



Best Practices in Managing Air Permit Compliance ... You Have Your Air Permit, Now What?

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Introductions – Your Instructors

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Permit is Issued!!
Shifting Focus to Permit Compliance

Know your Permit Like the Back of Your Hand...

- ▶ Read and understand your permit (it is a contract & a living document!)
- ▶ Highlight “action items” (as opposed to factual statements)
 - Control requirements
 - Emissions Limits
 - Operational restrictions
 - Reporting deadlines
 - Monitoring
 - Recordkeeping
 - Etc.
- ▶ Federal Requirements (i.e., NESHAP, NSPS)
 - Go to the regulation
 - ◆ Compliance tasks – control requirements, monitoring, recordkeeping, reporting, etc.
 - ◆ Reporting deadlines
 - ◆ Notification of Compliance Status (NOCS) requirements





Items to Identify Immediately

- ▶ Notification requirements:
 - Commence Construction
 - Begin Operation
 - Others?
- ▶ Immediate reporting triggers:
 - Malfunction/Deviation notification and reporting timelines
 - Emissions exceedances
 - Others?
- ▶ Monitoring requirements
 - Continuous
 - Daily/weekly/monthly
- ▶ Recordkeeping requirements
 - Daily/weekly/monthly
 - Rolling 12-month
- ▶ How are you required to demonstrate compliance?
 - Compliance testing requirements (deadline, frequency, etc.)
 - Emissions calculations
- ▶ Operating permit application deadline

Emissions Limits and Control Requirements

- ▶ For each emissions limit and control requirement
 - Identify the compliance demonstration for each limit
 - ◆ Examples - Stack Testing, emissions calculations with prescribed methods/formulas, monitoring, AP-42, Potential to Emit, etc.
 - Are emissions dependent on operational restrictions? (e.g., throughput, flowrate, pressure drop, etc.)
 - ◆ Determine how you will ensure operational restrictions are enforced
 - Develop plan to demonstrate compliance as required:
 - ◆ Data collection frequency
 - ◆ Spreadsheet tool
 - ◆ Continuous Emissions Monitoring System (CEMS)
 - ◆ Data storage retention
 - Make sure tools reflect current operation
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Implementing Compliance Process

Step 1: Develop an Environmental Records Registry

- ▶ Develop a registry or map of each required environmental record.
 - People-process-tool
 - ◆ Select registry owner(s)
 - ◆ Develop process for development and maintenance of registry
 - ◆ Choose a tool / technology (e.g. spreadsheet)
- ▶ Discover and document each environmental record
- ▶ Define key record attributes
 - ◆ Location or process for locating
 - ◆ Frequency
 - ◆ Owner
 - ◆ Format
 - ◆ Review process
 - ◆ Others?
- ▶ Common Gaps
 - Construction permit requirements not incorporated into Title V
 - Insignificant activities

Step 2: Review the Environmental Records

- ▶ Implement a standard process for periodically reviewing records.
 - Using registry of records list, develop methodology for risk based periodic review
 - Include record discovery reviews (is the record there?) and content reviews (is the record complete and accurate?)
 - Capture root causes for issues
 - Implement procedures for handling missing data (consult regulatory requirements)
 - Develop and implement continual improvement processes
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Step 3: Develop an Environmental Compliance Calendar

- ▶ Implement a compliance calendar to track key deadlines and a process for keeping it current.
 - Technology Selection
 - Define stakeholders
 - Operations
 - Supervisors
 - Management
 - Use technology to enhance visibility of deadlines to multiple interested stakeholders; make it easy for stakeholders
 - Consider development of interim/internal milestones or deadlines for major reports or other multi-step regulatory tasks
 - Implement hierarchy of notifications
 - Integrate the use of compliance calendar for status and planning meetings
 - E.g. weekly staff meetings or shift changes

What Else is Can/Should I be Doing?

