PSCI

PHARMACEUTICAL SUPPLY CHAIN INITIATIVE

PSCI - Auditor Training

Shanghai, November 21-23, 2017

Dr Birgit Skuballa, PSCI Vice Chair

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Welcome and introduction

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Anti-Trust

While some activities among competitors are both legal and beneficial to the industry, group activities of competitors are inherently suspect under the antitrust/anti-competition laws of the US, UK and other countries in which our companies do business. Agreements between or among competitors need not be formal to raise questions under antitrust laws, but may include any kind of understanding, formal or informal, secretive or public, under which each of the participants can reasonably expect that another will follow a particular course of action or conduct. Each of the participants in this meeting is responsible for seeing that topics which may give an appearance of an agreement that would violate the antitrust laws are not discussed. It is the responsibility of each participant in the first instance to avoid raising improper subjects for discussion, such as those identified below.

It is the sole purpose of this meeting to provide a forum for expression of various points of view on topics described in the agenda and participants should adhere to that agenda. Under no circumstances shall this meeting be used as a means for competing companies to reach any understanding, expressed or implied, which tends to restrict competition, or in any way to impair the ability of members to exercise independent business judgment regarding matters affecting competition.

Topics of discussion that should be specifically avoided are:

- Price fixing
- Product discounts, rebates, pricing policies, levels of production or sales and marketing terms customer and territorial allocation
- Standards setting (when its purpose is to limit the availability and selection of products, limit competition, restrict entry into an industry, inhibit innovation or inhibit the ability of competitors to compete)
- Codes of ethics administered in a way that could inhibit or restrict competition
- Group boycotts
- Validity of patents
- On-going litigation
- Specific R&D, sales or marketing activities or plans, or confidential product, product development, production or testing strategies or other proprietary knowledge or information

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What is the PSCI?

The Pharmaceutical Supply Chain Initiative

The **PSCI** was formed as a **non-profit business membership** organization in 2006 and is legally established in the United States.

Our **PURPOSE** is to **bring together the pharmaceutical industry** to formalize, implement, and champion **responsible supply chain practices.**

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Our Vision, Mission and Ethos

Our **VISION** is to establish and promote responsible practices that will continuously improve ethics labor, health, safety and environmentally sustainable outcomes for our supply chains.

Our **MISSION** is to provide members with a forum to establish industry principles that guide ethics, labor, health & safety, environmental sustainability, and management systems practices to support continuous improvement of suppliers' capabilities.

Our **ETHOS**:

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What are the PSCI Principles?

The PSCI created **Industry Principles for Responsible Supply Chain Management**.

These five Principles outline our **expectations for sustainable supply chains in our industry** and provide descriptions of our expectations for pharmaceutical supply chain partners:

To put these into practice simply, our comprehensive Implementation Guidance provides:

- ✓ **Clarity** about the Principles in each of the five areas
- ✓ A **framework** for improvement
- ✓ **Examples** of how to meet the PSCI expectations

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What are your expectations for the next two days?

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Our Expectations for the Next Two Days

- To ensure that everyone leaves this room with a clear understanding of the PSCI Principles, the available tools for conducting a PSCI Audit and the PSCI Auditing expectations with a special focus on the HSE sections

- To have an open and honest discussion about the challenges you may be facing while carrying out PSCI Audits

- To address these challenges by sharing our expertise on conducting PSCI HSE Audits and audit report writing

- To highlight certain Do's and Don'ts while carrying out PSCI HSE Audits and report writing

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PSCI Auditor Training Agenda (1)

