are not being released into the atmosphere during outside storage.

6. Fugitive Emissions and Leak Detection

i. The permanent total enclosure ("PTE") proposed under Provision 7-2 of the draft CP is insufficient to ensure that all fugitive EO emissions at the Facility are captured and controlled to ensure compliance with Sections 9.16(b) and (g) of the Act. While the proposed PTE does satisfy the requirement under Section 9.16(j) of the Act (to install a PTE), it does not ensure that *all* sources of EO emission from the Facility are captured. The

Act is unambiguous - the Facility must "demonstrate[] that it captures, *100% of all* [EO] emissions." *See* 415 ILCS 5/9.16(b). *All* EO emissions from the Facility must be captured, as contrasted with the Act's requirement that EO emissions specifically from exhaust points be reduced by 99.9%.

a. Further, IEPA has not provided (and, most likely, no information has been provided by Sterigenics to the Agency) information regarding the ability of the proposed PTE to effectively and reliably prevent the release of fugitive EO emissions from the Facility. IEPA acknowledged that no records were available regarding the PTE system in the Agency's August 5, 2019 response to the FOIA request (No. 109478).

ii. In order to ensure that the Facility captures 100% of all EO emissions, the CP must address the following deficiencies:

a. Ensure that no new or spent drum containing EO is stored outside the facility. More specifically, the CP must ensure that both new (sealed) drums of EO and spent drums of EO are stored inside the boundaries of the PTE (provision 3.b.iii of the draft CP, for example, only requires that the Facility ensure that drums of EO be kept sealed and that no release of EO from these drums occurs - the permit makes no mention of *how* the Facility will prevent such a release and does not specify how spent/used EO drums are to be handled).

b. Require the Facility to implement a leak detection and repair ("LDAR") program to more readily prevent, detect and repair potential sources of EO from connection points (e.g., valves and connectors) throughout the Facility. The installation and maintenance of a PTE cannot adequately prevent or remedy the release of EO from such connection points. The CP should specify action limits for the LDAR program to require that the Facility immediately repair any identified leaks or shut-down the Facility.

c. Require the Facility to maintain the PTE at all times that EO may be present, which includes periods when the Facility is not operating. Provision 7-2(a) of the draft CP only requires operation of the PTE "whenever the facility is in operation." The CP does not define what constitutes "operation" of the Facility. EO emissions may be (and, in fact, are likely) present in the Facility for a period of time after the Facility has shut-down (for example, following a temporary shutdown to performance maintenance). Further, per our previous comments, EO emissions from storage drums or leaking components occur regardless of whether the Facility is operating.

d. Specify how doors and windows are continuously monitored to ensure they remain closed to preserve the required pressure differential in the PTE.

e. Require the Facility to submit pressure monitoring system measurements to IEPA for review on a monthly basis (the draft CP only requires that the Facility record and maintain such records under provisions 7-2(a)(ii) and (b)).

f. IEPA (or Sterigenics) must evaluate possible EO fugitive releases that can escape the building enclosure and, based on a toxicological analysis, determine action levels that would trigger a shutdown of the Facility. These action levels should be based on a specific time-based pressure drop duration that would warrant a facility shutdown to protect public health.

g. The draft CP does not require or provide any means to alert Facility personnel that a pressure drop below 0.007 inches of water has occurred. The CP should.

h. Specify the minimum design specifications for the pressure monitoring devices, which should include a requirement that all such devices are able to measure pressure differential to at least the nearest 0.001 inches of water.

7. Malfunction and Continuous Operation of Pollution Controls

The CP must - but does not - prevent the Facility from operating when the pollution control equipment is not operating, when elevated ambient air impacts are observed, when the Facility is not capturing 100% of EO emissions, or when the pollution controls are not achieving a 99.9% reduction in EO emissions from the Facility. The CP should contain such minimum requirements that preclude the Facility from operating at *any* time the pollution control equipment is not operating or malfunctions, and/or when there is a pressure drop or other event indicating that emissions are not being contained by the Facility's PTE.

