White Paper

Guaranteeing Subpart-O EtO SWEL1 and SWEL2 Compliance[1] with LESNI EO CAPs and Picarro CEMS

PICARRO

LESNI®
The Air Purification People

Figure 1: *LESNI EO Catalytic Abatement Plant (EO CAP), with Picarro Continuous Emissions Monitoring System (CEMS) inset.*

SUMMARY

In early 2024, before the release of the final “Commercial Sterilizer NESHAP” (40 CFR Pt 63, Subpart-O), Picarro and LESNI published a first collaborative white paper demonstrating conservatively that LESNI EO Catalytic Abatement Plants could deliver at least 99.991% ethylene oxide (EtO, EO) destruction removal efficiency (DRE) based on “In vs Out” data taken at a US-based commercial sterilizer. In the year since that paper was released, Subpart-O has been published, with clear DRE limits set even higher than the original values proposed in the draft, and with language providing specifics on reporting methodologies. Since then, Picarro has commissioned a significant number of Subpart-O compliant EtO CEMS and has performed site-wide emission limit (SWEL) DRE analysis on many more LESNI EO CAPs using the final Subpart-O methodologies. These efforts tested both SWEL1 (determined relative to EtO pounds used) and SWEL2 (determined by blended stream-specific DREs) compliance pathways and found that LESNI EO CAPs can comfortably achieve one and often two orders of magnitude improvements upon the required DRE, with stack EtO concentrations typically averaging below 5 ppb.

In this second white paper, we first detail significant technological features in LESNI EO CAP and Picarro CEMS that simplify and consolidate compliance reporting, and which provide proactive and often automated DRE calculations and alarming along with a color-coded alert system. We then show fully-calculated SWEL compliance results from two facilities in the US: Facility A, complying by SWEL1, and Facility B, complying by SWEL2. Both have LESNI EO CAPs, while Facility B also employs dry beds for Group 2 abatement. **We show that both facilities are able to comfortably achieve SWEL compliance, with actual emissions that are 15x (SWEL1) and 14x (SWEL2) lower, respectively, than their required limitations. The LESNI EO CAPs at these facilities have average EtO outlet concentrations below 2 ppb, resulting in remarkable 99.99934% and 99.99948% DREs, respectively, about 15x and 20x better than the most stringent DRE requirements of the Subpart-O NESHAP.**

[1] See details of guarantee on page 2

We further show that, despite Picarro data that proves compliance at Facility B, recent stack test data from an OE-FTIR suggests that a theoretical OE-FTIR *CEMS* would report stack EtO emissions about 22x higher than truth, erroneously leading to perceived emissions at 156% of compliance limits.

By presenting these Subpart-O equations using real-world data from operating commercial sterilizer facilities, we hope to give existing and future customers a clear sense for just how well LESNI and Picarro solutions perform. When facilities considering LESNI EO CAP and Picarro CEMS place their orders, we want them to do so with the peace of mind that these technologies will easily bring about, and continually demonstrate, emissions compliance. In fact, we are pleased to announce that properly maintained LESNI EO CAPs equipped with Picarro CEMS can be guaranteed[1] to comfortably meet the 2024 Subpart-O NESHAP Site-Wide Emissions Limitations for both SWEL1 and SWEL2.

INTRODUCTION

Ethylene Oxide ("EtO", "EO") is widely considered to be the most effective and adaptable way of sterilizing medical equipment, and is used to sterilize more than half of the medical devices in the United States each year—conservatively at least 20 billion devices based on a 2017 study.[2] The US EPA performed a reassessment of the risk associated with exposure to EtO through its IRIS (Integrated Risk Information System) program in 2016[3], finding that the cancer risk associated with EtO was high even at very low lifetime exposure rates. After this finding, and amidst increasing scrutiny from community groups, EPA moved to significantly reduce fugitive emissions and worker exposure at facilities using or producing EtO. It did so through revisions to the Subpart-O NESHAP[4] (which limits commercial sterilizer emissions), the HON rule[5] (which limits fenceline concentrations for large industrial sites using or producing EtO), and the FIFRA rule[6] (for sterilizers and other facilities where workers might be exposed to EtO).

The Subpart-O NESHAP established site-wide emissions limitations (SWELs) in lbs/year—determined as a function of EtO used annually, and/or using specific destruction removal efficiencies by process stream—as the principal compliance mechanism for proving compliance with emissions reductions goals. These DREs are noted and differentiated in the table below, which reproduces and slightly clarifies the contents of Subpart-O Table 6.

[1] Performance Guarantee: To achieve the guaranteed 99.99+% Destruction Removal Efficiency (DRE) with LESNI's EtO Catalytic Abatement System, it is imperative that customers adhere to the specified operational requirements. These include maintaining consistent EtO inlet concentrations at 50% or above the operating capacity within daily and 30-day rolling sum EtO mass loads along with implementing robust monitoring and reporting solutions such as those offered by Picarro. Deviations from these operational parameters may result in reduced efficiency and non-compliance with regulatory standards. Picarro and LESNI can also only guarantee successful compliance associated with their equipment, and cannot certify that other technologies used for abatement as part of a blended SWEL will always meet their DRE requirements.

[2] Gamma Industry Processing Alliance White Paper: https://gipalliance.net/wp-content/uploads/2013/01/GIPA-WP-GIPA-iia-Sterilization-Modalities-FINAL-Version-2017-October-308772.pdf

[3] IRIS for EtO CASRN 75-21-8, December 2016, https://iris.epa.gov/ChemicalLanding/&substance_nmbr=1025

[4] 40 CFR 63, Supbart-O: https://www.ecfr.gov/current/title-40/chapter-I/subchapter-C/part-63/subpart-O

[5] Hazardous Organics NESHAP: https://www.epa.gov/system/files/documents/2024-04/san9327_hon_pr-i-and-ii_socmi-nsps_final_preamble.prepublication.pdf

[6] Federal Insecticide Fungicide, Rodenticide Act, https://www.epa.gov/enforcement/federal-insecticide-fungicide-and-rodenticide-act-fifra-and-federal-facilities

Compliance Pathway	Emissions Stream	Facility Source Classification	New vs Existing	Tons/yr EtO Used	DRE (%)
SWEL1	ALL	N/A	Exist. & New	≥30	99.99
				10<30	99.9
				1<10	99.8
				<1	99
SWEL2	SCV	N/A	Exist. & New	≥30	99.99
				10<30	99.9
				1<10	99.8
				<1	99
	ARV	N/A	Existing	≥30	99.9
				10<30	99.6
				1<10	99
				<1	99
			New	≥30	99.9
				10<30	99.9
				1<10	99
				<1	99
	CEV	Major	Exist. & New	N/A	99.94
		Area	Exist. & New	≥60	99.9
				<60	99
	Group 1	Major	Exist. & New	N/A	97
		Area	Exist. & New	≥40	98
				<40	80
	Group 2	Major	Exist. & New	N/A	86
		Area	Existing	≥20	98
				4<20	80
				<4	<1 ppm*
			New	≥20	98
				4<20	80
				<4	80

Table 1. *Subpart-O NESHAP destruction efficiencies shown by SWEL pathway (SWEL1 in* ***orange****; SWEL2 in* ***green****), process stream, facility source classification, Legacy Status, and EtO use. *For sterilizers using fewer than 4 tons of EtO per year, a measurement showing less than 1 ppm in the chamber must be used before the chamber can be opened.*

Both before and after the publication of the final Subpart-O NESHAP, commercial sterilizers and medical device manufacturers had expressed concerns about their ability to achieve the stringent removal efficiencies required of sterilizers—up to 99.99% on an ongoing average basis (see Table 1, and see subsequent section for definitions).

Though some of the original concern stemmed from a misreading of the NESHAP rule, much of the remaining concern was justified based on limitations of incumbent monitoring, and to some extent abatement, technologies used throughout the sterilization industry. For example, consider Group 2 emissions of EtO from post-aeration sterilized materials. Facilities using more than 20 tons per year must prove a 98% reduction in these emissions (see Table 1). Many areas used to store quarantined goods have concentrations of EtO around 100 ppb. In order for a facility to demonstrate compliance with the source-specific reduction requirement under SWEL2, monitoring equipment at the abatement system outlets from these areas would have to have lower detection limits of 2 ppb just to demonstrate the compliance limit, not to demonstrate whether a facility was below it. While Picarro can comfortably demonstrate this level of destruction efficiency due to its 0.25 ppb guaranteed lower detection limit, this is very hard, and frequently impossible, for most other technologies.

