PSCI
PHARMACEUTICAL
SUPPLY CHAIN
INITIATIVE

Sustainability & Environmental Performance Management

PSCI

PHARMACEUTICAL SUPPLY CHAIN INITIATIVE

Emerging Regulatory Framework for Assessing Environmental Liabilities in India

Presented by

HITESH KAUSHIK

COUNTRY MANAGER and ASSOCIATE

GOLDER ASSOCIATES CONSULTING INDIA PVT. LTD.

PSCI
PHARMACEUTICAL SUPPLY CHAIN INITIATIVE

Bio

since 2009:	Golder Associates Consulting India Pvt Ltd, Delhi, India-Country Manager, Associate, Environmental Discipline Leader
2008:	Golder Associates Pty Ltd – Queensland, Australia-Senior Geotechnical Engineer
2006:	Consulting Engineering Services (I) Private Limited – New Delhi, India-Deputy General Manager
2002:	Master of Engineering, Geotechnical Engineering, University of Rajasthan, India
1999:	Agra Earth & Environmental Engineering Ltd i/a UMA Engineering Ltd, Canada, Rajasthan, India-Senior Drainage Engineer
1992:	C C Patel & Associates Pvt. Ltd – New Delhi, India-Assistant Engineer
1990:	Mohata Construction – New Delhi, India-Site Engineer
1989:	Bachelor of Civil Engineering, National Institute of Technology, Allahabad, Uttar Pradesh, India

Hitesh Kaushik
Email: hkaushik@golder.com

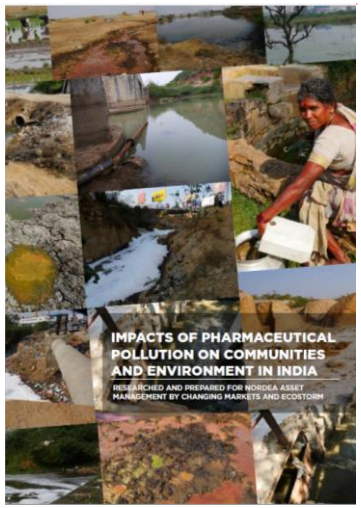
Agenda

PSCI
PHARMACEUTICAL
SUPPLY CHAIN
INITIATIVE

1	In the News
2	Background
3	Roadblocks
4	Types of Environmental Impacts
5	Current Legal Scenario
6	Rules vs Guidelines
7	Environmental Liability
8	Categories of Liabilities
9	Valuation of Liabilities
10	A Proactive Approach

In the News

PSCI
PHARMACEUTICAL SUPPLY CHAIN INITIATIVE



Pollution puts pharmaceutical supply chains under the spotlight

Pollution levels in the river systems close to manufacturing plants in Hyderabad were 70 per cent higher than in rivers and streams beyond.

In the News

National Green Tribunal Slaps Hefty Fines For Pollution In Mathura

For causing continuous air, water and ground pollution in the Yamuna riverbed.

In the News

Another polluting unit shut down in TTC area

Chemical effluents were being released into the water.

In the News

59 Maharashtra industries fined for illegal hazardous waste disposal

For unlawful storage and disposal of large quantities of hazardous waste in their premises.

In the News

CLOSURE NOTICE ISSUED TO SIX FACTORIES IN PALGHAR

MPCB gives 48-hour deadline to the units after surprise check finds acidity levels of released effluents too high.

Camlin Fine Sciences in MIDC Tarapur was among the units asked to shut operation

In the News

Laid to waste: Pollution, contamination of groundwater plagues Dera Bassi

SEWER FROM FACTORIES POISON GROUNDWATER

Background

PSCI
PHARMACEUTICAL SUPPLY CHAIN INITIATIVE

- Rapid industrialization in India → generation of large quantities of solid and liquid waste.
- Inadequately treated industrial waste (often hazardous in nature) dumped on land or discharged into water bodies.
- 17 categories of highly polluting industries identified by CPCB.
- **Basic Drugs & Pharmaceuticals Manufacturing** – a fast growing industrial sector – classified as a highly polluting industry.
- Special attention from SPCB/PCC on major polluting industries with progress regularly monitored by CPCB.

Roadblocks

PSCI
PHARMACEUTICAL SUPPLY CHAIN INITIATIVE

- Multiple environmental regulations to comply with plus amendments – no unified legislation.
- Pharmaceuticals in the environment – emerging area and not regulated – lack of know-how on management.
- Facilitatory payments demanded by the regulatory authorities for permit applications and renewals.
- No standard operating procedures for the pollution control board activities – much of it being the discretion of the officials.
- Lack of regular facility inspections by the authorities.
- No central database on the environmental status of industrial areas.

Types of Environmental Impacts

PSCI
PHARMACEUTICAL SUPPLY CHAIN INITIATIVE

- **Impacts on Soil and Groundwater**
  - Illegal dumping or discharge on open parcels of land;
  - Breaches of landfill with seepage into the subsoil and potentially into the aquifer;
  - Spills/ leaks of hazardous wastes during transportation;
  - Leaks from underground tanks or pipelines.

Typically for aquifers to get contaminated, overlying soils will tend to be contaminated first. Therefore, soil and groundwater contamination often occur simultaneously and are therefore assessed at the same time.

- **Impacts on Surface Water**
  - Runoff from dumping sites entering surface water bodies;
  - Direct discharge into nearby streams or nalla's that ultimately discharge into larger surface water bodies.

Current Legal Scenario

PSCI
PHARMACEUTICAL SUPPLY CHAIN INITIATIVE

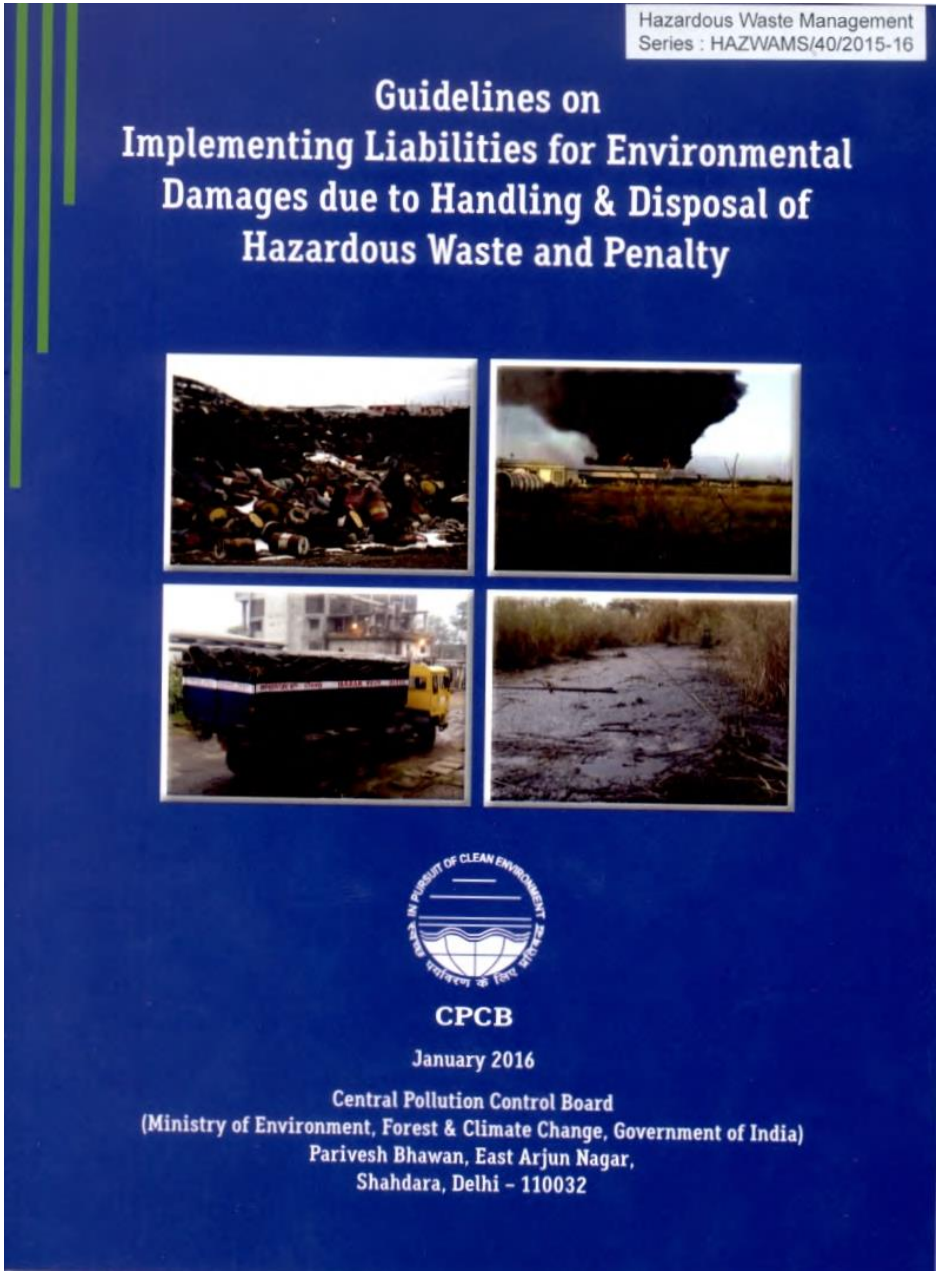
- National Environment Policy - Ministry of Environment, Forests & Climate Change in 2006;
- Section 9 of the Environment (Protection) Act, 1986;
- Rule 12 of Environment (Protection) Rules, 1986 and amendments made thereof;
- National Green Tribunal Act 2010.

Existing regulatory framework requires a potential polluter to be liable for all damages caused to the environment or third parties due to improper handling of the hazardous wastes or disposal of the hazardous wastes.

Current Legal Scenario

PSCI
PHARMACEUTICAL SUPPLY CHAIN INITIATIVE

- Incidences of fire, spillage, illegal disposal, etc. of hazardous waste necessitates imposition of liability for damages caused to the environment or third party including financial penalty for violation of the provisions of the Rules.
- Assessing these liabilities and translating the same in terms of monetary value are challenges before the implementing agencies such as SPCBs/ PCCs.
- To address the above, guidelines have been prepared along with description of liabilities, approach for valuation, methodology for levying financial penalties.



Guidelines on Implementing Liabilities for Environmental Damages due to Handling & Disposal of Hazardous Waste and Penalty

Rules vs Guidelines

PSCI
PHARMACEUTICAL
SUPPLY CHAIN
INITIATIVE

- **Rules** must be followed, and there will be a negative consequence associated with noncompliance.

- **Guidelines** are recommended best practices that aim to set standards in the future.

Environmental Liability

PSCI
PHARMACEUTICAL SUPPLY CHAIN INITIATIVE

- A legal obligation to make a future expenditure due to the past or ongoing manufacture, use, release or threatened release of a particular substance or other activities that adversely affect the environment or human health.
- Refer to the cleanup obligations, potential for fines, penalties for violations of environmental laws.
- Required to be imposed retroactively with strict liability for clean-up costs.
- Applicable for the actual environmental damages or alleged releases of pollutants that makes the responsible party obligated to pay for environmental remediation expenses.

Categories of Liabilities

PSCI
PHARMACEUTICAL SUPPLY CHAIN INITIATIVE

- Liability for taking up immediate measures
  - Emergency response measures with respect to spillage, improper disposal, fire or mishandling of hazardous waste
- Liability for assessment of contamination
  - Phase I and Phase II Site Assessments
- Liability for remediation of contaminated sites
- Compensation liability
  - Liability to pay for natural resource damages
  - Compensation to the third parties for personal injury, property damage, and economic loss

Valuation of Liabilities

PSCI
PHARMACEUTICAL SUPPLY CHAIN INITIATIVE

- **“Strict Liability”** exercised on the responsible party i.e. liability on the responsible party without finding a fault (such as negligence or wrongful intent);

- If two or more persons are liable in respect of same liability, **“Joint and Several Liability"** imposed. i.e. a claimant may pursue an obligation against any one party as if they were jointly liable and it becomes responsibility of the defendants to sort out their respective proportions of liability and payment;

- SPCBs/PCCs to send proposals (with background details) to CPCB for approval for imposing financial penalty on defaulting party. SPCB/PCC may file a criminal court case, especially in cases of gross violations;

Valuation of Liabilities

PSCI
PHARMACEUTICAL SUPPLY CHAIN INITIATIVE

- Immediate response liability of not less than INR 10,00,000/- incase of a suspected impact;
  - Captures cost of immediate response and Phase I ESA
  - Does not mean that responsible party pay this amount, only indicates liability.
- Incase SPCBs / PCCs initiate immediate response, liability is two times the immediate response liability and interest as decided by the SPCB/PCC;
- Immediate response liability may be increased up to a maximum of INR 4,50,00,000/- depending on the type and extent of contamination;
- Additional remediation liability based on remediation technology and compensatory liabilities.

Valuation of Liabilities

PSCI
PHARMACEUTICAL SUPPLY CHAIN INITIATIVE

- If responsible party does not undertake actions, in spite of the SPCBs/PCCs directions, SPCB shall undertake the immediate response, assessments and remediation work to the desired clean-up levels and fix the liability for the same by imposing two to three times the costs incurred along with interest;
- If responsible party does not respond, SPCBs/PCCs shall file FIR under Code of Criminal Procedure (CrPC) or approach National Green Tribunal or appropriate courts, for initiating proceedings and recovery of the said amount from the responsible party along with the interest;
- If the responsible party is not traceable, then the SPCBs/PCCs may undertake the immediate response, assessments and remediation on their own or by engaging third party and file FIR for necessary investigation and for recovery of liability;
- The occupier, transporter, importer or operator of a facility, may insure for an appropriate amount (depending on types of hazardous waste, quantum, possible impacts etc.) with insurance company to meet various environmental damage liabilities including compensation liability in the event of environmental damages due to handling and disposal of disposal of hazardous waste.

A Proactive Approach

PSCI
PHARMACEUTICAL
SUPPLY CHAIN
INITIATIVE

- In the absence of clear legislations, leading manufacturers and supply chains have devised risk management strategies including
  - Increased efforts to adhere to permit conditions;
  - Field environmental assessments to understand gaps and areas of improvement in current operations;
  - Detailed soil and groundwater investigations, if necessary, to understand potential for onsite/ offsite impacts.

PSCI

PHARMACEUTICAL SUPPLY CHAIN INITIATIVE

THANK YOU

PSCI

PHARMACEUTICAL SUPPLY CHAIN INITIATIVE

Managing Active Pharmaceutical Ingredients in Manufacturing Effluent

Presented by

Bharat Shevkar

Manager External Supply EHS&S

Johnson & Johnson

PSCI
PHARMACEUTICAL
SUPPLY CHAIN
INITIATIVE

Bio

Manager EHS&S External Supply, Johnson & Johnson

J&J PIE Committee Member

Tasks:

Supplier EHS&S Audit Program Management (India, Southeast Asia, Australia, New Zealand)

Supplier Capability

Lead J&J External Supply PIE Program

Education:

M.Sc. Environmental Science

Advance Diploma in Industrial Safety

Work experience:

16 years in field of EHS&S

Bharat Shevkar
Johnson & Johnson
Manager EHS&S External Supply
Email: bshevkar@its.jnj.com

Agenda

PSCI
PHARMACEUTICAL
SUPPLY CHAIN
INITIATIVE

1. Importance of managing active pharmaceutical ingredients (API) in manufacturing effluent
2. Evaluating a site wastewater program and improving programs through the maturity ladder concept
3. Calculating API discharge concentration PEC and comparing it to the PNEC
4. Reducing API process losses to waste water and what to do when the PNEC is exceeded
5. Antimicrobial Resistance (AMR) Roadmap Update

Agenda

PSCI
PHARMACEUTICAL SUPPLY CHAIN INITIATIVE

1. Importance of managing active pharmaceutical ingredients (API) in manufacturing effluent
2. Evaluating a site wastewater program and improving programs through the maturity ladder concept
3. Calculating API discharge concentration PEC and comparing it to the PNEC
4. Reducing API process losses to waste water and what to do when the PNEC is exceeded
5. Antimicrobial Resistance (AMR) Roadmap Update

PSCI
PHARMACEUTICAL SUPPLY CHAIN INITIATIVE

Why is managing active pharmaceutical ingredients (API) in manufacturing effluent important?

- First, and foremost, we all need to do what we can protect the environment.
  - The ecosystem serves your community, protecting it improves quality of life
- It's good 'business-sense'
  - Stakeholder concerns are prompting regulators to take actions that will impact our business model
  - Sustainable Investors and product procurement programs are extending their research across the supply chain and considering the addition of 'environmental considerations' to their decision-making process

PSCI

PHARMACEUTICAL INDUSTRY **PRINCIPLES** FOR RESPONSIBLE SUPPLY CHAIN MANAGEMENT

Environment

Suppliers shall operate in an environmentally responsible and efficient manner to minimize adverse impacts on the environment. Suppliers are encouraged to conserve natural resources, to avoid the use of hazardous materials where possible and to engage in activities that reuse and recycle. The environmental elements include:

1. Environmental Authorizations
Suppliers shall comply with all applicable environmental regulations. All required environmental permits, licenses, information registrations and restrictions shall be obtained and their operational and reporting requirements followed.

2. Waste and Emissions
Suppliers shall have systems in place to ensure the safe handling, movement, storage, recycling, reuse, or management of waste, air emissions and wastewater discharges. Any waste, wastewater or emissions with the potential to adversely impact human or environmental health shall be appropriately managed, controlled and treated prior to release into the environment.

3. Spills and Releases
Suppliers shall have systems in place to prevent and mitigate accidental spills and releases to the environment.

PHARMACEUTICAL INDUSTRY **PRINCIPLES** FOR RESPONSIBLE SUPPLY CHAIN MANAGEMENT

Environment

Suppliers shall operate in an environmentally responsible and efficient manner to minimize adverse impacts on the environment. Suppliers are encouraged to conserve natural resources, to avoid the use of hazardous materials where possible and to engage in activities that reuse and recycle. The environmental elements include:

1. Environmental Authorizations
Suppliers shall comply with all applicable environmental regulations. All required environmental permits, licenses, information registrations and restrictions shall be obtained and their operational and reporting requirements followed.

2. Waste and Emissions
Suppliers shall have systems in place to ensure the safe handling, movement, storage, recycling, reuse, or management of waste, air emissions and wastewater discharges. Any waste, wastewater or emissions with the potential to adversely impact human or environmental health shall be appropriately managed, controlled and treated prior to release into the environment.

3. Spills and Releases
Suppliers shall have systems in place to prevent and mitigate accidental spills and releases to the environment.

PSCI
PHARMACEUTICAL SUPPLY CHAIN INITIATIVE

Why is managing active pharmaceutical ingredients (API) in manufacturing effluent important?

Focus on the Pharmaceutical Supply Chain

1. **Mistra Pharma** - Swedish research center briefs EU Parliament, recommends including manufacturing losses in drug approval decision (June 2, 2015)

2. **Sum of Us** – Activist group proposes link between antibiotic contamination from Chinese suppliers and antimicrobial resistance. The report, 'Bad Medicines' names several major companies (June 11, 2015)

3. **Nordea** - The largest Nordic financial services firm expresses concerns with water pollution in India from pharmaceutical suppliers (June 21, 2015 and follow up report in 2016)

4. **SAICM** – UNEP declares pharmaceuticals as a new emerging policy issue with focus on developing countries (October, 2015)

1

MISTRA
The Swedish Foundation for Strategic Environmental Research

2

Sum Of + Us

3

Nordea

4

saicm
UNEP

It is clear that there is a Global Focus on Manufacturing Efficiency

What is the industry doing to improve public perceptions?
The Eco-Pharmaco-Stewardship 'Pillars'

PSCI
PHARMACEUTICAL SUPPLY CHAIN INITIATIVE

The **Industry Proposal**: the Eco-Pharmaco-Stewardship (EPS)

Pillar 1

Cooperation in R&D: Intelligence-led Assessment of pharmaceuticals in the Environment (iPiE)

- As part of the iPiE project, industry, academia and regulators will develop together models to predict pharmaceutical substance properties and the associated environmental risk potential

Pillar 2

Managing discharges from manufacturing

- Share best practices
- Benchmark operations
- Establish standards
- Define control measures

Pillar 3

Extended Environmental Risk Assessment (eERA)

- Evaluate and limit the potential adverse environmental effects from new drugs as well as "legacy" APIs
- Establishing an ongoing monitoring system throughout the product's life-cycle

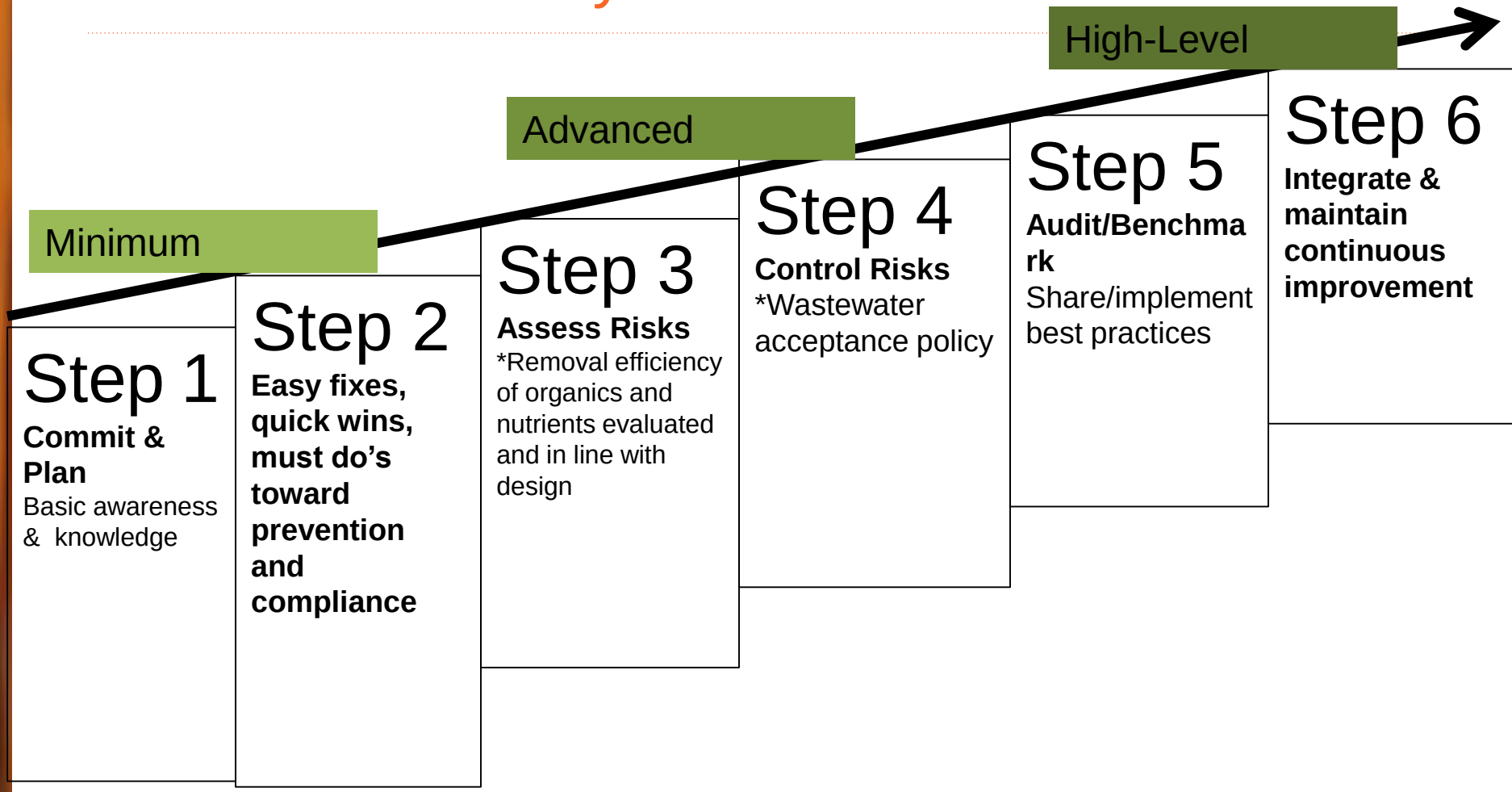
Agenda

PSCI
PHARMACEUTICAL SUPPLY CHAIN INITIATIVE

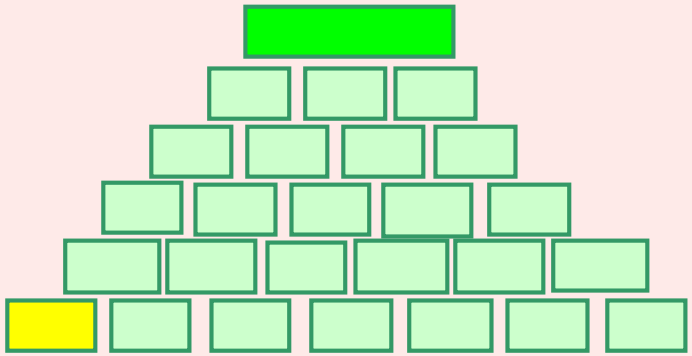
1. Importance of managing active pharmaceutical ingredients (API) in manufacturing effluent
2. Evaluating a site wastewater program and improving programs through the maturity ladder concept
3. Calculating API discharge concentration PEC and comparing it to the PNEC
4. Reducing API process losses to waste water and what to do when the PNEC is exceeded
5. Antimicrobial Resistance (AMR) Roadmap Update

PSCI
PHARMACEUTICAL SUPPLY CHAIN INITIATIVE

Wastewater Maturity Ladder



WWT Level 1:Commit & Plan - Basic Awareness & Knowledge



	0. No / Not Relevant	1. Partially In Place	2. Basic / Minimum	3. Mostly In Place	4. Completely In Place
WWT Level 1:Commit & Plan - Basic Awareness & Knowledge					
1.1 Does the organization understand (and has described) the fate and nature of its effluent waters (flow data, effluent characteristics) and does it understand the regulatory limits to be rescpected. Is it fully permitted.		x			
1.2 Are the effluent characteristics regulary monitored, are the effluent limits respected ? Are significant effluent variations monitored and effluent standard deviations reported.		x			
1.3 Has the organization assigned qualified persons for WWT program?		x			
1.4 Do the WWT responsible person(s) and WWT operators have basic training?		x			
1.5 Does the organization fully understand the design capacity and current performance of the WWT facility (Flow rate, volumes, COD/BOD, loads, etc.)		x			
1.6 Do general safety and quality procedures exist related to wastewater?		x			
25% Installed	0	6	0	0	0
Color of pyramid element:	0.25				

PSCI
PHARMACEUTICAL SUPPLY CHAIN INITIATIVE

A word about permits

- Most discharge permits will address established parameters, e.g., control of pH, biological oxygen demand, chemical oxygen demand, etc.
- Some discharge permits include periodic general toxicity testing, i.e., whole effluent toxicity
- Most discharge permits will NOT directly address active pharmaceutical ingredients (APIs) but DO include a ‘general duty’ clause, i.e., “No toxics in toxic amounts”.
- Zero discharge doesn’t always equal ‘zero risk’
  - Ground dispersion may result in:
    - Dermal/inhalation exposure to applicator and/or recreational users
    - Edible vegetation and/or groundwater users
    - Terrestrial organisms
    - Mist inhalation from opened cooling uses

Agenda

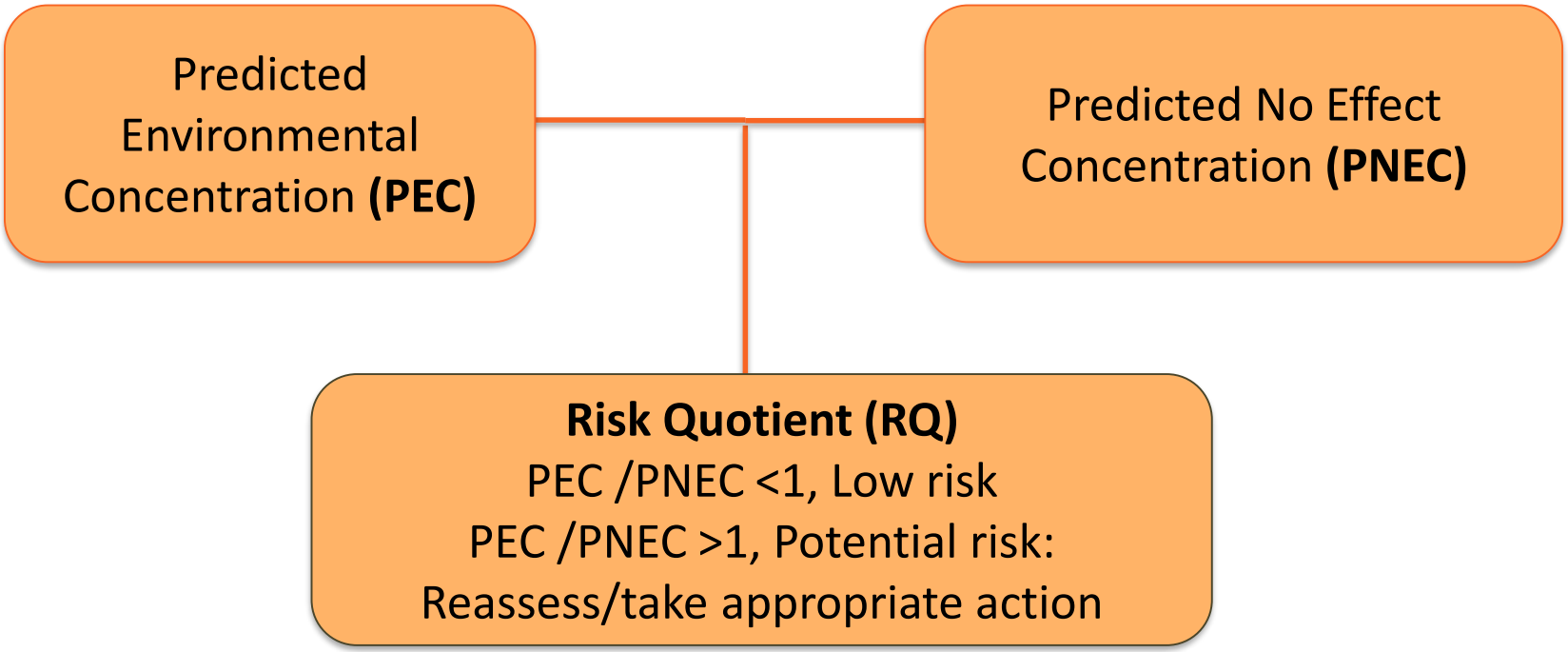
PSCI
PHARMACEUTICAL
SUPPLY CHAIN
INITIATIVE

1. Importance of managing active pharmaceutical ingredients (API) in manufacturing effluent
2. Evaluating a site wastewater program and improving programs through the maturity ladder concept
3. Calculating API discharge concentration PEC and comparing it to the PNEC
4. Reducing API process losses to waste water and what to do when the PNEC is exceeded
5. Antimicrobial Resistance (AMR) Roadmap Update

PSCI
PHARMACEUTICAL SUPPLY CHAIN INITIATIVE

What is an Environmental Risk Assessment?