8. Stack Height

i. Provision 4.a.ii of the draft CP grants Sterigenics the permission, subject to approval by the Village of Willowbrook, to extend the height of the newly constructed stack to 87 feet above-ground. Provision 4.a.ii is inappropriate. If the Agency has determined through dispersion modeling or other methods that an 87 foot stack is necessary to protect, or beneficial to, public health, it cannot and should not allow the Facility to recommence operation until such time as the higher stack is constructed. The underlying intent of the Act (415 ILCS 5/9.16) and this draft CP is to ensure that public and environmental impact from EO emissions are minimized to the greatest extent possible. If IEPA or Sterigenics have determined that a taller 87-foot stack will provide for greater reductions in EO emission impacts to human health and the environment, it cannot issue the CP without making such stack height a requirement.

ii. IEPA has no legal basis to provide Sterigenics the option to install a higher stack because of the Agency's concerns regarding whether the Village of Willowbrook would grant such a stack height under the village's zoning ordinances. To the extent that is a concern, IEPA and Sterigenics must work to resolve any zoning issues *prior* to issuance of this CP. Indeed, just recently, the planning and zoning council for the City of Waukegan rejected the request by Medline Industries for authorization to install a taller stack that was permitted under IEPA's Medline Permit.

9. <u>Air Dispersion Modeling</u>

i. IEPA must perform air dispersion modeling that evaluates all potential stack heights authorized by the CP. The ambient air modeling submitted in support of the June 2019 CP application to IEPA (and obtained from IEPA via the July 24, 2019 FOIA) *only* evaluated the impact from an 87-foot stack. Modeling scenarios with shorter stack heights were not present (and, presumably, not evaluated by IEPA). As noted above, the draft CP does not *require* that the Facility install an 87-foot stack; nor is there any guarantee that the Village of Willowbrook will authorize the construction of an 87-foot stack under its municipal ordinances. Moreover, the Act explicitly prohibits operation of the Facility unless air dispersion modeling uses actual "emissions and stack parameter data" from the EO source emissions test conducted pursuant to the Act. *See* 415 ILCS 9.16(f)(1)(B). IEPA cannot issue this CP on the basis of ambient modeling data that does not reflect actual, required, stack parameter metrics.

   a. To that end, IEPA should determine, through modeling, the minimum stack height required to provide the greatest reduction in EO emissions impact to human health and the environment.

ii. On behalf of the Villages,[3] GHD reviewed Sterigenics' aforementioned air dispersion modeling evaluation for the Facility. GHD provides the following observations and critiques of this modeling:

   a. Sterigenics also operates the Willowbrook II (WB2) facility located about 400 ft. northwest from the Willowbrook I (WB1) facility. While WB2 is not currently operational, that facility may recommence operation in the future. The potential emissions of EO from WB2 were not accounted for in the air dispersion modeling.

[3] P. Farber & Associates, LLC submitted separate public comments regarding the air dispersion modeling relied upon by IEPA. Many of Mr. Farber's critiques were also identified by GHD and are discussed in this comment. As above, the Villages support the comments of Mr. Farber.

Given the close proximity of the two facilities and the potential for WB2 to operate in the foreseeable future, potential emissions of EO from WB2 must be accounted for (i) before IEPA issues the CP to the Facility to recommence operation of WB1, and (ii) as part of future ambient air dispersion modeling for the Facility as required under the Section 9.16(f) of the Act.

b. It appears that only the building structures from WB1 and WB2 were included in the building downwash evaluation with the Building Profile Input Program ("BPIP") pre-processor. Whereas the surrounding buildings seem to be shorter than the WB1 building, the neighboring building structures should also be included in the downwash evaluation with BPIP.

c. The base elevation of the main meteorological tower (PROFBASE) used in the input file is 188.4 meters. Based on the location of the Argonne National Laboratory surface station, the base elevation should be approximately 230 meters.