Management of Change Process

- ▶ Develop and implement a Management of Change (MOC) process
 - Train engineering and operational staff to incorporate environmental review into ALL projects
 - Integrate process with capital projects review
 - MOC checklist should facilitate a swift and effective review
 - Utilize consultants' expertise to help complete the process
 - Document findings for future reference



Thorough Environmental Review

- ▶ How is project described?
- ▶ Look for key terms and phrases:
 - Debottlenecking
 - Increasing efficiency/throughput
 - Six-sigma/Lean manufacturing
 - Process improvement
- ▶ Seemingly benign terms/phrases:
 - Like-kind replacement
 - Piping configuration change
 - Valve/pump/connector replacement




MOC Review - Common Permitting Triggers

- ▶ Install New Emission Unit
- ▶ Modify Existing Emission Unit
 - Changes in emissions resulting from physical change
 - ◆ Debottlenecking, replacement, increased capacity, etc.
 - Relocating existing equipment
 - Changes in control equipment
- ▶ Change to Existing Permit Terms
 - Changes in emissions (e.g., new stack test)
 - Change in equipment operation
 - Change in products/raw materials
 - Changes in production rate



Reminder - General Permit Hierarchy

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- ▶ Exemptions
 - ▶ Permits-by-Rule (PBRs)
 - ▶ General permits
 - ▶ Minor state level construction permit
 - ▶ Federally enforceable synthetic minor permit
 - ▶ Permit with Federal NSR
 - PSD
 - Offset Permit (NANSR)
 - ▶ Title V operating permits

Tracking Regulatory Updates

- ▶ Regulations go through revision periodically – is someone tracking how these updates impact your facility?
- ▶ Every 8 years EPA performs Risk and Technology Reviews (RTRs) for NESHAP standards. Recently updated rules:
 - 40 CFR 63, Subpart FFFF - Miscellaneous Organic NESHAP (MON)
 - 40 CFR 63, Subpart EEEEE - Iron and Steel Foundries NESHAP
 - 40 CFR 63, Subpart M MMMM - Flexible Polyurethane Foam Fabrication Operations NESHAP...
- ▶ Many RTRs are overdue. With recent enforcement and consent orders, EPA has a focus to move forward on these reviews.
- ▶ Take away – find a way to follow regulatory updates:
 - Federal Register email alerts
 - State agency email alerts
 - Other environmental newsletters

Internal Audits

- ▶ Use cross-functional teams of internal personnel to self-assess multimedia compliance on a regular basis.
 - Self-audit process enhances employee understanding and ownership of environmental requirements
 - Cross-functional teams intended to prevent personnel from auditing their own work areas
 - Internal teams may provide more relevant and realistic suggestions for improvement
 - May be performed more frequently than external audits
 - May be more focused and/or flexible
 - Less expensive than third party review

External (3rd Party) Audits

- ▶ Use outside auditors to assess multimedia compliance risk on a regular basis.
 - Train operations/maintenance personnel on how to deal with agency inspections
 - Introduce a different perspective
 - Provide additional resources, expertise and experience
 - Provide new ideas for:
 - ◆ Compliance management systems
 - ◆ Compliance efficiency
 - ◆ Monitoring, documentation and recordkeeping
 - ◆ Reporting
- ▶ Be aware of EPA and OEPA's audit policies for self-disclosure/consider attorney-client privilege

Data Validation Systems

- ▶ Implement quality systems and processes for monitoring and reporting environmental metrics
 - Data QA/QC
 - ◆ CEMS QA/QC Procedures – dictated by regulation
 - ◆ Who is checking your calculations?
 - Self QA/QC
 - Peer Review
 - ISO 14000 or ISO-like Standard Procedures

Consider Technology Options

- ▶ Do you have any existing technology tools that could be utilized for environmental tasks? (i.e. SharePoint, Cority, etc.)
- ▶ Develop an electronic records and document repositior
 - Scan in paper files
 - Use electronic checklists
- ▶ Implement an automated compliance calendar to track key deadlines and a process for keeping it current
- ▶ Implement an environmental task tracking system to manage environmental obligations

Share the Load

Teamwork

Work performed
combined effort
organized cooperation
working together or a
- better res



Establish Roles and Responsibilities

- ▶ Develop roles and responsibilities that are strictly compliance focused.
 - Define compliance roles and/or map existing roles/jobs to EHS functions
 - Smart Organization Design
 - ◆ Assess the various environmental tasks and obligations
 - ◆ Spread out and push down environmental responsibilities where possible
 - ◆ Look for opportunities to gain efficiencies through aggregated work functions
 - Inject EHS goals into individual performance evaluations and compensation
 - Integrate roles / job functions to business processes