Aware of these concerns, and eager to show our technological advantage, Picarro and LESNI co-authored a white paper in early 2024 (https://www.picarro.com/eto/LesniPicarroWP) examining the real-world performance of a LESNI EO Catalytic Abatement Plant in the US. In this paper, we were able to demonstrate comfortable 99.991+% DRE on an average basis, significantly exceeding the highest DRE required in the ***draft*** Subpart-O rule, 99.94%[6] . While the results of that study showed excellent DRE on the LESNI, and sensitivity on the Picarro, the authors discovered evidence of a cracked burner (seen through an enrichment of methane in Picarro's stack EtO data) that likely contributed to sub-optimal DRE performance on the LESNI EO CAP. The facility was aware of this maintenance issue after an unplanned shut down, and was scheduled to have it repaired in a few months. However, absent publishable data from other LESNI EO CAPs at the time, the authors chose to publish these (already excellent) results, since they comfortably achieved DREs well above the most stringent draft requirement of 99.94%.

In the year since that first paper, Picarro has collected EtO data on many LESNI EO CAPs across the world, running in a variety of different sterilizer facilities, and has found that the efficiency of LESNI EO CAPs is actually ***significantly*** higher than the first white paper indicated, typically 10-20x higher than the revised standard of 99.99%. This paper discusses two of these cases, breaking down DRE success by both SWEL1 and SWEL2 compliance pathways.

DISCUSSION OF TERMS

The Subpart O NESHAP provides three possible compliance pathways for emissions reporting: SWEL1, SWEL2, and DRE, all of which can be achieved using Picarro and LESNI technologies.

The Subpart-O NESHAP provided new naming conventions for the five processes sources it regulates in commercial sterilizers. It also provided three possible compliance pathways for emissions reporting: SWEL1, SWEL2, and continuous DRE, all of which can be achieved using Picarro and LESNI technologies. We define and explain these process sources and compliance pathways in the section below, giving context for the concentrations of EtO expected in each case, and the sorts of considerations around measurement at each. In this and subsequent sections, we provide the relevant citation within the rule using the convention used within the rule itself of format §63.36# (#)(#). This convention removes the leading "40 CFR" since all cross-references are from 40 CFR (the Clean Air Act) unless otherwise mentioned.

[7] Draft Subpart-O NESHAP: https://www.epa.gov/system/files/documents/202403/7055_etosterilizers_final_20240301_admin_disc.pdf

Process Streams

SCV: Sterilizer Chamber Vents (§63.362 (c)) have the highest concentration of any of the sources defined in the NESHAP, since they are the vents that directly remove EtO at levels up to 100% from the chamber. While this concentration diminishes with time with each N_2 purge or air wash, the concentration coming from an SCV is typically at least in the 1000s of ppm, and potentially as high as 100% EtO, which is why the SCV stream is the only stream that does not have an option for inlet/outlet monitoring for SWEL2 compliance.

ARV: Aeration Room Vents (§63.362 (d)) receive air from product after sterilization, when it is undergoing heated aeration in dedicated aeration cells or rooms. EtO concentrations in ARVs are typically on order double-digit ppms, and in larger sterilizers with dedicated large aeration chambers these concentrations often do not drop significantly by time of day or week, because product is being sterilized and moved to and from aeration on an ongoing basis every few hours. In smaller facilities where aeration is performed in dedicated cells, the concentration of air coming from aeration can diminish to roughly 1 ppm or below before product is removed since loading can be more periodic.

CEV: Chamber Exhaust Vents (§63.362 (e)) also have high concentrations, but nowhere near as high as SCVs. These vents, historically known as "back vents" do not exist on all sterilizer chambers, but function to remove high EtO from chambers while product is automatically transferred or manually unloaded by operators. These signals are punctuated and brief, typically lasting on order of few minutes, often reaching 5000+ ppm at their peak.

Group 1: Also referred to as G1 in this paper, Group 1 (§63.362 (f)) are fugitive emissions of EtO from products leaving sterilization pre-aeration, and from areas and components that handle high EtO, like sterilizer chamber vaults, SCV pumps, and drums or cylinders. Though occasional events can lead to significant enrichment of EtO in these streams, they typically range from sub-ppm to double digit ppm.

Group 2: Also referred to as G2 in this paper, Group 2 (§63.362 (g)) are fugitive emissions of EtO from sterilized product after it leaves aeration. Perhaps surprisingly, while these emissions are released more slowly than those in other areas, Group 2 areas without dedicated abatement have historically seen some of the highest continuous EtO concentrations within sterilization facilities. This is due to a combination of lower historical regulatory requirements for this stage in the sterilization process, and because large quantities of sterile goods post-aeration may sit, off-gassing, in relatively stagnant air for many days before they are shipped out. When properly implemented, Group 2 streams range from roughly 100 ppb to over a 1 ppm. Despite these low concentrations, the total emissions from these areas, typically abated at very high flow rates, can constitute 2% or more of the total EtO sent to abatement.

Compliance Pathways

DRE: Destruction Removal Efficiency refers to the calculated percentage of destruction or removal of EtO based on the measured concentrations of the inlet and outlet. DRE also refers to a stream-by-stream compliance pathway available to facilities. A facility may in theory choose to comply via DRE directly for each emissions stream, measuring the total lbs of EtO sent to each control device and the mass emission rate of each of their outlet. While this pathway requires the least formalized method, it comes with challenges. It demands a significant number of sample points and requires continuous compliance with the actual destruction efficiency of each emission source. This can be particularly difficult for certain sources with low inlet concentrations. It also provides major challenges during periods of low demand.

This method is not practical for the majority of facilities and is not anticipated to be a serious compliance option. Therefore, we do not provide a case study in this paper, but reference the general concept of DRE throughout.

The SWEL1 compliance pathway is the simplest computationally, assessing compliance by comparing scale weight EtO use and stack emissions over a rolling 30-day window, targeting >99.99% DRE for most facilities.

SWEL1: Site-Wide Emission Limitation based upon Facility EtO use (§63.362 (j)(1)). In this simplest compliance pathway, the amount of ethylene oxide sent to abatement is assessed indirectly by summing the total pounds of EtO used across all facility chambers over a 30-day rolling period. This is measured using calibrated scales that hold the individual EtO drums, cylinders, or cartridges. This 30-day summation is provided to recognize that emissions are not necessarily tied to the exact day EtO is dispensed into a sterilizer chamber and to provide a critical smoothing function for facilities that do not sterilize every day. This rolling calculation does not average the DRE individually on a day-to-day basis (which could lead to negative efficiencies on days when sterilization is not occurring since EtO will continue to exhaust to the stack from ARV, G1, and G2 sources), but rather sums the total pounds used over 30 days, and the total pounds emitted (as recorded by one or more CEMS) over the same period. In this approach, all stacks must be measured at the outlet, but not at the inlet, and the emissions from all stacks are combined to determine the total EtO emissions. A key disadvantage of SWEL1 is that the SCV DRE standard (always the highest of the process streams) is applied to the total emissions, whether they come from Group 1, Group 2, Aeration, CEV or SCV (SCV constitutes roughly 95%+[7] of the total EtO sent to abatement), giving slightly less leeway to the operator. However, SWEL 1 requires the least complex CEMS configuration. Each emissions source (stack) must have a sampling point and umbilical, and for facilities with only one stack, compliance can be demonstrated with just one CEMS and a single umbilical.

Figure 2: *Ducting around a LESNI EO CAP showing the sophisticated management of process air by valving.*

SWEL2: Site-Wide Emission Limitation by Emissions Streams (§63.362 (j)(2)) is an alternative compliance pathway created for facilities that are not well-suited for SWEL1 compliance, particularly when their low-level process streams (namely Group 1 and 2) are treated using lower-efficiency abatement technologies such as dry beds.[8] Under this compliance approach, facilities can quantify the inlet masses and outlet emissions

[8] Based on Picarro calculations at several commercial sterilizer facilities.

[9] These technologies, which typically achieve 95-99% DRE, can reduce the overall efficiency of the SWEL2 approach when other technologies are performing at higher DREs, but are accounted for accordingly in the emissions reduction requirement. They have their place in the technological landscape for managing high-flow sources in particular.

from multiple streams while using the lower efficiency standards associated with those stream types. The SWEL is calculated using the total amount of EtO sent to the control device over a 30-day window, applying the appropriate emissions reductions standards for each differentiated stream (e.g. Group 1, Group 2), using the SCV standard for all other consolidated streams, and summing up the “allowed” emissions by stream to calculate the limitation for the site. This approach often results in a significantly higher site-wide emission limitation (e.g. 3 lbs instead of 0.5 lbs allowed per month). Because compliance with this approach is achieved by demonstrating that the emissions for each 30-operating day period are at or below the site-wide emission limitation total (e.g. lbs emitted for Group 1 + Group 2 lbs + All others = SWEL allowed), facilities have some flexibility on the individual DREs by process stream so long as a small drop in the efficiency of one stream (e.g. if Group 1 fell to 97.6%) is compensated for by the efficiency of another (e.g. by Group 2 coming in at 99%). The specifics around this accounting are shown in the SWEL2 example later in this paper.

SWEL2 compliance configurations can be implemented with as few as three and as many as nine CEMS monitoring points, depending on just how closely a facility wishes to shave off emissions limitations, and based on how the facility is configured.

