ILLINOIS ENVIRONMENTAL PROTECTION AGENCY
1021 NORTH GRAND AVENUE EAST, P.O. BOX 19276, SPRINGFIELD, ILLINOIS 62794-9276 • (217) 782-3397
JB PRITZKER, GOVERNOR **JOHN J. KIM**, DIRECTOR

Responsiveness Summary

September 20, 2019

Issuance of a Construction Permit
Sterigenics U.S. LLC - Willowbrook I

Facility Identification No.: 043110AAC
Application No.: 19060030

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4302 N. Main Street, Rockford, IL 61103 (815) 987-7760
595 S. State Street, Elgin, IL 60123 (847) 608-3131
2125 S. First Street, Champaign, IL 61820 (217) 278-5800
2009 Mall Street Collinsville, IL 62234 (618) 346-5120
9511 Harrison Street, Des Plaines, IL 60016 (847) 294-4000
412 SW Washington Street, Suite D, Peoria, IL 61602 (309) 671-3022
2309 W. Main Street, Suite 116, Marion, IL 62959 (618) 993-7200
100 W. Randolph Street, Suite 4-500, Chicago, IL 60601

INTRODUCTION

This document is a Responsiveness Summary prepared by the Illinois EPA in conjunction with the issuance of a construction permit to an ethylene oxide sterilization source, Sterigenics US, LLC, for a suite of enhancements to its Willowbrook I facility located in Willowbrook, Illinois. The construction permit issued by the Illinois EPA on this same date authorizes the installation of control improvements that are necessary for Sterigenics to comply with the newly-enacted requirements of the Matt Haller Act. *See,* Public Act 101-0022, codified at 415 ILCS 5/9.16. As part of the commitments made by the Illinois EPA when scheduling the August 1, 2019, public meeting, this document provides a written response to significant, permit-related comments raised at the meeting and during the related public comment period.

PUBLIC OUTREACH

Recognizing the significant public interest in the permitting action and based on communications with local elected officials, the Illinois EPA held a public meeting at Ashton Place in Willowbrook on the evening of August 1, 2019, to allow the public to submit comments about the draft construction permit.

Though not required by statute or regulation, the Illinois EPA borrowed from a historical practice of offering the public the opportunity to meet with Illinois EPA officials in advance of the permitting of controversial projects. To ensure that the public benefited from an orderly process that guaranteed the right of public comment, the Illinois EPA made use of the hallmarks of a traditional informational hearing for the occasion. This approach included the following: public notice of the meeting that was distributed on the Agency's website, and forwarded to numerous elected officials, notice of a 30-day public comment period and notice of a draft construction permit; convening of a panel of Illinois EPA staff to address questions at the meeting, including the manager of the Bureau of Air/Permit Section's construction unit group, an emissions testing specialist from the Bureau of Air, and both a Hearing Officer and a Community Relations Coordinator from the Office of Community Relations; transcribing of the hearing by a court reporter; and, the preparation of this Responsiveness Summary to address all significant permit-related comments raised at the public meeting and during the comment period.

Over 500 people participated in Illinois EPA's public outreach in this matter. The Illinois EPA considered all comments in its final permit decision. Public comments generally expressed disapproval of the project, urging the Illinois EPA to deny the permit application. Comments also addressed why Sterigenics would be afforded a second chance of operating its facility given their history of alleged violations.

This Responsiveness Summary responds to the questions and concerns raised relative to this construction permit. Notably, the document addresses the Illinois EPA's role under the Environmental Protection Act and the relevant legal authorities that underlie the Illinois EPA's responses to many of the questions and comments on the permit decision.

Comments are shown in conventional text and responses are shown in boldface. Comments and responses are arranged by subject matter, paraphrasing and grouping similar comments and questions. Numerous comments in this document are depicted in a condensed or paraphrased form, rather than recited in full. In other instances, comments are retained in original form because of their complexity or level of specificity.

All significant comments relating to the draft construction permit or that otherwise fall within the Illinois EPA's scope of permit authority are being addressed in this Responsiveness Summary. This framework necessarily does not answer some of the comments raised at the public meeting or during the comment period but is appropriate because of the inability to address matters outside of the Illinois EPA's regulatory expertise.

QUESTIONS AND AGENCY RESPONSES

Permitting

1. The application was not complete.

The application contained the necessary information for the Illinois EPA to issue the construction permit. As a general rule, permit forms seek information to assist an agency's evaluation of an application, however, the Illinois EPA is not without jurisdiction to base its permit decision on matters outside of the permit forms (e.g. its own institutional knowledge or judgement). In this instance, the application contained sufficient information to demonstrate that the source would not cause a violation of the Act.

2. The permit should be denied. It is within the Illinois EPA's discretion.

Under the Environmental Protection Act, the Illinois EPA is required to issue a permit to an applicant upon proof that the proposed facility or equipment will not cause a violation of the Act or promulgated regulations. *See, 415 ILCS 5/39(a).* This standard is a mandatory one, expressed in the language of the provision as a "duty" that is imposed upon the Illinois EPA. While agency deliberation of certain aspects of the permit may be grounded in the exercise of discretion, the broader legal standard governing permit issuance or denial limits the discretion of the Illinois EPA. In its application, Sterigenics addresses changes that would be made to the facility to comply with the new law. As such, in this instance, the Illinois EPA finds that the legal standard noted above has been met. Nothing in the record, including the public comments on the draft construction permit, adduces otherwise.

3. Is it an option for IEPA to modify the permit for approval without further public comment or meeting?

The Agency may issue a construction permit that includes changes from the draft permit provided to the public for comment. As a general matter, this routinely occurs as public comments on a draft permit help identify changes that should be made.

4. The Illinois EPA cannot ignore public comment and approve the construction permit.

The Illinois EPA reviewed all comments raised at the public meeting and submitted during the public comment period. The Illinois EPA is generally responding to all comments that are significant and, as frequently happens, is making various changes to the permit in response to the comments. These changes include various enhancements to the terms of the permit, as discussed later in this document.

5. Why isn't the Illinois Department of Public Health study a consideration in the construction permit action?

Based upon the recommendation in the ATSDR report, the Illinois Department of Public Health conducted a cancer study of the Willowbrook area. The study is separate and distinct from the actions of the Illinois EPA and speaks for itself. This study is not a relevant consideration in the construction permit action, as it does not reflect requirements of the Environmental Protection Act or its implementing regulations.

6. Why isn't the completed or impending ATSDR report a consideration in the construction permit action?

At the request of USEPA, ATSDR performed an assessment of human health risk posed by emissions of the hazardous air pollutant ethylene oxide from Sterigenics' facility in Willowbrook. ATSDR is currently preparing a second report that would be similar in nature but based on additional information gathered after the completion of the first report. The initial report and the impending report are separate and distinct from the actions of the Illinois EPA and are not relevant to the permitting action.

7. What permit now governs Sterigenics' operation?

The current CAAPP permit for Sterigenics' source, which addresses both Willowbrook facilities, generally sets forth the applicable emission standards, testing, record-keeping, reporting and monitoring requirements that govern Sterigenics' operations.

Sterigenics' operation of the control improvements for the Willowbrook I facility will be governed, in the short term, by the issued construction permit. This will assure that, upon a potential future resumption of operations at the Willowbrook I facility, the more stringent control requirements of the construction permit will govern.

8. The application reveals that Sterigenics is asking the Illinois EPA to operate its facility under the issued construction permit until the CAAPP permit can be revised. Can this construction

permit be used by Sterigenics to resume its operations before the proper operating permit can be issued?

The Illinois EPA is including the authorization to operate the control improvements addressed by the comment. *See,* Condition 12. The condition will allow Sterigenics to operate the control improvements until the requisite operating permit is revised to incorporate the terms of the construction permit.[1] The CAAPP's available procedures result in the same effect.[2] As a practical matter, Sterigenics' obligation to comply with the requirements of the construction permit will assure that the substantive emission standards of the new law will apply prospectively.

9. While Sterigenics may not immediately resume operations at the Willowbrook II facility, there is potential for it to reopen in the future. There are serious concerns that the combined emissions impact from both of Willowbrook facilities could generate harmful levels of ethylene oxide to the atmosphere, which Illinois EPA should assess now before the construction permit issues.

Neither the permit or the dispersion modeling addressed in the permit application for the control improvements at Willowbrook I facility account for the resumption in operation of the Willowbrook II facility. Because Willowbrook II is currently idled by the Consent Order, the Illinois EPA will not address the impact of the idled plant's emissions in this permit action. A resumption in operation of the Willowbrook II facility would require Sterigenics to address applicable requirements through an application for construction permit. As the two facilities are viewed as a single CAAPP source, the Illinois EPA would expect the construction permit application for the Willowbrook II facility to include modeling for both facilities.

10. No company should be permitted to operate if that company poses a risk of serious health issues to the public.

Permits for the construction or operation of emissions units or control equipment may be acquired under the Environmental Protection Act upon a showing that there is no violation of the Act or applicable regulations. 415 ILCS 5/39(a). Except for some requirements that are developed on a health-based standard (e.g., National Ambient Air Quality Standards), this legal standard for permit issuance may not appear to directly account for risks posed to human health from a particular activity or exposure to a particular pollutant. This does not mean that the permitting process ignores these risks, only that they are accounted for, indirectly, through an evaluation of the rules and regulations that a stationary source must meet when constructing and operating new emissions units or control devices. The Act

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[1] **Sterigenics submitted an application for CAAPP renewal to the Illinois EPA on September 6, 2019.**

[2] **In the absence of operating authority for terms from a recently-acquired construction permit, a CAAPP source typically seeks a minor modification to incorporate those terms into the CAAPP permit in accordance the 415 ILCS 5/39.5(14)(a). The net result is that upon submission of the application, a source may operate under the terms of the proposed application until the CAAPP permit is revised by the Illinois EPA. 415 ILCS 5/39.5(a)(vi).**

contains several enforcement provisions that are available to restrain violations, such as injunctions that can be sought by prosecutorial authorities under Sections 42(e) and 43, and by any persons adversely affected in fact under Section 45. Other statutory or common law remedies exist that complement the enforcement remedies under the Act.

11. What is the scope of review by both the USEPA and the Illinois EPA in approving a construction permit?

The Illinois EPA is the sole authority for reviewing and acting on an application for a permit for a minor construction project in Illinois, i.e., a proposed project that would not be considered a major project under the USEPA's rules for Prevention of Significant Deterioration (PSD), 40 CFR 52.21. This is the type of project addressed by Sterigenics' application for control improvements. USEPA does not have a formal role in the Illinois EPA's administration of minor source permits.

The scope of the Illinois EPA's review of Sterigenics' application for a construction permit is generally framed by the new emission control requirements under the new law.

12. If data logs or data collection mechanisms at the Sterigenics facility are altered, deleted or proven incorrect, the Illinois EPA should revoke the construction permit.

Permit revocation is governed by the regulations established by the Pollution Control Board. More specifically, revocation of a construction permit on grounds that the permittee violates permit conditions, or fails to comply with any other requirement of the Board's regulations, is only authorized by way of an enforcement action. *See,* 35 IAC 201. In other words, the Illinois EPA cannot unilaterally revoke a construction permit, or impose conditional permit requirements that would effectuate the same, in response to alleged violations of the permit or other substantive requirements. The only recourse available to the Illinois EPA would be to seek enforcement through the Attorney General's Office.

13. What is the Illinois EPA's time-frame for permit decision? Is the permit decision being fast-tracked?

The permit is not being fast-tracked, as the time-frame for permit decision is governed by the Environmental Protection Act. The relevant provisions of Section 39(a) of the Act provide that if there is no action by the Illinois EPA within 90 days of receipt of the permit application, the applicant may deem the permit issued by operation of law. *See,* 415 ILCS 5/39(a). A permit that is issued by operation of law is simply a type of enforcement shield, protecting a permittee from the allegation that the source is constructing or operating without a permit. A permit issued by operation of law does not provide for substantive requirements that would ordinarily appear in a permit, such as the limits on ethylene oxide in Condition 3, the usage limits for ethylene oxide in Condition 5, the operational requirements for the PTE in Condition 6 and the numerous other testing, monitoring, recordkeeping and reporting

requirements detailed in the permit. Consequently, the Illinois EPA strives to avoid permit issuance by default.

14. The preconditioning and aeration rooms are heated. Should the heating for these rooms be included in emissions, given that this is part of their operation? If upgrades or changes are being made to heating systems, do they need to be re-evaluated under the New Source Performance Standards (NSPS), 40 CFR 60 Subpart Dc?

Further evaluation of heating is not necessary. The application did not address and the construction permit (Condition 1(d)) does not provide for changes to process equipment at the facility that would increase sterilization capacity or emissions.

15. Condition 5 limits the usages of ethylene oxide and propylene oxide on a monthly and annual basis. Condition 9(c) requires recordkeeping for the usages of these materials with "supporting data and calculations." However, Condition 9(c) does not detail the specific supporting data that must also be recorded. This condition also does not address reporting of material usages. Annual reports are not frequent enough to track monthly limits, which should be reported promptly and not allowed to continue until an annual check is performed.

The supporting data for which records must be kept is the underlying data from which the monthly and annual usages of materials are calculated. Since the drum for each sterilization chamber sits on a separate weigh scale, it is expected that this support data would consist of data for the beginning and ending weight of each drum of a material as used during each month, which values are combined to calculate the total usage of the material during the month.

It is not necessary for the construction permit to require frequent, routine reporting of the facility's usages of either ethylene oxide or propylene oxide. Compliance with these limits is appropriately addressed as Condition 9(b) of the construction permit generally requires Sterigenics to promptly report deviations from the requirements of the permit. In this regard, as is standard practice for pollution control permits, the construction permit requires Sterigenics to specifically notify the Illinois EPA of any noncompliance. This is appropriate as sources have the legal obligation for compliance.

16. Condition 5 would provide for compliance with annual limits to be determined on a rolling basis from 12 consecutive months of data with the first compliance period beginning in March 2019. Why would the compliance period start at that time? Is this time set so Sterigenics can make up for lost production with increased usage later in the year?

March 2019 was selected as the start of the first compliance period for the <u>annual</u> limit for emissions of ethylene oxide simply because it would provide for a compliance determination to be made for this limit, if and whenever the operation of the facility might resume. It was not selected to let Sterigenics "make up" for lost production. In this regard, Condition 5 also

limits the facility's emissions of ethylene oxide to 8.5 pounds per month. By way of further explanation, the compliance period for the annual emission limit should not start with the month in which operation would resume. In that case, compliance with the annual limit would not be able to be determined for the first eleven months after resuming operation of the facility. On the other hand, a compliance period that would begin before March 2019 could address months before the improvements to the emission controls addressed by the permit would have occurred.

Permit Conditions

17. The construction permit must prevent the facility from operating when the pollution control equipment is not operating. The draft permit does not include such a condition.

The permit mandates that the control system must be utilized during sterilization operations. More specifically, the permit requires: all components of a control system (i.e., Deoxx™ scrubber, AAT scrubber, initial DBA device and final DBA device) must be operating whenever any sterilizing chamber is being evacuated (Condition 3(c)(i)(A)); the segment of a control system for the backvents (i.e., AAT scrubber, initial DBA device and the final DBA device) shall be operated whenever any sterilizing chamber is being ventilated (Condition 3(c)(i)(B)); and the DBA device shall be operated whenever sterilized material is being moved from a sterilizing chamber to an aeration room or stored at the facility (Condition 3(c)(i)(C)). These requirements assure that the proper control systems (or system components) are operating any time the various emissions units are capable of emitting ethylene oxide or propylene oxide through normal uses.

18. Why does draft Condition 2.3(a) refer to the seal order, knowing that the seal order is not going to remain effective? It is a misrepresentation for the draft permit to address the seal order.

The draft construction permit referred to the seal order because it was in effect when the draft construction permit was distributed to the public. The Illinois EPA referenced the seal order in the draft construction permit to emphasize that the permit did not authorize Sterigenics to operate its facility in violation of the requirements of the seal order. Because the seal order operated independently of the Illinois EPA's permitting of the facility, the draft construction permit simply observed that it did not affect the operation of the seal order, which, at the time, compelled the source to remain closed. Because the seal order was removed following the recent entry of the Consent Order, Condition 2.3(a) now refers to the Consent Order rather than the seal order.

Matt Haller Act

19. What does the Act require, and will it be applied?

The Matt Haller Act (also referred to as the "new law"), codified at 415 ILCS 5/9.16 of the Environmental Protection Act, was enacted by the 101st General Assembly in the most recent legislative session and became effective upon Governor JB Pritzker's signature on June 21, 2019. The new law provides some incomparable provisions for the protection of public health from the emissions of ethylene oxide caused by sterilization operations in Illinois. Notable among these requirements are 100% capture of ethylene oxide emissions from these operations and a reduction in ethylene oxide emissions to the atmosphere from each exhaust point at the ethylene oxide sterilization source of at least 99.9% or to 0.2 parts per million. [415 ILCS 5/9.16(b)].

The new law requires affected sources to conduct initial emission testing to confirm compliance, accompanied by test protocol submissions by the source, and review and approvals by the Illinois EPA. [415 ILCS 5/9.16(b)]. Significantly, the law requires an immediate shut-down of operations at an ethylene oxide sterilization source upon the source becoming aware of a failed emissions test, followed by additional analyses, reporting and emission testing prior to a resumption in operations. [415 ILCS 5/9.16(c)]. Additional requirements include: the development and implementation of a an ambient air monitoring plan for collecting and evaluating air samples of ethylene oxide offsite during a multi-day sampling period every calendar quarter, [415 ILCS 5/9.16(e)]; dispersion modeling conducted using, among other things, the initial stack testing data and accepted United States Environmental Protection Agency methodologies [415 ILCS 5/9.16(e)]; certifications from Sterigenics' suppliers attesting that the sterilization or fumigation of their product(s) (including packaged products) is the only method to completely sterilize or fumigate the product(s) [415 ILCS 5/9.16(g)(i]); and a certification from the Illinois EPA that Sterigenics' control system makes use of technology that achieves the "greatest reduction in ethylene oxide emissions that are currently available [415 ILCS 5/9.16(g)(ii)].

As it relates to this permitting action, the Matt Haller Act requires an ethylene oxide sterilization source to obtain a construction permit for modifications made to the source to comply with the law's requirements. *See,* 415 ILCS 5/9.16(j). Sterigenics submitted its construction permit application to the Illinois EPA on June 24, 2019. The submission prompted a permit review that must be completed in 90 days, which ends on September 22, 2019. The construction permit only concerns itself with provisions of the new law that directly relate to the control improvements addressed by the permit application. This explains why the construction permit incorporates the law's requirements for Sterigenics to comply with the substantive capture and control standards (Condition 2-1(a)); the mandate for shutdown of facility operations upon an emission testing failure (Condition 2-1(b)) and testing (Condition 8-1 for permanent total enclosure; Condition 8-2 for initial and annual emission testing requirements).

Those provisions of the new law that are not addressed in the construction permit still apply to Sterigenics' operations, as they derive their origin of authority independently of the Illinois EPA's authority used in issuing construction permits under the Environmental Protection Act. Sterigenics is thus expected to meet those remaining obligations, including its various submissions of plans to the Illinois EPA, in the future.

20. The new law states that the company operating with ethylene oxide must capture 100% of its emissions.

This statement is true. Specifically, the new law provides that an ethylene oxide sterilization source must demonstrate that it captures 100% of all its emissions. 415 ILCS 5/9.16(b)(1). This capture efficiency is to be achieved by Sterigenics through use of a permanent total enclosure (PTE) system that is addressed by the construction permit. In addition, the new law provides that once the source captures its ethylene oxide emissions, it must achieve a reduction in emissions from each emission point at the source by at least 99.9% or to 0.2 parts per million. 415 ILCS 5/9.16(b)(1). This control efficiency is to be achieved by the sterilizers, backvents, aeration room and the finished products room, and demonstrated by Sterigenics through emission testing addressed in Condition 8-2. The PTE and control improvements will drastically reduce emissions of ethylene oxide from the source.

Permanent Total Enclosure

21. The stated goal of this construction permit in Condition 1 is to address improvements to the emission control measures for ethylene oxide sterilization operations and propylene oxide emissions for treatment of foods. It is unclear what the changes made to the facility to achieve permanent total enclosure will involve.