Training Staff

- ▶ Develop an environmental training program.
 - Develop a training needs matrix matching the skill/capability/knowledge with the job function
 - Identify Training Modules
 - ◆ Management Level Awareness
 - ◆ Supervisor Training
 - ◆ Operations Training
 - ◆ Regulatory Required Training
 - Make training available to internal trainers
 - Find key external training courses
 - Hire consultants for custom trainings, where needed
 - Develop and implement a training tracking program to plan
 - Use audits findings and incident root causes to enhance training materials

Promoting Employee Involvement

- ▶ Implement initiatives that enhance employee ownership of environmental management system.
 - Education and Training
 - Individual and group task responsibilities
 - ◆ What needs to be done, by when, and by whom
 - Annual refresher training
 - Quick reference posters or flip charts
 - ◆ Need to understand WHY
 - Employee Accountability & Incentives
 - ◆ Environmental performance goals for production and maintenance supervisors
 - ◆ Environmental initiatives (e.g., tie environmental metrics to merit/bonus structure)
 - ◆ Employee Recognition



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**Workshop J: Best Practices in
Air Permit Compliance ... You
Have Your Air Permit, Now
What?**

Kathleen Parsons – Associate Director Plant and Project Engineering

Manufacturing Site Perspective

Objective: To provide tips and tools from the manufacturing perspective that can be customized to your industry and site to ensure successful implementation of a new environmental permit.

For many capital projects, receiving an environmental permit is the easiest step in the process. There is a significant amount of work involved in implementing new assets in a manner that is compliant with the permit, state, and federal regulations.

The best practices for ensuring compliance will build upon one another with the end goal of right, first time implementation. These tips are meant to provide ideas for other sites to customize for their specific needs. Some projects are significantly more complex than others and may require additional tools and other simplified projects may not require the same level of detail.

Top 5: Best Practices to Ensure Compliance

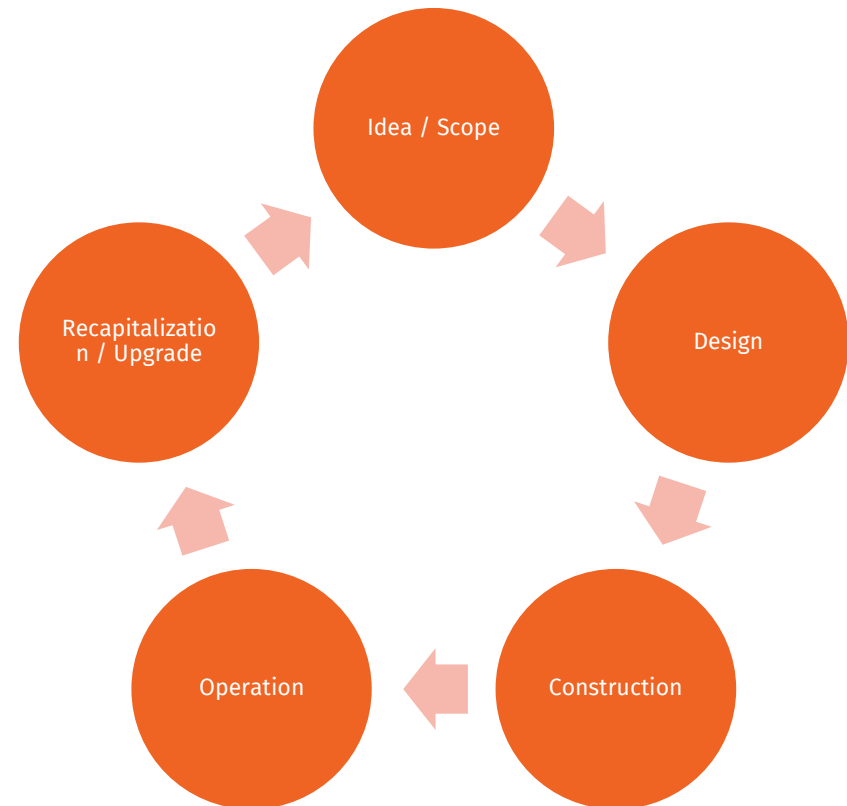
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- Integration in Project Delivery
 - Identification of Applicable Requirements
 - Design Specification Requirements
 - Compliance Determination and Monitoring
 - Implementation in Business Processes