- Good management practices may not eliminate all API released to water
- Your responsibility is to know whether the amount released could have a potential impact on the environment and to take appropriate action
- Environmental Risk Assessment requires data and professional judgment



PSCI
PHARMACEUTICAL SUPPLY CHAIN INITIATIVE

PEC Data Collection & Analysis

- Review batch records to determine API losses
- Estimate ***daily*** API losses (account for batch and cleaning cycles)
- Estimate treatment plant removal efficiency using the API chemical and physical properties, literature, or assume 0%
- Get wastewater and receiving water flows

Examples

On-Site

batch records	wastewater POG[1]
product yield	wastewater flows
batch/year	WWTP unit ops
cleaning cycles	API analyses[2]

Off-Site

POTW flow
POTW unit ops
receiving water flow

1 POG = Point of Generation
2 API analysis of wastewater, solvent waste, solid waste, etc.

PSCI
PHARMACEUTICAL SUPPLY CHAIN INITIATIVE

Deriving the PNEC

$$\text{PNEC} = \frac{\text{Lowest Effect Concentration (LC) } \textit{or} \text{ No Observed Effect Concentration (NOEC)}}{\text{Assessment Factor (AF)}}$$

- ***Lowest Effect Concentration (LC)***: The smallest amount of a substance that will harm an organism. Expressed as LC_{50} or EC_{50}
- ***No Observed Effect Concentration (NOEC)***: The amount of a substance where no harm to an organism has been observed

- ***Assessment Factor***: Factor used to account for uncertainties; varies inversely with strength of data set

PSCI
PHARMACEUTICAL SUPPLY CHAIN INITIATIVE

Calculating the Risk Quotient

$$\text{Risk Quotient (RQ)} = \frac{\text{PEC}}{\text{PNEC}} = \text{<1 or >1?}$$

Risk Quotient		
Less than (<) 1	Indicates that the expected concentration is lower than the concentration indicating low/no potential environmental risk	
Greater than (>) 1	Indicates that the expected concentration exceeds the no-effect concentration indicating the potential for risk	

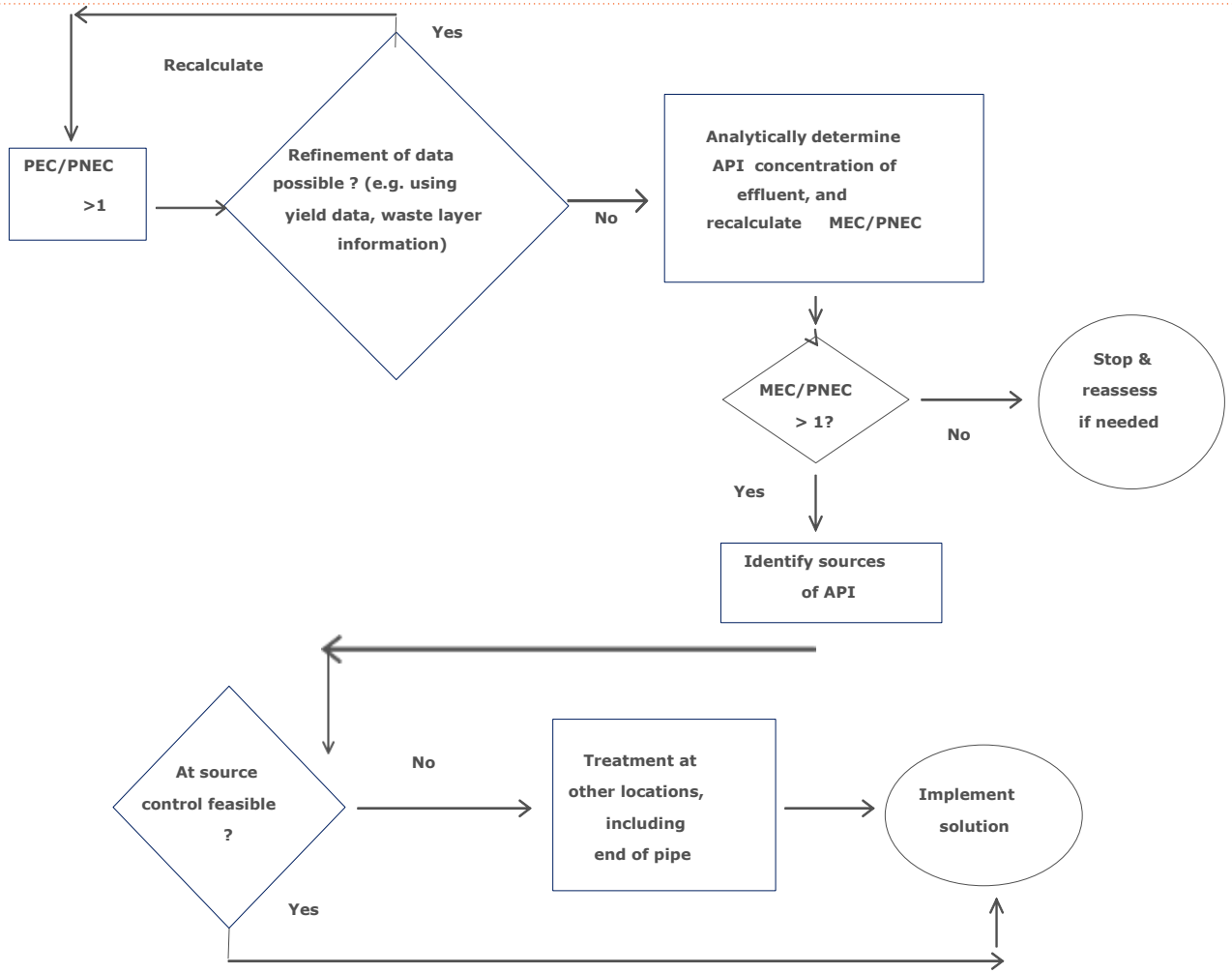
Agenda

PSCI
PHARMACEUTICAL SUPPLY CHAIN INITIATIVE

1. Importance of managing active pharmaceutical ingredients (API) in manufacturing effluent
2. Evaluating a site wastewater program and improving programs through the maturity ladder concept
3. Calculating API discharge concentration PEC and comparing it to the PNEC
4. **Reducing API process losses to waste water and what to do when the PNEC is exceeded**
5. Antimicrobial Resistance (AMR) Roadmap Update

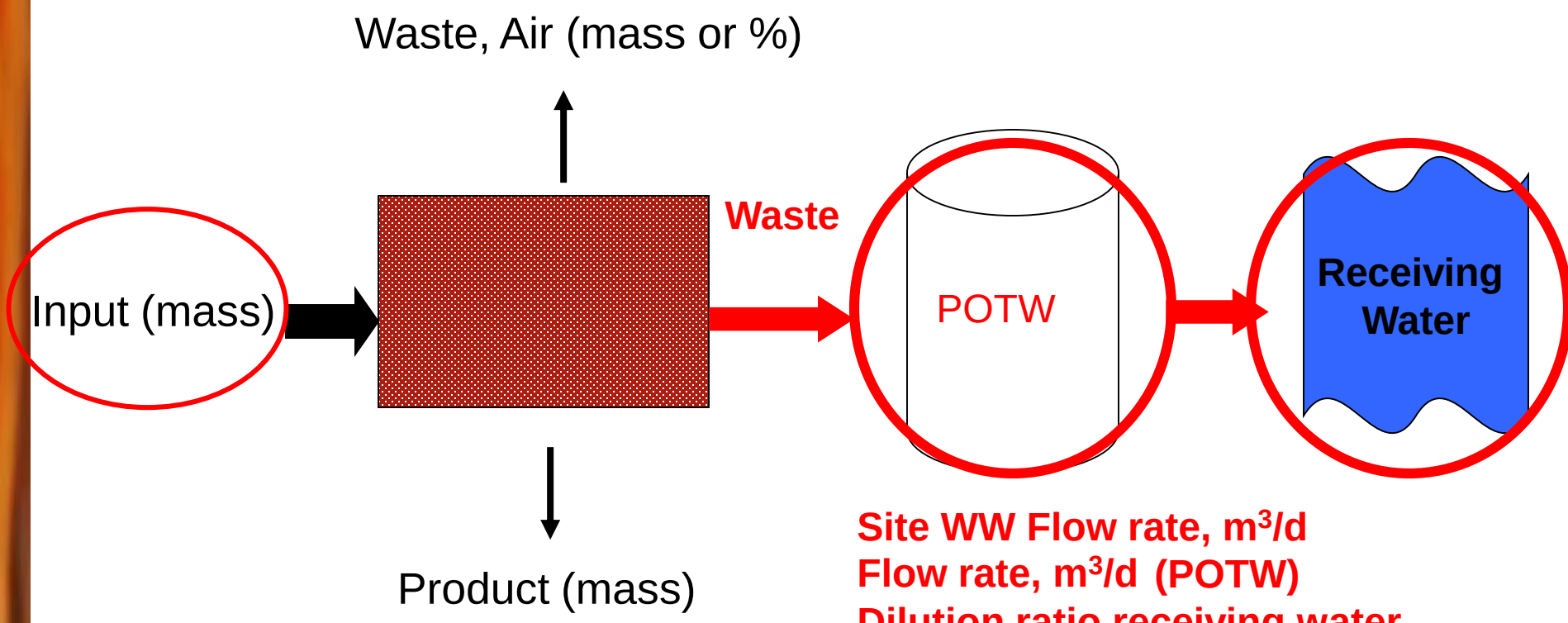
PSCI
PHARMACEUTICAL SUPPLY CHAIN INITIATIVE

Risk refinement flowchart



Refining the Mass Balance Approach with POTW & dilution effects

PSCI
PHARMACEUTICAL SUPPLY CHAIN INITIATIVE



Site WW Flow rate, m^3/d
Flow rate, m^3/d (POTW)
Dilution ratio receiving water

PSCI
PHARMACEUTICAL SUPPLY CHAIN INITIATIVE

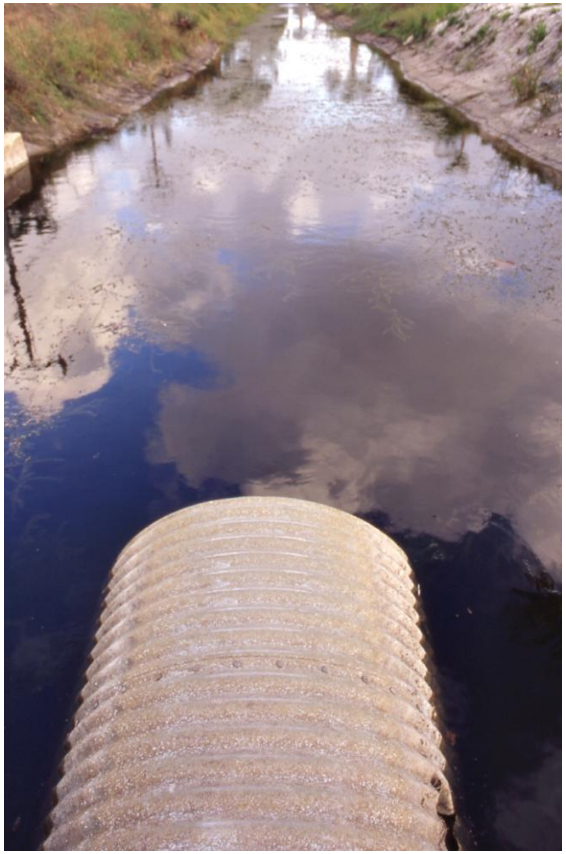
Risk refinement actions

Use Good Management Practices

- Eliminate direct sewer discharges of rejected/spilled material
- Use dry cleaning practices as much as practical with appropriate disposal
- Minimize equipment rinse discharge

Implement these practices and then re-calculate RQ

If RQ still greater than 1, further action needed



Agenda

PSCI
PHARMACEUTICAL SUPPLY CHAIN INITIATIVE

1. Importance of managing active pharmaceutical ingredients (API) in manufacturing effluent
2. Evaluating a site wastewater program and improving programs through the maturity ladder concept
3. Calculating API discharge concentration PEC and comparing it to the PNEC
4. Reducing API process losses to waste water and what to do when the PNEC is exceeded
5. Antimicrobial Resistance (AMR) Roadmap Update

AMR Alliance

PSCI
PHARMACEUTICAL SUPPLY CHAIN INITIATIVE

- IFPMA* launched **AMR Alliance:**
  - ✓ 100 Signatories of the **Davos declaration**
  - ✓ 13 Signatories of the **UN General Assembly Roadmap**
- Aims AMR Alliance:
  - ✓ Communicate progress
  - ✓ Stakeholder collaboration
  - ✓ Manage amendments to the declaration and the roadmap
- AMR Alliance is initiating work streams in the following:
  - ✓ Environment
  - ✓ Appropriate use
  - ✓ Access
  - ✓ Research and Science
  - ✓ Communications
  - ✓ Amendments

* International Federation of Pharmaceutical Manufacturers and Associations

EHS leaders working group = Environment Working Group of AMR Alliance

PSCI
PHARMACEUTICAL SUPPLY CHAIN INITIATIVE

- Proposal to integrate '**EHS leaders working group' (13 signatories)** as the '**Environment Working Group**' of AMR Alliance

- Asks of the working group:
  - ✓ Suggest some simple metrics for reporting
  - ✓ Make use of the standardised 'management' framework for each working group (tbd)
  - ✓ Complete external environment scan

- First progress communication AMR Alliance: Davos 2018 meeting

PSCI
PHARMACEUTICAL SUPPLY CHAIN INITIATIVE

Extract AMR UNGA Roadmap (update September 2016)

We support **measures to reduce environmental pollution from production of antibiotics,** and will

13 signatories

i. Review our own manufacturing and supply chains to assess good practice in controlling releases of antibiotics into the environment.

ii. Establish a common framework for managing antibiotic discharge, building on existing work such as PSCI , and start to apply it across our own manufacturing and supply chain by 2018.

iii. Work with stakeholders to develop a practical mechanism to transparently demonstrate that our supply chains meet the standards in the framework.

iv. Work with independent technical experts to establish science-driven, risk-based targets for discharge concentrations for antibiotics and good practice methods to reduce environmental impact of manufacturing discharges, by 2020.

Thank you

PSCI
PHARMACEUTICAL SUPPLY CHAIN INITIATIVE

Caldwell, D. J., Mertens, B., Kappler, K., Senac, T., Journel, R., Wilson, P., Meyerhoff, R. D., Parke, N. J., Mastrocco, F., Mattson, B., Murray-Smith, R., Dolan, D. G., Straub, J. O., Wiedemann, M., Hartmann, A. and Finan, D. S. (2015), A risk-based approach to managing active pharmaceutical ingredients in manufacturing effluent. Environ Toxicol Chem. doi:10.1002/etc.3163

Bharat Shevkar

Email: bshevkar@its.jnj.com

The Pharmaceutical Supply Chain Initiative

Need more information?

Visit: www.pscinitiative.org

Email: the PSCI Secretariat at info@pscinitiative.org

CHWMEG®

Globally Promoting Responsible Waste Stewardship

Responsible Waste Stewardship - What is your Vendor Doing?

David Chng, Asia Pacific Director

tel: +65 9237 8445

asia-pacific@chwmeg.org

PSCI
PHARMACEUTICAL SUPPLY CHAIN INITIATIVE

Bio

- David has a background in Mechanical Engineering from the Singapore Polytechnic, and a MBA in International Business and Marketing from the University of Oregon, USA.
- In the last 15 years, David has been running his own business consulting company that works with foreign companies to develop their marketing efforts in Asia.
- David is versatile in understanding the needs of companies from various industries.
- He represents CHWMEG in Asia Pacific, working with member companies to manage their business risks associated with their supply chain, particularly with waste disposal.
- He also believes in educating/creating awareness on the importance of responsible waste stewardship with both local companies and MNCs.

David Chng
Asia Pacific Director
Email: asia-pacific@chwmeg.org

PSCI

PHARMACEUTICAL SUPPLY CHAIN INITIATIVE

QUIZ :

Amount that US EPA has collected from PRPs to clean up waste disposal sites in the USA.

a) US$25,000,000.00

b) US$250,000,000.00

c) US$25,000,000,000.00

PSCI
PHARMACEUTICAL SUPPLY CHAIN INITIATIVE

Fact:

Amount that US EPA has collected from PRPs to clean up waste disposal sites in the USA.

PSCI
PHARMACEUTICAL SUPPLY CHAIN INITIATIVE

Reported:

€119,000,000,000

- *>450,000 sites* - Known contaminated sites .
- > 3 millions sites - Potentially contaminated sites
- €240m per year over 25 years for identification costs

(Luca Marmo, Environment Directorate-General, EU, 16 May 2013)

PSCI
PHARMACEUTICAL
SUPPLY CHAIN
INITIATIVE

Asia:?

- Many countries, different standards
- Enforcement problems and consistency issues
- Case of WHEN countries will to choose to strictly enforce

Are you willing to take the risks?

MEP 环保部

April 2014

"…as much as 10 trillion RMB could be invested to support the soil and groundwater cleanup scheme…"

- Director-general of MEP's department of Ecology

https://chemlinked.com/news/chemical-news/china-mep-issued-five-environmental-protection-standards-concerning-contaminated-sites - 26 February 2014

YALE environment360

A private industry body, the Jiangsu Institute of the Environmental Industry, has predicted that between 2014 and 2020 China's soil remediation market could be worth **nearly $110 billion**.

Extracted from a three-part series on soil pollution in China. The series is a joint project between Yale Environment 360 *and* Chinadialogue*, with support from the Pulitzer Center on Crisis Reporting. A Chinese language version of this article is available at* Chinadialogue

India

- Google search and find huge list of environmental problems
- “Environmental damage costs India $80bn a year (5.7% of 2009 GDP)”
  - The Financial Times, July 17, 2013 by: Victor Mallet in New Delhi
  - World bank Report 2013
- Responsible Waste Stewardship is your job – you have to make the difference


WHY?

Responsible Waste Stewardship

Why Does it Matter ?

Manufacturers and their supply-chain should be concerned about the proper management of their wastes

- Brand value/perception of brand owners at stake
- Impacts on material suppliers and contract
- Legal implications
- Financial liabilities & Diminished profits
- Impacts to the environment and communities
  - Protect environment and human health
- ISO 14001 includes this requirement

What is Review/Audit a Facility?

A Factual Representation Of The Facility and its Operation On The Day Of The Site Visit.

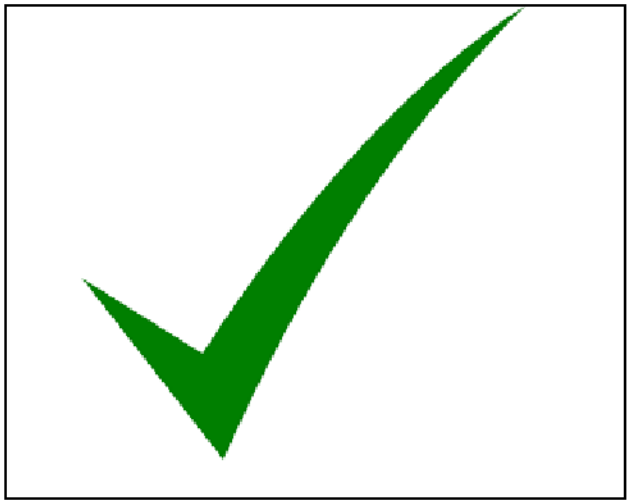
A Reasonable Representation Of Any Historic Conditions.


MANAGEMENT
INCIDENT HISTORY
OPERATIONS
COMMUNITY RELATIONS
DESIGN
LOCATION
HYDROGEOLOGY
REGULATORY COMPLIANCE
INSURANCE
SECURITY
FINANCIAL STRENGTH

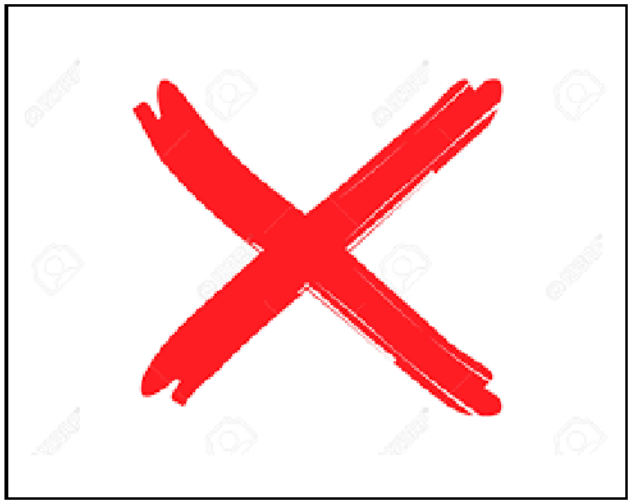

THIRD PARTY LIABILITIES
BRAND THREATS
SUPPLY CHAIN QUALITY CONCERNS
IMPROPER WASTE MANAGEMENT
COMMUNITY IMPACTS
SUSTAINABILITY & RISK MANAGEMENT – STEMMING THE RISING TIDE OF THREATS
AFP


Regulatory Compliance
Management Personnel
Geology/Groundwater
Financial Strength
Location
Insurance
Incident Notifications/
Remedial Actions
Design
Security
Operations
Community Relations

What's Next ?



OR



Sometimes, it's obvious yes or no by just looking at the information collected.

Most of the time, it is not so obvious as there are so many factors about the facility has to be considered, plus the situation at the local operations will also vary from location to location.

LOW RISK

?

or

HIGH RISK

LOW RISK

- ALL MODERN TECHNOLOGY
- GOOD HOUSEKEEPING
- EXCELLENT SECURITY
- ZERO DISCHARGE
- ON-SITE LABORATORY
- ON-SITE FIRE PROTECTION
- EXTENSIVE RECENT INVESTMENT
- REMOTE AREA/NO NEARBY WATERWAYS
- ENVIRONMENTAL MONITORING
- AUTOMATED OPERATIONS & CONTROLS

MODERATE RISK

SOME MODERN TECHNOLOGY

GOOD HOUSEKEEPING

EXCELLENT SECURITY

CONTAINMENT FEATURES

ON-SITE LABORATORY

ON-SITE RESIDUALS MGMT

SOME RECENT INVESTMENT

SOME UNCOVERED OPERATION AREAS

URBAN SETTING/ADJACENT RESIDENCES

NEARBY WATERWAY

GOOD SECURITY

COVERED STORAGE AND PROCESS AREAS

OUTDATED INCINERATOR TECHNOLOGY

INADEQUATE AIR POLLUTION CONTROLS

URBAN SETTING/ADJACENT RESIDENCES

NO RECENT INVESTMENT

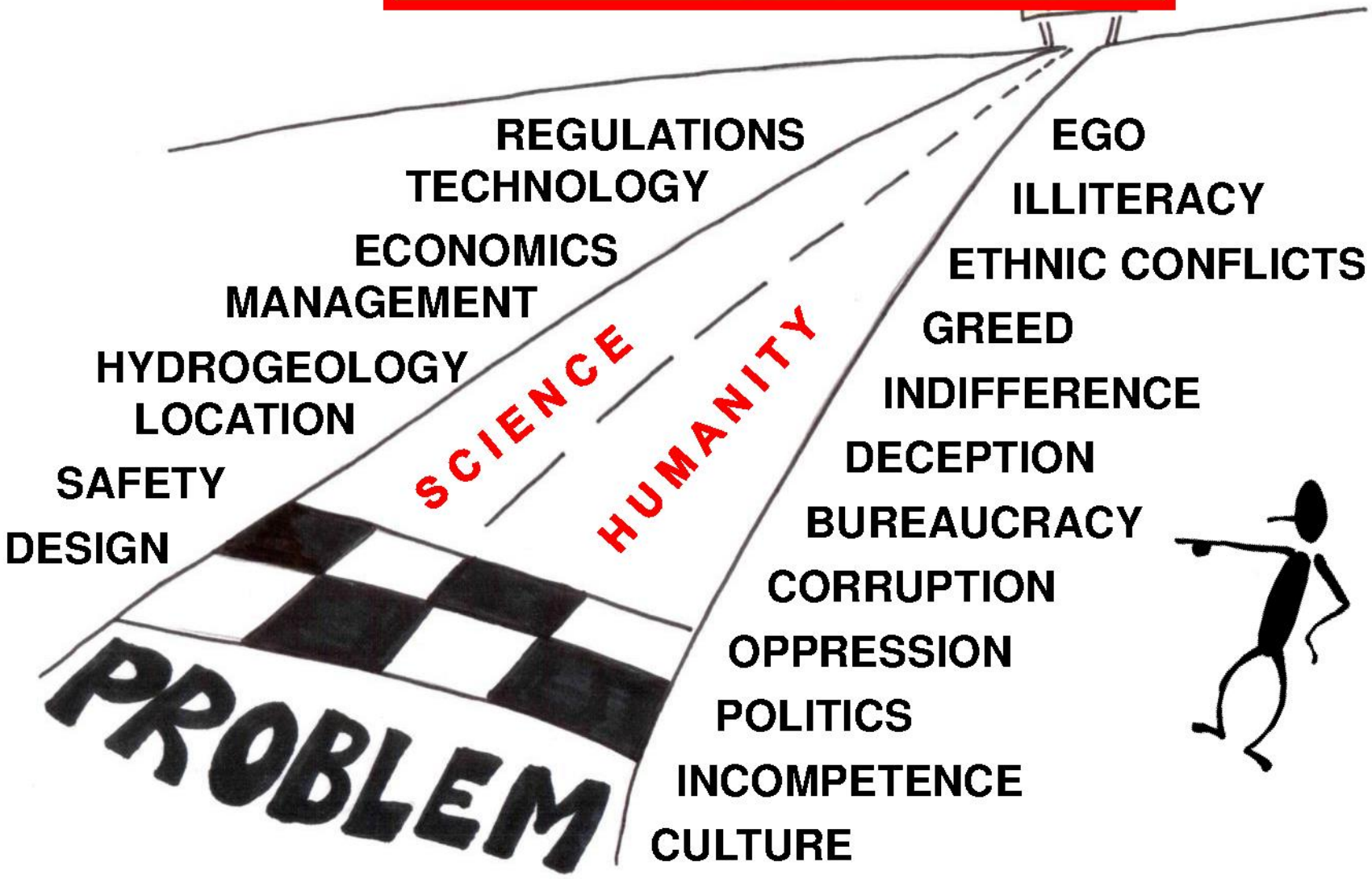
POOR HOUSEKEEPING

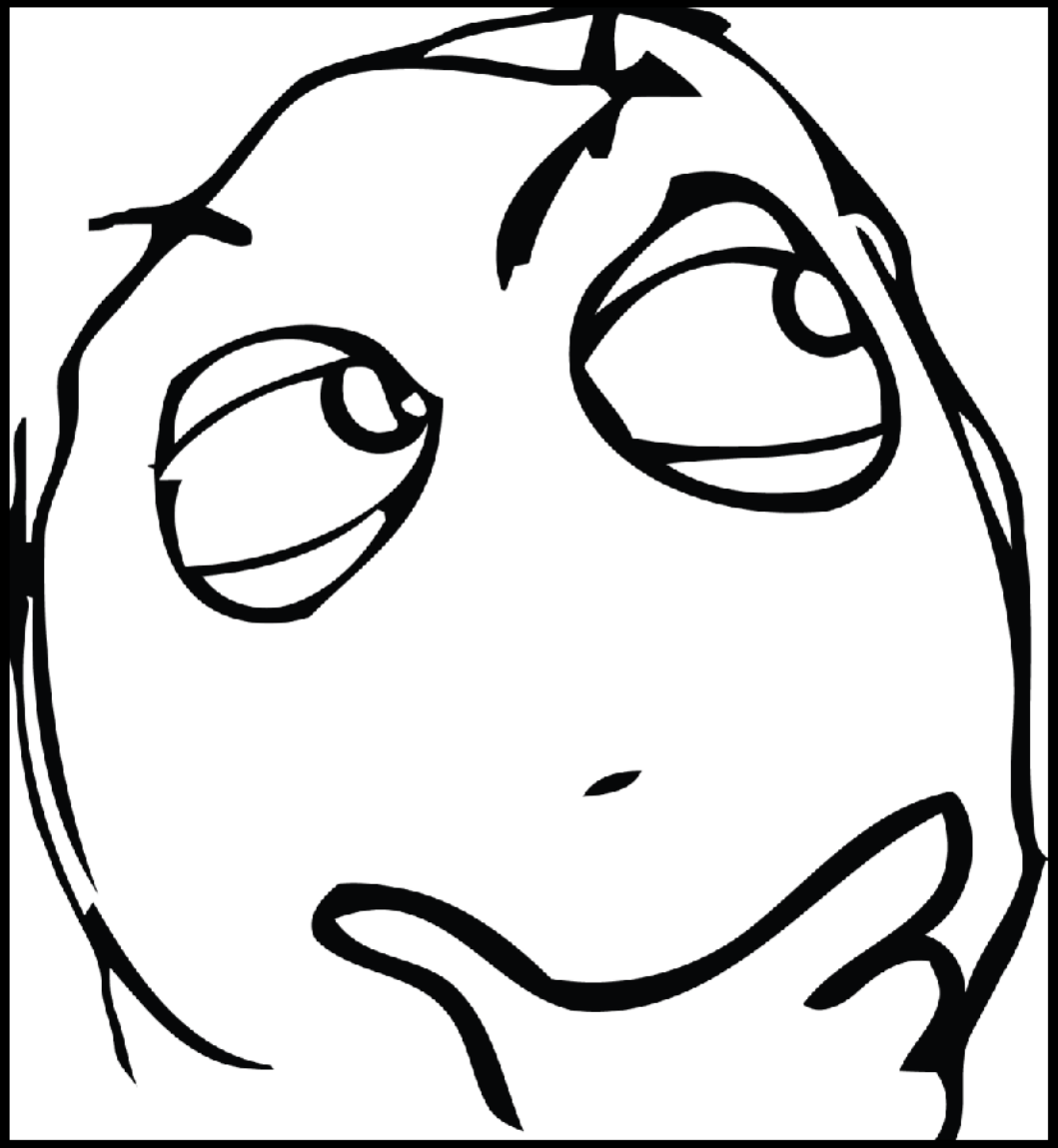
POOR ASH MANAGEMENT

POOR FACILITY CONDITION

HIGH RISK

ADDITIONAL CONSIDERATIONS





HIGH

MEDIUM

LOW

PONDER THE RISK.....

LOW RISKS?

MEDIUM RISKS?

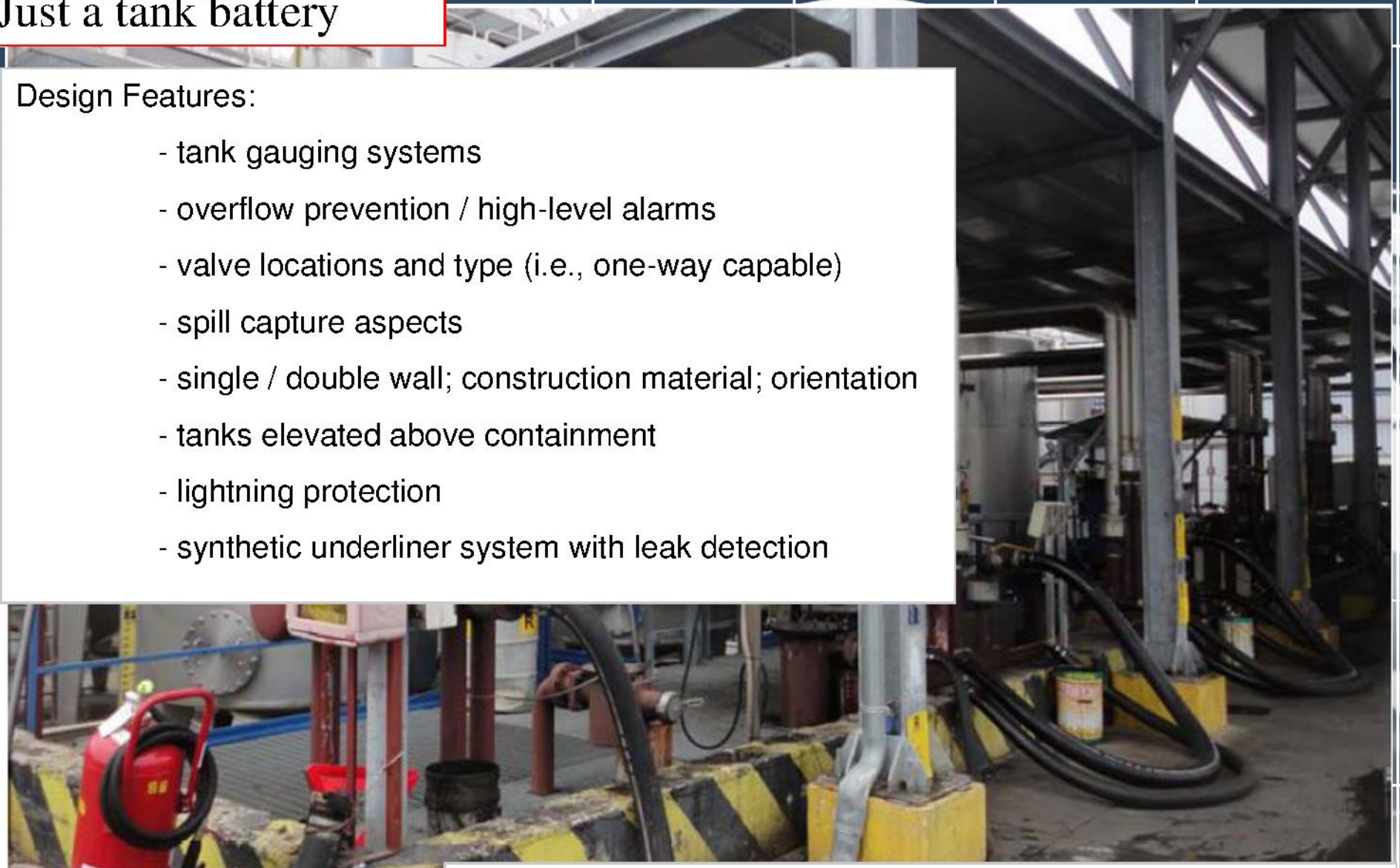
HIGH RISKS?

The key is in the details of information gathered

Just a tank battery

Design Features:

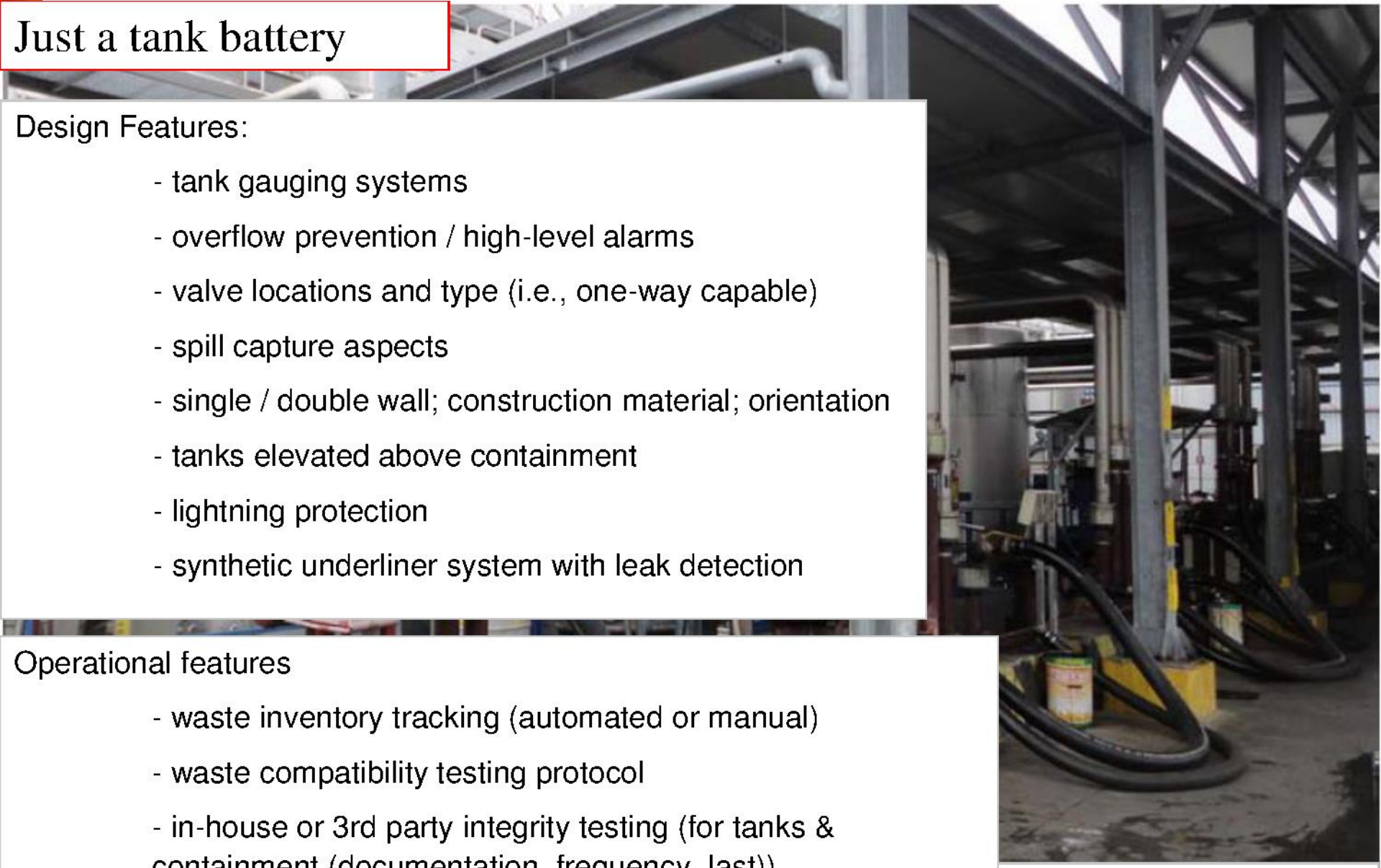
- tank gauging systems
- overflow prevention / high-level alarms
- valve locations and type (i.e., one-way capable)
- spill capture aspects
- single / double wall; construction material; orientation
- tanks elevated above containment
- lightning protection
- synthetic underliner system with leak detection



Regulatory Features: Secondary containment is present. The most recent regulatory inspection was passed.

Maintenance: No obvious issues within the operating area.

Just a tank battery



Design Features:

- tank gauging systems
- overflow prevention / high-level alarms
- valve locations and type (i.e., one-way capable)
- spill capture aspects
- single / double wall; construction material; orientation
- tanks elevated above containment
- lightning protection
- synthetic underliner system with leak detection

Operational features

- waste inventory tracking (automated or manual)
- waste compatibility testing protocol
- in-house or 3rd party integrity testing (for tanks & containment (documentation, frequency, last))
- type of integrity testing (wall thickness or hydrostatic)

econdary containment
nspection was passed.
operating area.

Just a tank battery

Design Features:

- tank gauging systems
- overflow prevention / high-level a
- valve locations and type (i.e., one
- spill capture aspects
- single / double wall; construction material; orientation
- tanks elevated above containment
- lightning protection
- synthetic underliner system with leak detection

Air Emission Controls

- specific waste types / tanks
- closed loop system
- maintenance program

Operational features

- waste inventory tracking (automated or manual)
- waste compatibility testing protocol
- in-house or 3rd party integrity testing (for tanks & containment (documentation, frequency, last))
- type of integrity testing (wall thickness or hydrostatic)

Secondary containment is
s passed.

area.

Just a tank battery

Design Features:

- tank gaging systems
- overflow prevention / high-level alar
- valve locations and type (i.e., one-w
- spill capture aspects
- single / double wall;
- tanks elevated abov
- lightning protection
- synthetic underliner

Air Emission Controls

- type for individual waste types / tanks
- closed loop system
- maintenance program

Transfer Station Features:

- who is off-loading the waste (trucker or facility staff)
- paved or unpaved
- secondary containment design
- spill / precipitation management (none, manually regulated, or automatic)
- electrical grounding systems

Operational features

- waste inventory trac
- waste compatibility testing protocol
- in-house or 3rd party integrity testing (for tanks & containment (documentation, frequency, last))
- type of integrity testing (wall thickness or hydrostatic)

ent is present. The most

area.

