FALL 2024

PICARRO ETO CONFERENCE

Streamlining Emissions Compliance in the Sterilization Industry

OCTOBER 28-30 // ATLANTA, GEORGIA

PICARRO

FALL 2024

PICARRO ETO CONFERENCE

Streamlining Emissions Compliance in the Sterilization Industry

PICARRO

EtO Done Right

A New Approach

Alex Balkanski

President & CEO

Thank You

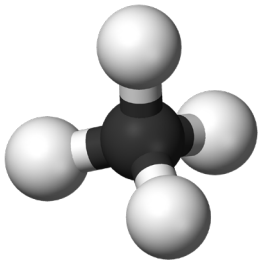
COMMUNITY OF KEY STAKEHOLDERS

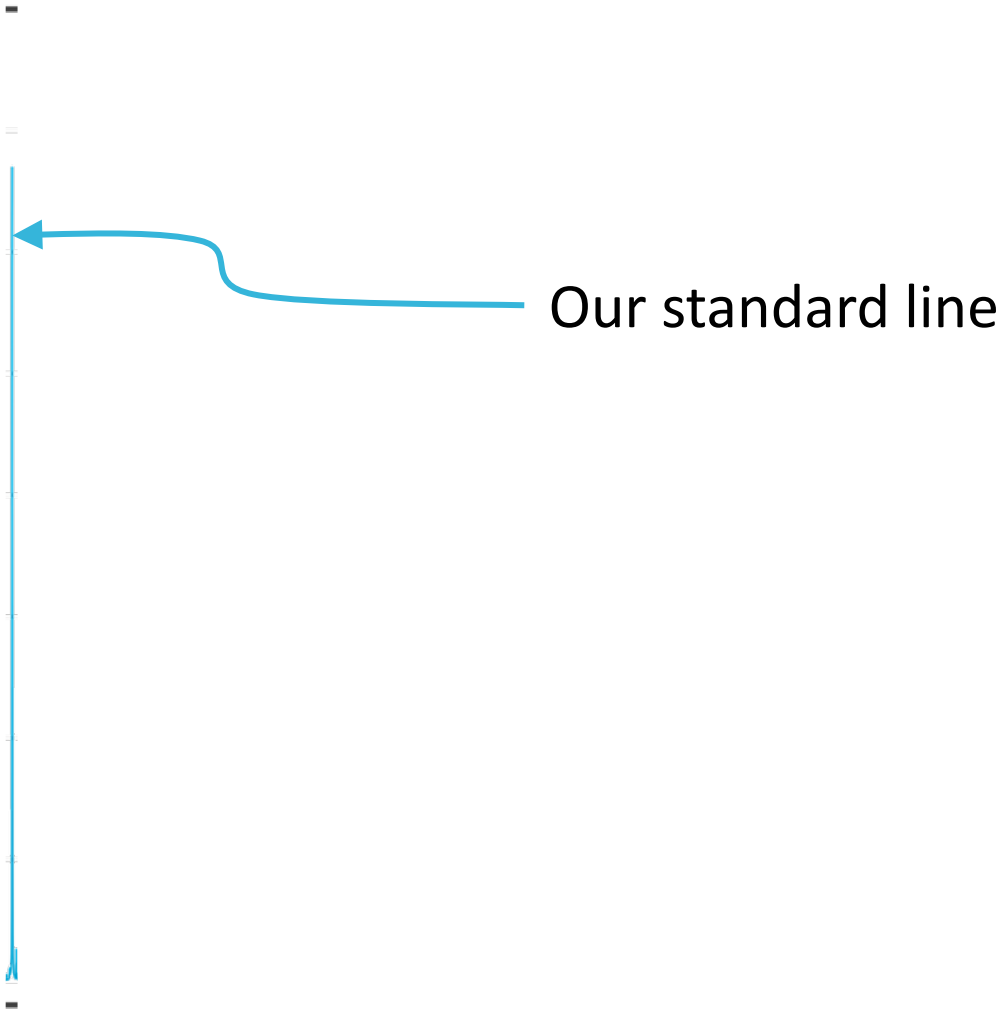
“YOU CAN’T FIX WHAT YOU DON’T KNOW”

TRUSTED DATA

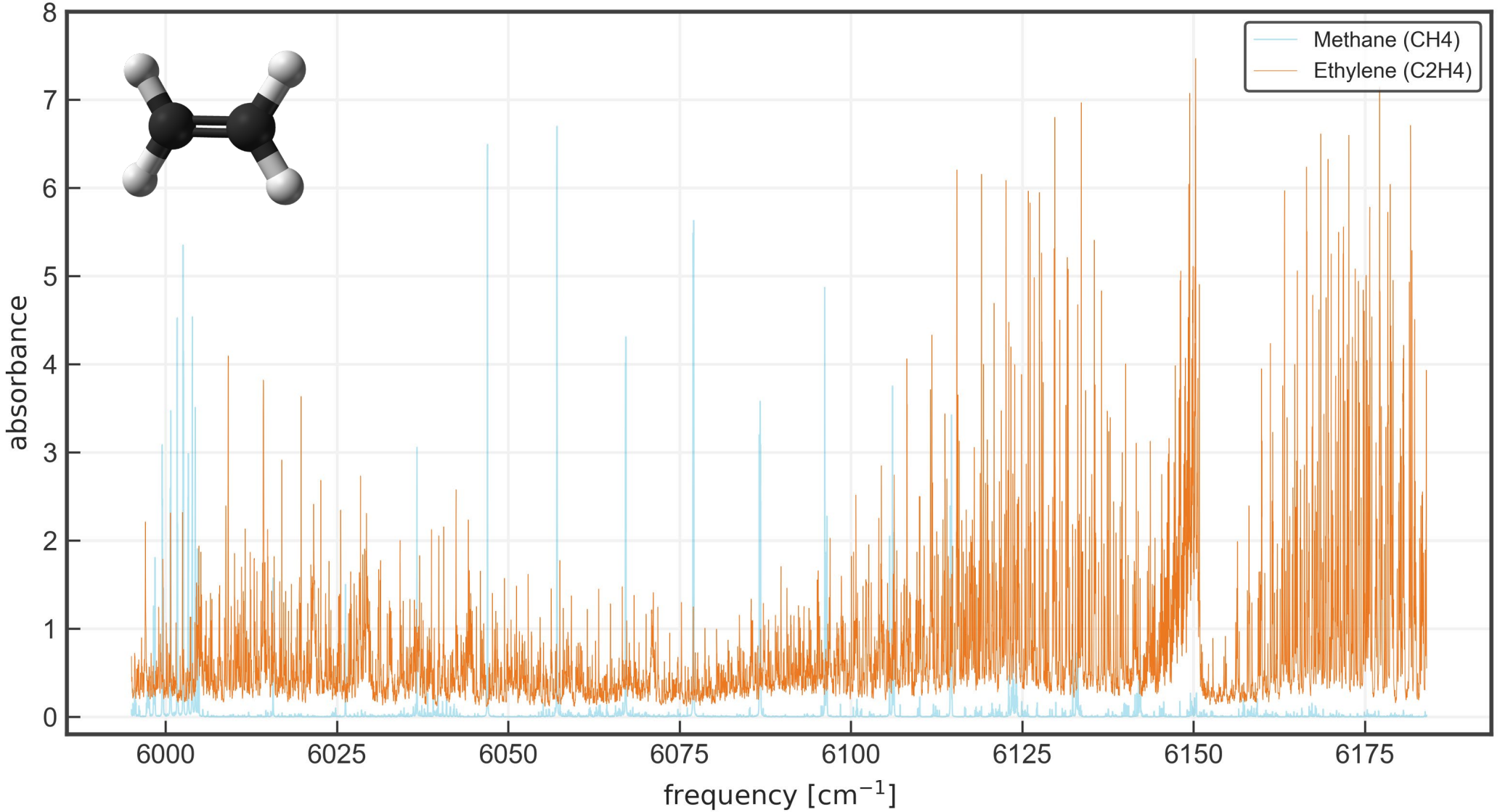
WHY ARE WE DOING EtO?

Methane

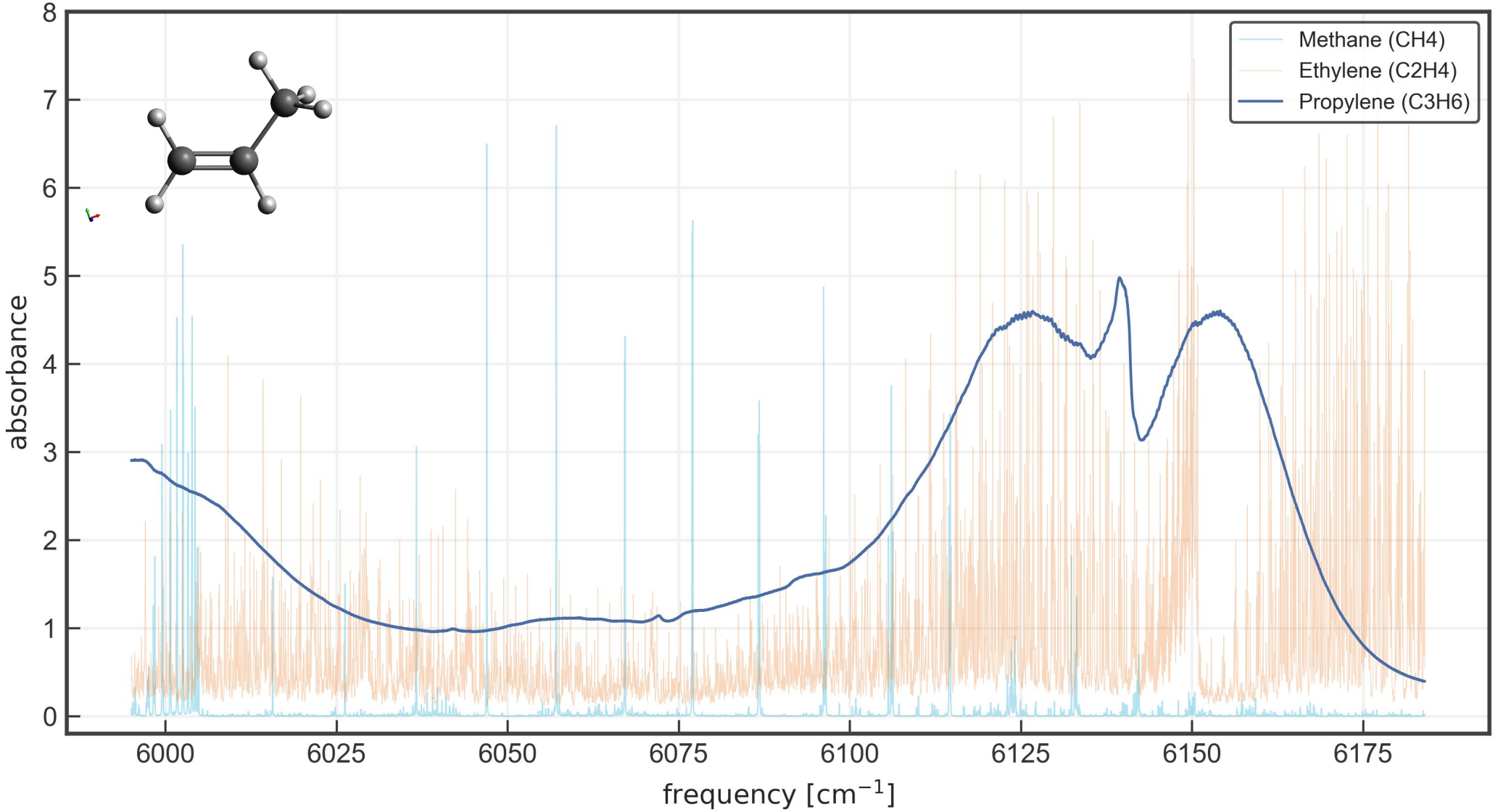




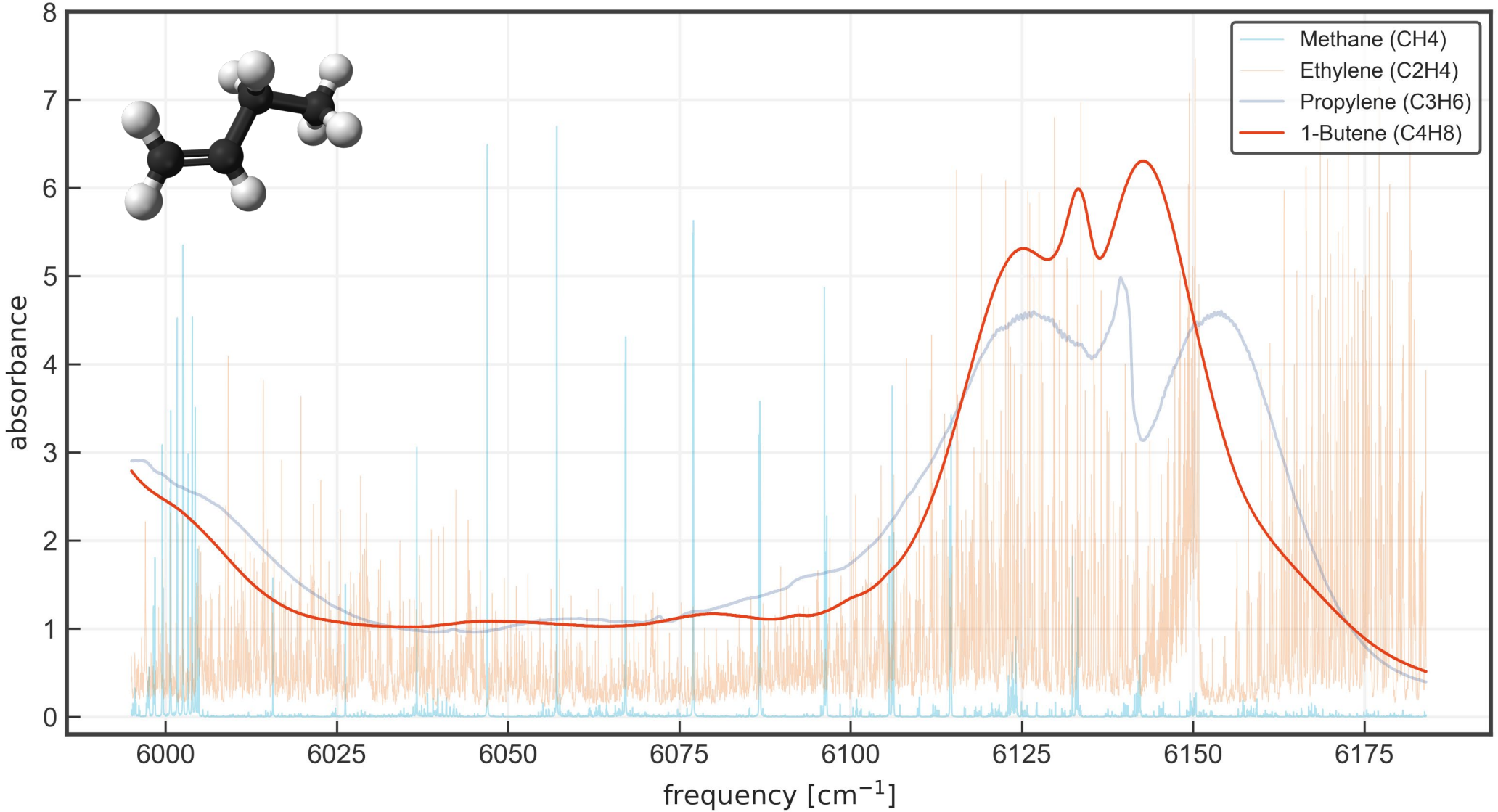
Ethylene


Methane (CH4)
Ethylene (C2H4)
absorbance
frequency [cm^{-1}]
0
1
2
3
4
5
6
7
8
6000
6025
6050
6075
6100
6125
6150
6175

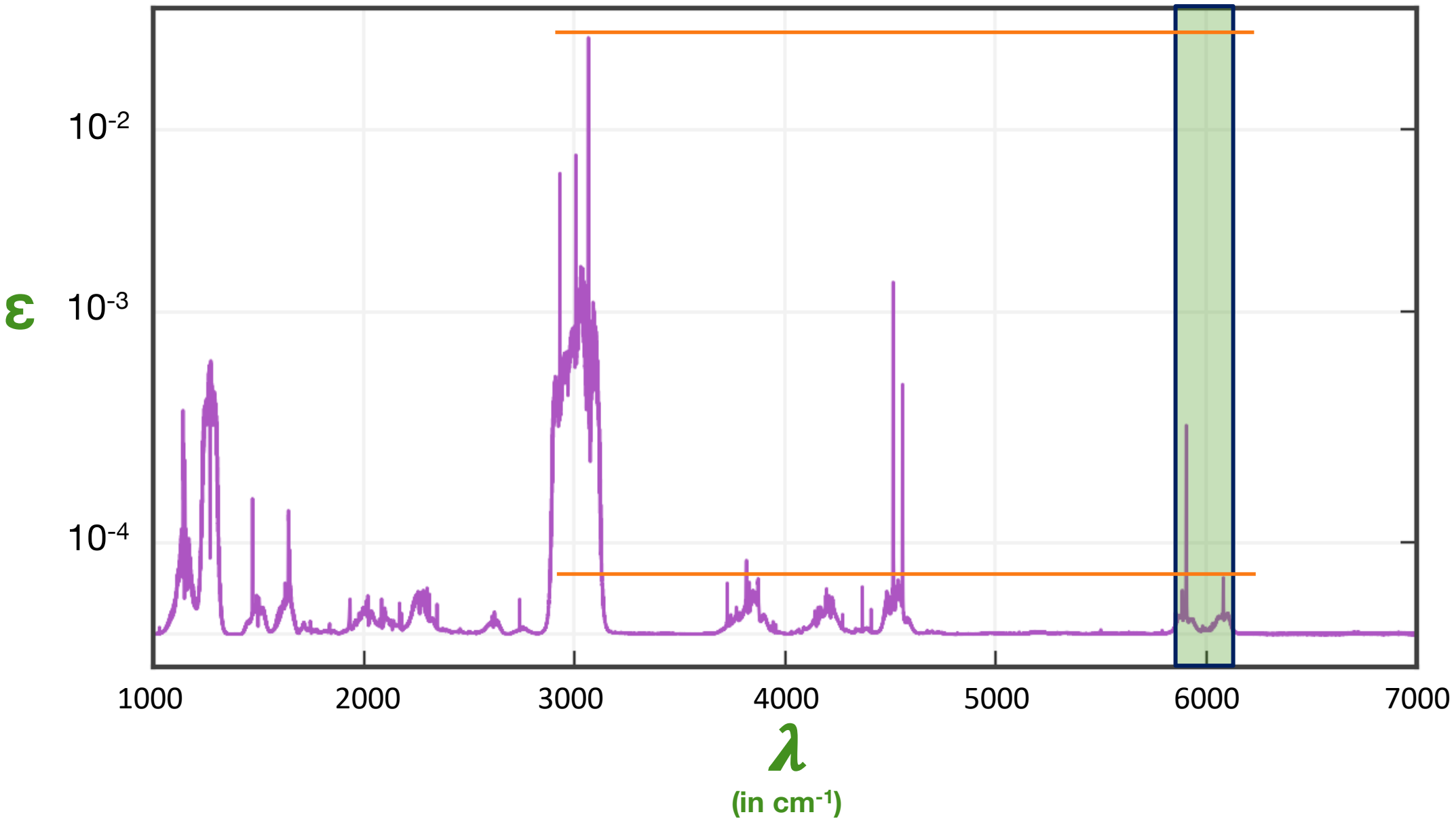
Propylene


Methane (CH4)
Ethylene (C2H4)
Propylene (C3H6)
absorbance
frequency [cm^{-1}]
0
1
2
3
4
5
6
7
8
6000
6025
6050
6075
6100
6125
6150
6175

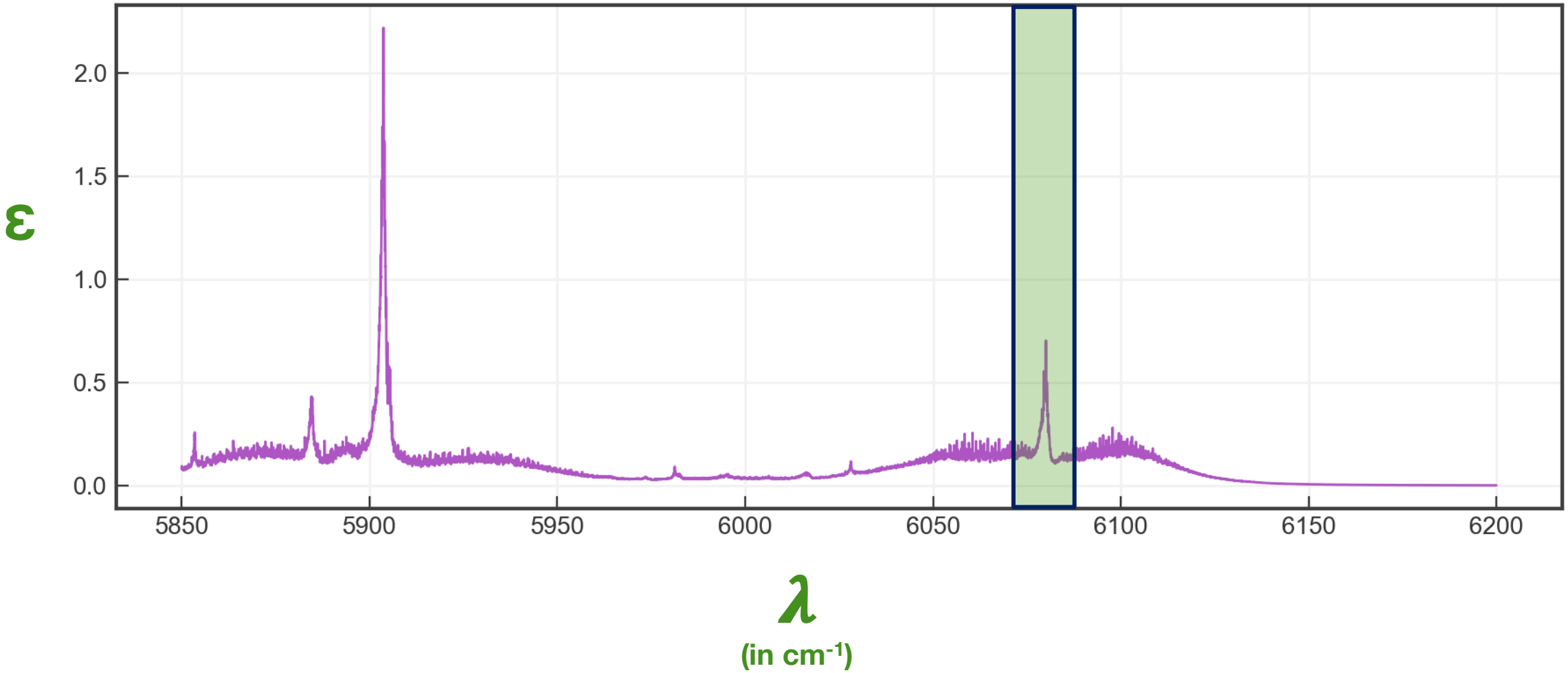
Butene


Methane (CH4)
Ethylene (C2H4)
Propylene (C3H6)
1-Butene (C4H8)
absorbance
frequency [cm^{-1}]
0
1
2
3
4
5
6
7
8
6000
6025
6050
6075
6100
6125
6150
6175