Integration in Project Delivery

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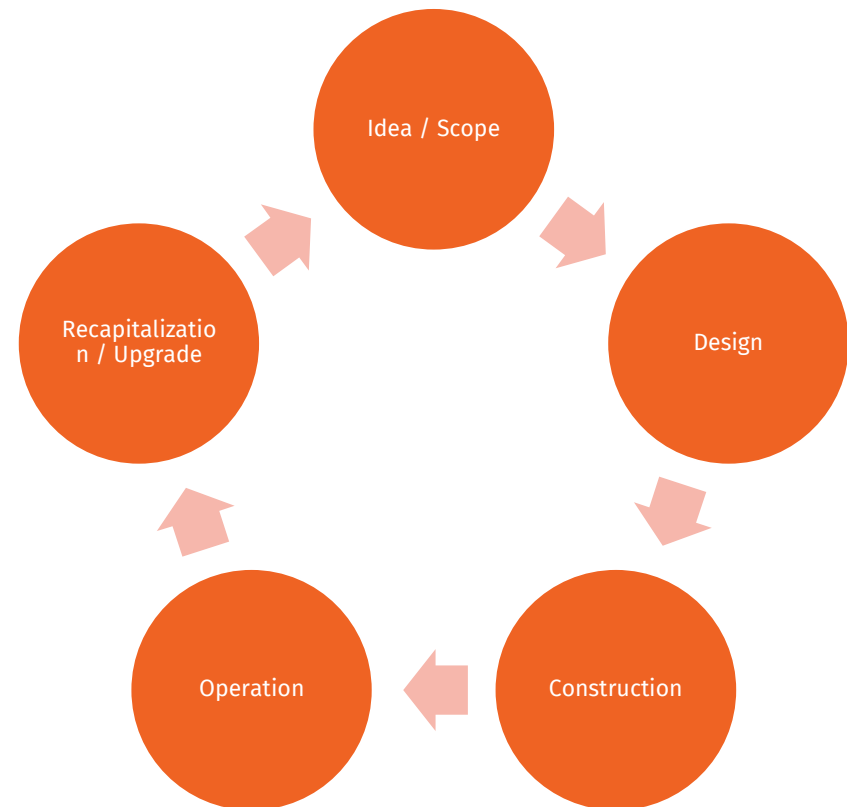
Environmental Role In Capital Projects

To deliver right, first time capital assets that are capable of complying with all environmental regulations it is imperative the environmental organization is engaged with the project team throughout the lifecycle of the project.



Environmental Role In Capital Projects

1. Scope – Conduct initial permit and regulatory assessment
2. Design – Establish initial design to submit permit application. Understand how changes to design impact the permit and regulatory applicability
3. Construction – Confirm delivered asset meets design and permit requirements.
4. Operation – Ensure all compliance monitoring is live prior to startup
5. Recap/Upgrade – Identify technology to improve environmental footprint



How is integration achieved?

There are several options to integrate into project delivery at a site or company level. Each site will need to tailor the approach based on their organization structure and resource availability:

1. An environmental or HSE team within the capital delivery organization that is also connected to the site environmental or HSE teams
2. A dedicated environmental or HSE specialist to support capital projects
3. A business process with gate reviews that will prevent funding decisions without environmental or HSE input
4. A contractor resource

Build Relationships with the Engineering Function – Learn the Project Delivery Process and Understand the Manufacturing Process

Identification of Requirements

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Develop a Comprehensive List of Requirements

The permit for a capital project has been issued...what is next?

1. Communicate the permit has been issued to the project team and that construction can commence
2. Issue a change control, as needed, to capture updates required to business processes for the issuance of a new permit
3. Review the permit and applicability for the new assets that have been permitted to identify all requirements in the permit, state regulations and federal regulations as applicable

How to Identify Applicable Requirements?

Objective: Create an Excel file with all applicable permit, state, and/or federal requirements. TIP – This could be an activity you ask a consultant to complete!

Step 1: Convert permit and regulations to Excel

Step 2: For each statement indicate if it is applicable to the site and new assets

Step 3: Indicate if the requirement is a design, compliance, or reporting requirement

Assemble Permit, State and Federal Requirements

Emission Limitations and Standards [326 IAC 2-7-5(1)]

D.5.1 Synthesized Pharmaceutical Manufacturing Operations [326 IAC 8-5-3]

(a) Volatile organic compound emissions from all reactors, distillation operations, filters, crystallizers, centrifuges, and vacuum dryers, which have the potential to emit VOC greater than 15 pounds per day, shall be controlled by surface condensers or equivalent controls.