- The simplest SWEL2 compliance configuration utilizes a CEMS-3, and can be implemented with a single time-shared cabinet with three sampling umbilicals running to three points (2 outlet, 1 inlet). This configuration is typically favored by facilities that have historically separated out their Group 2 emissions to a passive abatement source, running high flow rates, and the remainder of its emissions streams to a single abator like a LESNI EO CAP. With this CEMS-3 configuration, a single additional “in” umbilical in addition to the two “outs” enables a facility to utilize a much higher blended SWEL.
- In its most complex but permissive form, SWEL2 compliance can be implemented with nine points measuring the in and out concentrations of ARV, Group 1, Group 2, and CEV, and the outlet of the SCV. (The SCV inlet is not measured directly because the NESHAP does not require it, and because the scale weight of EtO is the most relevant/accurate measure of the mass of EtO leaving the chambers via the SCV stream to abatement.) In this configuration, a highly tailored approach allows for the most lenient SWEL DREs, but at significantly higher operating expense, requiring e.g. 3 separate CEMS-3 cabinets, or a CEMS-4, a CEMS-3 and a CEMS-2.

It bears noting that many facilities can achieve compliance with a single time-shared cabinet running three sample umbilicals, as described above. This is because the primary driver of higher emissions is the high flow and lower efficiency associated with Group 2 emissions treated through dry beds. As noted above, Picarro’s observations at multiple facilities show that Group 2 sources can account for up to, and even sometimes more than, 2% of the facility’s total EtO emissions, as post-aeration materials continue to outgas over several days.

LESNI EO CATALYTIC ABATEMENT PLANTS

LESNI is a well-recognized industry leader in the engineering and implementation of emissions abatement systems for the most challenging industrial sectors, offering a portfolio of solutions including chemical scrubbers and solvent recovery systems, as well as catalytic, recuperative, and regenerative thermal oxidizers. They are recognized for their industry-leading mitigation of EtO from sterilization process emissions streams.

LESNI names its EO abatement product a “Catalytic Abatement Plant” because the system design is significantly more sophisticated than a simple catalytic oxidizer—it is a whole abatement system designed with efficiency, consistency, and process optimization in mind. Chamber gas, which can consist of nearly pure EtO, is pumped to the EO CAP (“Vacuum Pumps (SCV)” in Figure 3), entering at the balancer tank (a.k.a “peak shaver”) and dissolving in solution. The water in the balancer tank is recirculated over a stripper media column, and a counterflow of air typically from aeration (ARV) and other low-EtO process streams is run across the water to slowly strip the EtO out of the balancer tank and toward the catalytic oxidizer.

Figure 3: *One configuration of a LESNI EO CAP, which Picarro Technology shows abates EtO Emissions well beyond the new NESHAP requirements promulgated by the US EPA. Featured are the balancer water tank (bottom center), scrubber column (upper center- left), and various process gas ducting (top right, middle left). The CatOx beds can be seen as a silver rectangle just above the burner in the middle right of the background.*

The balancer can be thought of as an EtO battery—chamber evacuations “charge” the balancer with EtO, while a constant flow of aeration air, dynamically balanced between the stripper column and CatOx, slowly “deplete” the battery, pulling EtO out of solution over a matter of hours. This has the effect of slowing the pulse of EtO going to the CatOx so that it can be maintained at a safe concentration well below the lower explosive limit (LEL).[9] Systems with water-sealed liquid ring chamber vacuum pumps (preferable over oil seals, which can send oil mist to the CatOx), can now also take advantage of the CAP’s balancer tank, pumping away the waste water to the balancer and fresh water back to the pump, so that the dissolved EtO can be removed from the pump seal, extending the lifetime of the pump and helping it reach lower vacuum.

Within the CatOx itself, the EtO is destroyed, converted to CO_2 and H_2O vapor, as the EtO-laden air stream comes in contact with a low-temperature catalyst distributed across multiple beds in series. This reaction is exothermic, creating enough heat that the burner on the CatOx can be switched off for long periods of time as the exotherm keeps the bed temperature at its set point. A high efficiency heat exchanger situated after the catalytic bed recuperates heat from the abated effluent stream, directing this heat to the the line upstream of the bed to allow pre-heating of the incoming gas stream. Like the exothermic heating of the bed, this recuperation reduces the total amount of fuel (e.g. natural gas, propane) needed to power the CAP.

[10] EtO MSDS: https://www.osha.gov/chemicaldata/575

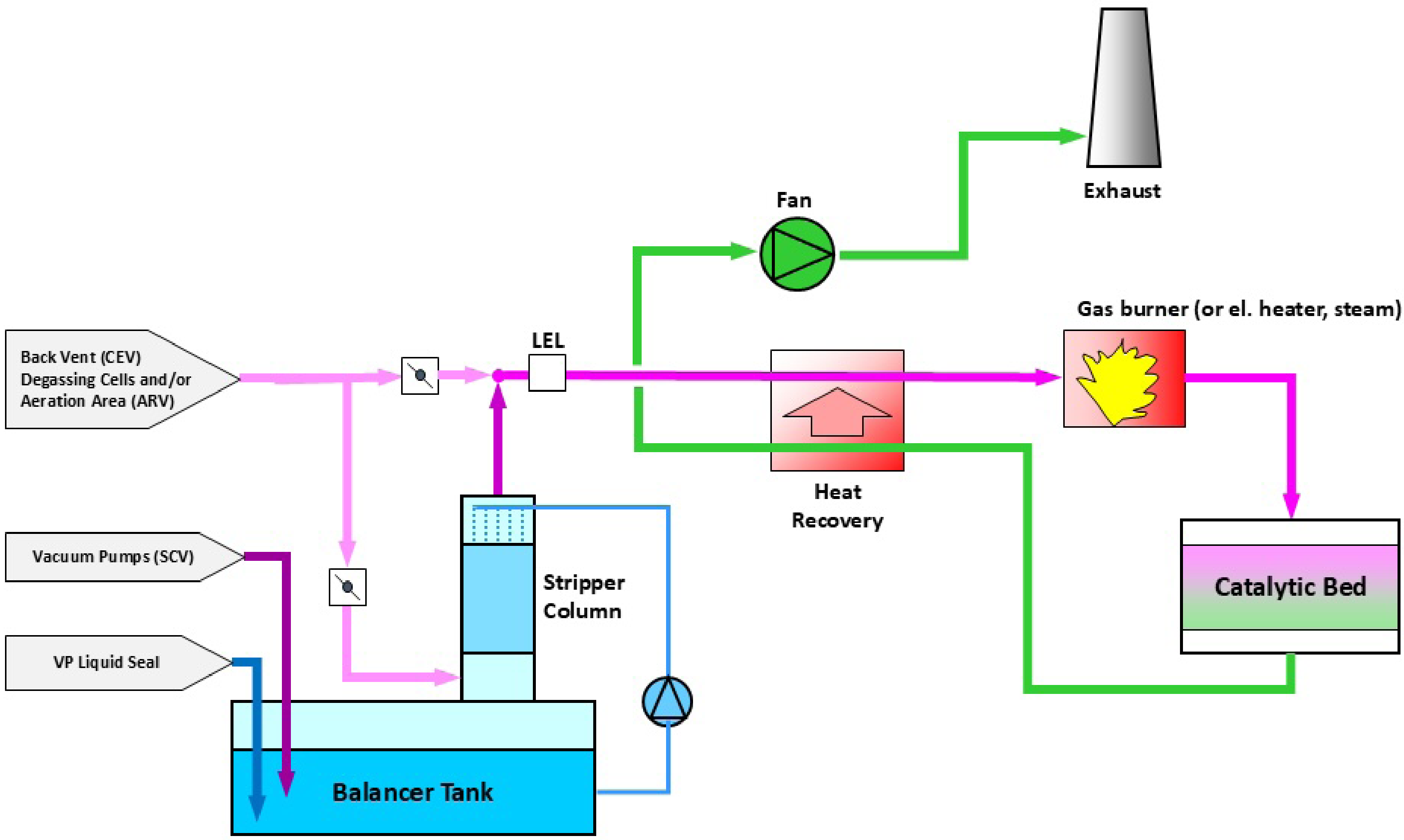

Figure 4: *LESNI EO CAP. The Balancer uses water and aeration cell air to modulate EtO concentrations at the CatOx, ensuring safe and efficient destruction efficiency. The CatOx recaptures the heat produced by EtO destruction to minimize the primary energy needed to maintain the CatOx bed temperature.*

PICARRO CEMS

Picarro's EtO Continuous Emissions Monitoring System (CEMS) was developed iteratively through collaboration with industry to ensure appropriate technological features for the commercial sterilizer setting, and proactive compliance with 40 CFR 63, Subpart-O ("The Commercial Sterilizer NESHAP"); 40 CFR 60, Appendix B, Performance Specification 19 (PS-19); and 40 CFR 60, Appendix F and Quality Assurance Procedure 7 (Procedure 7).