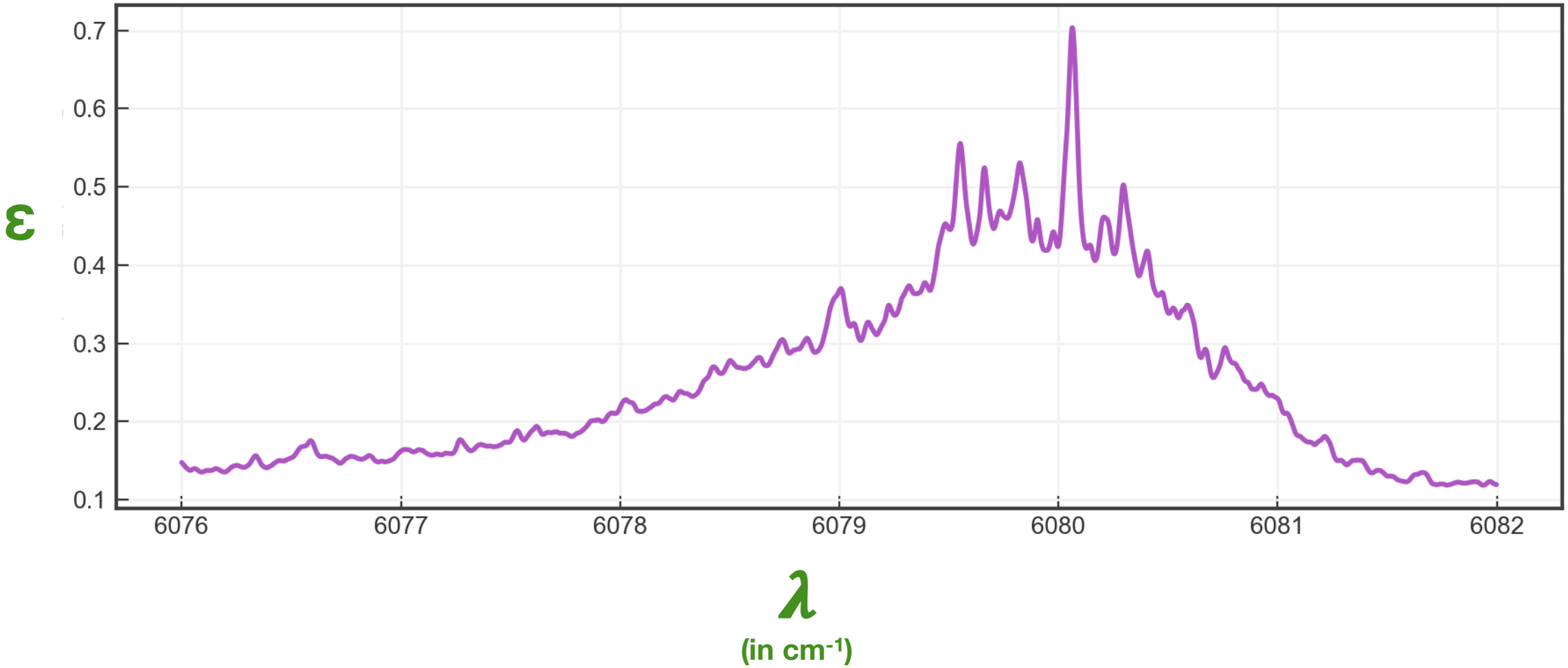
EtO



EtO over 350 wavenumbers

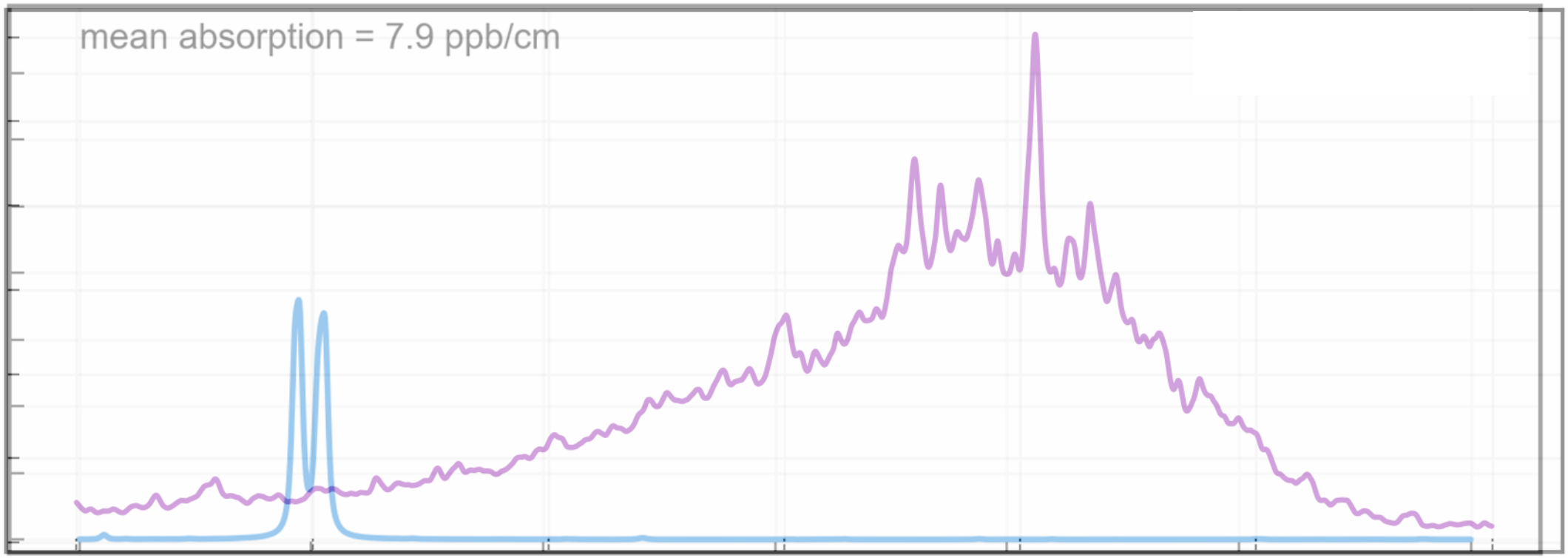


EtO over 6 wavenumbers



PICARRO

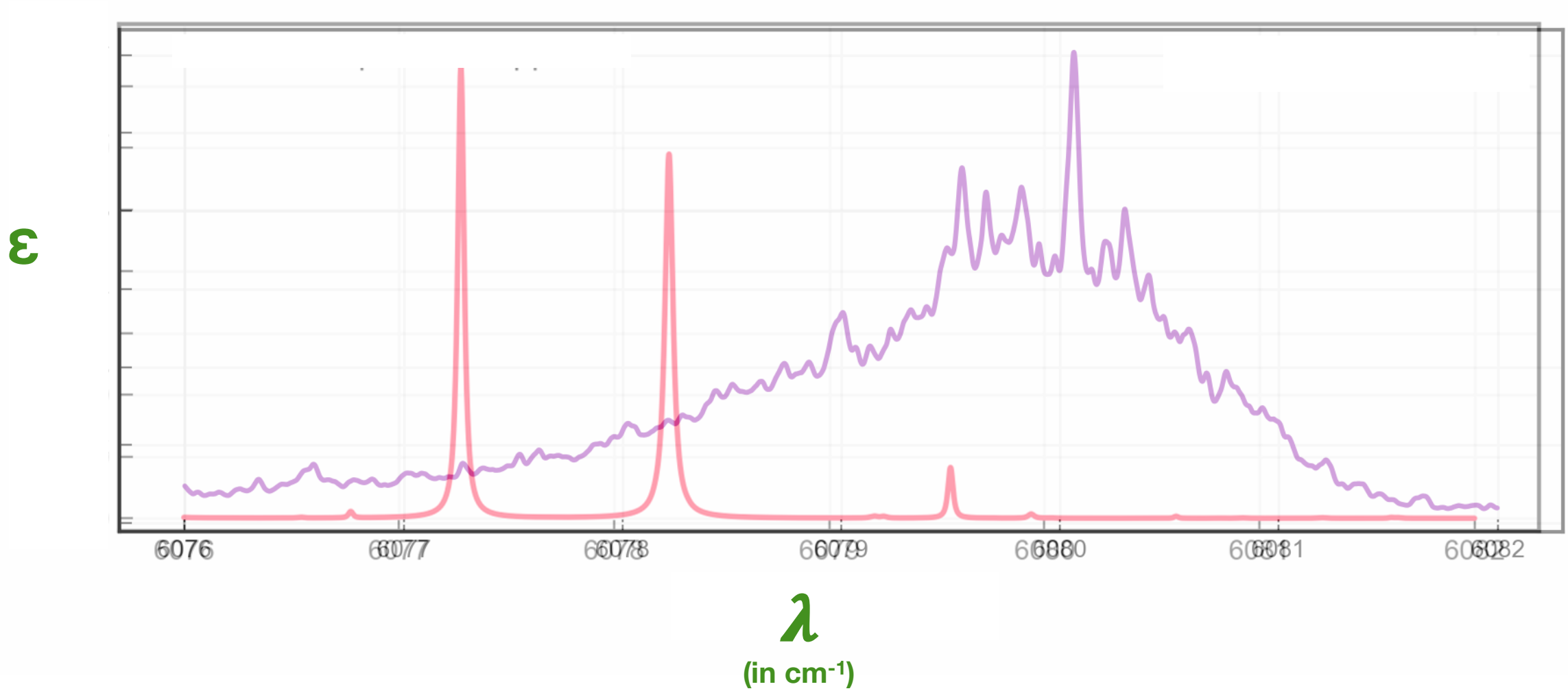
EtO over 6 wavenumbers

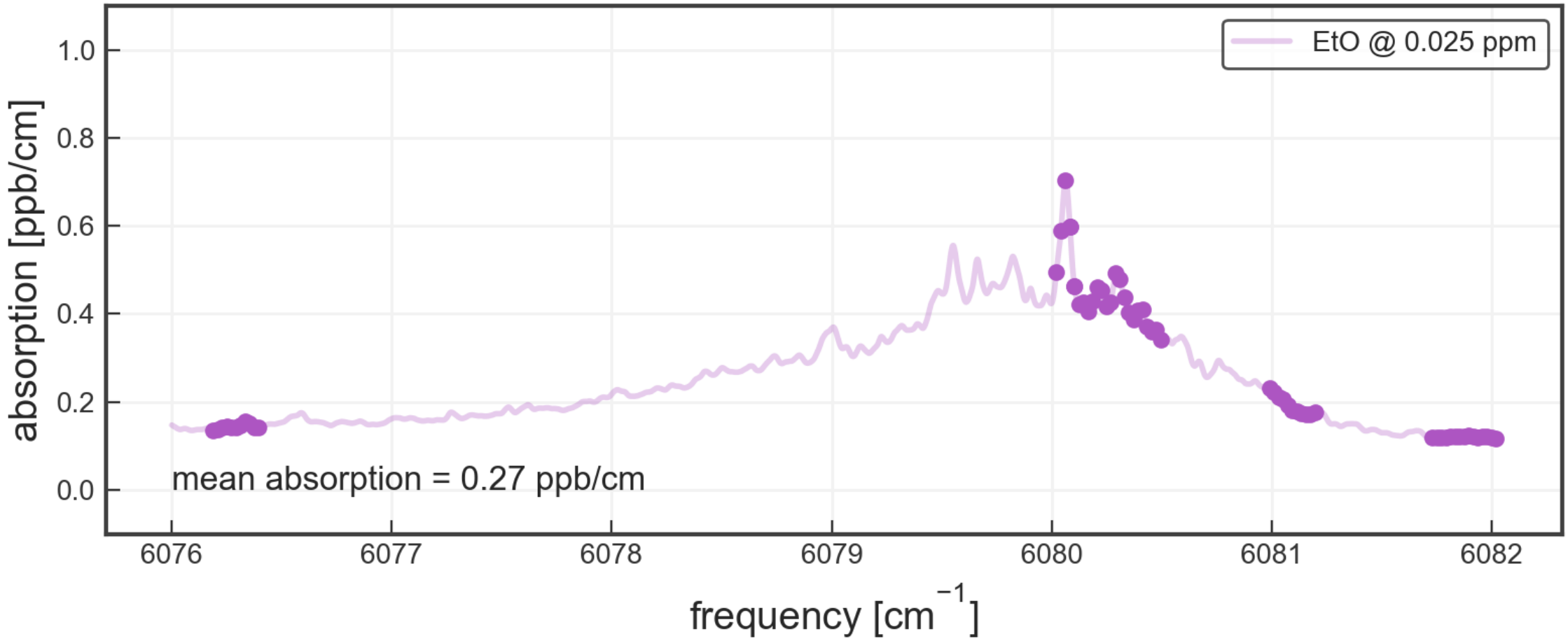


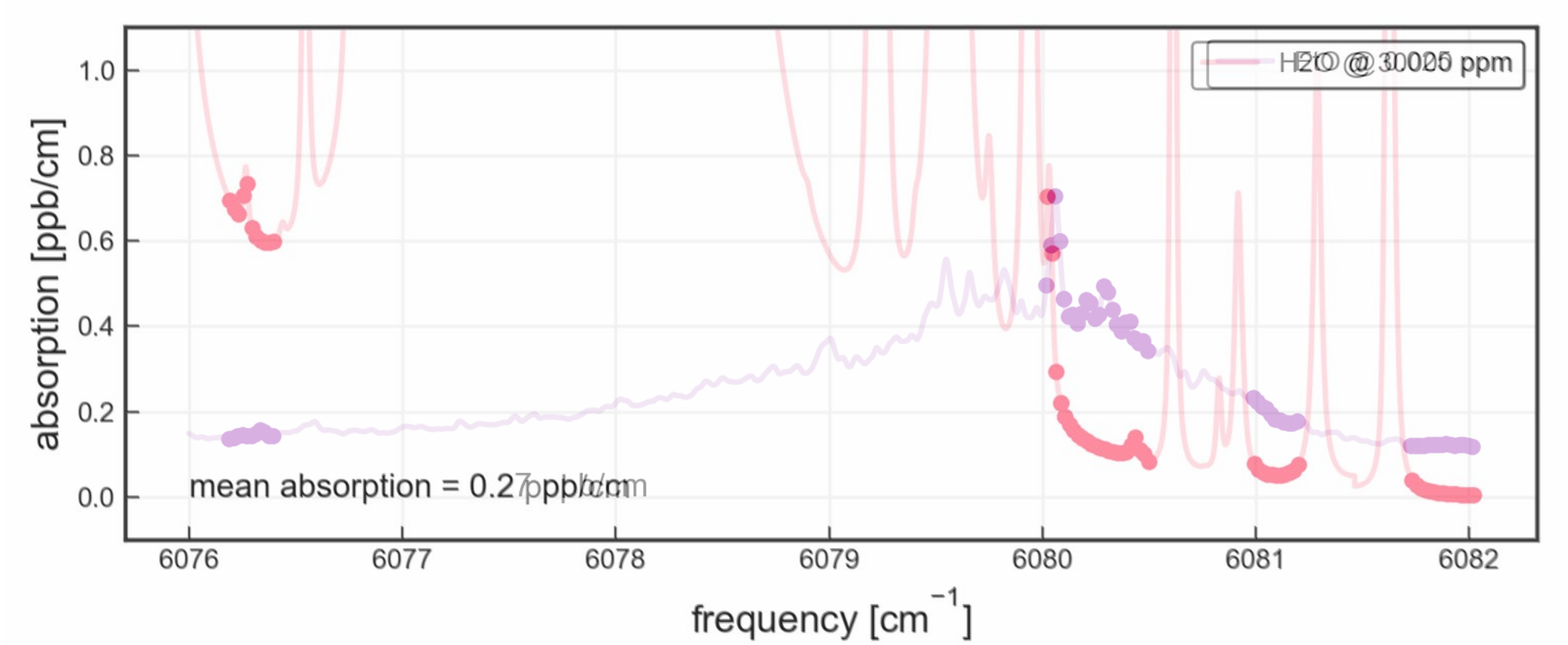
(in cm^{-1})

PICARRO

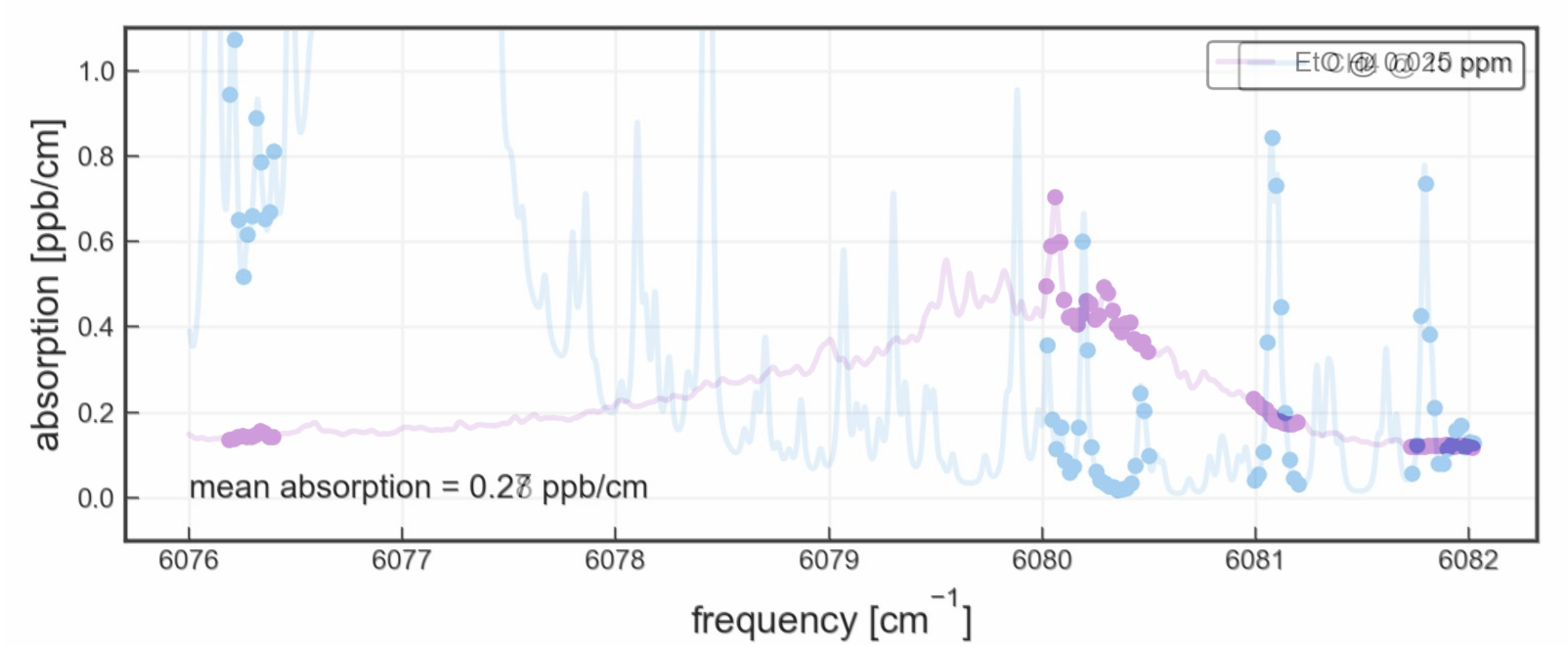
EtO over 6 wavenumbers



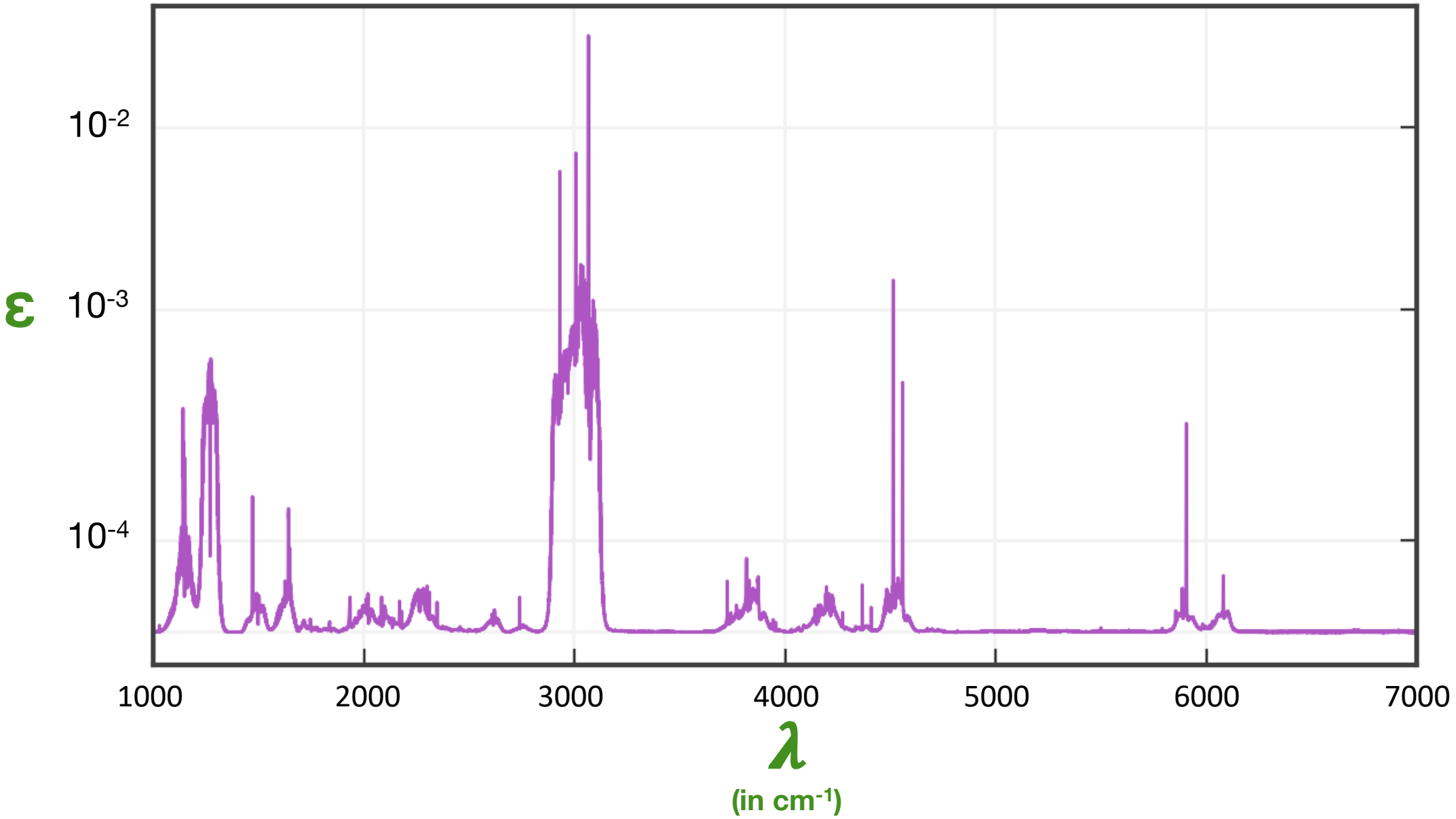

EtO @ 0.025 ppm
absorption [ppb/cm]
1.0
0.8
0.6
0.4
0.2
0.0
mean absorption = 0.27 ppb/cm
6076
6077
6078
6079
6080
6081
6082
frequency [cm^{-1}]


absorption [ppb/cm]
1.0
0.8
0.6
0.4
0.2
0.0
6076
6077
6078
6079
6080
6081
6082
frequency [cm^{-1}]
mean absorption = 0.27 ppb/cm
H2O @ 30025 ppm

PICARRO


absorption [ppb/cm]
1.0
0.8
0.6
0.4
0.2
0.0
6076
6077
6078
6079
6080
6081
6082
frequency [cm^{-1}]
mean absorption = 0.27 ppb/cm
EtOH @ 0.025 ppm

EtO



$$A \propto \varepsilon \bullet \ell$$

Thank You

FALL 2024

PICARRO ETO CONFERENCE

Streamlining Emissions Compliance in the Sterilization Industry

PICARRO

Presentation 1

Facts Alone Will NOT Save Us

Raymond Stanford
President, Steritec

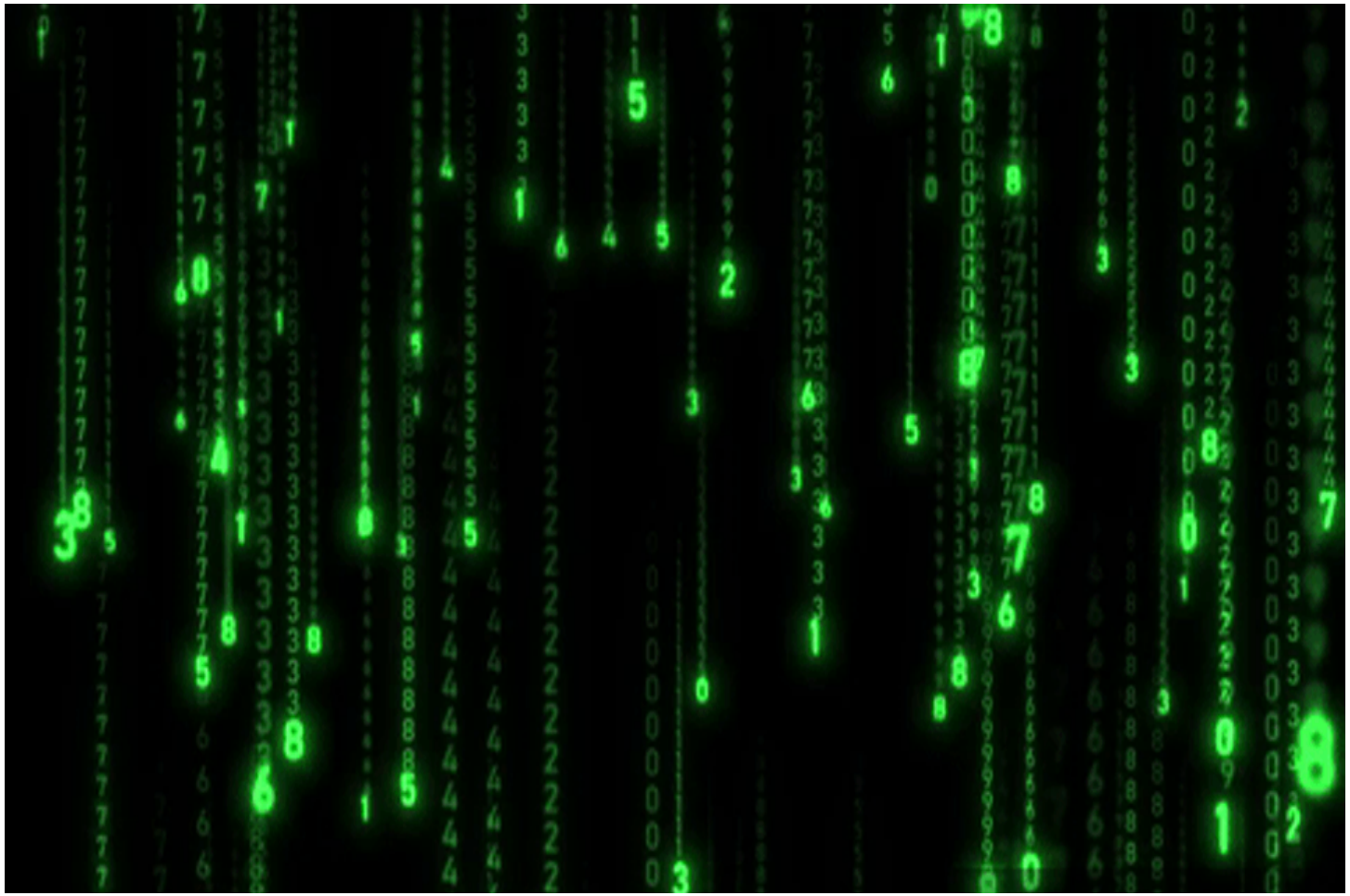
Dusty Abney, PhD
Executive Account Manager, Steritec

Who is this guy?

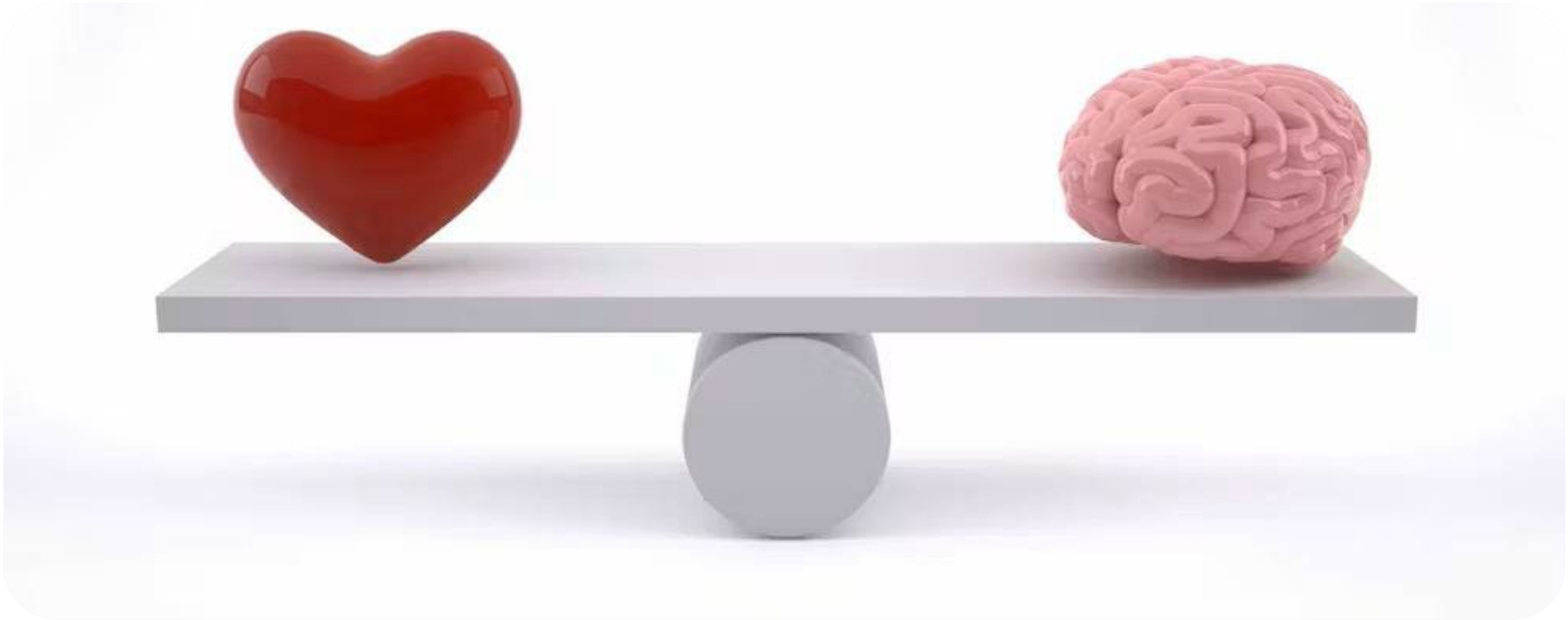
Are We as Prepared as We Think?

Facts Are Our Go-To

- Those of us who live in facts/data are comfortable
- The gen-pop THINKS they understand facts and stats
- To some extent we're all lead by emotions



Facts Versus Feelings Isn’t the Way to Think about Communicating Science

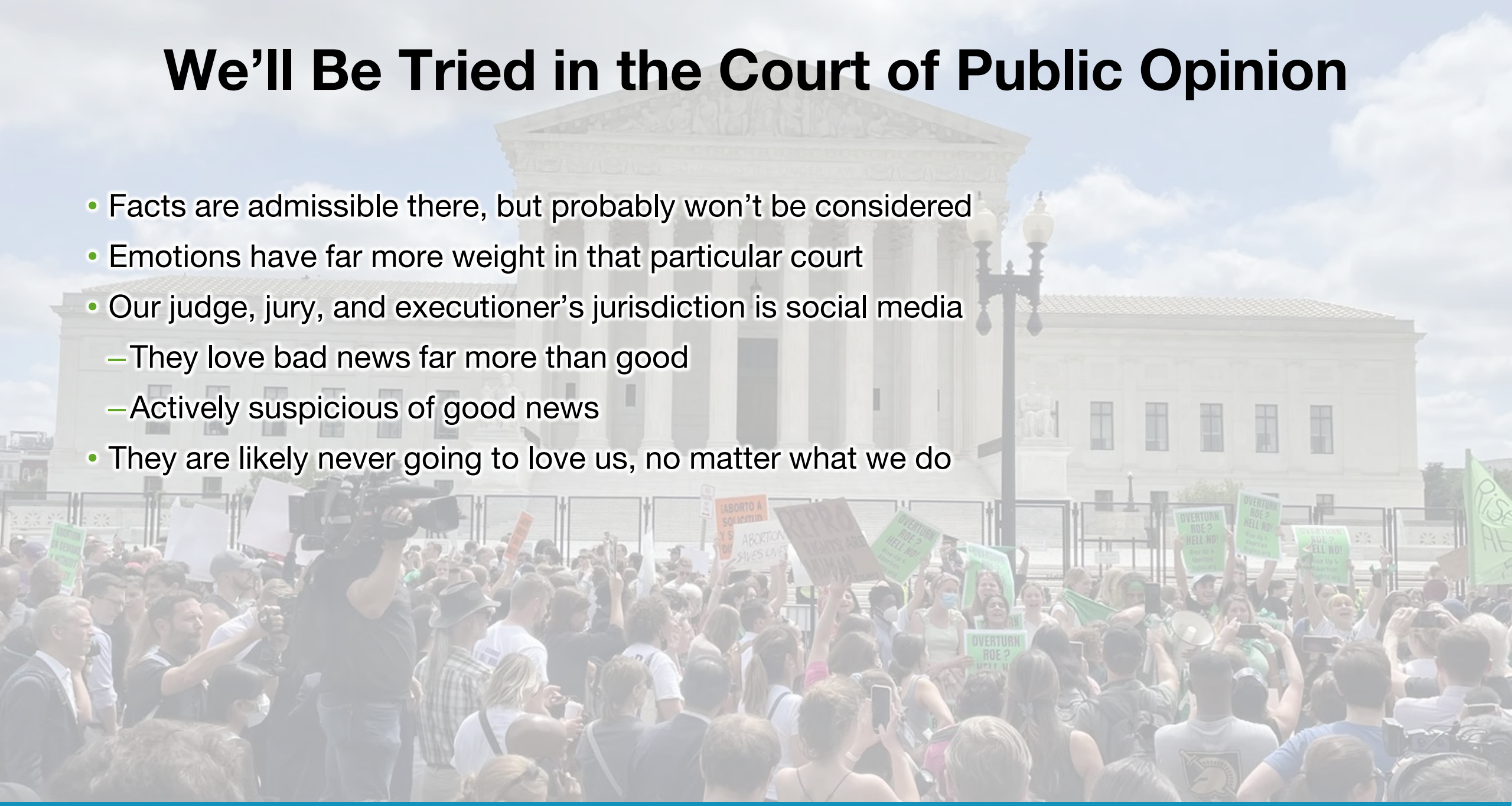


People are complex, social and affected by a diverse range of influences depending on the situation. We want to hold accurate views, but emotion, group identities and conflicting goals can get in the way.

https://theconversation.com/facts-versus-feelings-isnt-the-way-to-think-about-communicating-science-80255

We'll Be Tried in the Court of Public Opinion

- Facts are admissible there, but probably won't be considered
- Emotions have far more weight in that particular court
- Our judge, jury, and executioner's jurisdiction is social media
  - They love bad news far more than good
  - Actively suspicious of good news
- They are likely never going to love us, no matter what we do



Relevant and Related Commonalities

Ag Is a Cautionary Tale

BEEF. IT'S WHAT'S FOR DINNER.®

Cattle: The Ultimate Upcyclers

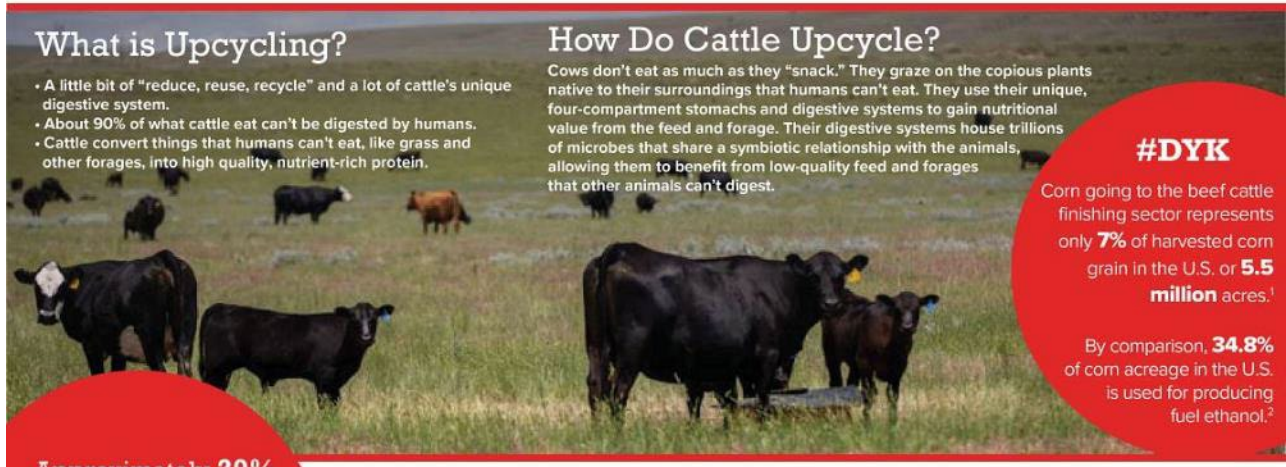
Every day, cattle graze and unknowingly turn natural resources like solar energy and pastureland into high-quality proteins and other invaluable products. They're upcyclers that take otherwise useless materials, add nutritional and environmental value, and transform them into something more — a better product in disguise.

What is Upcycling?

- A little bit of "reduce, reuse, recycle" and a lot of cattle's unique digestive system.
- About 90% of what cattle eat can't be digested by humans.
- Cattle convert things that humans can't eat, like grass and other forages, into high quality, nutrient-rich protein.

How Do Cattle Upcycle?

Cows don't eat as much as they "snack." They graze on the copious plants native to their surroundings that humans can't eat. They use their unique, four-compartment stomachs and digestive systems to gain nutritional value from the feed and forage. Their digestive systems house trillions of microbes that share a symbiotic relationship with the animals, allowing them to benefit from low-quality feed and forages that other animals can't digest.



#DYK

Corn going to the beef cattle finishing sector represents only **7%** of harvested corn grain in the U.S. or **5.5 million** acres.[1]

By comparison, **34.8%** of corn acreage in the U.S. is used for producing fuel ethanol.[2]

Approximately **29%** of the land in the U.S. is pasture or rangeland that is too wet, rocky, steep, or arid to support cultivated agriculture.[3] This land is able to support cattle, sheep, and goats — and protein upcycling.

Impact: A Circular Economy

The real value in upcycling is adding renewed value to products. Chief among those benefits are:

1. Reduced Landfill
Cattle can feed on byproducts from biofuel and food production industries, such as distiller grains and wheat millings, reducing the volume of waste going to landfills.

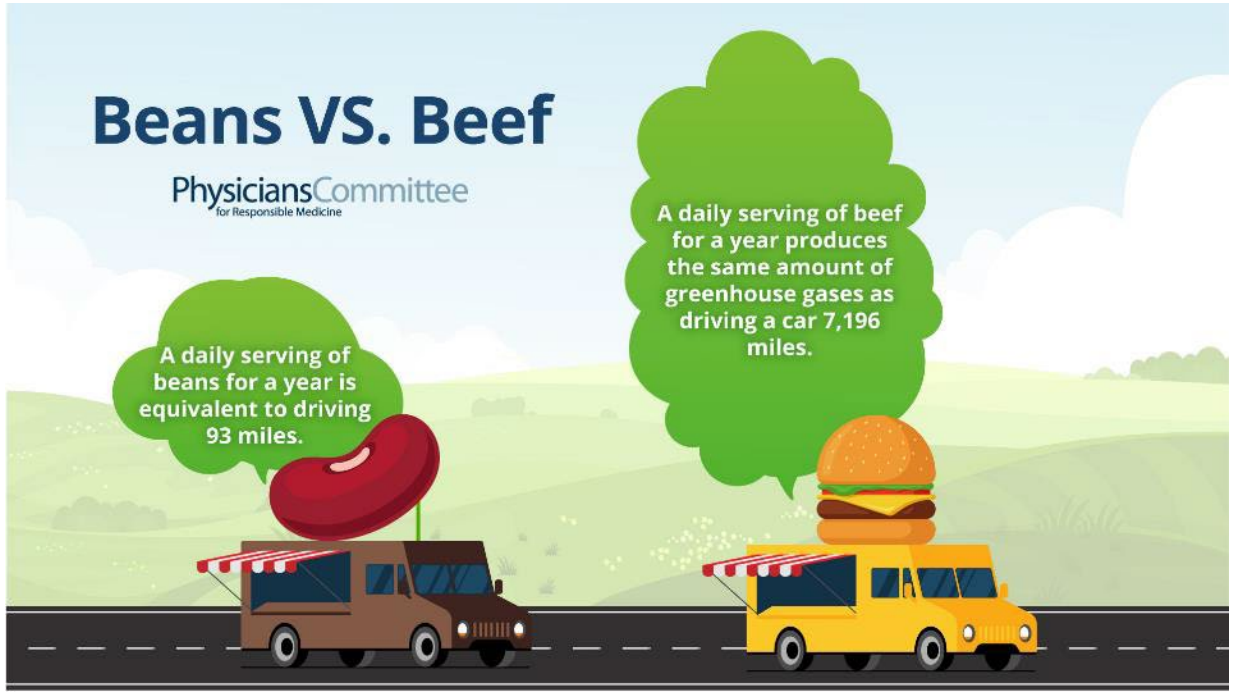
2. More than Meat
More than 44% of an animal's live weight transforms into other goods such as:
- Leather
- Pharmaceuticals
- Cosmetics
- Pet food

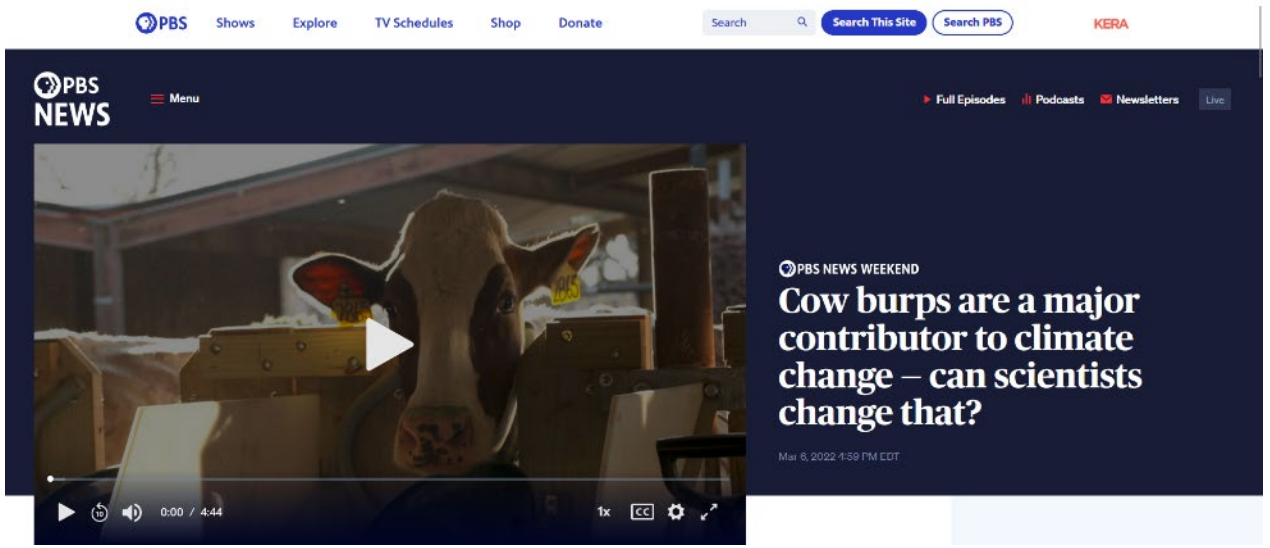
3. An Improved Ecosystem
Properly managed cattle grazing can improve rangeland and wildlife habitats. As the global population continues to grow, ruminant animals like beef cattle can help us make more protein with less.

