

Workshop H

# EHS 101...Basics in Air Permitting and Compliance

Sustainability & Environmental Health & Safety Symposium  
Cincinnati, Ohio  
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# Introduction

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# Course Overview

- Key Definitions
- Air Permitting Overview
- State-Specific Permitting Programs
- General Permitting Process

# Key Definitions



# Key Definitions

- Air Pollutant:

- Anything released to the atmosphere other than uncombined water vapor or heat

- Criteria Pollutant:

- Nitrogen oxides ( $\text{NO}_x$ )
- Carbon monoxide (CO)
- Sulfur dioxide ( $\text{SO}_2$ )
- Particulate matter < 10 microns ( $\text{PM}_{10}$ )
- Particulate matter < 2.5 microns ( $\text{PM}_{2.5}$ )
- Volatile organic compounds (VOC) – ozone
- Lead (Pb)



# Key Definitions (cont'd)

- Volatile Organic Compound (VOC):
  - any organic compound (i.e., contains carbon) which participates in atmospheric photochemical reactions
  - Specifically excludes a long list of compounds such as:
    - Acetone
    - Chlorinated solvents (methylene chloride, trichloroethylene)
    - CFCs



# Key Definitions (cont'd)

- Hazardous Air Pollutants (HAP):
  - 188 specific compounds listed in 1990 Clean Air Act Amendments
  - Includes common paint solvents such as toluene, xylene and methanol
  - Includes certain metals such as manganese, chromium, lead, nickel and mercury
  - Ammonia is not a HAP

# Key Definitions (cont'd)

- Emission unit:
  - Each separate operation or activity that results or may result in the emission of any air contaminant
  - Sometimes used interchangeably with “source”





# Key Definitions (cont'd)

- Potential to Emit (PTE):
  - Used to determine applicability of many regulations
  - **Maximum capacity** of an emissions unit or stationary source to emit an air pollutant under its physical and operational design
  - Generally assumes operation at **8,760 hours/year**
  - Generally does **not** consider the use of air pollution control equipment
  - Can include emission limiting factors if they are made part of an enforceable permit

# Key Definitions (cont'd)

- Definition of “Major” Source (under Title V):
  - Facility-wide PTE of any criteria pollutant > 100 TPY
  - Facility-wide PTE of any single HAP > 10 TPY
  - Facility-wide PTE of all HAPs combined > 25 TPY

# Air Permitting Overview



# Permitting Basics

- Permits are the primary tool for EPA to regulate industry
- Used as a mechanism to consolidate applicable regulations and communicate them to the source
- Used to impose emission limits, operating conditions, monitoring/recordkeeping, reporting and testing requirements
- Two basic categories of air permits:
  - Installation/Construction
  - Operating

# Permitting – Overview (cont'd)

- Some states combine installation/construction authorization and operating requirements into one permit document
- All states have permit exemptions and streamlined permitting paths for smaller sources

# Ohio EPA Air Permitting System



# Ohio Permit Exemptions

- Permanent PTI Exemptions
  - Found in OAC 3745-31-03
  - Based on process-type
  - Examples:
    - Boilers < 10 mmBTU/hr
    - Maintenance Welding
    - Aqueous Parts Washers
  - No notification required