PSCI
PHARMACEUTICAL
SUPPLY CHAIN
INITIATIVE

The Review/Audit Process

Stages of the Process

Pre Visit - Preparation

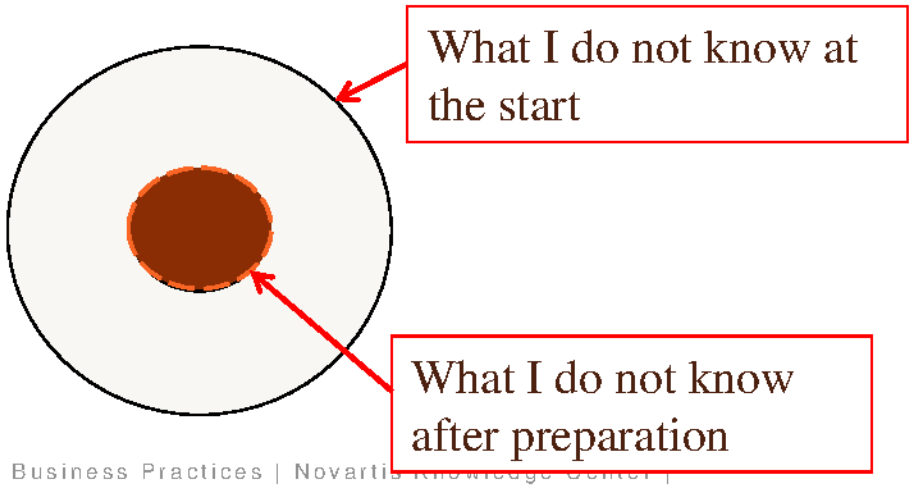
Site Visit - Verification

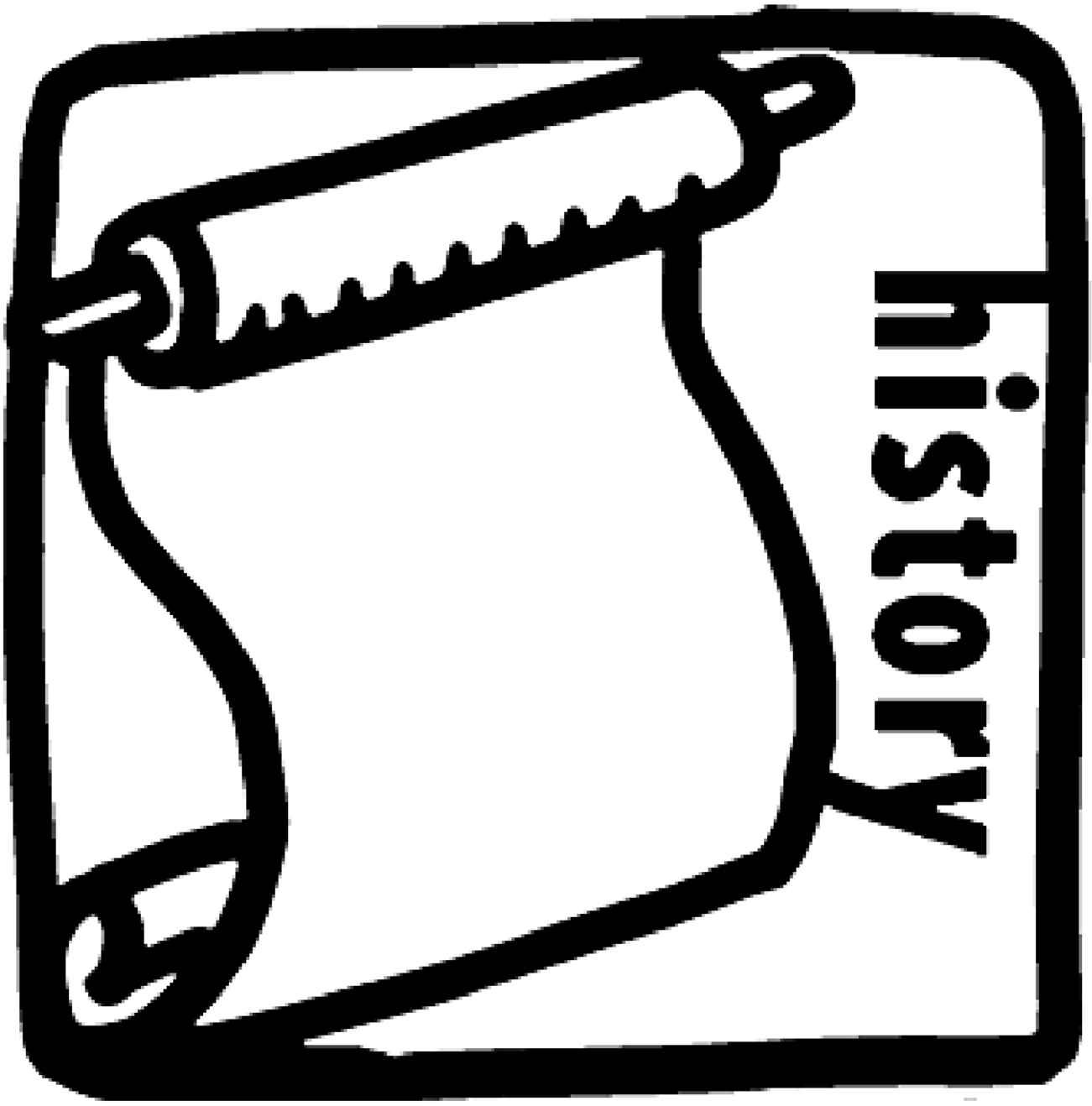
Post Visit - Evaluation

Write the Report/Final Evaluation

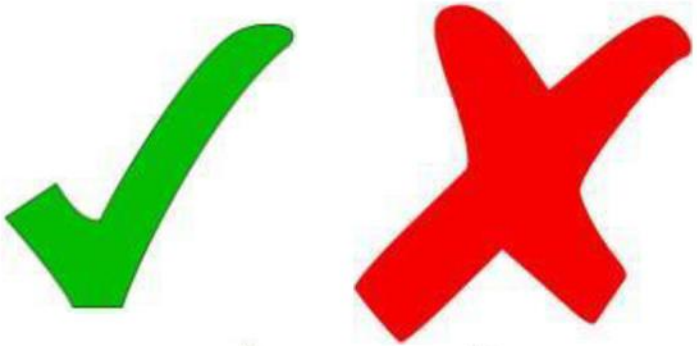
Key preparation steps before the site visit

- Verify the facility's physical location and evaluate the access route.
- Access data from regulatory, advocacy group, and company web pages
- CHECK for newspaper reports/news release on the facility
- Contact regulatory staff (case specific, interpreter help)
- Google Earth historic review




history


PESTICIDE




harmful/irritant
toxic
flammable
corrosive
radioactive
explosive


TIRES


DRAIN CLEAN
ANTI-FREEZ
BRAKE FLUID


PAINT THINNER
INSECT SPRAY
AntiFreeze Coolant

CUSTOMERS


Chevron
Phillips
Chemical Company LLC


United
Technologies


DOW CORNING


Honeywell


ExxonMobil


Shell


intel


Panasonic


BOEING


lenovo


hp
invent


xerox


NIKE


FUJIFILM


BFGoodrich

NABL

National Accreditation Board for Testing and Calibration Laboratories

Department of Science & Technology, India

CERTIFICATE OF ACCREDITATION

TCR ENGINEERING SERVICES PRIVATE LIMITED

has been assessed and accredited in accordance with the standard

ISO/IEC 17025:2005

"General Requirements for the Competence of Testing & Calibration Laboratories"

for its facilities at

MUMBAI

in the field of

CHEMICAL TESTING

Certificate Number T-0367

Issue Date 08/02/2008 Valid Until 07/02/2010

This certificate remains valid for the Scope of Accreditation as specified in the annexure subject to continued satisfactory compliance to the above standard & the additional requirements of NABL.

Signed for and on behalf of NABL

Dr. Aparna Dhawan, Convener | Dr B. Hari Gopal, Director | Dr T. Ramasami, Chairman

CQC

ISO14001 CERTIFICATE

Certificate No.: 09-2001-0123

We hereby certify that

ABB Chongqing Transformer Co., Ltd

No.1 Huayan South Village, Jiulongpo District, Chongqing, P.R.China

by reason of its

Environmental Management System

has been awarded this certificate for compliance with the standard

ISO14001: 1996

The Environmental Management System Applies in the following area:

Design, Manufacture, Service of Power Transformer (0.03-1000MVA) and Shunt Reactor (0.2-180MVAR) and Related Management Activities

Date of issue: Apr. 20, 2004 Date of expiry: Apr. 25, 2007

Signed by: Li huailin

CHINA QUALITY CERTIFICATION CENTRE

CSR Program?

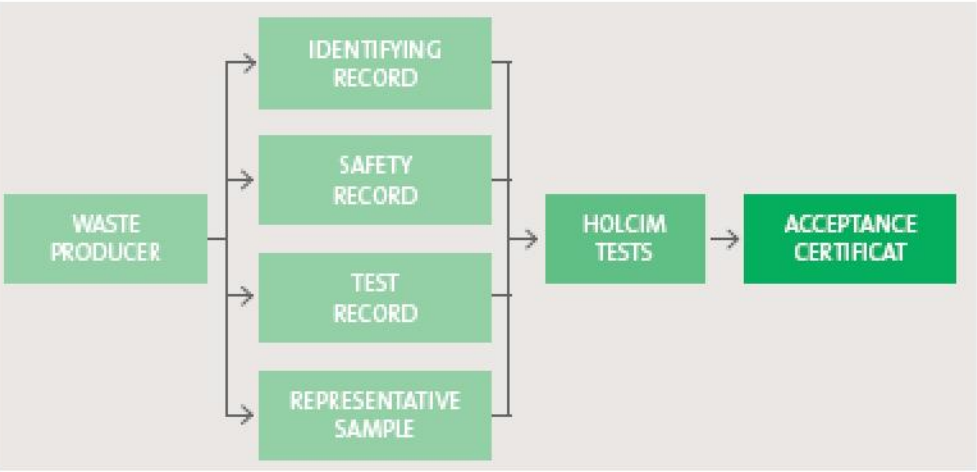
SUSTAINABILITY

GREENHOUSE GAS

RECOMMENDED AUDIT/REVIEW AGENDA

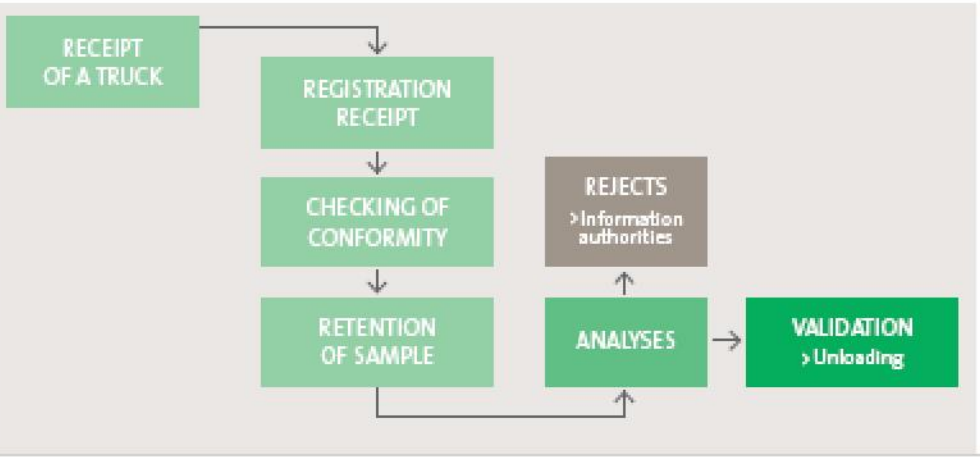
INTRODUCTIONS
BRIEF OVERVIEW
SITE TOUR
DOCUMENT REVIEW
CLOSING DISCUSSION

ACCEPTANCE PROCEDURES



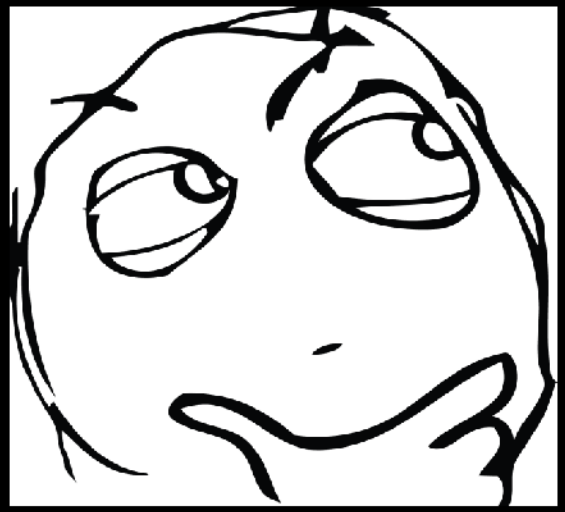
RECEPTION PROCEDURES

Different measurements
(levels of chlorine, heavy metals, halogenates etc.) are carried out in our laboratory on each delivery before unloading.



RELIANCE ON GENERATOR?

PERIODIC SAMPLING & APPROVAL UPDATES?



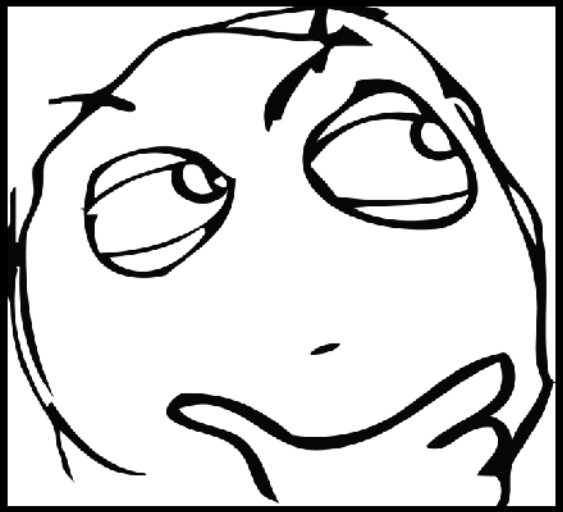
DEDICATED APPROVALS GROUP?

INSIGHTS.....


WHERE DOES
THE WASTE
ACTUALLY GO?

EXTENSIVE INVENTORY?

LARGE ON-SITE STORAGE?



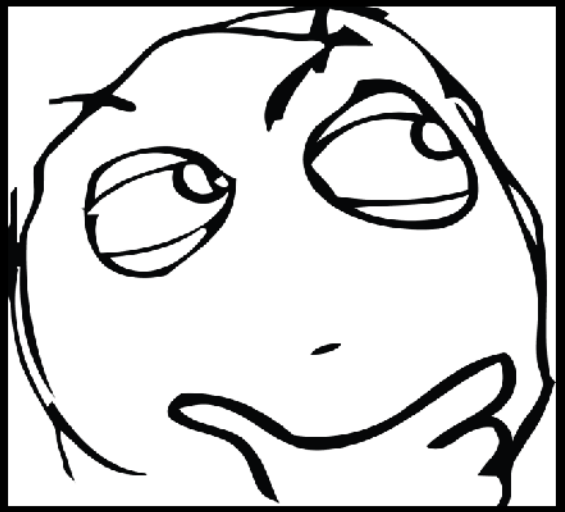
LIMITED ON-SITE STORAGE?

INSIGHTS.....


WITH YOUR SKILL AND WILL, YOU
CAN MAKE ACCIDENTS NIL
SAFETY

FATALITIES/CHEMICAL EXPOSURE INJURIES

DART RATE > INDUSTRY AVERAGE

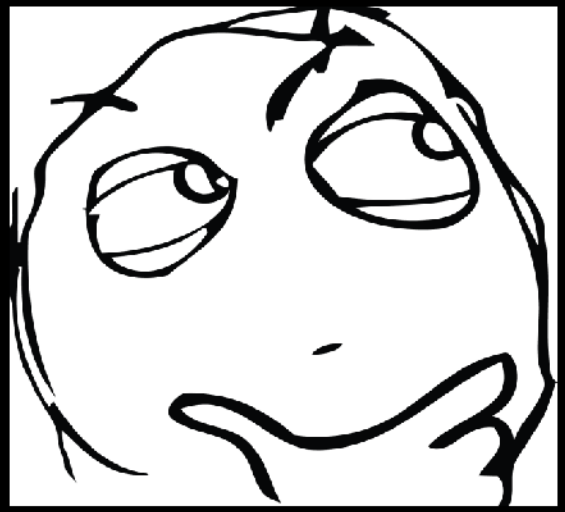


INSIGHTS…..

LONG TERM SAFETY PERFORMANCE

NO OBVIOUS SAFETY CULTURE

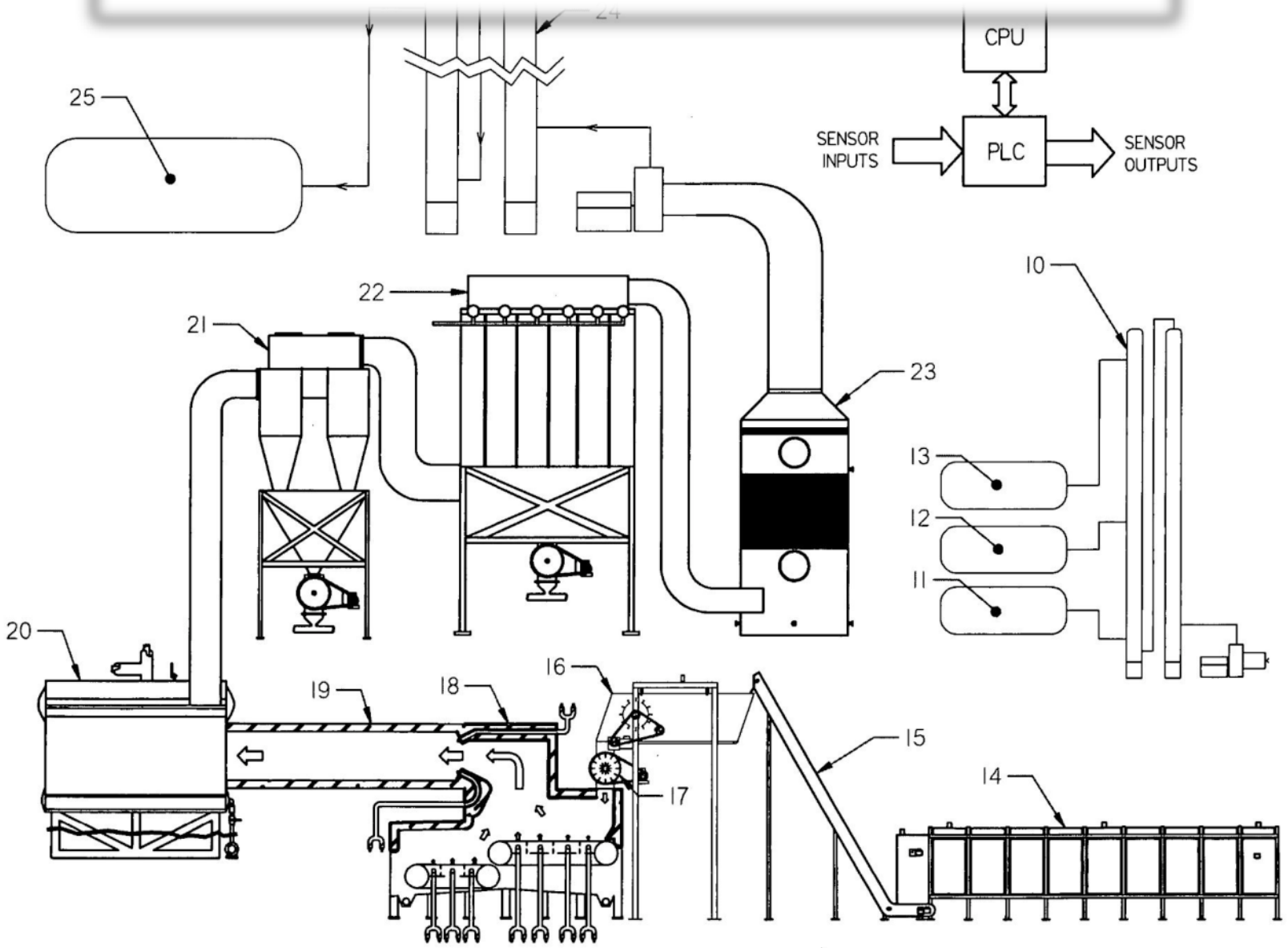
3RD PARTY HEALTH & SAFETY SUPPORT



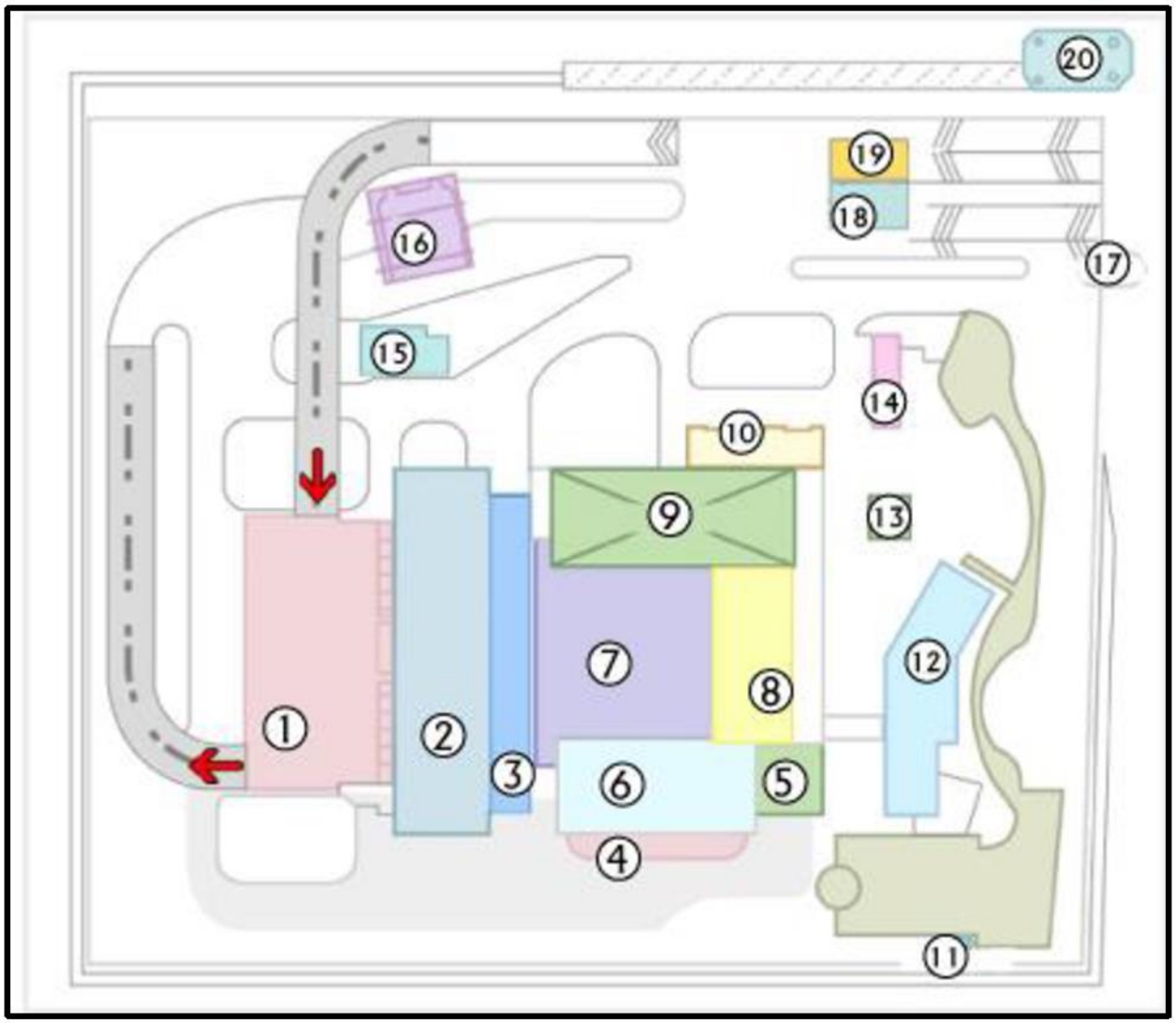
PONDER THE RISK.....

ON-SITE DEDICATED SAFETY MANAGER

FACILITY DESIGN

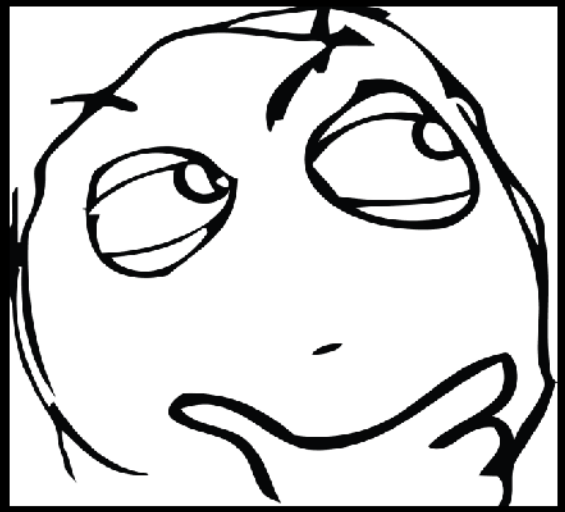


FACILITY LAYOUT



OUTDOOR UNCOVERED STORAGE

LARGE CAPACITY WASTE STORAGE AREAS WITH PROTECTIONS

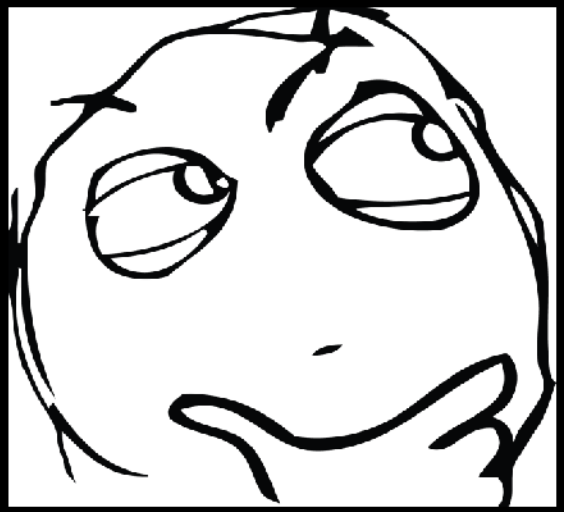


INDOOR STORAGE WITH PROTECTIONS & SMALL CAPACITY

INSIGHTS.....

PROCESSES WITH MANUAL HANDLING OF WASTE
HIGH TOUCH PROCESSES IN DEVELOPING NATIONS

HIGH TECH PROCESSES W/ HETEROGENOUS WASTES

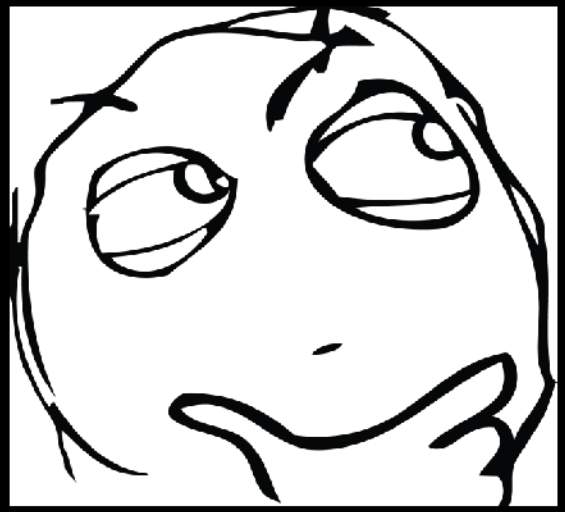


INSIGHTS.....

LOW TECH ESTABLISHED
PROCESSES W/ CONTROLS

WET HUMID SHALLOW GROUNDWATER LOCATIONS
URBAN LOCATIONS
PRIVATELY OWNED WITH LITTLE AIRSPACE REMAINING

TYPICAL ENGINEERED LANDFILLS



INSIGHTS.....

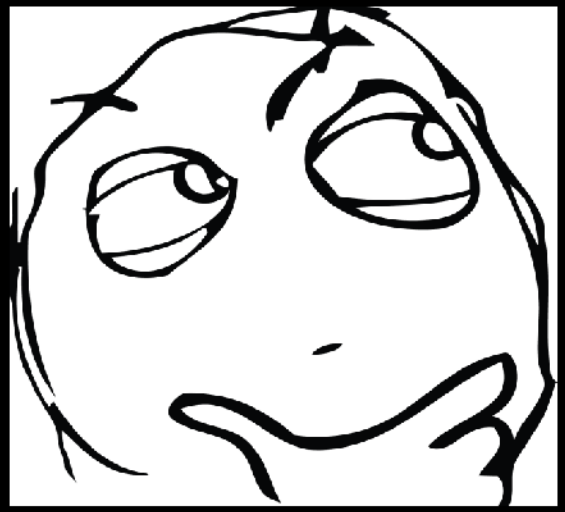
HIGHLY REGULATED
LARGE COMPANY
OPERATED
FACILITIES IN
DRY REMOTE AREAS

REGULATORY COMPLIANCE


Ministry of Environment and Natural Resources
DEPARTEMEN KELAUTAN DAN PERIKANAN
CIVIL SINGAPORE DEFENCE
ZHB
กรมควบคุมมลพิษ
Pollution Control Department
National Environment Agency
http://www.
Ministry for the Environment
Manatū Mō Te Taiao
EPA
South Australia

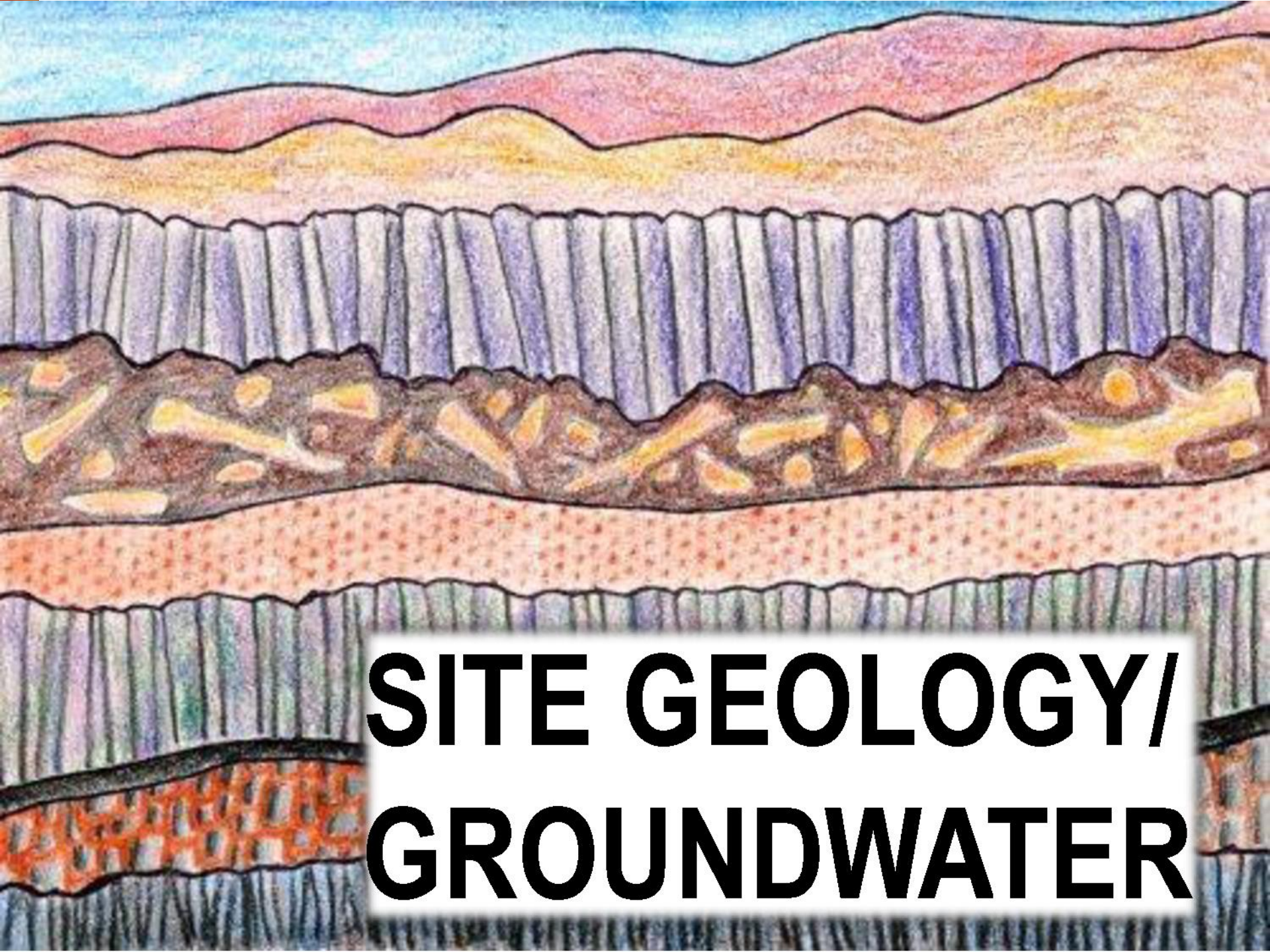
NOT REGULATED
INFREQUENT REGULATORY INSPECTIONS
ENVIRONMENTAL CRIMES
FRICTION WITH REGULATORS