Picarro's EtO CEMS is based around a broadband Cavity Ring-Down Spectrometer (CRDS), providing the sensitivity and selectivity necessary to achieve a lower detection limit of 0.25 ppb. CRDS technology also provides industry-leading stability and selectivity for EtO measurements, as well as an instantaneous response and one-second measurement interval. The CRDS instrument also reports highly precise concentrations of methane (CH_4), carbon dioxide (CO_2), and water vapor (H_2O) which allow engineers to validate destruction efficiencies through passive tracer (CH_4) and stoichiometric-ratio tracer (CO_2 + H_2O) methods discussed in a recent white paper with Carus LLC (https://www.picarro.com/eto/CarusWP).

Figure 5: The Picarro EtO CEMS. State-of-the-art Picarro CRDS technology sits within a NEMA-12 (or better) industrial enclosure, with an umbilical connecting the system to the stack, where flow monitoring and sample probes feed back essential parameters, sample and calibration gases to enable real-time monitoring of concentrations and computation of mass emissions.

The Picarro CEMS is built around four main components shown in Figure 4:

1. **A system cabinet (left middle)** including the analytical instrument, gas handling equipment, calibration gases, PLCs, HMI, and electronics.
2. **A heated sample umbilical (right middle)**, which conditions sample gas to stay above its dew point during the transit from the stack to the analyzer. The umbilical contains the sample line itself, a calibration "bias line" (to send calibration gas to overflow at the probe), and signal and power cables for the probes.
3. **A heated sample probe (upper right)**, which protrudes into the stack to sample gas which is then pulled to the analyzer.
4. **A flow probe (upper left)** which, in the case of the flow meters Picarro uses, measures a differential pressure across multiple sample points to determine the flow of air in the stack. This flow data in turn allows the CEMS to continuously determine mass emissions when combined with EtO concentration data from the analyzer.

Picarro offers a variety of CEMS configurations to match the need in the sterilization community and the compliance pathways offered by the Subpart-O NESHAP, and can accommodate up to four measurement points per CEMS cabinet set up as either pure outlet measurements, or IN/OUT configurations for SWEL2 compliance. With four time-shared umbilicals in a single cabinet, the Picarro CEMS can comfortably meet or exceed the quadrant rule (a valid measurement per stack per 15-minute window), even when factoring in the strict response time requirements of Performance Specification 19[10].

In two upcoming sections, we outline one SWEL1 and one SWEL2 compliance example using real-world data, and we discuss the exact Picarro CEMS configurations and LESNI EO CAPs needed to prove that these compliance pathways are achieved successfully.

[11] Performance Specification 19 Section 11.0(g) https://www.epa.gov/system/files/documents/2024-07/ps-19-and-appendices.pdf

TECHNOLOGICAL PARTNERSHIP

As part of an effort to grow LESNI and Picarro's partnership and provide customers with more value and peace of mind, Picarro and LESNI have established common communications protocols to send signals back and forth between the LESNI EO CAP and Picarro CEMS. This exchange of information provides an analytical framework for LESNI to track the ongoing efficacy of its catalyst bed using Picarro's concentration/mass emissions numbers. It also largely eliminates the need for facilities to send catalyst samples back for DRE testing unless a problem is observed in the stack data. The exchange of signals also includes the transmission of catalyst bed temperatures from the LESNI to the Picarro CEMS, fulfilling one the reporting requirements of §63.363(d)(4), which requires the recording of the minimum bed temperature of, and maximum temperature differential across, the catalyst beds.

Picarro also recognizes the importance of consolidating record keeping with other partners and associated data streams, e.g.:

- The CEMS is now also able to log data from differential pressure sensors, a preferred method for demonstrating compliance with the Method 204[11] permanent total enclosure requirements outlined in §63.362(h)(1).
- The CEMS can also automatically incorporate daily total EtO usage based on scale weight measurements provided by partner companies, making the process of determining SWEL compliance on a 30-day rolling basis completely automated (i.e. there is no need for operators to manually calculate EtO lbs used from scale weights, enter them into the Picarro CEMS DAS, or calculate the DRE). The software includes alerts to notify a facility when the 30-day rolling average drops below a warning threshold, and again if it drops below the compliance threshold.

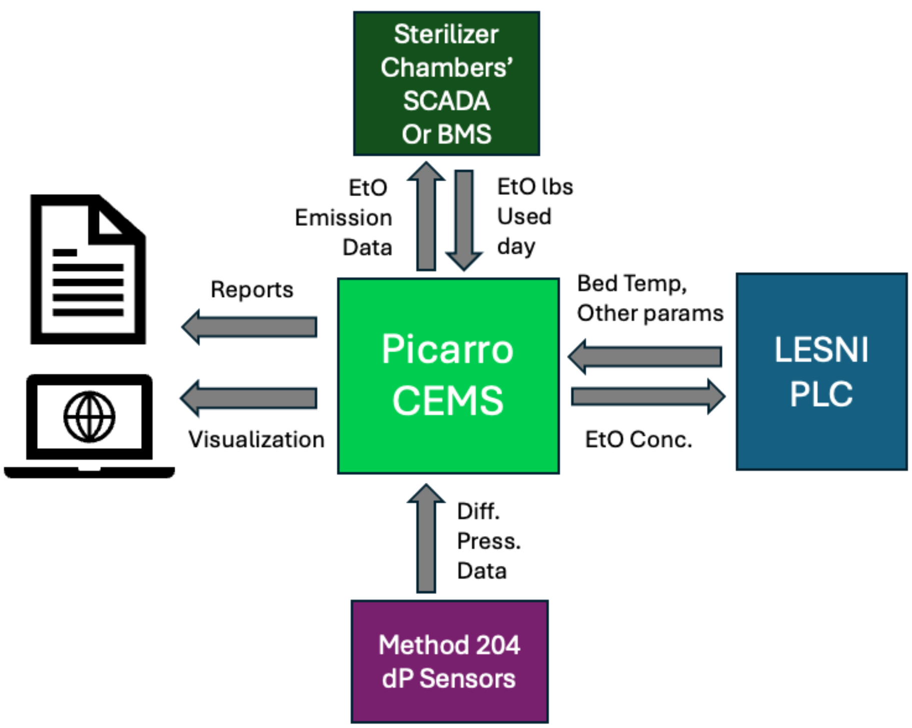

Figure 6: *Information exchange enabled by technological partnerships.*

[12] Method 204 can be found in Appendix M of 40 CFR part 51.