# Ohio Permit Exemptions (cont'd)

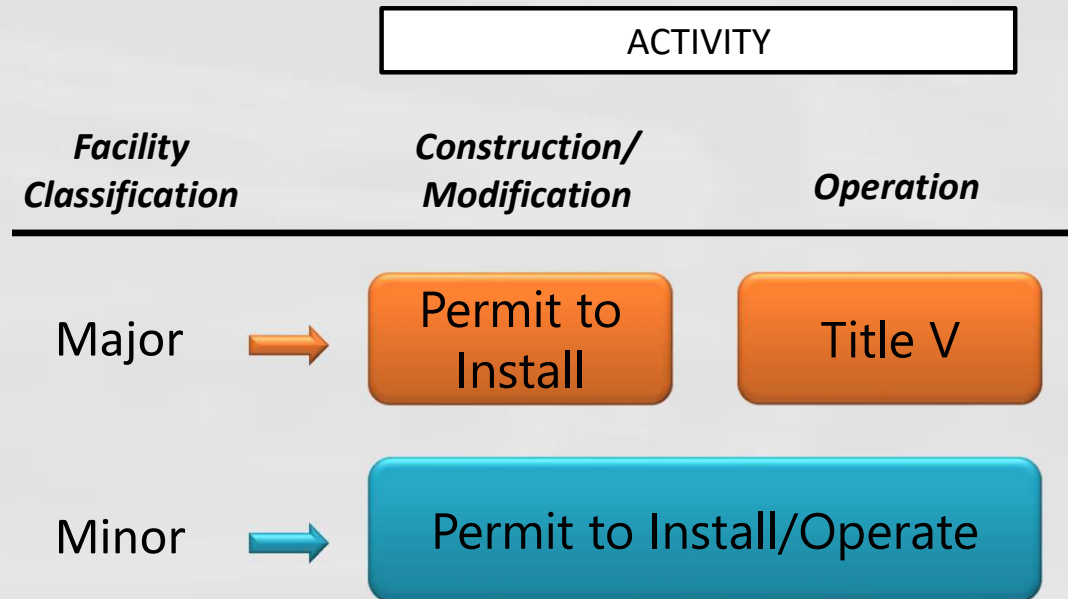
- De Minimis Exemption
  - Found in OAC 3745-15-05
  - Exempts sources with PTE < 10 lbs/day
  - If PTE is > 10 lbs/day, but actual emissions are less, can maintain daily records to prove exemption
  - Sum of similar sources can't be > 25 TPY
  - No notification required



# Ohio Permit Exemptions (cont'd)

- Permit by Rule
  - Found in OAC 3745-31-03
  - Standard permit terms written into regulations
  - Must notify OEPA with 1-page form
  - Covers the following:
    - emergency electrical generators;
    - resin injection/compression molding equipment;
    - small crushing and screening plants;
    - soil-vapor extraction and soil-liquid extraction remediation activities;
    - auto body refinishing facilities;
    - gasoline dispensing facilities;
    - natural gas fired boilers and heaters; and
    - printing facilities

# Ohio Permits



# Synthetic Minor in Ohio

- Synthetic Minor:
  - A permit in which a company accepts voluntary emission limits in order to avoid major source status
  - Limits can be on one emission unit or over entire facility
  - Permit will impose record keeping/reporting requirements to “prove” that source is staying below major source thresholds

# Kentucky DEP Air Permitting System



# Kentucky Air Permit Regulations

## *(401 KAR 52)*

- Various forms of construction & operating permits
  - Registration
  - State Origin permits
  - Conditional Major/FESOP Permits
  - Title V Permits

# KY Construction & Operating Permits

## *Who Doesn't Need One?*

- The following are exempt from permitting:
  - Residential wood heaters
  - Minor sources of non-process fugitive emissions
  - Minor source sawmills (5,000 BFH or less)
  - Asbestos demo
  - Open burning
  - Vehicles and roads

# KY Construction & Operating Permits

## *Who Doesn't Need One?*

- The following are exempt from permitting:
  - “Trivial Activities”
  - List posted at DAQ website
    - Janitorial services & products
    - Handheld tools (buffing, grinding, drilling, etc.)
    - Brazing/soldering/welding with no HAP emissions
    - Bench scale laboratory & testing equipment

# KY Construction & Operating Permits

## *Who Doesn't Need One?*

- The following are exempt from permitting:
  - <2 TPY of a single HAP;
  - <5 TPY of combined HAPs;
  - <10 TPY of a regulated air pollutant; and
  - The source is not subject to a NSPS or NESHAP
- These permit triggers are based on Potential to Emit for the entire site (not an individual emission unit)



# KY Construction & Operating Permits

## *Who Needs One? . . . . . Everyone else*

Minor Sources	Registration	PTE $\geq 2$ but $< 10$ tpy of any HAP, PTE $\geq 5$ but $< 25$ tpy of combined HAPs, PTE $\geq 10$ but $< 25$ tpy of any RAP Source is subject to an NSPS or NESHAP
	State Origin Permit	PTE $< 10$ tpy of any HAP, PTE $< 25$ tpy of combined HAPs PTE $\geq 25$ but $< 100$ tpy of any RAP Source is subject to an NSPS or NESHAP.
Conditional Major/FESOP		Potentially major source but emissions limited to minor artificially
Major Sources	Title V	PTE $\geq 10$ tpy of any HAP, PTE $\geq 25$ tpy of combined HAPs PTE $\geq 100$ tpy of any RAP Sources PTE not limited by a permit.
RAP = Regulated Air Pollutants		