DAY 1 – Tuesday, Nov 21, 2017

08:30 – 09:00	Registration, coffee/tea	
09:00 – 09:15	Welcome, introduction and meeting expectations	Birgit Skuballa (Bayer)
Introduction to PSCI Audits – documents, audit protocols, process and report writing		
09:15 – 10:30	Introduction to PSCI key documents related to audits	Birgit Skuballa (Bayer)
	Overview of the PSCI audit process	Birgit Skuballa (Bayer)
	PSCI SAQ / Audit Report templates	Birgit Skuballa (Bayer)
	Audit report writing and classification of findings	Birgit Skuballa (Bayer)
10:30 – 10:45	BREAK	
10:45 – 11:45	Group exercises on writing findings and classification of findings	Birgit Skuballa (Bayer)
Process Safety		
11:45 – 12:45	Introduction to process safety management & regulations	Wenjia XU (J&J)
12:45 – 13:45	LUNCH	
13:45 – 15:00	Storage and handling of hazardous and flammable chemicals	Wenjia XU (J&J)
	Centrifuge safety	Wenjia XU (J&J)
15:00 – 15:15	BREAK	
15:15 – 16:00	Reaction thermal hazards and emergency vent sizing	Lamy Bao (BMS)
	Summary of process safety management	
16:00 – 17:00	Dust hazards and explosion protection	Hui Ting Shang (Elanco)
	Montage of previous incidents	Hui Ting Shang (Elanco)
17:00 – 17:30	EXAM Part 1	Birgit Skuballa (Bayer)
17:30 – 18:30	China Sustainability Collaboration Group Discussion	PSCI Members
19:00 – 21:00	Dinner, restaurant TBC (within 5 mins from hotel)	PSCI Members

DAY 2 – Wednesday, Nov 22, 2017

08:30 – 09:00	Registration	
Environmental Protection		
09:00 – 10:30	Environment expectations & current drivers	Rachel Rae (Eli Lilly)
	Pharmaceuticals in the environment & wastewater	Rachel Rae (Eli Lilly)
	Storm water management	Rachel Rae (Eli Lilly)
10:30 – 10:45	BREAK	
10:45 – 11:45	Authorizations and permits	Caroline O'Brien (AstraZeneca)
	Management systems	Caroline O'Brien (AstraZeneca)
	Material storage	Caroline O'Brien (AstraZeneca)
	Air emissions control	Caroline O'Brien (AstraZeneca)
	Waste management	Caroline O'Brien (AstraZeneca)
Emergency Preparedness and Response		
11:45 – 12:45	Fire safety	Tony Wu (XL Gap)
12:45 – 13:45	LUNCH	
Occupational Health and Industrial Hygiene		
13:45– 15:00	PSCI industrial hygiene (IH) principles & critical findings	Li Liu (Boehringer-ingelheim) David Lu (Consultant)
	Start with the SDS – do we align?	Li Liu (Boehringer-ingelheim) David Lu (Consultant)
	Fundamentals of control banding	Li Liu (Boehringer-ingelheim) David Lu (Consultant)
15:00 – 15:15	BREAK	
15:15 – 16:15	Group exercise on industrial hygiene	Li Liu (Boehringer-ingelheim) David Lu (Consultant)
16:15 – 16:45	Hierarchy of controls in pharma	Li Liu (Boehringer-ingelheim) David Lu (Consultant)
	Red flags for IH & calibration exercise	Li Liu (Boehringer-ingelheim) David Lu (Consultant)
16:45 – 17:15	EXAM Part 2	ALL

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PSCI Auditor Training Agenda (2)

DAY 3 – Thursday, Nov 23, 2017

08:30 – 09:00	Registration	
General Safety		
09:00 – 10:30	High risk work programs	Pierre Reuse (Novartis)
	Red flags for dangerous working	Pierre Reuse (Novartis)
10:30 – 10:45	BREAK	
Final		
10:45 – 11:15	EXAM Part 3	ALL
11:15 – 11:45	SUMMARY & CLOSE	Birgit Skuballa (Bayer)
11.45 – 12.00	Distribution of Certificates	ALL

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Now let´s get started !

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General Guidance on PSCI Audits

Presented by

Dr. Birgit Skuballa

Bayer AG, Germany

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Bio

PSCI Role:	as of 1/2018: PSCI Chair, Board Liaison Audit WS
Company Role since 06/2017:	Bayer AG Corporate Health, Safety & Sustainability, Head of HSE MS, Audit Strategy & Planning
09/08	Bayer Health Care , HQ Leverkusen – Head of HSE Management Systems & Audits
02/07:	Bayer Schering Pharma, Berlin: HSE Audit and Management System Responsible
12/02:	Schering AG, Headquarter Berlin – GMP Auditor for APIs and Corporate HSE Lead Auditor
07/02:	Schering SpA, PH Production Site, Segrate, Italy
05/99	Schering AG, Berlin – QHSE Management System, Responsible Care Coordinator
02/95	Schering AG, Production site Bergkamen, Germany: Chemical Process Development
1994:	Postdoc at Nagoya University, Japan
1992:	PHD in Organic Chemistry, University Karlsruhe
Areas of expertise:	HSE and Social Auditing, GMP Auditing, Non financial Reporting, Sustainability Reporting, OE Greenbelt