1. NASS. 2021. Steers and Heifers Commercial Slaughter GE 500, 2019/2020. Found on USDA/NASS QuickStats Ad-hoc Query Tool.
2. U.S. Bioenergy Statistics 2019/2020. 2021. Found on USDA ERS - U.S. Bioenergy Statistics.
3. USDA ERS. 2021. 2012 ERS Major Uses of Land. Found on USDA ERS - Major Land Uses.

To learn more about the upcycling process and cattle's role in sustainability, visit **BeefItsWhatsForDinner.com.**

BEEF. Funded by Beef Farmers and Ranchers


Beans VS. Beef
PhysiciansCommittee
for Responsible Medicine
A daily serving of beef for a year produces the same amount of greenhouse gases as driving a car 7,196 miles.
A daily serving of beans for a year is equivalent to driving 93 miles.


PBS
Shows
Explore
TV Schedules
Shop
Donate
Search
Search This Site
Search PBS
KERA
PBS NEWS
Menu
Full Episodes
Podcasts
Newsletters
Live
0:00 / 4:44
1x
PBS NEWS WEEKEND
Cow burps are a major contributor to climate change – can scientists change that?
Mar 6, 2022 1:59 PM EDT


BBC LEARNING ENGLISH
News Review
Gassy cows and global warming


Ditch the Meat to Fight the Heat
PCRM.org/ClimateChange
PAID FOR BY THE PHYSICIANS COMMITTEE FOR RESPONSIBLE MEDICINE

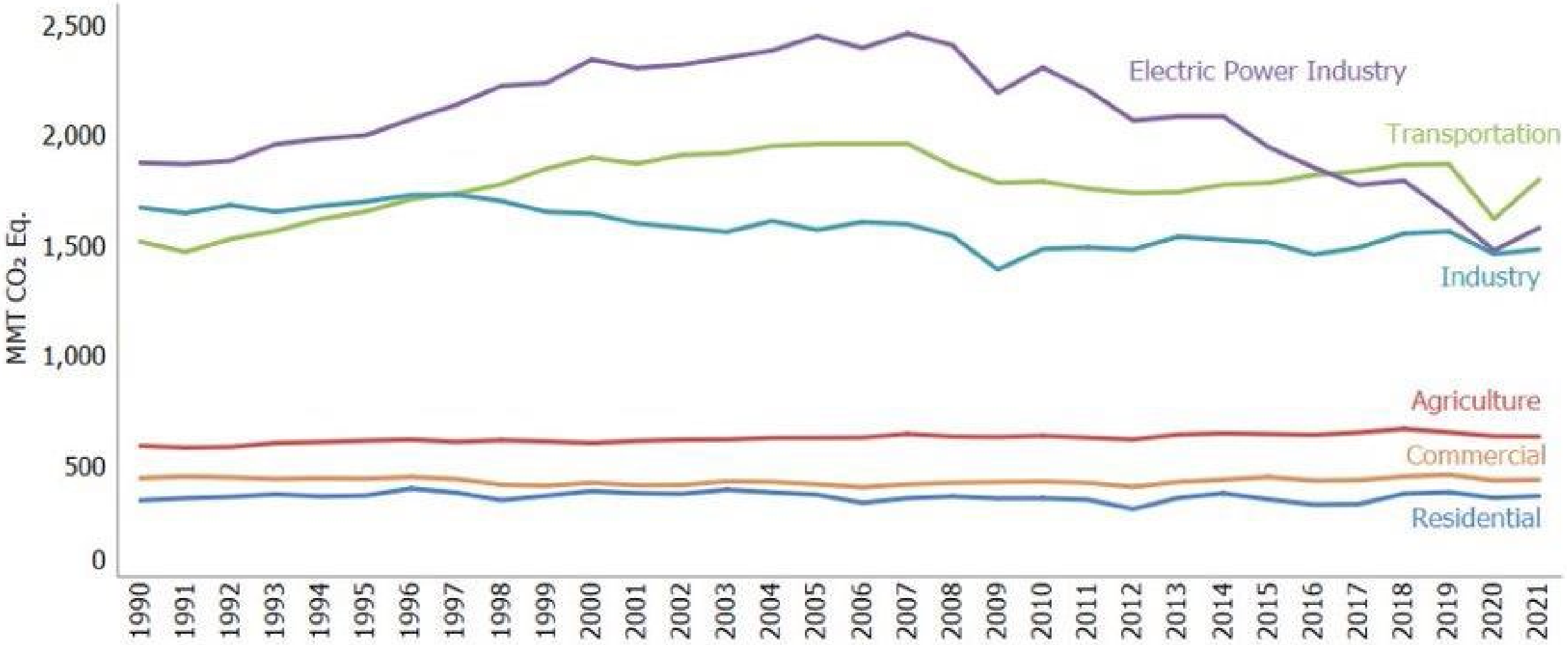
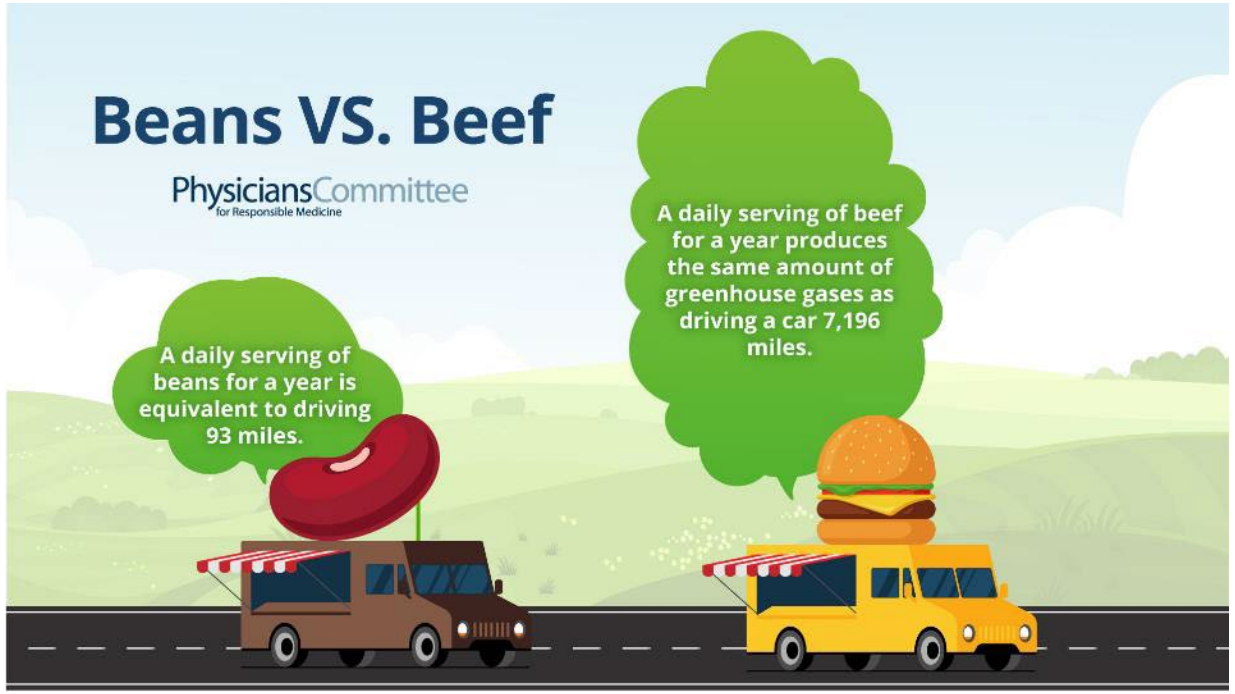
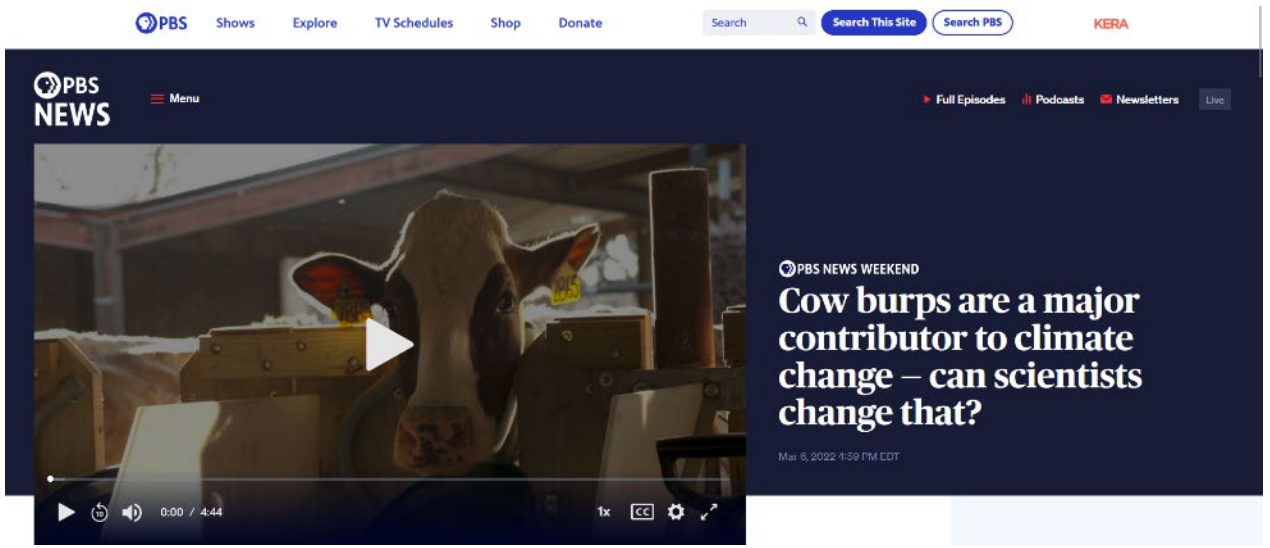


Figure 6: *U.S. Greenhouse Gas Emissions Allocated to Economic Sectors*

https://www.epa.gov/system/files/documents/2024-04/us-ghg-inventory-2024-main-text.pdf


Beans VS. Beef
PhysiciansCommittee
for Responsible Medicine
A daily serving of beef for a year produces the same amount of greenhouse gases as driving a car 7,196 miles.
A daily serving of beans for a year is equivalent to driving 93 miles.


PBS
Shows
Explore
TV Schedules
Shop
Donate
Search
Search This Site
Search PBS
KERA
PBS NEWS
Menu
Full Episodes
Podcasts
Newsletters
Live
0:00 / 4:44
1x
PBS NEWS WEEKEND
Cow burps are a major contributor to climate change – can scientists change that?
Mar 6, 2022 1:59 PM EDT


BBC LEARNING ENGLISH
News Review
Gassy cows and global warming


Ditch the Meat to Fight the Heat
PCRM.org/ClimateChange
PAID FOR BY THE PHYSICIANS COMMITTEE FOR RESPONSIBLE MEDICINE

Less than 7% of PCRM Members are Actual Physicians

PCRM is Harshly Criticized by Physicians and the American Medical Association

PCRM Has Connections to Radical Animal Extremist Groups

https://protecttheharvest.com/what-you-need-to-know/overview-of-animal-rights-organizations/physicians-committee-for-responsible-medicine-pcrm-who-they-really-are

Maybe You've Invested in Your Community…

CITY OF Athens

Government | Departments | Community | Business

Home › News Flash

News

Posted on: July 24, 2024

Steritec Loan

Members of the Athens City Council, the Athens Economic Development Corporation (AEDC), and Raymond Stanford from Steritec Services LLC celebrated the approval of a $1.9 million loan to the company on July 22. The funding will support the installation of abatement equipment to comply with EPA regulations and promote local economic growth.

…But Have They Invested in You?


AI generated image of an “Ethylene Oxide company”
Linkedin


MR. NEWTON, I THINK YOU'RE FACING SOME SERIOUS LIABILITY IF YOU PURSUE PUBLISHING THESE "LAWS"!

Sept. 2022, Cook County, IL

FORNEK v STERIGENICS

Plaintiff claims years of exposure to trace amounts of EO from Defendant's facility caused her cancer.

Although Defendant was compliant with regulations at the time, Plaintiff argued that new EPA computer modeling classified Defendant as liable retroactively.

Judge refuses to let the defense present scientific evidence refuting the claim.

Judgement:

Plaintiff $363 Million

Nov. 2022, Cook County, IL

FORNEK v STERIGENICS

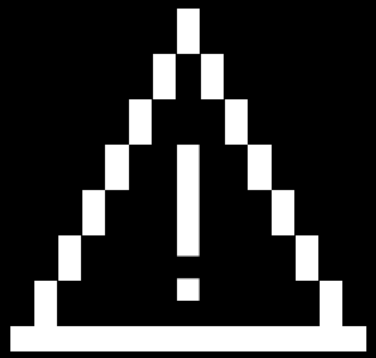
Plaintiff claims exposure to trace amounts of EO from Defendant's facility caused her cancer.

Less than two months later in the same courthouse, the defense is allowed to show evidence that EO occurs naturally in the environment and the human body and that exposure levels calculated by Plaintiff's own experts were only slightly above background level.

Judgement:

Defendant

"Ethylene Oxide: How Dubious Regulatory Science Has Fueled Vicious Cycle of Litigation and Overregulation"
- Washington Legal Foundation



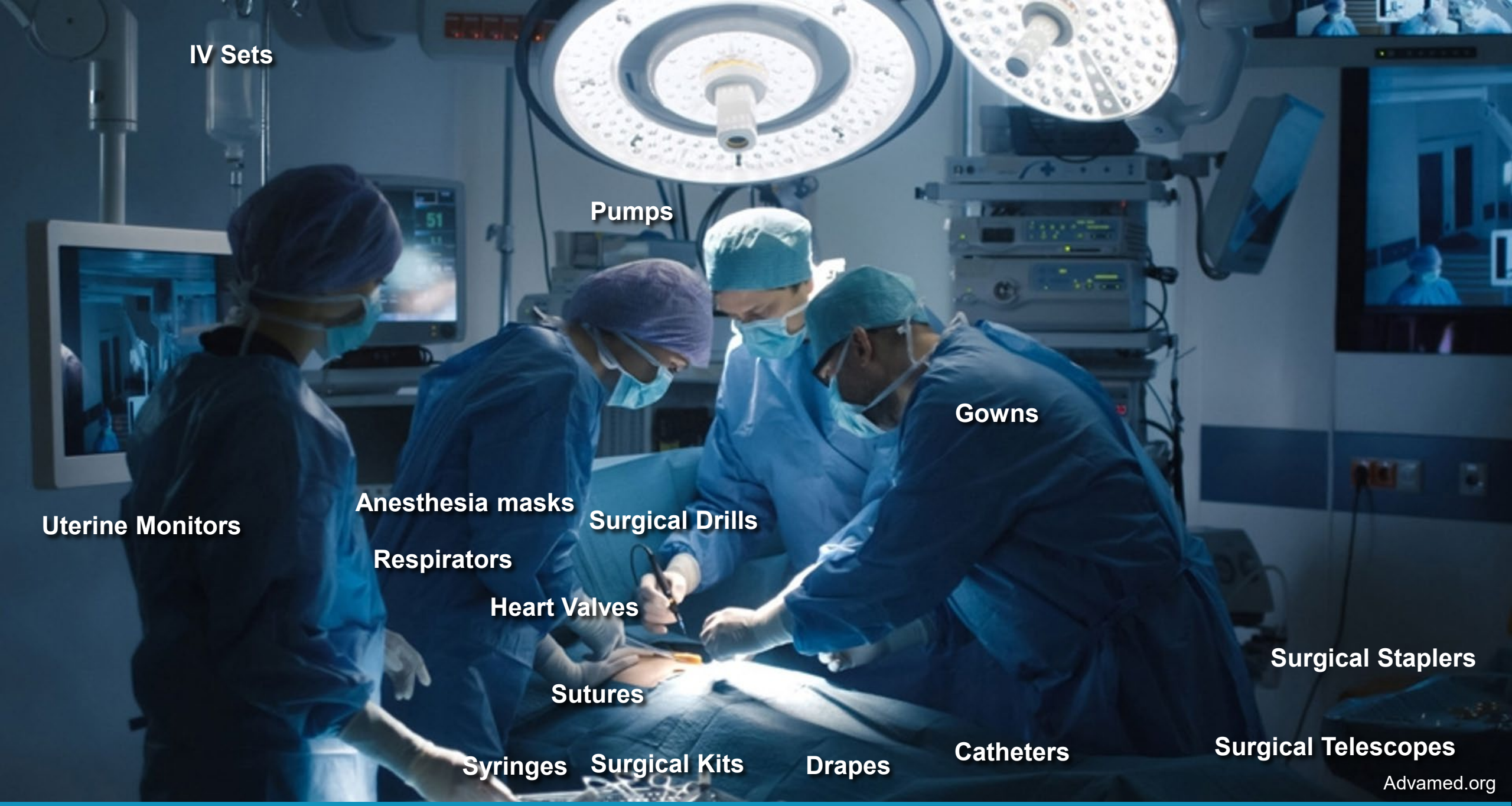
DATA UNAVAILABLE

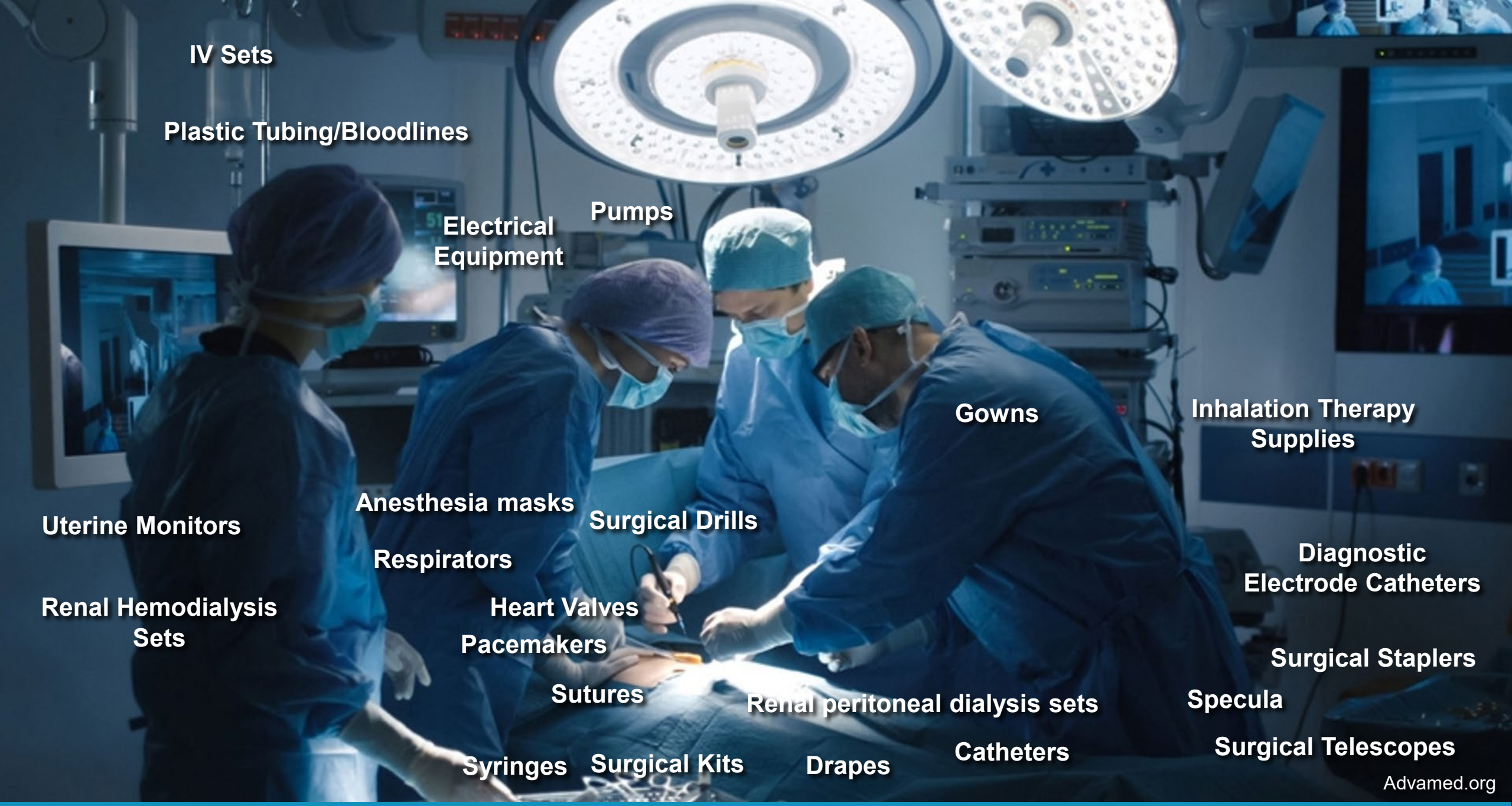

Gowns
Surgical Drills
Respirators
Sutures
Surgical Kits
Drapes

Advamed.org


IV Sets
Gowns
Anesthesia masks
Surgical Drills
Respirators
Sutures
Syringes
Surgical Kits
Drapes
Catheters
Surgical Telescopes

Advamed.org


IV Sets
Pumps
Gowns
Anesthesia masks
Surgical Drills
Uterine Monitors
Respirators
Heart Valves
Surgical Staplers
Sutures
Surgical Telescopes
Catheters
Syringes
Surgical Kits
Drapes
Advamed.org


IV Sets
Plastic Tubing/Bloodlines
Electrical Equipment
Pumps
Gowns
Inhalation Therapy Supplies
Anesthesia masks
Surgical Drills
Uterine Monitors
Respirators
Diagnostic Electrode Catheters
Renal Hemodialysis Sets
Heart Valves
Pacemakers
Surgical Staplers
Sutures
Renal peritoneal dialysis sets
Specula
Catheters
Surgical Telescopes
Syringes
Surgical Kits
Drapes

Advamed.org

If EO were banned, a vast number of surgeries could not be safely performed, and many critical medical devices would no longer be available for use.

EO is used to sterilize over **20 Billion** Medical devices each year.

Approximately **50%** of sterile medical devices are treated with EO.

EPA.GOV

EO enables the sterilization of crucial medical devices that would be damaged by other methods.

The properties of EO allow it to penetrate and sterilize without removing products from the manufacturers' packaging.


Artificial cardiac pacemaker


BREAK!

FALL 2024

PICARRO ETO CONFERENCE

Streamlining Emissions Compliance in the Sterilization Industry

PICARRO

Panel 1

Quirks of the New NESHAP Subpart O Regulation

Amy Moore
Managing Consultant, Trinity Consultants

Content

01

Introduction

Trinity Consultants Celebrating 50 Years 1974 2024

Panelist profile

Amy Moore

Managing Consultant | Trinity Consultants

Amy has a BS in Chemical Engineering from the University of Arkansas and has been with Trinity since 2014. Her focus areas include air permitting and compliance, hazardous waste compliance, oil pollution prevention planning, stormwater and wastewater permitting and compliance, and chemical reporting. She is based in Little Rock but works from the Rogers, AR satellite office. She is fond of writing, hiking, interior design, and talking about herself in the third person.

Contact Info

Office Location: Little Rock, AR
Telephone: (479) 422-5102
amoore@trinityconsultants.com

 |

Trinity Consultants

Company Information

How We Started

Started in 1974 by **one consultant** in Dallas, Texas serving clients' **air quality** regulatory compliance needs.

Who We Are

Today, we are **over 2,000 employees** in more than **85 locations** on **four continents.**

What We Do

We help organizations overcome complex, mission-critical **EHS, engineering, and science** challenges through **consulting, technology, training, and staffing** support.

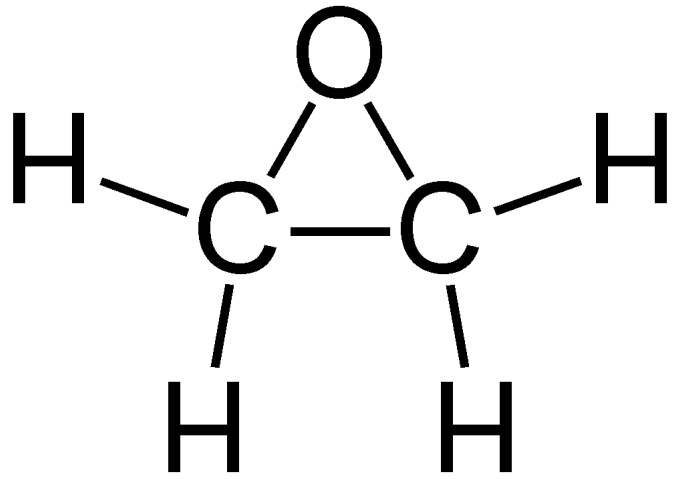
 |

Trinity Consultants

Office Locations

02

Historical Subpart O

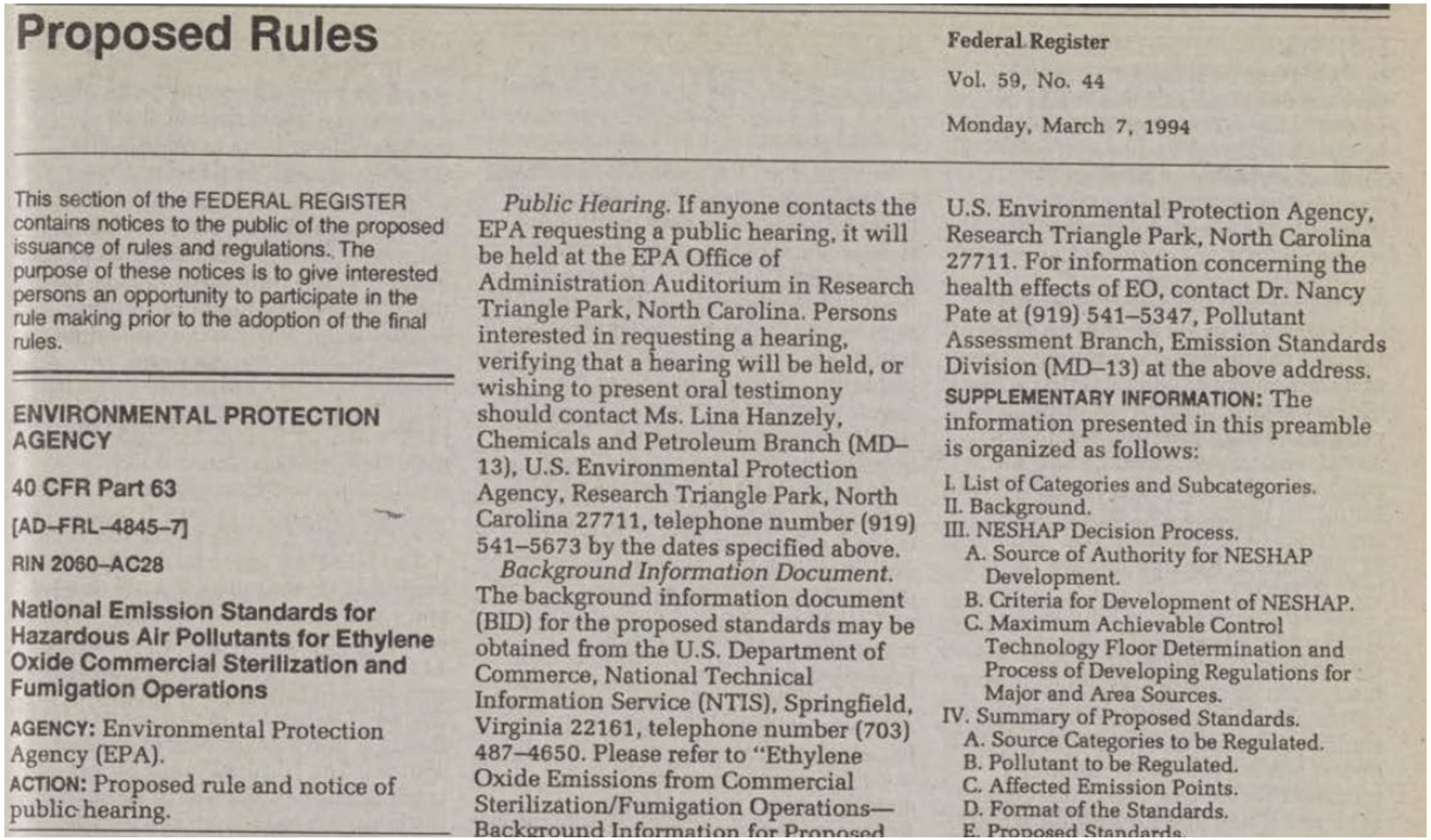


Trinity Consultants Celebrating 50 1974 2024 Years

1994 Proposed Subpart O Rule

Proposed Rule – 3/7/1994

The proposed rule aimed for a capital cost effectiveness of roughly $10,000/ton to $20,000/ton of EtO controlled.



Proposed Rules

Federal Register
Vol. 59, No. 44
Monday, March 7, 1994

This section of the FEDERAL REGISTER contains notices to the public of the proposed issuance of rules and regulations. The purpose of these notices is to give interested persons an opportunity to participate in the rule making prior to the adoption of the final rules.

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 63

[AD–FRL–4845–7]

RIN 2060–AC28

National Emission Standards for Hazardous Air Pollutants for Ethylene Oxide Commercial Sterilization and Fumigation Operations

AGENCY: Environmental Protection Agency (EPA).

ACTION: Proposed rule and notice of public hearing.

Public Hearing. If anyone contacts the EPA requesting a public hearing, it will be held at the EPA Office of Administration Auditorium in Research Triangle Park, North Carolina. Persons interested in requesting a hearing, verifying that a hearing will be held, or wishing to present oral testimony should contact Ms. Lina Hanzely, Chemicals and Petroleum Branch (MD–13), U.S. Environmental Protection Agency, Research Triangle Park, North Carolina 27711, telephone number (919) 541–5673 by the dates specified above.