# Indiana DEM Air Permitting System



# Indiana Air Permit Regulations

## *(326 IAC 2)*

- Various forms of construction & operating permits
  - Registration
  - Source Specific Operating Agreement (SSOA)
  - Permit by Rule (PBR)
  - Minor Source Operating Permit (MSOP)
  - FESOP Permits (limit below Title V)
  - Part 70/Title V Permits

# IN Permitting Thresholds

Pollutant	Exemption	Registration	MSOP	FESOP	Part 70/Title V
Particulate Matter (PM)	< 5 TPY	≥ 5 and < 25 TPY	≥ 25 TPY	Federally enforceable limits below Title V threshold for whichever relevant pollutants require a limit to avoid Title V applicability	> 100 TPY
PM <sub>10</sub>	< 5 TPY	≥ 5 and < 25 TPY	≥ 25 TPY		> 100 TPY
Sulfur Dioxide (SO <sub>2</sub> )	< 10 TPY	≥ 10 and < 25 TPY	≥ 25 TPY		> 100 TPY
Nitrogen Oxides (NO <sub>x</sub> )	< 10 TPY	≥ 10 and < 25 TPY	≥ 25 TPY		> 100 TPY
VOC for sources not required to use air pollution control equipment to comply with applicable provisions of 326 IAC 8	< 10 TPY	≥ 10 and < 25 TPY	≥ 25 TPY		> 100 TPY
VOC for sources required to use air pollution control equipment to comply with applicable provisions of 326 IAC 8	< 5 TPY	≥ 5 and < 25 TPY			> 100 TPY
Carbon Monoxide (CO)	< 25 TPY	≥ 25 and < 100 TPY	≥ 100 TPY		> 100 TPY
Lead (Pb)	< 0.2 TPY	≥ 0.2 and < 5 TPY	≥ 5 TPY		> 100 TPY
Hazardous Air Pollutants (pursuant to Section 11(b) of the Clean Air Act)	< 10 TPY single HAP or < 25 TPY of Total HAPs	Not Applicable	< 10 TPY single HAP or < 25 TPY of Total HAPs		≥ 10 TPY single HAP or ≥ 25 TPY of Total HAPs

# General Permitting Process



# Permitting Process

1. Prepare application
  - Describe process
  - Estimate emissions (emission factors, mass balance, stack test, etc)
  - Complete forms with technical data
  - Evaluate compliance with applicable regulations
2. Submit application using State-specified process (i.e., OEPA eBusiness, KYDAQ e-Forms)
3. State reviews application and drafts permit terms

## Permitting Process (cont'd)

4. If permit involves control equipment or synthetic minor limits, frequently the state issues a draft permit with 30-day comment period
5. After 30-day period ends, the state considers comments, then issues final permit to applicant

# Permit Planning

- Permit process generally takes 3-6 months
- Cannot construct/modify source until final permit is received in most cases
  - Management must consider permitting when making strategic business plans



# Issued Permit Contents

- Emission Limits
  - lb/hr, TPY, etc.
- Operational Restrictions
  - Gallons coating/year, etc.
- Monitoring
  - Periodic tracking of key process parameters (ie., monthly coating usage)
- Record Keeping
  - Logging of monitoring data
- Reporting
  - Periodic reports to Agency documenting compliance status
- Testing
  - Method for determining compliance

Questions?

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**Workshop H**



Jason R. Krawczyk  
Eli Lilly & Company  
Lilly Corporate Center  
Indianapolis, Indiana

# Introduction to Lilly

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Lilly is a medicine company with a focus of turning science into healing to make life better for people around the world.

- Founded on May 10, 1876
- Headquartered in Indianapolis, Indiana
- Employs nearly 43,000 employees worldwide
- Research and development facilities located in 7 countries
- Manufacturing plants located in 7 countries
- Products marketed in approximately 110 countries.

# Lilly's Indiana Air Permitted Facilities

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Lilly operates numerous manufacturing and support facilities within Indiana and is in the process of permitting a new greenfield manufacturing site in Lebanon.

- Lilly Corporate Center – PSD Minor TVOP
- Lilly Technology Center – PSD Major TVOP (Combined Source)
- Lilly Distribution Facility – MSOP
- Lilly Aviation Facility – PBR
- Lilly Lebanon Facility (LP1/LP2) – Greenfield PSD Minor NSC & TVOP (Combined Source)

Indiana was granted SIP approval from USEPA for its air permitting program. Therefore, all permit applications whether for a modification to an existing source or the construction of a greenfield source are submitted to IDEM.