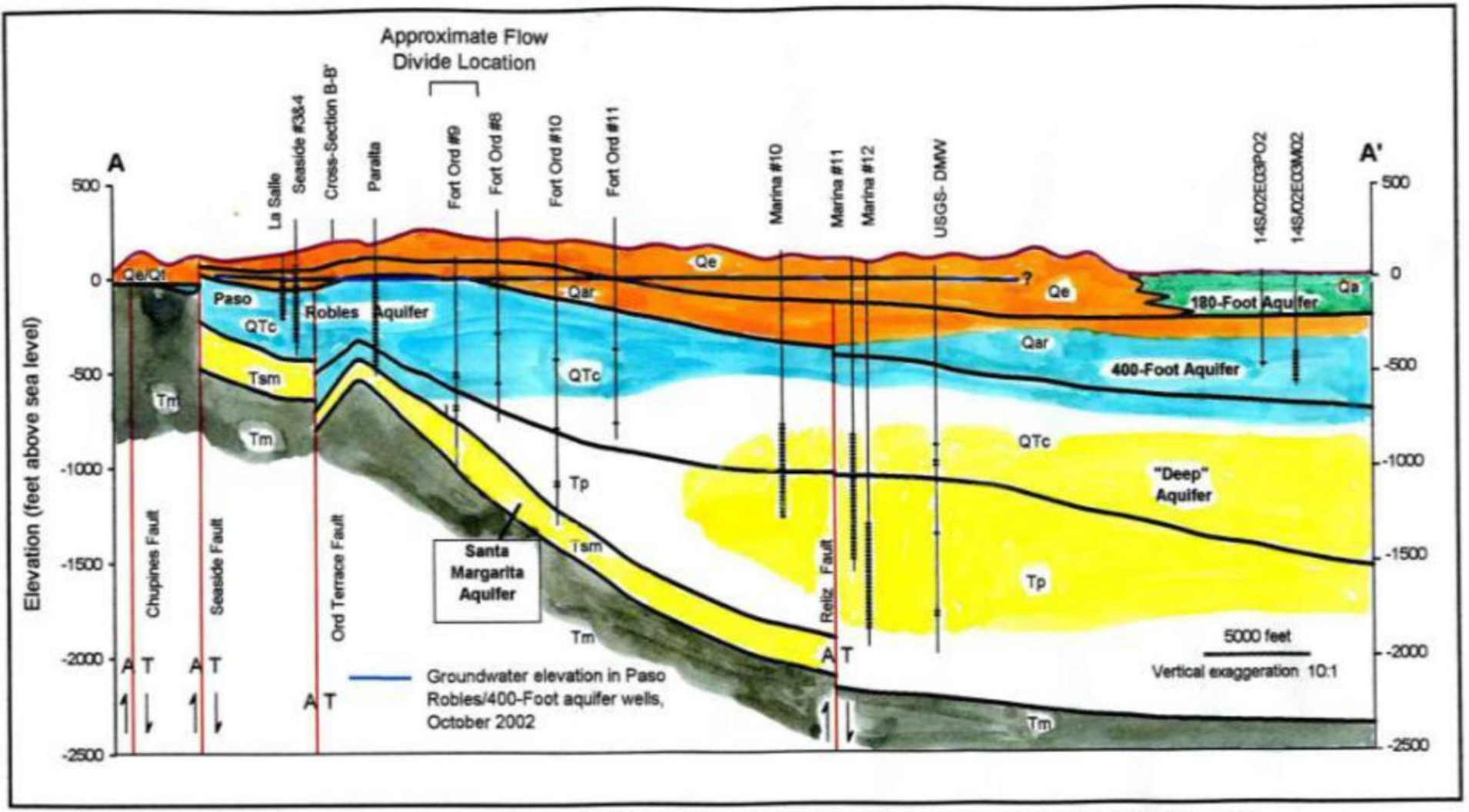
ANNUAL REGULATORY INSPECTIONS
PERMITS IN LONG RENEWAL

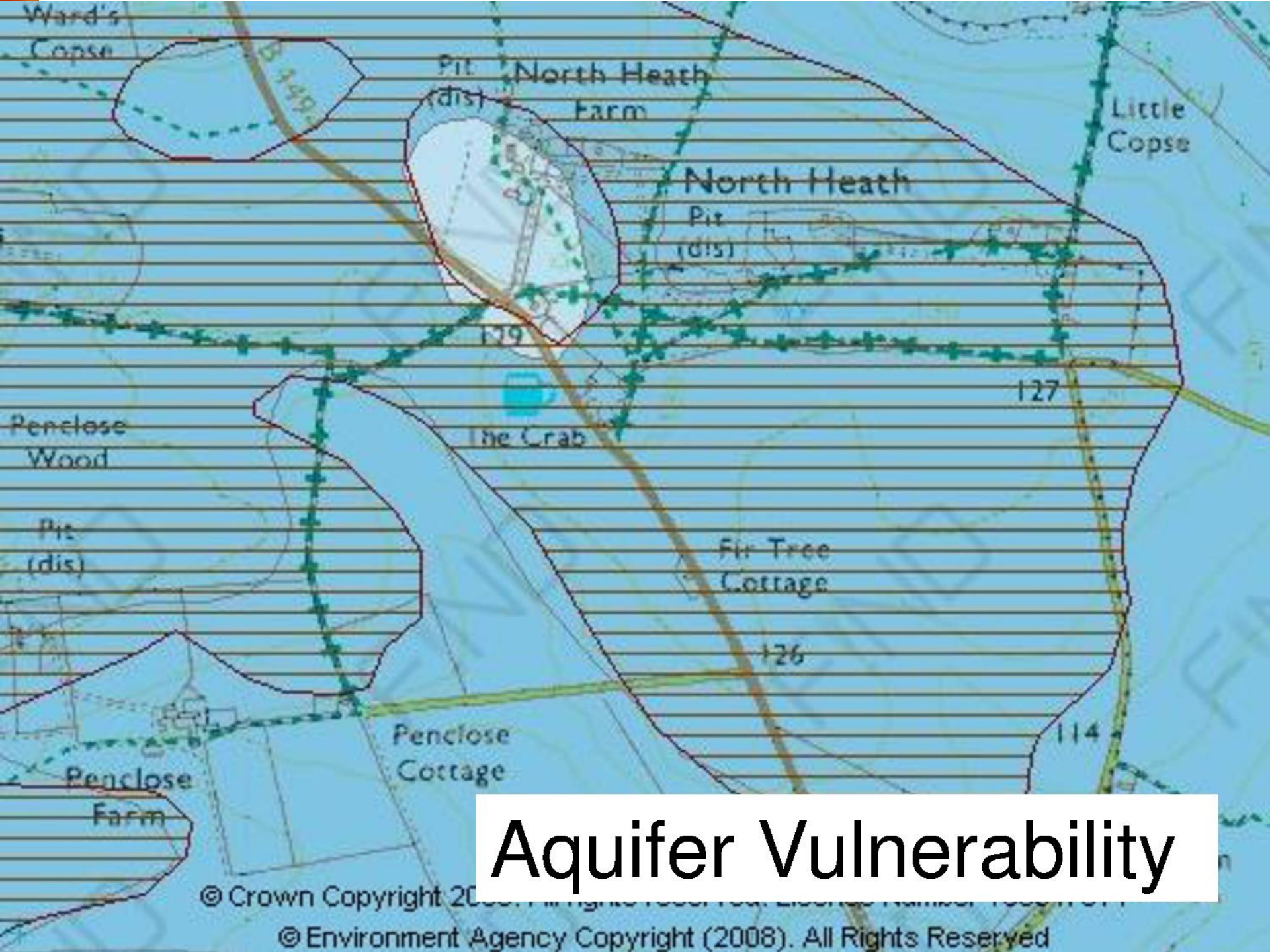


MULTIPLE AGENCY REGULATION
VERY FREQUENT INSPECTIONS
ALL PERMITS CURRENT

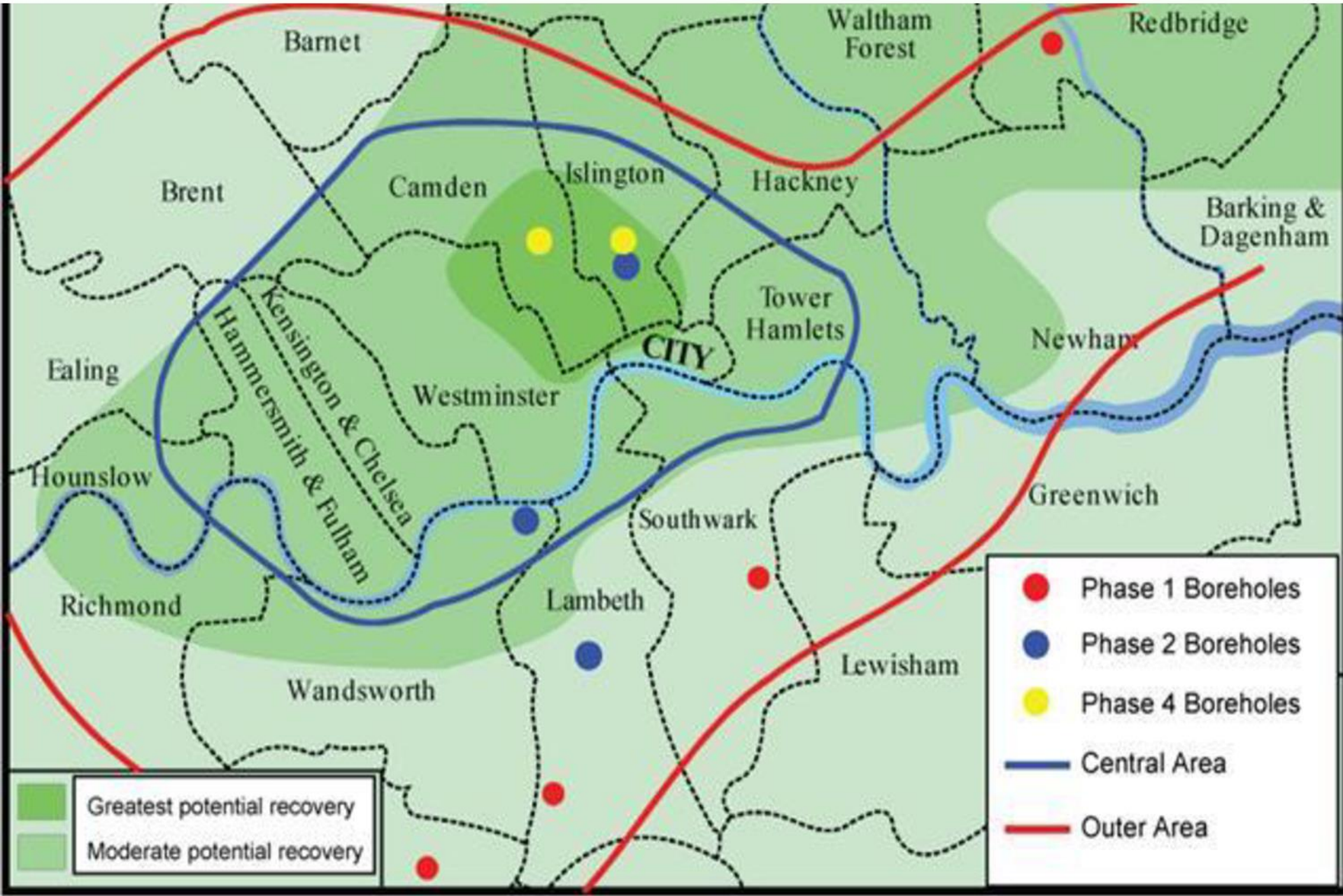
INSIGHTS.....


SITE GEOLOGY/
GROUNDWATER


Approximate Flow Divide Location
A
A'
La Salle
Seaside #3&4
Cross-Section B-B'
Paralta
Fort Ord #9
Fort Ord #8
Fort Ord #10
Fort Ord #11
Marina #10
Marina #11
Marina #12
USGS- DMW
14S/02E03P02
14S/02E03M02
Elevation (feet above sea level)
500
0
-500
-1000
-1500
-2000
-2500
Qe/Qt
Paso Robles Aquifer
QTc
Tsm
Tm
Qe
Qar
?
Qa
180-Foot Aquifer
400-Foot Aquifer
"Deep" Aquifer
Tp
Santa Margarita Aquifer
Chupines Fault
Seaside Fault
Ord Terrace Fault
Reliz Fault
A T
Groundwater elevation in Paso Robles/400-Foot aquifer wells, October 2002
5000 feet
Vertical exaggeration 10:1



Proximity to Water Supplies

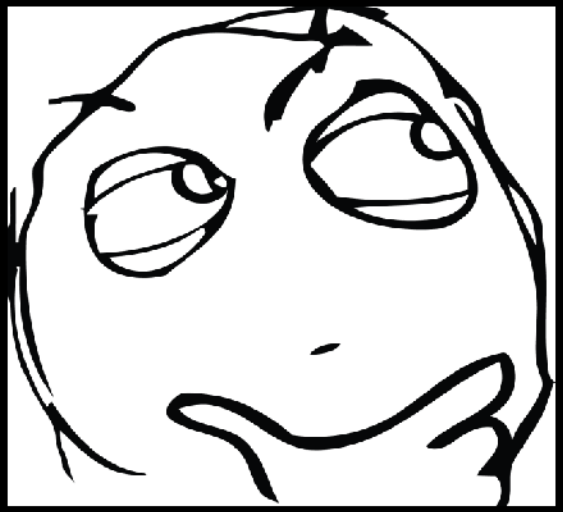


Groundwater Monitoring

Scale: 1:25,000 at A3

ANY NEARBY WATER SUPPLY
KARST GEOLOGY AREAS

HISTORICAL GROUNDWATER
CONTAMINATION & REMEDIATION



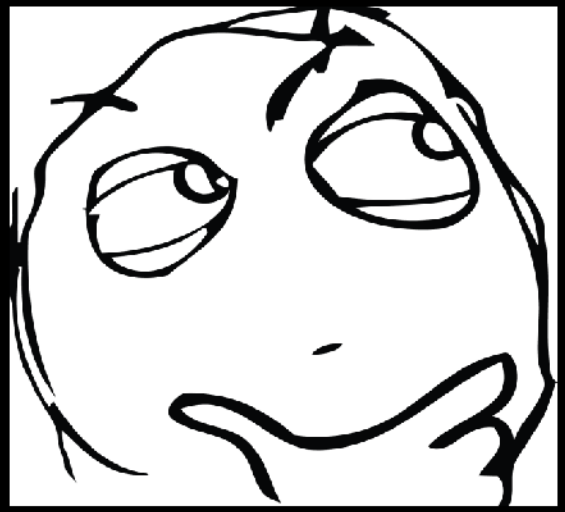
ARID CLIMATE
NO GROUNDWATER RESOURCES

INSIGHTS.....

ADJACENT TO ANY WATERWAY
POPULATION >1000 WITHIN 1 MILE
ADJACENT RESIDENCES

INDUSTRIAL PARK SETTING
MIXED LAND-USE AREA

REMOTE AND RURAL



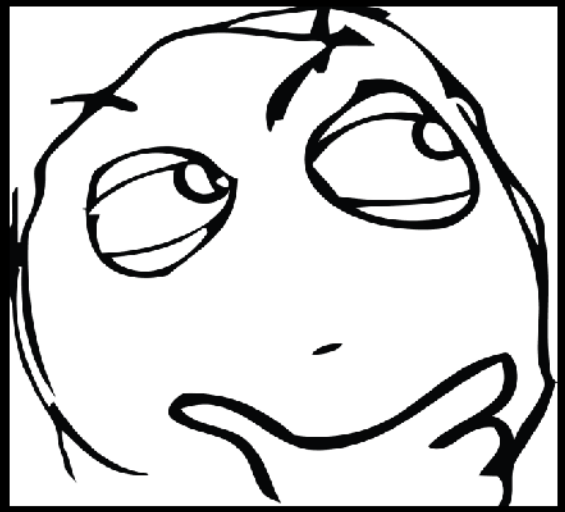
INSIGHTS.....

INCIDENTS & REMEDIAL ACTIONS

FREQUENT INCIDENTS
PENDING CORRECTIVE ACTION

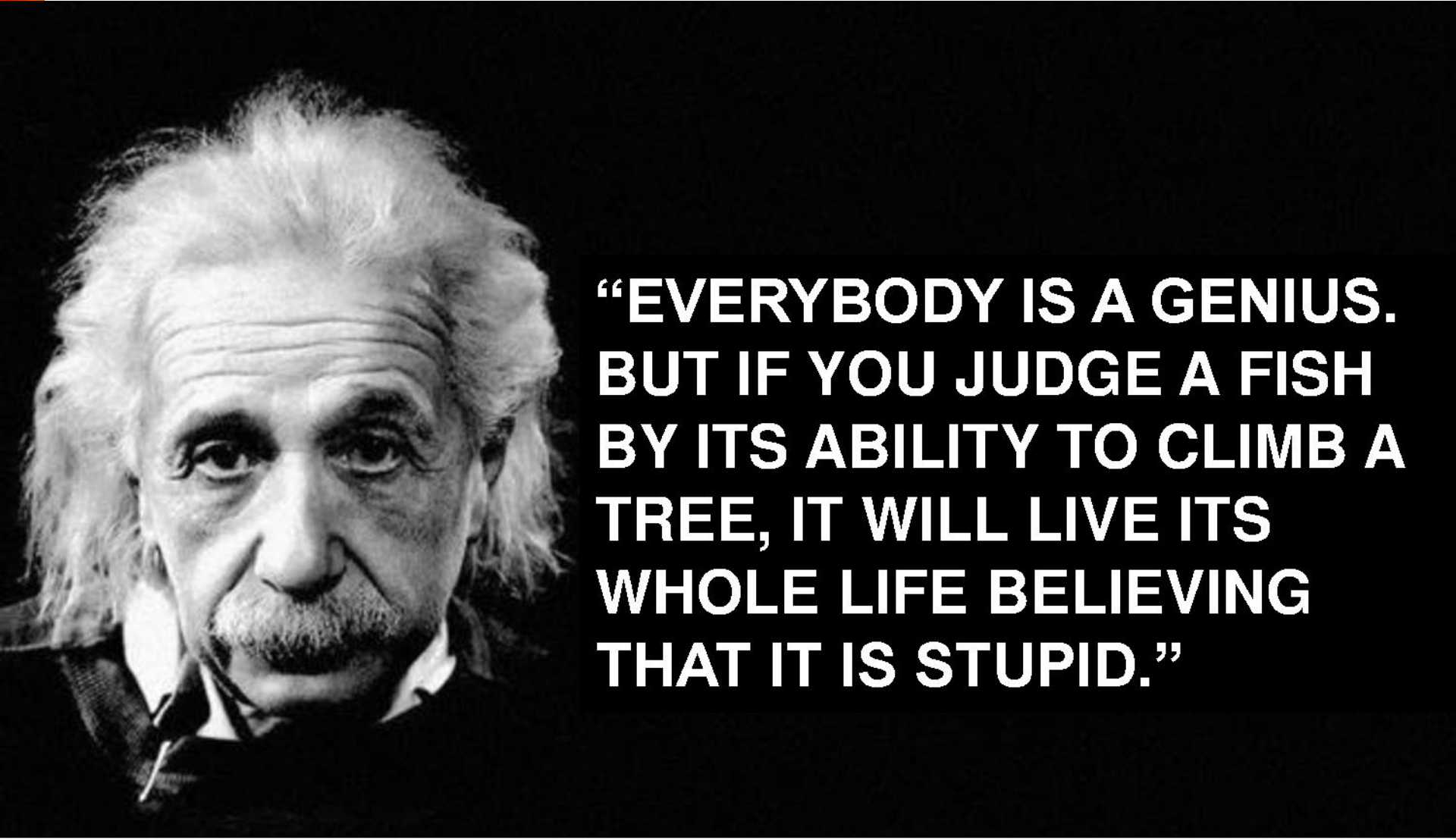
SOME INCIDENTS
HISTORY OF CORRECTIVE ACTION
ON-GOING REMEDIATION

NO INCIDENTS
NO HISTORY OF
CORRECTIVE ACTION



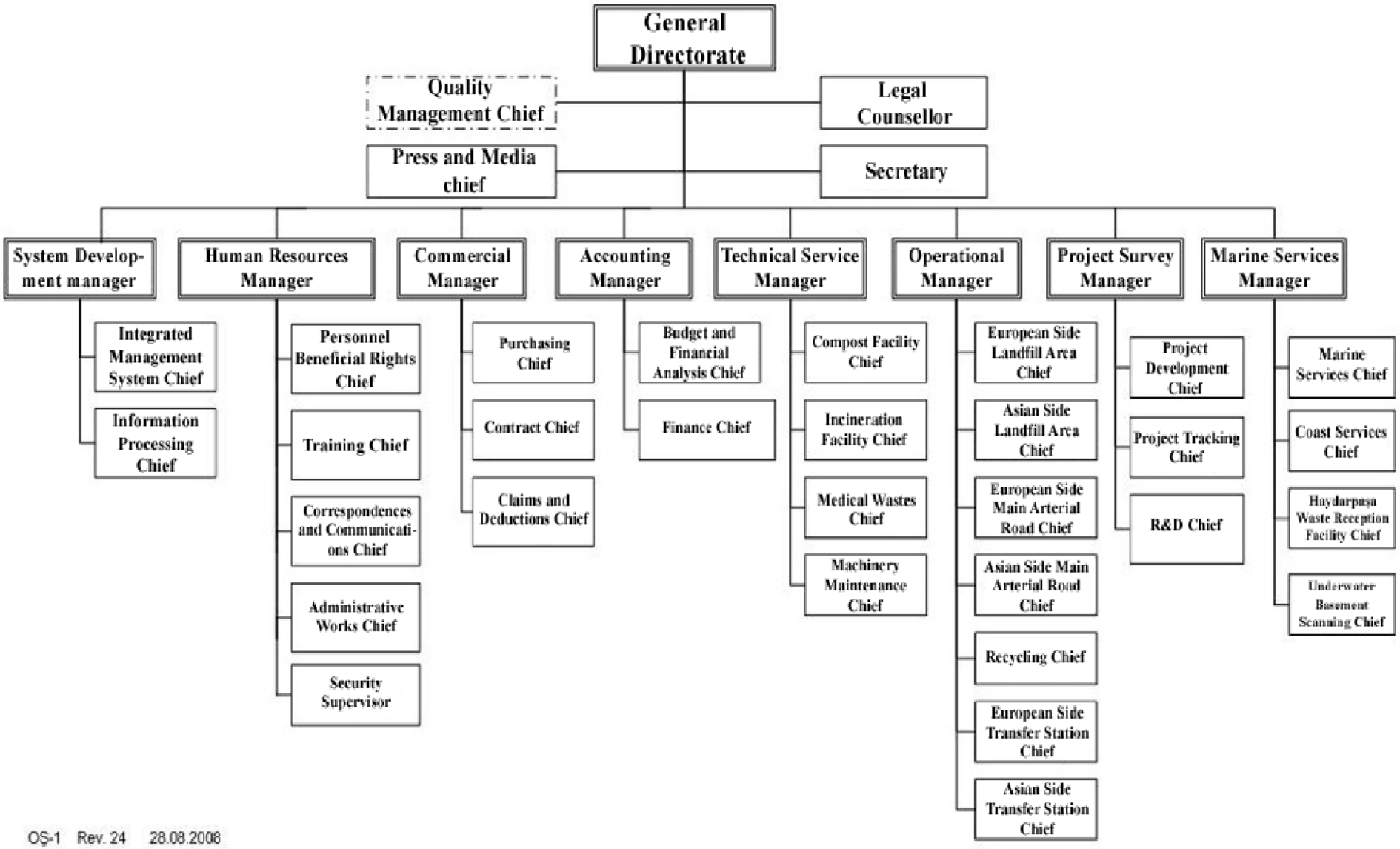
INSIGHTS.....

MANAGEMENT/PERSONNEL



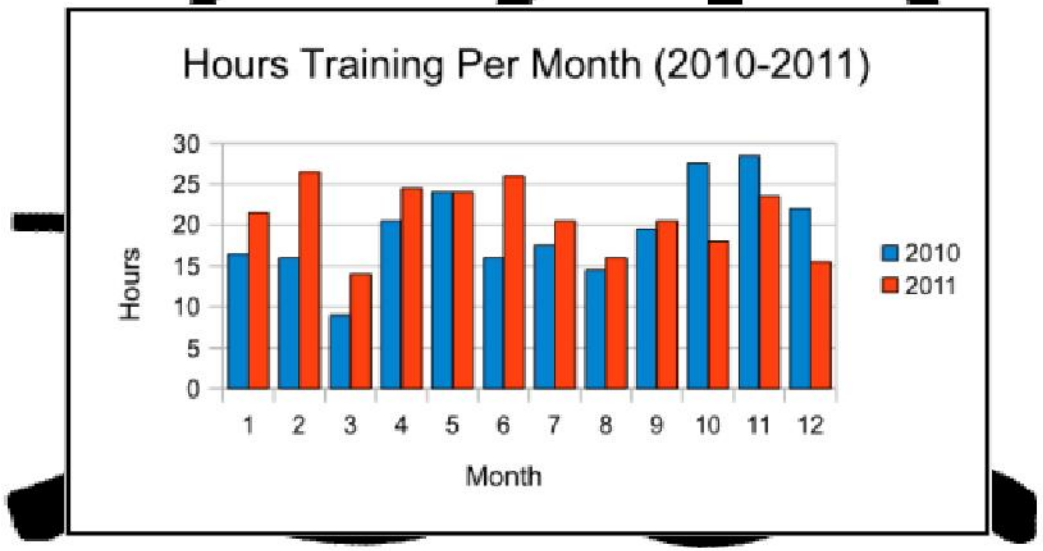
EDUCATION + QUALIFICATIONS + EXPERIENCE + COMPETENCY

ORGANIZATION CHART



training


TRAINING
TOPICS


Hours Training Per Month (2010-2011)
Hours
30
25
20
15
10
5
0
1
2
3
4
5
6
7
8
9
10
11
12
Month
2010
2011

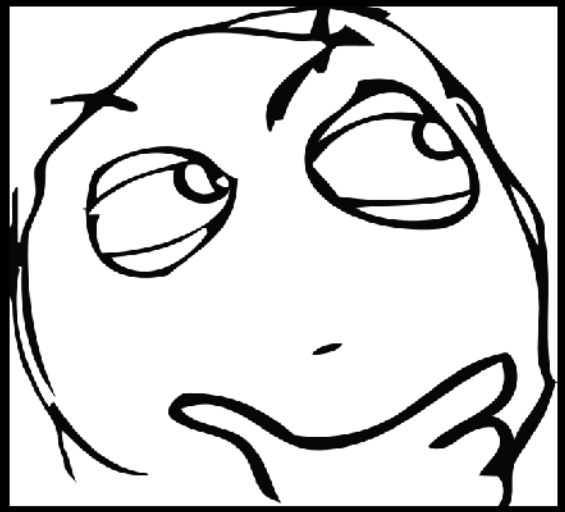
INTERNAL?
EXTERNAL?

AUDIT - an assessment of policies and procedures to determine if they are being properly followed/implemented.


EMERGENCY
RESPONSE PLAN

MINIMUM ON-SITE MANAGEMENT EXPERIENCE
NO 3RD PARTY TECHNICAL SUPPORT & OVERSIGHT
LIMITED MANAGEMENT SYSTEMS
MINIMAL FIRE PROTECTION

RELEVANT SITE MANAGEMENT EXPERIENCE
SOME MANAGEMENT SYSTEMS



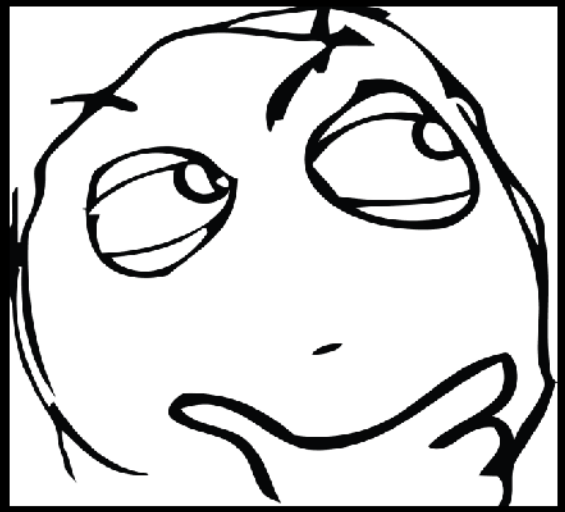
EXPERIENCED & ROBUST
MANAGEMENT TEAM
MANY MGMT SYSTEMS
24/7 AUTOMATED FIRE
PROTECTION

INSIGHTS.....


FINANCIAL STRENGTH

FAILURE TO DISCLOSE FINANCIALS
NO RECENT CAPITAL INVESTMENTS
LOW OWNER'S EQUITY
HEAVY DEBT SERVICE

VARIABLE BALANCE SHEET



STRONG BALANCE SHEET
ANNUAL CAPITAL IMPROVEMENTS
LOW DEBT SERVICE

INSIGHTS.....

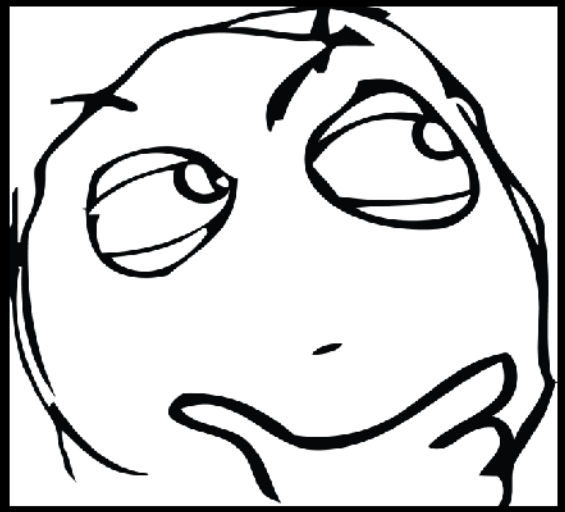
INSURANCE


INSURANCE
CLAIM FORM
COVERAGE LIMITS
DEDUCTIBLES
EXCLUSIONS
ACCIDENT / INCIDENT INFORMATION

NO ENVIRONMENTAL LIABILITY INSURANCE

MINIMUM INSURANCE COVERAGE

INSURANCE LIMITS
IN EXCESS OF REQUIREMENTS



INSIGHTS…..

COMMUNITY RELATIONS

Hybrid News Limited
asian correspondent.com

APRIL 2013

Over 500 villagers protest China factory pollution

By AP News Sep 18, 2011 3:30AM UTC

BEIJING (AP) — Hundreds of villagers in eastern China have demonstrated in recent days against pollution they say is caused by a solar panel factory, with some protesters storming the compound an Sunday.

COMMUNITY COMPLAINTS

More than 500 villagers in Zhejiang province's Haining city gathered in front of the Zhejiang

Fukushima protesters urge Japan to abandon nuclear power

Tens of thousands join Fukushima protest march in Tokyo amid continuing fears over radiation

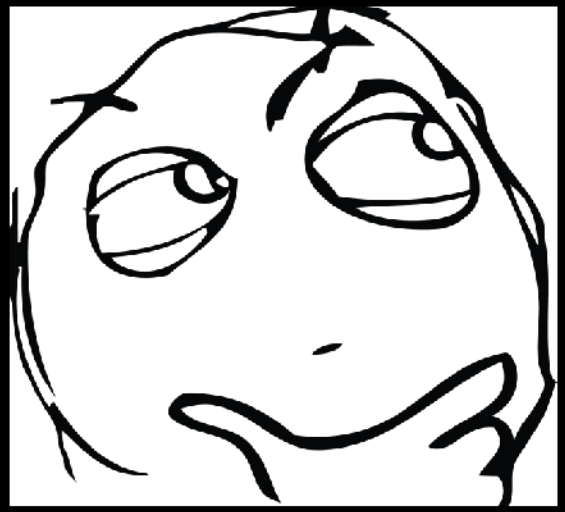
Justin McCurry in Tokyo
guardian.co.uk, Monday 19 September 2011 13.48 BST
Article history

PROACTIVE COMMUNITY PROGRAMS

LONG TERM COMMUNITY COMPLAINTS
LONG TERM COMMUNITY OPPOSITION
EXTENSIVE MEDIA COVERAGE

PERIODIC MINOR COMPLAINTS

WIDESPREAD COMMUNITY SUPPORT / ENGAGEMENT



INSIGHTS.....

EMPLOYEE & CONTRACTOR BACKGROUND CHECKS

LOW RISK

?

or

HIGH RISK


CHWMEG®
REPORT

CONTENTS

Section/Topic

Executive Summary

Altman Z Financial Strength Graph*

Risk Assessment System (RAS) Summary Table*

RAS Graphs*

FACILITY QUESTIONNAIRE Page

A: GENERAL INFORMATION 2

B: FACILITY OPERATIONS XX

C: FACILITY DESIGN XX

D: REGULATORY COMPLIANCE XX

E: SITE GEOLOGY/GROUNDWATER XX

F: LOCATION XX

G: INCIDENT NOTIFICATIONS AND REMEDIAL ACTIONS XX

H: MANAGEMENT PERSONNEL XX

I: FINANCIAL STRENGTH XX

J: INSURANCE XX

K: COMMUNITY RELATIONS XX

L: SECURITY XX

ATTACHMENTS

A: FACILITY COMMENTS & CONTRACTOR RESPONSE

B: SITE PLOT PLAN

C: SITE PHOTOGRAPHS WITH REFERENCE PLOT PLAN

D: FIGURES

E: CLOSURE PLAN & CLOSURE COST ESTIMATE

F: FINANCIAL INFORMATION

G: INSURANCE INFORMATION

H: ADDITIONAL RELEVANT INFORMATION PROVIDED BY FACILITY

I: EXPLANATION OF THE ALTMAN "Z" SCORE*

J: OTHER FACILITY CUSTOMERS AS IDENTIFIED BY RCRA BRS DATA*

K: FACILITY TRANS-SHIPMENT FACILITIES AS IDENTIFIED BY BRS & TRI DATA*

L: RISK ASSESSMENT SYSTEM OVERVIEW AND FACILITY-SPECIFIC DATA*

* *Information provided by CHWMEG, Inc. Administrator*


Regulatory Compliance
Management Personnel
Geology/Groundwater
Financial Strength
Location
Insurance
Incident Notifications/
Remedial Actions
Design
Security
Operations
Community Relations

Who/What is CHWMEG ?

CHWMEG is a non-profit trade association comprising of over **280** member enterprises, comprising of nearly **800** individual manufacturing and other "industrial" companies interested in efficiently managing the risks associated with the waste management aspects of their environmental stewardship program.

CHWMEG's objectives include assisting these companies in assessing and minimizing their business risks associated with the management of manufacturing-related wastes.

Chevron Phillips Chemical Company LLC

United Technologies

DOW CORNING

Abbott

Honeywell

ExxonMobil

Shell

intel

Panasonic

syngenta

BOEING

lenovo

GE

hp invent

Pfizer

xerox

NIKE

FUJIFILM

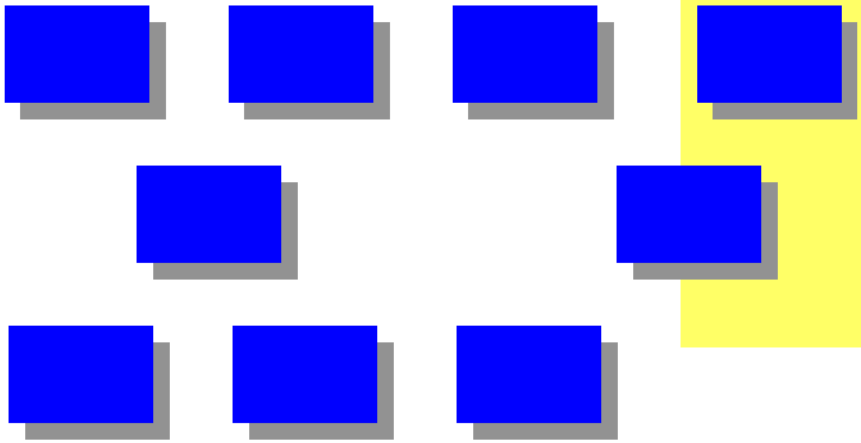
BFGoodrich

3M

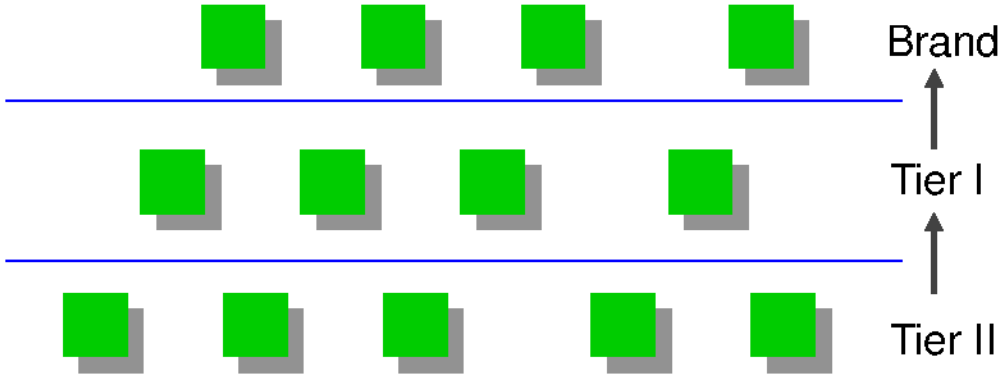
NORTHROP GRUMMAN

News Corp

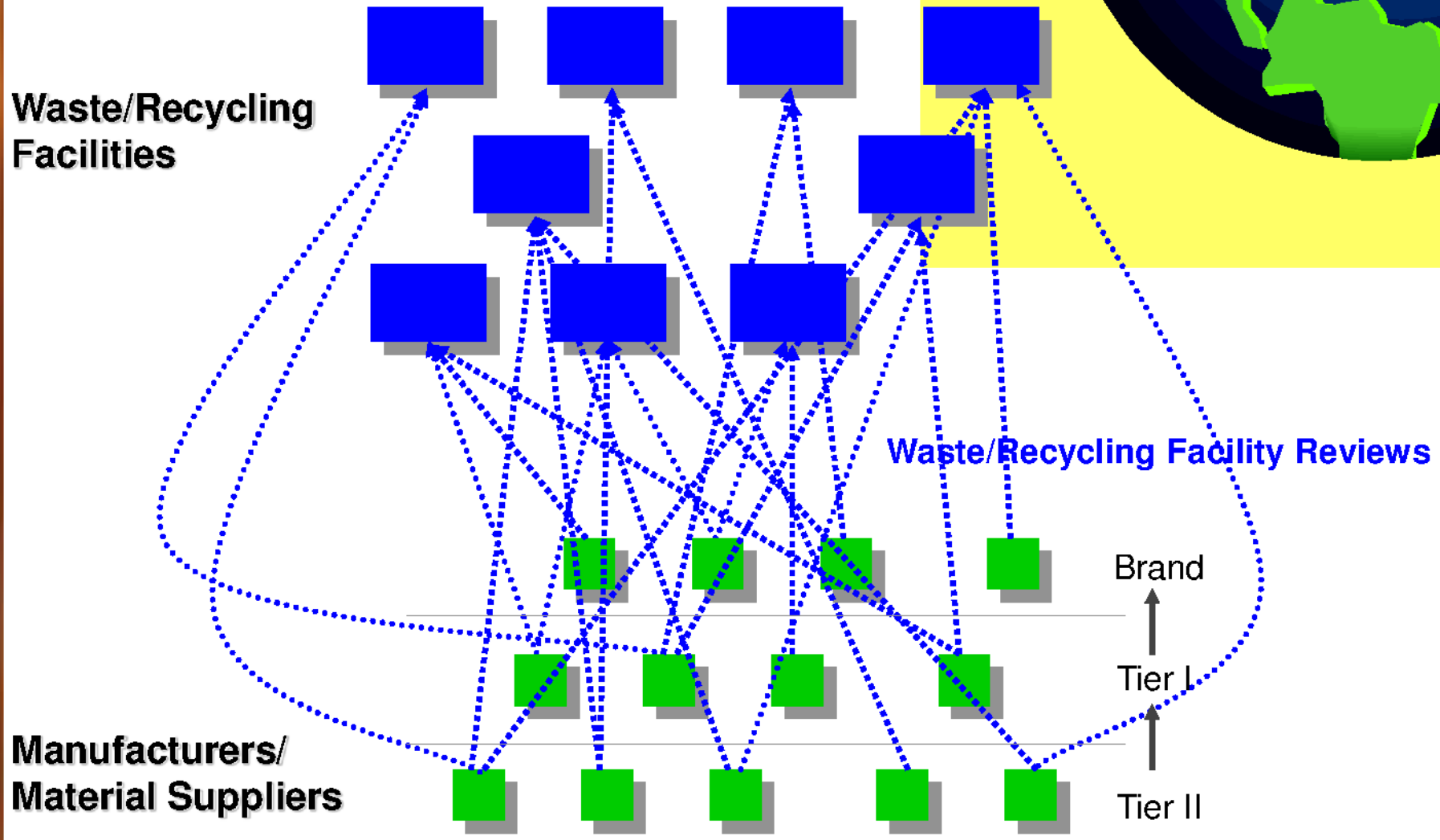
Waste/Recycling Facilities



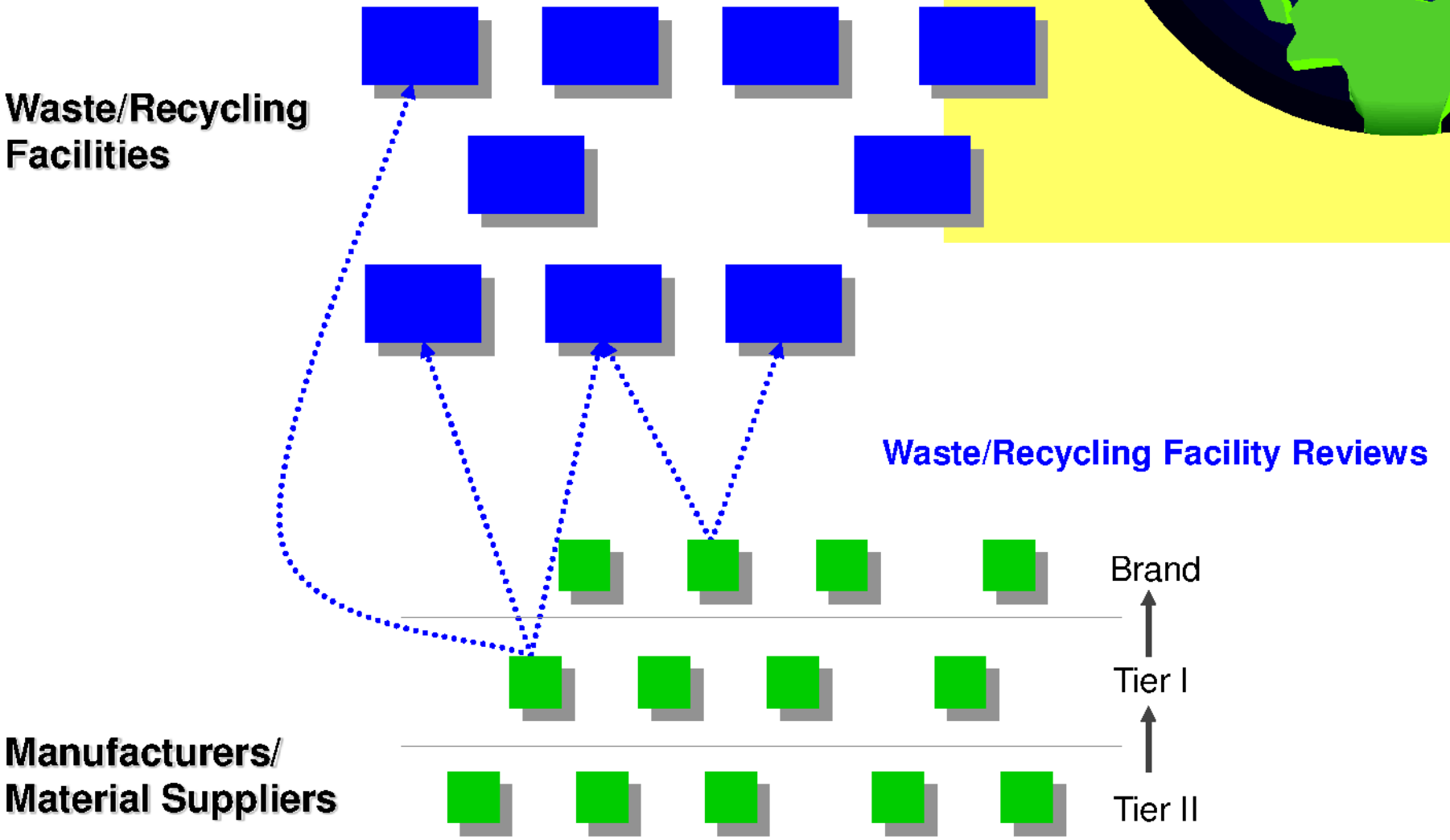
Manufacturers/ Material Suppliers (Users of Waste/Recycling Services)