Background Information Document. The background information document (BID) for the proposed standards may be obtained from the U.S. Department of Commerce, National Technical Information Service (NTIS), Springfield, Virginia 22161, telephone number (703) 487–4650. Please refer to "Ethylene Oxide Emissions from Commercial Sterilization/Fumigation Operations—Background Information for Proposed

U.S. Environmental Protection Agency, Research Triangle Park, North Carolina 27711. For information concerning the health effects of EO, contact Dr. Nancy Pate at (919) 541–5347, Pollutant Assessment Branch, Emission Standards Division (MD–13) at the above address.

SUPPLEMENTARY INFORMATION: The information presented in this preamble is organized as follows:

I. List of Categories and Subcategories.
II. Background.
III. NESHAP Decision Process.
  A. Source of Authority for NESHAP Development.
  B. Criteria for Development of NESHAP.
  C. Maximum Achievable Control Technology Floor Determination and Process of Developing Regulations for Major and Area Sources.
IV. Summary of Proposed Standards.
  A. Source Categories to be Regulated.
  B. Pollutant to be Regulated.
  C. Affected Emission Points.
  D. Format of the Standards.
  E. Proposed Standards.

 |

Originally Promulgated Rule Highlights

Promulgated Rule – 12/6/1994

01 Economic Impacts

The rule estimated nationwide annualized costs for existing commercial EO sterilization facilities of about $6.6 million beyond baseline.

Total estimated cost to comply with the rule for a large facility was $600,000.

02 Emission Standards

< 1 ton EtO: no controls required.

1 – 10 tons EtO: 99% emissions reduction for sterilization chamber vents (SCV), no aeration room vent (ARV) controls required, 5300 ppmv max concentration for chamber exhaust vent (CEV) emissions.

>10 tons EtO: 99% SCV emissions reduction, 99% ARV or 1 ppm outlet, 99% CEV emissions reduction.

 |

RTR and Rule Update Timeline

01
12/12/2019

Advanced Notice of Proposed Rulemaking

- RTR Incoming
- EPA was aware of balancer/abator systems driving a new MACT floor

02
6/5/2020, 5/10/2021

Proposed Information Collection Request (ICR) and 2nd Notice

- Main ICR document: 14-tab Excel file
- 3 additional supplemental files

03
4/11/2023

Proposed Air Toxics Rule for EtO Sterilization Facilities

- SCV limits for 1, 10, and 40 tpy EtO
- Total compliance cost: $68,000,000
- Lb/hr limit or up to 99.98% DRE

04
6/1/2023

Extension of Comment Period

- 15-day extension
- 450 pages of public comments submitted

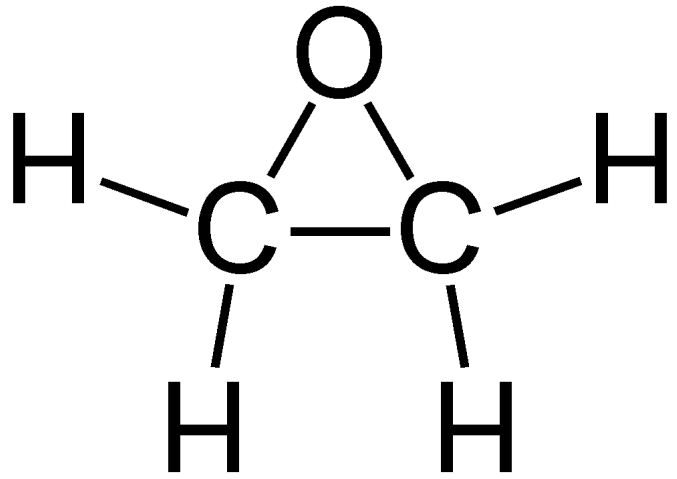
05
4/5/2024

Final Air Toxics Rule for EtO Sterilization Facilities

- Max 99.99% DRE
- More complicated compliance structure
- Total capital investment cost $313mil

04

Compliance Options



Trinity Consultants Celebrating 50 Years

Small Entity Compliance Guide

https://www.epa.gov/system/files/documents/2024-04/secg.pdf

Emissions reductions options based on:

01

What Source

- Sterilization Chamber Vent (SCV)
- Aeration Room Vent (ARV)
- Chamber Exhaust Vent (CEV)
- Group 1 Emissions
- Group 2 Emissions

02

How Much EtO Used

- SCV: 1 tpy, 10-30, ≥30
- ARV: <10 tpy, 10-30, ≥30
- CEV: <60 tpy, ≥60
- Group 1: <40 tpy, ≥40
- Group 2: <4 tpy, 4-20, ≥20

03

Source Installation

- Existing Sources
- New Sources

04

Source Type

- Area Source (<10 tpy single HAP, <25 tpy combination HAP)
- Major Source (≥10 tpy single HAP, ≥25 tpy combination HAP)

Small Entity Compliance Guide

https://www.epa.gov/system/files/documents/2024-04/secg.pdf

Table 1. Summary of Standards for Commercial Sterilization Facilities

Emission source	Existing or new?	EtO use	Standards
SCV	Existing and new	At least 30 tpy	99.99% emission reduction[1]
		At least 10 tpy but less than 30 tpy	99.9% emission reduction[1]
		At least 1 but less than 10 tpy	99.8% emission reduction[1]
		Less than 1 tpy	99% emission reduction[2]
ARV	Existing	At least 30 tpy	99.9% emission reduction[1]
		At least 10 tpy but less than 30 tpy	99.6% emission reduction[1]
		Less than 10 tpy	99% emission reduction[2]
	New	At least 10 tpy	99.9% emission reduction[1]
		Less than 10 tpy	99% emission reduction[2]
CEVs at major source facilities	Existing and new	N/A	99.94% emission reduction
CEVs at area source facilities	Existing and new	At least 60 tpy	99.9% emission reduction[1]
		Less than 60 tpy	99% emission reduction[2]
Group 1 room air emissions at major sources	Existing and new	N/A	97% emission reduction[3]
Group 1 room air emissions at area sources	Existing and new	At least 40 tpy	98% emission reduction[1,3]
		Less than 40 tpy	80% emission reduction[2,3]
Group 2 room air emissions at major sources	Existing and new	N/A	86% emission reduction[3]
Group 2 room air emissions at area sources	Existing	At least 20 tpy	98% emission reduction[1,3]
		At least 4 but less than 20 tpy	80% emission reduction[1,3]
		Less than 4 tpy	Lower the EtO concentration within each sterilization chamber to 1 ppm before the chamber can be opened[2,4]
	New	At least 20 tpy	98% emission reduction[1,3]
		Less than 20 tpy	80% emission reduction[2,3]

Compliance Demonstration Options

40 CFR 63.362/363, Subpart O Tables 1-5

01

Emissions Reduction - Individual Streams

Each set of SCV, ARV, CEV, Group 1 and Group 2 must be continuously monitored as an individual emissions stream using a CEMS.

02

Tiny Sources

Performance testing on a per-year or triennial schedule for sources that use less than 100 lb/yr.

03

Combined Streams or Sitewide Limit

Depending on the approach these are based on either EtO usage or on measured EtO inlet emissions to the control device and the most stringent applicable limit.

 |

Equation 1 to paragraph (i)(2)(i)

$$CES_{Combined} = M_{30day} * (1 - Max(ER)) \quad \text{(Eq. 1)}$$

How to Demonstrate Compliance

CES-1

Combined Emission Streams.

This option is available after all emission streams are combined prior to the control device. This option is very similar to the SWEL-1 approach.

Unlike SWEL-1, you are required to use a CEMS to measure the combined EtO inlet to the control device versus calculating the EtO usage and apply the most stringent DRE.

An example of this would be a facility with a single control device feeding all SCV, ARV, CEV, Groups 1 & 2 streams to the control.

Equation 2 to paragraph (i)(2)(i)

$$CES_{Streams} = \sum_{i=1}^{n} (M_{c,i} * (1 - ER_i)) + \sum_{j=1}^{m} (M_{c,j} * (1 - ER_j)) \quad \text{(Eq. 2)}$$

How to Demonstrate Compliance

CES-2

Combined Emission Streams by Source Type.

This is a refinement of the CES-1 approach by placing a CEMS monitor at the inlet of each non-SCV source type to apply lower DREs to streams.

Each non-SCV emissions type must be segregated. All sources (CEV, ARV, Group 1, Group 2) would require separate CEMS monitoring systems prior to those streams combining with any other stream. If not possible, most stringent DRE for the combination would be used. For example, Group 1 with CEV would require 99.9. SCV inlet is a calculated value based on EtO feed.

You must use a CEMS to measure the inlet emissions to the control device.

Pro: allows facilities to utilize lower DREs where applicable.

Con: much higher cost in exhaust/facility design and in CEMS installation.

Equation 3 to paragraph (j)(1)(i)

$$SWEL_{Fac} = M_{Fac} * 0.99 * (1 - ER_{SCV}) \quad \text{(Eq. 3)}$$

How to Demonstrate Compliance

SWEL-1

Sitewide Emission Limit based on total EtO usage.

This is the simplest approach.

Emission limit = 30-day mass charge of EtO * 0.99 (assumes 1% loss in product) * (1-DRE) where the DRE is the most stringent (for most facilities this will be 99.99% or 0.9999.)

Measure the mass of EtO used to the nearest 0.1 lb. If your EtO from SDS, etc. is not 100%, this mass is multiplied/adjusted by the wt% EtO of the gas.

For SWEL-1, you know your EtO wt%, you know the corresponding 30-day charge and you know the DRE to use.

Equation 5 to paragraph (j)(2)(i)

$$SWEL_{Streams} = \sum_{i=1}^{n} (M_{c,i} * (1 - ER_i)) + \sum_{j=1}^{m} (M_{c,j} * (1 - ER_j)) \qquad \text{(Eq. 5)}$$

How to Demonstrate Compliance

SWEL-2

Sitewide Emission Limit Based on Individual Streams.

This option calculates the sitewide limit based on measured SCV feed CEMS for the inlet of all non-SCV sources.

Thus, you have to have a CEMS monitor at each non-sterilization vent inlet prior to combining with any other stream (CEV, ARV, Group 1, Group 2). Otherwise, non-SCV combined stream subject to most stringent DRE of stream components.

The SCV portion is similar to SWEL-1 in that it uses a correction factor, essentially 0.99, and the mass fed to the sterilizers as discussed above.

 |

Things to Remember...

Compliance Quirks

The only time SCV CEMS inlet used is CES-1. All other options are based on EtO usage.

For CES-2, SWEL-1, SWEL-2 some form of EtO feed is used and based on 30-day usage recorded to nearest 0.1 lb.

CES-2 and SWEL-2 require inlet CEMS for all non-SCV streams.

 |

Compliance Demonstration Timeline

40 CFR 63.360(j)

01

What Source

- Sterilization Chamber Vent (SCV)
- Aeration Room Vent (ARV)
- Chamber Exhaust Vent (CEV)
- Group 1 Emissions
- Group 2 Emissions

02

Facility Type

- Existing (constructed before April 13, 2023)
- New (construction commenced after April 13, 2023)

03

How Much EtO Used – Existing ONLY

- SCV: <1 tpy, ≥1
- ARV: <10 tpy, ≥10
- Area Source CEV: <60 tpy, ≥60
- Area Source Group 1: <40 tpy, ≥40
- Area Source Group 2: <4 tpy, ≥4

When to Demonstrate Compliance

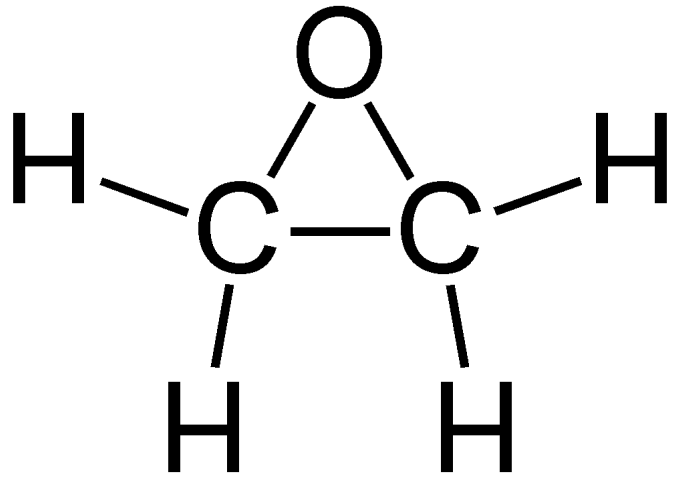
Emission source	Existing or new?	EtO use	Submit Initial Notification of Applicability by…	Demonstrate Compliance with Emission Standards by…	Submit Notification of Compliance Status by…
SCV	Existing	At least 1 tpy	August 5, 2024.	October 5, 2026	December 7, 2026
		Less than 1 tpy	August 5, 2024.	October 5, 2027.	December 6, 2027.
	New	N/A[3]	August 5, 2024, or 120 days after startup of the source, whichever is later.	October 7, 2024, or 180 days after startup of the source, whichever is later.	December 5, 2024, or 240 days after startup of the source, whichever is later.
ARV	Existing	At least 10 tpy	August 5, 2024.	October 5, 2026.	December 7, 2026.
		Less than 10 tpy	August 5, 2024.	October 5, 2027.	December 6, 2027.
	New	N/A	August 5, 2024, or 120 days after startup of the source, whichever is later.	October 7, 2024, or 180 days after startup of the source, whichever is later.	December 5, 2024, or 240 days after startup of the source, whichever is later.
CEVs at major source facilities	Existing	N/A	August 5, 2024.	October 5, 2027.	December 6, 2027.
	New		August 5, 2024, or 120 days after startup of the source, whichever is later.	October 7, 2024, or 180 days after startup of the source, whichever is later.	December 5, 2024, or 240 days after startup of the source, whichever is later.
CEVs at area source facilities	Existing	At least 60 tpy	August 5, 2024.	October 5, 2026.	December 7, 2026.
		Less than 60 tpy	August 5, 2024.	October 5, 2027.	December 6, 2027.
	New	N/A	August 5, 2024, or 120 days after startup of the source, whichever is later.	October 7, 2024, or 180 days after startup of the source, whichever is later.	December 5, 2024, or 240 days after startup of the source, whichever is later.
Group 1 room air	Existing	N/A	August 5, 2024.	October 5, 2027.	December 6, 2027.

When to Demonstrate Compliance

Emission source	Existing or new?	EtO use	Submit Initial Notification of Applicability by…	Demonstrate Compliance with Emission Standards by…	Submit Notification of Compliance Status by…
emissions at major sources	New		August 5, 2024, or 120 days after startup of the source, whichever is later.	October 7, 2024, or 180 days after startup of the source, whichever is later.	December 5, 2024, or 240 days after startup of the source, whichever is later.
Group 1 room air emissions at area sources	Existing	At least 40 tpy	August 5, 2024.	October 5, 2026.	December 7, 2026.
		Less than 40 tpy	August 5, 2024.	October 5, 2027.	December 6, 2027.
	New	N/A	August 5, 2024, or 120 days after startup of the source, whichever is later.	October 7, 2024, or 180 days after startup of the source, whichever is later.	December 5, 2024, or 240 days after startup of the source, whichever is later.
Group 2 room air emissions at major sources	Existing	N/A	August 5, 2024.	October 5, 2027.	December 6, 2027.
	New		August 5, 2024, or 120 days after startup of the source, whichever is later.	October 7, 2024, or 180 days after startup of the source, whichever is later.	December 5, 2024, or 240 days after startup of the source, whichever is later.
Group 2 room air emissions at area sources	Existing	At least 4 tpy	August 5, 2024.	October 5, 2026.	December 7, 2026.
		Less than 4 tpy	August 5, 2024.	October 5, 2027.	December 6, 2027.
	New	N/A	August 5, 2024, or 120 days after startup of the source, whichever is later.	October 7, 2024, or 180 days after startup of the source, whichever is later.	December 5, 2024, or 240 days after startup of the source, whichever is later.

05

Regulatory Mindfulness



Trinity Consultants Celebrating 50 1974 2024 Years

Small Entity Compliance Guide

https://www.epa.gov/system/files/documents/2024-04/secg.pdf

Table 1. Summary of Standards for Commercial Sterilization Facilities

Emission source	Existing or new?	EtO use	Standards
SCV	Existing and new	At least 30 tpy	99.99% emission reduction[1]
		At least 10 tpy but less than 30 tpy	99.9% emission reduction[1]
		At least 1 but less than 10 tpy	99.8% emission reduction[1]
		Less than 1 tpy	99% emission reduction[2]
ARV	Existing	At least 30 tpy	99.9% emission reduction[1]
		At least 10 tpy but less than 30 tpy	99.6% emission reduction[1]
		Less than 10 tpy	99% emission reduction[2]
	New	At least 10 tpy	99.9% emission reduction[1]
		Less than 10 tpy	99% emission reduction[2]
CEVs at major source facilities	Existing and new	N/A	99.94% emission reduction
CEVs at area source facilities	Existing and new	At least 60 tpy	99.9% emission reduction[1]
		Less than 60 tpy	99% emission reduction[2]
Group 1 room air emissions at major sources	Existing and new	N/A	97% emission reduction[3]
Group 1 room air emissions at area sources	Existing and new	At least 40 tpy	98% emission reduction[1,3]
		Less than 40 tpy	80% emission reduction[2,3]
Group 2 room air emissions at major sources	Existing and new	N/A	86% emission reduction[3]
Group 2 room air emissions at area sources	Existing	At least 20 tpy	98% emission reduction[1,3]
		At least 4 but less than 20 tpy	80% emission reduction[1,3]
		Less than 4 tpy	Lower the EtO concentration within each sterilization chamber to 1 ppm before the chamber can be opened[2,4]
	New	At least 20 tpy	98% emission reduction[1,3]
		Less than 20 tpy	80% emission reduction[2,3]

 |

Small Entity Compliance Guide

https://www.epa.gov/system/files/documents/2024-04/secg.pdf

1 For existing sources, the standard applies if a facility has met or exceeded the specified EtO use within any consecutive 12-month period after April 7, 2025. The standard also applies if a facility with previous EtO use below the specified amount has subsequently increased its EtO use to the specified EtO use range for a consecutive 12-month period after April 7, 2025.

2 For existing sources, the standard applies if a facility has used less than the specified EtO use within all consecutive 12-month periods after April 7, 2026.

3 To ensure compliance with the emission limit, we are requiring each facility to operate sources with these emissions in accordance with the permanent total enclosure (PTE) requirements of EPA Method 204 of appendix M to 40 CFR part 51.

4 Owners and operators may also apply for an alternative means of emission limitation under CAA section 112(h)(3).

Tiny Sources

For facilities with EtO usage of less than 100 lb/yr:

Non-Area Sources or Area Sources without PTE	Annual inlet/outlet performance testing (Method 1, 2A/2B/2C, 3A/3B, 4, 320 or ASTM D6348-12) Track EtO usage Monitor control device parameters
Area Sources with Group 2 PTE	As above, except: Monitor differential pressure for PTE Triennial inlet/outlet performance testing

Initial Compliance Demonstration

01 – Compliance Demonstration Method and Deadline

Performance Specification 19 – within 180 days after the applicable compliance date

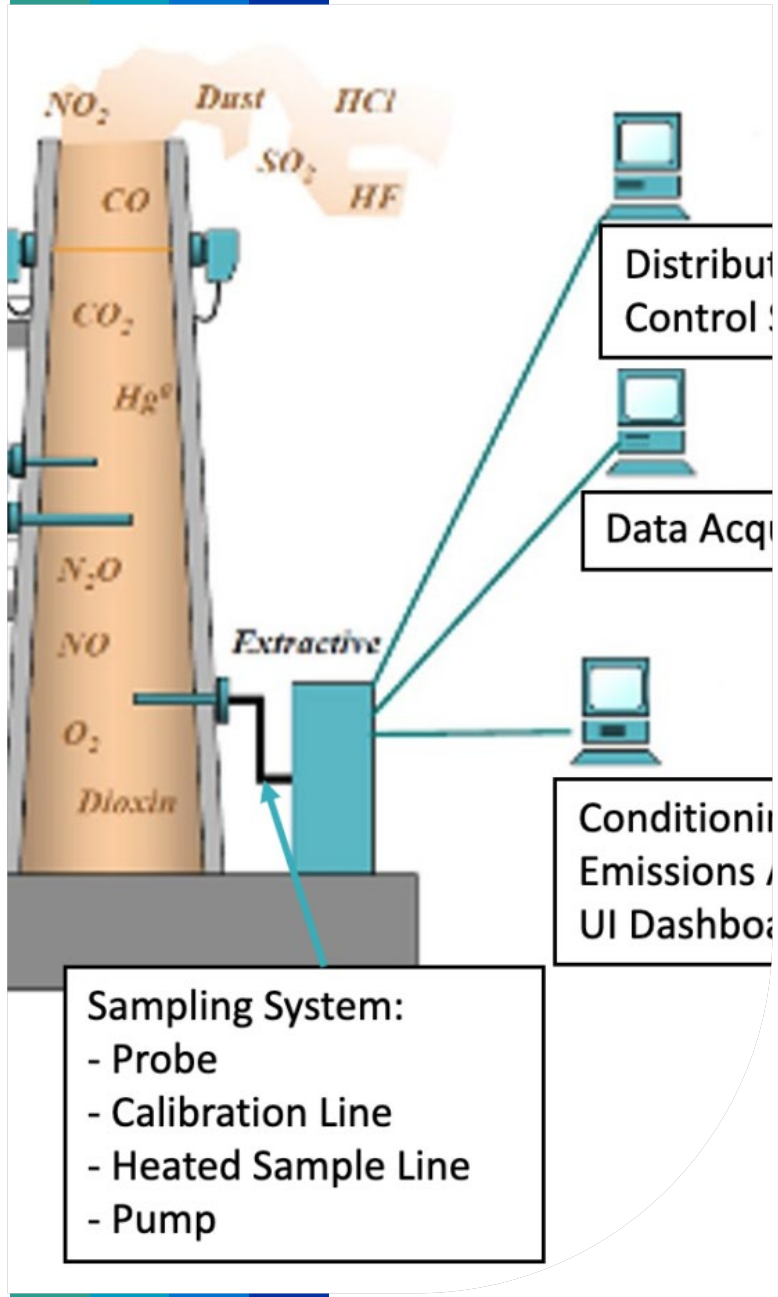
02 – Initial Performance Test

The first 30 operating days after the PS-19 certification per Appendix A of the subpart.

03 – Quirks

You are allowed to time-share the CEMS as long as:

- The CEMS is approx. equidistant from the measurement points;
- The sampling time is 3 times CEMS response time;
- The CEMS completes at least one cycle for all measurements within 15 minutes; and
- PS-19 requirements are met.



 |

Ongoing Compliance - CEMS

Where monitoring requirements come home to roost…

01

Install and configure the unit – single-stack or common stack.

Remember that SCV EtO usage may be weighed on 3 of 4 compliance options.

02

Quirk: If you have control devices working in parallel with multiple stacks, you have to determine hourly flow-weighted average pollutant emission rates.

03

Quirk: If room air emissions are subject to an emissions standard and split between two or more controls, you have to monitor before the emissions are combined with other streams.

 |

Ongoing Compliance - PTE

Where monitoring requirements come home to roost…

01

Initial compliance: Method 204

02

Continuous Compliance – Pressure Differential Monitoring

- Install, operate, calibrate, maintain
- Operate whenever the facility is operating
- 0.007 in wc over a 3-hour rolling average

03

Quirks:

All data collected during an operating hour must be used, even in portions of the facility covered by the PTE that are not operated for a complete hour.

You must record manually at least hourly if your automatic device is malfunctioning!

Monitor siting is important!

 |

Ongoing Compliance - PTE

Where monitoring requirements come home to roost…

01

Initial compliance: Method 204

02

Continuous Compliance – Flow Rate Monitoring System

- Install, operate, calibrate, maintain
- Operate whenever the facility is operating
- Record every 15 minutes, 3-hour rolling average

03

Quirks: This system is subject to many of the same calibration requirements as a CEMS, i.e., daily zero and upscale calibration drift testing to 3% of span, initial and annual relative accuracy testing!

Site-Specific CEMS Monitoring Plan

- **Hardcopy and electronic portions required**

- **Electronic:**
  - Submit plan to EPA via CEDRI;
  - The unit or stack ID number(s);
  - Monitoring location(s);
  - The EtO monitoring methodology used (i.e., CEMS);
  - EtO monitoring system information, including, but not limited to unique system and component ID numbers;
  - The make, model, and serial number of the monitoring equipment;
  - The sample acquisition method;
  - Formulas used to calculate emissions;
  - Monitor span and range information (if applicable).

 |

Site-Specific CEMS Monitoring Plan

- **Hardcopy and electronic required**

- **Hardcopy:**
  - Schematics and/or blueprints showing the location of the monitoring system(s) and test ports;
  - Data flow diagrams;
  - Test protocols;
  - Monitor span and range calculations (if applicable);
  - Miscellaneous technical justifications.

- **Quirk: the requirements for the plan under 40 CFR 75.53(g) are incredibly comprehensive, advise you check compliance line-by-line!**

Overarching Plan requirement…

Site-Specific Monitoring Plan

Quirk: alternative monitoring must be approved by EPA!

Required under the General Provisions (see 40 CFR 63.8)

Covers operation and maintenance of all continuous monitoring

Your CEMS Monitoring Plan is a part of this

Also includes QA/QC procedures to assure data quality

PTE monitoring requirements and data assurance is also a part of this plan

Any alternative monitoring options are included here

Site-Specific Test Plan

- **Required under the General Provisions (see 40 CFR 63.7)**
- **Must be submitted to EPA or delegated authority**
- **The test plan shall include:**
  - A test program summary;
  - The test schedule;
  - Data quality objectives
  - Internal and external quality assurance (QA) program.

- **Plan or any future changes must be approved within 30 days of receipt by Administrator**
- **Alternative methods must be approved by Administrator!**
- **Waiver requests must be made at least 60 days before testing is required**

Recordkeeping

- Initial Notification
- Notification of Compliance Status
- All EtO documentation and monitoring records
- All PTE monitoring records
- Site-Specific Monitoring Plan
- Test Plans and Protocols, test results
- Deviation information

- Five years for monitoring data

- Quirks:
  - Lifetime of the unit for CEMS monitoring plans and details (or until no longer subject)
  - Electronic recordkeeping allowed if records submitted via CEDRI

Reporting

- **Submit to EPA and delegated authority (if applicable)**
- **Initial Notification**
- **Notification of Compliance Status**
- **Initial Compliance Report**
- **Quarterly Compliance Reports**
- **Construction and Reconstruction Information**
- **Performance Tests and CEMS Performance Demonstrations**

- **NOTE: The compliance reports in particular are BEASTS, read the requirements VERY CAREFULLY to make sure you are including all required information!**

Other things to keep in mind…

Subpart O has a significant number of quirks to be aware of.

How are you limited if your streams are combined? Is CES or SWEL the way to go if you have combined streams? What to do with product that is going to be re-sterilized? Where are PTEs required?

Combined Streams

If you have any combined emissions streams, you cannot demonstrate compliance against the individual stream limits!

CES vs. SWEL

Which option to use is going to be based on how many CEMS you want to install and which control efficiency you want to try to meet (remember that most restrictive DRE applies).

Permanent Total Enclosure

PTEs are REQUIRED for Group 1 and Group 2 emissions!

PTEs require an initial compliance demonstration and ongoing monitoring!

Rework or Reprocessing

Product that is being held for reprocessing is offgassing and is therefore part of the Group 2 emissions. If you are showing compliance via monitoring of individual streams it must be stored in a Group 2 area!

Other things to keep in mind…

Subpart O has a significant number of quirks to be aware of.

Can you trust the reg as it is written? If you operate an existing facility are you required to submit an IN or NoCS? How much data is required for a combined-streams approach? What performance specifications are you required to follow?

Reporting Obligations

Even if you are an existing source, this regulation requires you to submit a fresh Initial Notification and Notification of Compliance Status!

Combined Streams

All combined-streams approaches are based upon a rolling 30 days of operating data!

Typos

Be aware that there are typos within the rule! Initial compliance procedures are located at 63.365(f), NOT (g)!

Performance Specification 19

PS-19 is EtO-specific, vs. the prior performance specifications for FTIR CEMS (PS-15) or VOC (PS-8). Part of your initial compliance demonstration will be a PS-19 certification!

Thank you

Amy Moore

Managing Consultant | Trinity Consultants

479-422-5102
amoore@trinityconsultants.com

Justin Sullivan

Senior Consultant | Trinity Consultants

251-767-3918
justin.sullivan@trinityconsultants.com

Shannon Lynn, P.E.

Principal Consultant | Trinity Consultants

501-454-6264
slynn@trinityconsultants.com

Trinity Consultants

Celebrating 50 1974 2024 Years


LUNCH!

FALL 2024

PICARRO ETO CONFERENCE

Streamlining Emissions Compliance in the Sterilization Industry

PICARRO

Presentation 2

Control of Fugitive EtO Emissions in the Post-Aeration Supply Chain

Melissa Petruska
VP of Product Development, Sonata Scientific

The Company

- **Sonata Scientific,** Danbury, Connecticut, was founded in 2018 to apply its surface chemistry technology to critical air quality challenges

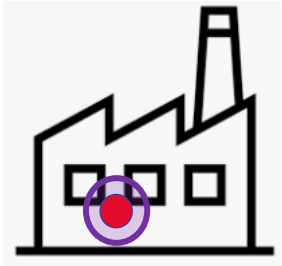
- Non-dilutive funding from FDA for technology development
  - FDA SBIR: *Reduced EtO emissions to safeguard biomedical supply chains*, FAIN#R44D007588

SONATA SCIENTIFIC

EtO Fugitives in the Medical Device Supply Chain

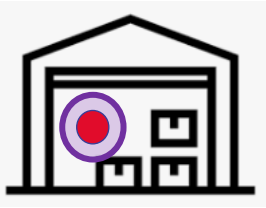
- **Fugitive EtO emissions** occur post-aeration and throughout the supply chain
  - Contribute to overall EtO emissions from sterilization facilities and warehouses
- Current strategies focus on centralized abatement to reduce EtO fugitives
- Sonata's solution delivers ***localized EtO control*** at all stages of the post-aeration cycle
  - Ductless for simple integration into existing supply chains

Our first product is a ductless unit designed to locally address fugitive EtO emissions.