The new requirements for control of the emissions of ethylene oxide from the facility, as per Section 9.16(b) of the new law, are stated in Condition 2(a). The further description or specificity sought by this comment as to certain improvements that will be made to achieve permanent total enclosure does not need to be included in the construction permit. In this regard, this air pollution control construction permit allows Sterigenics to make changes at the facility as are needed to achieve permanent total enclosure. The ultimate requirement for these changes, i.e., achievement of permanent total enclosure, is clearly stated.

22. As related to permanent total enclosure, it is not clear from the permit how the construction of the new partition and the transition room will be done or exactly where those will be located.

As explained above, the new requirements for control of emissions of ethylene oxide by Sterigenics, as per Section 9.16(b) of the new law, are stated in Condition 2(a). The further information sought by this comment as to certain improvements that will be made to achieve permanent total enclosure is not required to be provided in the permit nor is it the practice of the Illinois EPA.

23. Are the sterilization chambers in an enclosed room or open to the hallway? Are the aeration rooms fully enclosed? How are the hallways near those locations monitored for ethylene oxide and for ventilation?

The sterilization chambers and aeration rooms are not in their own separate rooms. The sterilization chambers are accessible from the "work aisle." This is a broad interior "hallway" running through the center of the facility in which pallets of unsterilized material are loaded by forklift into the sterilization chambers and the sterilized material is unloaded by forklift. The sterilized material is then transported through interior passage ways at the facility to the aeration rooms.

The permit would not require monitoring of the work aisle or other passages inside the facility for ethylene oxide itself. This is because the ethylene oxide released in these areas is required to be captured and controlled. These releases will be an inherent aspect of the sterilization process as pallets of sterilized material are being transported inside the facility, particularly pallets of newly sterilized material from the sterilization chambers.

The "ventilation" for the work aisle and other internal passages at the facility will be addressed through the operational monitoring that must be conducted at the facility relative

to achievement of permanent total enclosure. The issued permit specifies that there must be at least two devices for monitoring pressure differential in the work aisle so that the capture of the ethylene oxide released in this area is confirmed. Another monitoring device is required in the storage area for sterilized product, which is adjacent to the entrances to the two of the three aeration rooms at the facility.

24. Condition 3(b) would require permanent total enclosure (PTE) for all areas of the facility where ethylene oxide may be used or released. This includes the sterilization chambers, work aisles, aeration rooms, and storage areas for fully processed materials. However, it would not include an area where full or empty drums or containers of ethylene oxide would be stored. This would not comply with 100 percent capture as any leaks from the drums in this area would vent directly to the atmosphere. The drum storage area needs to be enclosed in the permanent total enclosure to comply with 100 percent capture.

The drum storage does not need to be within the permanent total enclosure because this area is not an exhaust point for ethylene oxide. Both new drums and "empty" drums of ethylene oxide that are held in this area must be sealed. In this regard, ethylene oxide is transported in specially designed, stainless steel, pressurized, double-wall containers, which are commonly referred to as drums. Each drum has a fitting at the top through which ethylene oxide may be removed. At the facility, these fittings are only opened after the drum has been moved inside the facility and is being connected to the feed system for one of the sterilization chambers. When the contents of a drum are used up, the drum is again closed before being returned to the storage area preventing the loss of the residual ethylene oxide still contained in the empty drum.

To confirm that drums for ethylene oxide are properly sealed when they are held in the drum storage area, the issued construction permit requires recordkeeping related to these drums. It provides that the paperwork that Sterigenics maintains for these drums, including the verification of drum integrity, shall also be required records pursuant to the permit.

25. The proposed single stack location is furthest from the product loading doors. Maintaining adequate negative pressure in a distant corridor requires further attention and validation.

The location of the stack is not a critical factor for capture of emissions. The achievement of permanent total enclosure, including capture of emissions at the loadout doors, will not rely on the natural draft from a new or modified stack. Achievement of permanent total enclosure for the facility will entail changes to the existing mechanical ventilation system. These changes will include changes to the fans associated with the control devices, as well as installation of an appropriately sized fan at the new or modified stack itself.

26. If doors or windows closer to the stack than the product loading doors are allowed to be open, doing so would create air flow that would take away from the negative pressure for the product shipping area and loading doors. The building has several doors between the proposed stack location and the loadout bays. A few are declared natural draft openings.

Additionally, many undeclared doors and several undeclared windows line the exterior walls and may be opened unless either permanently sealed or connected to remote alarms, such as at the fire department. Additional safeguards are needed to ensure compliance with 100 percent capture.

As discussed, the mechanical ventilation system for the facility must be designed and operated to maintain permanent total enclosure. There are only a few doors and windows along the exterior walls of the facility. The windows are sealed. For this permit, it would be unreasonable to presume that the doors would now begin to be kept open. Moreover, because doors may be necessary for emergency exit or entry to the facility, it would not be appropriate to require that they be sealed. The opening of these doors and windows, if they were ever unsealed, would be addressed on an ongoing basis, by the continuous operational monitoring required under the permit. If a door or window that is normally kept closed is opened, it will reduce the pressure differential between the inside of the facility and the outside. This would be measured and recorded by the monitoring system. Appropriate action could be instituted if sufficient pressure differential is not maintained. Additional monitoring for the status of individual doors and windows that are capable of being opened, as requested by this comment, need not be required by the permit.

27. In the application, page 13, Sterigenics states that Criterion 4 of Method 204 will be met as follows, "Sterigenics will maintain all doors and windows not covered in Criterion No. 3 closed during normal operations and therefore Criterion 4 is satisfied." This is not an enforceable statement. A tamper proof indicator of door status linked to an external entity, such as the fire department, would ensure accountability and would create records for enforcement. Such a provision should be included in the permit.

The statement in the application addressed by this comment would not serve to ensure that doors and windows that are normally kept closed would never be opened. However, the status of doors and windows at the facility will be addressed by the permit by the operational monitoring that is required for the permanent total enclosure.

28. Ethylene oxide may be pulled outside by the trucks leaving the loading dock as they pull air behind them. This situation would be a violation of the 100 percent capture provision and should be tested.

This phenomenon posed in this comment is not a concern for the facility. Sterigenics has explained that its practice for load out of material is to only open a loadout door at the facility once the truck is in place and to close the loadout door once the truck is loaded. This practice is followed because of the danger to the operator of the fork lift truck from potentially driving off the loadout dock if a door is open and a truck is not in place.

29. The area outside the loading dock should have sensitive ethylene oxide monitors in the parts per billion to parts per trillion range located near the ground. These monitors would

help verify the proper functioning of the capture system. They would also act as an alarm in the event of failure.

Ambient air monitoring, as essentially suggested by this comment, would not be a useful method to verify effective capture. For example, it would not be able to distinguish between loss of ethylene oxide from the loading dock and background concentrations of ethylene oxide in the ambient air. Moreover, the approach to ongoing compliance inherent in Method 204 is assuring that once a capture system has been demonstrated to provide permanent total enclosure, the capture system is operated and maintained in the manner and condition for which compliance has been demonstrated.

30. For initial development and periodic checks of the permanent total enclosure, a smoke test might prove useful.

Use of smoke tubes is one of the techniques that is identified in Section 8.4 of Method 204 for verification of the direction of air flow through natural draft openings.

31. Condition 1(b)(i) describes the construction of a transition room to bring material to be sterilized into the permanent total enclosure. There is no further description of the details of this room including such basics as its location, the size of doors on each side of this room, or the mechanism by which the "transition" feature would work such as airlock style doors and emergency-only overrides. Will there be an engineered control to ensure only one door is open at a time? It seems that if there was an emergency where both doors are opened (override of control), there should be a direct alarm to fire department like a fire alarm. Architectural plans should also be submitted.

The transition room at the facility would be constructed between the west end of the work aisle and the area where pallets of unsterilized material are kept. It was neither necessary nor appropriate for the application to include detailed construction drawings for this room. This room must be designed and operated, with other changes that are being made to the facility for permanent total enclosure, to maintain total enclosure. Sterigenics has explained that the room will be designed so that only one set of doors will normally ever be open. However, it is not appropriate for the permit to dictate actions that must occur in the event of emergencies that affect the operation of the transition room or to presume that a separate alarm to the local fire department is necessary.

32. Would the construction of the transition room for material entering the permanent total enclosure create another natural draft opening? In the application, the transition room door is not identified as a natural draft opening.

The construction of the transition room will eliminate a natural draft opening that would otherwise be present at the facility. This room will be designed and constructed so that only one set of doors, either the doors next to the unsterilized material storage area or the doors going into the work aisle, can be open at any given time.

33. A transition room should also be required for sterilized product leaving the permanent total enclosure.

A transition room for load out would not avoid the need to address the loadout doors for compliance with the relevant criteria for permanent total enclosure. This is because load out of material from the facility involves sterilized material. This is different than the situation for the planned transition room through which unsterilized material will pass. For this material entering the permanent total enclosure, the transition room will serve to eliminate a natural draft opening that is currently present at the facility.

34. The exemption in Condition 3(b)(ii) from the first criterion for a permanent total enclosure is very concerning (Criterion 5-1 in USEPA's Method 204, "Criteria for And Verification of a Permanent or Temporary Total Enclosure," which is codified at 40 CFR Part 51 Appendix M.) This criterion is that any VOC emitting point should be four equivalent diameters away from any natural draft opening in the enclosure. It seems from the statements in the application and in the draft permit that the exception from Criterion 5-1 would be provided because it would not be appropriate to apply this requirement if product is considered a VOC emitting point while being loaded onto a truck for shipping. Since the product is considered a VOC emitting point, this necessitates the exception provided for by Method 204.

This is correct, it would not be appropriate to apply this requirement if product is considered a VOC emitting point while being loaded onto a truck for shipping. This necessitates the exception provided for by Method 204.

35. If one criterion for permanent total enclosure is modified, other criteria may need to be modified, such as the facial velocity criterion, in order to adequately maintain the permanent total enclosure.

The circumstances of the loading dock are such that an increase in the required facial velocity of air flow for the doors at the loading dock is not warranted. The loading dock is not on the exterior of the building. Access to the loading dock is through two doors on the west side of the building through which trucks are backed up to the actual loading dock. Only the front portions of the trucks extend outside of the building and are in the open during loading. The loading doors themselves will be equipped with sealing systems that reduce the amount of open area that is present between the wall of the loading dock and a truck during loading.

36. It appears that the exemption from the first criterion for total enclosure would be provided to Sterigenics for its convenience rather than for physical merit.

This exception is warranted on a technical basis, not simply for convenience. This exception enables Sterigenics to ship its sterilized product from the facility. If this exception, which is allowed for by Method 204, were not provided, sterilized product could not be shipped from the facility. This is because a material that is considered to be emitting organic material

would be passing through a natural draft opening and, as such, could never be at least the specified distance from any natural draft opening. In such circumstances, compliance with the other criteria in Method 204 is considered sufficient to show the achievement of permanent total enclosure.

37. By way of comparison, the Illinois EPA granted a construction permit for a printing plant in October 2018 (ID No. 179473AAI). Presumably, this plant has product that is printed inside the permanent total enclosure that must be removed from the enclosure to ship to customers. That construction permit also referred to Method 204 but the plant was not granted an exception to Criterion 5-1 that would accommodate product being removed from the permanent total enclosure though a natural draft opening.

The circumstances of the printing plant that is addressed by this comment are different than those would be present at Sterigenics. At this printing plant, packaging material is printed using solvent-based inks. The printed packaging material is dried in a natural gas-fired oven that is part of the printing press, evaporating the organic solvent before the printed material leaves the enclosure. As such, it was not appropriate for that plant to consider the printed material from the press to be a source of emissions. In contrast, the construction permit for this facility is premised on the sterilized product still continuing to contribute to the emissions of the facility even after it has undergone aeration.

38. The justifications for the exception for Sterigenics require further explanation to provide confidence that 100 percent capture would be reliably maintained in the loadout area.

The exception to Criterion 5-1 allowed by Method 204 is being provided because, as addressed in statements in the application and in the draft permit, it would not be appropriate to keep this requirement since sterilized product is considered a VOC emitting point while being loaded onto trucks for shipping. If the exception were not provided, sterilized product would never be able to be shipped out from the facility.

39. The third criterion for a permanent total enclosure (Criterion 5-4 of Method 204), as addressed in Condition 6-1(a)(ii)), requires that the direction of air flow through all openings to be into the enclosure at all times. There is no stated mechanism by which compliance with this requirement can be demonstrated.

The direction of air flow through openings is addressed in Method 204 as it also provides the procedure for testing to confirm permanent total enclosure. With respect to the direction of air flow through individual natural draft openings during testing for permanent total enclosure, Section 8.4 of Method 204 provides as follows:

Verify that the direction of air flow through all NDO's is inward. If FV [face velocity] is less than 9,000 m/hr (500 fpm), the continuous inward flow of air shall be verified using streamers, smoke tubes, or tracer gases. Monitor the direction of air flow for at least 1 hour, with checks made no more than 10 minutes apart. If FV is greater than 9,000 m/hr (500 fpm),

the direction of air flow through the NDOs shall be presumed to be inward at all times without verification.

40. For the permanent total enclosure, operational monitoring for pressure differential would be used to show compliance. However, there are concerns with such monitoring. In Condition 7-2, which describes operational monitoring for the permanent total enclosure by means of pressure differential, Condition 7-2(a)(i)(A) would provide that a pressure monitor along the east side of the building does not need to be operational if no sterilizers on that side of the building are operating. This provision appears to be based on the mistaken assumption that use of ethylene oxide in this area is linked to use of ethylene oxide in this area. This is irrelevant to the determination of permanent total enclosure. This monitor should always be used to address compliance. The monitoring along the east side of the building is very relevant for this requirement. An open door on this wall could compromise the total enclosure. This monitor needs to be required all the time.

The issued permit does not include the provision from the draft permit addressed by this comment. Monitoring of pressure differential at the east side of the facility is required for this area even if the sterilization chambers in this area are not being used. Incidentally, it should be understood that the enhanced capture system for the facility will pull air from a number of points in the facility. This system must be designed to appropriately maintain negative air pressure throughout the facility.

41. The draft permit should require a pressure differential monitor in the area of the loading docks.

The issued construction permit requires that one of the monitors for pressure differential now be located in the area of the loading dock. Upon consideration, a monitor in this location is appropriate. On the other hand, a monitor is not needed in the center of the work aisle, as monitoring is now always required for the east section of the work aisle.

42. Another concern with using pressure difference monitoring for permanent total enclosure is it is unclear whether the facial velocity of 200 fpm (which can alternatively be measured by the difference in pressure between the interior and exterior of the permanent total enclosure) is sufficient to maintain an inward flow of air at all times. Method 204 specifies that these are separate concepts. The minimum average facial velocity shall be 3600 meter/hour (200 feet per minute (fpm)). Separately, flow of air must be inward. These concepts must therefore be separately verified, and both are required. For comparison, 200 fpm translates to 2.3 mph, which is slower than the typical adult walking pace, about 3 mph. So, what happens then, when a person walks out the door and takes a trail of swirling air behind them or a truck leaves the loading dock and swirling air follows the truck as it pulls out of the bay? Method 204 calls for a facial velocity of at least 200 fpm. A study needs to be done at this facility to determine if that facial velocity is sufficient or if it should be increased and if increased, what facial velocity would be required to maintain 100 percent capture, particularly in areas like the loading dock?

Additional study is not needed for the doors at the loading dock. As already discussed, Sterigenics has explained that its practice for loadout is to only open a loadout door once a truck is in place and to close the loadout door once the truck is loaded. In addition, loadout does not take place at the exterior of the building. Trailer trucks back into the loading dock so that only the front end of the truck extends out into the driveway. Wind currents do not directly impinge on the back end of the trucks during loading. Seal systems will also be in place surrounding the loadout doors. The area through which air is drawn into the facility during loadout will be a fraction of the area of the door that is open during loadout. The facial velocity at the loading dock will typically be substantially greater than shown in the conservative calculations provided in the application.

43. On the point of showing inward air flow, one suggestion would be requiring a ribbon at each natural draft opening for easy verification. Video cameras showing ribbon position would allow a third-party audit and provide confidence that this provision is being met at all times.

The approach suggested by this comment is not technically sound. In particular, it would rely on video cameras and review of the images collected by the cameras by individuals for evidence of compliance or noncompliance. Issues that are posed would include positioning of the cameras, lighting, focus, contrast and image quality, as well as the subjective nature of the review of the images. This approach would not provide immediate feedback to the source on the operation of the permanent total enclosure. Monitoring of pressure differential will directly provide immediate, objective information for the permanent total enclosure.

44. The specific monitor model(s), parameters, specifications and maintenance schedule for proper upkeep of pressure difference monitors to address permanent total enclosure needs to be specified here for practical enforceability.

Practical enforceability in permits involves the clarity in applicable limits and the method(s) by which compliance with those limits is to be determined. The use of particular monitoring instruments does not need to be specified. Sources are responsible for selecting monitoring instruments that can make the necessary measurements and then properly installing, operating and maintaining those instruments.

45. Sensitivity limits should be listed for the monitoring systems for pressure differential so that it is clear what is required from the devices.

In the issued construction permit, the sensitivity of the monitoring devices for pressure differential is addressed. Condition 7-2(a)(ii) provides that these devices must be designed so as to be able to measure pressure differential to the nearest 0.001 inches of water. This is about 15 percent of the minimum pressure differential that is required, 0.007 inches of water.

46. Where is (are) the comparison probe(s) located for measuring difference in pressure? With such small differences in pressure, the comparison probe is important to consider. If the comparison probe is located indoors, there could be seasonal differences in relative pressure due to heating and cooling? If the probe is outdoors, how does that work given normal wind patterns and constantly shifting pressures, often much higher than the target difference in pressure required for the permanent total enclosure?

It is expected that the probes for pressure outside the permanent total enclosure will be located on the roof of the facility. This will reduce the impact of building downwash and localized air turbulence due to the building and other nearby structures on these measurements.

47. Condition 7-2(d) provides for extended time to work out problems in establishing the monitoring system for the permanent total enclosure and its associated logs. Condition 7-2(d) appears to allow extra time for difficulties in implementing the pressure difference monitors. These difficulties need to be resolved before operations with ethylene oxide can resume. Resolution of these difficulties requires air handling and building specifications. Resolution does not require the use of ethylene oxide. All difficulties must be resolved before ethylene oxide use can be resumed.

The permit requires verification of the permanent total enclosure before the facility may resume operation using ethylene oxide. It is expected that any difficulties with the monitoring for pressure differential will generally be resolved before such operation would occur. However, there still may be difficulties that only arise or become apparent during the course of operation.

48. An additional mechanism by which permanent total enclosure could be demonstrated might be to include ethylene oxide monitors of sufficient sensitivity in suspected problem areas such as just outside of the natural draft openings. Sterigenics maintains that it monitors ethylene oxide concentrations throughout the building. Are monitors located in the loading dock area and in the hallway outside the aeration rooms? What is the sensitivity level of these monitors?

Additional monitoring, as suggested by this comment, would not be a practical means to assure that total enclosure is maintained for the facility. The operational monitoring systems that Sterigenics has inside the facility are not suitable for such monitoring as they are designed to address matters such as worker safety and prevention of an explosion. The monitoring that is suggested by this comment would necessarily involve ambient monitoring. It would not provide real-time information about the permanent total enclosure at the facility. It would also not serve to directly address the presence of total enclosure at the facility. As recognized by Method 204, pressure differential is an appropriate and effective way to monitor for total enclosure.

49. Are all the scrubbers located together? It is unclear whether there is a pressure monitor in every area containing a control device.

Pressure monitoring is not required in area in which the initial scrubber for the sterilization chambers is located. This area is on the interior of the facility. Pressure monitoring is required for the room where the other control devices are located, which is next to an exterior wall.

50. The wording in Condition 7-2(a)(ii) should be changed to "independent" measurements for statistical purposes.

It is appropriate that this condition require separate measurements as a common meaning of the term "separate" is intended, e.g., individual or distinct. Any benefit from changing the wording of this condition as suggested by this comment would be outweighed by the fact that it would use a term that is not typically used when addressing monitoring systems.

51. Condition 7-2(a)(ii) addresses recordkeeping in the event of failure of the continuous monitoring equipment for permanent total enclosure. There should be a requirement that the auto-recorder must be repaired promptly. The process by which will be enforced needs to be spelled out.