# Indiana Air Permitting Considerations



A complete application must be submitted prior to construction and/or operation of new emission units...unless the change qualifies as an Administrative Amendment change.

If the change qualifies for an Administrative Amendment, per 326 IAC 2-7-11(c)(3) “The source may implement the changes addressed in the request for an administrative amendment immediately upon submittal of the request”.

EHS professionals should be aware of the various [thresholds](#) that trigger the need for a construction or operating approval. Operations and facility delivery staff should be aware of the [timelines](#) associated with obtaining an air permit approval.

Example:

*IDEM’s Minor Source Modification has a 45-day timeframe issuance whereas a Significant Permit Modification has a 270-day timeframe.*

# Developing a Comprehensive List of Potentially Applicable Requirements

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Before any new equipment is ordered, a comprehensive list of potentially applicable state and federal requirements should be developed.

- To determine potentially applicable requirements, PTE must first be quantified for the new emission unit(s). PTE will determine the permit level and most applicable state and federal rules.
- Permitting timeframes can be identified and built into the project plan based on estimated permit level.
- In-house EHS staff or external environmental consultants can be utilized to perform analyses.
- The requirements should be used to guide design criteria, including any additional equipment or instrumentation needs.
- Design information, permit level, and state and federal rule applicability requirements are needed for the air permit application.
- Use the information to issue a change control (as needed) to capture updates required to business processes pending the issuance of a new permit.

# Environmental Design

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Design requirements for the new equipment have been identified based on permit, state, and federal regulations. Ensure the project team and environmental team have also consulted any applicable company or site standards for any additional requirements for the project.

Consider asking “How will the site comply?” for each applicable requirement as additional equipment may need to be included in the design (i.e., I/O for data communication, instrumentation, etc.). Instrumentation requirements that may be needed to aid in the calculation of emissions required by a permit.

Example:

*The site is required to calculate storage tank emissions. How will this be achieved? The simplest methodology is to install a flow meter to calculate flow in or out of the tank depending on whether it's a fixed or floating roof tank but does the project design include a flow meter?*



# Development of Compliance Determinations



- For each applicable requirement it is necessary to identify how compliance will be determined and how compliance will be monitored
- This step of the permit compliance process will set the site up for successful reporting and agency inspections in the future as the site will have documentation of compliance for every requirement in the permit, state and federal regulations
- The applicable requirements and design specification files will be the basis for building compliance determinations
- Initiate development of applicable SOPs for equipment, ensuring documentation of environmental requirements.
- Initiate development of job aides to assist those directly interacting with new equipment.

# Considerations when Developing Compliance Determinations

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For compliance determinations consider the following questions:

1. Does this requirement trigger an action? How will the site comply with the requirement?
2. Does the site need to maintain data to comply with this requirement?
3. Are there upper and/or lower bounds an asset must operate within?
4. Is a one-time compliance determination and documentation required?
5. Do assets and spare parts need to be added to the site's maintenance program?
6. Is it clear where records are maintained and how they are gathered for reporting? What is the record retention period?
7. Who is responsible for system monitoring? Are expectations clear?

# Site Business Processes

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*Lilly*

Based on the output of the compliance determination consider what, if any, updates are required to the site's existing compliance systems:

- Compliance Calendar
- Emission Inventory and Calculations
- LeakDas or other LDAR management process
- Process Monitoring Plans
- Maintenance Plan and Spare Part Strategy
- Data Historian
- Alarm Rationalization – Delta V
- Recordkeeping and reporting instructions and templates

***Actions should be captured as part of the project or permit change control. Incorporating all compliance related actions within one change control provides a quick, concise summary of how the site implemented a new permit***

# After Permit Issuance

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- Perform applicable FMEAs to identify the impact that an equipment failure can have, to prioritize risk of events, and ensure appropriate controls are in place to prevent a non-compliance
- Install and validate equipment through commissioning & qualification.
- Complete development of applicable SOPs and job aides.
- Train appropriate staff internally on SOPs and equipment operation.
- Update the site compliance calendar (monitoring frequencies, applicable testing timelines, reporting frequencies, preventive maintenance frequencies, etc.).
- Ensure appropriate records are scheduled to be recorded on the requisite frequencies.
- Begin operations.