Dr Birgit Isabelle Skuballa
Bayer AG, Leverkusen, Germany
Head of HSE MS, Audit Strat. & Plan.
Email: birgit.skuballa@bayer.com

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Agenda

01 **PSCI Key Documents**

02 **PSCI SAQ & Audit Report Templates**

03 **PSCI Audit Process**

04 **Audit Report Writing**

05 **Group Exercise**

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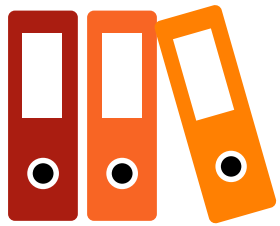
PSCI Key Documents



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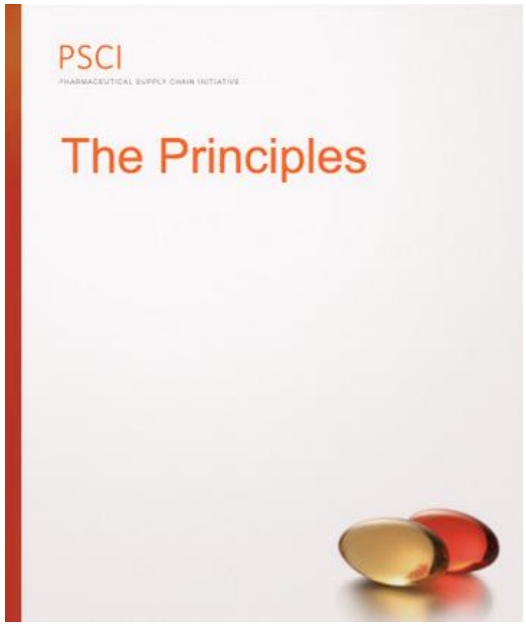
PSCI Key Documents



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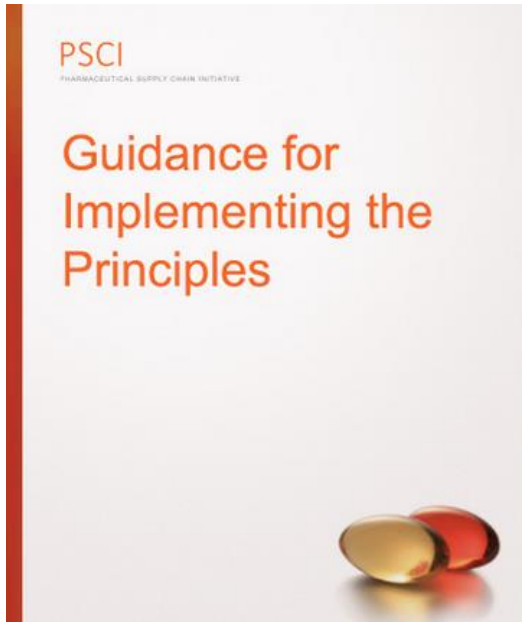

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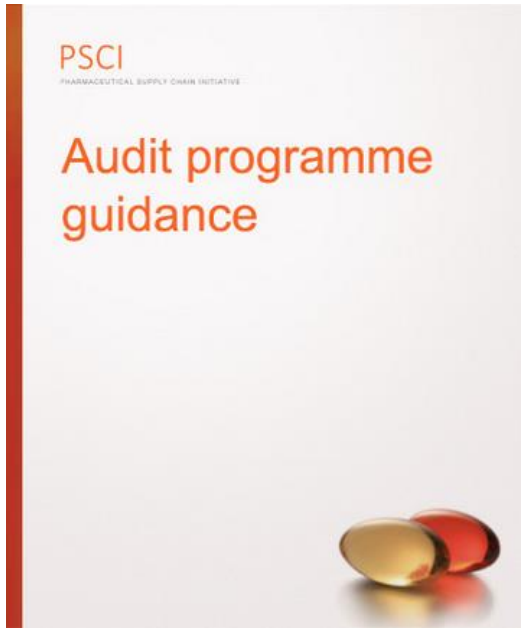