The requirement for prompt repair of monitoring equipment is embodied in the general requirement that the facility be operated and maintained in accordance with good air pollution control practice. It is unnecessary and impractical to specify the actions that must be taken to repair monitoring equipment. This would appropriately be addressed on a "case-by-case" basis, considering factors such as the nature of the needed repair, whether the repair is made as a preventative measure or a response to failure of equipment, and the effort expended in reducing the time that the monitoring equipment was not in service. In this regard, Sterigenics will need to timely undertake measures necessary to satisfy its obligation to have an operational continuous emissions monitoring system.

52. Condition 7-2(a)(ii) requires that pressure difference recordings are to be made every 5 minutes. In the construction permit issued by the Illinois EPA in 2018 for permanent total enclosure at a printing plant (ID No. 179473AAI), the requirement was to record pressure differences at least every minute. Why would this condition be less stringent?

In the issued construction permit, Condition 7-2 (a) (ii) requires measurements for pressure differential at least every minute, rather than at least every five minutes. Accordingly, the required frequency for these measurements will be the same as that for the plant cited in this comment.

53. Why would recording for pressure difference only be required on a rolling 3-hour average? This could mask large spikes and troughs. It would be very informative to have the maximum and minimum for these time periods as well as the standard deviation. The

additional data would help demonstrate that the correct pressure is being consistently maintained.

A three-hour average, rolled hourly, is appropriate for this operational monitoring. It would provide data that is representative of the actual operation of the permanent total enclosure and would not be distorted by short-term fluctuations in pressure differential. In this regard, data from continuous operational monitoring of control devices is routinely applied on a three-hour average. As this monitoring for the facility will involve monitoring of pressure differential, with probes both inside and outside the enclosure, the averaging time needs to be long enough that routine fluctuations in measurements by the monitoring devices do not bias the compliance determination. Three-hour averages will provide definitive data for the permanent total enclosure. In this regard, the statistical information for the data for pressure differential that this comment suggests be required would not be relevant to determining whether the required level of pressure differential has been maintained at the facility for total enclosure.

54. In its application, page 12, Sterigenics states the following, "Loading Through Two Dock Doors 8'x10' with 50% effective seals (Normal practice is to only load one truck at a time through one door)." Members of the public have seen multiple dock doors/loading bays in use at the same time. There are three dock doors. Two of those are claimed as natural draft openings, only one is assumed to be used at a time. How will the permit address the assumption that only one will be in use at a time?

In its application, Sterigenics did not assume that only one door would be open at a time, although loading of one truck at a time with only one open loading door has been its normal practice. Rather, notwithstanding its normal practice for loadout, Sterigenics conservatively assumed in the application that two trucks would be loaded at a time, with two loading doors open. (Two doors @ 80 square feet each, with 50 percent seal with the truck being loaded, times two equals a total area of 80 square feet.)

55. What would be done with the third loadout door? It is not claimed as a natural draft opening. It would most appropriately be permanently sealed under the provisions of Method 204, as would other doors not clamed as natural draft openings. Otherwise, there should be alarms that connect outside the building for the third loadout door being opened.

Method 204 does not require that doors into an enclosure that are closed during the operation of a source, and thus are not addressed as natural draft openings, be physically sealed. As specifically related to the "third loadout door" at this facility, Sterigenics plans to develop the permanent total enclosure to be able to have two open loadout doors at a time. As this is the case, any two out of the three doors may be open at a time. It is not necessary to specifically identify a particular loadout door that must be kept closed and no longer used. It is also not appropriate to require an alarm to address the possibility that three loadout doors would be open at once. The normal practice for the facility, as stated by Sterigenics, would be to have only one loadout door open at a time. In addition, whether the three

loadout doors at the facility, which are all at the front of the building toward the south, are open at the same time would be clearly visible.

56. The idea that there can be 50 percent effective seals is very misleading. The seal either seals with calculable minor gaps or it does not seal according to how accurately the driver matches his trailer to the seal. There are more effective systems in use elsewhere.

As implied by this comment, Sterigenics has been very conservative in only assuming that the dock seals installed on the loadout doors at the facility would provide only a 50 percent seal. In actual practice, the dock seals would be more effective.

57. Section 9.16(b) of the new law requires 100 percent capture. A "50 percent efficiency seal" does not comply with this requirement, particularly since no assurances are in place to demonstrate that a successful enclosure has been created and that these follow the criteria in Method 204.

This comment confuses the statutory requirement for capture of emissions with the measures that would be taken to comply with this statutory requirement. In particular, the calculations included in the application by Sterigenics to show that a face velocity of at least 200 feet per minute would be achieved through the loadout doors are based on the door seals reducing the area of the actual natural draft opening by at least 50 percent. This is a conservative assumption for the actual open area between the wall of the loading dock and a truck during loadout.

58. Testing for the permanent total enclosure in Condition 8-1 (a) indicates the tester must be independent and qualified. What are these qualifications? Is there an approved vendor list? If not, why not?

The terms "independent" and "qualified" do not need to be defined in the permit because these terms are used with their standard, dictionary meanings. The requirement that the testing firm be "independent" means that it must be a separate entity from Sterigenics, be objective and be free from influence. The requirement that the testing firm be "qualified" means that it has the necessary qualities and is fit and competent to perform the testing that is to be conducted.

The Illinois EPA does not maintain a list of "approved testing" firms. Among other things, this is because it is more effective to address testing firms on a case-by-case basis as part of the review of the protocol submitted for a particular planned test.

59. Are there established methods for testing a permanent total enclosure? They should be listed in the permit as the required method?

The methods for testing for permanent total enclosures are part of Method 204. The issued permit specifies that the testing for Permanent Total Enclosure must be in accordance with the procedures set forth in Method 204.

60. Condition 8-1(c)(iii) provides that the conditions under which testing is conducted must be representative. This is not practically enforceable. A minimum list of what constitutes "normal conditions" needs to be known, such as ventilation systems need to be up and running as if the sterilization facility were operating and need to include a list of specifications such as temperature and humidity ranges that can be easily verified by an inspector.

As a general matter, the operating conditions under which testing will be performed are appropriately addressed as part of the review of the protocol submitted for the required test. More significantly, if after a test is performed, it is subsequently determined that testing was conducted under operating conditions that are not representative, the Illinois EPA may require testing to be repeated. This would be the case if testing was conducted under operating conditions that would potentially overstate the effectiveness of capture of the emission at the facility compared to how the facility is typically operated. This repeat testing would be required to be conducted under operating conditions that are representative of how the facility has actually been operated.

61. In Condition 8-1(c)(iv), the minimum measurement locations for testing need to be specified, with a provision for additional measurement locations. The minimum number of independent test runs and analysis guidelines should also be specified, either by listing them or referencing an established method.

In the issued construction permit, Condition 8-1(a) specifies that the testing for permanent total enclosure shall be conducted in accordance with the applicable procedures contained in Method 204. Other changes to this condition requested by this comment are not appropriate. As a general matter, they address matters that are relevant for emissions testing but not for testing of permanent total enclosure. Testing or verification of permanent total enclosure is far simpler. Measurements of the gas flow are only required for gas flow out of the enclosure through ducts and hoods. The velocity of air flow into the enclosure through the natural draft openings is calculated by dividing the measured air flow out of the enclosure by the total area of the natural draft openings. The direction of air flow through each natural draft opening must be verified if the calculated velocity is less than 9,000 meters/hour (500 feet/ minute).

62. Condition 8-1(b) provides for initial testing of the permanent total enclosure but not regular follow up testing to ensure it is still working properly. This regular checkup testing needs to be included.

Periodic follow-up testing of the permanent total enclosure is not needed. Once the initial testing has been completed demonstrating that the criteria for permanent total enclosure have been met, the operational monitoring for pressure differential will directly address

ongoing compliance. However, the permit does provide for further testing for total enclosure upon specific request by the Illinois EPA.

63. Rather than requiring permanent total enclosure, a better solution would be to identify the leaky processes first and then correct the leaks or utilize a leak detection and repair program. It should not be presumed that permanent total enclosure will capture the emissions.

Permanent total enclosure is a sound approach to capture the emissions of ethylene oxide of the facility, including the "other releases." Further, it is mandated by the new law. The incidental releases are not the result of leaks from specific pieces of equipment. Rather they are the result of activities at the facility that are inherent in sterilization of material with ethylene oxide, notably the transfer of pallets of sterilized material through the work aisle and interior passage ways at the facility. Thus, there are no leaks to be fixed, identified or measured.

64. The permit should require Sterigenics to implement a leak detection and repair program to promptly identify and fix any unintended release of ethylene oxide. A leak detection and repair program would not facilitate provide 100 percent capture.

Sterigenics will implement a leak detection and repair program for valves and piping components at the facility for purposes of reducing risks to staff and equipment at the facility. This program uses monitoring devices that are located inside the facility to detect leaks. However, as this is the case and any leaks would occur within the enclosure, the permit does not need to address this program.

65. The permit would not require a minimum off-gassing time, which could result in sterilized equipment being removed from the permanent total enclosure while still capable of emitting ethylene oxide.

The required duration of aeration of pallets of different sterilized material is a matter that is addressed as a part of the protocols for processing different materials. This time varies from product to product because the protocols for sterilization are product-specific. As such, it is not appropriate for the permit to simply set a minimum duration for aeration. Moreover, as the required duration of aeration of different products is addressed in the sterilization protocols, this subject need not be addressed by the permit.

66. Condition 6-1(a)(i) requires that the permanent total enclosure be maintained when the "affected facility" is in "operation" but in this context "operation" is not adequately defined. Condition 3(b)(i) specifies where the permanent total enclosure must be maintained but it does not specify when it must be maintained. For example, may Sterigenics cease to maintain the permanent total enclosure if there are sterilized materials in the aeration rooms and it asserts that all ethylene oxide has been evaporated from them?

In fact, Condition 3(b)(i) addresses when total enclosure must be maintained. It requires operation of the facility with permanent total enclosure for all areas of the facility in which ethylene oxide is used or may be released, including the storage and handling of sterilized material prior to load out.

67. Are there any Illinois rules regarding the installation and operation of Permanent Total Enclosure system?

Illinois has certain rules that address permanent total enclosure by reference to USEPA Method 204. These rules are applicable to processes such as printing presses and coating lines. As the rules applicable to ethylene oxide sterilization sources are federal, these are not Illinois rules wherein Method 204 is applied to commercial sterilization sources.

68. The opening of a window or a door at the facility that is supposed to be kept closed might be sufficient to defeat permanent total enclosure.

It is uncertain that the opening of one door that is supposed to be kept closed would be sufficient to defeat the permanent total enclosure. However, this possibility is addressed by the ongoing monitoring for pressure differential between the inside and the outside of the enclosure. A drop in the monitored pressure differential from the normal range would be an indication that something may have occurred that is worthy of investigation by facility personnel. A drop in pressure differential below the required level would indicate a lapse in total enclosure, necessitating corrective action and triggering a requirement for reporting of a deviation to the Illinois EPA, which would be reviewed.

69. The new law specifically requires a subject source to "immediately cease ethylene oxide sterilization and notify the Agency within 24 hours of becoming aware of the failed emissions test." However, the permit does not provide for cessation of operations in the event of a breach of permanent total enclosure during normal operations.

The differences in the contexts in which required emission testing would conducted at the facility and permanent total enclosure must be maintained are such that an interruption in total enclosure does not warrant a cessation of operation. Emission testing is only expected to be conducted on an initial and thereafter periodic, annual basis for the specific purpose of demonstrating compliance with the emission standards in Section 9.16(b) of the new law. Failure of an emission test will have implications for compliance until a new test is conducted. Moreover, before such further testing is conducted, Section 9.16(c) of the new law provides that the reasons or causes for the failed test are to be investigated, identified and remedied. In contrast, the presence of permanent total enclosure will be addressed on an ongoing basis by continuous monitoring for pressure differential. A lapse in permanent total enclosure may have no implications for subsequent operation. The cause of the lapse may be able to be readily remedied. Whether the situation has been corrected and total enclosure has been restored will be demonstrated by monitoring data.

70. Condition 4(c) should provide that existing stacks and roof vents may no longer be used after construction of the new stack, to avoid the reading that they can continue to be used in the 30 days prior to their being sealed.

Condition 4(c) addresses the timing for the sealing of existing stack and roof vents. Other provisions in the permit address when the existing stacks and roof vents can no longer be used. In particular, Condition 4(a)(ii) provides that the replacement of the existing stacks must be completed before the facility resumes operation. Condition 8-1(b)(i) provides that testing of the permanent total enclosure, which necessarily involves discontinuing the use of the existing stacks and roof vents, must be completed before the initial emissions testing of the facility with improvements is conducted.

Emissions Control

71. Very little is specified about the emissions control systems, even the existing systems. The permit reads more like a permission to explore market options document and not an enforceable construction document. These pieces of equipment are not widely available like a toaster, for example. There are likely only a few manufacturers that produce these kinds of items and only a few models that meet the required specifications for sensitivity. Sterigenics should have specified the models, specifications, applicable parameters and maintenance requirements for those devices in its application. Simply saying that manuals must be provided and equipment must be properly maintained is insufficient for practical enforceability. Specific schedules and values must be included. Specific values will assist inspectors in verifying that permit criteria are being met. The absence of this information makes the permit unenforceable.

Further specificity is not needed to make the permit enforceable. The new limits and control requirements that would apply to the facility's emissions of ethylene oxide are clear. The construction permit requires Sterigenics to conduct emission testing, emission monitoring, operational monitoring and recordkeeping to show compliance with these new limits and control requirements. The permit requires that control devices be operated in a manner that is consistent with how they were operated during the testing that shows compliance, specifying the operating parameters of control devices that must be addressed. The permit also requires Sterigenics to prepare plans that document how it operates and maintains the dry bed absorption devices, as they are an essential aspect of improved control of emissions. The permit generally requires operation and maintenance of all control devices in accordance with good air pollution control practice. However, it is not necessary or practical for the construction permit to dictate specific maintenance actions, with schedules, for the control devices. This would only be necessary if implementation of these work practices was the means by which compliance with the requirement to control emissions would be shown, which is not the case.

72. Condition 7-3(c) appears to provide choices for how flow of gas to individual beds in the dry beds absorber devices is determined. These need to be resolved before the permit is issued for practical enforceability.

Condition 7-3(c) is clear that the Permittee must operate instrumentation for the dry bed absorber devices for the flow of gas to individual beds. There are various ways that this could physically be done, as is appropriately recognized by this condition which lays out three options by which Sterigenics may collect this information.

73. Condition 7-3(d) is insufficiently specific in what the required parameters are. For operation, is pH required to be included in the log? Temperatures? Pressures? In the maintenance log, does the bed number need to be recorded? How about the concentrations of chemicals in the spent bed? Perhaps a "Notes" section about appearance for other observations that

may be helpful? What minimum parameters need to be included and what value ranges should the inspector be looking for to easily identify any immediate problems.

Condition 7-3(d) addresses the operation, calibration and maintenance of the monitoring systems and instrumentation required by the permit. This condition addressed information related to the operation and maintenance of the monitoring systems and not the data that is to be measured and recorded, which is addressed elsewhere in the permit.

74. Condition 9(a)(i) provides that device-specific information must be kept on file. This information should have been provided in the permit application to facilitate the creation of an enforceable permit document.

Condition 9(a)(i) appropriately requires Sterigenics to keep a file at the facility that contains certain detailed information about the design, operation and maintenance of the dry bed absorption devices. This will require that this information be kept up-to-date and be available for both the operating personnel of Sterigenics and the inspectors of the Illinois EPA.

75. Condition 9(a)(i)(A) - "Spent" should be defined here according to manufacturer's specifications.

The term "spent" does not need to be defined as the common meaning is intended. In particular, this condition simply requires Sterigenics to have written procedures for the practices it follows for disposal of the used sorbent that is removed from the dry bed absorber devices.

76. The permit should require that the spent sorbent be immediately replaced to return the device to full capacity. These kinds of parts should be required to be kept on hand for replacement and not ordered once the spent sorbent is removed to prevent situations when sorbent might be backordered.

Condition 6-3 generally requires Sterigenics to operate and maintain the emission control devices at the facility "…in a manner consistent with safety and good air pollution control practice for minimizing emissions." It is not necessary, for the permit to specify further requirements with regard to the replacement of sorbent in the individual beds in the dry bed absorbers. This is particularly true as typical practice for replacement of sorbent in a bed in a multi-bed device is to fill the bed with new sorbent immediately after the spent sorbent is emptied from the bed and to then return the bed to service

As this comment expresses concern that the timely replacement of sorbent in a bed might be delayed because of not having sufficient new sorbent on hand, the issued construction permit requires Sterigenics to maintain records for the amount of sorbent that it has on hand. It reasonably addresses the supply of sorbent for the dry bed absorption devices. If timely replacement of sorbent in a bed does not occur, this will also provide information to assess whether lack of new sorbent was a factor.

77. Condition 9(a)(ii)(A) - The minimum frequency for the evaluation of performance of individual beds in the dry bed absorber devices should be set. Reporting requirements should also be set. Perhaps inclusion in the quarterly report would be appropriate as supporting evidence for the reasonability of continuous emissions monitoring system reports.

The required evaluations for the dry bed absorber devices must be conducted on a schedule that is consistent with assuring effective operation and control of emissions by these devices. However, the actual operating level of the facility, the usage of ethylene oxide and the effectiveness of the scrubber(s) that precede these devices will determine the loading of ethylene oxide to the dry bed absorber devices and the rate at which the sorbent is consumed. A set schedule for the required evaluations in the construction permit would not provide for appropriate consideration of these factors.

78. Condition 9(a)(ii)(C) - When does information that must be recorded for not following operating or maintenance procedures for DBA devices need to be reported?

This information need not be routinely reported. The information specified in this condition is required to be kept because it would be relevant if there is a violation of an emission limit. In such case, a relevant consideration is whether control device(s) were properly operated and maintained, or whether improper operation or poor maintenance may have been a contributing factor in the violation. More generally, as control devices are to be properly operated and maintained, a deviation from established practices is worthy of being recorded with accompanying explanation. This information about operation and maintenance is then readily available to Illinois EPA staff during an on-site inspection.

79. In Condition 9(b), the reference to Conditions 6-2(a)(ii-iv) is incorrect. Such conditions do not exist. Perhaps it should be Condition 6-2(c)(ii-iv).

This error in the draft permit was corrected. In the issued construction permit, this condition requires that Sterigenics keep a log or other records to address compliance with Condition 3(c), which addresses the control systems that must be in operation when the different sterilization processes or operations at the facility are taking place.

80. Condition 7-3(a), which governs operational monitoring for scrubbers, continuous monitoring is required for the scrubbant flow rate, pH, and inlet temperature. There is no specification here for the frequency or type of recording or the definition of “continuous” in this context.

This shortcoming in the draft permit has been addressed in the issued construction permit. It provides that the continuous operational monitoring shall generally be conducted in accordance with 40 CFR 63.8(c). This provides that continuous monitoring entails automatically recording measured data at least every 15 minutes except during system

breakdowns, repair, maintenance and certain other periods in which it would be unreasonable to require collection of the measured data.

81. Condition 9(a)(ii)(B) has a recordkeeping requirement related to the performance of the dry bed absorber devices. How is this performance to be determined? If this is intended to be determined solely by data from the continuous emissions monitoring system, this data would not discriminate to the level of bed-level performance, as required by this condition.

In response to this comment, this condition in the issued construction permit requires recordkeeping related to the effect of sorbent replacement in a bed on overall performance of the control system for ethylene oxide, if any. In conjunction with sorbent replacement, it is appropriate that Sterigenics review the data from the continuous emissions monitoring system to see whether there is a discernable reduction in measured concentrations of ethylene oxide.

82. Condition 6-2(c) would not provide a precise list of data that must be collected, recorded, and reported for the scrubbers, regardless of the determination of whether the 99.9 percent or 0.2 ppmv standard is met. It would also lack practically enforceable specificity as to what those ranges should be for a properly maintained piece of equipment such as what the liquor level must be or pH or flow rates and temperatures. These requirements and their values should be explicitly specified and should not be difficult for the source to provide given that these scrubbers are existing devices that have been in operation.

For the scrubbers at the facility, this condition specifies the operating parameters for which continuous monitoring must be conducted. The initial emission testing of the facility required by Section 9.16(b) of the new law, which will be the basis for the values of these operating parameters, has not yet been conducted. The past operation of the scrubbers, before the new law was adopted, should not be the basis of the values for these parameters.