- (1) If surface condensers are used, the condenser outlet gas temperature must not exceed 25 oC) when condensing VOC of vapor pressure greater than forty (40) kilo Pascals
- (2) If surface condensers are used, the condenser outlet gas temperature must not exceed 20 oC) when condensing VOC of vapor pressure greater than twenty (20) kilo Pascals
- (3) If surface condensers are used, the condenser outlet gas temperature must not exceed 15 oC) when condensing VOC of vapor pressure greater than ten (10) kilo Pascals (1.5 pounds per square inch)
- (4) If surface condensers are used, the condenser outlet gas temperature must not exceed 10 oC) when condensing VOC of vapor pressure greater than seven (7) kilo Pascals (1 pound per square inch)
- (5) If surface condensers are used, the condenser outlet gas temperature must not exceed 5 oC) when condensing VOC of vapor pressure greater than three and a half (3.5) kilo Pascals (0.5 pounds per square inch)
- (6) The vapor pressures listed in (1) through (5) above shall be measured at twenty degrees Celsius
- (7) If equivalent controls are used, the Volatile Organic Compound emissions must be controlled by using a surface condenser which meets the requirements of (1) through (5) above.

40 CFR Subpart GGG Design Requirements

Part and Section	Paragraph/Condition	Regulatory Text
63.1254 Standards: Process Vents	a(1)	<p>(1) Process-based emission reduction requirement</p> <p>(i) Uncontrolled HAP emissions from the sum of all process vents within a process that are not subject to the requirements of paragraph (a)(3) of this section shall be reduced by 93 percent or greater by weight, or as specified in paragraph (a)(1)(ii) of this section. Notification of changes in the compliance method shall be reported according to the procedures in § 63.1260(h).</p> <p>(ii) Any one or more vents within a process may be controlled in accordance with any of the procedures in paragraphs (a)(1)(ii)(A) through (D) of this section. All other vents within the process must be controlled as specified in paragraph (a)(1)(i) of this section.</p> <p>(A) To outlet concentrations less than or equal to 20 ppmv as TOC and less than or equal to 20 ppmv as hydrogen halides and halogens;</p> <p>(B) By a flare that meets the requirements of § 63.11(b);</p> <p>(C) By a control device specified in § 63.1257(a)(4); or</p> <p>(D) In accordance with the alternative standard specified in paragraph (c) of this section.</p>
	a(2)	(2) Process-Based annual mass limit

Identify Applicability and Type of Requirement

An example of identification of applicable requirements for a state regulation incorporated in Lilly's Title V Permit:

Emission Limitations and Standards [326 IAC 2-7-5(1)]		Applicability
D.5.1 Synthesized Pharmaceutical Manufacturing Operations [326 IAC 8-5-3]		
(a)	Volatile organic compound emissions from all reactors, distillation operations, filters, crystallizers, centrifuges, and vacuum dryers, which have the potential to emit VOC greater than 15 pounds per day, shall be controlled by surface condensers or equivalent controls.	Design
(1)	If surface condensers are used, the condenser outlet gas temperature must not exceed minus twenty five degrees Celsius (-25 oC) when condensing VOC of vapor pressure greater than forty (40) kilo Pascals (5.8 pounds per square inch);	N/A
(2)	If surface condensers are used, the condenser outlet gas temperature must not exceed minus fifteen degrees Celsius (-15 oC) when condensing VOC of vapor pressure greater than twenty (20) kilo Pascals (2.9 pounds per square inch);	N/A
(3)	If surface condensers are used, the condenser outlet gas temperature must not exceed zero degrees Celsius (0 oC) when condensing VOC of vapor pressure greater than ten (10) kilo Pascals (1.5 pounds per square inch);	N/A
(4)	If surface condensers are used, the condenser outlet gas temperature must not exceed ten degrees Celsius (10 oC) when condensing VOC of vapor pressure greater than seven (7) kilo Pascals (1 pound per square inch);	N/A
(5)	If surface condensers are used, the condenser outlet gas temperature must not exceed twenty five degrees Celsius (25 oC) when condensing VOC of vapor pressure greater than three and a half (3.5) kilo Pascals (0.5 pound per square inch);	Compliance
Compliance Monitoring Requirements [326 IAC 2-7-5(1)] [326 IAC 2-7-6(1)]		
D.5.2 Synthesized Pharmaceutical Manufacturing Operations [326 IAC 8-5-3]		
(a)	For emitting units, subject to Condition D.5.1, controlled by a surface condenser, the Permittee shall record the condenser outlet gas temperature for the batch when the emitting unit is emitting VOC.	Recordkeeping

Design Specification

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Environmental Design

Environmental design specification for new assets is a two-part approach:

1. Requirements: Are the design requirements clear? Does the regulatory language need to be simplified for incorporation into project design documents?
2. Integration in Project Design: Is there a process in place to ensure environmental design is incorporated into the overall project design? Is there accountability for the project to document both the design requirement and how the requirement is met for the project?