Sterilization facility

Transportation



Warehousing

SONATA SCIENTIFIC

Sonata Scientific Helios Product Line

Effective

99+% DRE *for* fugitives

Handles EtO excursions up to 50 ppm

High performance in varied environments

Versatile

Ductless, mobile

Local EtO control

Compact, space-saving design

Clean Footprint

Eliminates Acetaldehyde and other EtO byproducts

Odorless

Quiet

Plug and Play

Room Temperature

Rapid start-up

Minimum maintenance

SONATA SCIENTIFIC

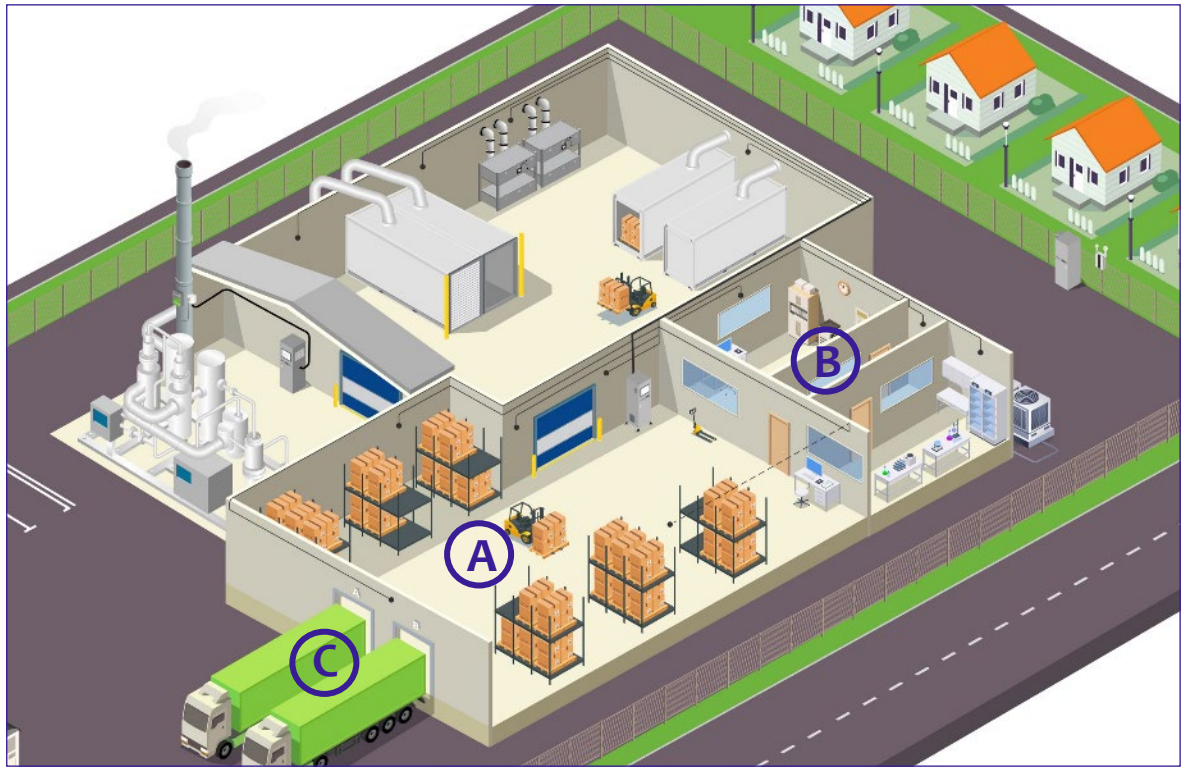
Helios Products Throughout the Supply Chain

A. **Group 2 emissions:** quarantine, post-aeration, PTEs

B. **Adjacent spaces:** office areas, control rooms, laboratories

C. **Transportation**

D. **Warehouses** (not shown)



Graphic courtesy of Picarro

SONATA SCIENTIFIC

Helios Technology Evaluation: Laboratory-Scale Demo

Helios 2.0 (0.5-20 SLM)

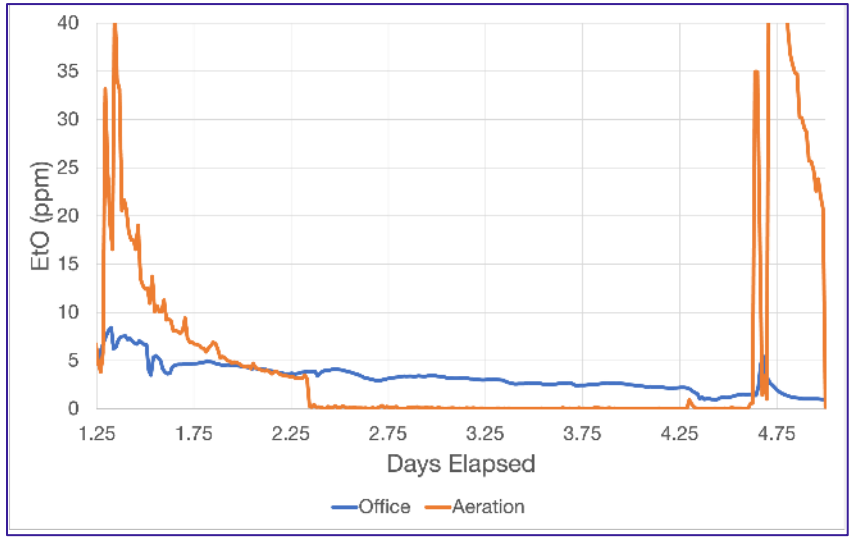
- Study conducted with Picarro using simulated sterilizer environments
- Simulated environments based on real-world sterilization facility ambients
  - EtO concentration
  - Relative Humidity
  - Indoor contaminants
- EtO inlet and outlet concentrations measured with Picarro WMS

[Emerging Strategies for EtO Abatement and Monitoring in the Workplace: Sonata Scientific's Helios and Picarro's Workplace Monitoring System | Picarro]

SONATA SCIENTIFIC

Fugitive EtO Control in Sterilization Facilities

Representative EtO levels in aeration and office areas



Facility data collected by Picarro

EtO control in simulated environment

Helios DRE* for typical fugitive EtO levels

EtO Inlet (ppb)	EtO Outlet (ppb)	DRE (%)
56	ND**	99.6***
140	0.4	99.7
330	1.7	99.5
500	2.5	99.5
1000	6.4	99.4
5000	25	99.5

* EtO inlet/outlet concentration measured with Picarro WMS
** Non-detect (<0.25 ppb)
*** Assessed using detection limit of 0.25 ppb

Helios products designed to control EtO fugitives in sterilization facilities

Emerging Strategies for EtO Abatement and Monitoring in the Workplace: Sonata Scientific's Helios and Picarro's Workplace Monitoring System | Picarro

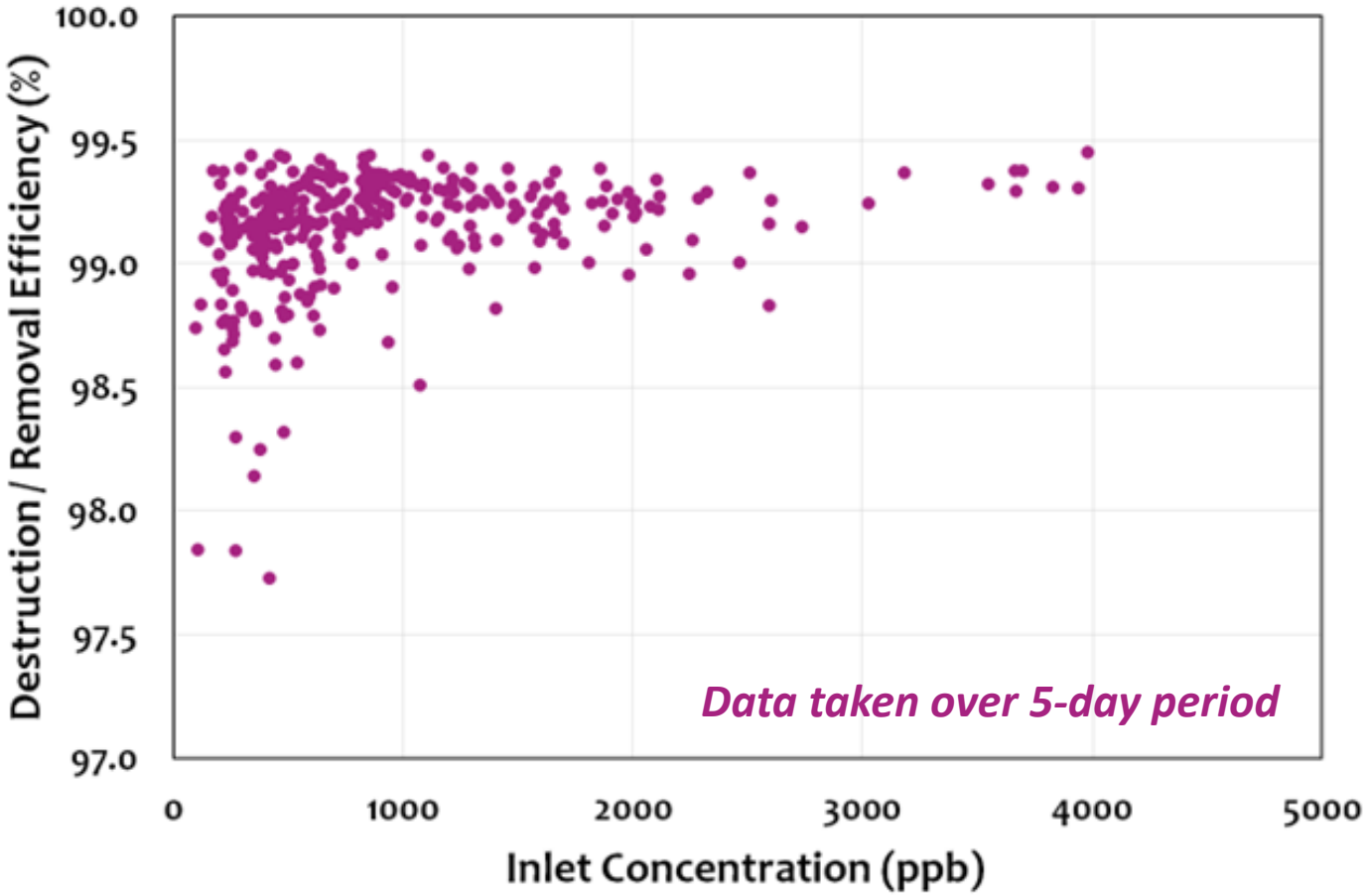
SONATA SCIENTIFIC

Helios MP100

- Multiple prototypes in evaluation at customer sterilization facilities
  - 100 CFM
  - 120 V, ductless solution
- Excellent performance demonstrated by our partners
  - EtO DRE at 99+%
  - Safe operation in enclosed spaces
- 500 CFM product will launch early next year

SONATA SCIENTIFIC

Helios MP-100 Evaluation at Sterilization Facility

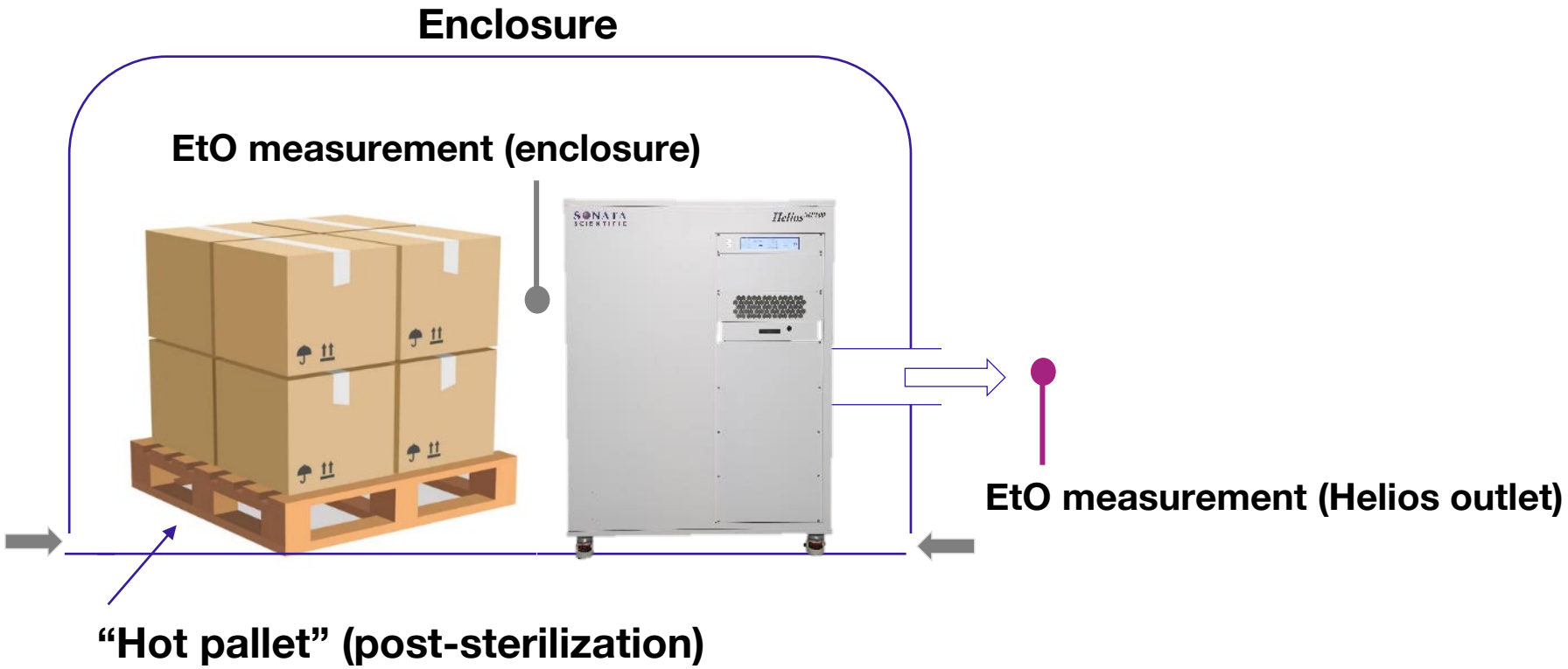


98+% DRE for EtO fugitives in area adjacent to quarantine zone

This study was conducted at a commercial sterilizer in collaboration with Picarro

SONATA SCIENTIFIC

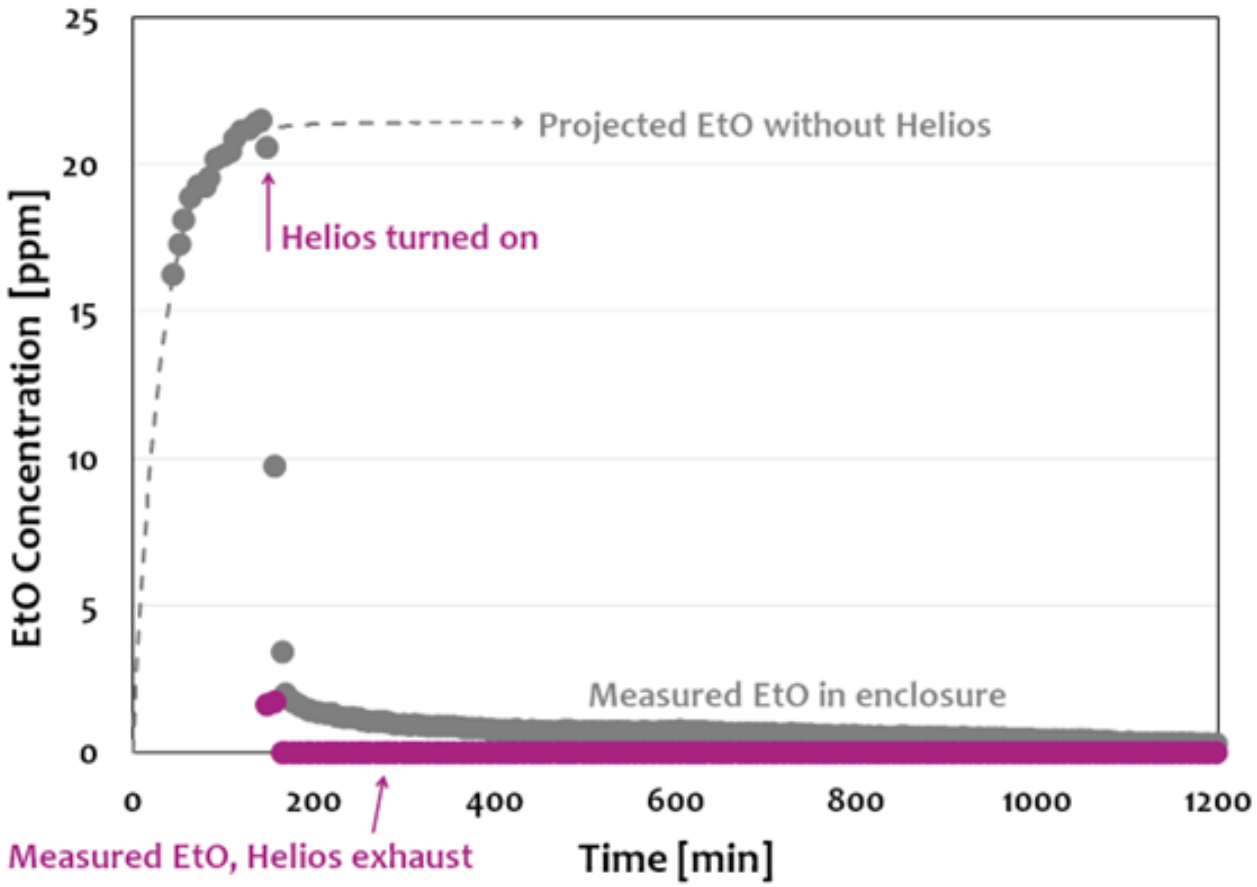
Control of Fugitives Post-Sterilization



Helios EtO control products demonstrated in post-aeration area

SONATA SCIENTIFIC

Removal of EtO from a Sterilized Pallet in an Enclosure



99+% DRE with <10 ppb at system outlet

SONATA SCIENTIFIC

Summary

- Fugitive EtO emissions are a well-known issue throughout the medical device supply chain
  - Sterilization facility, transportation, distribution centers
- Sonata's Helios product line is specifically designed to address fugitive EtO emissions
  - Extensive testing in a range of environments
- EtO control prototypes have been deployed in multiple sterilizer facilities with excellent results
  - First round of evaluation at 100 CFM
  - Launching 500 CFM product in 2025

SONATA SCIENTIFIC

Thank you!

www.sonatascientific.com

sales@sonatascientific.com

SONATA SCIENTIFIC

FALL 2024

PICARRO ETO CONFERENCE

Streamlining Emissions Compliance in the Sterilization Industry

PICARRO

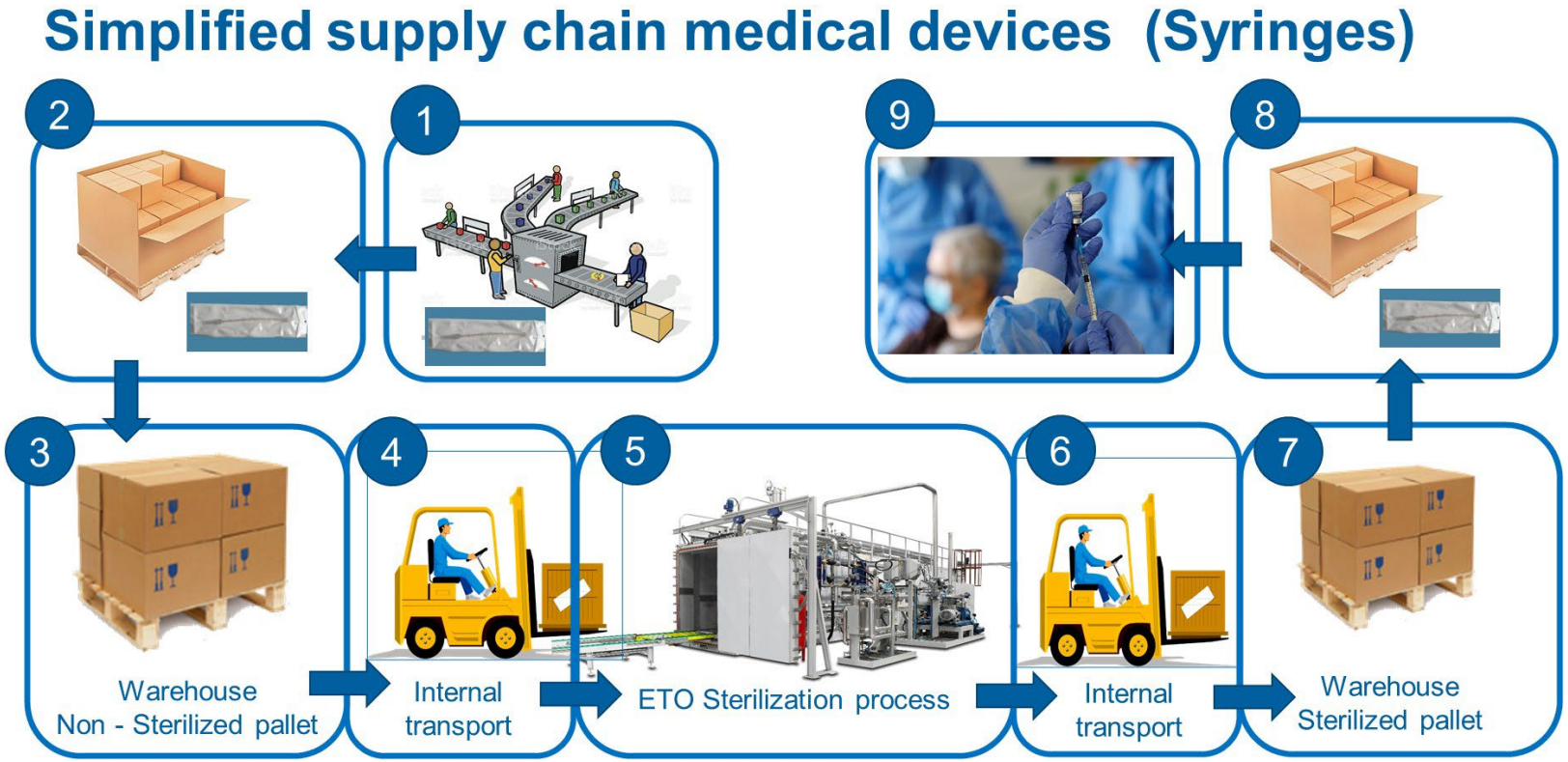
Presentation 3

Automating SWEL and Workplace Compliance from Chamber to Stack: Smart, Sustainable, Integrated Solutions for the new EtO NESHAP and FIFRA

Jordi Martinez
Sterilization Technologies Product Development, Telstar

Jonathan Bent
Program Manager, Picarro

The Medical Supply Chain for EO Sterilization

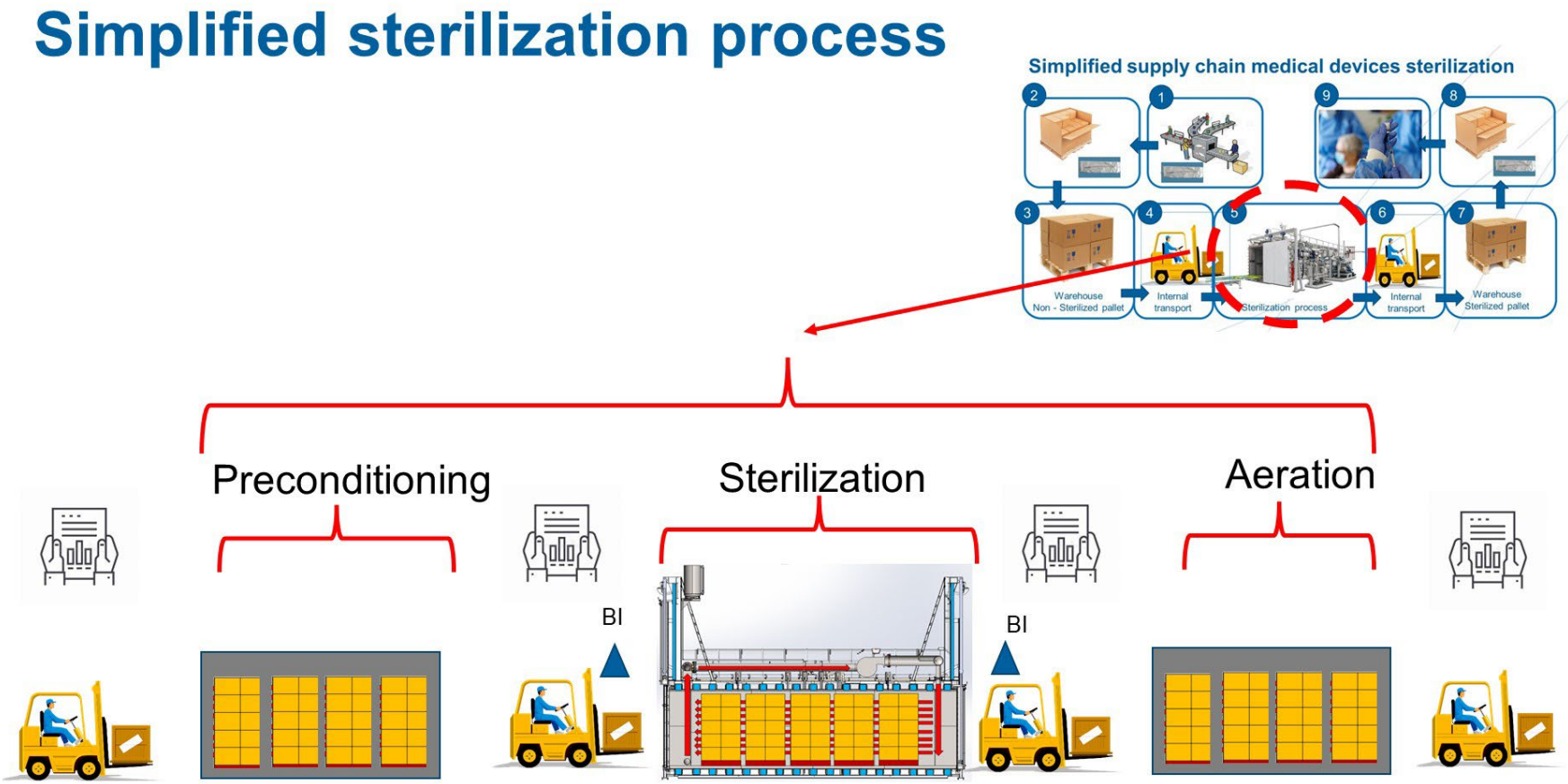


Source: ISPE Singapore – Digital transformation EO sterilization - Telstar

1 – Medical devices manufacturing
2 – Packaging
3 – Warehouse pallets non- sterilized
4 – Logistics and loading
5 – EtO Sterilizing process
6 – Unloading and logistics
7 – Warehouse pallet sterilized

The Medical Supply Chain for EO Sterilization: Detail

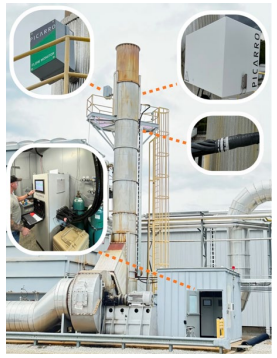
Sterilization process is split in preconditioning, sterilization & aeration phases



Source: ISPE Singapore – Digital transformation EO sterilization - Telstar

Major Pressures* on the Sterilization and Medical Device Manufacturing Industries

Emissions Reductions Adjacent Community Protection



EtO NESHAP (National Emission Standards for Hazardous Air Pollutants)
- Updates/Reduces Emissions Standards.
- Requires CEMS monitoring and updates reporting requirements
- Likely forces new control technologies
- US-based, but other countries signal following US's lead.

Worker Exposure Reduction

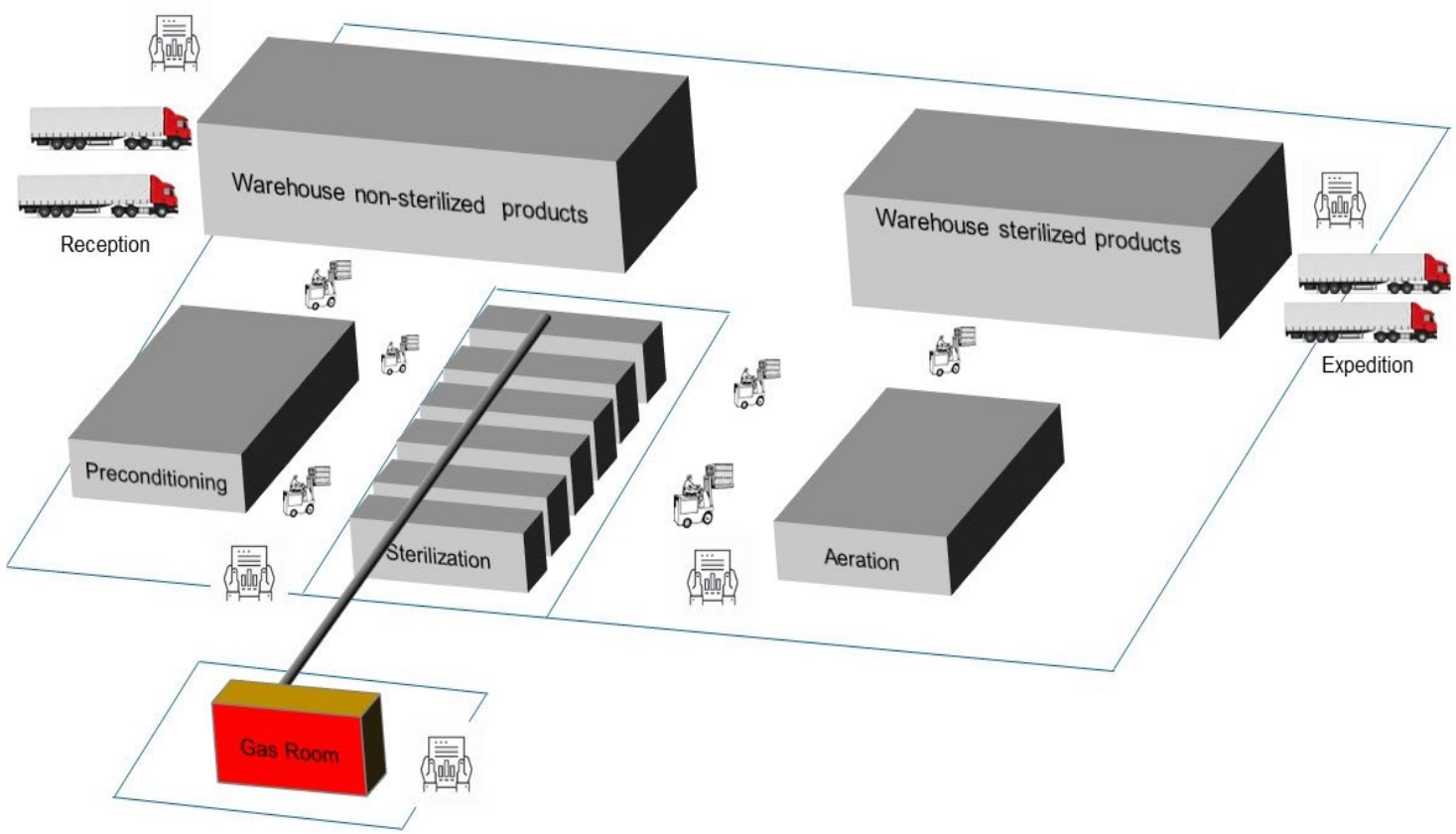
USA FIFRA (Federal Insecticide, Fungicide, and Rodenticide Act)
- TBD in ~Jan 2025
- Assumes worker exposure remit from OSHA
- Stricter lower worker exposure limits
- US-based, but other countries signal following US's lead.

Protect Healthcare System, Patient Outcome

Market
- Keep prices competitive and medical devices readily available

* Other local, state, and international regs also apply

Readiness for NESHAP and FIFRA: Traditional Sterilization Layouts



Considerations:

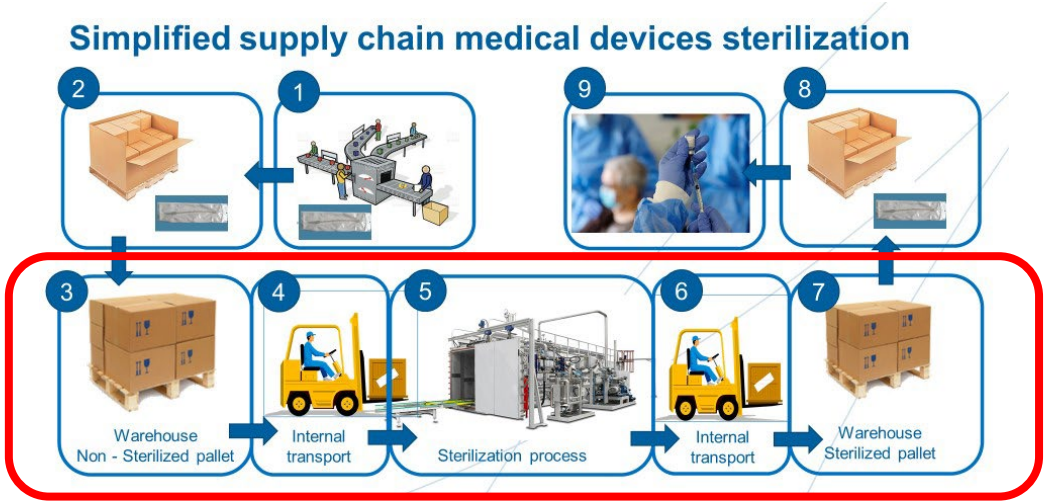
- Legacy abatement and air circulation systems
- Minimal or no monitoring systems for EO at ppb-ppm levels
- Non-linear and manual movement of product between precon, sterilization, aeration, warehouse, and trucks
- Manual loading /unloading process
- BI instead of parametric release
- Reactive/preventive maintenance only

Readiness for NESHAP and FIFRA: What is a smart factory?

The **Smart Factory** is a “concept for expressing the end goal of digitization in manufacturing.