83. The recordkeeping requirement for instances when there is a malfunction in the automatic data recorder does not address pH, which is a vital component of the function of the scrubber as acidic conditions are required for the control of ethylene oxide by the scrubber.

The issued construction permit requires data for pH to be recorded at least every eight hours if there is a malfunction in the recorder. This frequency is appropriate because the volumes of material in the scrubbers are such that changes in pH occur gradually. In addition, samples of scrubbant material will have to be physically taken from a scrubber to obtain this data.

84. Condition 6-2(c)(i)(A) includes a requirement for flow rate and pH but not inlet temperature as does Condition 7-3(a). These requirements should be consistent.

Inlet temperature is addressed by Condition 7-3(a) because it is an operating parameter that is relevant for the operation of a scrubber controlling a gaseous pollutant and is readily monitored. However, the effect of temperature on the operation of the scrubbers is not

expected to be significant enough to address this parameter in Condition 6-2(c)(i)(A), which sets requirements for the operating parameters of the scrubbers if the facility is being operated to comply with the 99.9 percent reduction requirement for emissions.

85. Operational monitoring data on a rolling 3-hour basis can easily mask spikes and troughs. For example, a rolling 3-hour average might look fine, but if the emissions spike every time a chamber evacuates, that might be problematic and might need to be examined. A maximum, minimum, and standard deviation should be added to the recordkeeping requirements to support those values and to give a more complete picture of the data.

Under air pollution control regulations, monitoring for the operating parameters of control devices is commonly required to be conducted to obtain data on a three-hour average. This ensures that the data is representative and can be relied upon if needed for purposes of enforcement. For this facility, this is an appropriate time frame, particularly as dry bed absorption devices will be used to control emissions. Additional statistical information for the recorded data, as requested by this comment, would not have direct value for the implementation of the substantive requirements of the permit.

86. In regard to data collection, please define the intervals meant by "continuous" monitoring. Manual collection defines that data must be collected every hour. Automated data collection intervals are not defined but should be.

The issued construction permit provides that automated measurements must be taken at least every minute and this data must be recorded on an hourly average and a rolling three-hour average.

87. Conditions 6-2(c)(ii) and 6-3 are inconsistent with one another. Condition 6-3 requires maintenance and operation to be consistent with good air pollution control practice at all times. Condition 6-2(c)(ii) only requires good practices in the period before emissions testing is conducted.

There is not an inconsistency between these conditions. Condition 6-2(c)(ii) addresses operation before initial emission testing has been completed. During this period, control devices cannot be held to values of the specified operating parameters that are consistent with those during testing. For this period, Condition 6-2(c)(ii) makes clear that the control devices must still be operated in accordance with good air pollution control practice. On the other hand, Condition 6-3 addresses operation of control devices after initial emission testing is completed, when control devices must be operated in a manner that is consistent with the manner in which they were operated during testing.

88. As Section 9.16(b) of the new law provides for two alternative limits for emissions of ethylene oxide from a sterilization facility, i.e., either 99 percent reduction or 0.2 ppm, it would seem that with a single stack, the 0.2 ppm limit would not be consistent with the "greatest reduction" considering the limits in the permit for usage of ethylene oxide.

As a legal matter, the requirements that apply to emissions and usage of ethylene oxide by the facility are separate and independent. The emissions of the facility will be constrained by the statutory requirements in Section 9.16(b) of the new law (as restated in Condition 2-1(a)) and by the emission limits set by the permit (Condition 3(a)). Section 9.16(b) of the new law sets numerical emission standards that address the effectiveness with which emissions must be controlled. These standards address emissions in relative terms, i.e., the percentage of ethylene oxide that is emitted compared to entering the control devices (efficiency or the amount of ethylene oxide in the exhaust stream compared to the volume of the exhaust stream (concentration). The "permit limits" address the amount of ethylene oxide emitted by the facility. These limits relate to the impacts of the facility on ambient air quality, as has been evaluated with dispersion modeling. Finally, the usage of ethylene oxide by the facility is separately limited by the permit (Condition 5(a)).

However, as appears to be observed by this commenter, to comply with the permit limits for emissions of the facility based on the permitted usage of ethylene oxide, the facility's average emission control efficiency on a monthly and annual basis would have to be substantially greater than 99.9 percent and the average concentration of ethylene oxide in the exhaust would have to be substantially below 0.2 ppm. However, this is not sufficient reason for the permit to set emission standards for ethylene oxide that are more stringent than those in the new law. It is reasonable and to be expected that a facility will design and operate its emission control system to comply with applicable emission standards with a margin of compliance.

89. As related to Section 9.16(g) of the new law, would Sterigenics be required to comply with the 99.9 percent reduction requirement for the facility, rather than the 0.2 ppm limit, given the facility's permitted usage of ethylene oxide to be considered compliant with the "greatest reduction" requirement in Section 9.16(g) of the Act?

As already discussed, if the facility were to operate at its permitted annual usage of ethylene oxide, emissions of ethylene oxide would have to be controlled by more than 99.9 percent. However, this would be the consequence of the level of operation of the facility and the annual limit for emissions of ethylene oxide set by permit. For purposes of Section 9.16(b) of the new law, Sterigenics could still elect to show compliance with either of the emission standards set in Section 9.16(b) of the new law. Likewise, the requirement of Section 9.16(g) of the new law related to control technology is separate from the limit on annual emissions of ethylene oxide set by the permit.

90. How would emissions of ethylene oxide be measured to determine compliance with the applicable limit on annual emissions set by the permit?

The permit is based on continuous emissions monitoring being the principle way that emissions of ethylene oxide would be measured to determine compliance with the limits for monthly and annual emissions set by the permit. While continuous emissions monitoring

specifically for ethylene oxide may be new, this monitoring will utilize equipment and methodology that is now in routine use for monitoring of emissions of organic pollutants other than ethylene oxide. In this regard, continuous emissions monitoring for ethylene oxide is a matter of applying an existing type of monitoring system to a new pollutant and potentially refining the methodology for that equipment to provide the necessary level of sensitivity. Moreover, as addressed in certain other comments, it is appropriate for the permit to be based on the routine use of continuous emissions monitoring at the facility as this should provide the most accurate information for the emissions of the facility for the periods of time between the required annual emission tests. The operational monitoring required by the permit will be a secondary way that emissions of ethylene oxide will be determined.

Facility Oversight

91. Are you only planning to check in on Sterigenics annually?

No. Given the concerns for sources of ethylene oxide emissions, the new law expressly mandates at least one unannounced inspection by the Illinois EPA each year. However, the Illinois EPA has broader authority under Section 4 of the Environmental Protection Act to conduct announced and unannounced inspections of sources including Sterigenics. Illinois EPA also has broad authority to request information from air emissions source. Illinois EPA is committed to utilizing its statutory authority to ensure that the Sterigenics meets its obligations under the construction permit, the new law and the Consent Order.

Additional oversight will occur as Sterigenics submits various plans required by the Matt Haller Act and the Consent Order, including:

- **review and approval of permanent total enclosure demonstration;**
- **review and approval of an emission testing protocol, addressing the manner of testing, test methods, operating conditions and the independent third-party company performing the test;**
- **witnessing of emissions testing by Illinois EPA;**
- **review and approval of emission testing results;**
- **review and approval of a monitoring plan for identifying the manner, equipment and locations for continuously collecting emissions;**
- **review and approval of ambient monitoring plan, addressing ambient monitoring conducted during a 30-day period of operation, as detailed by the Consent Order;**
- **review and approval of an ambient monitoring plan identifying the means of collecting and analyzing samples of ethylene oxide emissions, on a quarterly basis, at the property boundaries and select community locations, and the independent third-party company performing the monitoring; and**
- **review and approval of a plan for conducting dispersion modeling, incorporating the initial emissions testing data and meeting USEPA methodologies.**

92. The permit is full of monitoring requirements, but it doesn't address what happens if Sterigenics or the Illinois EPA identify an issue.

As a general matter, permits address applicable requirements and the means to assure compliance with such requirements, rather than the actions or consequences that would ensue from issues encountered in attempts to implement or comply with an issued permit. This is, in part, because one cannot anticipate all issues that might later develop, much less how those might be appropriately addressed in the permitting context. Further, some issues that may develop may not be permitting considerations but compliance or enforcement considerations. However, as noted above, the Illinois EPA will be overseeing Sterigenics operations in a myriad of ways and will appropriately address any identified issues.

93. Was the Illinois EPA conducting routine inspections of Sterigenics?

Sterigenics currently operates pursuant to an existing CAAPP permit. As such, under federal air program guidance, the Illinois EPA inspects this source on a routine frequency. In addition, Sterigenics was the subject of periodic report reviews. Post issuance of its seal order, the Bureau of Air inspected the facility on a near weekly basis, conducting 27 inspections between February when the seal order was effectuated, and September when the Consent Order was entered, and the seal order was lifted, a period of time when the source was not operating and thus was not impacting human health or the environment.

94. Was Illinois EPA aware of the fact the back vents were not controlled?

The federal rule for commercial sterilizers such as Sterigenics was first adopted in November 1994. That rule addressed control of sterilization operations including the back vents. In July 1997, USEPA became aware of explosions at several facilities nationwide due to oxidizers being overfed with ethylene oxide. This was later determined to be caused by anomalies at the backvents. The USEPA concluded that there were no available mechanisms to regulate ethylene oxide flow from back vents to control devices and, in November 2001, revised the federal rule to remove the requirement for control of back vents. In April 2006, the USEPA reviewed its rule retaining the 1994 version, as amended in 2001.

The Illinois EPA historically has been aware of the regulatory status of the back vents. Specifically, the Illinois was aware of whether the back vents were required to be controlled, whether they were controlled, whether the requisite emissions testing had occurred, and whether it demonstrated compliance with applicable requirements. In December 2016, when the federal government completed its reevaluation of the IRIS for ethylene oxide, the back vents were not required to be controlled. Subsequently, control of the back vents resulted from the efforts of the Illinois EPA and its federal partner following that reevaluation.

Storage and Transport of Ethylene Oxide

95. Why is the Illinois EPA allowing transport and storage of ethylene oxide in a residential area?

The Illinois EPA is not empowered to make decisions relating to zoning. Whether and where transport and storage of ethylene oxide may occur is generally a matter for local units of government.

96. Why is outdoor storage of ethylene oxide being allowed?

The legislature did not address outdoor drum storage or transport in the recently enacted legislation. Additionally, there are no otherwise applicable requirements under the Illinois Environmental Protection Act and regulations thereunder. Rather, the drums are subject to requirements outside the Agency's purview. For example, drum storage is addressed by international standards recommending storage of the drums in a "well-ventilated, fire-proof area, preferably away from other chemicals and outdoors." Thus, storage of drums outside of a building is consistent with applicable recommendations and not an issue for the Illinois EPA's consideration.

Ethylene oxide is stored in drums each with 400 pounds of ethylene oxide. New and empty drums of ethylene oxide stored outside at the Willowbrook facility must be sealed. The drums at issue are specially designed, stainless steel, pressurized and double-walled. Each drum has fittings, including pressure valves. These fittings are opened when connecting a drum to the feed system for one of the chambers at the station that serves that chamber.

97. What happened to the drums that were onsite when the seal order was effectuated?

When the Agency effectuated its seal order, there were full, partially full and empty drums present at the Willowbrook site. Subsequently, these drums were removed from the site. Based on available information, all drums were removed in accordance with applicable requirements.

98. Does drum storage pose a risk of explosion? What would the Agency's response be to an explosion? The source should be fined $1 million and shut down.

Ethylene oxide is a flammable gas. However, as with other flammable materials, risks associated with storage, transport and use can be appropriately managed. This is the case with ethylene oxide. There is no available information that indicates that the Willowbrook facility has caused any explosions. A root cause analysis would ensue subsequent to any such event, and the Agency would take any necessary or appropriate compliance and enforcement measures. However, with regard to the suggestion of the imposition of a one-million-dollar civil penalty for any such event, the Agency notes that civil penalties are dictated by the

Illinois Environmental Protection Act with a current penalty scheme of $50,000 per violation and $10,000 for each continuing day of violation.

99. How will the drums be protected from accidental damage, which could cause release of ethylene oxide?

As an initial point, the drums or canisters in which ethylene oxide is transported are designed to prevent releases of ethylene oxide from accidental damage. The drums in the storage area are only readily accessible to facility staff. In the event of any damage to a drum that might threaten the integrity of a drum, the drum can be moved inside the facility and the contents transferred to a drum that has not sustained any damage.

100. Condition 3(b)(iii) states "In the drum storage area next to the affected facility, all drums for ethylene oxide shall be kept sealed and the Permittee shall not dispense or otherwise allow the release of ethylene oxide from any of these drums while they are in this area. How will Sterigenics show that it complies with this requirement?

The issued construction permit provides that the records that Sterigenics would keep as matter of its normal practice to document that drums for ethylene oxide in the outside storage area are sealed and are not leaking are considered records required by the permit. Because the normal operating practice for the facility will involve inspection of any drums before they are placed in the outside storage, the permit does not include any further requirements for the documentations that would be completed for these inspections.

Emissions Testing or Stack Testing

101. What is emissions testing or stack testing and why is it not performed before the permit is issued and before the controls are used at the source to confirm that the controls will work and should be permitted?

Stack testing is a tool used to determine a source's compliance status with applicable control efficiencies. Sterigenics is subject to a control efficiency. In accordance with the new law, compliance with this efficiency will be determined by an initial stack test, and thereafter annual stack testing. Stack testing appropriately and necessarily is to be conducted after construction or installation of the enhancements authorized by the construction permit are in place.

This construction permit is required for the enhancements at issue under the new law and stack testing before its issuance is not an option. Further, the purpose of the testing is to assess the efficiency of the control systems when in use at the source. As such, the testing necessarily must occur after issuance of the construction permit and when in use at the source.

102. Why are the details of the emissions testing to be performed not set forth in the permit?

As provided in the new law, and reiterated in the construction permit, the details of the testing will be set forth in an emissions test protocol. This protocol shall be submitted by Sterigenics and, after review and approval by the Illinois EPA, will serve as the guide for testing. To keep the public informed, the Illinois EPA has committed to making this protocol available on its web page.

103. What is the purpose of the emissions or stack testing?

Site-specific emissions testing will be required to ensure that the technology as specifically applied at Sterigenics satisfies the requirements of the new law and the terms of the construction permit.

104. Will you be using the same approach to emissions testing as was used in the past?

No. Previous testing was performed to ensure compliance with the federal NESHAP applicable to commercial sterilization sources. As such, the methods and the approach were consistent with the testing aspects of the federal regulation. Testing under the construction permit will rely upon different methods and approach, some of which is addressed in the permit, and all of which will be addressed in the protocol to be submitted for Illinois EPA review and approval.

105. Will Sterigenics be conducting the testing or who will be conducting the emissions testing?

As set forth in the new law, the initial and annual emissions testing must be conducted by an independent third-party company. Indeed, most emissions testing conducted for purposes under the Illinois Environmental Protection Act is conducted by third parties with relevant experience and with no financial connection to the facility undergoing the testing.

106. In Condition 8-2(c), a minimum of three test runs should be required. Please specify that there must be a minimum of three valid runs and specify what valid means.

This condition appropriately addresses a general aspect of emission testing consistent with the relevant requirements of state rules at 35 IAC 283.240. Most emission tests are composed of three separate test runs. These rules address the possibility that "…one of the test runs must be discontinued because of forced shutdown, failure of an irreplaceable portion of the sample train, extreme meteorological conditions, malfunction or other dissimilar or non-representative circumstances," in which case the results of two test runs may be used when determining compliance.

107. For the provisions of Condition 2-1(b), what constitutes a failed emissions test? Is this only for emission testing?

Condition 2-1(b) reflects specific provisions in Section 9.16(c) of the new law that would be applicable in the event of a failed emission test. For this purpose, a failed emission test would be a test that showed that the facility was not complying with the statutory requirements for control of emissions of ethylene oxide in Section 9.16(b) of the new law. For example, if Sterigenics conducted emission testing with the objective of showing emissions of no more than 0.2 ppm, a failed test would show that this limit was exceeded.

The new law does not specify circumstances other than a failed test for which the operation of the facility must cease. The new law specifies the steps that a source must take to resume operation, including taking action to address the cause(s) for the failed test and having a new test conducted that shows that those actions were effective in restoring compliance with the statutory requirements for control of emissions.

108. The draft permit would provide two options for emission testing. One option needs to be chosen and spelled out. Those procedures and parameters should be fully described so the public knows how to hold Sterigenics accountable for achieving compliance and Sterigenics knows the standards that it needs to meet.

The permit appropriately addresses two approaches to emission testing, as Section 9.16(b) of the new law provides two, alternative emission standards for the emissions of ethylene oxide of this facility, i.e., either at least 99.9 percent reduction in emissions of ethylene oxide or emissions of no more than 0.2 ppm. The standard with which Sterigenics intends to comply and for which it will have emission testing conducted will be addressed in the protocol that Sterigenics must submit to the Illinois EPA prior to emission testing. It will also be apparent

based on the scope of testing. Testing to address the concentration standard will only need to address emissions. Testing to address the emission reduction standard will need to include measurement of ethylene oxide entering the control devices, as well as controlled emissions of the facility.

109. Condition 2-1(b) addresses actions that Sterigenics must take if an emissions test fails to show that the facility's emissions are reduced by at least 99.9 percent or to no more than 0.2 parts per million. This is an either/or statement. It would be best to say both emission standards should be met or that the stricter standard should be met. Allowing the facility to comply with either standards is not in the public interest.

As stated in Condition 2-1(a) and repeated in Condition 2-1(b), Section 9.16(b) of the new law sets two alternative emission standards for an ethylene oxide sterilization facility. It does not require a facility to meet both standards.

In addition, it is not uncommon for alternative emission standards to be adopted for emission units with standards that are addressed in different terms. For example, one standard may address the minimum efficiency of the emission control system, relating the allowed emissions to the amount of material entering the control system. Another standard may limit the concentration of emissions or the amount of emissions relative to the volume of the exhaust. This practice serves to set standards that more appropriately address a number of units that differ in key aspects, or individual units that have different modes of operation or whose mode of operation evolves over time.

110. If Sterigenics fails an emission test, who reviews the required root cause analysis to see if Sterigenics truly arrived at the root cause? An independent expert in the field of sterilization would be better able to make that type of judgement than the Illinois EPA.

The Illinois EPA would be responsible for reviewing the report for the root cause analysis given its experience and expertise with the operation of emission control devices and with root cause analyses. If necessary, the Illinois EPA could solicit the assistance of USEPA or other experts when reviewing the report.

111. Condition 6-2(c)(iii). If the control devices are not run with the same parameters during testing as they are for normal operations, then the test would not address normal operation and therefore could not verify compliance.

Emissions testing is to be performed under conditions that are representative of how the source normally operates. How a source operates during successful testing establishes parameters on future operations until the next test event.

Backvent Controls

112. Who required the control of the backvents and did the controls work?

In December 2016, USEPA completed a reevaluation of its Integrated Risk Information System (IRIS) for ethylene oxide. Specifically, USEPA classified ethylene oxide as a human carcinogen, posing a greater risk of cancer than previously known if people are exposed for many years. USEPA then began to assess potential risks from certain sources, one of whom was Sterigenics. Among other things, USEPA asked the Agency for Toxic Substances and Disease Registry (ATSDR) to evaluate any public health implications for persons living in and working in the Village of Willowbrook based on a very limited amount of ambient data collected by the USEPA in May 2018. ATSDR responded by letter in July 2018 recommending the control of the commercial sterilization backvents to reduce emissions.

Following receipt of limited ambient air sampling data in June 2018 (and prior to the ATSDR's recommendation), Illinois EPA engaged in communications with the USEPA and Sterigenics regarding emissions from the source and potential measures to reduce the same. On June 11, 2018, Sterigenics applied for and on June 26, 2018 received a construction permit from the Illinois EPA to control emissions from the sterilization back vents. That construction permit required emissions testing of backvent emissions pursuant to an emissions testing protocol. Both the Illinois EPA and the USEPA reviewed the protocol, witnessed the emissions testing event in September 2018, and reviewed the emissions test results. The test was performed in a manner that was consistent with the June 2018 construction permit, as well as the NESHAP Subpart O test methods. The purpose of the test was to demonstrate the effectiveness of the pollution controls to remove ethylene oxide from the chamber exhaust vent cycle (back vents) at conditions that should have represented the highest amount of ethylene oxide through the back vents. The testing demonstrated a control efficiency of at least 99%, or a 99% reduction in emissions. Further, the emissions were well within the emissions limits set forth in the CAAPP permit issued in June 2015.