Integrate the Environmental Design Requirements into the Project Design – A silo approach will lead to rework, additional costs and schedule delays

Environmental Design – Part 1

Design requirements for the new assets 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?

Environmental Design – Part 1

40 CFR 63 Subpart GGG Design Requirements						
Part and Section	Paragraph/Condition	Maximum Vapor of Total HAP	Storage Tank Capacity Requirement	Regulatory Text	Simplified Rule Text	Notes:
61.1253 Standards: Storage tanks		Less than 13.1 kPa	No design requirements			
61.1253 Standards: Storage tanks	b	Greater than or equal to 13.1 kPa	Greater than or equal to 38 m ³ and less than 75 m ³	(b) The owner or operator of a storage tank shall equip the affected storage tank with either a fixed roof with internal floating roof, an external floating roof, an external floating roof converted to an internal floating roof, or a closed-vent system meeting the conditions of § 63.1252(b) with a control device that meets any of the following conditions:	A storage tank should be equipped with a fixed roof with internal floating roof, external floating roof, an external floating roof converted to an internal floating roof or a closed-vent system with a control device that meets one of the following:	A closed vent system should have a flow indicator that takes readings once every 15 minutes. Proper maintenance of the bypass lines are required and visual inspections once a month are recommended to be recorded. Per 63.11(b) Flares must have diameter of 3 inches or greater, are non-assisted, have a hydrogen content of 8.0 percent (by volume) or greater, and are designed for and operated with an exit velocity less than 37.2 m/sec (122 ft/sec). If non assisted, the heating value should be 7.45 M/scm (200 Btu/scf) or greater. 63.1257(a)(4) describes the exemptions from compliance demonstrations for control devices specified below: (i) A boiler or process heater with a design heat input capacity of 44 megawatts or greater. (ii) A boiler or process heater into which the emission stream is introduced with the primary fuel. (iii) A boiler or process heater burning hazardous waste for which the owner or operator: (A) Has been issued a final permit under 40 CFR part 270 and complies with the requirements of 40 CFR part 266, subpart H, or (B) Has certified compliance with the interim status requirements of 40 CFR part 266, subpart H.
61.1253 Standards: Storage tanks	b(1)			(1) Reduces inlet emissions of total HAP by 90 percent by weight or greater;	(1) Reduces inlet emissions of total HAP by 90% by weight or greater;	
61.1253 Standards: Storage tanks	b(2)			(2) Reduces emissions to outlet concentrations less than or equal to 20 ppmv as TOC and less than or equal to 20 ppmv as hydrogen halides and halogens;	(2) Reduces emissions to outlet concentrations less than or equal to 20 ppmv as TOC and less than or equal to 20 ppmv as hydrogen halides and halogens	
61.1253 Standards: Storage tanks	b(3)			(3) Use an enclosed combustion device that provides a minimum residence time of 0.5 seconds at a minimum temperature of 760 °C;	(3) The control device should provide a minimum residence time of 0.5 seconds at a minimum temperature of 760 °C;	
	b(4)			(4) Use a flare that meets the requirements of § 63.11(b); or	(4) The flare should meet the requirements of 63.11(b);	
61.1253 Standards: Storage tanks	b(5)			(5) Use a control device specified in § 63.1257(a)(4).	(5) Use a control device specified in § 63.1257(a)(4).	

This tool was developed by Trinity Consultants on behalf of Eli Lilly and Company

How to Document Design Specification?