Ideally: Active Engagement by the Entire Supply Chain

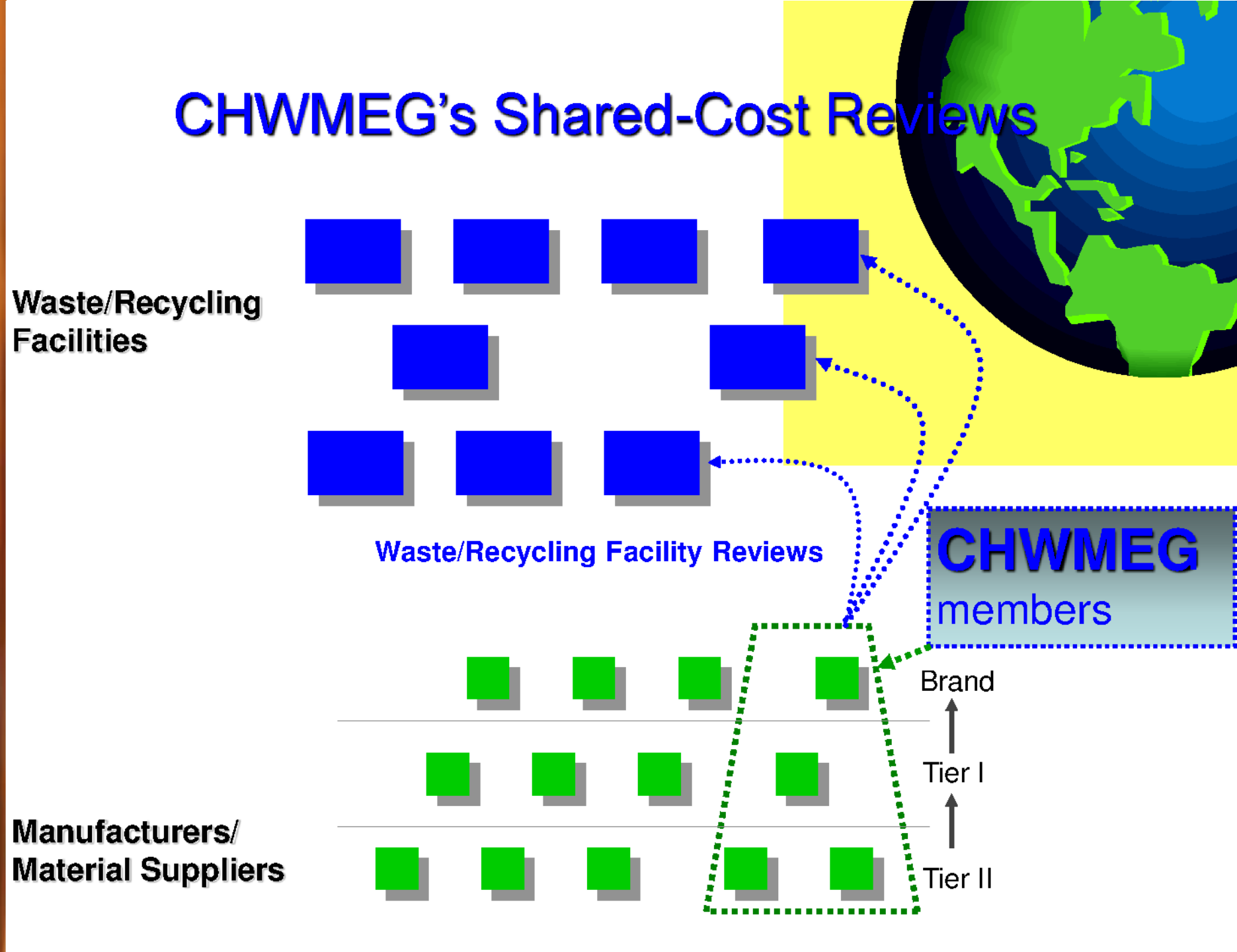


Reality: Limited or Zero Supply Chain Engagement



- CHWMEG provides streamlining and cost-sharing opportunities to all tiers for improved waste/ environmental stewardship

CHWMEG's Shared-Cost Reviews



CHWMEG Facility Review Program Participation Benefits (1 of 2)

- Individual member cost savings exceeds US$1 million for some
  - member savings =
    - cost to collect CHWMEG-type information
      - about a facility, less…
    - cost to obtain CHWMEG report for a facility
- Aggregate member savings (thru 2016) exceeds US$51 million

CHWMEG Facility Review Program Participation Benefits (2 of 2)

- Assists with supplier risk management and *cost-avoidance* (avoided facility clean-up expenses cannot be estimated, but are real; members report that CHWMEG information has "guided" them away from poor suppliers)
- Outcomes from engaged members reduces environmental aspects and improves local conditions
- Product "environmental footprint" is reduced

CHWMEG's Contribution

- Objective, comprehensive risk information
- Conducted by "worlds-best" and most experienced 3rd party facility reviewers
- Cost sharing provides information-gathering support at substantial cost savings

Facilities Reviewed in Asia

Country	No. of Facilities		Country	No. of Facilities
China (incld HKG)	41		Singapore	10
India	15		South Korea	6
Indonesia	3		Sri Lanka	1
Japan	7		Taiwan	4
Malaysia	6		Thailand	8
Philippines	6		Turkey	9
Russia	3		Ukraine	1
Saudi Arabia	2		Vietnam	2
Israel	4			
Australia	21		New Zealand	4
Total Countries	**18**			
No. of Facilities	**153**			

Technically, Australia and New Zealand are not part of Asia but they are put in together because of coverage for AP office

PSCI
PHARMACEUTICAL
SUPPLY CHAIN
INITIATIVE

Conclusion:

No real right or wrong as it all depends on the local conditions and availability of alternative facilities that can manage your waste. The key is gathering the correct, detailed information to help you make an informed decision, and how to manage the risks associated with using a particular facility with the information gathered.

Mr. David Chng

asia-pacific@chwmeg.org

Tel: +65 92378445

Globally Promoting Responsible Waste Stewardship

end of presentation

Industrial Hygiene

PSCI

PHARMACEUTICAL SUPPLY CHAIN INITIATIVE

PSCI Potent Compound Banding System

Presented by

Pinky Bhatt, CIH

[Project Manager – India, South East Asia and Middle East]

[International Safety Systems, Inc.]

PSCI
PHARMACEUTICAL SUPPLY CHAIN INITIATIVE

Bio

International Safety Systems, Inc.

- Graduate from BITS, Pilani
- Certified Industrial Hygienist from the American Board of Industrial Hygiene
- Project Manager with ISS, India office

Pinky Bhatt, CIH
International Safety Systems, Inc.
Email: pinky.bhatt@issehs.com

Agenda

PSCI
PHARMACEUTICAL
SUPPLY CHAIN
INITIATIVE

1. Control Banding
2. Exposure and Hierarchy of Controls – general guidelines
3. Controls verification/validation
4. Q & A

Agenda

PSCI
PHARMACEUTICAL
SUPPLY CHAIN
INITIATIVE

1. Control Banding
2. Exposure and Hierarchy of Controls – general guidelines
3. Controls verification/validation
4. Q & A

PSCI
PHARMACEUTICAL SUPPLY CHAIN INITIATIVE

Control Banding – What is it?

Occupational Health Categorization technique to identify controls and working environment based on potency/toxicity of compounds.

- A band describes a distinct range of OELs
- The control banding is categorized – 1-5
- 1 being the least potent and 5 being the most potent
- Different organizations may have different bands
- Generally the banding system is similar

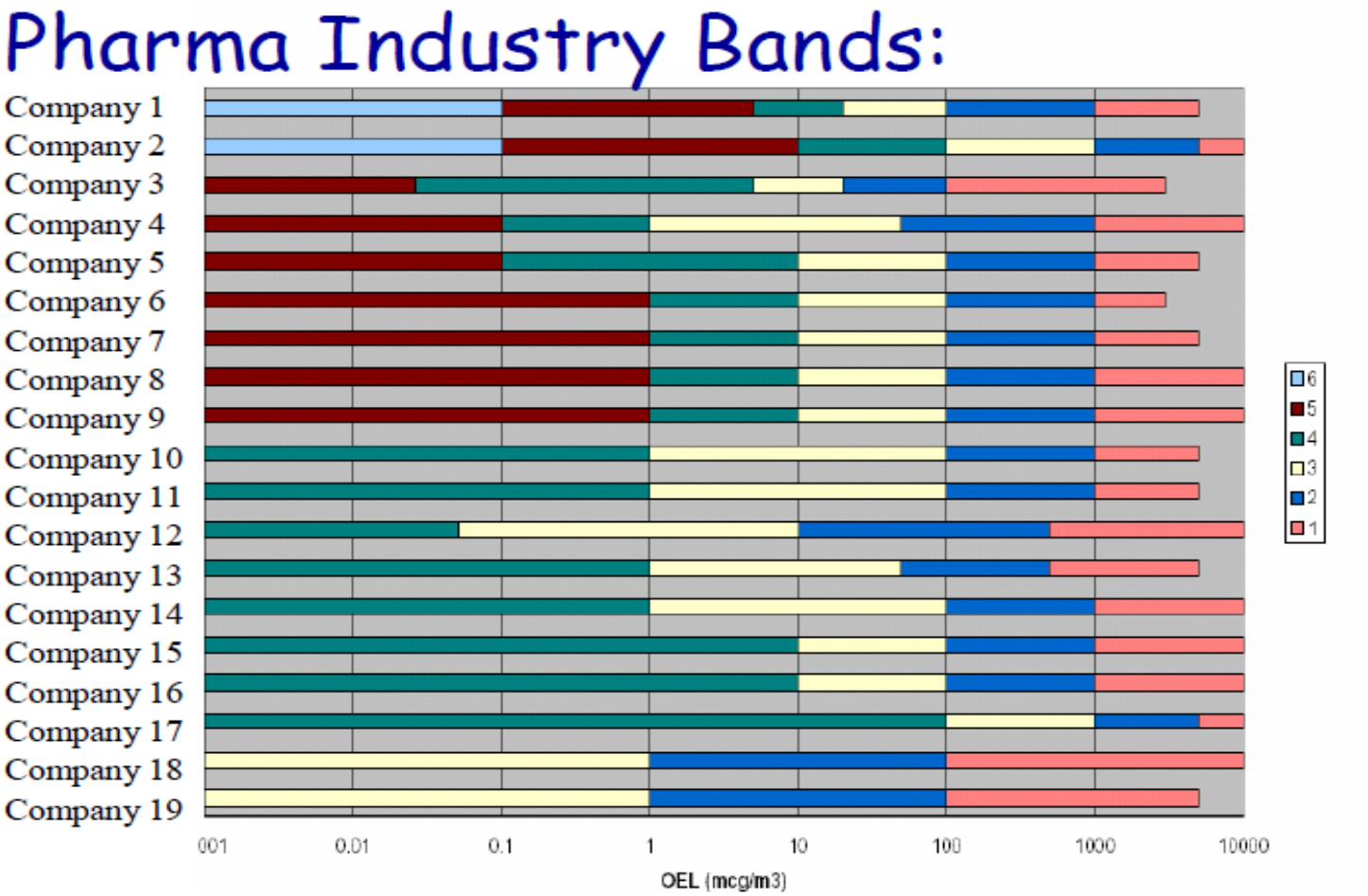
Common Banding system

OEB	Range of OEL ($\mu g/m^3$)	Description
1	> 1000	Not harmful, not irritating and/or low pharmacological activity, unlikely to be carcinogen or reproductive toxin
2	100-1000	Harmful, may be irritant and/or moderate pharmacological activity
3	10-100	Moderately toxic and/or high pharmacological activity, possibility of being carcinogen or reproductive toxin exists
4	1-10	Toxic, may be corrosive, Known to be carcinogen and/or reproductive toxin, sensitizing or genotoxic and/or very high pharmacological activity
5	< 1	Extremely toxic and corrosive, known to be carcinogen and/or reproductive toxin, sensitizing or genotoxic and/or extremely high pharmacological activity

Similar for major pharmaceutical companies, may differ slightly and hence very much essential to mention the range

PSCI
PHARMACEUTICAL SUPPLY CHAIN INITIATIVE

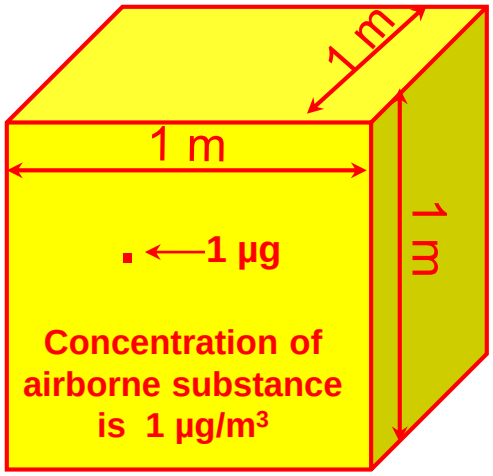
Different banding systems



Units of OELs

Particulate airborne substances:

- µg/m^3 - micrograms of airborne substance per cubic meter of air
- mg/m^3 - milligrams of airborne substance per cubic meter of air



Vapor/gaseous airborne substances:

- ppm (parts per million) - the parts of airborne substance per million parts of air
- ppb (parts per billion - the parts of airborne substance per billion parts of air)

OELs and OEBs

Occupational Exposure Limits (OELs)

- Airborne concentration of a substance
- Repeated exposure to the substance below exposure limit day after day is unlikely to produce adverse health effects in healthy workers
- Guidelines to control the potential workplace health hazards
- Established based on
  - industrial experience
  - experiments on humans
  - and/or experiments on animals

Exposure limits are not
a fine line between safe and dangerous concentrations

OELs and OEBs

Occupational Exposure Bands (OEBs)

- Exposure limits are not available/ developed for lot of APIs
- OEB is determined based on toxicity of an API
- Control strategy is established based on OEB levels
- Validated exposure monitoring methods are not available for many APIs
- Additional measurements such as surrogate can be used if validated analytical methods are not available

Some more information based on OEBs

Criteria	OEB 1	OEB 2	OEB 3	OEB4	OEB 5
Irritation	Normally not an irritant	Slight to moderate	Moderate	Corrosive	Extremely corrosive
Likelihood of Chronic effects (Cancer, reproductive)	Unlikely	Unlikely	Possible/Probable	Known	Known
Reversibility	Reversible	Reversible	Reversible/Slowly reversible	Irreversible	Irreversible
Disability	Unlikely	Unlikely	Possible/Probable	Known	Known

PSCI
PHARMACEUTICAL
SUPPLY CHAIN
INITIATIVE

Agenda

1. Control Banding
2. **Exposure and Hierarchy of Controls - general guidelines**
3. Controls verification/validation
4. Q & A

Exposure

- Risk = *f* (Hazard, Exposure)

- Exposure potential depends upon
  - Physical properties such as moisture content, fluffiness, particle size
  - Quantity
  - Duration
  - Frequency
  - Process controls
  - Engineering controls
  - Administrative controls
  - PPE/RPE

PSCI
PHARMACEUTICAL SUPPLY CHAIN INITIATIVE

Hierarchy of Controls

Elimination

Substitution

Process Changes

Engineering Controls

Administrative Controls

Personal Protective Equipment

Respiratory Protective Equipment

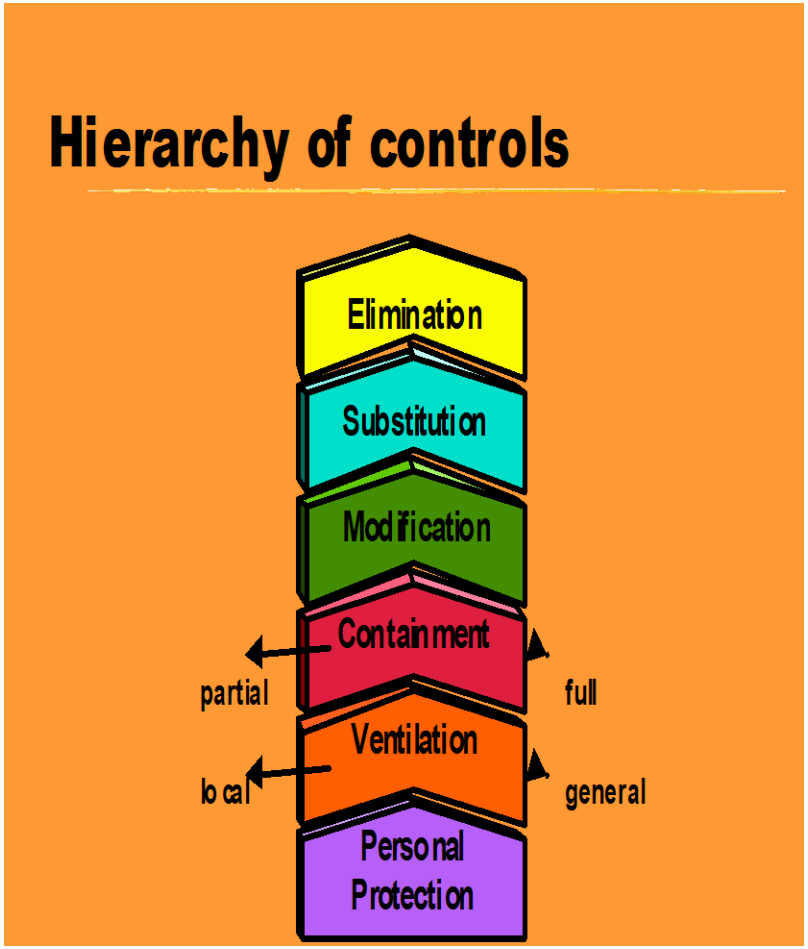
Exposure controls are implemented if exposure assessment confirms exposures or 95th percentile exposure estimate (statistically determined exposure profile) are above OEL or ½ of OEL if feasible

PSCI
PHARMACEUTICAL SUPPLY CHAIN INITIATIVE

Containment and Control Strategies

The choices:

- Can exposure source be eliminated or substituted?
- Can exposure be controlled at source (use process, or engineering options)
- Consider procedures or administrative controls
- Consider PPE as a last resort



Technologies to Consider - example

OEB LEVEL	*OEL Range (ug/m3)*	*Control Technology & Material handling options:*
1	*> 1000*	*General Ventilation, drums, Intermediate Bulk Containers(IBCs) , typical sealing systems*
2	*100 - 1000*	*Local Exhaust Ventilation, drums, IBCs, improved sealing systems*
3	*10 - 100*	*Laminar Flow , IBCs preferred, split butterfly valves or improved sealing systems, wash in place*
4	*1 – 10*	*Negative pressure isolator, IBCs recommended, Rapid Transfer Ports , spilt butterfly sealing valves, flexible film containment, Clean In Place (CIP)*
5	*< 1*	*Remote Operations, use OEB4 techniques, CIP*

Recommended elements to be covered under exposure controls

PSCI
PHARMACEUTICAL SUPPLY CHAIN INITIATIVE

- Facility Design
- Room and Work Surfaces
- HVAC Systems
- Local Exhaust Ventilation
- Process Equipment
- Unit Operations: Weighing, charging, milling, blending, sieving, etc.
- Laboratories
- Product Transfers
- Maintenance and Cleaning
- Medical Surveillance
- Work Methods and SOPs
- PPE and Respirators
- Waste Containment and Disposal
- Additional items…

General Handling Philosophy - example

OEB	Controls
1	Open handling permitted after assessing exposures
2	Open handling acceptable after assessing exposures for low dust-generating operations . Consider ventilation, close transfer
3	Same as OEB 2, consider quantity
4	Open handling not permitted for large scale operation (i.e., > 1kg powder and 22 L, Liquid. For small scale, use fume hoods or other ventilated control device
5	Open handling not permitted.

LEV and Capture Devices - example

OEB	Controls
1	LEV may be necessary to minimize dust or vapor levels at process points.
2	Same as OEB 1
3	LEV required at all dust or vapor generating operations and exhausted to the outside through HEPA filters. Fume hoods and other open-face containment acceptable only with face velocities of 80-120 fpm (0.5 m/s). Most APIs are solids and fume hoods are typically used for handling liquids.
4	LEV required at all dust or vapor generating operations and exhausted to the outside through HEPA filters. Full enclosure (containment) ventilation systems recommended. Fume hoods and other open-face containment devices are not permitted for production and pilot plant scale.
5	Full enclosure (containment) ventilation systems required. Fume hoods and other open-face containment devices not permitted.

PSCI
PHARMACEUTICAL SUPPLY CHAIN INITIATIVE

LEV and Capture Devices

- No thumb rule
- Decision may differ case by case
- Decisions best taken by a trained Industrial Hygienist and the site EHS team after reviewing toxicological data, usage conditions, API properties to name a few
- What about APIs near categorization borders?
  - API with OEL 12 µg/m^3 OEB 3 or 4??
  - API with OEL 9 µg/m^3 OEB???

PSCI
PHARMACEUTICAL SUPPLY CHAIN INITIATIVE

Laboratories (< 1 kg scale) - example

- OEB 1-3:
  - Standard laboratory design to meet exposure control requirements
- OEB 4:
  - No Open Handling of Solids, No Floor Drains
  - All process equipment (e.g., mixers, rotovaps, etc.) should be within a hood when in-use.
  - Single Pass Air strongly recommended
  - Chemicals stored in ventilated storage cabinets
  - Plumbed emergency eye wash and safety showers
  - Offices outside laboratory space
  - Lab Space negative to adjacent corridors/offices
- OEB 5: OEB 4+ Laboratory design to include use of isolators, provision of air locks

Zoning

PSCI
PHARMACEUTICAL SUPPLY CHAIN INITIATIVE

- Red
  - Potentially contaminated area
  - Not used for gowning
- Yellow
  - Less or no contamination
  - De-gowning area
- Green Zoning
  - Clean non-contaminated area
  - Paper work is done
  - Gowning is done

Gowning and de-gowning for Low OEB 3, OEB 4 and OEB 5 - example

PSCI
PHARMACEUTICAL SUPPLY CHAIN INITIATIVE

- Two pairs of disposable (if feasible)
  - Gloves
  - Gowns
  - Shoe Cover
- Safe disposal of outer pair after work is performed in Red Zone just before entering Yellow Zone to prevent potential contamination in Green Zones.

PSCI
PHARMACEUTICAL SUPPLY CHAIN INITIATIVE

Personal Protective Equipment

- Respiratory Protective Equipment
  - Air purifying respirators
    - Filters (for particulates)
    - Cartridges (for gases and vapors)
    - Canisters
  - Powered Air Purifying Respirators
  - Atmosphere Supplying
    - Supplied Air Respirators
    - Self Contained Breathing Apparatus
    - Combination of above two
- Skin protection
  - Capability of the material to protect

PSCI
PHARMACEUTICAL
SUPPLY CHAIN
INITIATIVE

Agenda

1. Control Banding
2. Exposure and Hierarchy of Controls – general guidelines
3. Controls verification/validation
4. Q & A

Exposure Assessment

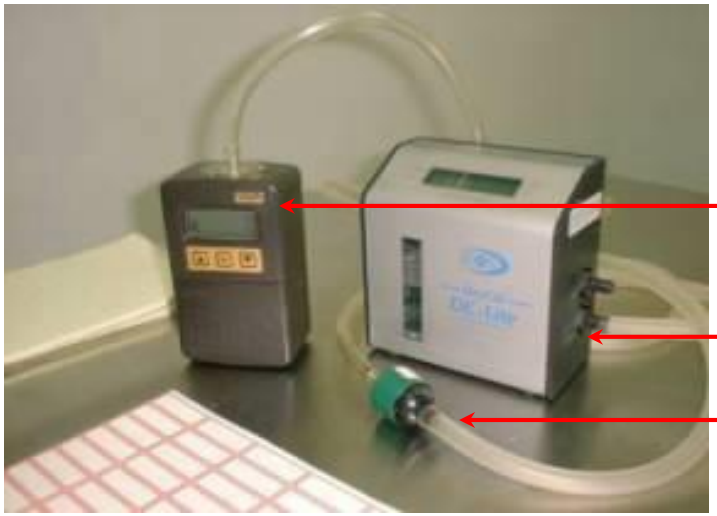
PSCI
PHARMACEUTICAL
SUPPLY CHAIN
INITIATIVE

- One of the preferred methods to verify control measures provided
- Qualitative Exposure Assessment
- Quantitative Exposure Assessment
  - Active monitoring with surface wipe sampling
  - Detector tubes (not relevant for APIs, only for solvents)
  - Passive monitoring
  - Direct reading (mainly for solvents and only indicative method)

PSCI
PHARMACEUTICAL
SUPPLY CHAIN
INITIATIVE

Active Air Monitoring

Sampling media



Sampling pump

Calibrator

Sampling media

PSCI
PHARMACEUTICAL SUPPLY CHAIN INITIATIVE

Active Air Monitoring

- American Industrial Hygiene Association (AIHA) accredited laboratory and/or ISO 17025 certified
- API specific methods developed for sampling and analysis
- Levels of detection extremely low – as low as Nano grams or micrograms to obtain interpretable data for APIs and surrogates
- Gravimetric methods are not recommended as it is normally very difficult to achieve interpretable results for APIs with very low limits
- Surrogate monitoring (Lactose, Naproxen Sodium, Mannitol) performed for low OEL APIs (OEB 3, 4 and 5 typically) where API sampling and analytical method is not available
- Similar train for other products that can be sampled and the results compared to the other API limits

Containment Validation
Good Practices Guidelines - ISPE

PSCI
PHARMACEUTICAL SUPPLY CHAIN INITIATIVE

- International Society for Pharmaceutical Engineering (ISPE) developed guidelines
- Standardized Measurement of Equipment Particulate Airborne Concentration (SMEPAC) Committee
- ISPE Good Practice Guide: Assessing the Particulate Containment Performance of Pharmaceutical Equipment
- Standardized method of measuring
  - Performance of containment systems against specific challenge
  - Establish an agreed and valid method that can be used to meet the requirements of practitioners and supplier organizations
- Performed for Isolator, flexible film containment, Laminar Flow booth, single point transfer system, ventilated balance enclosure
- Lactose, Naproxen sodium, Mannitol used as surrogate

PSCI
PHARMACEUTICAL
SUPPLY CHAIN
INITIATIVE

Agenda

1. Control Banding
2. Exposure and Hierarchy of Controls – general guidelines
3. Controls verification/validation
4. Q & A

PSCI

PHARMACEUTICAL SUPPLY CHAIN INITIATIVE

LEV and HVAC Concepts and Design

Presented by

Arun Verma

Business Head – Clean Process & Containment

PSCI
PHARMACEUTICAL SUPPLY CHAIN INITIATIVE

Bio

Business Head – Clean Process & Containment

Camfil Air Filtration India Pvt Ltd.