A Smart Factory is a highly digitized shop floor that continuously collects and shares data through connected machines, devices, and production systems”.
Main characteristics Smart factory:

- Connected
- Optimized
- Transparent
- Proactive
- Agile

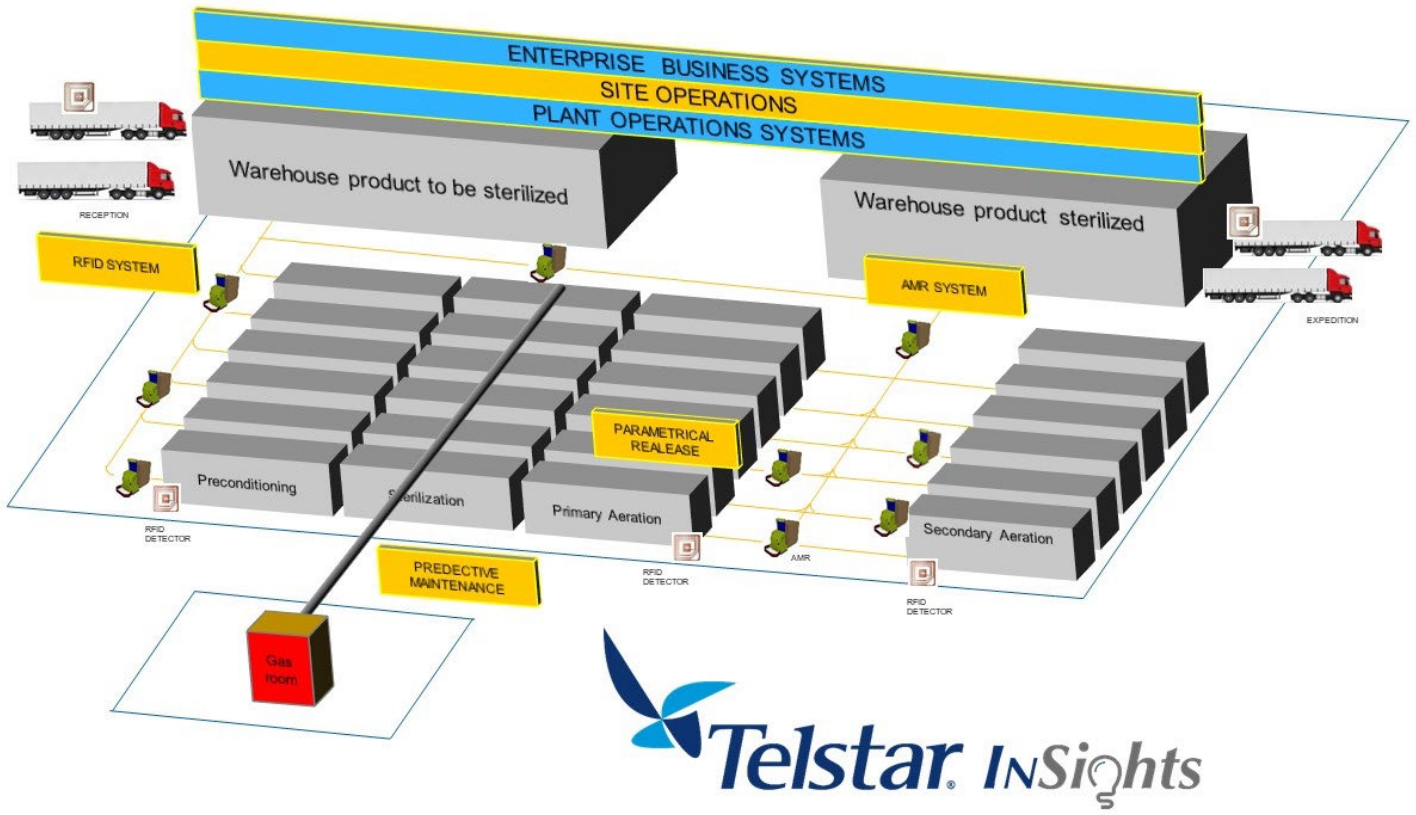


Traditional Sterilization Layouts:

- Not connected
- Not optimized
- Not Proactive
- Not Agile

Readiness for NESHAP and FIFRA: Automation
Through New Construction and Retrofits

Smart factory



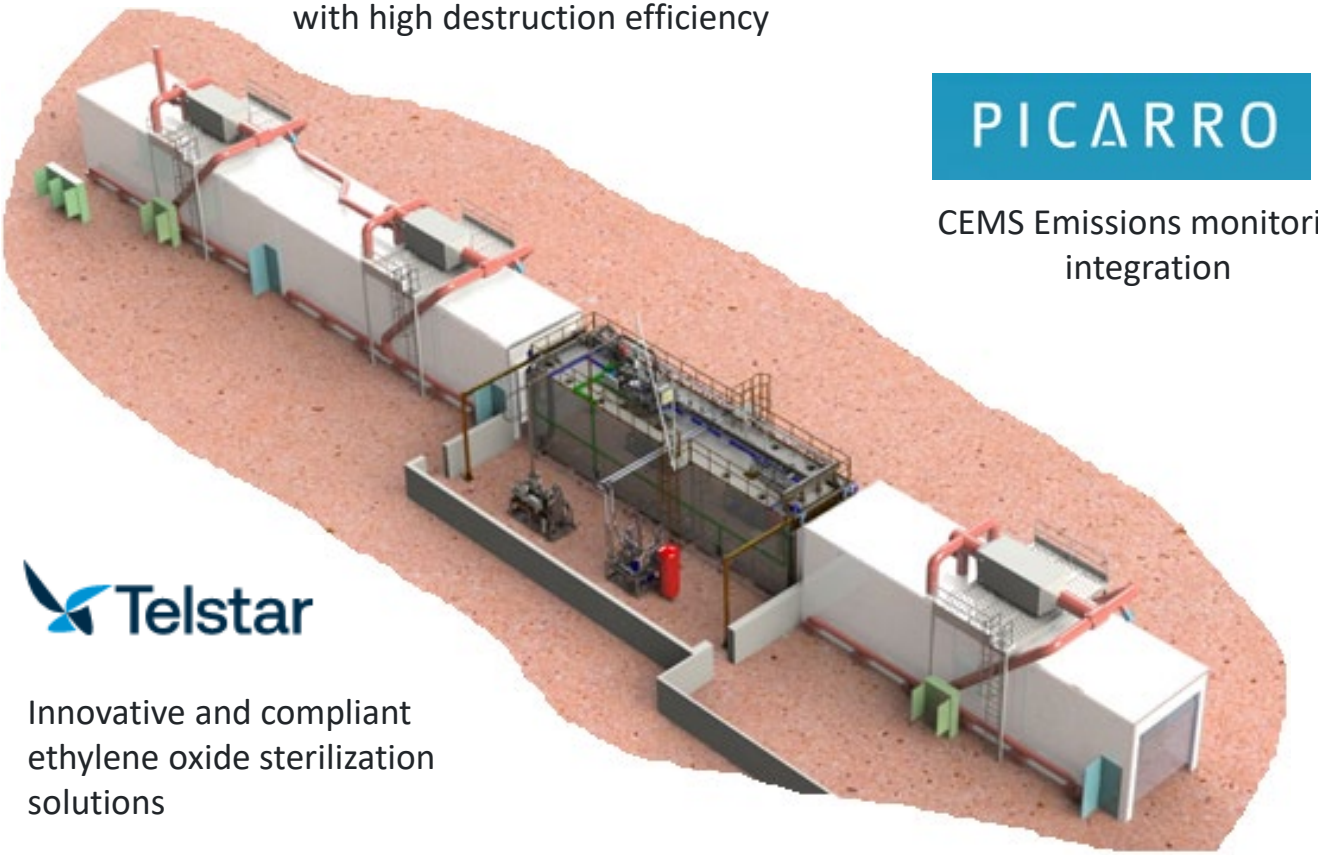
Considerations:

- Improved management of fugitive EO emissions
- Reduced worker exposure
- Reduction in operator-error
- Parametric release over BIs
- CEMS Emissions monitoring integration
- Exposure and process monitoring automation in the workplace.
- Predictively-driven maintenance system of the sterilization plant

Readiness for NESHAP and FIFRA: Automation
Through New Construction

LESNI
The Air Purification People

Safe and reliable "state of the art" system that meets the current stringent regulation with high destruction efficiency



PICARRO

CEMS Emissions monitoring integration

Telstar

Innovative and compliant ethylene oxide sterilization solutions

Considerations:

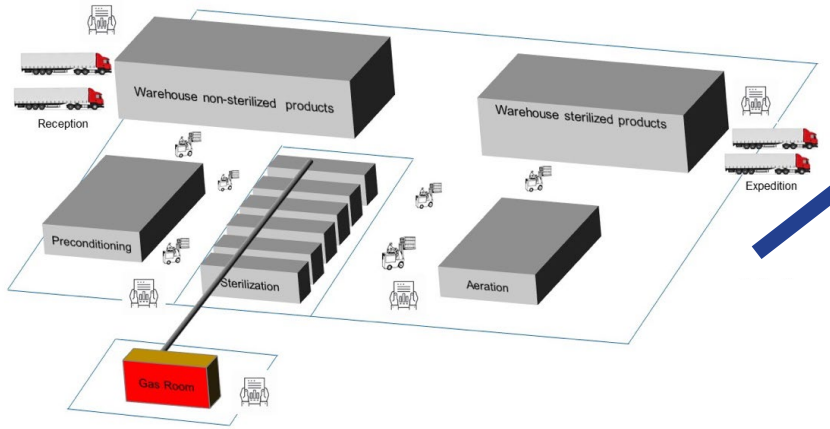
- Improved management of fugitive EO emissions
- Reduced worker exposure
- Reduction in operator-error
- Parametric release over BIs
- CEMS Emissions monitoring integration
- Exposure and process monitoring automation in the workplace.
- Predictively-driven maintenance system of the sterilization plant

Are existing plants prepared for current trends?

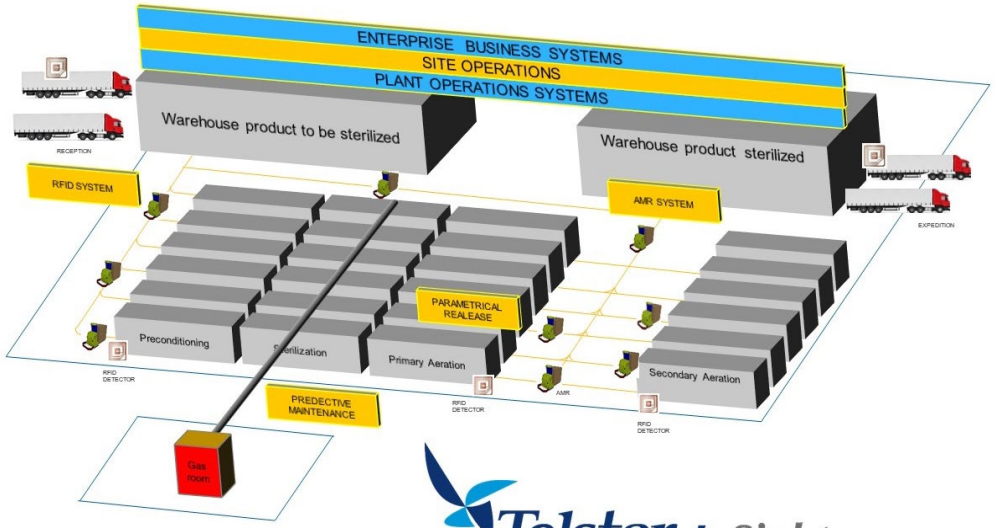
Examples upgrading strategies:

Case 1 - End-to-End EtO Emissions Management Solution

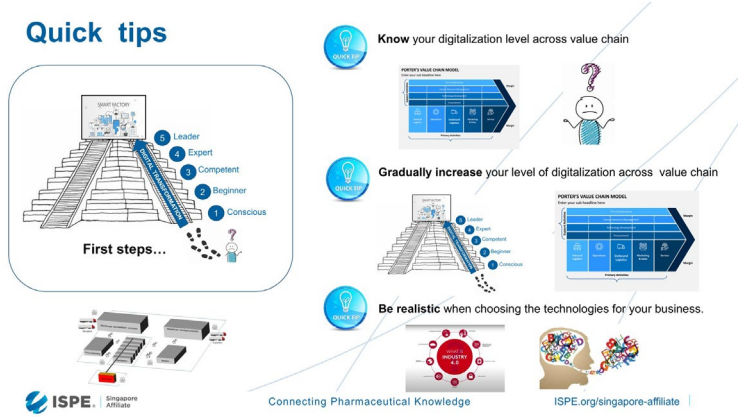
Case 2 - Automatization to limit exposure



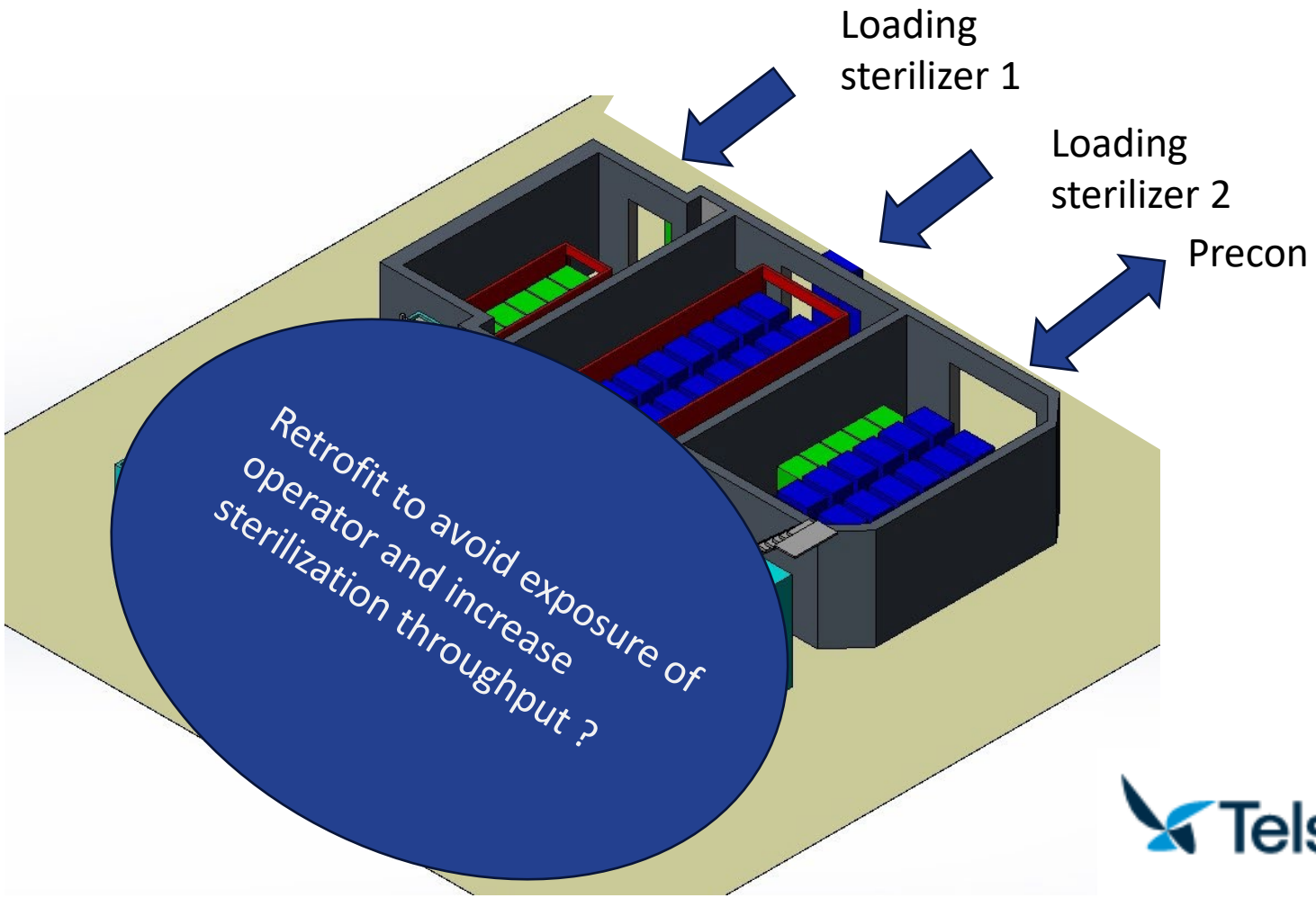
Facility enhancements



Telstar INSights



These don’t need to be greenfield sites

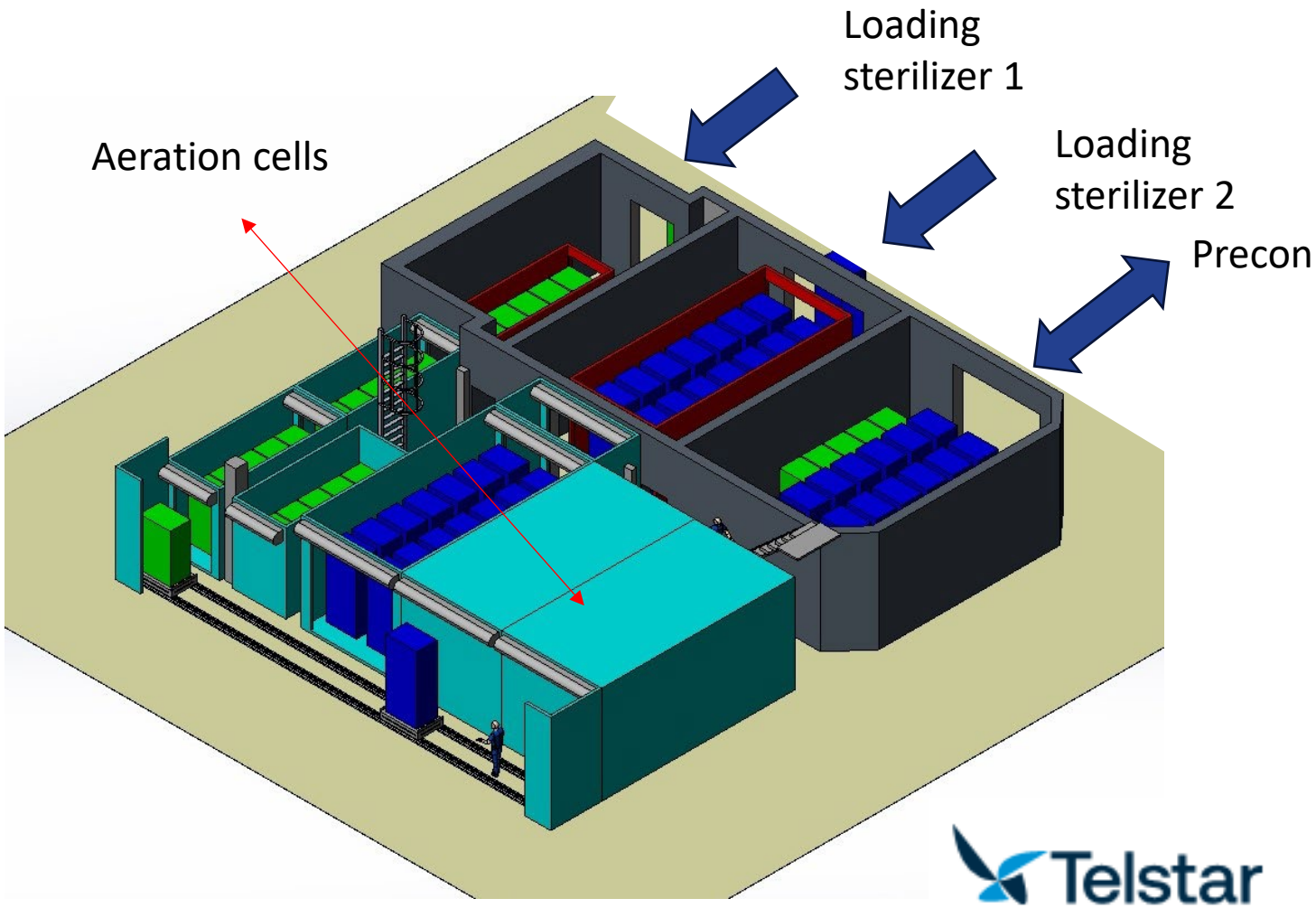


Retrofits can bring much of the same functionality as new construction

Telstar

Some pictures: Loading/unloading, transition bridge, inside the chamber

These don’t need to be greenfield sites



Retrofits can bring much of the same functionality as new construction

Phase 1 (done):

- Increased sterilization throughput
- Automated unloading activities
- In this example:
  - ✓ Install primary & secondary aeration cells
  - ✓ Replace outdated air purification system

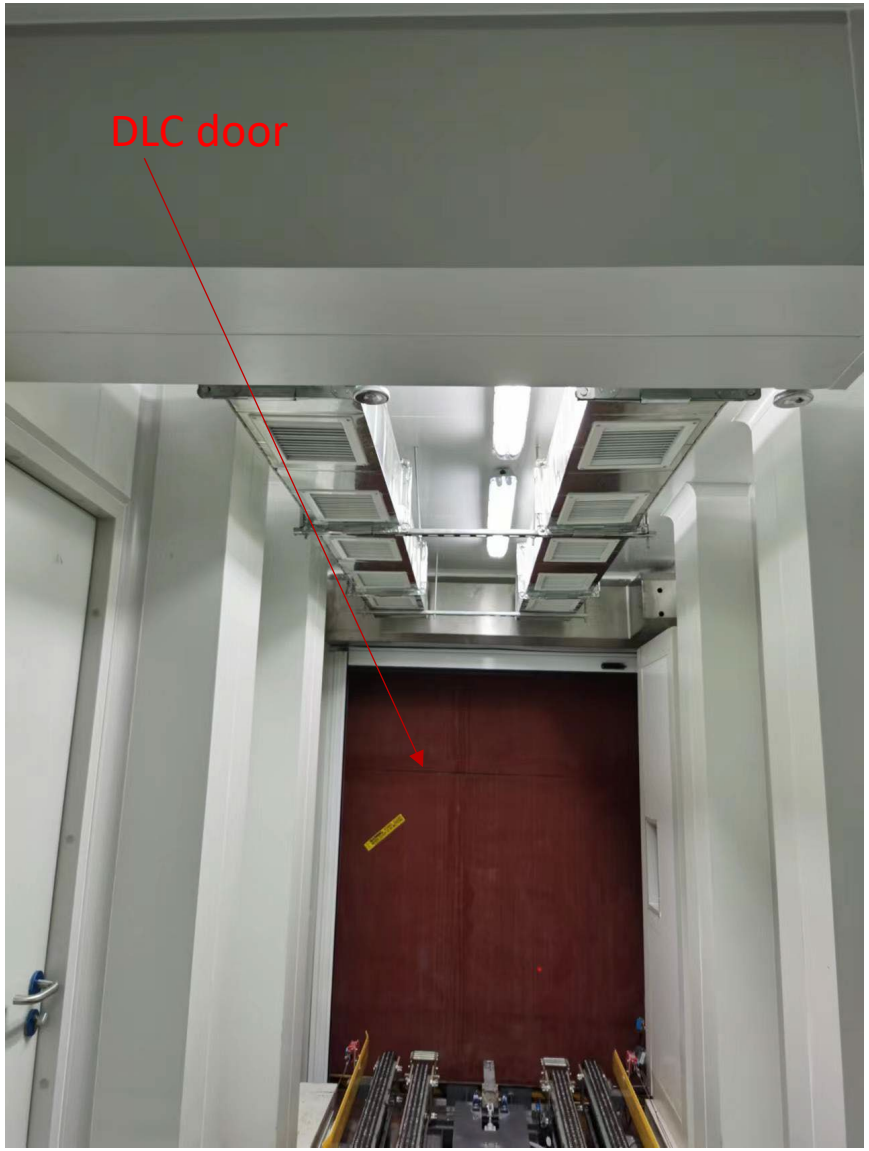
Phase 2:

- CEMS Emissions monitoring integration
- Exposure and process monitoring automation in the workplace.

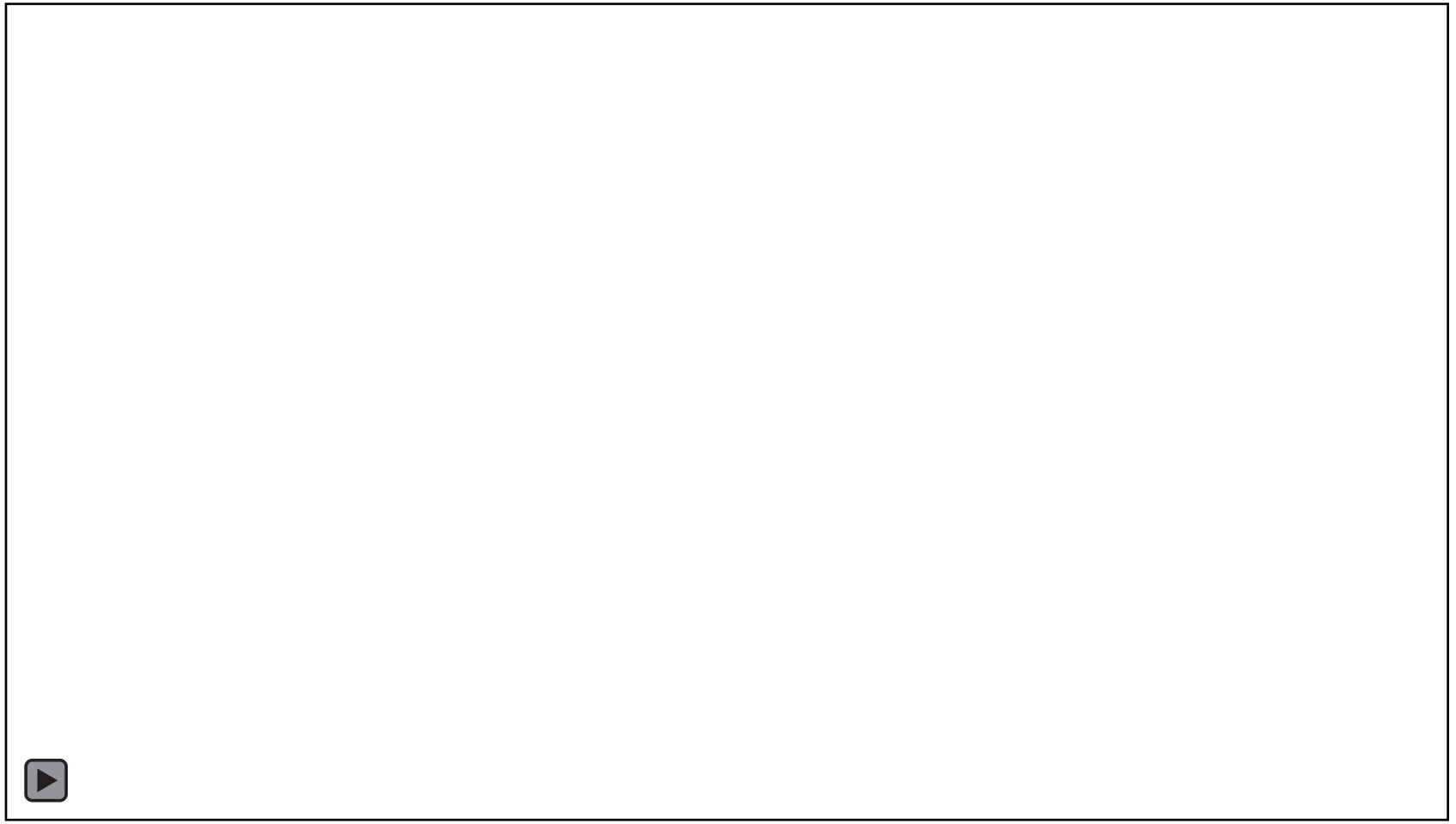
Phase 3

- Autonomous Mobile robots (AMR/AGV)
- Predictive Maintenance

Inside aerations cells

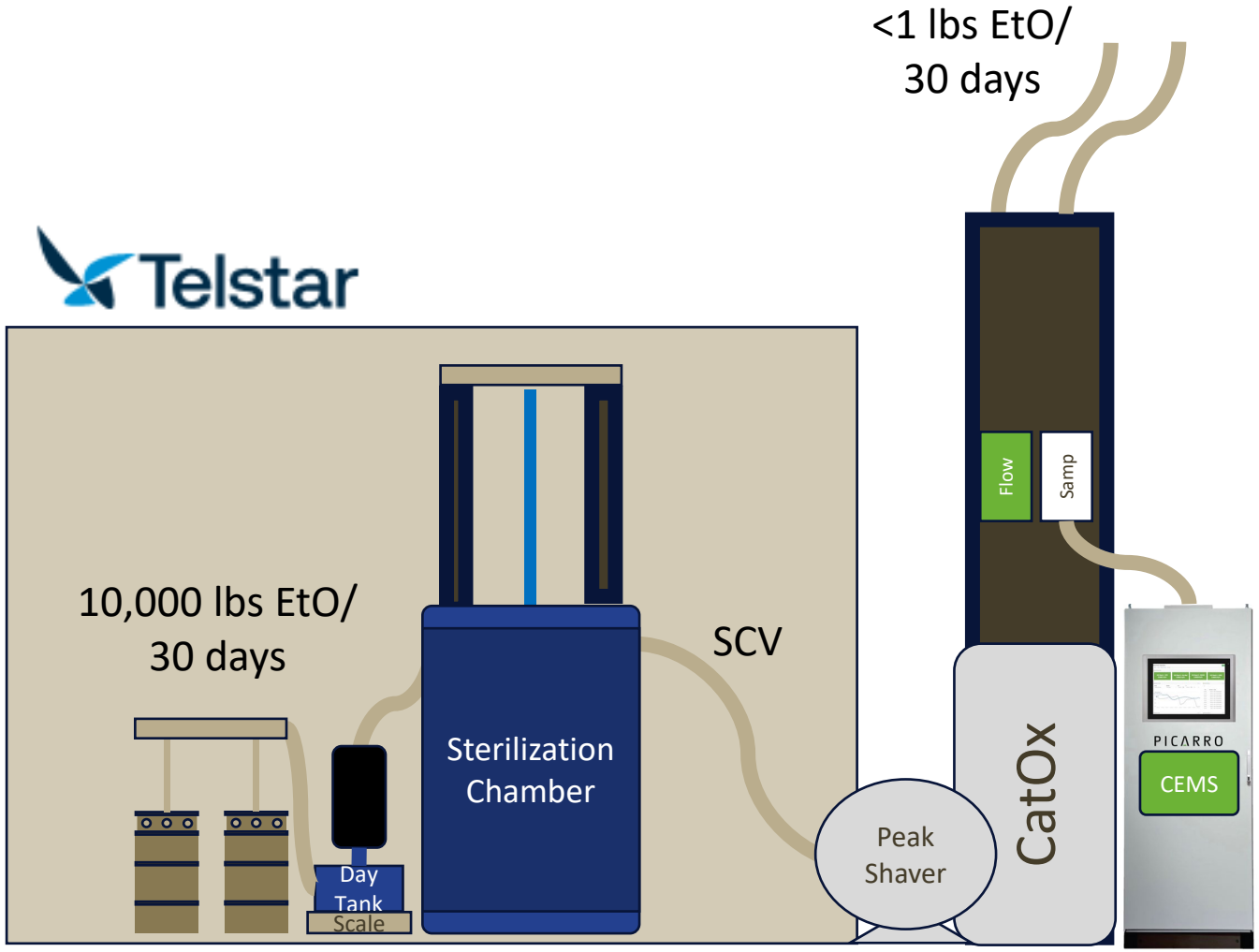


How it works



Telstar-Picarro Integration Case 1: CEMS

End-to-End EtO Emissions Management Solution for the EtO Subpart O NESHAP



Picarro and Telstar end-to-end EtO Emissions management solution.

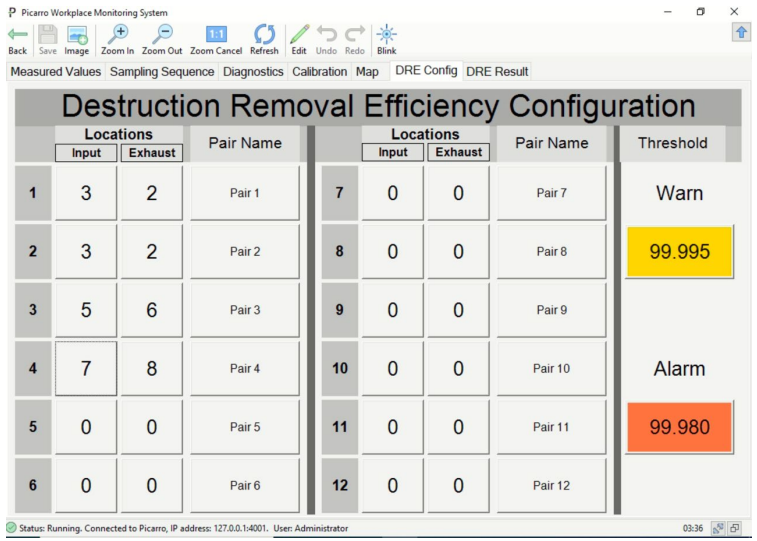
Primarily intended for SWEL by EtO Usage NESHAP compliance pathway

Dramatically simplifies the process of logging ins and outs

Automates the process of proving ongoing compliance.