A design checklist could be used to document the requirements and alignment of both the project team and environmental team

#	Equipment	Design Requirement	Documents Used for Validation or Document Location	Project Confirmation	Signature	Date	Environmental Confirmation	Signature	Date
Pharma MACT Design Requirements									
1	Storage Tank: Capacity: Greater than or equal to 38 m ³ and less than 75 m ³ Stored Material Max Vapor Pressure: Greater than or equal to 13.1 kPa	A storage tank should be equipped with a fixed roof with internal floating roof, external floating roof, an external floating roof converted to an internal floating roof or a closed-vent system with a control device that meets one of the following: (1) Reduces inlet emissions of total HAP by 90% by weight or greater; (2) Reduces emissions to outlet concentrations less than or equal to 20 ppmv as TOC and less than or equal to 20 ppmv as hydrogen halides and halogens (3) The control device should provide a minimum residence time of 0.5 seconds at a minimum temperature of 760 °C; (4) The flare should meet the requirements of 63.11(b); (5) Use a control device specified in § 63.1257(a)(4).							

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Compliance Determination and Monitoring

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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

Development of Compliance Determinations

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 the asset 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 time?
7. Who is responsible for system monitoring? Are expectations clear?

Compliance Documentation

An example of Compliance Determination and Monitoring:

Emission Limitations and Standards [326 IAC 2-7-5(1)]		Applicability	Compliance Determination and Monitoring
D.5.1 Synthesized Pharmaceutical Manufacturing Operations [326 IAC 8-5-3]			
(a)	Volatile organic compound emissions from all reactors, distillation operations, filters, crystallizers, centrifuges, and vacuum dryers, which have the potential to emit VOC greater than 15 pounds per day, shall be controlled by surface condensers or equivalent controls.	Design	A surface condenser is installed downstream of the vacuum dryer.
(1)	If surface condensers are used, the condenser outlet gas temperature must not exceed minus twenty five degrees Celsius (-25 oC) when condensing VOC of vapor pressure greater than forty (40) kilo Pascals (5.8 pounds per square inch);	N/A	N/A
(2)	If surface condensers are used, the condenser outlet gas temperature must not exceed minus fifteen degrees Celsius (-15 oC) when condensing VOC of vapor pressure greater than twenty (20) kilo Pascals (2.9 pounds per square inch);	N/A	N/A
(3)	If surface condensers are used, the condenser outlet gas temperature must not exceed zero degrees Celsius (0 oC) when condensing VOC of vapor pressure greater than ten (10) kilo Pascals (1.5 pounds per square inch);	N/A	N/A
(4)	If surface condensers are used, the condenser outlet gas temperature must not exceed ten degrees Celsius (10 oC) when condensing VOC of vapor pressure greater than seven (7) kilo Pascals (1 pound per square inch);	N/A	N/A
(5)	If surface condensers are used, the condenser outlet gas temperature must not exceed twenty five degrees Celsius (25 oC) when condensing VOC of vapor pressure greater than three and a half (3.5) kilo Pascals (0.5 pound per square inch);	Compliance	Temperature data is recorded in data historian. Alarm strategy is setup in Delta V to alert operators to temperature excursions. The process team reviews alarm reports daily and temperature trends on a monthly basis.
Compliance Monitoring Requirements [326 IAC 2-7-5(1)] [326 IAC 2-7-6(1)]			
D.5.2 Synthesized Pharmaceutical Manufacturing Operations [326 IAC 8-5-3]			
(a)	For emitting units, subject to Condition D.5.1, controlled by a surface condenser, the Permittee shall record the condenser outlet gas temperature for the batch when the emitting unit is emitting VOC.	Recordkeeping	Data historian is used as the system for storing temperature data