113. Doesn't the ambient air monitoring conducted by the Village of Willowbrook suggest that the controls did not work?

No, the ambient air testing data does not speak to the success of the emissions testing. These two types of testing are separate and distinct and bear little relationship to each other.

Section 9.16(g) technology evaluation

114. There's no way that the Agency has made the independent findings that the technology that exists for each particular product Sterigenics proposed to sterilize is in fact the best that's possible available.

The draft construction permit contained a provision recognizing that the control improvements being made as part of this construction permit will satisfy the requirements of Section 9.16(g). In response to comments, the Illinois EPA is modifying its approach and issuing a separate certification. The Illinois EPA believes that the certification should be a stand-alone document and not enveloped as part of the permitting decision, as it is more in keeping with the new law's intent to create a certification process for the two, discrete standards that operate as conditions on the continued use of ethylene oxide by Sterigenics.

The Illinois EPA is issuing the certification required by Section 9.16(g) in parallel with this permit decision, in part, because it makes sense to certify the control systems contemporaneous with the permit review of the control improvements. Moreover, because nothing in the new law addresses the timing or the manner in which the Illinois EPA must act on its certification obligation under the provision. The remaining components of the new law as they relate to the Illinois EPA's oversight, including the review and approval of the emissions testing, CEMS monitoring, ambient air monitoring and other requirements, will be addressed as they arise.

It is noteworthy that the control system evaluation performed by the Illinois EPA did not include an examination of each product, or grouping of products, that will be treated by Sterigenics' control system upon resumption of operation. The Illinois EPA's responsibility set forth in Section 9.16(g) largely pertains to certifying available control technologies in terms of their emission reduction capabilities, which necessarily focuses on control systems that act to treat ethylene oxide emitted by one or more of sterilization chambers. As a fundamental matter, the control system for a facility using ethylene oxide for sterilization or fumigation will achieve, both by design and in practice, a range of control performance irrespective of the individual or product groupings that are treated in the sterilizing chambers. While the supplier certifications are part of a separate requirement of the same provision, their consideration by the Illinois EPA within the context of the technology review would be of little to no value. It should be mentioned that a plain reading of the dual certification requirements of Section 9.16(g) does not indicate, in either express or implied language by the General Assembly, that the control system evaluation is linked with the supplier certifications.

115. There are no objective criteria concerning the certification of control technology evident in the Illinois EPA's draft construction permit. What research has been done to ensure that they comply with this certification requirement?

The Illinois EPA acknowledges that the certification of control technology referenced in the draft construction permit does not elaborate upon the considerations made by the Illinois EPA in fulfilling its obligation under the Matt Haller Act. However, the statute does not detail any accompanying requirements for a formal finding of fact(s) or technical support on the face of the certification. In fact, most certifications, including those that carry a legal significance, are of a short form variety, with supporting justifications commonly being found in a companion document or in the administrative record of the agency's deliberation.

It is also noteworthy that the standard for the Illinois EPA's certification under 9.16(g) is rather abbreviated itself. The yardstick for measuring the Illinois EPA's evaluation is that the affected source's control system employs technology that achieves the "greatest reduction in ethylene oxide currently available." Neither the phrase nor the individual terms are defined by the statute, effectively leaving their meaning and implementation of the phrase to the Illinois EPA's discretion.

In this instance, the Illinois EPA's certification for the control technology is fully documented in a companion document. The memorandum dated September 20, 2019, provides a detailed account of the evaluation. Among other things, the document explains why the control improvements authorized in the construction permit will assure that the control system employed by the Willowbrook I facility produces "the greatest reduction in ethylene oxide emissions currently available."

More specifically, the memorandum discusses the improvements that Sterigenics will make to its existing control system for the different "processes" at Willowbrook I that release ethylene oxide, i.e., the evacuation of the sterilization chambers, the use of the backvents on the chambers, the aeration of sterilized material, and "fugitive emissions," including releases from transfer and storage of sterilized material. Fugitive emissions would be directly addressed with the required permanent total enclosure and a new absorption device. Absorption with an appropriate sorbent is highly effective for control of low concentrations of a gaseous pollutant. For the other processes, additional control would be provided by making more use of two existing control devices at the Willowbrook I facility to also control evacuation of the sterilization chambers, and by installation of another absorption device. Notably, four control devices, in series, will now be used for the evacuation of the chambers, i.e., two acid scrubbers and two absorption devices. The initial control of emissions by the scrubbers will facilitate effective control by the existing absorption device. The second absorption device will act as a polisher device for further control of emissions.

The memorandum also discusses the control systems at other sources that use ethylene oxide for sterilization, based on information obtained by the Illinois EPA from permits and related documents outside the application. This review shows that other sources are commonly controlled with devices of the same type as at this facility. Although some sources use afterburners or oxidation for control, it should not be considered more effective than the combination of controls that Sterigenics would use. Lastly, a review of the emission

standards currently in place for other sources confirms that the emission standards set forth in the new law are more stringent.

116. The Illinois EPA must certify and not merely determine that the control technology employed by Sterigenics meets the legal standard set forth in Section 9.16(g). In section 1.b.iii.c. of the permit, the Illinois EPA makes the statement that is has determined "the facility's emissions control systems would use the technology that produces the greatest reduction in ethylene oxide available."

This statement is true. As a matter of law, a certification is regarded as an act of attesting to, or an affirmation of, something as being true or as to meeting a certain standard. A certification signifies a type of authoritative confirmation, or proof of conclusiveness, that would not extend to an ordinary act of approval. By requiring a certification of control technology under Section 9.16(g), the General Assembly intended for it to have a meaning commensurate with its legal connotation. Given the Illinois EPA's long-standing expertise in the field of air pollution control, the certification can be viewed as a means of providing credible assurance that the affected source (i.e., Sterigenics) will be able to meet one of the two condition precedents for using ethylene oxide under Section 9.16(g).

117. The Agency may not rest on the assumption the facility is using the best technology as a proxy for making an independent determination that each product sterilization method is the best and most stringent technology available.

The legal standard governing the Illinois EPA's certification obligation in Section 9.16(g) is centered on a review of technology. The Illinois EPA's review under Section 9.16(g) need not incorporate a review of the separate supplier certifications because the latter does not provide relevant information that would affect the emission reduction capabilities with respect to available control systems.

118. It's particularly troubling that the Illinois EPA seems to be equating the facility standards of Subsection B to the product-based standards that are in Subsection G.

The Illinois EPA does not equate the concentration and mass-based emission standards of Section 9.16(b) with the dual certification requirements of Section 9.16(g). The former sets alternate standards of performance. The latter establishes a set of additional requirements for Sterigenics to resume operation. The technology certification by the Illinois EPA in Section 9.16(g) is not a product-based standard, as the comment claims, but a technology-forcing standard.

119. Condition 1(c) states that with the various improvements described in Condition 1(b) the facility's emission control system would use technology that produces the greatest reduction in ethylene oxide emissions, as is now required by Section 9.16(g) of the new law, without reference to an independent description of what that technology should look like in an ideal facility, such as an air pollution control board regulatory document.

To provide further clarity as to the technology upon which this determination is based, and in response to certain comments on the draft permit related to this technology, the issued construction permit provides that this technology consists of permanent total enclosure and the specific improvements to the emission control system as would be allowed by the permit as described in Condition 1(b)(ii) of the permit.

120. Under Section 9.16(g) of the new law, a requirement for a facility subject to this section is that "the Agency has certified that the facility's emission control system uses technology that produces the greatest reduction in ethylene oxide emissions currently available." What are the requirements that a facility must meet to qualify as having technology that "produces the greatest reduction in ethylene oxide emissions currently available?"

As provided in Section 9.16(g) of the new law and restated in this comment, Section 9.16(g) of the new law simply provides that the Illinois EPA must have certified that "…the facility's emission control system uses technology that produces the greatest reduction in ethylene oxide emissions currently available." The Illinois EPA simply considers this to mean that, in addition to permanent total enclosure, as would be addressed by the construction permit, a facility makes use of appropriate control devices to meet the legal standard. As discussed in the supporting memorandum accompanying the certification, a review of Sterigenics control measures and other known control systems confirms this showing.

121. If relevant USEPA standards for Maximum Achievable Control Technology (MACT) are included in the determination of "greatest reduction" and these standards change, what is the process for updating the Illinois standards for "greatest reduction," as governed by the Act?

If the USEPA revises its emission standards for commercial ethylene oxide sterilization facilities in the future, and further improvements would be needed at this facility to comply with the revised standards, Sterigenics would have to make such improvements. However, in the context of the current permit action, it is not appropriate to speculate on what a future regulatory development might mean for the certification of technology required by Section 9.16(g) of the Act.

122. Without the raised stack, can Sterigenics still be considered to have technology that provides the greatest reduction in ethylene oxide emissions?

The determination that the facility's emission control system uses technology that produces the greatest reduction in ethylene oxide emissions relates to the facility's systems for control of emissions. It does not address the height of the stack at the facility as a stack does not function to control emissions.

Section 9.16(g) supplier certifications

123. Sterigenics is required by law to have certification from its customers that ethylene oxide is the only way to sterilize each individual product they intend to sterilize with ethylene oxide. They have not produced these certifications. The permit application is incomplete because of the absence of the supplier certifications. Where are the suppler certifications? The permit should be denied in the absence of the certifications.

These comments refer to certification(s) required under Section 9.16(g) of the Act. An entity providing products to the affected facility for sterilization or fumigation can be viewed as a "supplier," which is the terminology in the statute, because the entity supplies the affected facility with the individual or grouped products to be sterilized or fumigated. The entity could also be viewed as a customer, in the sense that the affected facility is performing a service pertaining to such products.

Section 9.16(g) does not require the supplier certifications be provided to the Illinois EPA as part of the permit review for Sterigenics' control improvements. In fact, nothing in the new law suggests that the supplier certifications must be addressed by the Illinois EPA as part of any permit review process, or before the issuance of a construction permit for control improvements made pursuant to the new law. The only temporal element of the provision is that such certification(s) be forthcoming prior to Sterigenics "using ethylene oxide for sterilization or fumigation."

124. Illinois EPA must verify that for each product that Sterigenics proposes to sterilize, ethylene oxide is the only thing that can be used to sterilize that product. Illinois EPA must make independent findings to this effect.

The language of Section 9.16(g) does not require "findings" by the Illinois EPA with respect to the supplier certifications. The certification has a distinctly legal meaning, to attest or provide an assurance of the accuracy of a particular statement. A legal certification does not operate in a way that requires prior review and approval by others; by its nature, a certification is self-authenticating, obviating the need for someone else to review or approve it. As such, a review by the Illinois EPA of the supplier certifications is incongruous with the legal principles applying to formal certifications.

In contrast to the certification process of Section 9.16(g), the new law establishes a technical review and a formal approval process by the Illinois EPA of submissions made by ethylene oxide sterilization sources in no less than nine (9) instances. In each instance, the General Assembly created detailed provisions to govern the back-and-forth exchanges of information between the sources and the regulatory agency, often doing so in multiple paragraphs. The Illinois EPA does not and may not presume a right of review and approval is mandated by the legislature where, as here, the relevant statutory provisions do not even hint at it.

As discussed in the response above, the various product certifications that must be obtained by Sterigenics from its suppliers are not tied to the Illinois EPA's permit review of control improvements made pursuant to the new law.

125. The supplier certifications need to be made public for examination with a public comment period and public forum with the suppliers and Sterigenics present.

Nothing in Section 9.16 or the other provisions of the Environmental Protection Act suggests that the supplier certifications be subject to a public comment period or a hearing compelling the attendance of Sterigenics' suppliers. Public comment and hearings are staples of a public participation process that often accompanies governmental decision-making, most frequently either during or before the issuance of a final decision. As the supplier certifications are not a form of governmental action, it is not clear what purpose would be served by the proceedings suggested by the comment. Moreover, a legal certification does not depend upon some independent action by a third party for its execution. Based on the plain language of the provision, there is no indication that the supplier certifications under Section 9.16(g) must be examined or reviewed by the public prior to becoming effective.

There is also no authority under the new law or the other provisions of the Environmental Protection Act for the Illinois EPA to compel Sterigenics, much less "suppliers", to attend a hearing to address issues germane to the certifications.

Any certifications provided by Sterigenics to the Illinois EPA would be available under the Freedom of Information Act (FOIA), unless such information is exempted by relevant provisions of the Environmental Protection Act (as in the case of trade secrets under 415 ILCS 5/7 and 7.1 of the Act) or by other relevant statute (as in the case of FOIA).

126. How often would the company be required to certify that a product may only be sterilized completely by ethylene oxide?

The new law does not specify a limit on the term of a supplier certification or a frequency at which a certification must be renewed. The certification is a condition precedent to lifting a prohibition on Sterigenics' future use of ethylene oxide for sterilization or fumigation.

127. The supplier certifications should be rigorously enforced.

The new law provides that Sterigenics may not operate unless it "can provide a certification to the Agency by the supplier of a product to be sterilized or fumigated that ethylene oxide sterilization or fumigation is the only available method to completely sterilize or fumigate the product. It is fair to construe a violation of the requirement as a proper subject of an enforcement action brought under Title XII of the Act. Remedies available under the Act would include a civil action to recover penalties, 415 ILCS 5/42(a), a criminal action, 415 ILCS 5/44, a governmental action to restrain violations or for an immediate injunction, 415 ILCS 5/42(e) or 5/43, or a citizen action for injunction, 415 ILCS 5/45.

Some considerations are noted with respect to the potential enforcement under the Environmental Protection Act of the supplier certifications addressed by Section 9.16(g). This provision does not directly implicate a signatory to the certificate. While it may stand to reason that a supplier who signs a certification under the provision should be bound to the accuracy of the certification, enforcement of the accuracy of the certifications against such individuals may be challenging. The individuals who certify to the new law's method availability standard will likely be the only individuals who possess the relevant information for the certifications. In this regard, there is not a public database identifying the suppliers and products for which ethylene oxide treatment is the only method for complete sterilization or fumigation. Lastly, suppliers may be averse to providing supporting information to the Illinois EPA. That could aid in any such enforcement.

128. What is the process for appealing the supplier certifications?

Nothing in the new law contemplates a right of appeal of a supplier's certification under Section 9.16(g). As to the other provisions of the Environmental Protection Act, there does not appear to be any provision that would authorize an appeal of the supplier certification.

129. Will there be rules creating criteria for the supplier certifications, and will the criteria be revised when newer sterilization methods are approved in the future?

The new law does not authorize agency rulemaking for the provisions relating to supplier certifications.

130. How is the public assured that Sterigenics is obtaining the required certifications and that the certifications are complying with the requisite legal standard?

The new law does not specify the mechanics of how compliance with the supplier certifications is to be demonstrated. The new law also does not explicitly require the review and approval of the certifications by the Illinois EPA. It is unclear if enforcement under the Environmental Protection Act is an appropriate vehicle against the suppliers themselves to assure that the certifications are lawful.

131. The draft permit does not address the certifications required by Section 9.16(g) of the new law from entities that send product(s) to the facility for sterilization, which state that ethylene oxide sterilization is the only available method to sterilize to completely sterilize the product(s). How would this be dealt with?

The certifications addressed by this comment do not need to be addressed in this construction permit because they do not involve or relate to the control of the emissions of ethylene oxide and are directly addressed by Section 9.16(g) of the new law.

Continuous Emissions Monitoring System

132. What is Continuous Emissions Monitoring and why is it being required?

Continuous Emissions Monitoring is a tool used for, among other things, measuring concentrations out of an emissions stack. The Continuous Emissions Monitoring System (CEMS) that is required of Sterigenics, as set forth in the construction permit, is in addition to emissions testing, ambient monitoring in the community, and other periodic monitoring measures, such as recordkeeping and reporting set forth in the construction permit. When Sterigenics is operating, the CEMS will provide a measured concentration of ethylene oxide, which is in contrast to the historical assessment of emissions via calculation based on emissions testing and other relevant factors. A CEMS is not new technology. Nor is it untested or unreliable. However, its application to commercial sterilization operations is developing. It is in this regard that Sterigenics, in its cover letter to the construction permit application, indicated that it "looked forward to field testing."

The Illinois EPA, in this construction permitting action, is requiring the installation and use of a CEMS – a significant additional compliance tool - in response to concerns for the toxicity of ethylene oxide and for the source's ability to comply with applicable requirements. Also, this is consistent with the new law which requires the submission of a plan "describing how the owner or operator will continuously collect emissions information" at the source. That plan will be forthcoming with more details regarding the CEMS, but the obligation for a CEMS is captured as part of this permitting action. Consistent with its goal to keep the public informed, along with other information, the CEMS plan will be made available to the public.

133. Can the Agency cause the source to cease operation if its CEMS is not operating?

The CEMS is merely one aspect of the periodic monitoring required of Sterigenics. Indeed, other records relative to their operations and emissions are required by the construction permit. Further, the CEMS serves the purpose of data collection, not control of emissions. Thus, while data collection is a key component of compliance assurance, it does not directly affect the emissions of a source. The response to any failure to operate the requisite CEMS is a compliance and enforcement consideration upon which the Agency cannot speculate.

134. The control technology, particularly the emission monitoring system, is not proven and is untested. Sterigenics states, "We look forward to working with you to gain experience." Isn't that their job, to have the experience to get this done and to have that verified? And at this point, it cannot accomplish the goals, nor will it get the job done. Right there is reason number one to deny this permit.

In fact, the proposed modifications, which are expressly borne of the new law, should be viewed as a combination of conventional technologies.[3] Further, the Illinois EPA is recognizing the overall system of controls as satisfying the Act's requirement for using technology that will produce the greatest reduction in ETO emissions currently available. Moreover, as required by the new law and reiterated in the construction permit, the facility must test its improvements, once constructed.

The concern noted appears to stem from the permit application submitted by Sterigenics. In the cover letter to the application acknowledges that the selection of measurement technology (i.e., Fourier Transform Infrared (FTIR) spectroscopy) will be new to a sterilization facility. But, in the wake of concerns regarding the toxicity of ETO, the new law requires sterilizing facilities to monitor exhaust concentrations of ETO directly, rather than merely using parametric monitoring to assure that emission controls are operating effectively.

FTIRs have been utilized for the last 30 years to measure hundreds of different organic compounds, including ethylene oxide. When a few organic compounds are targeted for monitoring, as would be the case here, FTIRs can be further enhanced to measure emissions with significantly lower detection limits. Such an enhancement, which the source proposed in the permit application, does not make the proposed CEMS untested or unreliable.

135. The proposed continuous emissions monitoring system is not specifically identified in the draft permit. The permit describes the system as "such as a Max Analytical Technologies MAX StarBoost" rather than specifying the exact product. This needs to be specified here along with all operational, calibration, testing, and maintenance parameters for practical enforceability.

The permit addresses the required continuous emissions monitoring system. It specifies the performance specifications that the selected system must meet. It is not appropriate, and it is not Illinois EPA practice, to specify that a particular brand and model be used. Aside from the propriety of doing so, it would shift the burden for effective emissions monitoring from the source to the Illinois EPA. The responsibility to select and purchase an appropriate emissions monitoring system, and to then properly operate and maintain that system, lies with the source.

136. I am concerned that continuous emissions monitoring may be unproven for ethylene oxide. In the application, Sterigenics states "As IEPA is aware, we have proposed use of a CEMS even though no CEMS has been demonstrated as applied to a sterilization facility like our Willowbrook plant. We look forward to working with IEPA to gain field experience with such systems in the sterilization industry." This statement is concerning. Since this

[3] The proposed improvements generally consist of the ducting of all exhaust streams to a single stack, the polisher dry bed control system being added to the facility's existing wet acid scrubber, the proposed ducting the Deoxx acid scrubber to the aforementioned wet acid scrubber and changes to the facility to achieve a permanent total enclosure.

would appear to be pilot project for such an emissions monitoring system, multiple validation methods should be employed that such a system a) works b) is appropriate for the range of values seen c) is consistent over time. Validation should require not only measurements and calculations at several different segments of the system to ensure the concentration drops make sense and are consistent but also multiple analysis techniques by established method to support the data output of the continuous emissions monitoring system. Regular validation and checks (for example quarterly or annually) would be appropriate for such a pilot case. Given those concerns, what is the plan for verifying that the method for continuous emissions monitoring is adequate? A method should be spelled out or cited here including previously established methods for comparison and verification. Also, if this continuous emissions monitoring system does not adequately quantify, what is the alternative plan?