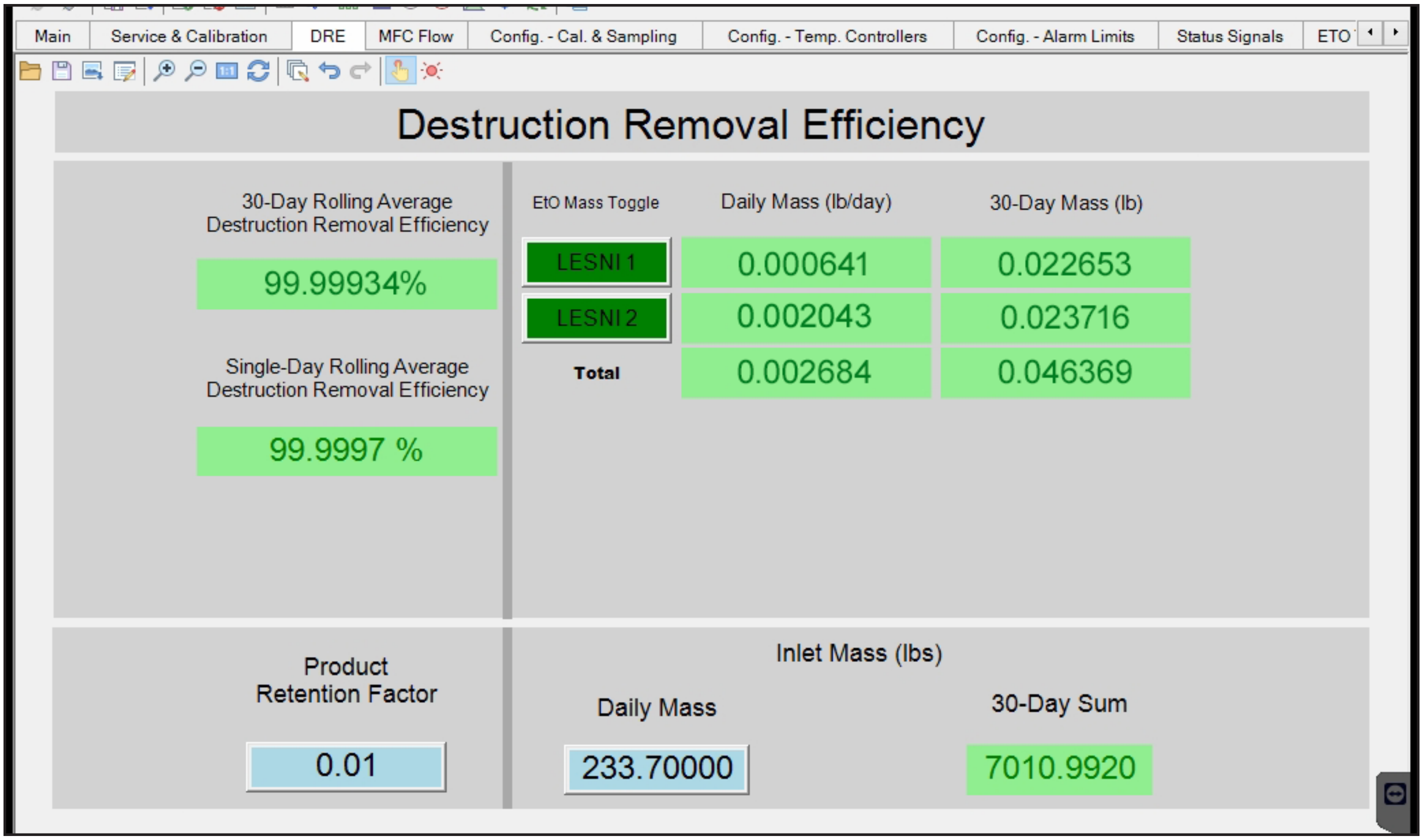

Figure 7: *Picarro CEMS, emissions calculations, and DRE calculations. Additional information about EtO use and catalyst bed temperature is shown in other tabs, made possible by the sharing of information between the Picarro CEMS, LESNI EO CAP, and other devices.*

SWEL1 CASE STUDY

The SWEL1 pathway is the most computationally straightforward pathway in the Subpart-O NESHAP, and is typically appropriate for facilities that manage smaller total air flows due to facility design and layout. Facility A, shown in this example, is located in the United States, and uses more than 40 tons/year of EtO, requiring it to maintain a 99.99% DRE on an ongoing basis. This value is calculated by comparing the total pounds of EtO used over the prior 30 days (as measured by scale weights) to the total emissions from all stacks over the same period, as quantified by the Picarro CEMS. This facility has two LESNI EO CAPs to distribute its process gas, add redundancy, and minimize downtime during maintenance events. In order for this facility to comply with SWEL1, it must continuously measure emissions from both LESNI stacks, and demonstrate their combined emissions are less than the allowable monthly limit.

In this case, the customer is operating a Picarro CEMS-2 where two sample umbilicals—one from each stack—are time-shared through a single CEMS cabinet, easily meeting the (15-minute) quadrant rule for data coverage per Performance Specification 19. When this customer first reached out to Picarro to assess their abatement system performance, they were considering SWEL2, which would have involved purchasing a significant number of dry bed scrubbers and building a large structure to house them, with an outlay in the low-8-figures. However, after a study conducted by Picarro, and compliance guidance from Picarro's regulatory experts, the facility realized it could avoid this costly project and comply via SWEL1 instead, as its LESNI EO CAPs ***already*** easily met the required 99.99%+ DRE in its current configuration. The layout of this facility is shown below, including the placement of the CEMS-2.

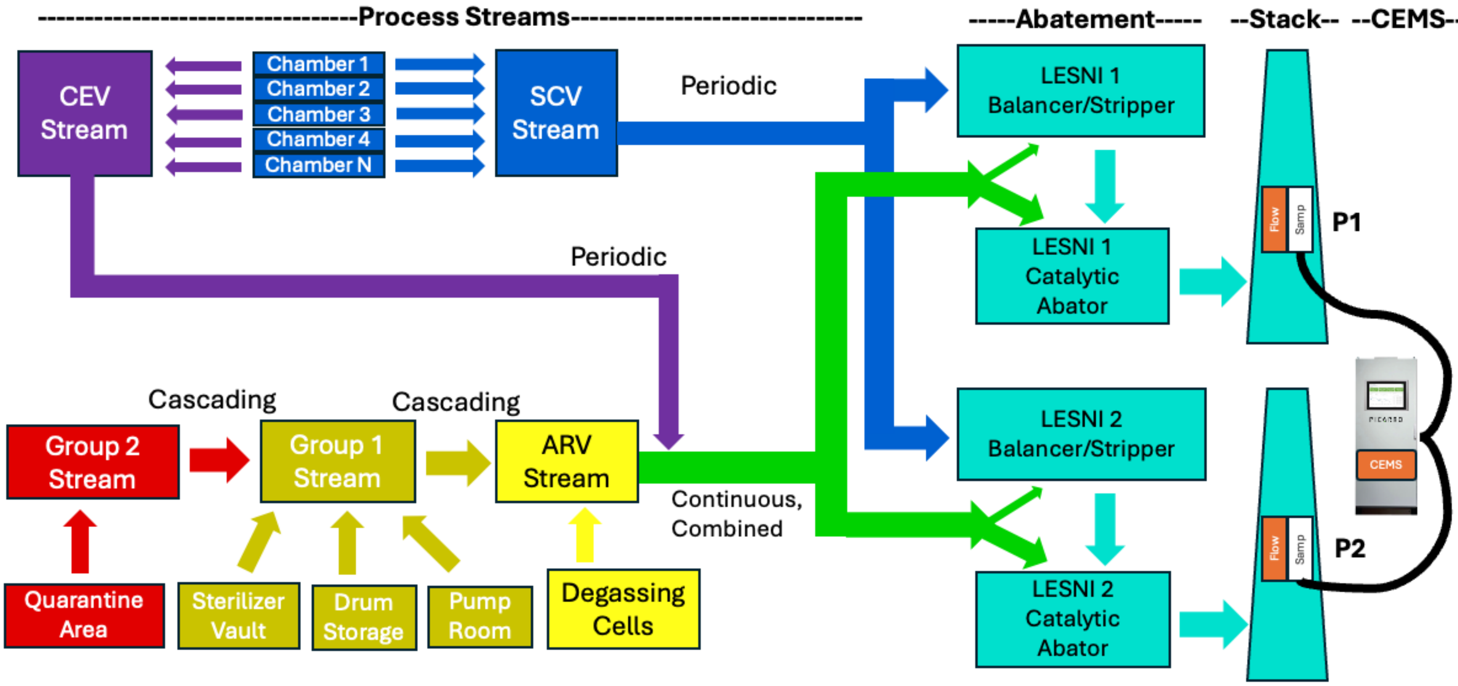

Figure 8: *One common, recommended` SWEL1 pathway, similar to the process and abatement seen at Facility A, showing cascading of process gases from Group 2 to Group 1 to Aeration to minimize the total gas flow needed for abating across these three processes. Here, the facility has two LESNI EO CAPs to provide parallel abatement, and to minimize downtime during maintenance periods. CEMS is provided at the outlet of each stack using a single shared CEMS-2 cabinet with sampling points designated as* ***P1*** *and* ***P2****, respectively, on the diagram.*

In order to demonstrate compliance, we set up a series of equations summing and comparing used and emitted EtO below. In these calculations, we use the convention of **green text** color to indicate actual data or derived data values, and **red text** color to indicate prescribed or calculated limitations (not actual observations).

We start by calculating the emissions in pounds per minute for each source (stack) by applying Equation 14 from §63.365(b)(6), as written for imperial units, using measured stack flows and outlet concentrations from the Picarro CEMS. We place these values in Table 2 along with the EtO usage as measured by the calibrated drum scales.

$$E_{APCD,o} = \frac{C_{EtO,i} * Q_o * \ 44.05}{385.1 \ * 10^9}$$

Equation 1: Total emissions from a source per minute.

Where:

$E_{APCD,o}$ = total mass of EtO emitted from the stack, in pounds per minute

$C_{EtO,i}$ = concentration of EtO in ppb

Q_o = volumetric flow rate standard in cubic feet per minute (SCFM) corrected to 68°F and 1 atmosphere of pressure (atm)

44.05 = molecular weight of EtO, in pounds per pound-mole (lb/lb-mole)

385.1 = standard volume constant, in SCF/pound-mole at 68°F and 1 Atm.