# Case Study: Lilly Lebanon Facility

## Greenfield Facility in Lebanon, Indiana

### LP1 Manufacturing:

- Peptides
- Small Molecules
- Oligonucleotides

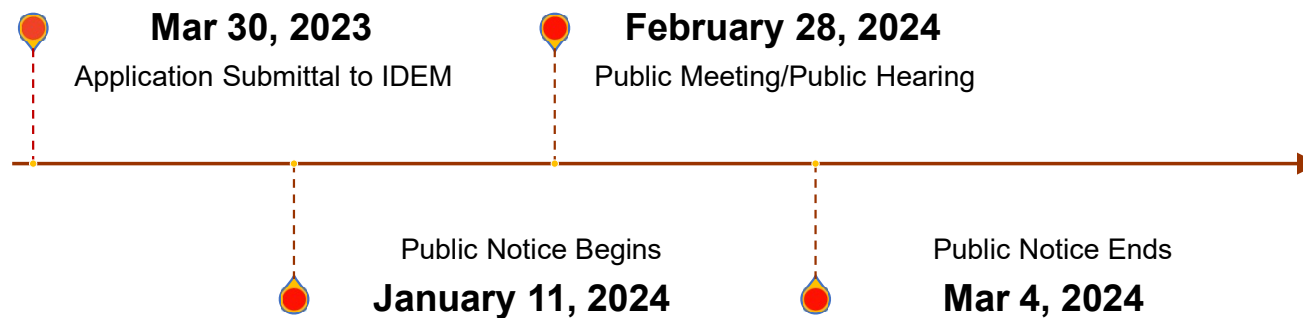
### LP2 Manufacturing:

- Gene Therapy Medicines



# Lilly Lebanon Facility: Permit & Source Status

## Permit Status Timeline:



Lilly's Lebanon Facility is a combined source since the LP1 & LP2 plants are located within a contiguous area, belong to the same industrial grouping, and are under common control of the same entity, they meet all the criteria of the major source definition under 326 IAC 2-7-1(22)(A).

Major Source Status:  
Title V (aka Part 70) – Major  
PSD – Minor  
Section 112 of CAA (HAP) – Major

# Major Source Thresholds

Pollutant	Title V (aka Part 70 Operating Permit)	Prevention of Significant Deterioration (PSD)	Hazardous Air Pollutants (HAPs)
	Potential to Emit (PTE) Threshold		
Carbon Monoxide (CO)	100 short tons per year (tpy)	100 short tpy	Not Applicable
Nitrogen Oxides (NOx)	100 short tpy	100 short tpy	Not Applicable
Particulate Matter (PM)	Not Applicable	100 short tpy	Not Applicable
Particulate Matter <10 microns (PM <sub>10</sub> )	100 short tpy	100 short tpy	Not Applicable
Particulate Matter <2.5 microns (PM <sub>2.5</sub> )	100 short tpy	100 short tpy	Not Applicable
Sulfur Dioxide (SO <sub>2</sub> )	100 short tpy	100 short tpy	Not Applicable
Volatile Organic Compounds (VOCs)	100 short tpy	100 short tpy	Not Applicable
Any Individual Hazardous Air Pollutant (HAP)	10 short tpy	Not Applicable	10 short tpy
Any Combination of HAPs	25 short tpy	Not Applicable	25 short tpy