Notwithstanding the concerns expressed in the application and in this comment, continuous emissions monitoring for ethylene oxide is not unproven and should be readily implemented for the facility. The specific concerns expressed in this comment are addressed by the requirement in the permit that the emissions monitoring system be designed and operated to meet the requirements of USEPA's Performance Specification 15, Performance Specification for Extractive FTIR Continuous Emissions Monitor Systems in Stationary Sources. They will also be addressed by means of the plan required by Section 9.16(d) of the new law, which will provide details on the methods and procedures to be used by Sterigenics to continuously collect emission data, and which will be reviewed and approved by the Illinois EPA.

137. USEPA Performance Specification 15 does not specify a sensitivity requirement for a monitoring system. This should be specified in this permit, just as was done in a construction permit for the Medline facility in Waukegan. The permit for Medline specifies that its emissions monitoring system shall be operated to maintain a limit for quantification that is no greater than 10 ppbv. A system with a 40 ppbv detection limit, as proposed in the application should be considered insufficient.

In the issued construction permit, Condition 7-1 specifies that the continuous emissions monitoring system must have a limit of quantification of no more than 20 ppm.

138. In Condition 7-1(a), certain specific requirements are listed for the continuous emissions monitoring system (USEPA Performance Specification 15). What is the protocol for operating the continuous emissions monitoring system, certification protocol, maintenance schedule, regular performance checks? An initial performance test, as addressed by Performance Specification 15 would not be sufficient above. The monitoring system should be checked periodically to ensure performance is maintained.

These subjects addressed in this comment will be addressed in the plan required by Section 9.16(d) of the new law that will describe how emission information will be collected. In this regard, this plan will need to address the subjects involved with continuous emissions monitoring that are addressed with Procedure 1 in 40 CFR 60 Appendix F, "Quality Assurance

Requirements for Gas Continuous Emission Monitoring Systems Used for Compliance Determination."

139. The continuous monitoring system for gas flow rate in the stack is required to be in the same area as the continuous emissions monitoring system. How far apart can they be? This should be specified and the devices should be located reasonably close together for determinations of emissions that require data measured by both monitoring systems.

The concern expressed in this comment is addressed as this monitoring system must meet USEPA's Performance Specification 6, "Specifications and Test Procedures for Continuous Emission Rate Monitoring Systems in Stationary Sources." This performance specification requires this monitoring system to be located so as to provide accurate determinations of the mass of emissions, e.g., pounds of pollutant emitted per hour.

140. Conditions 7-1(a) and (b) addressed data from the continuous emissions monitoring system that must recorded. How does that data need to be recorded and how should it be reported? How many readings are the minimum for any rolling averages?

This data must be collected on a one-hour and three-hour rolling average. Further requirements for the frequency of measurements and the recordkeeping of collected data will likely be established in the plan required by Section 9.16(d) of the new law.

141. Condition 7-1(e) lists an exception to the requirements for Conditions 7-1 (a), (b) and (c) if there are difficulties in initial calibration or certification such as obtaining calibration gases, relocation, and re-certification. What restrictions are placed on this?

The use of this provision would be subject to review by the Illinois EPA on a case-by-case basis. In this regard, the issued construction permit provides that reliance on this provision must be accompanied by notification to the Illinois EPA by Sterigenics. The nature of the specific difficulties that are encountered and the appropriateness and adequacy of Sterigenics' responses would then be considered.

142. For the limits for emissions of ethylene oxide in Condition 3(a), this condition provides that when data from the continuous emissions monitoring system is unavailable, emission data will be based on usage, operating data, and emissions factors from test results. How will this be done?

As a general matter, data for emissions of ethylene oxide during such periods would be determined from the measured usage of ethylene oxide during such period, operating data from the control systems to verify that they were being operated properly during such period, and a representative factor for control efficiency as measured or derived from measurements made during emission testing.

143. In Condition 10, the requirement for quarterly emissions reports starting the first full month after continuous emissions monitoring system certification. What is this certification process? Will resumption of operations be contingent on this certification? Isn't a continuous emission monitoring system a crucial requirement for showing compliance with the emission standards of Section 9.16(b) of the Act?

The certification process for an emissions monitor is the process by which fulfillment of the applicable performance specification is demonstrated. An emissions monitor must be certified before the data that it collects is considered reliable for purposes of directly determining compliance. Section 9.16(b) of the new law provides that initial and annual emission test must be conducted to confirm compliance with the emission standards that it established. The provisions for continuous emissions monitoring are established by the permit. Continued operation of the facility is permissible during an interruption in the operation of the continuous emissions monitoring system for several reasons. Among other things, such an interruption would not mean that the facility is not in compliance with substantive requirements for control of emissions. Other operational monitoring is required that would provide information upon which compliance could be determined.

Continuous emissions monitoring systems are sophisticated devices such that interruptions in operation should be anticipated. In this regard, the permit appropriately includes provisions to address difficulties that may be encountered with the emissions monitoring system. Such difficulties are inherent in the operation of emissions monitoring systems and are routinely addressed on a case-by-case basis considering the type of monitoring that is being conducted, the specific difficulty that was encountered and other relevant factors.

Incidentally, in the issued construction permit, the timing of the quarterly compliance reports is no longer related to the certification of the emissions monitoring systems. It is instead linked to the completion of the initial emission testing. This a more appropriate point at which to begin quarterly compliance reporting.

144. Condition 8-2(e) instructs the source to submit "accompanying documentation." What data are included in this set of documents? Does it include raw data and calibration data or weather data?

The accompanying documentation that must be included in reports submitted for emission testing is specified by Section 9.16(b)(d)(i) through (iv) of the new law. This documentation includes raw data and calibration data. It does not include weather data, which would not be relevant documentation for a test, as sterilization operations are conducted in a building.

145. Condition 10(a) would provide for changes to the emission monitoring systems to "improve the limit of quantification of these systems" to be reported in a quarterly report after the changes have been made. This is not acceptable. A comparison study must be made to show these changes are appropriate and correctly measure what they are designed to measure before implementation of the changes.

It is appropriate that changes to improve the limit of quantification of the emissions monitoring systems be able to proceed without the delays that would result from case-by-case review and approval of individual changes. In the issued permit, further information for such changes is required to be reported to show that such changes have improved the limit of quantification of the monitoring systems.

146. I have doubts as to the availability and accuracy of sub-ppm ethylene oxide calibration gases for the continuous emissions monitoring system. Ethylene oxide is a very reactive compound and can decompose over time. Despite the methods used by calibration gas manufacturers, I would bet the accuracy of these gases would degrade over time leading to inaccurate data recorded by the monitoring systems.

The deterioration of the calibration gases that are used as part of quality control for continuous emissions monitoring systems for gaseous pollutants is a matter that is well-recognized. Procedures and practices are implemented to address this phenomenon. For example, calibration gases have set expiration dates, after which date they should no longer be used.

147. Page 20 (Item 32) Explanation of how ongoing compliance will be demonstrated: "EO Concentration: CEMS unit to be installed in common stack." If there is not a common stack, will the continuous emissions monitoring system (CEMS) be installed in the existing stacks until a common one can be created at the final height?

The construction permit requires the continuous emissions monitoring system to be installed in a new or modified stack for the facility, which stack would be the one exhaust point for the sterilization facility. The CEMS would not be installed in an existing stack.

Parametric Monitoring

148. In no case should Sterigenics be allowed to substitute a parametric monitoring system for the required continuous emissions monitoring system. A parameter monitoring system, which might address a parameter such as pH of the scrubbant, would only indirectly address emissions and should not take the place of an emissions monitor.

"Parametric monitoring" would not take the place of continuous emissions monitoring for the facility. Rather it would serve as a necessary alternative to address any interruptions that might occur in the operation of the continuous emissions monitoring system. In this regard, it would not be appropriate to presume that any continuous emissions monitor system will always be in service, much less a monitoring system that involves an application of a monitoring technology to a new pollutant for which the technology has not historically been used. Regardless, this approach is not at all uncommon even where continuous emissions monitoring is also required.

149. All inputs and outputs of all processes and devices, including the sterilization chambers should be monitored. This includes monitoring for flow rates, concentrations and efficiencies. The monitoring required by the draft permit appears inadequate in that it is too coarse grained and unclear how compliance can be verified, or problems diagnosed.

The construction permit is appropriate as it addresses operational monitoring for the control devices and not process equipment at the facility. The function of the construction permit is to address control of emissions. Moreover, as the permit is based upon and requires continuous emissions monitoring for ethylene oxide, the operational monitoring for the control devices required by the permit is set at an appropriate level. This operational monitoring will not be the primary means to determine the emissions of ethylene oxide. However, it will be sufficient to address operation of the control system during any periods in which the continuous emissions monitoring system is out of service. It should provide ample information to determine whether elevated levels are the result of the failure of a particular control device.

150. At least for the initial year or two of operation, quarterly reporting is not adequate, and reporting should be more frequent.

The timing of reports required by the permit is appropriate, as deviations from applicable requirements are to be promptly reported to the Illinois EPA as they occur. The quarterly reports have a different role, as they require general information related to the operation of the facility.

Modeling and Stack Height

151. What is dispersion modeling and when is it utilized?

Dispersion modeling is the mathematical simulation of how air pollutants disperse in the ambient atmosphere. It is performed with computer models that include algorithms to solve equations that govern pollutant dispersion. The model relies upon inputs, such as stack height, stack emissions, meteorological conditions and topography, to predict ambient concentrations of pollutants from a source.

Charged with restoring, maintaining and enhancing air quality, the Illinois EPA's Bureau of Air engages in compliance, inspection, permitting and air quality planning and monitoring activities, to which end it employs a small number of modelers that support these activities. Most commonly, these modelers perform dispersion modeling or audit dispersion modeling in support of regulatory planning and development, or permitting actions, respectively.

152. How was dispersion modeling utilized relative to Sterigenics?

Relative to Sterigenics, modeling was utilized in support of the enforcement action brought by the Illinois Attorney General's Office and the DuPage County State's Attorney's Office, captioned 2018 CH 001329, and later in this construction permit transaction. In this permitting action, the Illinois EPA audited (performed audit modeling) the dispersion modeling submitted with the permit application by Sterigenics

153. What was the specific purpose for the dispersion modeling in the permitting context?

The dispersion modeling assessed the effects that the suite of enhancements addressed by the construction permit would have on ambient air quality, with an eye toward reducing impacts on the local community. The modeling reflects that at the stack heights contemplated by the permit, ethylene oxide air concentrations at all locations are lowered, thus any risks associated with the commercial sterilization operations are in turn reduced.

154. Was the modeling submitted as part of the permit application required under existing or new requirements under the Environmental Protection Act?

With respect to the permitting action, no modeling was statutorily or regulatorily required. However, given concerns for the toxicity of ethylene oxide, the source was requested to conduct and provide dispersion modeling. This is in addition to the dispersion modeling required under the new law, which is to be performed in the future, using data from emissions testing of the control system after completion of construction, start-up, and testing of the enhancements addressed by the construction permit.

155. Who performed the modeling submitted as part of the permitting action?

The dispersion modeling in the permit application was performed by a consulting group, on behalf of Sterigenics. This modeling was subsequently audited by Agency modelers. This approach was undertaken in the ordinary course and bore no relation to Agency capabilities, but rather was reflective on the obligation of the permit applicant to provide requisite information. While Sterigenics utilized an independent third-party consultant to perform the modeling, whether an applicant utilizes a consultant, and who that might be, is generally not within the Agency's control or decisional process. Moreover, the Agency does not maintain a list of, nor make recommendations, on such. Notably, the dispersion modeling required under the new law must be performed by an independent third party.

156. Does the modeling consider cumulative exposure to ethylene oxide or the results of the IDPH study?

In this permitting action, the dispersion modeling does not account for cumulative exposure to ethylene oxide. It addresses the ethylene oxide emissions from Sterigenics commercial sterilization operations at Willowbrook I. Further, it is addressing the likely emissions impacts of those operations, in the future, after a suite of enhancements have been made. The point of the modeling in the permitting context, at this juncture, is to confirm that the sterilization operations, with the authorized enhancements, will be effective in reducing impacts on ambient air quality to below the levels that USEPA considers acceptable. Modeling of past operational scenarios is not relevant to the Illinois EPA's permitting consideration. Similarly, consideration of the IDPH study is misplaced in the context of the permitting transaction, as it does not bear on how the source will operate prospectively under the Environmental Protection Act.

157. Why does the modeling assume that the source operates 24/7?

The modeling assumes the source operates 24/7 because it is, in fact, the mode of operation.

158. Isn't Sterigenics design value for exit gas velocity of 96.1 high and perhaps not representative of likely actual velocity?

The velocity is an appropriate value.

159. What is the explanation for the 1-kilometer radius in the modeling?

The modeling concentrates on a 1-kilometer radius. This is appropriate based on Agency modeling experience. Also, it is consistent with the federal modeling exercises relative to Sterigenics. Additionally, it is consistent with the relevant factors, such as terrain and the single stack which indicate that the sterilization operations will have a localized impact. Further, the purpose of the modeling is to capture the maximum impact and the maximum impact at the nearest residence from the sterilization operations. Beyond these points of maximum impact, the impacts from the source drop off. As such, modeling a larger radius would serve no relevant purpose.

160. Why did the Illinois EPA rely upon the urban option rather than a rural option in performing its dispersion modeling?

The Illinois EPA relied upon the urban option based on its considered judgement, as well as that of USEPA who recommended the urban option for purposes of, among other reasons, consistency in approach with relevant federal dispersion modeling. More specifically, USEPA's Office of Air Quality Planning and Standards (OAQPS) utilized the Urban mode in its recently released risk analysis, "*Risk Assessment Report for the Sterigenics Facility in Willowbrook, Illinois*" (August 2019). OAQPS assessed various factors available to inform the determination such as near field land use, population exposure per square kilometer, and urban heat island effects. Although land use in the immediate vicinity is suburban and is moderately developed (suggesting rural dispersion), the population density exceeded 750 people per square kilometer in most (at > 750 per km^2 urban mode is recommended) areas near Sterigenics. OAQPS determined that the broader Chicago-Joliet-Naperville urbanized, heat island influence, critical for characterizing night-time conditions and the depth of the boundary layer carried the greatest importance in choosing the use of Urban mode in their risk analysis. Illinois EPA concurred with USEPA's assessment and recommended that the applicant execute the model in urban mode for assessing impacts from the proposed plant improvements.

161. Why is the Illinois EPA not forcing the source to utilize an 87-foot stack?

The Illinois EPA is not in a position to dictate decisions of a unit of local government – in this instance the Village of Willowbrook. As such, the Illinois EPA cannot require the Village of Willowbrook to approve an ordinance allowing the increase in stack height to 87 feet. In turn, in this instance, it cannot require the source to utilize an 87-foot stack. Notwithstanding, it is the considered opinion of the Illinois EPA that 87 feet is an optimal height for an emissions stack at Willowbrook I. To this end, the permit requires Sterigenics to petition the Village for construction or extension of a stack to this height.

162. Is there an alternative to an 87-foot stack?

Yes. In recognition of comments received to the effect that an 87-foot extension is unlikely to receive the requisite Village approval, the Agency's construction permit affords an option for an extension of an existing stack to 50 feet consistent with existing ordinance provisions. Like the 87-foot stack height extension, the 50-foot stack height extension is supported by dispersion modeling submitted by Sterigenics and audited by the Illinois EPA. While not as effective as the taller stack, the 50-foot stack likewise reduces concentrations of ethylene oxide at all locations and thus reduces risks.

163. What is the point of a taller stack?

A taller stack is intended to reduce the impacts of downwash and improve dispersion. The presence of buildings near a stack can affect plume rise and initial dispersion of pollutants

within the atmosphere. The purpose of the stack height increase is to address the possibility of this occurring at Willowbrook I. Specifically, an extended stack would reduce the impacts of building-induced downwash of the plume, which may occur when the stack interacts with the building creating a current or eddy and pulling the plume to the ground, resulting in excessive nearby ambient concentrations. A stack height increase has no effect on the quantity of emissions. Rather, it limits downwash and thereby substantially reduces all ethylene oxide ambient impacts regardless of location.

164. Doesn't a higher stack merely spread the emissions coming out of the stack a greater distance.

No. Contrary to the expressed concerns of some commenters, at the noted stack heights, the ethylene oxide emissions from the commercial sterilization operations do not affect additional areas. Simply put, the footprint remains the same, but the impact in the affected footprint is markedly reduced.

165. Has any modeling information been made available to the public or will it be made available?

The dispersion modeling at the 87-foot height, as well as the audit modeling and an initial Agency technical support document, were made available to the public under the Freedom of Information Act during the pendency of the permitting action. The dispersion modeling at the 50-foot height was an outgrowth of public comment. As such, the modeling, audit modeling and technical support document have only recently been finalized. Consistent with its goal to keep the public informed, along with other information, the modeling and audit modeling, as well as modeling technical support document will be made available to the public upon request.

166. You know full well that your modeling won't work.

The dispersion modeling that has been submitted by Sterigenics, and audited by the Illinois EPA, indicates Sterigenics will not cause a lifetime cancer risk in the surrounding community that is above the 1 chance in 10,000 "upper bound" threshold that is relied upon by the USEPA. After the required improvements, the lifetime cancer risk from Sterigenics ethylene oxide emissions will be much closer to 1 chance in 1,000,000, USEPA's most protective standard. See pages 5 and 6 of Illinois EPA's Dispersion Modeling Memorandum dated September 20, 2019.

167. Will the control requirements be met without an 87-foot stack height? If not, and if the local municipality is not going to authorize an extension of the stack's height, why then does the permit consider the higher stack height as a possibility?

The initial modeling submitted with the permit application and the draft construction permit addressed a stack height of 87 feet, as reflected in draft Condition 4(b)(1). This is because

modeling conducted as part of the design of the improvements identified this as a height for a stack at which dispersion of emissions would not be negatively impacted, to a significant degree, by downwash due to the presence of other structures. However, because stack height is commonly a local prerogative related to zoning and is not something that the Illinois EPA can dictate as part of the construction permit, the Illinois EPA has re-considered the permit condition. The condition will still allow for the optional use of the higher stack height should Sterigenics obtain approval for its construction. However, the condition will now take into account a height for the new stack that is presently allowable under local ordinances.

168. The section in the application addressing dispersion modeling shows the proposed stack at the north-east corner of the building. This stack location does not appear to be 30 feet to the nearest plant boundary as specified in the application on p. 55 (Exhaust Point Information Table).

The Agency can confirm that the information utilized in the dispersion modeling is correct.

169. There are inconsistencies in the dimensions of the stack in the application. On application p. 55 in the Exhaust Point Information Table, the diameter is given as 2 ft. In the modeling information on p. 68, the stack diameter is given as 2.8 ft. This does not appear to be a rounding error.

The Agency can confirm that the information utilized in the dispersion modeling is correct.

170. Because gaseous ethylene oxide has a density greater than the atmosphere (relative gas density of 1.49 compared to 1.0), it will normally sink in the atmosphere over time.

In the atmosphere, ethylene oxide is in solution and, as such, does not sink or settle out due to the effect of gravity.

171. Condition 4(a) addresses a situation where the facility could potentially resume operations without fully increasing the stack height. Is this a way to bypass local control of building code?

This condition merely recognizes that the Village may ultimately approve construction of a taller stack than currently allowed by local ordinances. Such action may not occur until after the initial construction of a new or modified stack is completed.

172. Wouldn't the fan for the new stack need to be sized for the total dimensions?

The additional height of a stack with an extension to its height would not be a significant factor in the sizing of the fan for the stack.

173. Is the maximum stack height allowed without a variance known? If the final stack height is not 87 feet, is the application complete?

Based on comments on the draft permit submitted by the Village of Willowbrook, the maximum height of the stack currently allowed without a variance is now 50 feet. Sterigenics has supplemented the application to address this scenario.

174. The draft construction permit does not specify stack diameter.

It is not necessary for the permit to specify the diameter of the new stack. The effectiveness of the new stack in improving dispersion will be addressed by the dispersion modeling required under the new law, after the initial emission testing is completed, as further required by the new law.

175. In Condition 4(c), there appears to be a 30-day time limit on the operation of existing stacks after the new single stack is put in place, except when adding a stack extension. Does this mean that the old stacks are to remain operable until a final stack height is achieved? What is the time limit? This sounds like an unlimited extension to delay the closure of the old stacks and vents at which no continuous monitoring is occurring. This sounds like an invitation for manipulation.