10^9 = conversion factor for ppb

Day	EtO Used (lbs/day)	Stack 1 EtO (ppb)	Stack 2 EtO (ppb)	Stack 1 Flow (SCFM)	Stack 2 Flow (SCFM)	Stack 1 EtO Emitted (lbs/day)	Stack 2 EtO Emitted (lbs/day)	Total EtO Emitted (lbs/day)	DRE (%)
1-Aug	…	0.87	1.04	5489	5675	0.000785	0.000976	0.001761	…
2-Aug	…	0.91	0.75	5614	5594	0.000843	0.000693	0.001535	…
3-Aug	…	0.82	0.82	5678	5908	0.000765	0.000797	0.001562	…
4-Aug	…	0.92	1.56	5684	5737	0.000862	0.001479	0.002341	…
5-Aug	…	0.81	0.60	5598	5611	0.000748	0.000557	0.001304	…
6-Aug	…	0.80	0.60	5663	5738	0.000747	0.000566	0.001313	…
7-Aug	…	0.81	0.74	5671	6116	0.000759	0.000746	0.001505	…
…	…	…	…	…	…	…	…	…	…
30-Aug	…	0.67	2.21	5827	5600	0.000641	0.002043	0.002684	…
Minimum	…	0.47	0.42	5294	5427	0.000426	0.000383	0.000849	…
Maximum	…	1.24	2.21	5827	9084	0.001106	0.002043	0.002684	…
Average	233.7	0.83	0.84	5540	5812	0.000755	0.000791	0.001546	99.99934
Total	**7011**	**N/A**	**N/A**	**N/A**	**N/A**	**0.022653**	**0.023716**	**0.046369**	**99.99934**
Valid Records	30	30	30	30	30	30	30	30	
Operating Time	100%	100%	100%	100%	100%	100%	100%	100%	

Table 2: *Truncated 30-day record of EtO Used and Emitted at Facility A using a SWEL1 Compliance pathway. Lbs used is shown as an average over the 30-day period, not as individual day uses to maintain a slight distance between the facility who allowed use of this data and this white paper. Over the period, an average of 233.7 lbs/day was used, totaling 7011 lbs. Concentration measured at the stack, flow rates, and calculated mass emissions are shown. Note the remarkable sub-ppb EtO concentrations measured on almost all operating days because of the LESNI EO CAP's superior destruction efficiency and Picarro's extremely low detection limits.*

Taking an example from the first data point in Table 2 from August 1 on Stack 1, the mass emission shown in "Stack 1 EtO Emitted (lbs/day)" is calculated with Equation 1 and then multiplied by 60 and 24 to convert from emissions per minute to emissions per day.[12]

$$E_{APCD,o,day} = \frac{0.87 * 5489 * 44.05}{385.1 \ * 10^9} * \left(60 \frac{minutes}{hour} * 24 \frac{hours}{day}\right) = 0.000785\ lbs/day$$

Equation 2: Calculation of emissions in lbs/day for Stack 1, based on §63.365(b)(6) Equation 14.

[13] This differs slightly but not materially from the actual compliance approach which would average each quadrant to determine an hourly rate, and then add together the hourly emissions to determine the daily rate, and then add together the daily number to determine the 30-day. However, this approach is more convenient for this paper to avoid showing large amounts of data at the 15-minute level and up, and is computationally the same because the ultimate numbers are calculated from the 30-day sums.

We then sum the daily emissions numbers over the 30-day window (seen under the **Total** row in Table 2 for Stack 1 and Stack 2), and then add together those 30-day emissions sums:

$$E_{fac} = \sum^{n} \mathrm{E}_{o,i} = \mathrm{E}_{o,1} + \mathrm{E}_{o,2} = \mathbf{0.022653\ lbs} + \mathbf{0.023716\ lbs} = \mathbf{0.046369\ lbs}$$

Equation 3: Total emissions from Stacks 1 and 2 over 30 days, in lbs.

Where:

E_{Fac} = The total emissions from the facility over the previous 30-operating days, in pounds

$E_{o,i}$ = The 30-operating day rolling sum of emissions calculated at each exhaust stack, ***i***, monitored by an EtO CEMS

i = Exhaust stack index

n = Total number of exhaust stacks, here 2

The total pounds used are computed using an equation of this form (the specific equation is not spelled out in the Subpart-O NESHAP):

$$M_{30day} = \sum_{t=-30}^{0} M_{day,t} = (\mathbf{233.7}\ \boldsymbol{lbs} + \ldots lbs + \ldots lbs) = \mathbf{7011}\ \boldsymbol{lbs}$$

Equation 4: Mass sum of EtO used in lbs over the prior 30 days[13].

Where:

M_{30day} = Total EtO used during the 30-operating day period in lbs, measured from 30 days ago to today, as determined by scale weights

$M_{day,t}$ = Total daily EtO use, in lbs, for each operating day t from 30 days ago to today

t = day index where 0 is the final day of the 30-day period

We now place the 30-day total lbs used data into Equation 5 (Subpart-O Equation (3)) below, along with the relevant emissions reduction factor of 99.99% (0.9999), to determine the SWEL the facility must not exceed.

$$SWEL_{Fac} = M_{FAC} * 0.99 * (1 - ER_{SCV}) = 7011\ lbs * 0.99 * (1 - 0.9999) = 0.6941\ lbs$$

Equation 5: Destruction removal efficiency calculation used to determine SWEL1 "limitation" in lbs/month.

Where:

$SWEL_{Fac}$ = Allowable emissions limit in lbs/month based upon facility EtO use

M_{Fac} = Adjustment factor for EtO residual in sterilized product

ER_{SCV} = The applicable SCV emission reduction standard (see Table 1), displayed in decimal format based on the facility type, here 0.9999

0.99 = The adjustment factor to allow that up to 1% of EtO may leave the facility with sterile products.

[14] Here, we add in ellipses (...) because we are not providing the daily EtO pounds used in this white paper.

So the facility must emit less than 0.6941 lbs over 30 days. **The calculated value from Equation 3—0.046369 lbs—is about 15x lower than the allowable limitation, so this facility very comfortably meets SWEL1 thanks to the efficiency of their LESNI EO CAPs.** Out of a general interest, we compute the actual DRE for this SWEL1 by inverting this equation, shown below, retaining the 0.99 factor based on the estimate of EtO that doesn't go to controls.

$$DRE_{obs} = \left(1 - \left(\frac{0.046369\ lbs}{7011\ lbs * 0.99}\right)\right) * \frac{100\%}{1} = \mathbf{99.99934\%}$$

Equation 6: Calculated actual DRE based on totalized used EtO and totalized Emitted EtO.

The two LESNI EO CAPs in the facility working in parallel achieve a remarkable blended DRE of 99.99934%. This "five-nines" DRE determination is only possible because of the combined functional excellence of the LESNI EO CAP and the sensitivity of the Picarro EtO CEMS, which observed sub-ppb EtO concentrations on most operating days during this 30-day window.

SWEL2 CASE STUDY

In this example, Picarro measured the inlet and outlet of two abatement systems at a facility in the US that uses more than 40 tons of EtO per year, is classified as an Area Source, and plans to comply with Subpart-O using the SWEL2 compliance pathway. This facility sends most of its emissions streams to a LESNI EO CAP, except its Group 2 emissions, which it sends to a bank of dry beds. The facility sends its Group 1 emissions to the LESNI, and is independently measuring this inlet stream and the Group 2 inlet stream as part of a strategy to maximize its allowable SWEL. We analyze the ability of this facility to achieve and demonstrate compliance with a LESNI EO CAP and Picarro CEMS, and contrast these results with recent stack test data from an OE-FTIR system, which provide an estimate of whether the facility would be able to demonstrate compliance with an OE-FTIR CEMS.

In this example, the customer is using a Picarro CEMS-4 configuration on their LESNI and dry bed stacks with four points, designated **P1-P4:**

1. **P1, *Inlet*, Group 2:** measures the total mass of EtO coming from Group 2 areas, upstream of the dry beds themselves.
2. **P2, *Outlet*, Group 2:** the outlet (stack) of the dry beds used to abate the Group 2 emissions, which must meet a 98% DRE based on the facility size and source type.
3. **P3, *Inlet*, Group 1:** measures the total mass of EtO coming from just Group 1 areas, upstream of the LESNI EO CAP.
4. **P4, *Outlet*, LESNI EO CAP:** this outlet value is used for determining the DRE of both the Group 1 stream, and the remaining ARV/CEV/SCV stream since it is a representative (if conservative) measure of DRE from both streams as measured after the streams have been combined and abated. Here, the outlet concentration value must be able to prove a 99.99% DRE for the consolidated streams, and 98% for the Group 1 alone.