Tasks:

Application Engineering and Consulting Professional for Clean Processes mainly in Life Sciences , Containment and Comfort Applications. Specializes in Pharmaceutical Clean Room Filtration Solutions

Education:

BE Production Engineering

Work experience:

24 Years in HVAC Ventilation , Clean Processes , Comfort Filtration solutions

Arun Verma
Camfil Air Filtration India Pvt Ltd.
Business Head – Clean Process & Containment
Email: arun.verma@Camfil.com

Clean Air Expert – Since 1963…

- Swedish family owned business
- Started more than 50 years ago
- Top class products and services

Camfil factory 1960´s

Gösta Larson, founder

PSCI
PHARMACEUTICAL SUPPLY CHAIN INITIATIVE

CAMFIL GROUP

FILTERS

Comfort

Clean Process

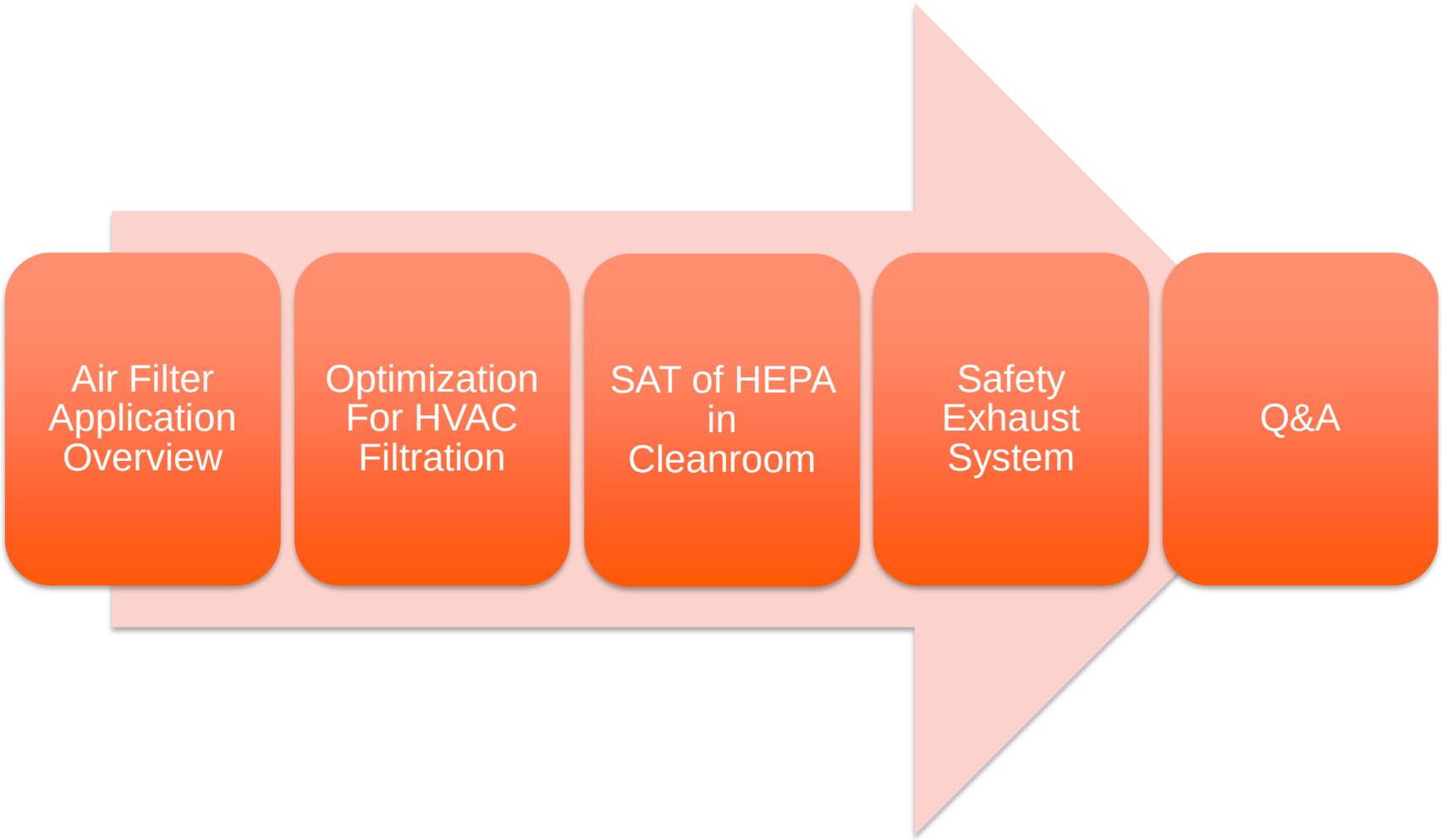
Industrial

Containment

AIR POLLUTION CONTROL

POWER SYSTEMS

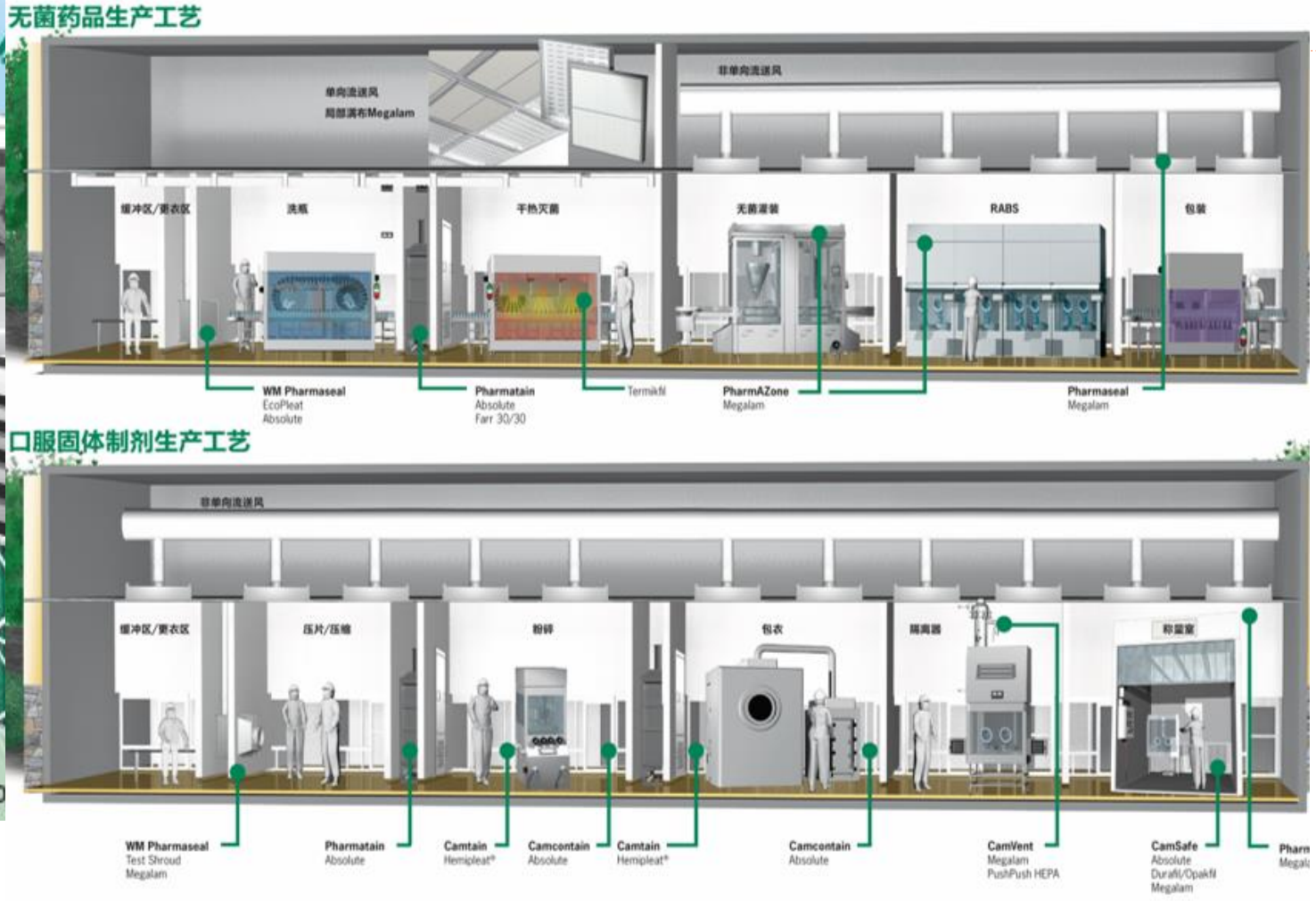
PSCI
PHARMACEUTICAL
SUPPLY CHAIN
INITIATIVE



PSCI
PHARMACEUTICAL
SUPPLY CHAIN
INITIATIVE

Air Filtration in Pharmaceutical Industry

Air Filtration Solution Introduction

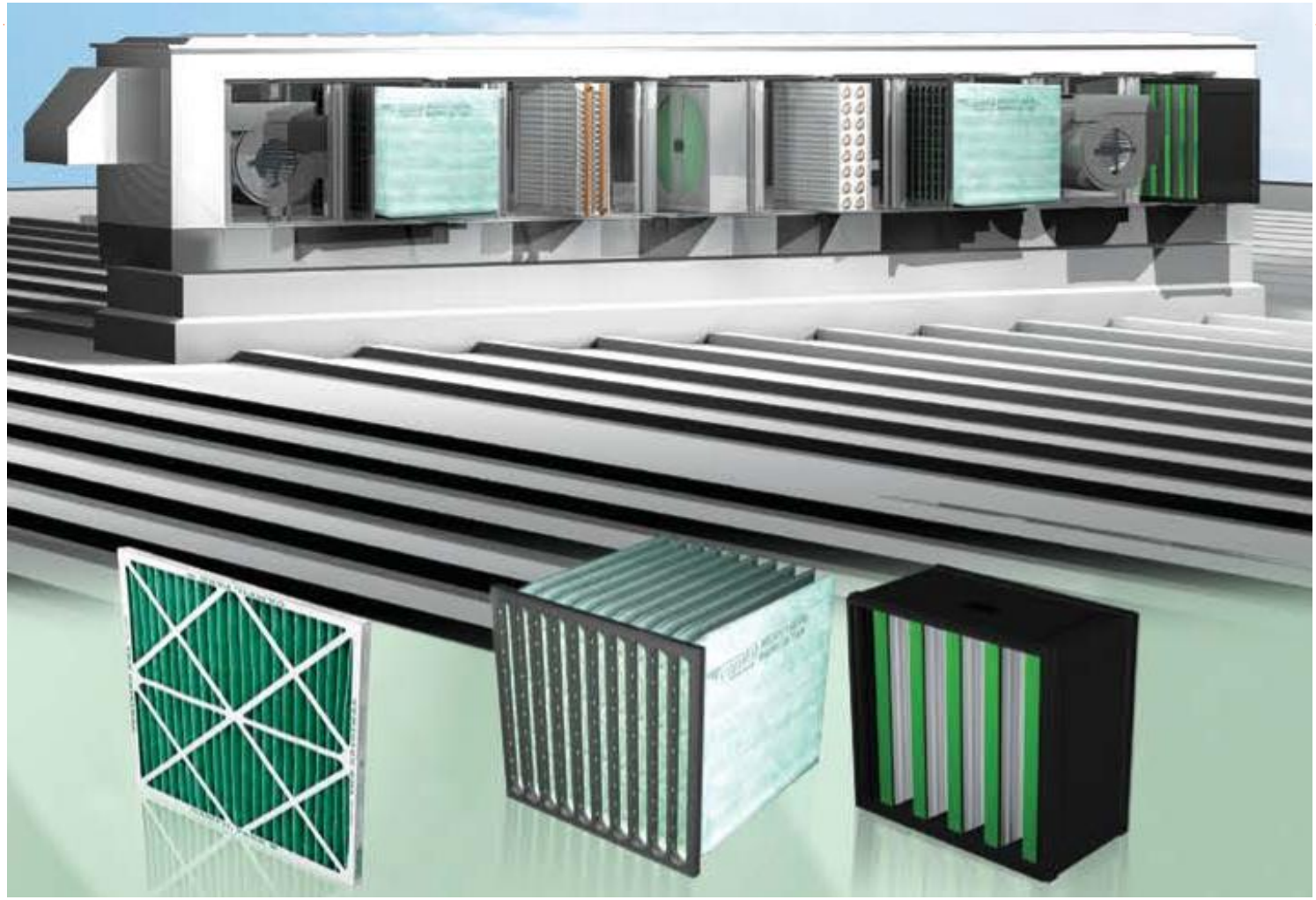


PSCI
PHARMACEUTICAL
SUPPLY CHAIN
INITIATIVE

Optimization For HVAC Filtration

PSCI
PHARMACEUTICAL
SUPPLY CHAIN
INITIATIVE

AHU Air Filter



Why we need “GOOD” air filter

PSCI
PHARMACEUTICAL
SUPPLY CHAIN
INITIATIVE

Improve Air Quality

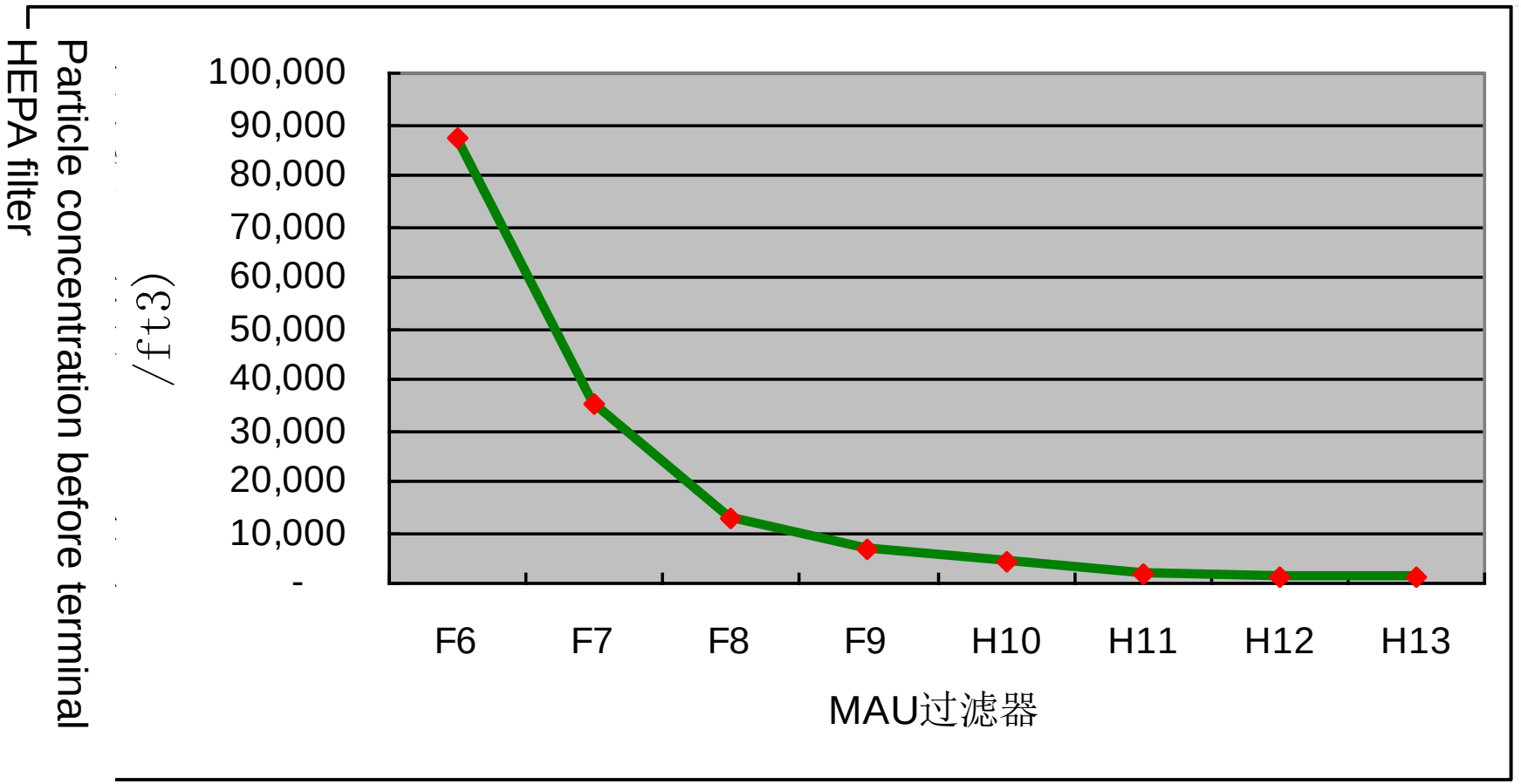
Reduce OPEX

PSCI
PHARMACEUTICAL SUPPLY CHAIN INITIATIVE

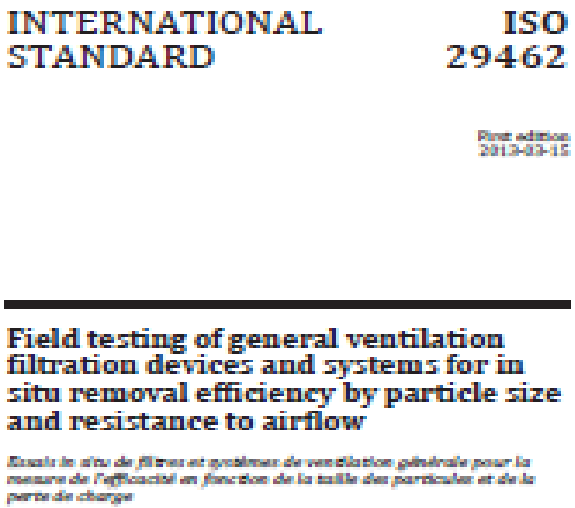
EN779:2012 Air Filter Classification

Group	Class	Final dP in Test（Pa）	Arrestance Am %	Eff @ 0.4μm Em %	Minimum Eff @ 0.4μm %
Coarse	G1	250	50≤Am<65	-	-
	G2	250	65≤Am<80	-	-
	G3	250	80≤Am<90	-	-
	G4	250	90≤Am	-	-
Medium	M5	450	-	40≤Em<60	-
	M6	450	-	60≤Em<80	-
Fine	F7	450	-	80≤Em<90	35
	F8	450	-	90≤Em<95	55
	F9	450	-	95≤Em	70

Impact of Fine filters' efficiency to HEPA's Lifetime



Efficiency of so called F8, F9 filters tested in site



INTERNATIONAL STANDARD

ISO 29462

First edition
2013-03-15

Field testing of general ventilation filtration devices and systems for in situ removal efficiency by particle size and resistance to airflow

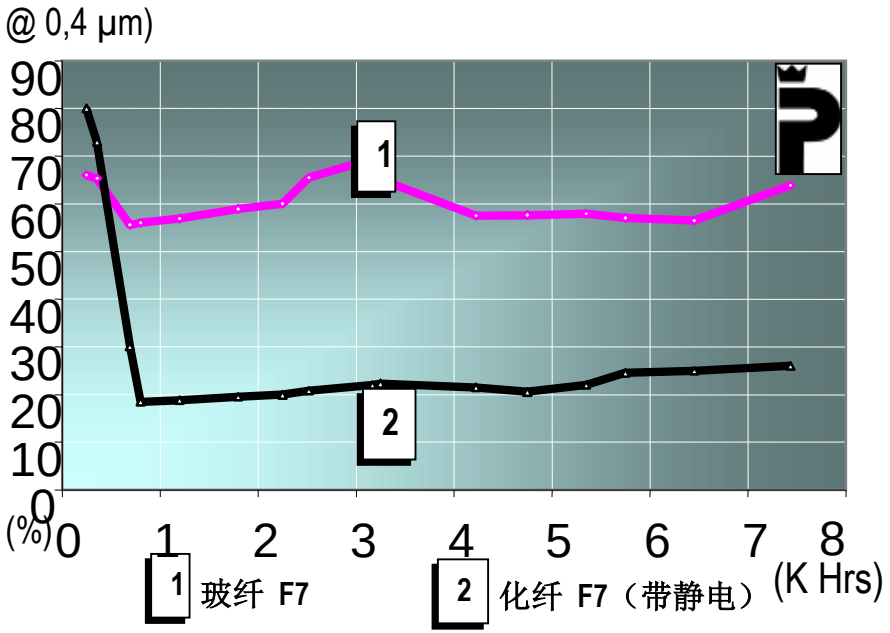
Essais in situ de filtres et systèmes de ventilation générale pour la mesure de l'efficacité en fonction de la taille des particules et de la perte de charge

标签效率	实际运行效率 (0.4um)
单 / F8	35%
单 / F8	16%
单 / F9	78%
单 / F9	20%

m as per ISO 29462

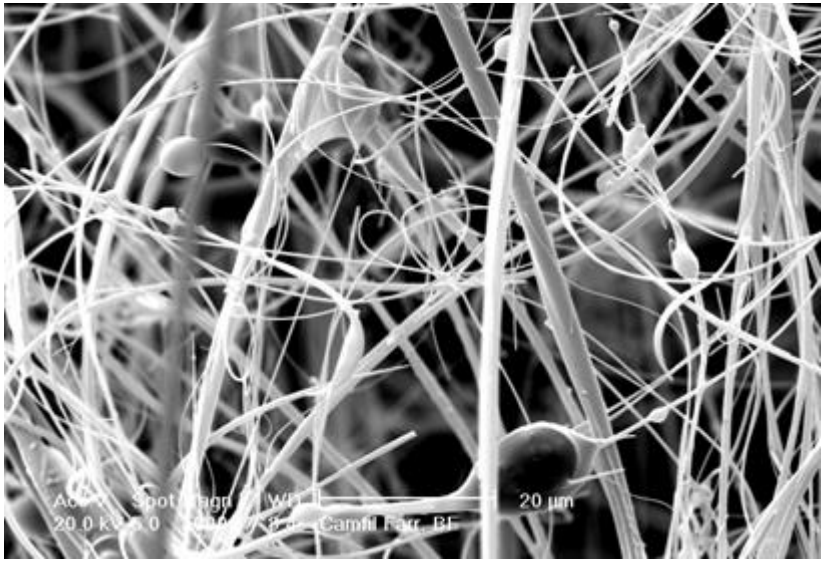
SP Test Result

- SP—An European famous three party organization , compared efficiency of two different kind of F7 filter under a real environment.
- Test result shows efficiency of synthetic fiber media filer will drop to 1/4 ~ 1/3 of initial efficiency very soon.



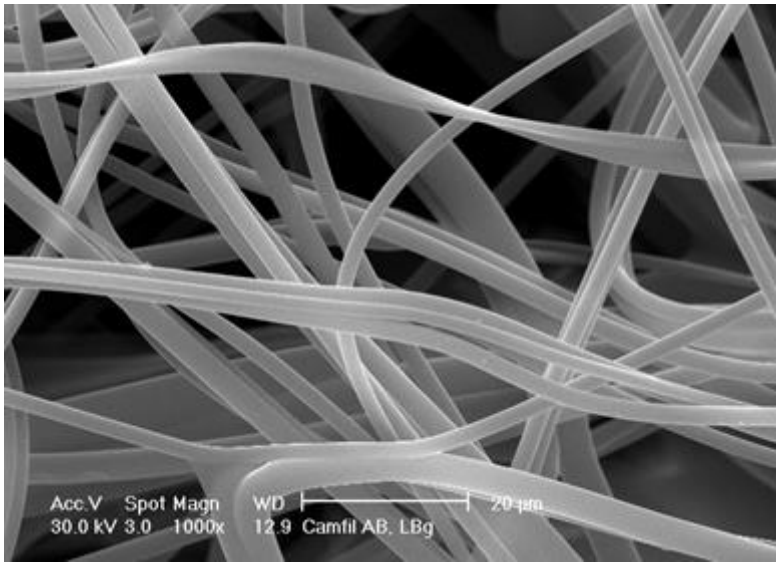
Filtration performance depends on media's microstructure

PSCI
PHARMACEUTICAL SUPPLY CHAIN INITIATIVE



1000 X

Glass Fiber, F7



1000 X

Synthetic Fiber with static electricity, F7

How to reduce OPEX of air filter

LCC of Air Filter

PSCI
PHARMACEUTICAL SUPPLY CHAIN INITIATIVE

Life Cycle Cost

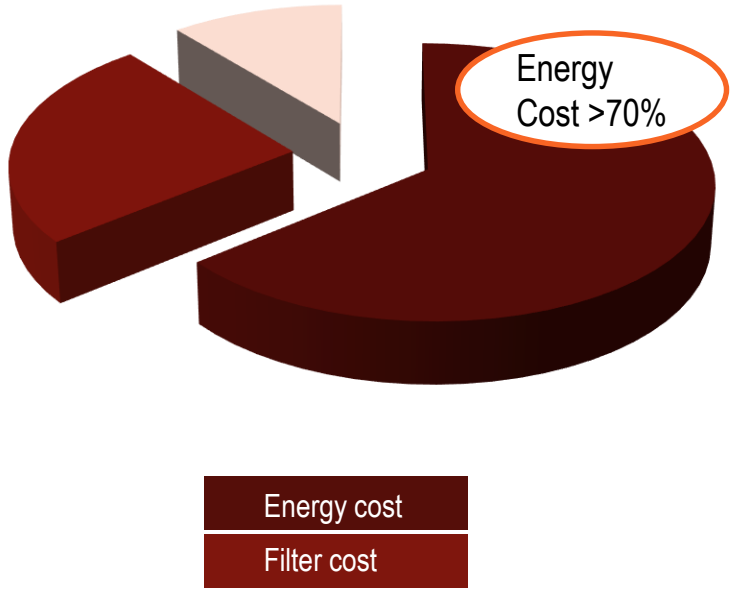
LCC=Filter purchase cost

+ Energy cost

+ Maintance

+ System cleaning

+ Waste disposal



Calculation of Energy Consumption

$$E = \frac{q \times dP \times t}{\eta \times 1000 \times 3600}$$

E=	Energy Consumption	[kWh /year]
q =	Airflow	[m^3/h]
dP =	**Average dP** [Pa]	
t =	Running time	[hour/year]
η =	Efficiency of Fan	

Example of Energy Calculation

- q=3400m^3/h
- dP = 1Pa
- t=8760 hours
- η = 0.5

$$E = \frac{3400 \times 1 \times 8760}{0.5 \times 1000 \times 3600}$$
$$= 16 \text{kWh} / Year$$

Why we need “GOOD” air filter

PSCI
PHARMACEUTICAL SUPPLY CHAIN INITIATIVE

Efficiency Failed → **Shorter HEPA life**

dP increased too fast → **Higher LCC cost**

PSCI
PHARMACEUTICAL
SUPPLY CHAIN
INITIATIVE

How to choose the right air filter with qualified efficiency and steady dP.

- Filter class defined by EN 779:2012
- Site test guarantee
- Certificated by Eurovent

PSCI
PHARMACEUTICAL
SUPPLY CHAIN
INITIATIVE

EN 779：2012 Test Rig

PSCI
PHARMACEUTICAL SUPPLY CHAIN INITIATIVE

Site test system as per ISO 29462-2013

File Edit Operate Tools Window Help

camfil FARR

Equipment | Site Info | Temp/RH | Zero Checks | Count | About
Parameters | Pre-Test | Velocity/DP | U/S Checks | Reports | Test Completed

Main | Vel/DP | Zero/USS/T/RH | U/S Time | All Counts | Site Info | Test Setup | Maintainance

Camfil Farr In-Situ Test System

Pump Flow (scfh): 30

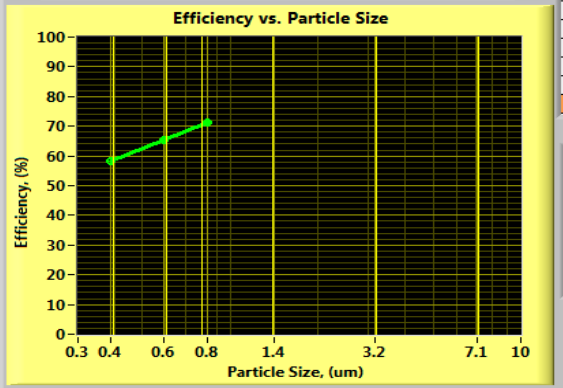
TestID

AHU Map — U/S Side (fpm)

	C1	C2	C3	C4	C5
R1	478	306	362	352	506
R2	381	320	388	358	380
R3	300	318	400	440	348
R4	362	319	422	348	372

Up Stream Space Test Locations

R2-C2 | R2-C3 | R3-C2 | R3-C3 | R3-C4



All D/S Count Da

	D/S Avg 1	D/S Avg 2	D/ Av
0.3 - 0.5	7568	7365	80
0.5 - 0.7	464	462	4
0.7 - 1.0	41	39	4
1.0 - 2.0	5	6	
2.0 - 5.0	0	0	
> 5.0	0	0	
Totals	8079	7872	85

Filter Efficiency

	Eff-1, (%)	Eff-2, (%)
0.3 - 0.5	58	59
0.5 - 0.7	65	66
0.7 - 1.0	71	71
1.0 - 2.0	84	84
2.0 - 5.0	100	100
> 5.0	NaN	NaN

Camfil Farr
1 North Corporate Drive
Riverdale, NJ 07457

PSCI
PHARMACEUTICAL SUPPLY CHAIN INITIATIVE

CFL Site Comparation test lab

- Test filtration solution performance under site environment
- Efficiency, Pressure drop, Energy cost, environmental PM concentration
- Remote control

PSCI
PHARMACEUTICAL SUPPLY CHAIN INITIATIVE

Classification of Energy Comsumption by Eurovent

Energy cost limit of different filter class /kWh					
Class	M5	M6	F7	F8	F9
A+	<450	<550	<800	<1000	<1250
A	600	650	950	1200	1450
B	700	800	1200	1500	1900
C	950	1100	1700	2000	2600
D	1200	1400	2200	3000	4000
E	>1200	>1400	>2200	>3000	>4000

PSCI
PHARMACEUTICAL SUPPLY CHAIN INITIATIVE

Eurovent A+ Filter

EUROVENT CERTIFIED PERFORMANCE
ENERGY EFFICIENCY

CAMFIL
Opakfil ES
OPGP-F7-0592/0592/0296-ES-25-B00

www.eurovent-certification.com

AIR FILTERS

F7

EN779: 2012

Nominal airflow:	0.944	m^3/s
Initial efficiency 0.4 µm:	44	%
Minimum efficiency 0.4 µm:	44	%
Annual Energy Consumption:	782	kWh/annum

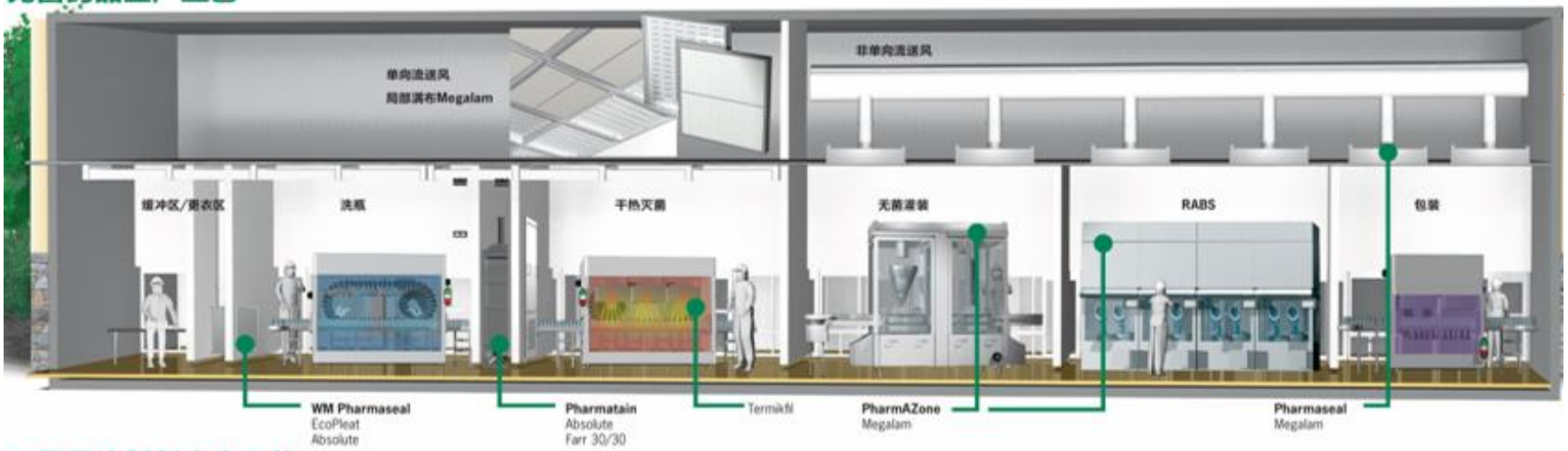
A+
A
B
C
D
E

A+ 2015

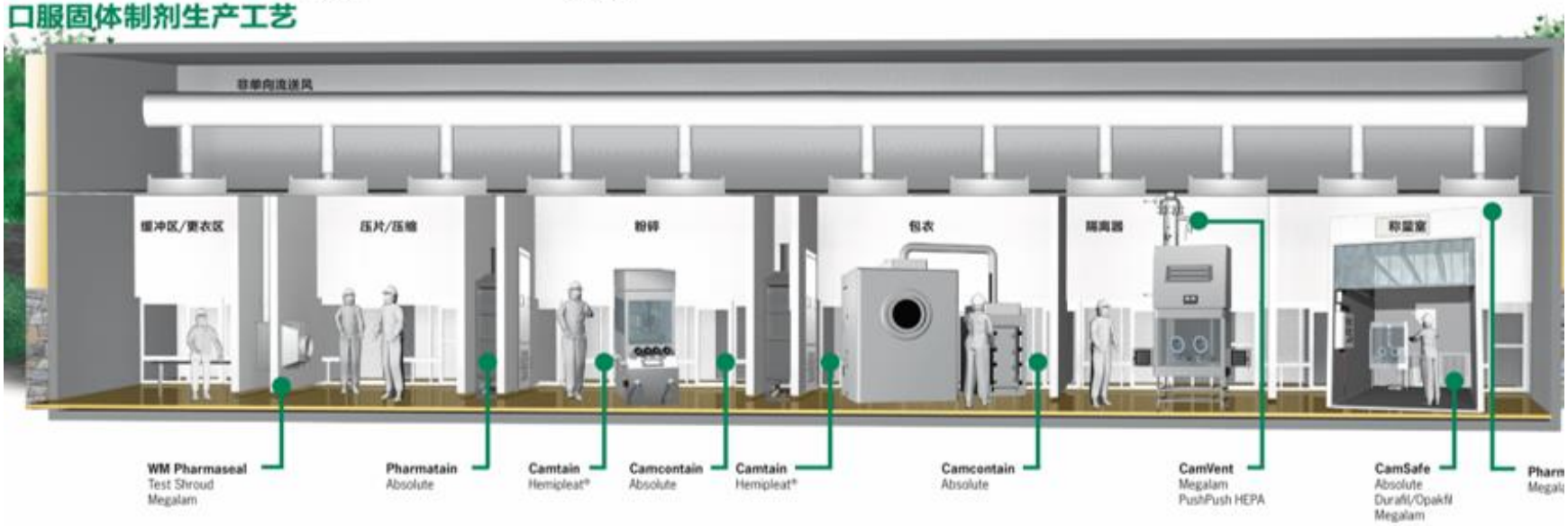
THRESHOLD REFERENCE SCALE YEAR : 2015
RS 4/C/001

Save at least 20% energy cost with A+ filter

无菌药品生产工艺



口服固体制剂生产工艺

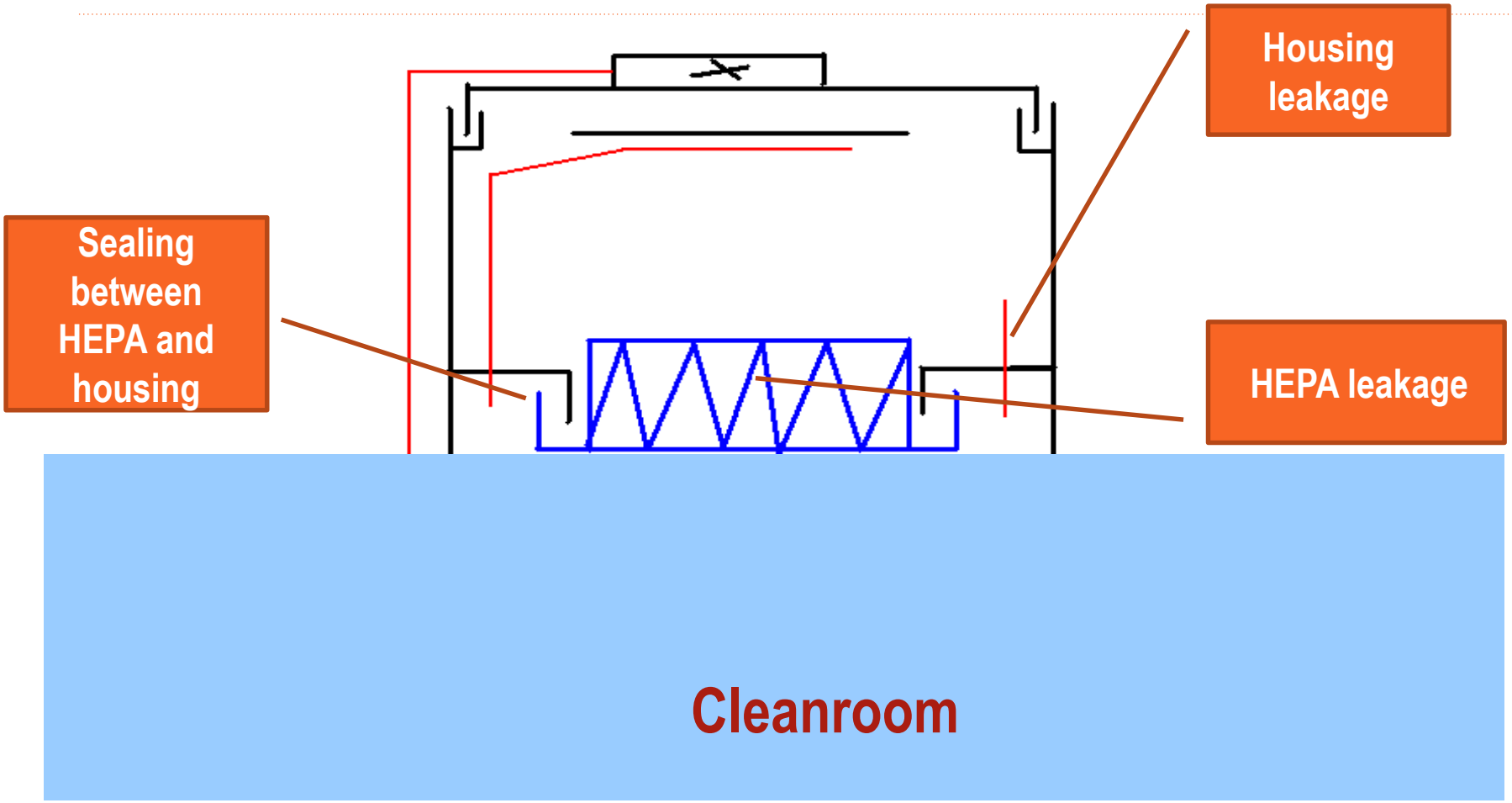


PSCI
PHARMACEUTICAL
SUPPLY CHAIN
INITIATIVE

Validation of HEPA filter in Cleanroom

PSCI
PHARMACEUTICAL SUPPLY CHAIN INITIATIVE

Possible reasons of >0.01% Leakage



Guarantee（1）- Reliable product design

✓Full weld design;

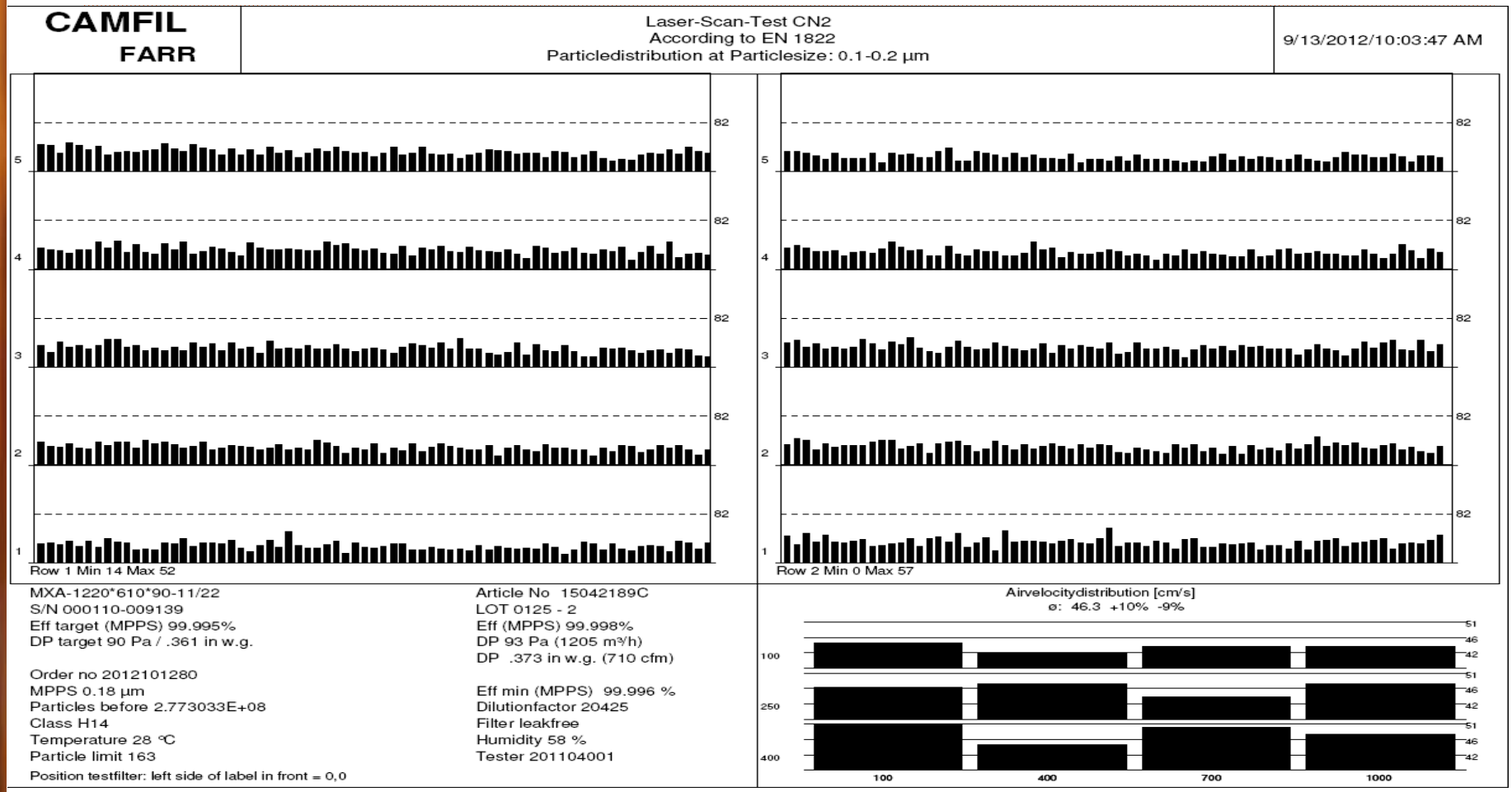
✓Tightness design for aerosol injection port, sampling port, valve adjust device;

✓Silicon liquid sealing.