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Implementing the PSCI Principles

What

The PSCI Principles

Give broad descriptions of what is expected of pharmaceutical supply chain partners

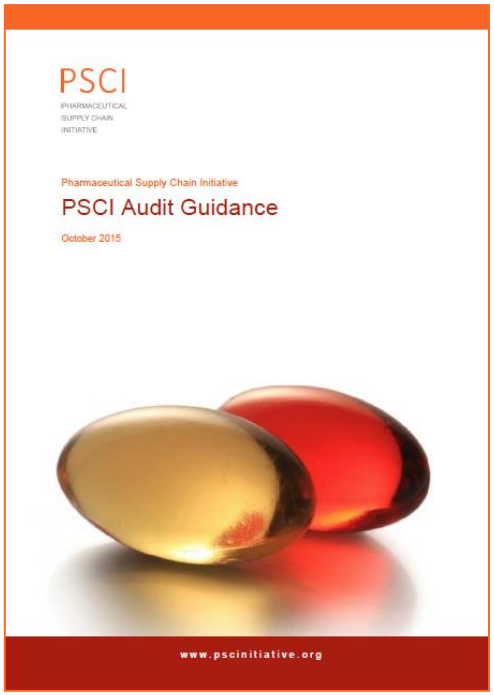
How

Implementation Guidance

- Further clarifies the Principles in each of the five areas
- Provides a framework for improvement
- Gives examples of how to meet the PSCI expectations

PSCI Audit Program Guidance

- Provides the methodology on how PSCI Audits are conducted and managed
- Gives a detailed overview of the audit process
- Clarifies auditor qualifications and roles/responsibilities



Contents

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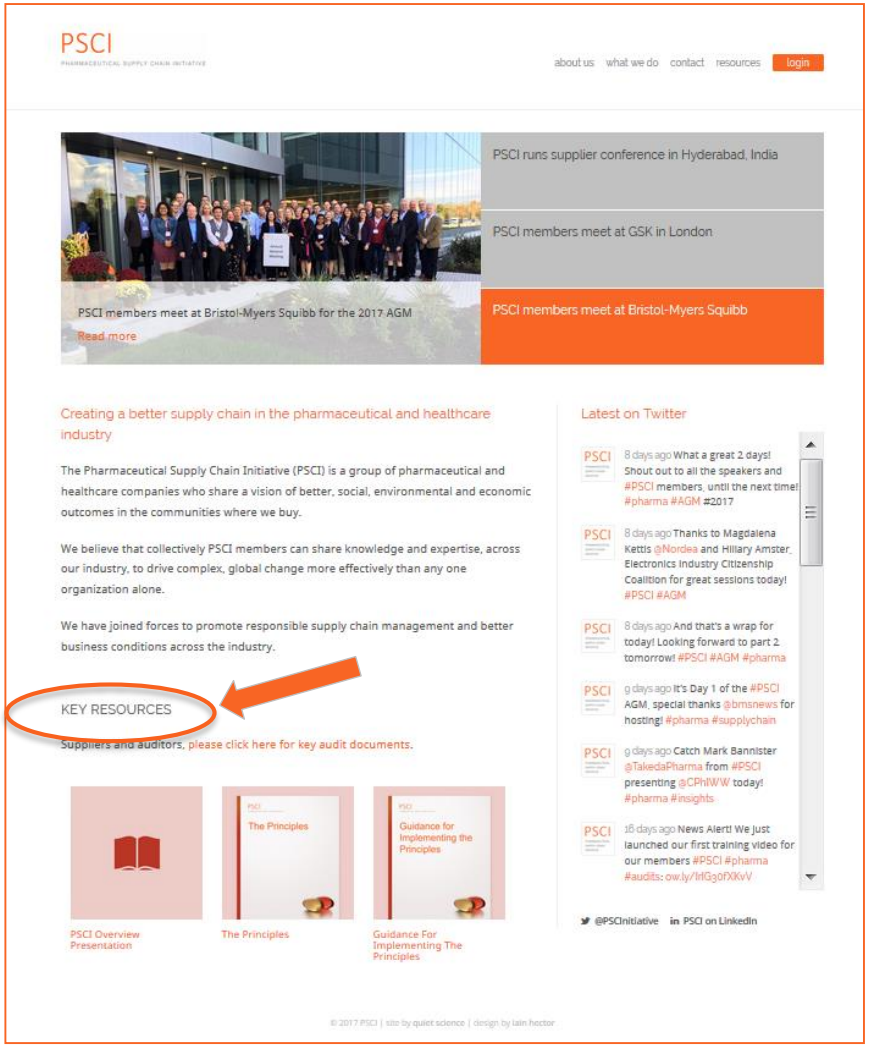
PSCI Homepage