The facility's process streams can be seen in the diagram below, which lays out the specifics of the process gas flow and the placement of the four Picarro CEMS umbilicals designated as **P1-P4.**

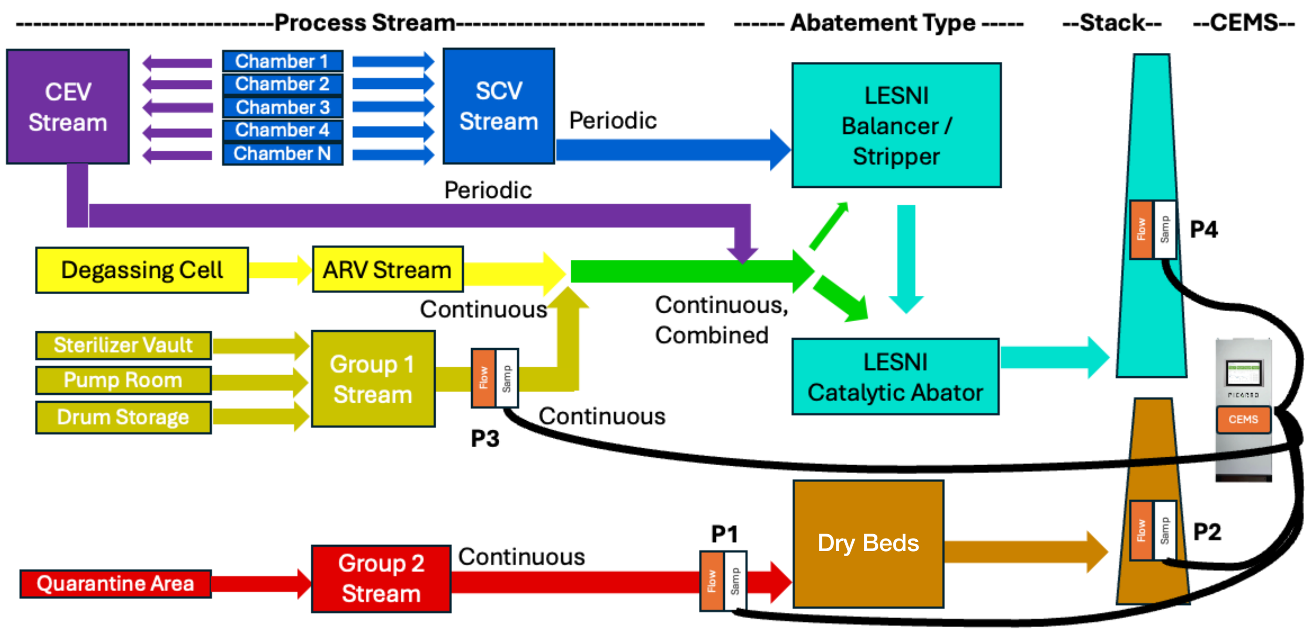

Figure 9: *: SWEL2 pathway at Facility B showing one stack measurement point each for the dry bed stack **(P2)** and LESNI stack **(P4)** and one inlet point each for Group 1 **(P3)** and Group 2 **(P1)**. ARV, CEV, and Group 1 air can be seen running to the LESNI EO CAP to function as diluent air for the CatOx, as described elsewhere in this paper.*

Since we have laid out many of the equations needed for both SWEL1 and SWEL2 compliance in the SWEL1 example, we skip some repetition in this instance. We also represent the data in a more condensed format than in the first example to focus on the SWEL2 component of the analysis.

We begin by reproducing Equation (2) from §63.362 (i)(2)(i) and explaining it in some detail, since its Sigma notation can obscure the total number of terms used in the actual compliance equation. It is important to recognize that the first half of the right side of the equation (containing index ***i***) will be expanded out to include as many non-SCV streams as the facility intends to monitor uniquely with in/out DRE to relax their SWEL. The second half of the equation (containing index ***j***) refers only to the SCV source (and by default any other source streams not specifically characterized by in/out). Here, the inlet mass is measured using scale weights like in SWEL1, not a measured inlet mass [14].

$$CES_{Streams} = \sum_{i=1}^{n} \left(M_{c,i} * (1 - ER_i)\right) + \sum_{j=1}^{m} \left(M_{c,j} * \left(1 - ER_j\right)\right)$$

Equation 7: A reproduction of §63.362 (i)(2)(i) Eq (2) showing the equation to compute SWEL2 emissions limitation.

Where:

CES*Streams* = The combined emission stream site-wide emissions limitation in lbs per month

$M_{c,i}$ = The 30-operating-day total mass sent to abatement/controls for each non-SCV constituent emission stream the facility wishes to individually characterize, as shown in this white paper's Equation 3 above

[15] It bears noting that these equations, as set up in Subpart-O, include a sort of double-accounting since the masses going to the Group 1 and 2 inlet lines are a subset of the mass being used to calculate the SCV SWEL. This has the effect of slightly relaxing the total emissions limitation. Though this could be accounted for by removing the $M_{c,i}$ masses from $M_{c,j}$, value before computing the combined stream SWEL, the rule specifically does not require this, so we follow the equations as written.

ER_i = The applicable emission reduction standards shown in Table 1 for each non-SCV constituent emission stream i (here, 0.98 for both Group 1 and 2)

i = Differentiated constituent emission stream index

n = Total number of differentiated constituent emission streams, 2

Mc,j = The 30-operating day total mass sent to controls/abatement for the consolidated emission streams containing SCV (here just one), as determined in accordance with Equation 10 of §63.364(f)(1)(i)(C)

ERj = The applicable SCV emission reduction standard shown in Table 1in decimal format, here 0.9999

j = SCV emission stream index, here just one

m = Total number of SCV emission streams, here just one

	Inlet Conc. (ppb)	Outlet Conc. (ppb)	Average Flow (CFM)	30-day Mass In (lbs)	30-day Mass Emissions (lbs)
Group 2	217	0.53	88500	95.00	0.232
Group 1	2072	1.03	1980	58.24	0.029*
SCV	N/A	1.03	5690	5698	0.029

Table 3: *Inlet and outlet concentrations in ppb (except inlet for SCV) and equivalents in lbs based on flow data. *Note that the 30-day mass emissions in lbs is the same for Group 1 and SCV because the concentration/mass emission is measured at the same* ***P4*** *sampling point, allowable for the rule if the streams are combined before abatement. Only one instance of this emissions number has to be included in the SWEL2 total because it would be duplicative to include both.*

The inlet average concentration, outlet average concentration, average flow, 30-day mass in, and 30-day mass emissions for each stream are shown in the table above.

For this facility, the equation for the SWEL limit is determined in the following way, expanding out the terms in the Sigma notation, and inserting the masses calculated from each of the component streams from the table above. Here, as in the first example, we show measured/calculated real data in **green**, and computed SWEL limitations (not the actual emissions) in **red.**

$$CES_{Streams} = M_{Group\ 2} * (1 - 0.98) + \ M_{Group\ 1} * (1 - 0.98) + \ M_{SCV} * (1 - 0.9999)$$
$$= 95.00\ lbs * (1 - 0.98) + \ 58.24\ lbs * (1 - 0.98) + \ 5698\ lbs * (1 - 0.9999) = \ 1.90 + 1.16 + 0.57 = 3.63\ lbs$$

Equation 8: SWEL2 ***allowed emissions*** *limit across Facility B, based on emissions reduction factors appropriate to the relevant stream and facility type, and* ***measured masses*** *entering the abatement systems.*

Based on this equation, the advantage the SWEL2 approach provides becomes very apparent. In an alternate SWEL1 configuration the facility would have to meet a SWEL of just 0.570 lbs/month. **Here, because the compliance is assessed based on the combined allowable masses of all measured streams (not based on the individual DREs) the facility has about 3 lbs more leeway per month, about 6.4x the limit that it would have through SWEL1.** As in the first example, we now substitute into this equation the actual computed mass emissions for each stream based on the measured mass emissions at **P2** and **P4** using the formula found in Equation 2 of this white paper.[15]

[16] As noted above, it would be inaccurate to double-count the 0.029 lb emissions value used for Group 1 with the same 0.029 lb value used for the other streams, so just one 0.029 lbs value is used to calculate the total facility emissions.

$$E_{Fac} = 0.232\ lbs + 0.029\ lbs = \mathbf{0.261\ lbs}$$

*Equation 9: Combined emissions measured at **P2** and **P4** stack sampling points at Facility B.*

At **0.261 lbs emitted**, **(7.2% of allowed)** this facility is comfortably within the SWEL2 allowed total emissions of 3.63 lbs by about a factor of **14x** thanks to the quality of the LESNI EO CAP and the Picarro CEMS characterizing the emissions streams. The performance of the dry beds abating Group 2 emissions is very solid at 99.6%, but it should be noted that the total comfort margin for this facility (as computed by the combination of the LESNI and dry beds' efficiencies) would be higher if dry beds didn't bring the average *DRE down.*[16]

While the configuration of this facility makes it challenging to assess the performance of the LESNI alone as if it were configured for SWEL1, we can roughly determine this efficiency by removing the pounds sent to dry beds from the total (for fairness, since these streams would have been sent to the LESNI under SWEL1, or otherwise abated by another technology) and recalculating DRE by:

$$M_{LESNI} = 5698\ lbs - 95\ lbs = \mathbf{5603\ lbs}$$

$$DRE_{obs} = \left(1 - \left(\frac{0.029\ lbs}{5603\ lbs * 0.99}\right)\right) * \frac{100\%}{1} = \mathbf{99.99948\%}$$

Equation 10: DRE for LESNI EO CAP at Facility B based on the total mass of EtO going to the CAP after removing the known mass going to the Group 2 dry beds.

This remarkable 99.99948% is very close to, but even better than the DRE seen in the first example, demonstrating the reliable and reproducible excellence that the LESNI EO CAP provides in EtO destruction when a Picarro CEMS is used to characterize the real, very low, emissions at the stack.

Competitor Comparison

Finally, we consider whether an alternate OE-FTIR technology would be able to demonstrate compliance for each of these stacks shown in the Facility B example. We do so because there is available stack test data from Facility B taken on a recent-model OE-FTIR showing 12 ppb on the Group 2 stack, and 15 ppb on the LESNI[17]. We also calculate whether an OE-FTIR CEMS reporting at its best-case-scenario published detection limit of 5 ppb would be able to demonstrate SWEL2 compliance.