The construction of the new or modified stack must be completed before the resumption of operation of the facility. The existing stacks and vents must then be sealed within 30 days. After this 30-day period, the existing stacks and vents cannot be used and must be sealed except as reasonably necessary to accommodate an increase in the height of the new stack. In particular, operation of the existing stacks and vents could resume on a temporary basis while an extension is bolted onto the top of the new stack. This is justified because of the long-term benefits for ambient air quality from a taller stack, i.e., better dispersion and lower ambient concentrations of ethylene oxide.

176. How will the continuous emissions monitoring system (CEMS) work if the facility operates with the existing stacks and vents during the period when a stack extension is being installed.

During the period when a stack extension is being installed, the continuous emissions monitoring system would not be used to determine emission of ethylene oxide. Instead, emissions would be determined from operational data, including operational monitoring for control devices and usage of ethylene oxide, and demonstrated control efficiencies. In this situation, operational monitoring data would also be used to confirm that emissions were properly controlled.

177. Condition 10(c)(vi) indicates that a reduction in operation may be warranted during the extension of the stack. What level of reduction would be required? Would a 1 percent reduction be sufficient? Would a greater reduction be appropriate?

During the installation of a stack extension, the construction permit requires that operation of the facility be reduced to the extent that is reasonably practical. This is an appropriate approach to the reduction of operation during an extension of the stack. It is neither appropriate or desirable to specify further requirements, particularly as the period of time that installing a stack extension would take cannot be known until specific plans are developed for, and local approval is provided for, any such extension.

178. How will compliance with the 99.9 percent reduction or 0.2 ppm limit be determined during the period when a stack extension is being installed in this situation? It is my understanding that these limits apply to total emissions, so all emissions need to be added together and examined for compliance?

During the period when a stack extension is being installed, operational monitoring data would also be used to determine whether emissions are properly controlled. The permit does not require that there ever be separate continuous emissions monitoring systems in the existing stacks and vents, only continuous emissions monitoring systems for the new or modified stack.

Risk

179. What ambient air concentrations of ethylene oxide are acceptable?

Ethylene oxide is one of 187 pollutants that Congress has classified as hazardous air pollutants. The Clean Air Act requires the USEPA to regulate hazardous air pollutants by setting limits on the amount of a particular HAP that specified industrial sources can emit. This is in contrast to criteria pollutants for which ambient standards are set that limit the amount of a pollutant that can be in the air.

USEPA acknowledges that exposure to a carcinogen creates some risk. But typically, USEPA has not attempted to address risks on a facility-specific basis if the risks to the most exposed person are under 100 in a million.

The concentration of ethylene oxide associated with a 100 in a million risk, for a lifetime of continuous exposure (For people living near a facility, exposure 24 hours/day, 365 days/year, for 70 years. For people working near a facility, exposure 8.5 hours/day, 5 days/week, 50 weeks/year, 25 years.), is .02 ug/m3. The concentration of ethylene oxide associated with a 1 in a million risk, for a lifetime of continuous exposure, is .0002 ug/m3. Concentrations and associated risks within this range have been deemed acceptable. These risks related to ethylene oxide are in addition to other risks. These calculated risks related to ethylene oxide are general and not specific to any one individual. These risks related to ethylene oxide are likely conservative with what USEPA considers health-protective assumptions.

180. What is risk?

As presented in USEPA's 2014 National Air Toxics Assessment (NATA), risk is defined as the probability that adverse effects to human health or the environment will occur due to a given hazard such as exposure to a toxic chemical or a mixture of toxic chemicals. As a means to quantify risk, it can be measured or estimated in numerical terms like "one chance in a thousand". In NATA, lifetime cancer risk represents the probability of contracting cancer over the course of a 70-year lifetime. A risk level of "N"-in-1 million implies that up to "N" people out of one million equally exposed people may contract cancer if exposed continuously (24 hours per day) to the specific concentration over an assumed 70-year lifetime. This would be in addition to cancer cases that would normally occur in one million unexposed people.

USEPA uses risk calculations as a basis for regulatory determination. Risk calculations are not used as a measure of personal risk for numerous reasons, not the least of which is the inability of determining personal exposure, which is critical in determining risk.

181. What is the estimated risk for the 87 feet and 50 feet scenarios?

In the dispersion modeling submitted by Sterigenics and reviewed by the Illinois EPA to ensure appropriate modeling methods were employed, the maximum 5-year concentrations

were reported for all "receptor" points within 1 kilometer of the facility. Employing the same risk calculation methods utilized by the USEPA's Office of Air Quality Planning and Standards in their August 2019 Risk Assessment for Willowbrook, Illinois EPA calculated the highest lifetime risk predicted by the dispersion model for both stack height scenarios. For the 87-foot stack height, the maximum predicted lifetime risk is 2.8 in a million. For the 50-foot stack height, the maximum predicted lifetime risk is 4.4 in a million.

Ambient Monitoring

182. What is ambient monitoring?

Ambient air monitoring is the systematic assessment of the level of a particular pollutant by measuring the quantity of pollutant in the outdoor air. It can be used to quantify pollution, inform and assess air quality goals and strategies as well as trends, support modeling, and support research among other. Most ambient monitoring is performed by states as part of their required ambient air monitoring networks. Most of this monitoring relates to criteria pollutants – the six pollutants for which national ambient air quality standards exist. Limited monitoring information exists on hazardous air pollutants.

183. What ambient monitoring is required of Sterigenics?

Sterigenics is required to perform ambient monitoring under the new law and under the Consent Order entered by the Office of the Attorney General and the DuPage County State's Attorney's Office. The new law requires that within 180 days after the effective date, Sterigenics shall submit an ambient air monitoring plan for review and approval by the Illinois EPA. This plan shall include, at minimum, a proposal for collection and analysis of ambient air samples for ethylene oxide near plant boundaries and in the community on a quarterly basis over multiple days. The plan shall include a schedule for implementation and identify the name and credentials of the independent third-party company that will perform the sampling and analysis.

The Consent Order requires that Sterigenics conduct ambient air monitoring pursuant to an air monitoring plan submitted to and approved by the Illinois EPA. Such monitoring shall commence no later than 14 days of the date of the Illinois EPA's approval of the stack test results report likewise required under the Consent Order after the conclusion of emissions or stack testing also required under the Consent Order, the construction permit and the new law.

184. The ambient sampling needs to span 24 hours.

Again, the ambient monitoring that is required of Sterigenics under the new law and the Consent Order will be conducted pursuant to an ambient air monitoring plan reviewed and approved by the Illinois EPA. The sampling would likely be in accordance with USEPA method TO15 and the sampling period will be 24 hours.

185. What will the ambient monitoring tell us?

It will tell us the amount of ethylene oxide in the ambient air. It will not directly identify the contributing source or sources of the ethylene oxide. The results of the ambient monitoring conducted by the USEPA after Sterigenics ceased operation pursuant to the Illinois EPA's Seal Order, suggest that Sterigenics is not the sole source of ethylene oxide emissions in the

relevant area. Indeed, one of the federal undertakings currently under way at a national level is an effort to establish urban baselines for ethylene oxide emissions and to better understand the sources that contribute to these baselines.

186. Will the USEPA or the Illinois EPA be undertaking any ambient monitoring.

With the ambient monitoring obligations incumbent on Sterigenics, there appears to be no purpose or need for monitoring by the state or federal regulatory agencies. This is particularly true given that the ambient monitoring activities of Sterigenics will be overseen by the Illinois EPA, who will have the benefit of consultation with the USEPA. This said, it warrants mention that the new law also imposed an obligation upon the Illinois EPA to develop and submit to the Pollution Control Board rules for ambient air testing to be performed by the Illinois EPA to determine the ambient levels of ethylene oxide throughout the state.

187. Ambient levels of ethylene oxide detected by monitors after Sterigenics' facility was shut down showed each of the ten monitors at 50% lower and at 90% lower at monitors closest to the facility. Why is there nothing contained in the construction permit detailing what will happen if ambient levels of ethylene oxide return to levels preceding the shutdown? What will the Illinois EPA do about the problem?

A construction permit contains emissions standards, as well as monitoring, reporting and other requirements that provide an assurance of compliance by the source at the emissions stack(s). A permit document is not suitable for addressing off-site, ambient impacts.

If elevated ambient concentrations of ethylene oxide are monitored, the Illinois EPA will examine the emissions data collected by Sterigenics' CEMs and investigate the facility's operations. If the investigation revealed that Sterigenics' operations was substantially contributing to the elevated levels, the Illinois EPA would evaluate compliance and enforcement options, including referral of the matter to the Attorney General's Office for enforcement under the Environmental Protection Act.

188. Is there a plan to make the ambient monitoring information available to the public?

Yes. The information would necessarily be available to the public under the Freedom of Information Act. However, consistent with its commitments regarding other information addressed in this Responsiveness Summary, the Illinois EPA is committed to making this information available on its web page. Similarly, the Illinois EPA will share the information with its federal partners, particularly the USEPA who may find the information instructive in its efforts relative to ethylene oxide.

189. For the permanent total enclosure, a fenceline ambient air monitoring program should be required to show that facility is indeed containing fugitive emissions as required by Section 9.16(b) of the new law.

Fenceline ambient monitoring would not provide useful information for the maintenance of permanent total enclosure. Ambient monitoring is conducted with evacuated canisters that typically collect a sample of the ambient air for period of at least 24 hours. The canister is then sent to a laboratory for analysis of the ethylene oxide content of the collected sample of air. Ambient monitoring would not provide timely data on an appropriate time period to address the ongoing maintenance of permanent total enclosure for the facility. In addition, fenceline ambient monitors would also measure background concentrations of ethylene oxide in the ambient air.

Historical

190. Is any of the past information regarding the facility such as annual emissions or ethylene oxide purchases and deliveries being considered as part of this permitting transaction.

Historic ethylene oxide deliveries and emissions are not directly relevant. Notwithstanding, the source is required to file and has filed Annual Emissions Reports with the Illinois EPA. These reports indicate that the source has been in compliance with applicable terms of its CAAPP permit. Such reports are available via request under the Freedom of Information Act. Further, the Agency notes that the ethylene oxide usage limits in the draft permit, which have been reduced from those in the CAAPP permit, are relevant to emissions and may be of interest in lieu of the purchase and delivery information.

191. Sterigenics has emitted greater amounts of ethylene oxide that what is allowed.

This comment is an enforcement consideration and not a permitting consideration. Notwithstanding, a review of the facility's Annual Emission Reports does not indicate that the source has exceeded its permit allowable limits.

192. The source has not acknowledged or accepted responsibility for its emissions.

The permitting process under the Act is distinct from the enforcement program, which is where the concerns raised by the comments should be addressed. The permitting of stationary sources to construct or operate emission sources is not tied to the legal considerations of whether a source should admit to violations or be made to account for allegations of past wrong-doing. With limited exceptions, the permitting process focuses on whether an applicant can show that its emission-related activities will prospectively comply with applicable air pollution requirements under the Act. It can be noted that courts reviewing permitting decisions by the Illinois EPA have frequently observed that permitting is no substitute for enforcement.[4] This means that issues relating to past non-compliance are usually best left to the Illinois EPA's enforcement program or to other prosecutorial authorities.

193. Past violations by the company should result in a permit denial.

Similar to the response above, allegations of past violations are generally not an appropriate basis for a permit denial, as permitting is not an appropriate substitute for an enforcement

[4] ***See,*** **ESG Watts v. Pollution Control Board, 286 Ill. App.3d 325, 335 (court acknowledging general recognition that it is improper for Illinois EPA to consider unadjudicated violations under Section 39(i)); Illinois EPA v. Pollution Control Board, 252 Ill. App.3d 828, 830 (3rd Dist. App. Ct., 1993)(appellate court affirming that "procedures for permit denial and enforcement of the Act are separate and distinct" and that Board did not error in "inference that the Agency improperly used the permit denial process as a substitute for the enforcement process").**

action. This is especially true in the present context, where the applicant is seeking a construction permit that will authorize it to make improvements to its facility or equipment so as to comply with the new law.

However, there are at least three limited exceptions to this general rule for permitting actions by the Illinois EPA that are set forth in Section 39(a) and (i) of the Act.[5] Section 39(a) is the relevant authority for this permit action, and it allows the Illinois EPA to consider an applicant's noncompliance that involves a contaminant's release to the environment. This language does not constrain the Illinois EPA's consideration to a single mode of action, meaning that such grounds could support the imposition of conditions for an issued permit or, alternatively, the denial of the permit. However, the language makes clear that the noncompliance cannot be merely alleged but must involve "prior adjudications[6]."

Section 39(a) was later amended to allow the Illinois EPA discretion to include terms to a permit relating to an applicant's "past compliance history" as may be warranted to remediate or prevent noncompliance. As compared to the language that appears in the older text, the amendment authorizes the Illinois EPA's consideration of an applicant's past noncompliance in issuing permits but does not authorize a permit denial. Additionally, the language is not confined to cases involving a release of a contaminant, thus applying to a broader set of circumstances involving noncompliance under the Act. However, the language is necessarily limited to adjudications and not mere allegations.[7]

In light of the statutory requirements concerning the Illinois EPA's scope of permit review, it must also be noted that the Consent Order entered by Sterigenics, the Attorney General's Office and the DuPage County State's Attorney's Office, as approved by the DuPage County Circuit Court on September 6, 2019, specifically allows for the use of the Consent Order in any subsequent permit proceeding authorized by Section 39 of the Act. *See,* Section II(1) of Consent Order. In this instance, the Illinois EPA will decline to deny Sterigenics' application for construction permit on the basis of this authority.

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[5] In addition to Section 39(a), Section 39(i) vests the Illinois EPA with authority under its implementation of the Resource Conservation and Recovery Act, 42 U.S.C. §§6901 et seq., to consider the prospective owner's or operator's history of repeated violations of federal, state or local laws concerning the operation of waste management facilities, or clean construction and demolition debris fill operation facilities. 415 ILCS 5/39(i)(1).

[6] An adjudication is an enforcement case whose merits are resolved through a formal ruling by a circuit court or the Pollution Control Board.

[7] This is because the phrase "past compliance history" is generally synonymous with past noncompliance, and such a constraint was likely intended by the General Assembly in both passages of the Act's licensing scheme to prevent infringement upon constitutionally protected interests. See, Martell v. Mauzy, 511 F. Supp. 729 (N.D. Ill., 1981)(court recognizing that once the broad enforcement powers of the Environmental Protection Act are employed to "punish violative conduct," there is a "clearly established and adjudicated basis for the denial of future permits…").

This decision recognizes that all the parties to the Consent Order, having negotiated in good faith and agreed to its making, indisputably contemplated that Sterigenics would pursue future efforts to assure that its ethylene oxide sterilization source will comply with the provisions of the Matt Haller Act and such other applicable requirements of the Environmental Protection Act and the Pollution Control Board's regulations. A denial of the permit application by the State of Illinois, through the Illinois EPA acting in its permitting capacity, would effectively negate many of the Consent Order's compliance terms and, indeed, would render superfluous the Matt Haller Act's specifically-delineated provisions tailored to Sterigenics' operations.

194. The source has been a "bad actor" and should not be permitted to operate its facility.

The Illinois EPA appreciates that this comment reflects a commonly-held view, as expressed by attendees of the public meeting and in comments submitted during the public comment period. However, the legal standard governing the Illinois EPA's review of application materials under the Act generally does not look to the past. As previously mentioned, the permitting process under the Environmental Protection Act usually focuses on the prospective ability of an applicant to comply with applicable requirements.

Leaks and Spills

195. How many leaks or spills are expected?

Leaks and spills are under the purview of the Illinois EPA's Bureau of Land. Measures are in place to prevent leaks and spills. Any leaks or spills would be addressed by the Illinois EPA as necessary and appropriate.

196. In the event there are leaks or spills, what is the recourse?

To the extent a leak or spill falls within the purview of the Illinois EPA, and to the extent it is a violation of the Environmental Protection Act or provisions thereunder, there is a clear statutory path for addressing the leak of spill. Specifically, the Environmental Protection Act provides several tools to the Agency under Title VIII Enforcement and Title XII Penalties.

197. Sterigenics has a well-documented history of spills.

The Illinois EPA is aware of two ethylene glycol spills from the Willowbrook facility occurring in October 2013 and September 2018. The 2013 spill was investigated by the Illinois EPA, referred for enforcement to the Attorney General's Office and settled by way of a consent order that was approved by the DuPage County Circuit Court in September 2015. A copy of the consent order is available at https://www2.illinois.gov/epa/topics/community-relations/sites/sterigenics/Documents/Sterigenics%20Consent%20Order%202015.pdf. The 2018 spill was investigated by the Illinois EPA and referred for enforcement to the Attorney General's Office.

Third Party

198. The company should not be allowed to conduct self-modeling, self-monitoring, self-testing and self-reporting as it relates to its emission-related activities. Independent third parties should perform these tasks.

The Illinois EPA does not possess the requisite legal authority under the Environmental Protection Act to perform, or to fund through a third party, these types of activities. In addition, the self-monitoring is an inherent aspect of the air pollution control program because the obligation for compliance is on the sources of emissions. As discussed above, the Illinois EPA's consideration of someone's past compliance history in a permit review is narrowly constrained and does not include the discretion to compel an independent third party to perform activities that are normally reserved to a permittee. From a programmatic perspective, advances in the development of current continuous emission monitoring systems no longer pose the general concerns, as reflected by the comment, regarding the reliability of emissions information that is generated, recorded and reported by a regulated entity. Notwithstanding, the source did not conduct the modeling it submitted but rather retained a third-party to perform such. Further, consistent with the new law, the source will not be performing emissions testing or monitoring itself, but rather is obligated to retain an "independent third-party company".

199. Testing companies should not be selected by Sterigenics, rather Illinois EPA and the Village of Willowbrook should make the selections.

The Illinois EPA does not possess the requisite legal authority to compel this type of requirement. In this context, the Act also does not provide such authority to local representatives. A selection process by someone other than Sterigenics would also call into question the data and work that is collected and performed by such contractors and the ability to hold Sterigenics accountable for such data.

200. Condition 8-2(b) the terms "qualified" "independent" and "experienced" need to be defined.

These terms do not need to be defined because the common meanings of these terms are used. For example, "qualified" means having the necessary qualities and being fit and competent.

Communications

201. What communications did Illinois EPA have with Sterigenics?

In addition to this construction permitting action, the Bureau of Air was also involved in an enforcement action (referred to the Office of the Attorney General on October 2, 2018) filed against the source by the Office of the Attorney General and the DuPage County State's Attorney's Office on October 30, 2018, and a seal order effectuated by the Director of the Illinois EPA on February 15, 2019. Litigation ensued relative to the enforcement action and the seal order, in which the Illinois EPA was represented by the Office of the Attorney General. The Illinois EPA was not involved in a single conversation with Sterigenics that did not involve counsel for the State, as well as for Sterigenics. Further, the conversations were directly related to the subject matter of the litigation.

Regarding the construction permitting action, the Illinois EPA had its first conversation with Sterigenics regarding the application for construction permit on May 17, 2019. This meeting was with the knowledge and agreement of respective counsel for the parties. Additionally, at the request of the Office of the Attorney General, Sterigenics provided an agenda for the meeting to confirm the topics to be covered during the meeting. The meeting was pre-applicational for the construction permit and such meetings are commonplace for permit applicants. The application for construction permit was submitted to the Illinois EPA on June 24, 2019, with periodic exchanges between the applicant and permitting authority in the ordinary course. Notably, at the time of the pre-application meeting with Sterigenics, the Illinois EPA had already received an application for construction permit from Medline, and had been working with Medline on this permitting transaction for many months.

202. When did discussions between the Illinois EPA or the Attorney General and Sterigenics start relating to the settlement of lifting the seal order?

The possibility of resolving the seal order litigation through settlement was initially raised in a phone call between Sterigenics' attorneys and the Attorney General's Office on February 22, 2019, two days after a federal court judge denied Sterigenics' motion for a temporary restraining order. The first settlement meeting concerning the same was held on March 6, 2019. The Illinois EPA had no communications with Sterigenics regarding this matter outside the presence of the Attorney General's Office.

203. The Illinois EPA owes it to the people of Illinois to be transparent in its decision-making. Why did the Agency work with Sterigenics under a veil of secrecy to negotiate the terms?