You can also find the PSCI Key Documents on the PSCI home page under the heading `KEY RESOURCES´

https://pscinitiative.org/home

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PSCI Self Assessment Questionnaires & Audit Report Templates

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PSCI Protocols - based on Supplier Categories

For auditing purposes, suppliers are categorized according to their activities:

- "A" - service providers
- "B" - component & material suppliers
- "C" - core suppliers & contract manufacturers

PSCI Self Assessment Questionnaires & Audit Report Protocols (Word Versions)

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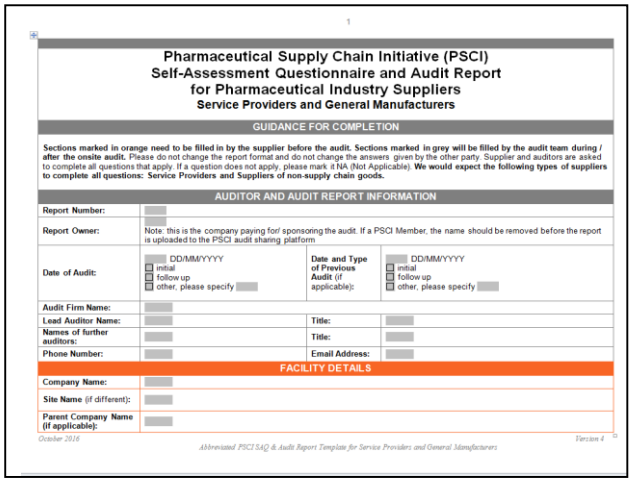


Pharmaceutical Supply Chain Initiative (PSCI)
Self-Assessment Questionnaire and Audit Report
for Pharmaceutical Industry Suppliers
Service Providers and General Manufacturers

GUIDANCE FOR COMPLETION

Sections marked in orange need to be filled in by the supplier before the audit. Sections marked in grey will be filled by the audit team during / after the onsite audit. Please do not change the report format and do not change the answers given by the other party. Supplier and auditors are asked to complete all questions that apply. If a question does not apply, please mark it NA (Not Applicable). We would expect the following types of suppliers to complete all questions: Service Providers and Suppliers of non-supply chain goods.

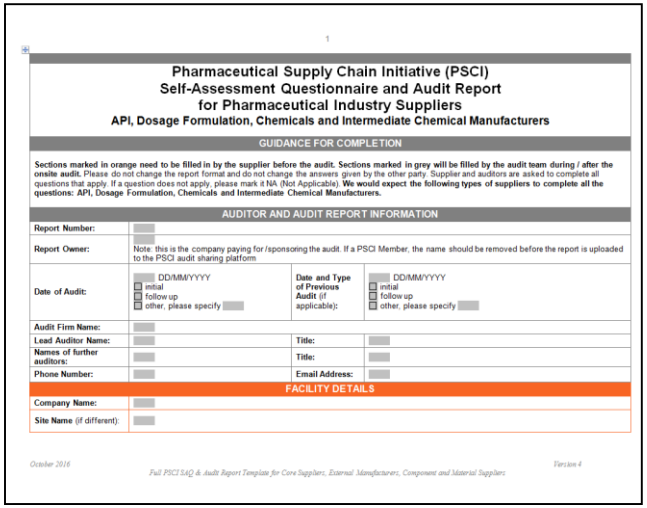
AUDITOR AND AUDIT REPORT INFORMATION

Report Number:			
Report Owner:	Note: this is the company paying for/ sponsoring the audit. If a PSCI Member, the name should be removed before the report is uploaded to the PSCI audit sharing platform		
Date of Audit:	DD/MM/YYYY ☐ initial ☐ follow up ☐ other, please specify	Date and Type of Previous Audit (if applicable):	DD/MM/YYYY ☐ initial ☐ follow up ☐ other, please specify
Audit Firm Name:			
Lead Auditor Name:		Title:	
Names of further auditors:		Title:	
Phone Number:		Email Address:	