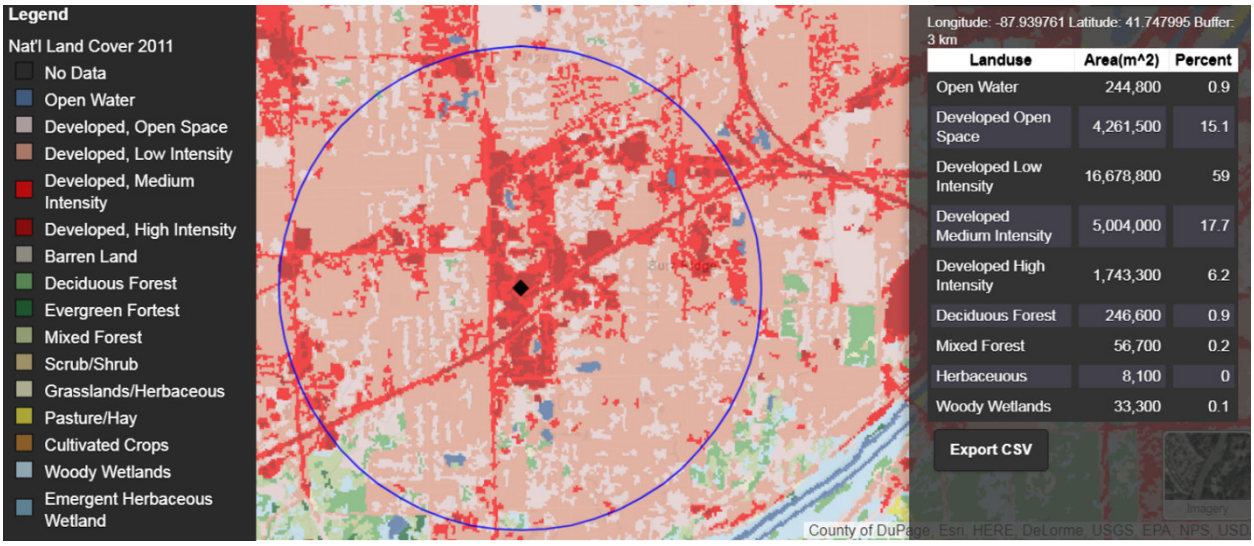
d. The modeling was based on the Facility's annual permitted emission limit of 84.8 lb/year (0.0097 lb/hr annualized). However, the Facility is permitted to emit EO on a monthly limit of 8.5 lb/month (0.0118 lb/hr annualized). IEPA should consider accounting for potential higher periods of EO emissions allowed under the higher monthly limit. The Agency should consider the potential higher emissions of EO happening on a shorter time basis and compare them to applicable health limits (e.g., Occupational Safety and Health Administration permissible exposure limits.

e. The modeling relies upon a stack velocity of 96.1 ft/s. It is unclear the basis for this higher stack velocity as more typical velocities for this type of stack generally fall in the range of 50-70 ft/s. Either the modeling should be performed with more representative stack velocities or IEPA should include as a permit condition that the Facility maintain a stack velocity of no less than 96.1 ft/s during all times the Facility is operating.

f. The air dispersion modeling used the urban option. Use of the urban option is not clearly justified. According to the National Land Cover 2011 map (below), the developed high intensity and medium intensity classifications account for only about 23.9% of the 3km radius area around the Facility. Based on the Auer method, because less than 50% of the area can be classified as urban, a rural classification is a more suitable modeling option for this evaluation. *See* Appendix W, Section 7.2.1.1 b.i (https://www3.epa.gov/ttn/scram/guidance/guide/appw_17.pdf) (providing the Auer Land Use Procedure to determine rural or urban classification); *see also* Appendix W, Section 7.2.1.1 b.ii (under an alternative method known as

Population Density Procedure, GHD estimates that the density inside the 3km radius of the Facility is approximately 90 people/km2, far less than the 750 people/km2 needed to classify an area as urban).

2011 National Land Cover Map



Thank you again for the opportunity to submit these comments. We hope and expect that the Agency takes the required steps to protect the public from any additional harm that will result from the operation of Sterigenics' Facility.

Sincerely,

/s/ Renee Cipriano

Renee Cipriano