Implementation in Business Process

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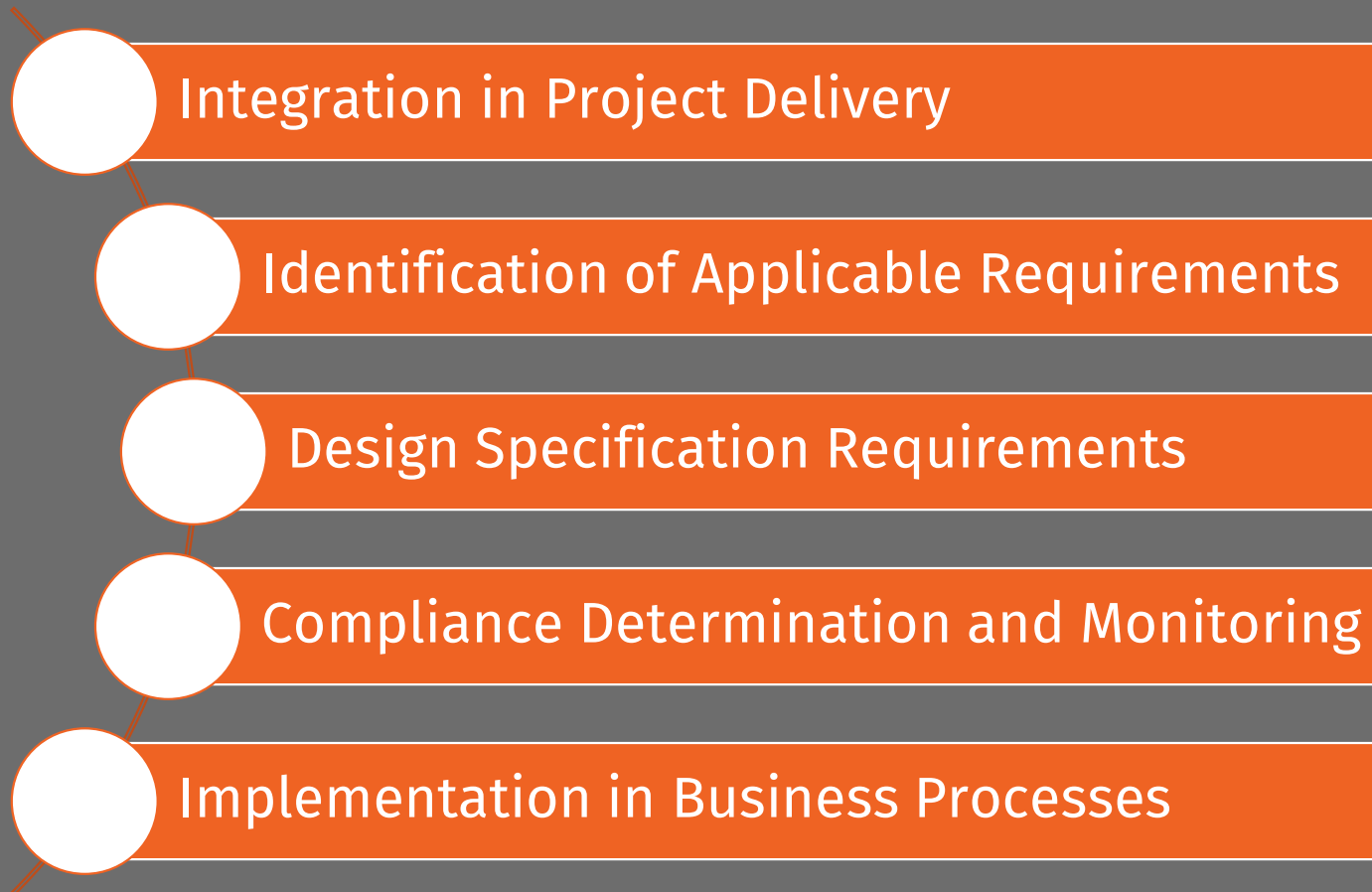
Site Business Processes

Based on the output of the compliance determination and monitoring activity 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

Top 5: Best Practices to Ensure Compliance

- 
- Integration in Project Delivery
 - Identification of Applicable Requirements
 - Design Specification Requirements
 - Compliance Determination and Monitoring
 - Implementation in Business Processes

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Biographical Information

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Ellen Hewitt is a Principal in Trinity's Columbus, Ohio office. Ellen supports both consulting and business development for Trinity's East Region as well as Trinity's Sustainability and Assurance team. In her 18 years at Trinity, she has managed numerous permitting and environmental compliance projects. Ellen manages multiple corporate accounts and has a strong focus on national regulatory initiatives.

Prior to working for Trinity, she worked for Ecolab as an engineer supporting manufacturing operations. Mrs. Hewitt earned a Bachelor of Science degree in Chemical Engineering from The Ohio State University. After graduation she obtained her Six Sigma Greenbelt Certification.

Mary Kathleen Parsons
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Kathleen is plant/project engineering manager with Eli Lilly and Company in Indianapolis, Indiana. She started the Eli Lilly and Company in June 2018 after serving for 6 years as a Senior Consultant with Trinity Consultants and 3 years as a Air Permit Engineer for BP in Indianapolis.
Saint Mary's College logo

She has a BS, Chemical Engineering from University of Notre Dame and a BS, Chemistry from Saint Mary's College.