PSCI
PHARMACEUTICAL
SUPPLY CHAIN
INITIATIVE

Guarantee（2）-Top manufacturing process

Guarantee (3) -Tough QC test



Guarantee（3）-Tough QC test for housing

1) 100% housing tightness test(>750Pa).

2) 100% Photometer scan test for housing and HEPA filter acc to ISO14644-3/ EN 1822

PSCI
PHARMACEUTICAL
SUPPLY CHAIN
INITIATIVE

Design concepts of Safety Exhaust System

Presenting CamSafe 3

What's in it for you?

- The best product in the market
- Allows you to be successful in
  - Bringing customer new added value benefits
  - Making the difference to competition thanks to some nice USPs
  - (Re-)positioning your BIBO offer at the right price level => increase your chance to success

Let's see…..(…we prove it…)

What makes CamSafe 3 brand new?

- Bended design, continuous welded in corners
  - Perfect permanent tightness
  - Very rigid gasket frame
  - Pressure tested up to 5000 Pa
- Camfil unique filter safety Clamping device
- Camfil unique scan system

PSCI
PHARMACEUTICAL
SUPPLY CHAIN
INITIATIVE

The Voice Of Customers

What is the most important for Customer to select a containment housing ?

The Voice Of Customers

PSCI
PHARMACEUTICAL SUPPLY CHAIN INITIATIVE

What is the most important for you to select a containment housing ?

POINTS . . .

- NO LEAK
  - Pass test over years
  - Both housing and filter pressure boundary
- FILTER INSTALLATION SAFE AND EASY
  - Very critical operation … you never know the result before control…
- In-situ validation
  - Easy to operation
  - Reliable test result

1 NO LEAK by construction

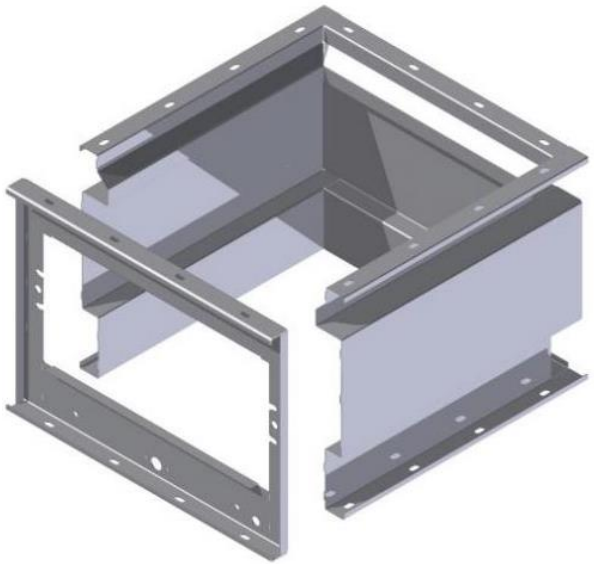
PSCI
PHARMACEUTICAL SUPPLY CHAIN INITIATIVE

Bended design

fully welded construction

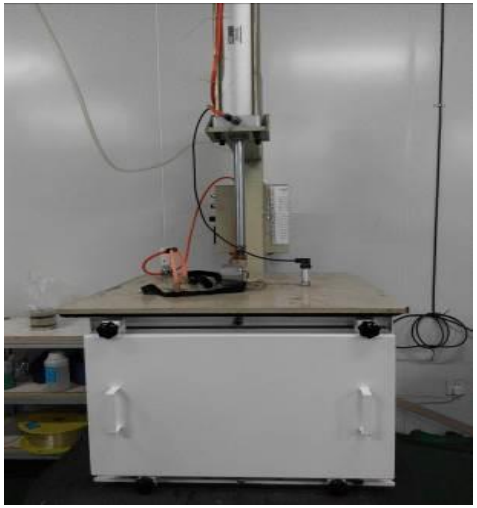
bended gasket frame

no mastic used



What Makes CamSafe 3 Unique ?

- Guaranteed SAFETY equipment
  - The only housing to meet **ISO 10648-2:1994 leak tightness Class 3** at **+/- 5000Pa**
  - **Permanent safety** guaranteed over time
    - Bended housing + fully welded

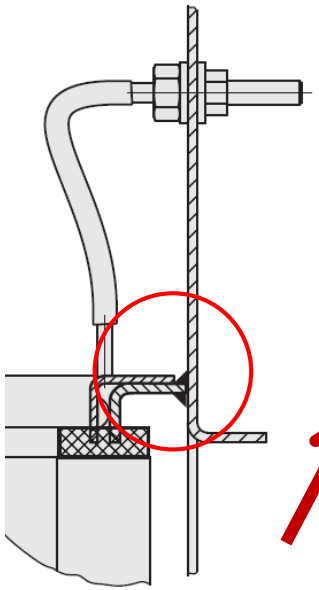


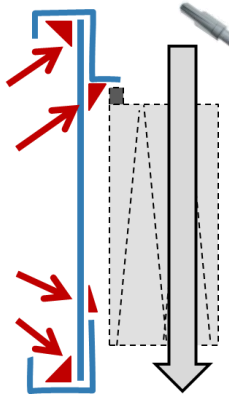
Look at lower grade options available : Housing and gasket frame tightness

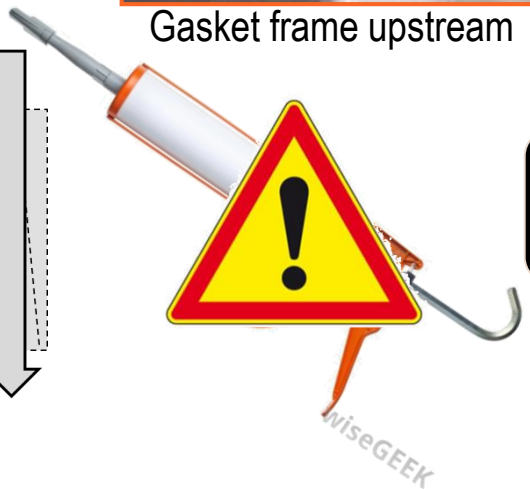
PSCI
PHARMACEUTICAL SUPPLY CHAIN INITIATIVE

- Main competitors
  - Spot welded and caulked with mastic sealant

Gasket frame upstream







Major risk for leaks over time !

2 FILTER INSTALLATION SAFE AND EASY

PSCI
PHARMACEUTICAL SUPPLY CHAIN INITIATIVE

What is the current practice ?

Or . .

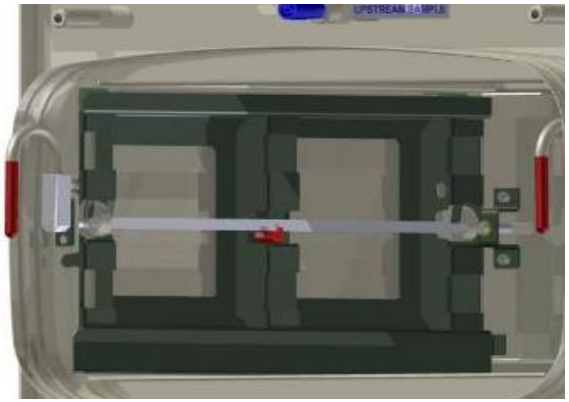
.

CamSafe 3 UPS – Unique clamping system ClampSafe

PSCI
PHARMACEUTICAL SUPPLY CHAIN INITIATIVE

The main advantages of the this new clamping system are:

1. Fool proof and 100% safe, the cover can not be fitted unless the HEPA filter is in position and clamped.
2. Location pin prevents the filter from being clamped if not in the correct position.
3. The clamping handles are in a more ergonomic vertical orientation making them easier to hold and operate through the PVC change bag.
4. The clamping system incorporates spring compensation to ensure a constant gasket seal.

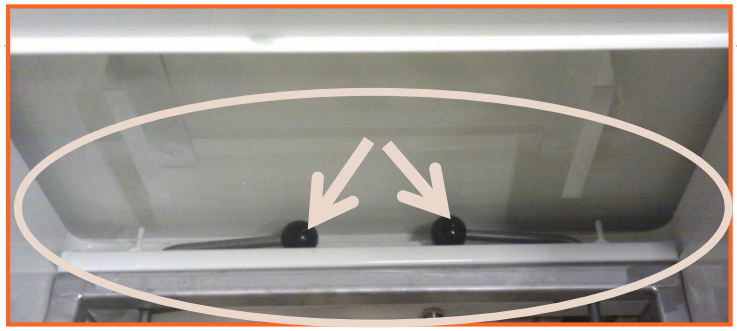


Some points to avoid during installation

PSCI
PHARMACEUTICAL SUPPLY CHAIN INITIATIVE

”Mechanical codings”

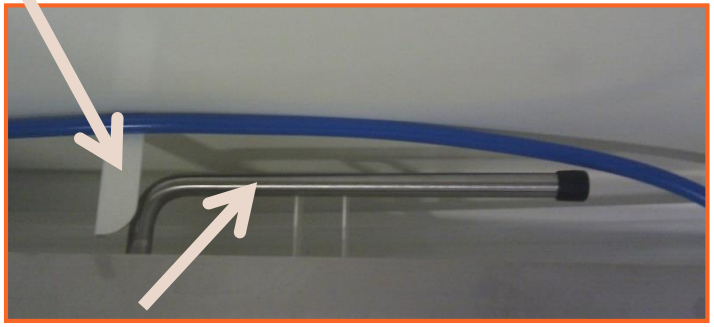
Shaft position ”filter clamped”



Door closed **AND** shaft at position ”filter unclamped” !

Major safety failure !

Mechanical coding



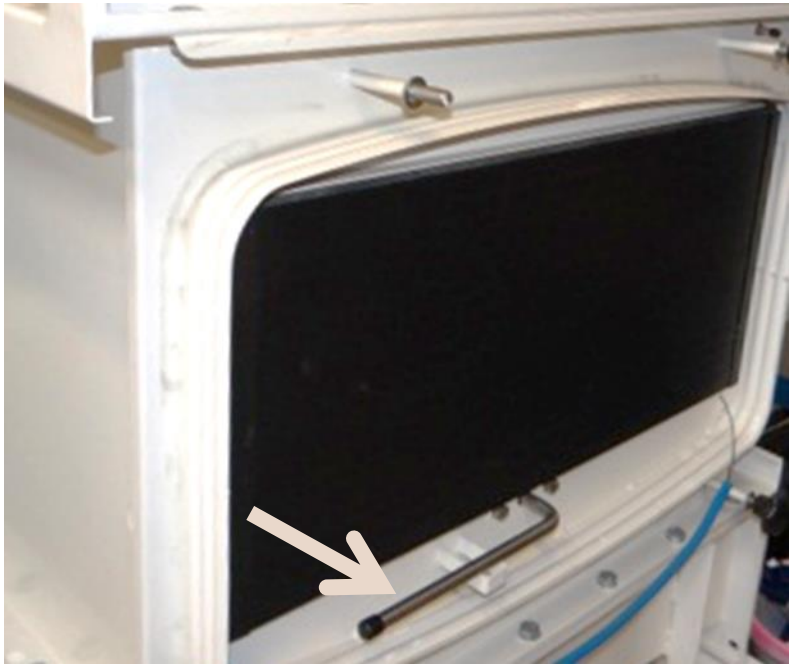
Shaft position ”filter clamped”

Door closed **AND** shaft not fully in position ”filter clamped” !

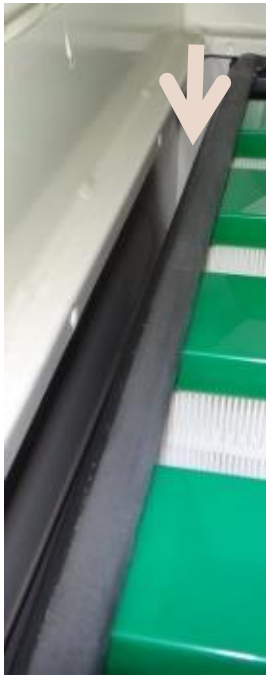
Some points to avoid during installation

PSCI
PHARMACEUTICAL SUPPLY CHAIN INITIATIVE

- Unsafe / dangerous design for <u>filter positioning</u>



Shaft position ”filter clamped”
BUT filter not fully sealed



Gap between filter frame and gasket frame

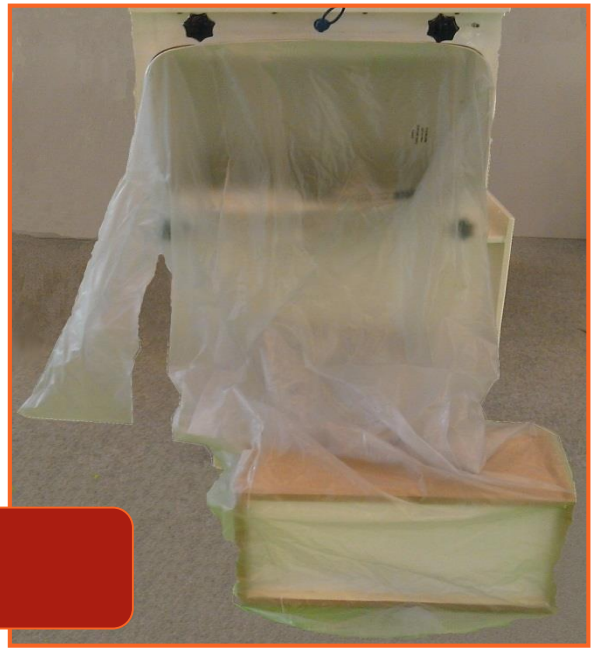
Fiter clamped AND door closed
BUT leaking filter when installed!

Major safety failure!

CamSafe 3 USP: Safety bag

PSCI
PHARMACEUTICAL SUPPLY CHAIN INITIATIVE

- Specially designed with safety in mind
  - Strong material, tear proof
  - Ergonomic design
  - Integrated O-ring
  - 80 mm groove (Trox 46 mm)
  - Operator safety



Previous “bag residue” securely removed

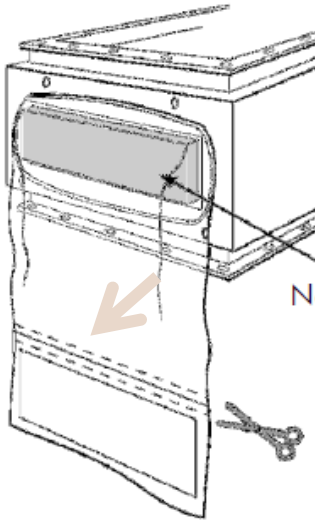
Real safety equipment !

Non compliant / unsafe “safety bag”

PSCI
PHARMACEUTICAL SUPPLY CHAIN INITIATIVE

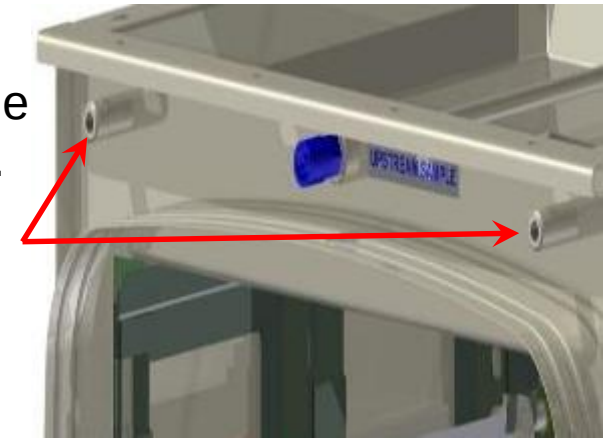
Not really designed as a “Safety device”

- Generally very rudimentary design and material
- « Previous bag residue »
  - remains in the next bag
  - or it needs a longer weld
- O-Ring not integrated => Not user-friendly



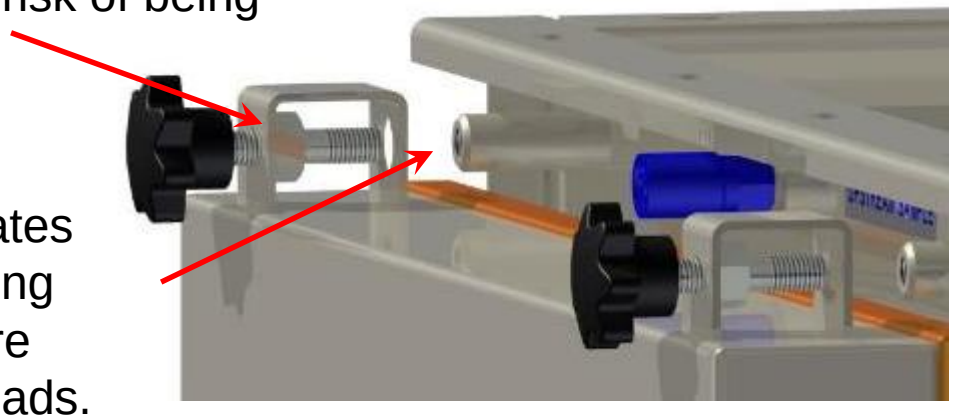
CamSafe 3 – Additional Safety Features

Cover fixing method is smooth and does not protrude passed the safe change ring.



Safer than a sharp male thread which has the risk of ripping the change bag.

Cover fixing knobs are retained, no risk of being lost.



Cover locates onto housing easy before screw threads.

CamSafe 3 UPS – Reliable scan system

PSCI
PHARMACEUTICAL SUPPLY CHAIN INITIATIVE

Upstream test section
- Aerosol injection
- Validated aerosol uniformity

Upstream aerosol sampling

Connect port for scan driver

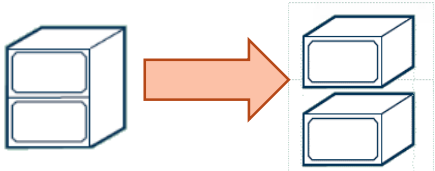
Downstream scan sampling

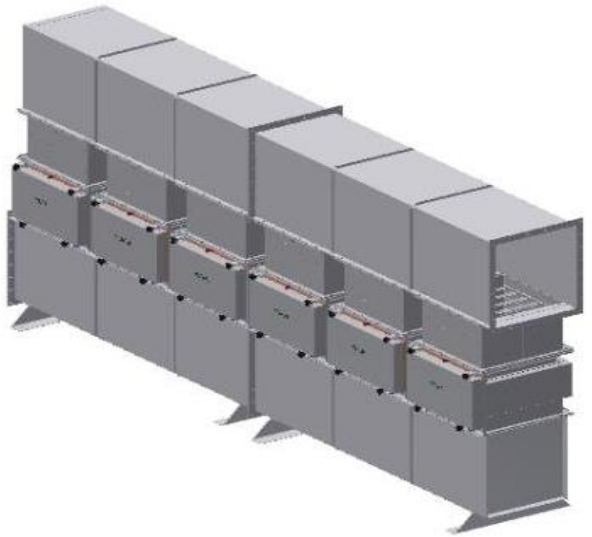
CamSafe 3 Range: Modularity & Flexibility

PSCI
PHARMACEUTICAL SUPPLY CHAIN INITIATIVE

Multiple combinations based on:

- Housings
  - Single filter 292mm
    - 610x610
    - 610x305
  - With pre-filter 45mm
    - 610x610
    - 610x305





- Ducting
  - 1 to 6 modules in parallel up to 20400 m3/h

CamSafe 3 – To be “Safe” is our mission

PSCI
PHARMACEUTICAL SUPPLY CHAIN INITIATIVE

100% safety features built in:

- No-leakage structure
- HEPA filter position
- Clamp handle position
- Clamp handle locking
- Cover positioning
- Real safe change bag
- Change bag protection
- SAT scan test

PSCI
PHARMACEUTICAL
SUPPLY CHAIN
INITIATIVE

Q&A ?

You can also send mail to me:

arun.verma@Camfil.com

PSCI

PHARMACEUTICAL SUPPLY CHAIN INITIATIVE

Potent Compound Containment Options & Applications

Presented by

Anil Nair

Business Lead – Dust Collection Systems

Camfil India

PSCI
PHARMACEUTICAL SUPPLY CHAIN INITIATIVE

Bio

Business Head – Air Pollution Control & Air Cleaners

Camfil Air Filtration India Pvt Ltd.

Tasks:

Application Engineering and Consulting Professional for Air Pollution Control – Dust Collection Systems Pharmaceutical Industry, Fume extraction, chemical wood working, mining etc. Designing and application of Air Cleaning solutions for factories , workplace , buildings and homes. Gas filtration solutions for odor and molecular filtration issues.

Member - ISHRAE

Education:

BE Mechanical Engineering

Work experience:

24 Years in the above areas

Anil Nair
Camfil Air Filtration India Pvt Ltd.
Business Head – Air Pollution Control & Air Cleaners
Email: anil.nair@Camfil.com

Why is Containment in Dust Collection so Important?

PSCI
PHARMACEUTICAL SUPPLY CHAIN INITIATIVE

1. The full containment of toxic dusts is essential to protect the workers from direct contact or inhalation of dusts, preventing acute or chronic health issues
2. Ensures compliance to legal obligations relating to the protection of personnel in the workplace and also emission limits to atmosphere
3. Good housekeeping is required to prevent the build-up of dust in the working environment, not only to protect workers health but also prevent the possibility of a secondary dust explosion
4. Fine dust particles can affect electrical and mechanical components, causing premature failure and a potential fire risk
5. FDA cGMP (current Good Manufacturing Practice) requires the containment of dusts to prevent cross-contamination of product ingredients to ensure the purity of the final product
6. Future proofing of equipment – manufacturing processes change over time so it is good business practice to specify a higher level of equipment to ensure higher containment levels can be achieved in the future

OEL – **Occupational Exposure Limit**

PSCI
PHARMACEUTICAL SUPPLY CHAIN INITIATIVE

- Definition:
  - "An **occupational exposure limit** is an upper **limit** on the acceptable concentration of a hazardous substance in workplace air for a particular material or class of materials"
- OEL's are typically set by competent national authorities and enforced by legislation to protect **occupational** safety and health – they are **legally binding** limits
- OEL's across EU member states may vary slightly but will be based on the IOELV (Indicative Occupational Exposure Limit Values) for each dust type
- The IOELV are derived via the Chemical Agents Directive (98/24/EC) and The Scientific Committee on Occupational Exposure Limits (SCOEL)

OEL's in the Pharmaceutical Industry

PSCI
PHARMACEUTICAL SUPPLY CHAIN INITIATIVE

- OEB – Occupational Exposure Band – A range of OEL values with an associated method of containment
- Ranges from OEB 1 with basic control procedures up to OEB 5 and beyond for full containment of the most hazardous materials
- Typically each pharmaceutical manufacturer will have set their own OEL's and OEB's for the hazardous materials they use
- The Limits set will be based on data from the raw material supplier, EU and national OEL data and their own risk assessments undertaken
- During drug manufacture the individual materials will be mixed to produce a compound which may be more hazardous than its constituent parts
- Each product manufactured will be specific to that manufacturer, hence the need for each company to undertake their own risk assessments and analysis

Containment – **Exposure Control**

PSCI
PHARMACEUTICAL SUPPLY CHAIN INITIATIVE

An example of a generic OEB / OEL Table

System	OEB	OEL	W	Hazardousness
Isolators, Drum Containment System, split valve system Big Bag discharging and filling	5	< 1 µg/m³	< 0,1 mg/day	Highly hazardous
Container with cone, split valve, Big Bag discharging and filling	4	1 - 10 µg/m³	0,1 - 1 mg/day	hazardous
Container with cone, split valve, Big Bag discharging and filling	3	10 - 100 µg/m³	1 - 10 mg/day	Mildly hazardous
Systems with increased seal for discharging and filling barrels and Big Bags	2	100 - 1000 µg/m³	10 - 100 mg/day	Almost non-hazardous
Open systems with local aspiration	1	1000 - 5000 µg/m³	> 100 mg/day	Non-hazardous

OEB - Occupational Exposure Band
OEL - Occupational Exposure Limit
W - API content

Containment – **Exposure Control**

PSCI
PHARMACEUTICAL SUPPLY CHAIN INITIATIVE

CONTAINMENT CONTROLS

Exposure limits determine manufacturing safeguards

OCCUPATIONAL EXPOSURE LIMIT	BAND	PRODUCTION REQUIREMENTS
>1–10 mg/m^3	1	Good manufacturing practices
>0.1–1 mg/m^3	2	Good manufacturing practices (with local exhaust ventilation)
>0.01–0.1 mg/m^3	3	Essentially no open handling (ventilated enclosures required)
>0.001–0.01 mg/m^3	3+	Virtually no open handling (containment systems required)
≤0.001 mg/m^3	4	No open handling (closed systems required)
≤0.001 mg/m^3	5	No manual operations/human intervention (robotics or remote operations required)

SOURCE: Merck & Co.

An example of a specific OEB Table from a pharmaceutical manufacturer.

PSCI
PHARMACEUTICAL SUPPLY CHAIN INITIATIVE

OEL – **APC Considerations**

- For each application involving potentially hazardous dusts we need to know the OEL, OEB and explosive characteristics (ATEX Zoning, Kst, Pmax and MIE) for all the materials the dust collector will be subjected to

- The presence of gases or solvents needs to be determined along with the associated % LEL value. The explosive potential of the dust/gas hybrid mixture can then be investigated

- Refer to the country specific OEL data where necessary and where information is not forthcoming – e.g. for the UK http://www.hse.gov.uk/pubns/books/eh40.htm

Camfil APC -Dust Collectors

- **Gold Series® Dust Collectors**
  - Widely used across a range of applications in the industries requiring harmful dust containment
  - Vertical filter cartridge installation for best practice
  - Each dust collector designed specifically around the application for which it is intended
  - Highest build quality and short lead-times
  - Numerous dust discharge options available for safe and easy waste dust disposal
  - Specific dust collector design for handling harmful, toxic dusts – Gold Series Camtain

Camtain – **APC Containment Solutions**

- **Surrogate Tested Dust Collection System for Performance Verification**
- The Gold Series Camtain® contained dust collection system has been surrogate tested for validated performance verification
- The ISPE GPG “Assessing the Particulate Containment Performance of Pharmaceutical Equipment” surrogate testing protocol was used as a guideline with an independently contracted, AIHA accredited laboratory (Bureau Veritas) performing the testing.
- Using 100% milled lactose as the surrogate, we collected over 48 personal, area and surface samples for both the BIBO cartridge filter change and continuous liner discharge operations.
- The GS CamtainTM can contain highly potent, toxic or allergenic compounds with an OEL ≥ 0.4 mcg/m3 for a time weighted average (TWA)
- Therefore we can comply with OEB 4 in most instances using the TWA
- Full test report data is available upon request

Camtain – **APC Containment Solutions**

Camtain Safe-change Filter Operation

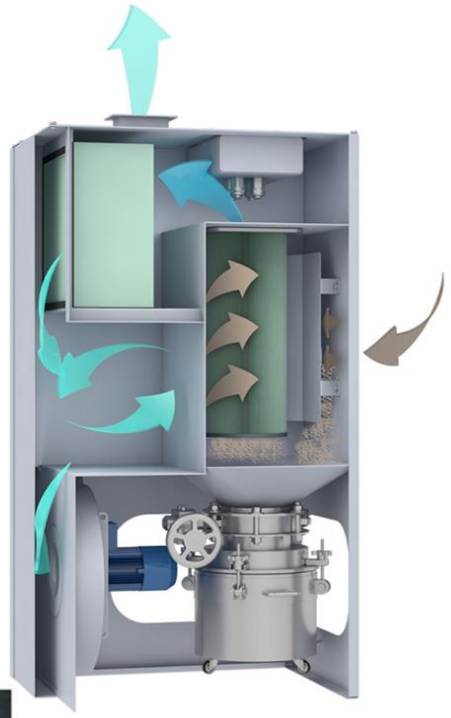
- A validated containment solution available for filter replacement
- One of the safest, easiest BIBO operations available on the dust collector market
- Used as the preferred dust collector for many major pharma manufacturers and OEM's across the world
- Full operation and training documentation provided to help with FDA cGMP compliance
- Also available on the High Vacuum dust collector range, providing a unique solution for the pharma industry

Quad Pulse – **APC Containment Solutions**

- QPP PX1 – QuadPulse Packaged, ATEX compliant, single cartridge dust collector
- Compact dust collector designed specifically for the containment market – incorporating the primary filter, HEPA, fan and collection bin in 1 packaged unit
- Compliments and completes the existing range of market leading containment dust collectors from Camfil APC – Gold Series Camtain dust collectors
- Unique features and benefits to meet the stringent demands from customers across a variety of focus markets

Quad Pulse - **Containment Features**

- Market leading safe change BIBO operations for the primary filter cartridge, HEPA filter and 35L waste dust collection bin
- Safely contains the harmful dusts during standard operation and during filter changes to achieve a high level of containment for worker safety and cross contamination prevention
- In-situ HEPA DOP filter testing capability
- Manual butterfly valve enables BIBO bin change to be carried out whilst the dust collector is running – no production down-time

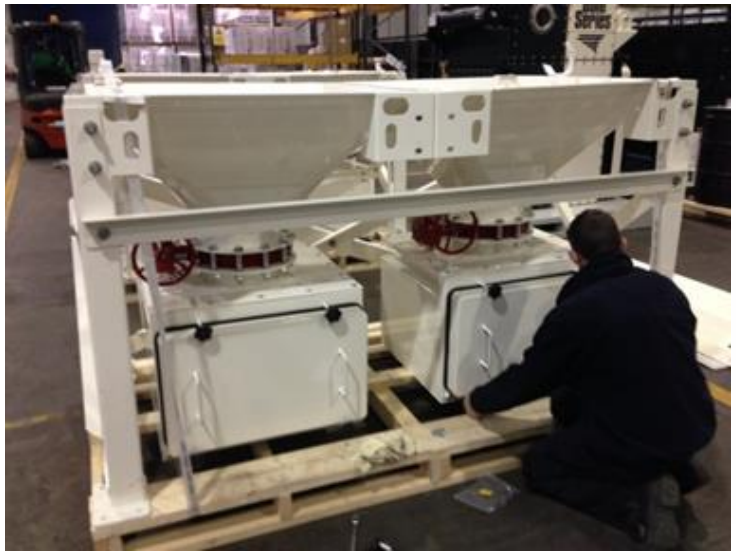


Camfil Pharma Solutions – **Dust Discharge Options**

PSCI
PHARMACEUTICAL SUPPLY CHAIN INITIATIVE

Safe Change BIBO Options

- Continuous liner with Dual Valve
- 35L BIBO Bin
- BIBO Drawer



Camsafe – **HEPA Containment Solution**

- Camsafe – Floor mounted BIBO HEPA section
- Required as a safety system ‘police filter’ to ensure hazardous dust is filtered from the clean air if there is a poor seal or a ruptured cartridge (very rare occurrence)
- Also ensures that the finest sub-micron dust particles that can pass through the primary filters are also collected - Hemipleat filtration efficiency 99.99% @ 0.5 micron
- ATEX Camsafe version available

PSCI
PHARMACEUTICAL SUPPLY CHAIN INITIATIVE

Pharmaceutical Industry Focus

Thank you for your attention

How can we help?

Anil Nair
Business Lead – Dust Collection Systems – Camfil India

anil.nair@camfil.com
www.camfilapc.com;www.camfil.in

PSCI

PHARMACEUTICAL SUPPLY CHAIN INITIATIVE

Dust Combustibility & Design of Protection Systems

Presented by

Anil Nair

Business Lead – Dust Collection Systems

Camfil India

PSCI
PHARMACEUTICAL SUPPLY CHAIN INITIATIVE

Bio

Business Head – Air Pollution Control & Air Cleaners

Camfil Air Filtration India Pvt Ltd.

Tasks:

Application Engineering and Consulting Professional for Air Pollution Control – Dust Collection Systems Pharmaceutical Industry, Fume extraction, chemical wood working, mining etc. Designing and application of Air Cleaning solutions for factories , workplace , buildings and homes. Gas filtration solutions for odor and molecular filtration issues.

Member - ISHRAE

Education:

BE Mechanical Engineering

Work experience:

24 Years in the above areas

Anil Nair
Camfil Air Filtration India Pvt Ltd.
Business Head – Air Pollution Control & Air Cleaners
Email: anil.nair@Camfil.com

Agenda

PSCI
PHARMACEUTICAL
SUPPLY CHAIN
INITIATIVE

- Introduction
- Part 1 - ATEX Directives
  - ATEX Theory
  - ATEX Zones and Categories
  - Explosion Prevention Measures
  - Dust Collection Basic Principles
  - Dust Explosions – how and where do they occur?
- Part 2 – Industry Specific ATEX Guidance
  - ATEX and dust collectors
  - Specific Industry Examples
  - Summary and Questions

PSCI
PHARMACEUTICAL
SUPPLY CHAIN
INITIATIVE

ATEX – An Explosive Topic

ATEX

PSCI
PHARMACEUTICAL
SUPPLY CHAIN
INITIATIVE

What is ATEX?

- ‘Atmosphere Explosive’
- EU Legal Framework for the prevention of explosions in the workplace
- Started in 1999 but compliance enforced from 2003
- Relates to new equipment and processes as well as existing equipment and applications
- A legal requirement for EU member states but also widely used across many non-EU countries for best practices
- NFPA – American equivalent of Atex

ATEX Directives - 3 Directives to follow

- **94/9/EC – ATEX 100** – Equipment and Protective Systems for Use in Potentially Explosive Atmospheres. This is applicable to for example dust collectors

- **1999/92/EC – ATEX 137** Covering work place safety, risk zones and protection.

- **2006/42/EC The Machinery Directive** – Is applicable for machines NOT covered in the 94/9/EC directive. “Machinery must be designed and constructed in such a way as to avoid any risk of explosion posed by the machinery itself or by gases, liquids, dust, vapors or other substances produced or used by the machinery.”

Equipment 94/9

- Equipment is classified in to 2 groups. Group I for mining related equipment and group II for other equipment.

- Then the equipment is classified according to it's level of safety, in 3 categories.
  - The most safe category is Category 1 - this equipment must be safe even if 2 safety system fails or in case of rare malfunctions.
  - Category 2 shall be safe if one safety system fails (malfunctions)
  - Category 3 equipment is only required to be safe at normal conditions. Depending on the level of safety the equipment can be used in different risk areas. It's also required to take so called foreseeable misuse into account.