The Illinois EPA agrees that its decision-making in this matter must be transparent, particularly with respect to being open and honest about who an agency is meeting or conversing with about a particular subject matter. Transparency in governmental actions is usually focused on decision-making, not the deliberative process when decisions are pending. Documents generated from a given decision-making process are subject to FOIA. And, in this

particular case, the Illinois EPA prepared a draft construction permit, and convened a public comment period and public meeting, to facilitate transparency and inform its final decision.

The fact that conference calls or meetings between Bureau of Air Permits Section staff and a permit applicant occur during the development of a permit is not improper and does not diminish transparency with respect to either process or decision-making. The Bureau of Air/Permits Section arranges phone calls and meetings with thousands of permit applicants each year. The permit program could not be administered without conferring one-on-one with permit applicants, as it would be impossible to convene open meetings or hearings every time the agency and applicant confer.

Process

204. The Illinois EPA should have held a public hearing rather than a public meeting.

Recognizing the significant public interest in the permitting action and based on communications with elected officials, the Illinois EPA scheduled a public meeting at the Ashton Place in Willowbrook, Illinois on the evening of August 1, 2019, to allow the public to comment about the draft construction permit.

In lieu of a hearing, the Illinois EPA borrowed from a historical practice of offering the public the opportunity to meet with Illinois EPA officials in advance of the permitting of controversial projects. To ensure that the public and elected officials benefited from an orderly process that guaranteed the right of public comment, and of agency responsiveness to those comments, the Illinois EPA made use of the hallmarks of a traditional informational hearing for the occasion. This approach included the following: public notice of the meeting that was distributed on the agency's website, and forwarded to numerous elected officials, notice of a 30-day public comment period and notice of a draft construction permit that was prepared by the BOA/Permits Section; convening of a panel of Illinois EPA staff to address questions at the meeting, including the manager of the BOA/Permits Section's construction unit group, a testing engineer from BOA/Compliance Section, and both a Hearing Officer and a Community Relations Coordinator from the Office of Community Relations; transcribing of the hearing by a court reporter; and the preparation by the Illinois EPA of a Responsiveness Summary to address all significant public comments and/or questions raised at the public meeting and during the comment period. When these added features are considered, the meeting that was held was tantamount to an informational hearing.

205. I believe that Sterigenics should have been required to attend the public meeting and should have been subject to cross-examination.

Permit procedures that are implemented by the Illinois EPA currently allow, but do not compel, a permit applicant to attend or participate in an information hearing. The same would be true for a meeting held in lieu of a hearing. This is because the focus of any hearing or meeting is the agency action approving or denying a permit. In this regard, the permitting process, administered by the Illinois EPA under the Illinois Environmental Protection Act for construction and operation of emission units or control equipment, is guided by applicable environmental laws and rules. If an applicant submits proof that the emission units or control equipment will achieve compliance, the permit must be granted.

Contested case hearings, 2 IAC 166.260 and 166.265, are not applicable to permitting actions by the Illinois EPA under the Illinois Environmental Protection Act, as they are subject to administrative review by the Illinois Pollution Control Board. Current procedures for informational hearings by the Illinois EPA do not allow for cross-examination of witnesses.

Alternatives to Sterilization

206. Why is the Illinois EPA allowing the use of sterilization at the Willowbrook facility when alternatives exist?

According to information available on the FDA web page, medical devices are sterilized in a variety of ways including using ethylene oxide sterilization. For many medical devices, this may be the sole method that effectively sterilizes and does not damage the devices. The FDA is working to advance innovative ways to sterilize with lower quantities of currently used sterilants as well as to sterilize through alternative means. The FDA has also worked with medical device manufacturers to mitigate sterilized medical equipment supply issues.

There is no ban on the use of ethylene oxide in Illinois. As such, in acting on the construction permit application from Sterigenics, the Illinois EPA had no basis to preclude usage of ethylene oxide provided the commercial sterilization operations will be constructed and operated so as not to cause a violation of the Illinois Environmental Protection Act.

207. Are products unnecessarily being sterilized with ethylene oxide at the Willowbrook facility?

Generally speaking, the Illinois EPA regulates the emissions units and emissions from the Willowbrook facility. However, as addressed elsewhere herein, Sterigenics will need to comply with the supplier product certifications requirements under Section 9.16 of the Act.

208. Why is Sterigenics still utilizing ethylene oxide to sterilize medical products when hospitals have ceased the practice?

Hospitals have not completely ceased their reliance on sterilization with ethylene oxide. Indeed, according to Illinois EPA records, there are approximately 20 hospitals that still operate ethylene oxide sterilizers. Further, for those hospitals that have ceased ethylene oxide sterilization operations, available information does not support the conclusion that they have ceased their reliance on medical goods and products that are sterilized with ethylene oxide. It is more likely that they have increased their reliance on products that have already been sterilized. Indeed, as noted elsewhere herein, the FDA acknowledges that sterilization has not yet evolved to the place where reliance on ethylene oxide is unnecessary or obsolete.

209. Why didn't Illinois EPA require Sterigenics to address alternatives to sterilization with ethylene oxide in its application?

As discussed elsewhere herein, the Illinois Environmental Protection Act and regulations thereunder address applications for construction permits, including the content of applications for construction permits and the attendant review process. The application and ultimately any construction permit would necessarily relate to emissions units or air pollution

control equipment, the emissions therefrom, applicable environmental laws and regulations and compliance therewith. Given this, apart from the obligation under the new Section 9.16 of the Act regarding supplier certifications, which requirement is separately addressed in this Responsiveness Summary, information regarding sterilization alternatives is not directly relevant to the permitting process and thus not addressed in the permit.

210. Does the permit allow the use of sterilants other than ethylene oxide or propylene oxide?

The application for construction permit and the construction permit itself, as well as previously issued operating permits, solely address the use of ethylene oxide and propylene oxide in the sterilization process. The source has not sought to use other sterilants nor has the Agency granted authorization to use other sterilants.

Ban

211. The Illinois EPA should ban the use of ethylene oxide, or either deny the application or close the facility

There exists no ban on the use or emission of ethylene oxide in Illinois. The Illinois EPA does not possess the requisite authority to ban the use of ethylene oxide by Sterigenics or other sources in Illinois. The Illinois EPA cannot deny the permit application or force a shut-down of the facility because of the use of ethylene oxide. The Illinois EPA's current authority for denial of the permit application or forcing the closure of the facility is governed by existing permitting and enforcement requirements of the Act, as described elsewhere in these responses.

212. Why are there no "rules" in place that prohibit or disallow the use of ethylene oxide near schools or parks?

A ban or other type of restriction on the use of a product is, in the first instance, the province of the General Assembly and not an administrative agency such as the Illinois EPA. Indeed, in the new law, the General Assembly has recently taken a step in this comment's direction, establishing location requirements for any new sterilizing or fumigant facility using ethylene oxide that was not in existence prior to January 1, 2020, and that requires a CAAPP permit. *See,* 415 ILCS 5/9.16(i).

Zoning

213. The Illinois EPA should establish the physical location of the source, such that the sterilizing processes using ethylene oxide are moved somewhere other than Willowbrook or to an unpopulated area.

The state's Environmental Protection Act does not vest the Illinois EPA with the requisite legal authority to act as a state-wide zoning authority.

214. Why can't the Illinois EPA mandate that Sterigenics' employees live within 5-10 miles of the source?

State laws and regulations concerning environmental protection generally address sources of pollution and not ancillary issues related to the residency of employees.

215. If ethylene oxide must be used to sterilize a specific medical device, companies who do not have a past history of violations should be used, provided that they are manufactured in non-residential areas. Sterigenics should not be allowed to resume operations in a highly-populated area.

The new law does not affect the location of existing sterilization sources in Illinois, though it does provide certain set-back requirements for new CAAPP sources. *See,* 415 ILCS 5/9.16(i). The Illinois EPA is lacking any other authority under the Environmental Protection Act to compel Sterigenics to re-locate.

As mentioned elsewhere, Sterigenics is obligated to comply with the certification requirements of Section 9.16(g) because they had been previously subject to a seal order.

Miscellaneous Comments or Questions

216. Rather than consider the issuance of construction permit allowing the source to reopen, why not fine them millions of dollars and require a healthcare fund for those in the community who have suffered from illness and respiratory disease.

A permit proceeding is not the appropriate venue for a civil penalty, and imposing penalties through the permit would be an unauthorized attempt to circumvent the Environmental Protection Act's enforcement process. A healthcare fund is likewise something for which the Illinois EPA does not possess the legal authority to establish in a construction or operating permit.

217. Article XI of the Illinois Constitution generally provides that every person has a right to a healthful environment that is enforceable through "appropriate legal proceedings subject to reasonable limitation and regulation as the General Assembly may provide by law." If Sterigenics is allowed to reopen, the Illinois EPA will be the subject of a lawsuit for violating the local communities' rights under this provision.

The right under the Illinois Constitution to a healthful environment is generally enforceable but subject to the General Assembly's right to prescribe reasonable limits or requirements. The constitutional right to a healthful environment was designed to remove a special injury requirement for standing, not to create an independent cause of action. *See,* People v. Pollution Control Board, 129 Ill.App.3d 958, 964 (Ill. 1985). Because the General Assembly has exercised its power to regulate environmental enforcement under the Environmental Protection Act, the right to a healthful environment under the Constitution is merely commensurate with the broad enforcement rights available under the Act. In addition, Illinois courts generally recognize that the Environmental Protection Act's enforcement provisions are intended for prosecuting polluters, not the Illinois EPA. *See,* Landfill, Inc., v. Pollution Control Board, 74 Ill.2d 541, 556 (Ill. 1978).

218. Why did you not consider the Precautionary Principle in your permit decision?

The Precautionary Principle is a strategy to address possible risks where scientific understanding may not yet be complete. As has been stated throughout this Responsiveness Summary, the Illinois Environmental Protect Act and regulations thereunder establish the review process for permitting actions. Consideration of this Principle is not part of this process. Notwithstanding, under the Illinois Environmental Protection Act, and as addressed more specifically herein, the Illinois EPA has assessed the emissions implications of Sterigenics' commercial sterilization operations and determined that construction and operation with the enhancements addressed under the construction permit, would not cause any violation of the Act.

219. Why did you not consider the Rio Declaration of 1992 in your permit decision?

The Rio Declaration of 1992 defines sustainable development and implementation and environmental preservation. It stresses citizen participation in policy development. As has been stated throughout this Responsiveness Summary, the Illinois Environmental Protect Act and regulations thereunder establish the review process for permitting actions. Consideration of this Declaration is not part of this process. Notwithstanding, the Illinois Environmental Protection Act, under which the relevant permitting action is issued, has as one of its several purposes "to restore, maintain and enhance the purity of the air of in Illinois in order to protect health, welfare, property, and the quality of life and to assure that no air contaminants are discharged into the atmosphere without being given the degree of treatment or control necessary to prevent pollution." The issued construction permit is consistent with this purpose. Also, the permitting action furthered the goals of public participation, as the permit was subject to notice and comment and a public meeting.

220. Were costs considered in the permit action?

Costs were not considered in this permitting determination. Nor do costs appear to have been a consideration under the new law. Specifically, among other things, the new law prohibits the source from using ethylene oxide for commercial sterilization purposes "unless the Illinois EPA has certified that the facility's emission control system uses technology that produces the greatest reduction in ethylene oxide emissions currently available."

221. Have private wells been tested at and near this facility?

In response to concerns of residents and local officials in Willowbrook and the surrounding area, in December 2018, the Illinois EPA and DuPage County Health Department coordinated efforts to identify private wells, obtain access from homeowners, and sample private wells near the Sterigenics facility for ethylene glycol and ethylene oxide. No contamination was found in any of the sampled wells.

This action was taken out of an abundance of caution as no groundwater contamination and thus no private well contamination was expected. More than 55 samples were taken from residences where Illinois EPA obtained access agreements.

222. Sterigenics has caused property values to decline and the permit should be denied.

Under the Environmental Protection Act, the Illinois EPA is required to issue a permit to an applicant upon proof that the proposed facility or equipment will not cause a violation of the Act or promulgated regulations. Property values are not reflected in the Act and to not therefore serve as a basis for denial.

223. There is an assumption that the controls that are used for emissions of ethylene oxide will be also appropriate for propylene oxide. This claim should have verification documents with testing performed on the control unit models by the manufacturer to show that

reduction levels for propylene oxide are substantially similar to reduction for ethylene oxide.

Sterigenics last used propylene oxide several years before the Seal Order was issued in February 2019 and it is uncertain whether propylene oxide will ever be used at the facility in the future. Section 9.16 of the new law does not contain requirements related to emissions of propylene oxide. Regardless, based on the similar chemical structures of propylene oxide and ethylene oxide, control devices for ethylene oxide will also control propylene oxide.

224. Since propylene oxide is listed as a hazardous air pollutant under the Clean Air Act, any permit that provides for usage of propylene oxide should include verifications for the appropriateness of any equipment specifically for propylene oxide. There should also be testing required to demonstrate that propylene oxide is being controlled at the expected efficiencies and levels. If these are not included in testing and control requirements, propylene oxide usage should not be permitted at the facility at all.

As discussed, Sterigenics will be enhancing the control measures at the facility for emissions of ethylene oxide. A secondary consequence of improved control measures would be reduction in emissions of propylene oxide if propylene oxide were used in the future at the facility.

225. Ethylene chlorohydrin sometimes gets formed during the ethylene oxide sterilization process. Would this compound be controlled?

Ethylene chlorohydrin is a liquid that may be formed during ethylene oxide sterilization. It has not been identified as a concern for the sterilization process. The presence of this compound on the surface of sterilized items, if any, is a matter that is addressed for the usage of the items.

226. Redundant communication links and power supplies should be required so there is no data loss.

The source has redundant power supplies from Commonwealth Edison designed to prevent loss of power at the plant.

227. Provide the names and positions of IEPA staff that will be making the decision regarding the draft Sterigenics construction permit (who is tasked with approving or denying it).

Any construction permit would be signed by Mr. Ray Pilapil, Manager of the Permit Section in the Bureau of Air, or his designee, Mr. Christopher Romaine, Manager of the Construction Permit Section in the Bureau of Air.

228. Who were the Illinois EPA staff at the public meeting on the draft construction permit and what are their credentials?

The Illinois EPA employees on the panel at the public meeting were, Chris Romaine, Manager of the Construction Permit Unit in the Bureau of Air; Kevin Mattison, stack test specialist in the Bureau of Air; Brad Frost, Manager of the Office of Community Relations; and Dean Studer, Agency Hearing Officer.

Attachment 1: Listing of Significant Changes Between the Draft Construction Permit and the Issued Construction Permit

Condition 1(c)

In the draft construction permit, this condition addressed the certification requested by Sterigenics with respect to Section 9.16(g) and stated that the Illinois EPA has determined that, with improvements to the control system addressed by the permit, the criteria for this certification would be met, i.e., "…the facility's emission control system would use technology that produces the greatest reduction in ethylene oxide emissions currently available." In the issued permit, Condition 1(c) is revised. The revised condition will recognize that the Illinois EPA, separate and apart from the permit, is certifying that with the permanent total enclosure and improvements to the emission control system addressed in Condition 1(b)(ii), the emission control system at the facility would use technology that meets the criterion in Section 9.16(g).

Condition 2-3(a)

This condition explicitly recognizes that this construction permit does not affect the provisions of the relevant legal order that also applies to this facility. For this purpose, this condition in the draft permit referred to the Seal Order as it was the order that was in effect at the time that the draft permit was distributed for public review. In the issued permit, this condition refers to the Consent Order. This is because the Seal Order is no longer in effect, having been replaced by the Consent Order.

Condition 4

This condition addresses the changes that would be made to the facility to have a single exhaust point. In the draft permit, this condition only addressed the construction of a new, taller stack. In the issued construction permit, this condition also addresses the possibility that these changes may involve modification of an existing stack. The changes to this condition are a response to comments that indicate the height of the new stack is now restricted by a new local ordinance. Accordingly, changes to an existing stack may be more effective in improving dispersion and reducing impacts on ambient air quality in Willowbrook and neighboring communities.

Condition 7-1(a)

In the issued construction permit, this condition, which addresses the required continuous emissions monitoring system for ethylene oxide, provides that this system shall be designed and operated to achieve a limit of limit of quantification of no more than 20 parts per billion by volume (ppbv). This corrects an omission in the draft permit that was identified in comments. The value that is specified is 10 percent of the limit that would apply for the concentration of ethylene oxide emissions, 0.2 ppmv.

Condition 7-2(a)(ii)

In the issued construction permit, this condition, which addresses the required operational monitoring for the permanent total enclosure, provides that this system shall be designed to provide measurements of pressure differential to at least the nearest 0.001 inches of water. This corrects an omission in the draft permit that was identified in comments. The specified value is about 15 percent of the required minimum pressure differential, 0.007 inches of water.

Condition 7-2(c)(a)(i)(A) and (F)

These conditions address the areas in which continuous operational monitoring devices for the permanent total enclosure are required to be located. In the issued construction permit, two devices are required for the work aisle, one at the west end and one at the east end. The draft permit would have required three devices (west, central and east). However, it would have also provided that a monitoring device was not required at the east end of the work aisle if the sterilization chambers served by that portion of the work aisle were not in use. The issued permit also provides that a monitoring device must be located in the area in which sterilized material is loaded out from the facility. The draft permit would not have required a monitoring device in this area. These changes respond to comments on the areas at the facility where pressure differential monitoring would be required. These comments requested that monitoring always be required at the east end of the work aisle and that monitoring also be required for the area in which sterilized material is loaded out from the facility.

Condition 9(b)

This condition addresses a log or other records that are required for the emission control devices. In the issued construction permit, this condition requires that Sterigenics keep records to identify periods, if any, when the requirements of Condition 3(c) for use control devices were not fulfilled. That is, periods when a particular operation or activity takes place at the facility and the control system for that operation or activity is not also being operated. In the draft permit, these records would only have been required for the scrubbers. In addition, the draft condition incorrectly referred to conditions that were not in the draft permit. These changes respond to comments requesting additional clarity in the permit as to the when the control devices at the facility must be operated, as well as a comment addressing the incorrect references in the draft condition.

Condition 9(c)(ii)

This new condition in the issued construction permit requires recordkeeping for the amount of sorbent for the dry bed absorption devices that is in inventory at the facility. This new condition responds to comments that expressed concern that an adequate supply of fresh sorbent should be kept at the facility. Otherwise, the replacement of sorbent in the dry bed absorption devices could be delayed because of a lack of fresh sorbent.

Condition 9(e)

This new condition in the issued construction permit addresses the documentation that Sterigenics keeps for ethylene oxide drums at the facility, both full and empty, prior to placing these drums in the drum storage area. This documentation addresses the inspections of these drums that are conducted to confirm that the drums are sealed. This new condition provides that, as inspection of drums for leakage is addressed, this documentation shall be considered to be records required by this permit. This new condition responds to comments that requested measures be required to ensure that ethylene oxide does not leak from drums in the drum storage area.

Condition 10(a)

This condition addresses the information that must be included in the quarterly reports that Sterigenics must submitted to the Illinois EPA for the facility. In the issued construction permit, more information is required to be included in these reports. In addition to information for monthly emissions and the results of emissions testing, these reports must now also include specific information for any changes that were made to the continuous emissions monitoring to improve the limit of quantification, a summary of the results of the ambient air monitoring for the previous quarter, and a summary for deviations during the quarter, if any. (Notification or reporting for deviations is separately required by the permit with such reports to be submitted within five days of an event.) In addition, the final quarterly for each year must include emission information for the year and information for usage of ethylene oxide for the year. These additions to the required contents of the quarterly reports respond to comments that requested that more information be required to be supplied in these reports.

Condition 12

This new condition in the issued construction permit addresses the operation of the facility with the improvements provided for by the construction permit. It provides that, until an operating permit is issued for affected facility that provides for operation of the improvements to control measures addressed by this constructtion permit, Sterigenics may operate the facility with these improvements pursuant to this construction permit provided that the facility is otherwise allowed to operate. This condition is included in the construction permit to address the roles of this construction permit and the existing operating permit for the facility for the operation of the facility. It responds to comments that sought reassurance that the facility is not allowed to resume operation based simply on the issuance of this construction permit or the existing operating permit. This is not the case because relevant requirements of the new law and the Consent Order must be fulfilled before any resumption of operation.