FACILITY DETAILS

Company Name:	
Site Name (if different):	
Parent Company Name (if applicable):	

October 2016 Version 4
Abbreviated PSCI SAQ & Audit Report Template for Service Providers and General Manufacturers



Pharmaceutical Supply Chain Initiative (PSCI)
Self-Assessment Questionnaire and Audit Report
for Pharmaceutical Industry Suppliers
API, Dosage Formulation, Chemicals and Intermediate Chemical Manufacturers

GUIDANCE FOR COMPLETION

Sections marked in orange need to be filled in by the supplier before the audit. Sections marked in grey will be filled by the audit team during / after the onsite audit. Please do not change the report format and do not change the answers given by the other party. Supplier and auditors are asked to complete all questions that apply. If a question does not apply, please mark it NA (Not Applicable). We would expect the following types of suppliers to complete all the questions: API, Dosage Formulation, Chemicals and Intermediate Chemical Manufacturers.

AUDITOR AND AUDIT REPORT INFORMATION

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Date of Audit:	DD/MM/YYYY ☐ initial ☐ follow up ☐ other, please specify	Date and Type of Previous Audit (if applicable):	DD/MM/YYYY ☐ initial ☐ follow up ☐ other, please specify
Audit Firm Name:			
Lead Auditor Name:		Title:	
Names of further auditors:		Title:	
Phone Number:		Email Address:	

FACILITY DETAILS

Company Name:	
Site Name (if different):	

October 2016 Version 4
Full PSCI SAQ & Audit Report Template for Core Suppliers, External Manufacturers, Component and Material Suppliers

Abbreviated PSCI Self Assessment Questionnaire (SAQ) & Audit Report Template for Service Providers & General Manufacturers

Full PSCI Self Assessment Questionnaire (SAQ) & Audit Report Template for Core Suppliers, External Manufacturers, Component and Material Suppliers

USE FOR "A" SUPPLIERS!!

USE FOR "B" and "C" SUPPLIERS!!

https://pscinitiative.org/resource?resource=31

https://pscinitiative.org/resource?resource=32

How to complete the "word" PSCI Audit Protocols (1)

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- Sections marked in **orange** need to be filled in by the **supplier** before the audit
- Sections marked in **grey** will be filled by the **audit team** during / after the onsite audit
- Please **do not change** the **report format** and **do not change** the **answers** given by the supplier in the SAQ section.
- Auditors are asked to complete **all questions** that apply. If a question does not apply, please mark it **NA** (Not Applicable)
- Comments of the auditors **should not be a simple copy and paste of the SAQ** answer provided by the supplier or **should not be a turn around of the audit question to an answer**. Comments should reflect auditors actual observations during onsite.
- Please insert **photographs** when applicable and feasible, following the instructions as mentioned in the audit protocol.

How to complete the " word" PSCI Audit Protocols (2)

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- Comments section **should not** be left blank.
- The Yes/No/NA tick box in the auditor section also should not be left blank.
- The Yes/No in the auditor section refers to the related PSCI question, but not as a confirmation to the information provided by the supplier.
- Examples:

Does the facility perform self-assessments and/or internal audits to improve the effectiveness of its labor, ethics and HSE (Health, Safety & Environment) practices?	Yes ☐ No ☒ How often: Please explain:	Yes ☐ No ☒ Comments The company does not carry out any kind of self-assessments or audits covering labor, ethics and HSE practices
Does the facility have security systems for controlling physical access to your facilities?	Yes ☐ No ☒ Please explain:	Yes ☒ No ☐ Comments The facility has a security system in place. - The facility has boundary walls - Security guards are placed at every entrance and - All visitors need to register in the security guard room.