- The classification is also divided by Gas and Dust, as they often requires different safety solutions.

Directive 94/9 – Selection of Equipment

- To sell approved equipment the supplier must ensure that the equipment is suitable for the intended use. This means that we need sufficient information from the customer
- The basic information is:
  - Dust data such as KST, PMax, MIE, MIT
  - ATEX Zoning
- The KST and PMax values are used for the explosion protection
- MIE is used for electric components as well a selection of antistatic bags and cartridges
- MIT is used for electric components mostly motors, they need to have a rated surface temp 75 degrees less than the MIT.

PSCI
PHARMACEUTICAL
SUPPLY CHAIN
INITIATIVE

1999/92/EC – The Work Place Directive

- This directive stipulates the employers responsibility, to make a risk assessment and divide areas with explosive dust present into Zones
- The zones relate to the occurrence of an explosive concentration
- If there is an explosive concentration constantly or frequently the area is classified as zone 20 (0 for gas)
- If an explosive concentration can occur infrequently during normal operation the area is classified as zone 21 (1 for gas)
- If an explosive concentration only can occur if something fails the area is classified as zone 22 (2 for gas)
- The higher probability of having a explosive concentration the more safe equipment must be used

PSCI
PHARMACEUTICAL SUPPLY CHAIN INITIATIVE

ATEX Zones

Dust EN 61241-10	Gas EN 60079-10	Details
Zone 20	Zone 0	A place in which an explosive atmosphere is continually or frequently present (more than 1000 hrs p.a)
Zone 21	Zone 1	A place in which an explosive atmosphere is likely to occur occasionally in normal operation (more than 10 hrs but less than 1000 hrs p.a)
Zone 22	Zone 2	A place in which an explosive atmosphere is not likely to occur in normal operation, but if it does it only occurs for short periods (more than 0.1 hrs but less than 10 hrs p.a). Alternatively if an explosive atmosphere can occur in case of a failure (e.g. if a cover opens or a bag is dropped)

Directive 1999/92/EC

PSCI
PHARMACEUTICAL
SUPPLY CHAIN
INITIATIVE

- The work place directive states:
- A plant must have a explosion protection plan that includes a zoning map and risk assessments
- The plant must ensure that only appropriate and approved equipment is used in the zoned areas
- The protection plan must be a living document, updated and maintained
- Staff must have appropriate training

Pulse frequency and zoning

- So in a dust collector running 8 h per day 300 days / year pulsing 50% of the time 4 times per minute and 1 s per pulse you would get 300*0.5*8*60*4 s = 140 hours = **Zone 21**

- We are far from the limit to zone 20 even if we run 3 shift we will not reach 1000 h. If we run 3 shift in a heavy application where we pulse continuously we might be in zone 20. The outcome from this can be questionable if you look at the actual amounts of dust.

The case for protection

PSCI
PHARMACEUTICAL
SUPPLY CHAIN
INITIATIVE

- There are manufacturers on the market that look at dust collectors as separate from the system

- They argue that as their dust collector does not contain any ignition sources they do not need to protect it unless the user requires this

This puts all responsibility on the user and provides…

…NO SAFETY

PSCI
PHARMACEUTICAL SUPPLY CHAIN INITIATIVE

ATEX Basics – What is a Dust Explosion?

- When a combustible substance is dispersed as a fine dust the surface exposed to the air is increased 1000's of times
- If the dust is ignited it will burn at a very high speed due to the large contact surface with the air
- This high combustion velocity will release a lot of energy that generates a rapid increase of temperature and pressure. Shock waves are formed

PSCI
PHARMACEUTICAL
SUPPLY CHAIN
INITIATIVE

Dust Explosion Pentagon

ATEX Basics – Explosive Dusts

- Organic dust from food industry, such as Baking flour, sugar, tea, spices, flavouring
- Synthetic organic dust, such as plastic grinding dust, powder paint, soap powder
- Metal dusts – Fine dust of Aluminium, Magnesium, Titanium, Chromium, in special cases fine un oxidized powder from any metal even Iron powder can explode
- Pharmaceutical dust – A large number of the powders used in this industry are explosive

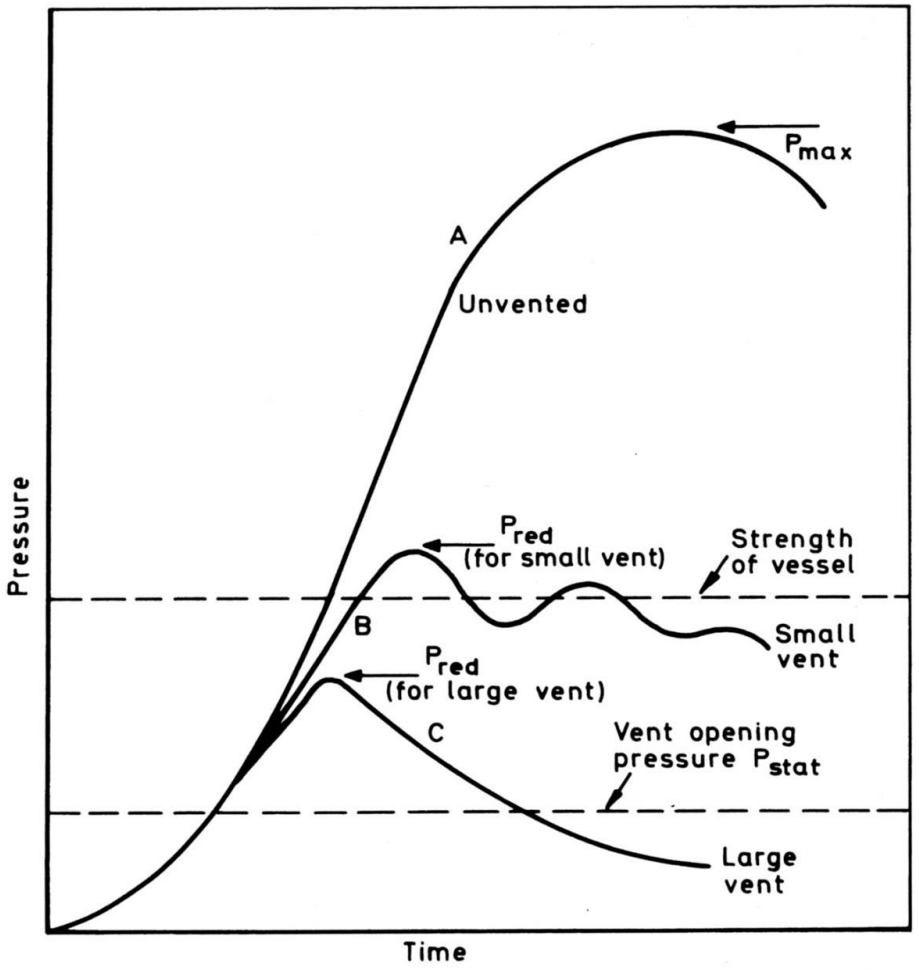
ATEX Basics – Data Requirements

PSCI
PHARMACEUTICAL SUPPLY CHAIN INITIATIVE

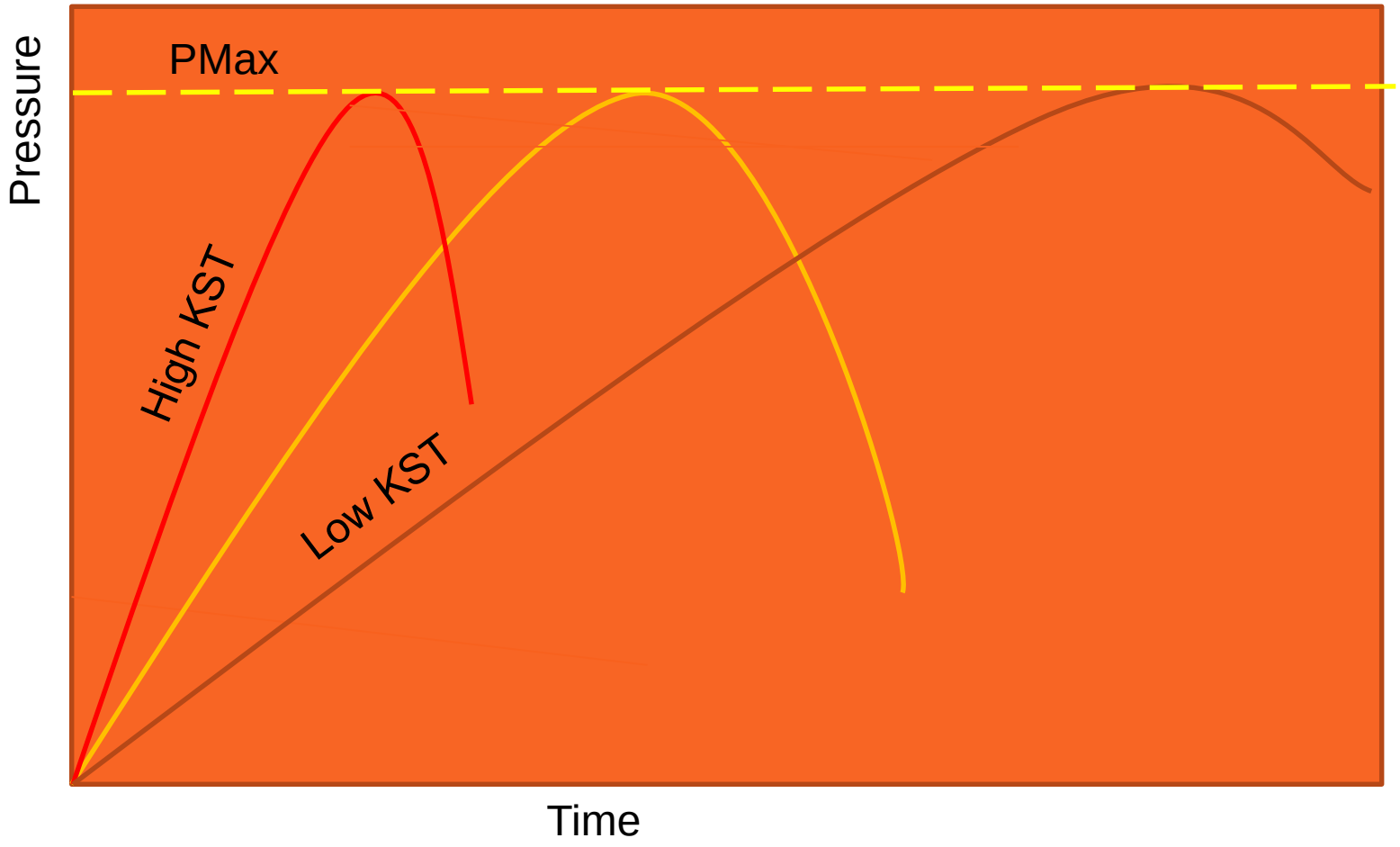
Kst is a measure that describes how quickly the pressure will rise. It's measured in Bar m/s. It always refers too the rate of pressure rise at "optimum" concentration and normalized for a 1 m^3 vessel

Pmax is a measure of the maximum pressure that you can get in a closed vessel at optimum concentration. It's measured in Bar. Note that a low KST dust can still have a significant PMax it will only get there a few 10 ms slower

Pred is the pressure reduced value whereby an explosion vent will open to relieve the explosion pressure inside the vessel / dust collector



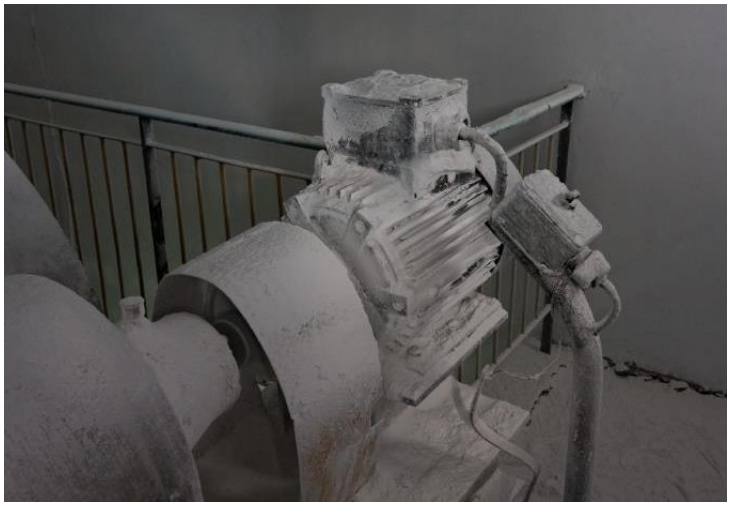
3 Dusts with different KST and the same PMax



ATEX Basics – Data Requirements cont…

PSCI
PHARMACEUTICAL
SUPPLY CHAIN
INITIATIVE

- The measure for ignition sensitivity in a cloud is mainly **Minimum Ignition Energy (MIE)** the smallest energy from an electric spark that will ignite the dust
- Several factors in a substance chemical composition affects the MIE apart from that the main factor is particle size. A smaller particle is easier to heat up and also to ignite
- Temperature is another important factor. Dust can be ignited by hot air or a hot surface. An electric motor that might be covered in a dust layer needs to have a limited surface temperature. The dust property is called MIT Layer and MIT Cloud



ATEX Basics - Ignition Sources

- Mechanical sparks (grinding, impact)
- The untrained maintenance guy
- Static electricity from non-conductors (dust and gas with MIE < 3 mJ, we add protection from <10 mJ)
- Static electricity from conductors such as metal parts and antistatic bags
- Hot surfaces (Motors, bearings)
- Fire (accidental or from hot work)
- Self ignition (Organic material, some metals)

ATEX Basics – Dust Classifications

PSCI
PHARMACEUTICAL
SUPPLY CHAIN
INITIATIVE

ST Class is a rough system of classifying dusts .

- ST Stands for staub that means ‘dust’ in German
- There are 3 classes ST1, ST2 and ST3
- ST1 1 – 199 Bar m/s
- ST2 200 – 299 Bar m/s
- ST3 300 – no upper limit!

KG is the same measure as KST but for a gas.

- Protection can be done in the same way as for dusts
- Due to restrictions in what can be released, gases are often present in low concentrations and only on a temporary basis

PSCI
PHARMACEUTICAL
SUPPLY CHAIN
INITIATIVE

Dust Explosions

- In large dust explosion accidents, dusty culverts and pipes often cause the spreading of the explosion
- An explosion travelling in a pipe will accelerate quickly
- The shock wave that preceeds the flame front accelerates faster
- As the degree of turbulence increase the pressure goes up
- Eventually the deflagration will turn into a detonation with very high pressures
- In a clean pipe the injected fuel from the explosion will convey the explosion in the pipe but if it’s strong enough it will die eventually
- Very small (-100 mm) pipes creates a cooling effect and it’s less likely that an explosion will be transmitted

PSCI
PHARMACEUTICAL SUPPLY CHAIN INITIATIVE

Explosion Consequences

- Shock waves that destroys equipment, parts of buildings and other structures
- Flying debris, glass, metal parts and stone
- High temperatures
- Risk of spreading to other buildings or parts of systems, causing further damage
- Fire
- And many times operators and other staff are injured or killed

Secondary Explosions

- Often larger then the primary explosion
- Occur in unexpected places
- Cause extensive damage
- Kill and injure people

PSCI
PHARMACEUTICAL SUPPLY CHAIN INITIATIVE

Secondary Explosions

- When an explosion occurs in a vessel it will propagate through any pipe connected to it
- In a dirty pipe (only a few mm is enough) the flames and shockwave will accelerate and the pressure increases
- Flames that exit through openings can disturb dust layers and create a huge explosion that destroys the building
- Flames that enter other vessels will create a much more powerful explosion and overpower most protective schemes

https://www.youtube.com/watch?v=Jg7mLSG-Yws

Why do Explosions Occur?

- **COMMON CAUSES – High level failures**
- Bad system design, no proper analysis of the function
- Lack of maintenance
- No routines to regularly inspect
- Lack of training
- Doing the same “low” risk procedure 10 000 times +1
- Lack of housekeeping
- Change of process without analysis and update of the system
- **INSUFFICIENT KNOWLEDGE**

PSCI
PHARMACEUTICAL SUPPLY CHAIN INITIATIVE

3 Steps to Dust Collection Explosion Prevention

1. A good system design that is basically safe

- Keeps the dust from spreading in the facility
- The design minimises risks, e.g dust settling in the ducts, potential for incendive sparks being generated, fire protection.
- Is also safe in case of an explosion - by design, location and protective systems.

2. Maintenance and inspection

- Documented regular maintenance and change of wear parts.
- Independent inspection by an experienced person

3. Training and work routines

- Basic training for all users, they should understand the purpose of the system and the remaining risks.
- Work permits and routines for dangerous work such as hot work.
- Training of production engineers, they need to understand.
- Routines for process changes, renewal of risk assesements.
- Emergency routines, what to do in case of fire, personel as well as fire brigade.

PSCI
PHARMACEUTICAL SUPPLY CHAIN INITIATIVE

ATEX Categories

ATEX Category	Typical Zone Suitability
1G 1D	Equip. suitable for zone 0 Equip. suitable for zone 20
2G 2D	Equip. suitable for zone 1 Equip. suitable for zone 21
3G 3D	Equip. suitable for zone 2 Equip. suitable for zone 22

ATEX Groups and Categories

PSCI
PHARMACEUTICAL SUPPLY CHAIN INITIATIVE

CATEGORY

1 – The most safe eqpt. For all zones (We can not supply this)

2 – Safe in Zones 21,22 / 1,2

3 – Only for Zone 22/2

Special conditions for use

What an ATEX Nameplate will look like

II 2D3G/3D- X T=125 C

GROUP

I – Mining equipment

II – Non mining equipment

D - Dust

G - Gas

Max surface temperature for the equipment

PSCI
PHARMACEUTICAL SUPPLY CHAIN INITIATIVE

Static Electricity - A Complex Problem

- A conductive material can discharge the energy stored in the entire part through a spark. This spark is much more dangerous than one from a non-conductor
- Some combinations of conductive materials and isolators pose the most potent danger. They can create something called a propagating brush discharge. To avoid this the isolation layer needs to be very thick or thin enough to allow a break through voltage of 4 kV or less. This is far more dangerous than normal static charge
- Using an antistatic bag without connecting it to earth creates a more dangerous combination then using a normal isolating bag

PSCI
PHARMACEUTICAL
SUPPLY CHAIN
INITIATIVE

Explosive dust properties - Concentration

- To create an explosive cloud you need a certain minimum concentration this is called the Lower Explosive Limit or LEL
- Typical minimum concentrations are in the range of 30 g/m^3 and up
- This means that almost all cartridge dust collection systems works with a concentration in the incoming air below the LEL
- During pulsing there will be a explosive cloud around the cleaned cartridge
- Other sub systems such as rotary valves or a dual valve creates small clouds periodically

Dust Collection – Basic Principles

PSCI
PHARMACEUTICAL
SUPPLY CHAIN
INITIATIVE

- Fine dust and fume particles are produced during many production processes and need dust extraction / collection equipment to remove them from the working environment

- Main Objectives:
  - Protect workers and the environment
  - Prevent explosions and fires
  - Protect machinery
  - Improve product quality / reduce contamination
  - Product reclamation

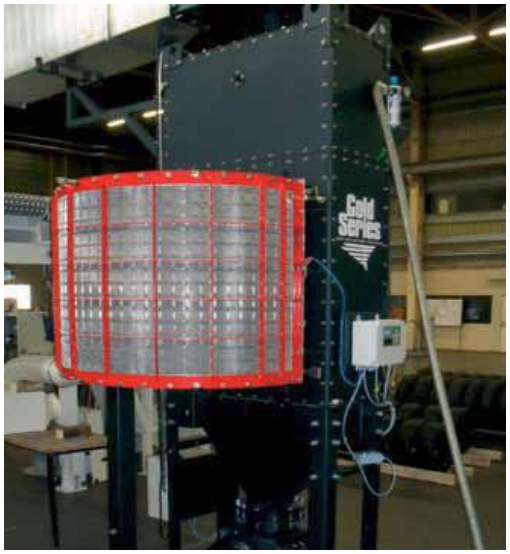
- Compliance with health and safety laws and environmental legislation
  - Exposure limits (OEL's) and emissions to atmosphere vary from country to country
  - Common E.U directives e.g. ATEX

ATEX Directives – Dust Collection

- **ATEX Equipment Directive**
  - The dust collector must comply with this directive if it is located in an ATEX Zone and/or it is collecting potentially explosive dust
  - Compliance is achieved by incorporating the necessary safety features determined by the explosive potential of the dust
  - Such safety measures include explosion vents, ATEX rated motors, chemical suppression systems, antistatic filters etc
  - NOTE: ATEX Zones can be inside and outside the dust collector as well as in the dirty air and clean air ducting

Explosion Prevention / Venting / Suppression

- Rule 1 - Eliminate Ignition Sources
- Rule 2 – Employ the appropriate explosion prevention and protection devices
- Safe explosion venting
  - Vent panel – to safe area
  - Flameless Venting
- Explosion Suppression
- Dust Collector reinforcement
- Ancillary Equipment
  - Non-return valve / damper
  - Slam-shut valve
  - Ducting modifications

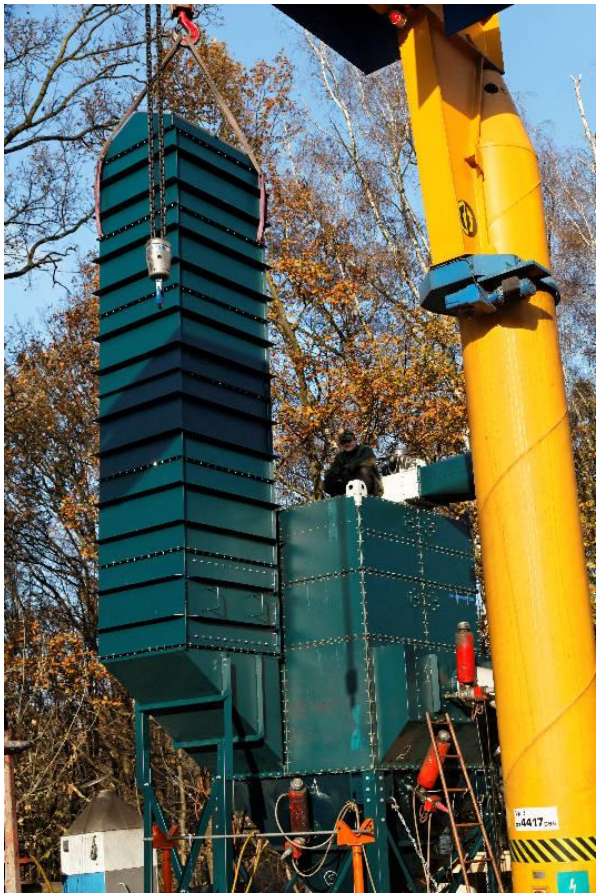


Explosion Venting

- Explosion vent panels are designed to open during an explosion event to release the explosion pressure wave and flame front into a designated safe area
- The safe area needs to be calculated to ensure no workers will be in the vicinity and prevent damage to nearby buildings or pieces of equipment
- The vent panel size will be calculated using all the parameters relating to the dust collector size and application specifics

Explosion Venting – Vent Ducts

- If units are installed indoors it's necessary to lead out the flames and pressure to the outside
- The duct creates a significant back pressure from un-burnt fuel that continues to explode inside the duct
- The max allowed length can be calculated with the vent standard
- Camfil APC has done testing that allows us to for some units use significantly longer ducts, up to 6 m
- This is valid for organic ST1 and ST2 dust

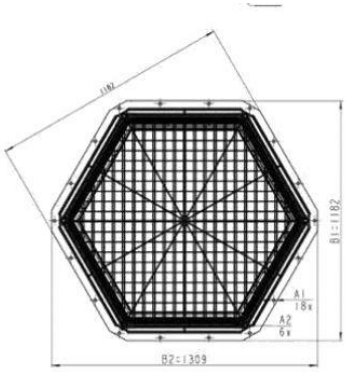


Flameless Venting

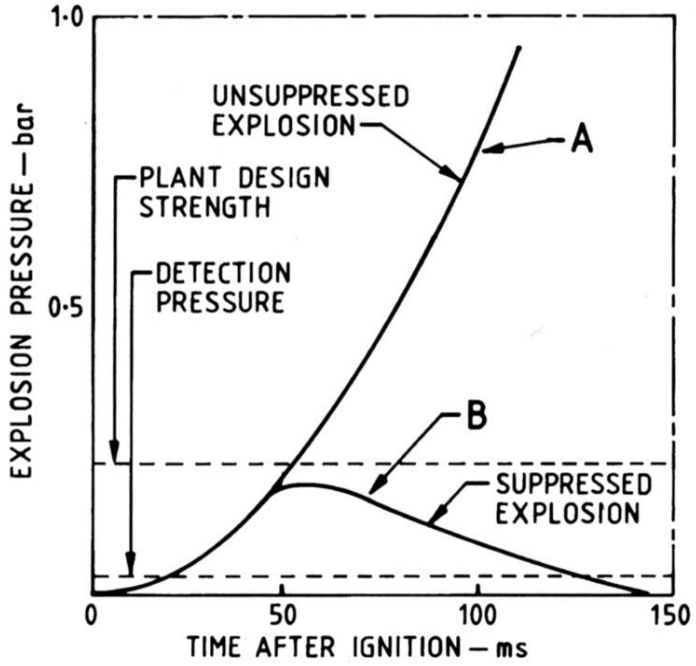
- A Flame quench is a device that is attached to the vent. The flame quench absorbs the energy from the flames and stops the flame. Some pressure and dust will penetrate

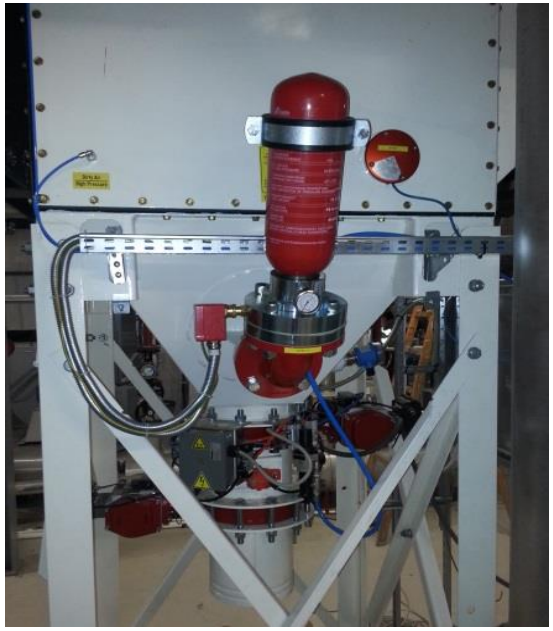
- There are many models and several suppliers. The efficiency is from 50 up to 70%. This means that we need more vent area. A FQ does not directly replace a normal vent

- The flame quenches have limits most can only handle organic dust. Other important parameters are KST, vessel volume, MESG



Suppression – Extinguish the primary explosion



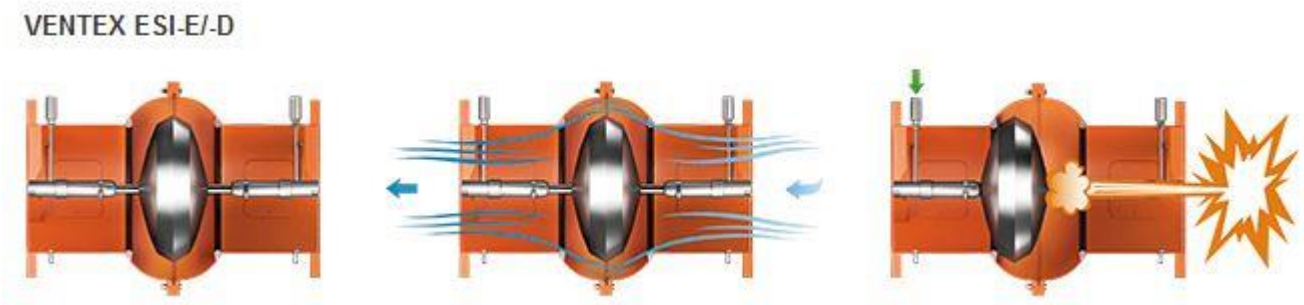


This is normally combined with a fast acting mechanical valve or a chemical barrier to protect the dirty side pipes

Outlet Isolation

- It may also be required to prevent an explosion from travelling through the clean side pipes. This can be done with an active valve or a passive Ventex valve
- Camfil has tested and verified that our ISMF filters can act as a passive flame barrier of organic ST 1 and ST2 dust.

Active flap valve

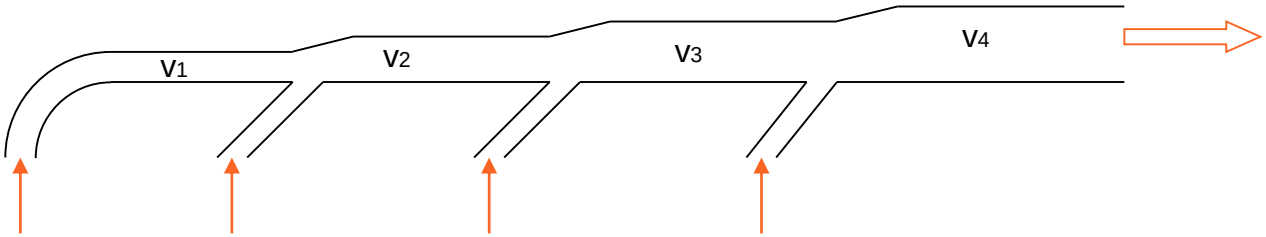


Dust Extraction System Design

- Well functioning capture devices (capture at source is the way if at all possible)
- Sufficient and slowly increasing transport velocity towards the dust collector. 15 – 25 m/s depending on the dust. Faster is not always better!
- Use 15 – 45 degree branches that connects from the side or top side
- Do not close individual suction points on a multi branched system. This might cause settling. Use multiple main pipes and or flushing systems to reduce problems
- If possible site the dust collector outside
- Electrically bond the entire system. Static electricity from large conductive object contains a lot of energy. Bonding integrated in the design is better then cables that can be forgotten or break even if the cables look ”sexy”
- Mark risk areas from venting and don’t use them for storage of flammable material or staff rest area
- Install protection such as explosion anti return dampers and venting. FALSE SAFETY IS THE WORST KIND! A statement from the supplier saying that “you don’t need protection” is no protection if there is an explosion
- Make sure that the system will shut down in case of explosion or fire
- Do not use the same system for explosive dust and things like weld fume, cigarettes or mix Al with FeO (there are other unsuitable combinations like CuO and Al)

Stepped System – Constant Flow

$V_1 <= V_2 <= V_3 <= V_4$



The duct diameter is changed step vise to maintain or slightly increase velocity towards the end. Velocity shall never be allowed to decrease.

All connections shall be at a 15 – 45 degree angle and to the side or top of the duct. This reduces pressure drop and facilitate material transport. A bigger system can be broken up in branches like this that runs all the way back to the unit.

PSCI
PHARMACEUTICAL
SUPPLY CHAIN
INITIATIVE

WHAT IF ..

You have a vent duct that will break if there is an explosion.

WHAT IF ..

Sub contractors don’t have training in fire safety

The risk area from your vent is covered by glass and extends to the public sidewalk.

The electrician did not have enough cable glands when he did your system. So it slowly fills up with combustible dust.

WHAT IF ...

Your system was designed by a untrained engineer

In case of an explosion the chock wave and flames will shatter the window and enter the workshop with bad consequences.....

PSCI
PHARMACEUTICAL
SUPPLY CHAIN
INITIATIVE

MOST ACCIDENTS CAN BE PREVENTED BY KNOWLEDGE

SOME ACCIDENTS ARE UNPREVENTABLE BUT THE CONSEQUENCES CAN BE LIMITED

PSCI
PHARMACEUTICAL SUPPLY CHAIN INITIATIVE

Pharma Industry – Case Study

- Pharma product manufacturing typically involves highly explosive dust such as API's in ST2 and sometimes ST3 type dusts
- Sometimes involves the use of solvents / gases for applications such as coating
- Normally requires dust collectors to be installed indoors in congested plant rooms
- Dusts are both explosive and harmful to human health and therefore require ATEX and containment solutions
- This solution was for a large multinational pharma manufacturer
- Issues of ST2 dust, indoor installation with space constraints, toxic dust requiring full containment solutions and a HEPA after-filter

Pharma Industry – Future Challenges

PSCI
PHARMACEUTICAL SUPPLY CHAIN INITIATIVE

- A move away from traditional batch processes to Continuous Manufacturing Processes
  - Smaller individual processing machines designed to operate 24/7
- API's becoming finer and therefore more reactive / explosive and more toxic
- Congested plant rooms will remain congested!

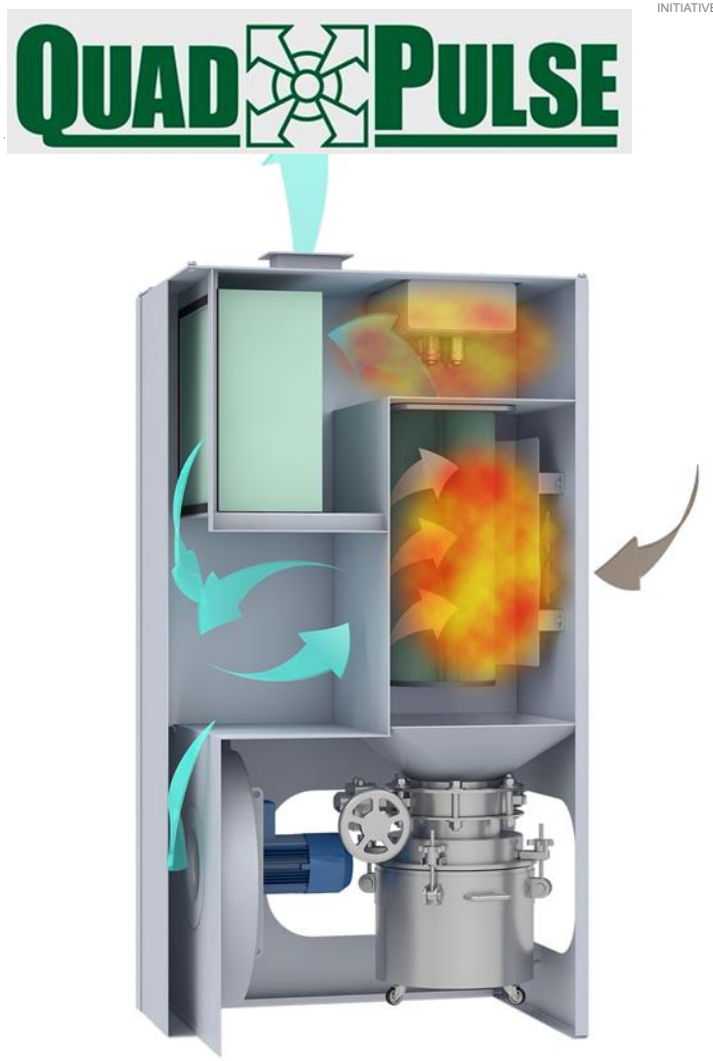
New Product Developments

PSCI
PHARMACEUTICAL SUPPLY CHAIN INITIATIVE

- The unit can withstand the reduced over pressure in case of an explosion **without the use of an explosion vent** and with the inlet closed (outlet open). The QPP is therefore very flexible in terms of where it can be installed

- The unit can also use a vent panel after the HEPA filter, this gives a lower risk of contamination in the plant room

- For high KST values and hybrid mixtures (dust and gas) suppression will be used



PSCI
PHARMACEUTICAL SUPPLY CHAIN INITIATIVE

Summary

- **Bad news:** Dust explosions and fires are major hazards with the potential to cause death and destruction

- **Good news:** The explosion and fire risk can be safely managed using the following rules:
  1. Use good housekeeping procedures
  2. Know your dusts – get them tested and it may save you money!
  3. Install well-designed dust extraction and collection systems, using experienced and reliable designers, installers and suppliers
  4. Apply the appropriate style of dust collector / wet scrubber
  5. Follow the ATEX directives to ensure the equipment being supplied has the required level of protection to minimise the risks and provide a safe and healthy working environment

Camfil APC – ATEX Training

Thank you for your attention

Any Questions?

Anil Nair
Business Lead – Dust Collection Systems – Camfil India

Anil.nair@camfil.com
www.camfilapc.com; www.Camfil.in