[17] Though dry bed abatement is an effective method for removing EtO at high flows and lower DREs, and though the results of this white paper and other studies suggest successful compliance with these dry beds, LESNI and Picarro cannot specifically guarantee that dry beds will always successfully enable blended SWEL2 compliance.

[18] These numbers are the OE-FTIR representation of the stack concentrations, not the real values.

	Inlet Conc., Picarro (ppb)	Outlet Conc., Picarro (ppb)	OE-FTIR Detection Limit (ppb)	OE-FTIR Historical Stack Test Data (ppb)	Average Flow (CFM)	30-day Mass Emissions Allowed Limit (lbs)	30-day Mass Emissions, Picarro (lbs)	Inferred 30-day Mass Emissions, OE-FTIR LDL (lbs)	Inferred 30-day Mass Emissions, OE-FTIR Stack Test (lbs)
Group 2	217	0.53	5	12	88,500	1.90	**0.232**	**2.189**	**5.253**
Group 1	2072	1.03	5	...	1980	1.16	0.029*	0.141*	0.422*
SCV	...	1.03	5	15	5690	0.57	**0.029**	**0.141**	**0.422**
Total	...	...	...	...	...	3.63	**0.261**	**2.33**	**5.675**
% of Allowed SWEL	...	...	...	...	...	...	**7.2%**	**65%**	**156%**

Table 4: *An expansion of Table 3 to include OE-FTIR detection limits and site stack test data to calculate the inferred mass emissions rate at the stacks. We use the convention of* ***green*** *to show that a stream is or would be compliant,* ***orange*** *when it is >50% of the compliance number, and* ***red*** *when it is not compliant. *Note that the Group 1 emissions don't need to be added into the emissions sum since they are already accounted for in the LESNI emissions data.*

Using the LDL of the OE-FTIR to compute a best-case scenario for SWEL2 compliance, the combined emissions for the two stacks measured at P2 and P4 would be 2.33 lbs, 65% of the SWEL. Using the actual stack test data measured at the site with OE-FTIR, the total would be 5.675 lbs, 156% of the allowed SWEL, erroneously suggesting non-compliance and overstating emissions by about 22x. This analysis shows how incredibly important detection limits on the Picarro CRDS CEMS are for demonstrating the true compliance a facility is achieving with its abatement equipment.

CONCLUSIONS

This paper represents a significant update to Picarro and LESNI's first white paper, providing evidence of the superlative destruction removal efficiency of LESNI EO Catalytic Abatement Plants. **Using Picarro's CRDS CEMS, we demonstrate remarkable outlet concentrations averaging between 0-3 ppb which are used to calculate destruction removal efficiencies of 99.99934% and 99.99948% on two facilities' LESNI EO CAPs, 15 and 20 times better than the most stringent Subpart-O NESHAP requirement.**

We provide specific fully spelled-out examples of the two preferred compliance pathways found in the NESHAP—SWEL1 (by EtO usage) and SWEL2 (stream-specific)—using real-world data measured on three LESNI EO CAPs with Picarro CRDS at two facilities in the US. We show how in the case of a SWEL1 pathway, a CEMS-2 comfortably proves compliance at the first facility by about a margin of **15x**, and that in the case of SWEL2, a CEMS-4 comfortably shows compliance at the second facility by about a factor of **14x**, limited primarily by the dry bed destruction efficiency added into the blended SWEL. These case studies apply the relevant compliance equations from observation to SWEL, and in the case of the SWEL2 compliance example, allow us to specifically determine the additional emissions allowances provided by an in/out SWEL2 methodology, here about **3 lbs/month**. We hope that these examples not only provide clear demonstration of the methods associated with computing compliance numbers, but also provide customers considering LESNI and Picarro solutions the confidence that these solutions will effectively guarantee Subpart-O compliance.

We show that Picarro's extremely low detection limit of 0.25 ppb is critical in proving compliance, and that the published lower detection limit (5 ppb) and actual stack test data (12, 15 ppb) from OE-FTIR provide evidence that this competitor technology likely cannot reliably demonstrate SWEL compliance on abatement systems which Picarro knows to be compliant. Here, as shown at Facility B, **OE-FTIR would potentially overstate facility emissions by about 22 times, and erroneously suggest that the facility is emitting at 156% of compliance levels.**

Though many elements of EtO regulations are in flux at the time of publication, the current compliance deadlines for the Subpart-O NESHAP come into effect in April of 2026 for larger facilities, and April of 2027 for smaller facilities. While Picarro and LESNI work with the greatest possible efficiency to meet the timelines demanded by our customers, the process of engineering, building, and shipping appropriate abatement solutions takes time. With these deadlines fast approaching, facilities are at significant risk if they have not confirmed the compliance of their existing abatement systems, or already placed an order for technologies like LESNI EO CAP that will allow them to meet the NESHAP requirements. Picarro and LESNI strongly recommend that commercial sterilizers in the US move aggressively and immediately to shore up their abatement performance and monitoring. We are quite certain that there is no better combination of technologies than LESNI's EO CAP and Picarro's CEMS to achieve and prove this compliance. Discover the peace of mind that our combined solutions bring by reaching out to
sales@lesni.com and eto@picarro.com.

GLOSSARY

See additional explanations of process gas and compliance nomenclature in **DISCUSSION OF TERMS**

ARV: Aeration Room Vent

CAP: Catalytic Abatement Plant

CatOx: Catalytic Oxidizer

CEMS: Continuous Emission Monitoring System

CEV: Chamber Exhaust Vent, a.k.a. “Back Vent”

CFM: Cubic Feet per Minute

CRDS: Cavity Ringdown Spectroscopy

EPA: Environmental Protection Agency

EtO, EO: Ethylene Oxide

FIFRA: Federal Insecticide Fungicide and Rodenticide Act

Group 1: Fugitive emissions from pre-aeration areas

Group 2: Emissions from post-aeration product

LDL: Lower Detection Limit

LEL: Lower Explosivity Limit

LESNI EO CAP: LESNI’s Ethylene Oxide Catalytic Abatement Plant

LOD: Level of Detection or Limit of Detection

NESHAP: National Emission Standard for Hazardous Air Pollutants

PPB: Parts per billion

PPM: Parts per million

PS-19: EPA Performance Specification 19

SCFM: Standard Cubic Feet per Minute

SCV: Sterilizer Chamber Vent

Subpart-O: The Commercial Sterilizer NESHAP (40 CFR Pt 63, Subpart-O)

SWEL: Site-Wide Emissions Limitation

SWEL1: SWEL by EtO Usage

SWEL2: SWEL by Emissions Stream

BIOGRAPHIES

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Jonathan earned his undergraduate in Environmental Science and Anthropology from Columbia University, and his Ph.D. in Oceanography from the Scripps Institution of Oceanography, where he studied the biogeochemistry of the carbon cycle, particularly in the Southern Ocean around Antarctica. He worked at the National Center for Atmospheric Research and NOAA before taking a position at Picarro in 2019. At Picarro he first worked as an application scientist in the Environmental vertical focusing on formaldehyde measurements and EtO. He was one of four founding members of Picarro's Environmental Solutions vertical in early 2023, where he served first as a Technical Lead, and most recently as a Senior Program Manager. His expertise lies in EtO sterilization, industrial monitoring, and regulatory compliance.

Sean Maamari, M.Sc.; Chairman and Co-Owner, LESNI

Sean is a graduate of University of Birmingham, UK with an M.Sc. degree in Chemical Engineering. Sean started his career in technical sales of chemicals and process equipment, selling to many of the world's leading chemical companies, and working internationally on industrial processes technology. During this time, he worked with Schott Glass (Mainz, Germany), as the product development manager for air pollution control and process engineering equipment in the UK and Ireland. In 1998, Sean joined LESNI as International Sales Manager, and in 2012 he assumed the role Director of Sales after a management buyout. He has been influential in developing air purification solutions and market sector integration, and in increasing LESNI brand awareness around the world.

Jens Hermann, M.Sc.; Global Sales & Marketing Director, LESNI

Jens is a graduate of University of Applied Sciences in Hannover, Germany. He finished his study with a MSc in Mechanical Engineering, specializing in process and environmental engineering techniques. Jens worked for the first 8 years of his career as a consultant with a focus on reengineering products and plants to achieve cost reduction, modularization, standardization, technical processes optimization, and subsequent reflection and implementation of these changes at the different IT systems, such as CAD, PDM, and ERP. Jens also spent three years at Continental Tires, developing passenger car tires for Audi and VW. He relocated to Denmark in 2008 to assume a position at LESNI, and has worked there ever since.

Additional Contributions:

The authors recognize and appreciate significant contributions from Sean Cronin, David Wells, Carmen Planells, Michael McDonald, James Schulz, Gregor Lucic and Dave Miller (Picarro), and from the staff at Facilities A and B.

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