# Lilly Lebanon Facility: PTE & Permitting

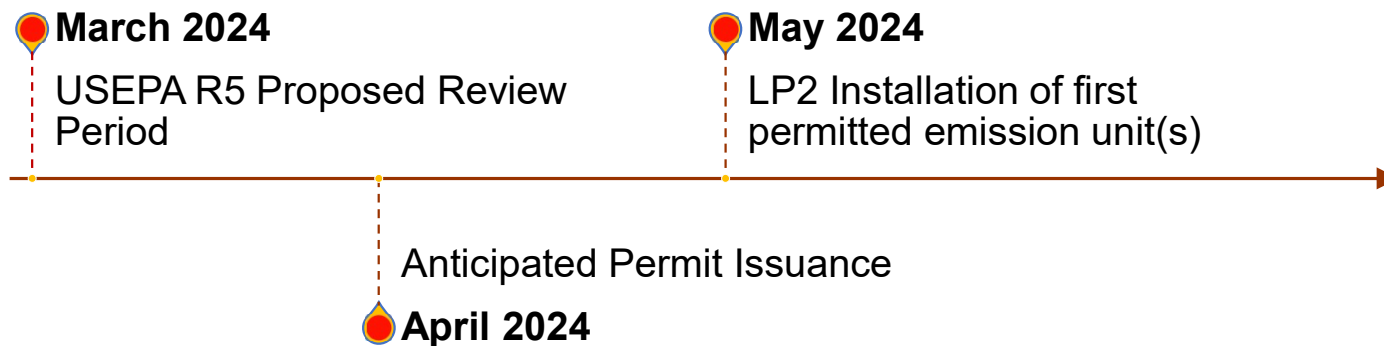
<b>Pollutant</b>	<b>Unrestricted PTE</b>
Carbon Monoxide (CO)	>100
Nitrogen Oxides (NO <sub>x</sub> )	>100
Particulate Matter (PM)	<100
Particulate Matter <10 microns (PM <sub>10</sub> )	<100
Particulate Matter <2.5 microns (PM <sub>2.5</sub> )	<100
Sulfur Dioxide (SO <sub>2</sub> )	<100
Volatile Organic Compounds (VOCs)	>100
Any Individual Hazardous Air Pollutant (HAP)	>10
Any Combination of HAPs	>25

Upon determination of PTE and evaluation of major source thresholds, Lilly opted to take synthetic minor emission limitations on CO, NO<sub>x</sub>, and VOC to restrict facility emissions below the 100 tpy PSD thresholds.

Since HAP emissions remain above the Title V major source thresholds, the source is still subject to the Title V Operating Permit program instead of qualifying for IDEM's FESOP program.



# Lilly Lebanon Facility: Near-term Next Steps



The initial issuance of the NSC & TVOP will grant Lilly the ability to install the permitted equipment at the rated capacities. Should changes occur to initial design parameters or planned equipment needs, additional permitting actions via amendments or modifications may be required.

Permitting obligations don't end with the initial issued permit, they begin.

# Presentation Acronyms



CAA	Clean Air Act	PBR	Permit-by-Rule
CO	Carbon Monoxide	PN	Public Notice
EHS	Environmental, Health & Safety	PSD	Prevention of Significant Deterioration
FESOP	Federally Enforceable State Operating Permit	PTE	Potential to Emit
FMEA	Failure Mode & Effects Analysis	R5	Region 5
HAP	Hazardous Air Pollutant	SIP	State Implementation Plan
IDEM	Indiana Department of Environmental Management	SOPs	Standard Operating Procedures
LDAR	Leak Detection and Repair	TPY	Tons per Year
MSOP	Minor Source Operating Permit	TVOP	Title V Operating Permit
NOx	Nitrogen Oxides	USEPA	United States Environmental Protection Agency
NSC	New Source Construction	VOC	Volatile Organic Compound

Questions?

*Lilly*

The Lilly logo is written in a white, elegant cursive script. A thin white vertical line is positioned to the left of the logo.

*Lilly*

## Contact Information

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## Biographical Information

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Ms. Padovani is the Vice President and one of the founding partners of EHS Technology Group, LLC, a full service environmental, health, and safety consulting firm. Her background is in environmental engineering and project management with an emphasis on long-standing compliance assistance relationships with various industrial facilities. For over twenty-five years, her responsibilities have included air pollution evaluation projects, PSD/BACT/RACT evaluations, air permitting, water pollution projects, hazardous waste projects, SARA Title III projects, regulatory negotiations, and multi-media compliance audits. Ms. Padovani is also a trained lead auditor for ISO 14001 and assists with internal auditing for Environmental Management Systems.

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Jason R. Krawczyk is a Senior Principal Associate in Eli Lilly & Company's Global Manufacturing Health, Safety, and Environmental team. At Lilly he serves as the company's global air compliance and permitting subject matter expert. Prior to his role at Lilly, Mr. Krawczyk spent four years as a Principal Consultant at ERM's Indianapolis, Indiana office and served as ERM's Global Air Quality Technical Community's Commercial Champion and as their North American Account Manager for the world's largest pharmaceutical company, by market cap. He has over seventeen years of experience working on a wide range of Clean Air Act issues, including 10 years of experience as a regulator for the Indiana Department of Environmental Management (IDEM) Air Permits Branch. In addition to his work experience as an industry leader, environmental consultant, and regulator, he has taken on a variety of voluntary leadership roles with Indiana, Midwest-based, and International environmental nonprofits and has served as Vice-President, Chairman, Vice-Chairman, and Director for these organizations.