Example shows 10,000 lbs/month use must be accompanied by <1 lb/month emissions to meet 99.99% DRE

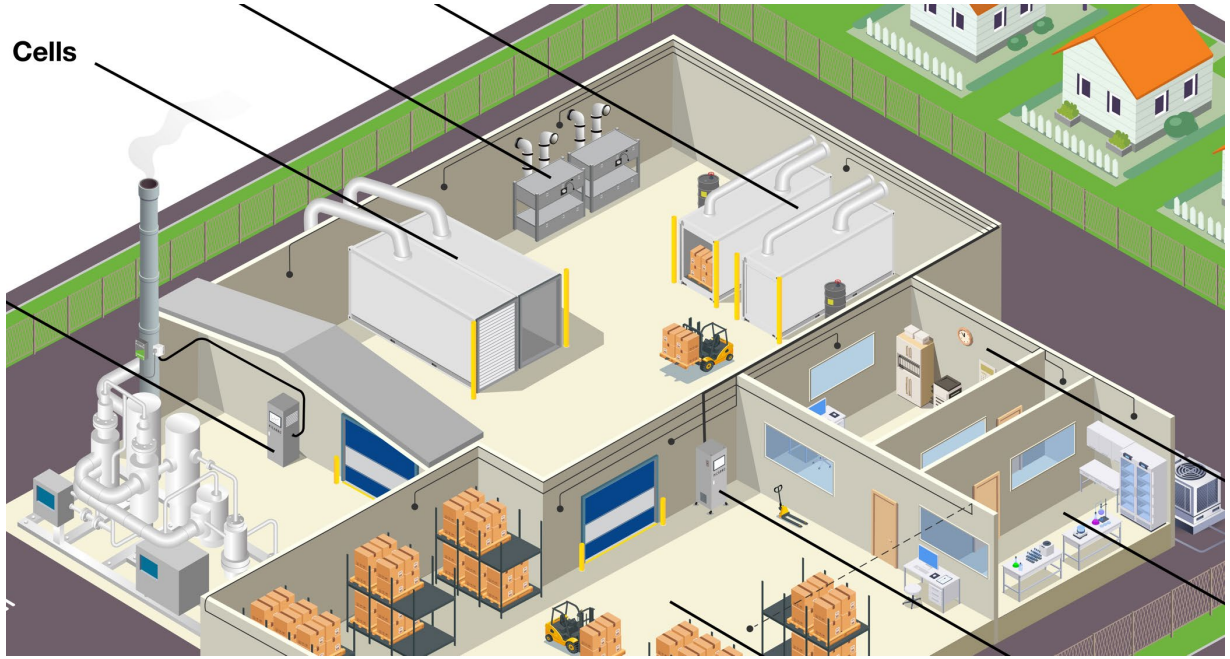
Case 1 CEMS Automation: Detail



- EtO usage on each chamber is directly measured via “Day Tank” mechanism and logged in the Telstar SCADA.
- At the end of each day, all LBs of EtO used is sent from the SCADA to the Picarro CEMS.
- Picarro CEMS updates a 30-day rolling accounting of pounds used per day.
- Picarro CEMS combines stack flow and stack measured EtO to provide a “EtO Out” on a daily total basis.
- Daily used and daily emitted numbers are summed on a 30-day rolling basis
- Normal, Warning, and Alarm levels of DRE can be set manually per facility-relevant rules to warn operators of possible DRE trends.
- Significant reduction in worker and compliance efforts: removes need for operators to manually enter and calculate use, emissions and DRE.
- CEMS is completely self-sustaining for cals, reporting, alarming

Telstar

Telstar-Picarro Integration Case 2: WMS
Process and Workplace Monitoring Integration



Integrate Telstar chambers and SCADA with Picarro Workplace Monitoring System

- Picarro WMS monitors EtO concentration at multiple points along the sterilization pathway for multiple chambers
- Roughly 100-1000x better sensitivity/LOD than Electrochemical sensors
- Reduction in “stuck sensor” behavior common with electrochemical sensors that lengthens Aeration steps.
- Reduction in interference false positives from EC sensors that interrupt and slow sterilization process.
- Automation and integration for 2-way signal pathways
- “Go To” automation to measure particular points when data is needed.

Conclusions

- New rules are changing the way facilities conduct EtO sterilization
- Companies stand to benefit from linear, intelligent, integrated, approaches to sterilization and to monitoring and reporting EtO emissions and exposure
- Combining Picarro CEMS reporting with Telstar SCADA metadata greatly simplifies compliance
- Integrating Picarro WMS with Telstar sterilization lines reduces liability for facilities and risk for workers
- Integration with trusted EtO-selective sensors reduces downtime, increasing throughput
- Retrofits and new construction can both benefit from this integrated approach

Thank you! Questions?


BREAK!

FALL 2024

PICARRO ETO CONFERENCE

Streamlining Emissions Compliance in the Sterilization Industry

PICARRO

Presentation 4

Advanced Air-Purification Solutions for Ethelyne Oxide

Jens Hermann
Global Sales and Marketing, LESNI

Agenda

Directory

- **LESNI A/S**
- **Typical Sterilization Process**
- **Actual Performance of LESNI EO CAP**
- **Technology Comparison**
- **New Functionality of LESNI EO CAP**
- **Advanced Solutions**

Agenda

Directory

LESNI A/S

Company

LESNI A/S is a 100% privately owned Danish company with more than 37 years of experience and 150 EtO Abatement Systems, and 75 Accelerated Preconditioning and Degassing Cells installed around the world.

Specialist in delivering solutions for toxic gases, Ethylene Oxide, VOC's, Halogenated organic compounds and Freon (ODS) that meet demanding legislation with emphasis on safety & reliability.

Experience within the Medical device, Chemical, Pharmaceutical, Food, Semiconductor, Recycling, Printing and many other industrial manufacturing industries.

AROUND THE WORLD

References

- **5 Continents**
- **40 countries, e.g. Australia, Brazil, China, Malaysia, Mexico, USA, Caribbean, Middle East, Europe.**
- **Exports** **> 95%**
  - **Inside EU** **~ 45 %**
  - **Rest of the world** **~ 50 %**

PURIFICATION SYSTEMS

Technologies

Absorption

- Physical
- Chemical

Adsorption

- Activated Carbon
- Zeolite

Oxidation

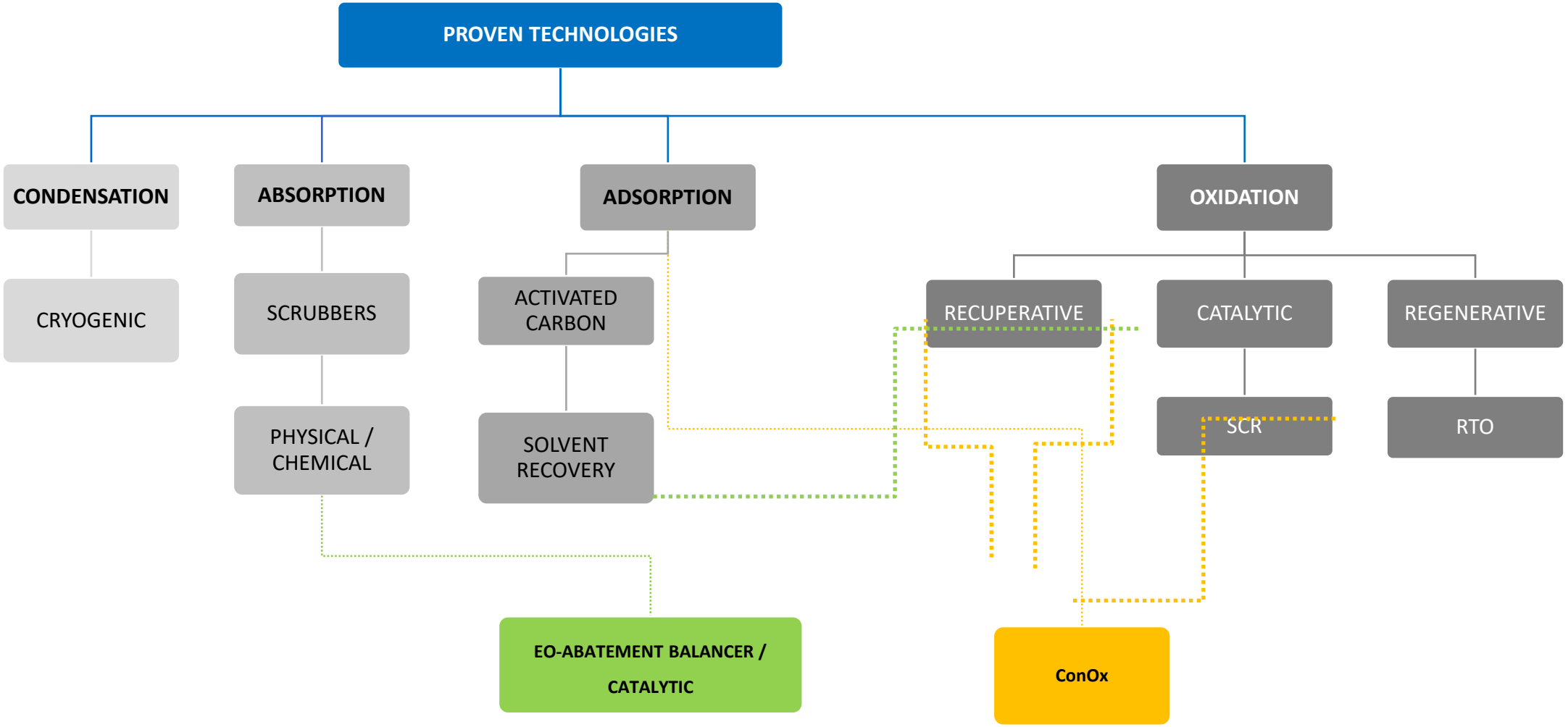
- Thermal
- Catalytic
- Recuperative
- Regenerative
- SCR

Solutions

- ConOx
- EtO-Abatement
- CFC–Abatement

PURIFICATION SYSTEMS

Technologies

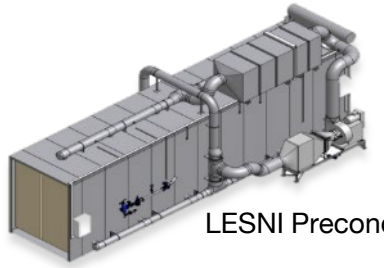


Agenda

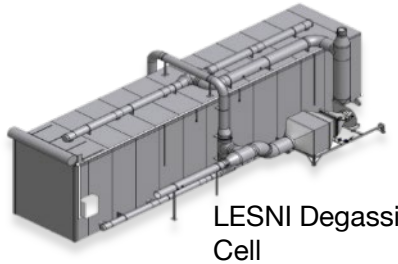
Directory

TYPICAL STERILIZATION PROCESS

Source of Emissions I

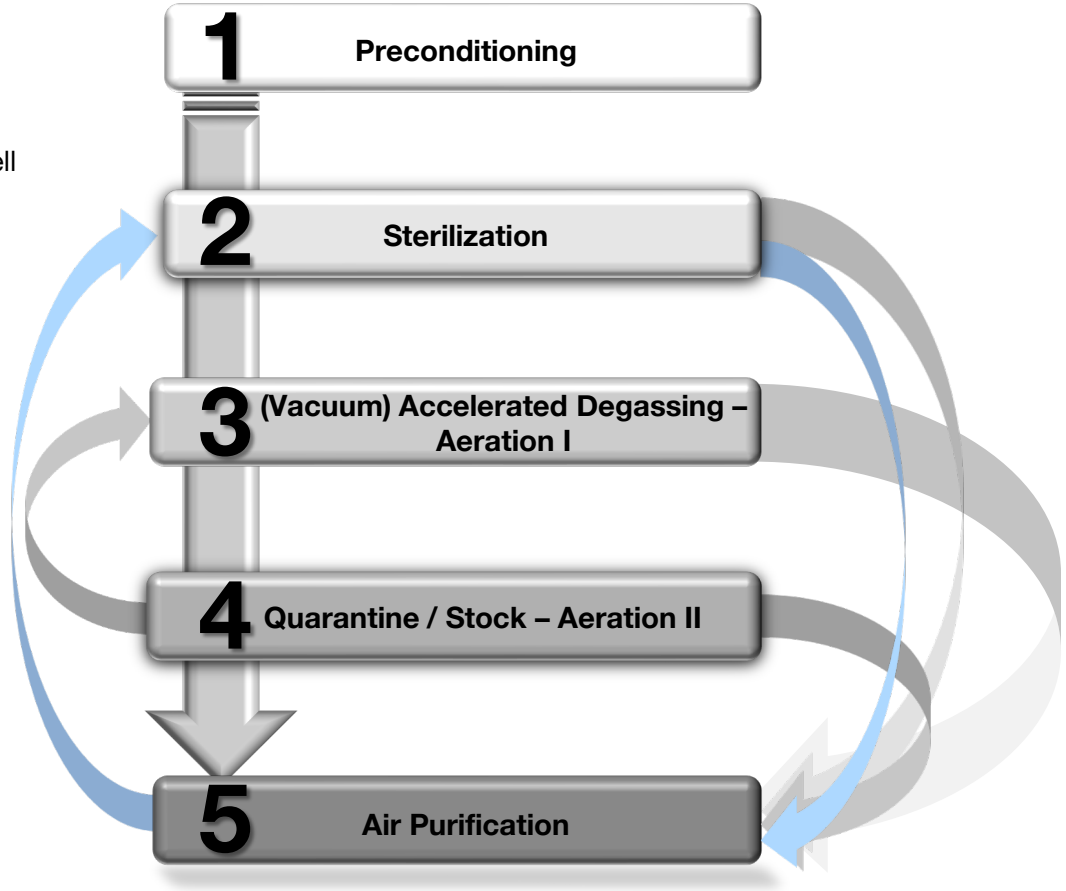


LESNI Preconditioning Cell



LESNI Degassing Cell

LESNI Catalytic-Abatement-Plant



with ethylene oxide contaminated air

with ethylene oxide contaminated water

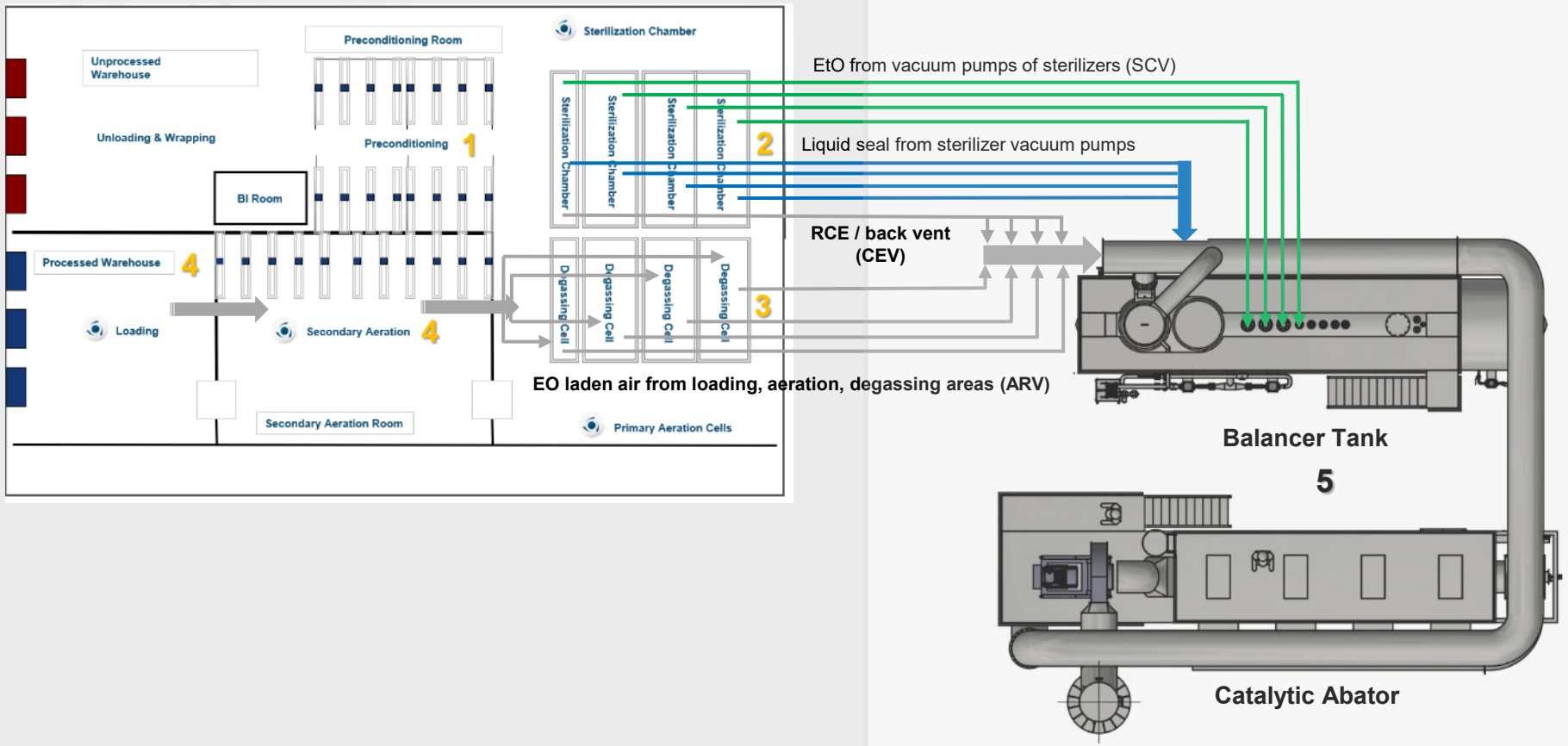
TYPICAL STERILIZATION PROCESS

Source of Emissions II

- **Sterilizer – High loads / levels above 25% LEL – INTERMITTENT** **2**
- **Sterilizer Back Vent, if used – Low concentration - INTERMITTENT** **2**
- **Vacuum pump – liquid seal - INTERMITTENT** **2**
- **Unloading / Transfer Zone - Low concentration - CONTINUOUS** **2/3**
- **Degassing / Aeration Cell – Low concentration - CONTINUOUS** **3**
- **Secondary Aeration rooms – Lower concentration - CONTINUOUS** **4**

TYPICAL STERILIZATION PROCESS

Source of Emissions III

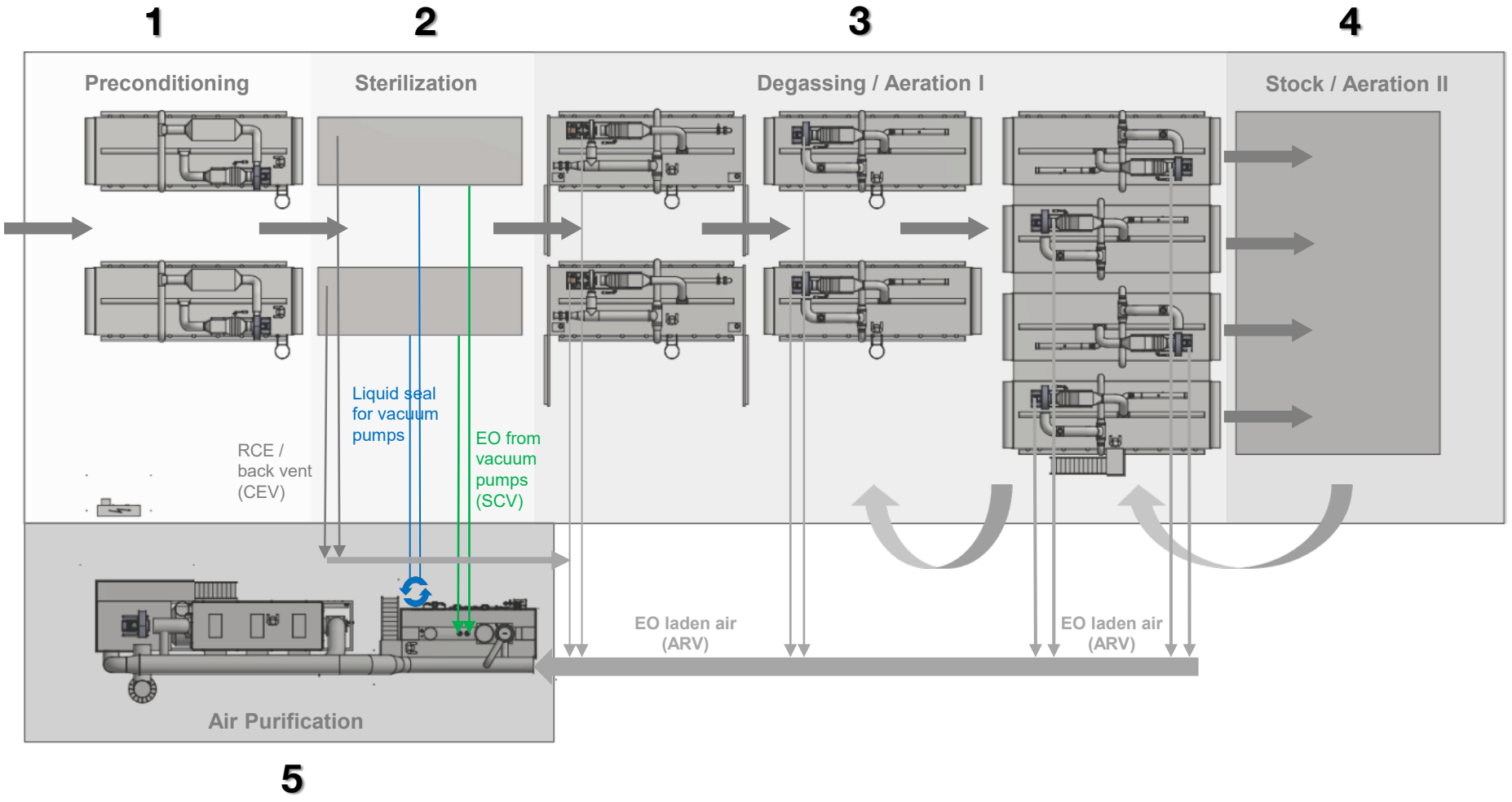


Sterilization Facility

LESNI Catalytic-Abatement-Plant

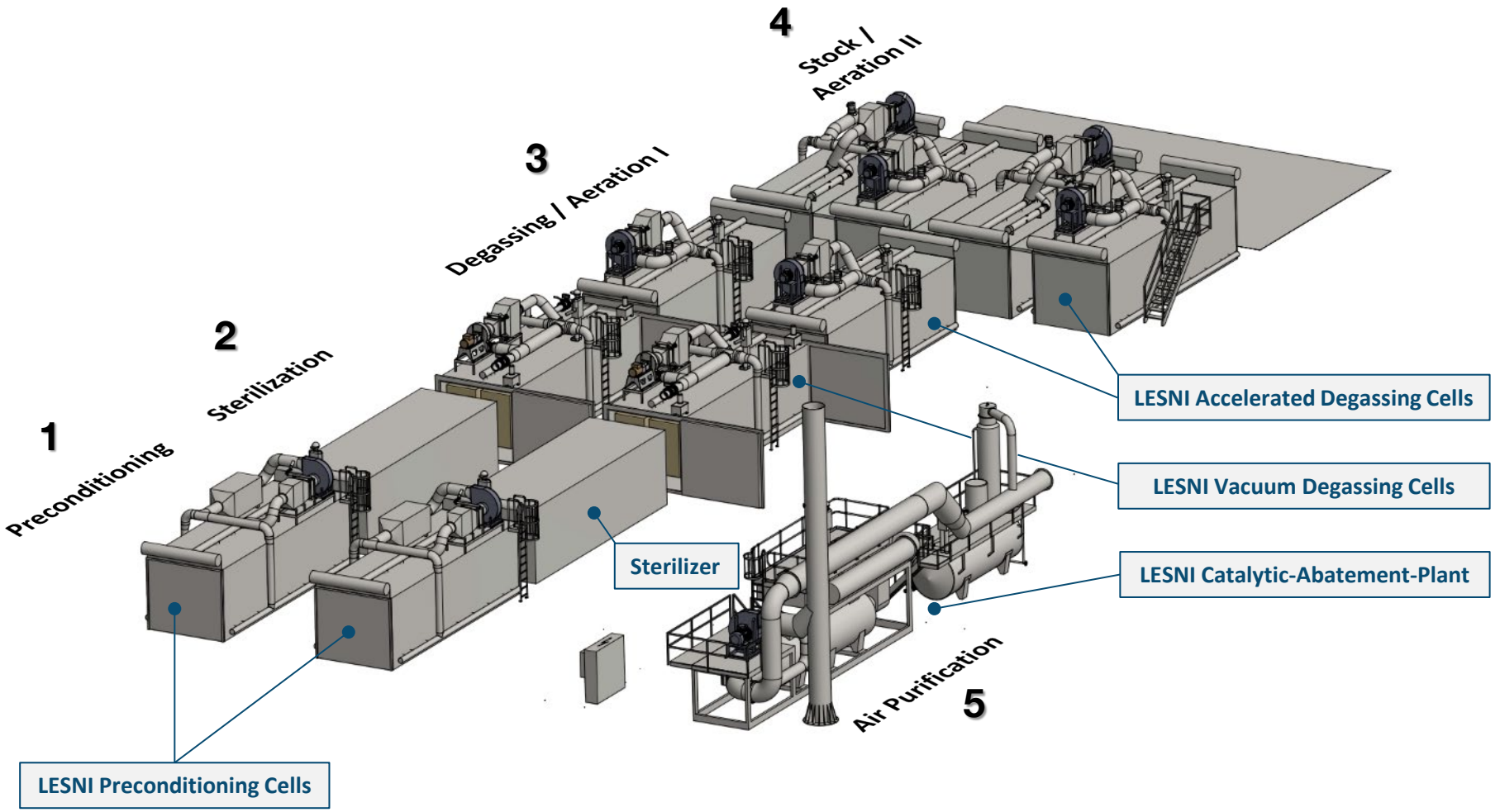
TYPICAL STERILIZATION PROCESS

Source of Emissions IV / Automated Process



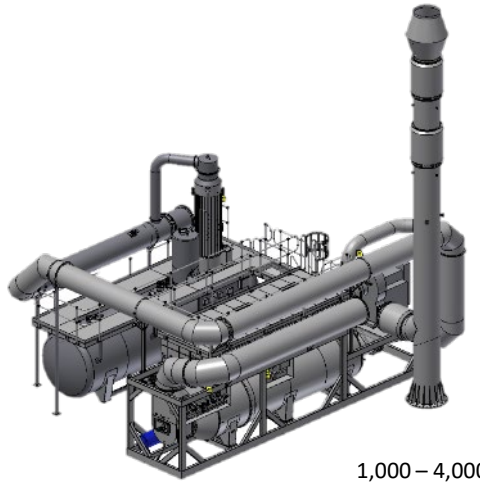
TYPICAL STERILIZATION PROCESS

Source of Emissions V / Automated Process



CATALYTIC ABATEMENT PLANT

Simple Flow Sheet



Agenda

Directory

LESNI A/S

Typical Sterilization Process

Actual Performance of LESNI EO CAP

Technology Comparison

New Functionality of LESNI EO CAP

Advanced Solutions

CATALYTIC ABATEMENT PLANT

Actual Performance

TA-Luft - Legislation limit of less than 0.5 mg/Nm³ (~270 ppb)

The majority of the LESNI EO CAPs have been built to fulfill the most stringent legislation limits according to German TA-Luft, to not exceed an outlet concentration of 0.5 mg/Nm³ (270 ppb) all the time, with destruction efficiency exceeding 99.9%, which was more than satisfactory for US before new EPA rules.

- None of the LESNI units failed to fulfill requested legislation limits.
- At the time state of the art measurement technologies (3 years and more), e.g., Gas Chromatography (GC), FTIR etc., were not able to reliably measure below 50 to 100 ppb.
  - With this limitation it was not possible to identify how good the performance and destruction efficiency of the LESNI Catalytic-Abatement-Plant's could be.

➡ ***LESNI is confident to guarantee a DRE of 99.99%.***

CATALYTIC ABATEMENT PLANT

Actual Performance

EPA - DRE of better than 99.99%

To fulfill a DRE of 99.99%, the outlet concentration of an abatement systems must be on average below 20 ppb, especially when talking about less EO from SCVs and higher airflows from ARVs.

- Actual monitoring results with Cavity Ring-Down Spectroscopy (CRDS) as well as Fourier Transform Infrared Spectroscopy (FTIR) of several existing LESNI units are proofing **outlet concentrations in a range from 0 to 5 ppb**, exceeding **DRE's of 99.99%.**

- Conceptual design improvements are in place to secure and guarantee the LESNI performance fulfilling EPAs requested DRE's, especially for the 99.99%.
  - **Higher operational temperature** to improve the catalytic oxidation process and conversion of EO, especially for periods with low concentrated process air from CEV and ARV.
  - **More catalyst** for increased **retention time** to secure the high destruction efficiency during catalytic conversion.
  - Improved air **turbulence** in the catalytic chambers.
  - **Improved stripping** process to balance inlet concentration to catalytic oxidizer even better.

➡ ***LESNI is confident to guarantee a DRE of 99.99%.***

CATALYTIC ABATEMENT PLANT

Actual Performance

Emissions – Total Mass Flow

The superiority and advantage of the LESNI solution when combining all the different sources of EO emissions into one system and reaching, e.g., better than 99.99%, means **less EO emitted** to the atmosphere by mass from the facility in comparison with, e.g., **3 technologies used** for abatement, still potentially compliant but **emitting more EO to the atmosphere than LESNI**.

CATALYTIC ABATEMENT PLANT

Actual Performance

Emissions – Total Mass Flow

An area source facility uses 36 tpy (**6,615 lbs./month**), and the facility chooses to control all of its SCVs, ARVs, and CEVs with a single abatement solution. From table 1 of the final rule (pages 14 through 16), the DREs that apply to the SCVs, ARVs, and CEVs are 99.99%, 99.9% and 99%, respectively.

In this example, suppose that, over 30 days of operation (which is the basis used for determining compliance in the final rule), the mass of EtO from the **SCVs** is **6,218 lbs.**, the mass of EtO from the **ARVs** is **265 lbs.**, and the mass of EtO from the **CEVs** is **66 lbs.,** meaning that the mass of EtO from the combined stream is **6,549 lbs.** (this is the standard breakdown of pre-abatement EtO that has been observed in this industry – 94% / 4% / 1%).

Under the first approach, the facility would apply

- **a 99.99% DRE** to the **entire abatement solution** (LESNI),

resulting in an emission limit of **0.655 lbs**.

Under the second approach, the facility would apply

- a **99.99% DRE** to the **SCV** stream (0,622 lbs.),
- a **99.9% DRE** to the **ARV** stream (0,265 lbs.),
- and **99% DRE** to the **CEV** stream (0,66 lbs.),

resulting in an emission limit of **1.547 lbs**.

FACTOR OF 2.4

Agenda

Directory

LESNI A/S

Typical Sterilization Process

Actual Performance of LESNI EO CAP

Technology Comparison

New Functionality of LESNI EO CAP

Advanced Solutions

CATALYTIC ABATEMENT PLANT

LESNI Concept – Technology Comparison

Technology Comparison

We have observed that almost all other different, installed process technologies to purify ethylene oxide emissions require a multi-step solution (scrubbers) or a polishing step to achieve the 99% or even the 99.99% DRE.

➡ ***LESNI EO CAPs are already prepared to achieve the 99.99% DRE!***

CATALYTIC ABATEMENT PLANT

LESNI Concept – Technology Comparison

Typical Source of Emission	Dry Adsorbent Filter	Wet Scrubber	Thermal Oxidizer	Catalytic Oxidizer	LESNI EO CAP – Balancer & Catalytic Oxidizer
HIGH EtO concentration - vacuum pump exhaust vent from single sterilizer (SCV)	X	✓ note 1	(✓) note 2	(✓) note 2	✓
HIGH EtO load - multiple sterilizers dumping at the same time (SCV)	X	(✓) note 2	X	X	✓
Back vents (CEV), aeration rooms, aeration cells (ARV)	(✓) note 3	X	X	(✓) note 3	✓
VERY LOW EtO concentration - fugitive air with EtO concentration less than 1 - 5 ppm (Group 1 + 2)	✓	X	X	(✓) note 3	✓
Liquid ring seal, where liquid ring pumps are used, condensate also need to be treated	X	(✓) note 2	(✓) note 2	(✓) note 3	✓
Combination of any of 1 & 2 & 3 & 4 & 5 simultaneously	X	X	X	X	✓
Comply with TA-Luft, any time, and with new EPA rules	X	✓ note 1	(✓) note 3	(✓) note 3	✓

note 1: multiple steps to reach low emission level

note 2: additional design and safety consideration

note 3: sized for such duty but high CAPEX & OPEX

Agenda

Directory

LESNI A/S

Typical Sterilization Process

Actual Performance of LESNI EO CAP

Technology Comparison

New Functionality of LESNI EO CAP

Advanced Solutions

CATALYTIC ABATEMENT PLANT

LESNI Concept – Advanced Solutions

Isolating of Balancer Tank

New functionality in the LESNI EO CAPs **prevents critical alarms** caused by the Balancer Tank.
This **avoids bypass situations**, thus keeping the catalytic abator running with aeration / degassing air, whilst only temporarily isolating Balancer Tank and EO dumping from sterilizer chamber vacuum pumps, resulting in **increased equipment availability and reliability**.

➡ ***Less reporting and less EO emitted during bypass situations.***

Agenda

Directory

LESNI A/S

Typical Sterilization Process

Actual Performance of LESNI EO CAP

Technology Comparison

New Functionality of LESNI EO CAP

Advanced Solutions

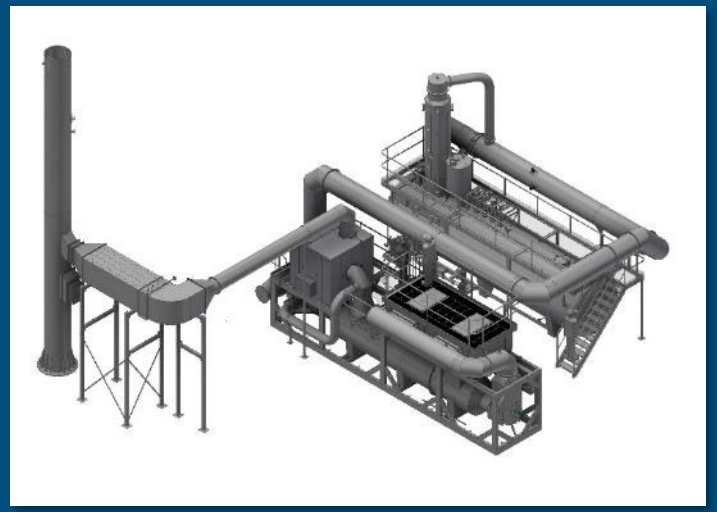
CATALYTIC ABATEMENT PLANT

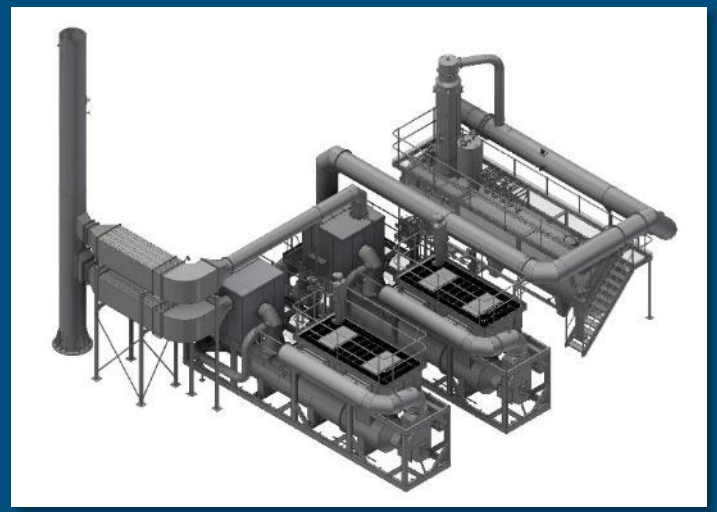
LESNI Concept – Advanced Solutions

Modular Concept

LESNI continues to support customer requirements by matching production capacity at different phases of their facility lifecycle.
Development work takes into consideration the **final capacity** and **actual needs** of engineering and construction in a **modular concept** to **reduce immediate capital investment** and prepare the system for **future expansion**.

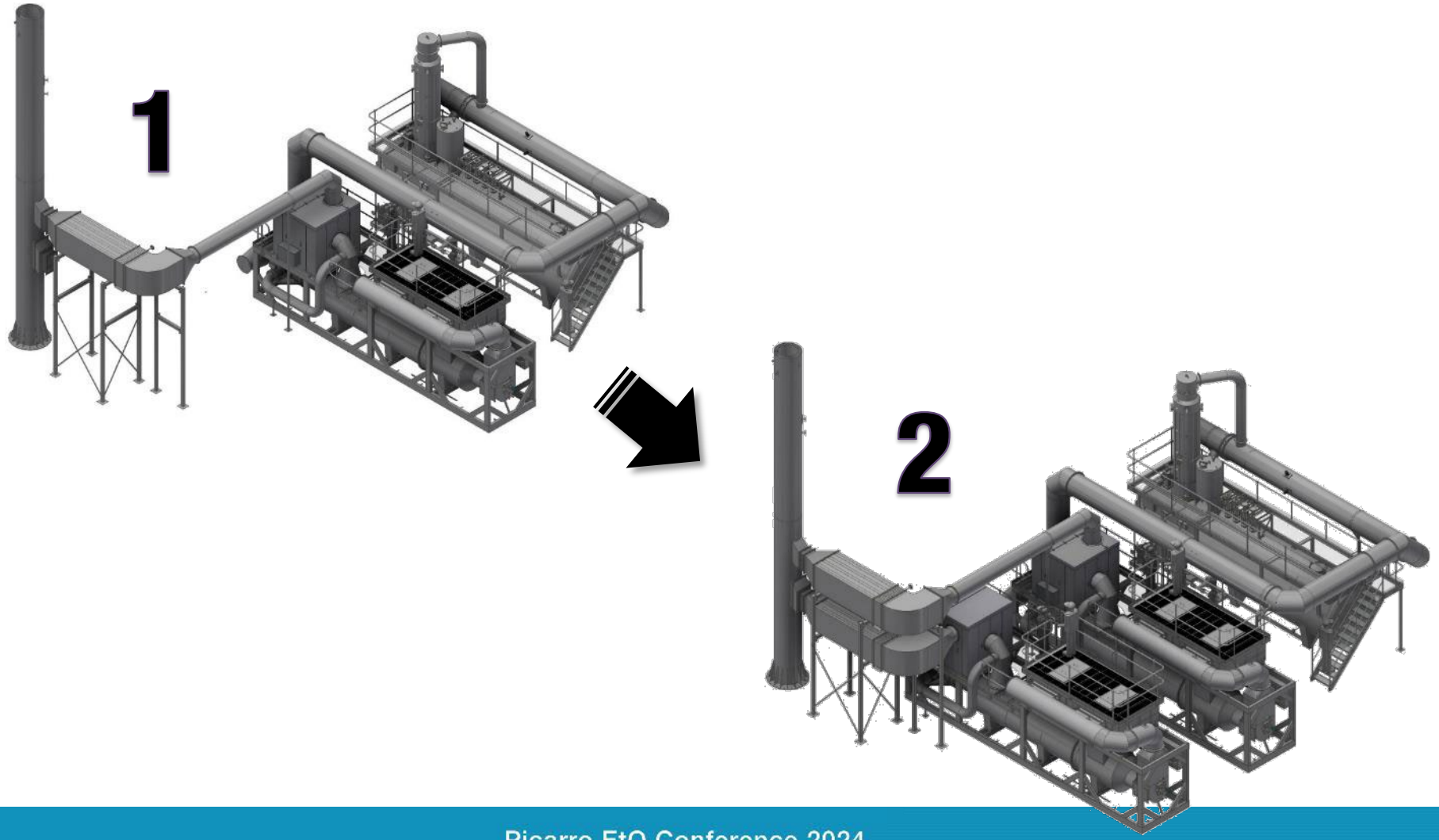
➡ ***Design is based on to building and extending the abatement plant in two steps.***





CATALYTIC ABATEMENT PLANT

LESNI Concept – Advanced Solutions

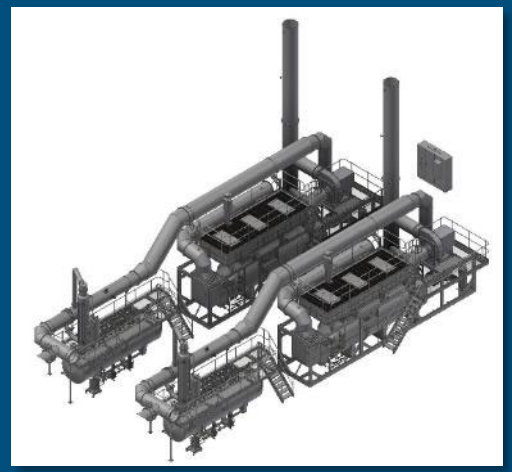


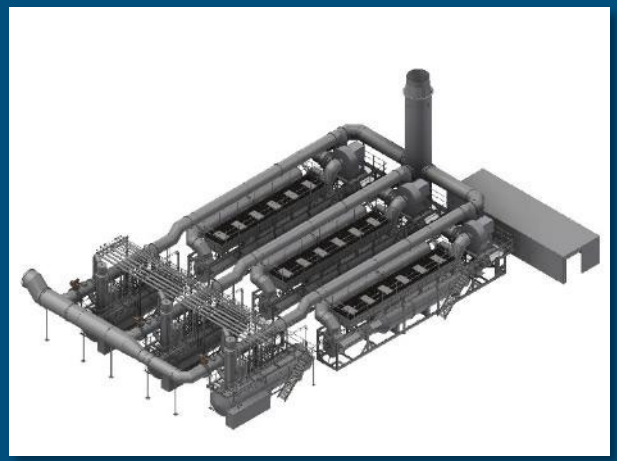
CATALYTIC ABATEMENT PLANT

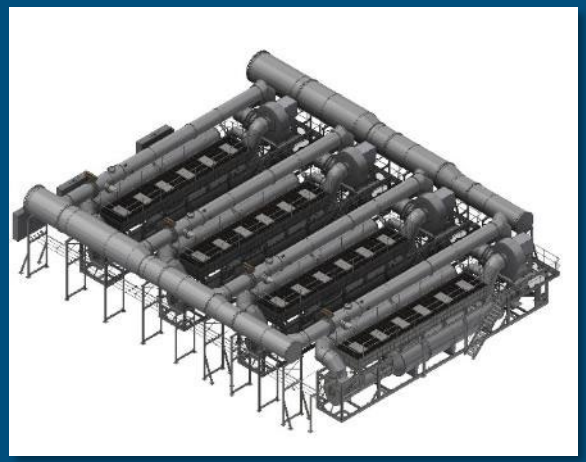
LESNI Concept – Advanced Solutions

Redundancy Concept

LESNI also developed the special construction of the Catalytic-Abatement-Plants,
designed to offer a **redundancy concept**, complete with interconnecting ductwork, actuated valves, and controls.
This feature allows the sterilization facility to have a certain redundancy designed and built up to 100%, to **reduce the downtime to a minimum**.

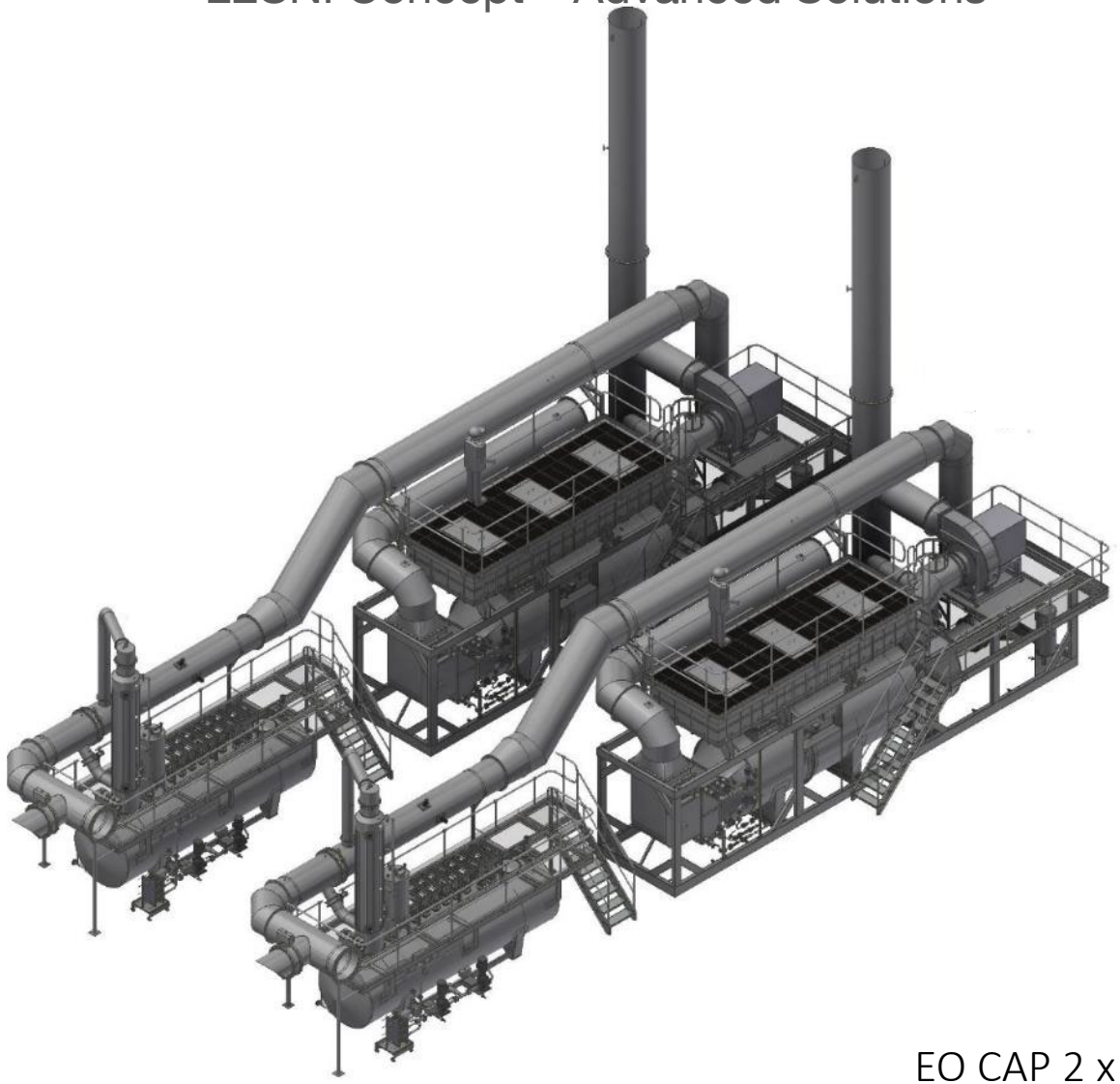






CATALYTIC ABATEMENT PLANT

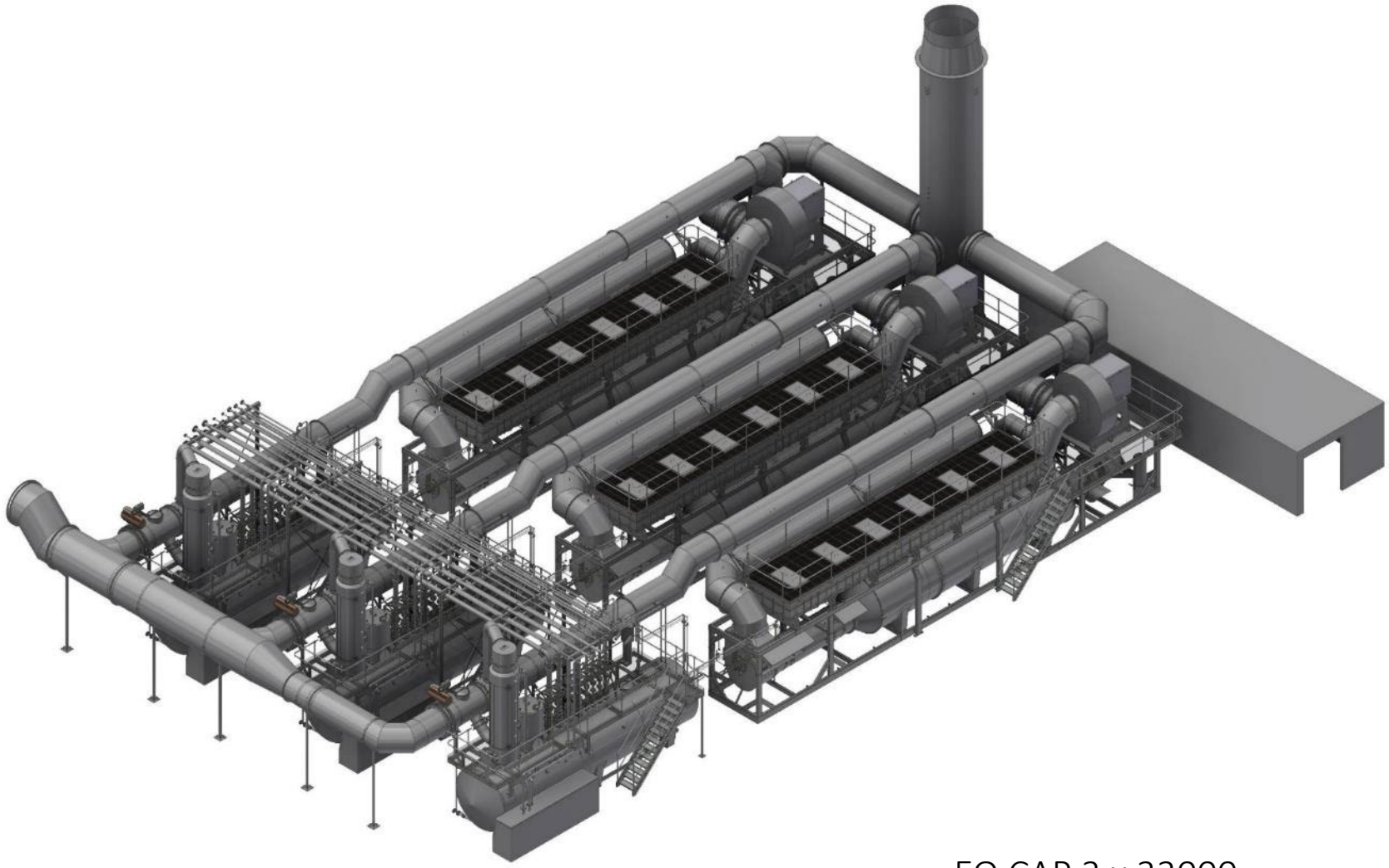
LESNI Concept – Advanced Solutions



EO CAP 2 x 15000

CATALYTIC ABATEMENT PLANT

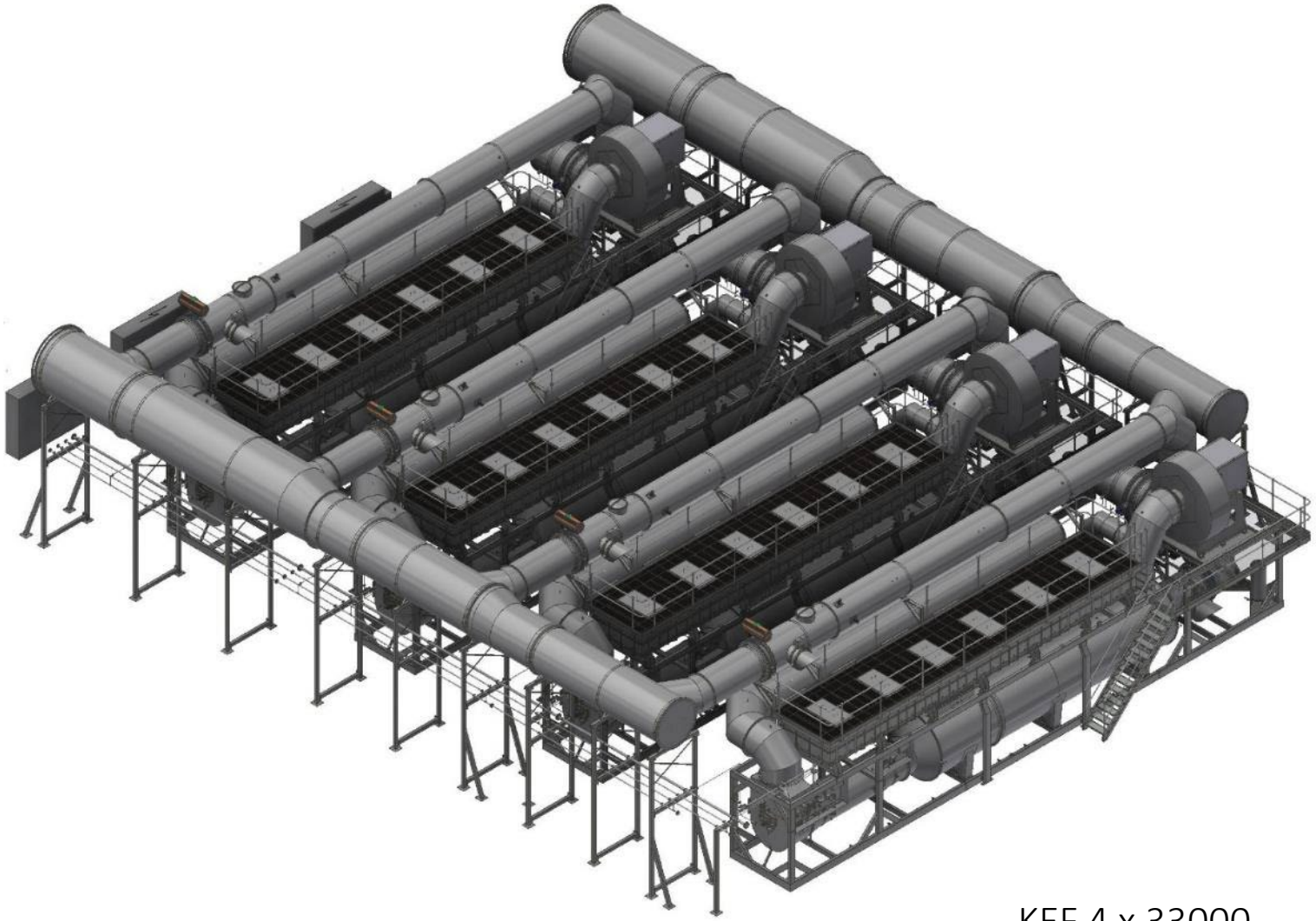
LESNI Concept – Advanced Solutions



EO CAP 3 x 33000

CATALYTIC ABATEMENT PLANT

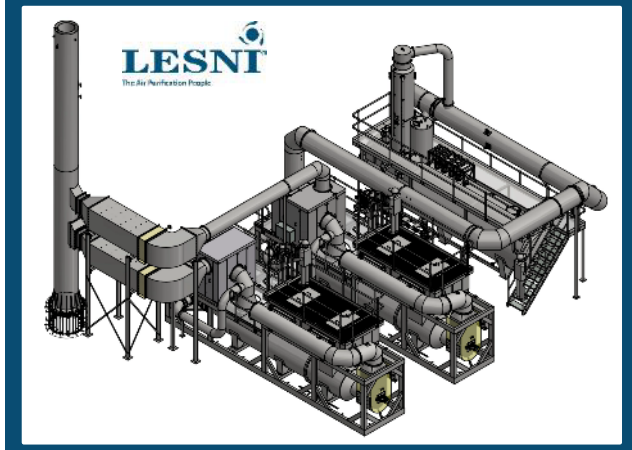
LESNI Concept – Advanced Solutions



KEF 4 x 33000

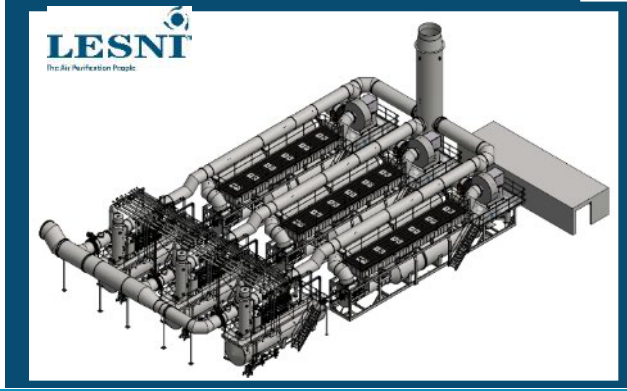
REFERENCES

Catalytic Abatement Plan



REFERENCES

Catalytic Abatement Plan



FALL 2024

PICARRO ETO CONFERENCE

Streamlining Emissions Compliance in the Sterilization Industry

PICARRO

Panel 2

Optimizing Medical Device Sterilization - A Facility Enhancement Roadmap

Panel Members

Ben Erickson

POND

James Preves

POND

Gregor Lucic

PICARRO

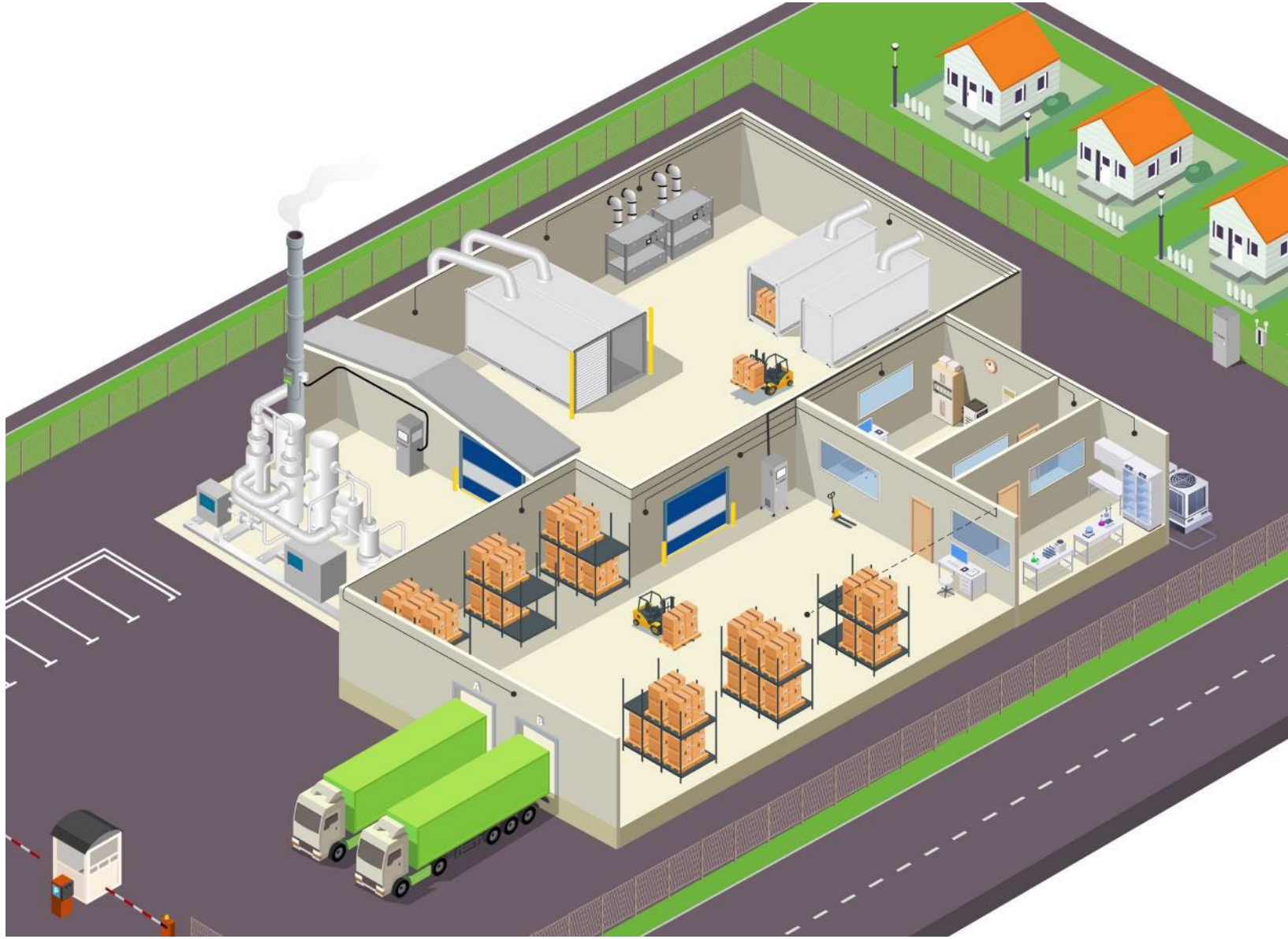
NESHAP (Subpart O)

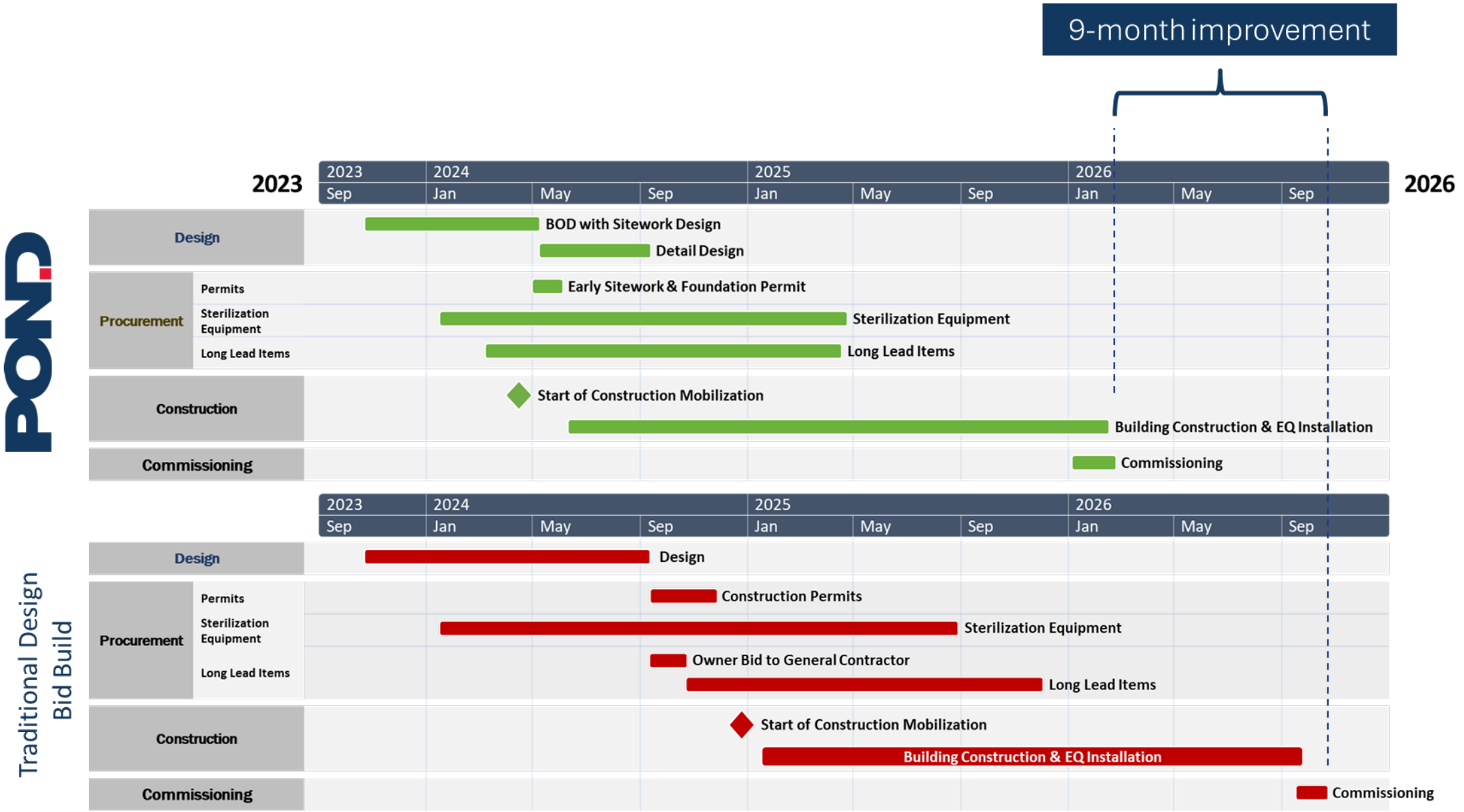
Sources

- Sterilization Chamber Vents (SCV)
- Aeration Room Vents (ARV)
- Chamber Exhaust Vents (CEV)
- Group 1 and Group 2 Emissions

Enhancements

- Permanent Total Enclosures (PTE)
- Airflow improvements
- Abatement Systems




9-month improvement
2023
2026
2023
2024
2025
2026
Sep
Jan
May
Sep
Jan
May
Sep
Jan
May
Sep
POND
Design
BOD with Sitework Design
Detail Design
Procurement
Permits
Early Sitework & Foundation Permit
Sterilization Equipment
Sterilization Equipment
Long Lead Items
Long Lead Items
Construction
Start of Construction Mobilization
Building Construction & EQ Installation
Commissioning
Commissioning
Traditional Design Bid Build
Design
Design
Procurement
Permits
Construction Permits
Sterilization Equipment
Sterilization Equipment
Owner Bid to General Contractor
Long Lead Items
Long Lead Items
Construction
Start of Construction Mobilization
Building Construction & EQ Installation
Commissioning
Commissioning

Thank you and Closing Thoughts!

FALL 2024

PICARRO ETO CONFERENCE

Streamlining Emissions Compliance in the Sterilization Industry

PICARRO

Meet for the bus at 4:45!

Please remember to bring you ID!