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PSCI SAQ/Audit Report templates in excel

We needed a tool that

- Allows us to extract data and analyse findings/trends
- Remains user friendly
- Can be updated easily
- Allow tracking of progress made to resolve audit findings
- Looks professional

Abbreviated PSCI Self Assessment Questionnaire (SAQ) & Audit Report Template for Service Providers & General Manufacturers:

https://pscinitiative.org/resource?resource=318

Full PSCI Self Assessment Questionnaire (SAQ) & Audit Report Template for Core Suppliers, External Manufacturers, Component and Material Suppliers

https://pscinitiative.org/resource?resource=319

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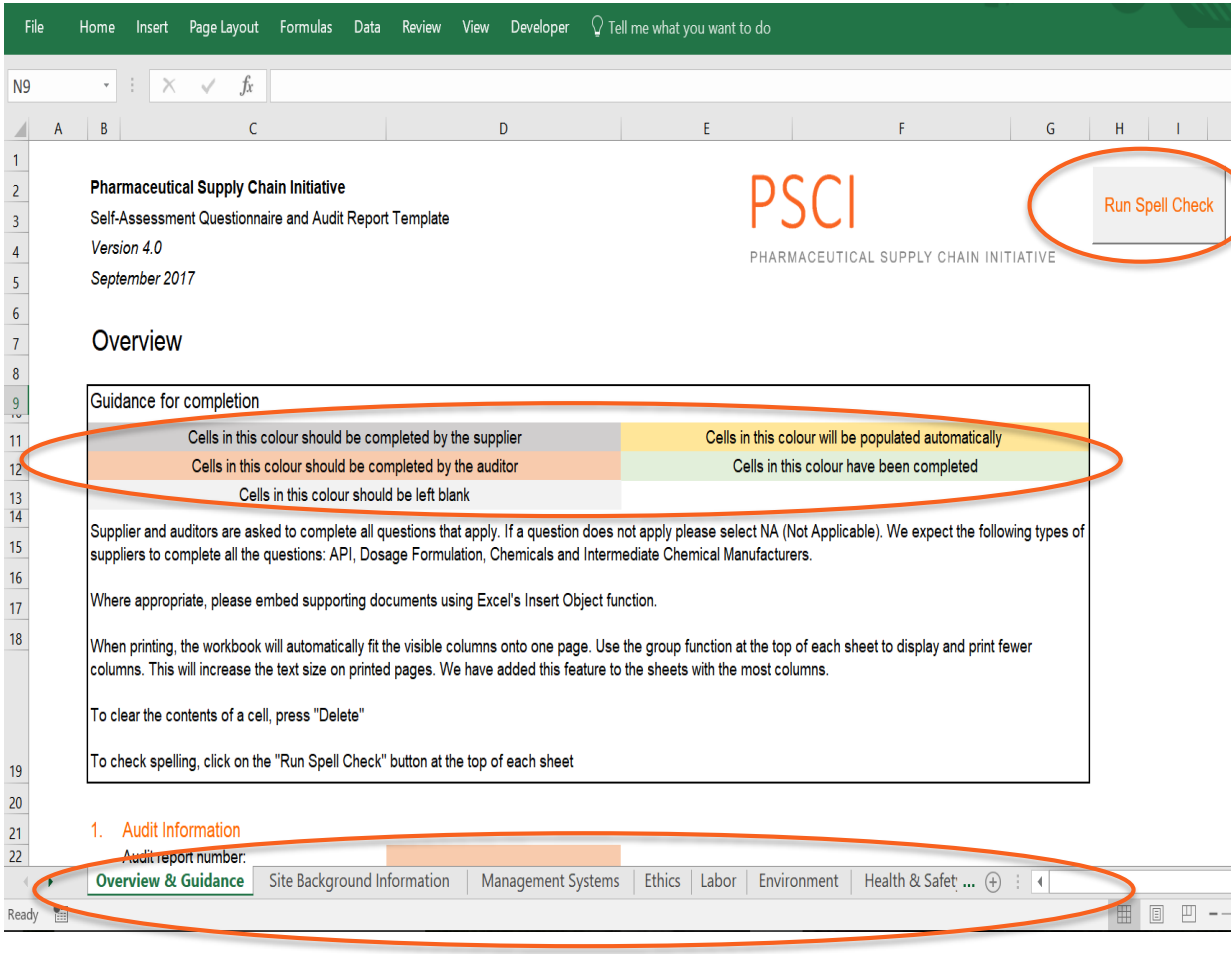
Excel templates: key features (1)

- Separate tabs for the separate sections of PSCI Principles
- Extra tab for company specific questions (which can be removed before sharing)
- Colour coding to make obvious who should complete each section
- Integrated spell check function
- Green highlighting to track completed cells



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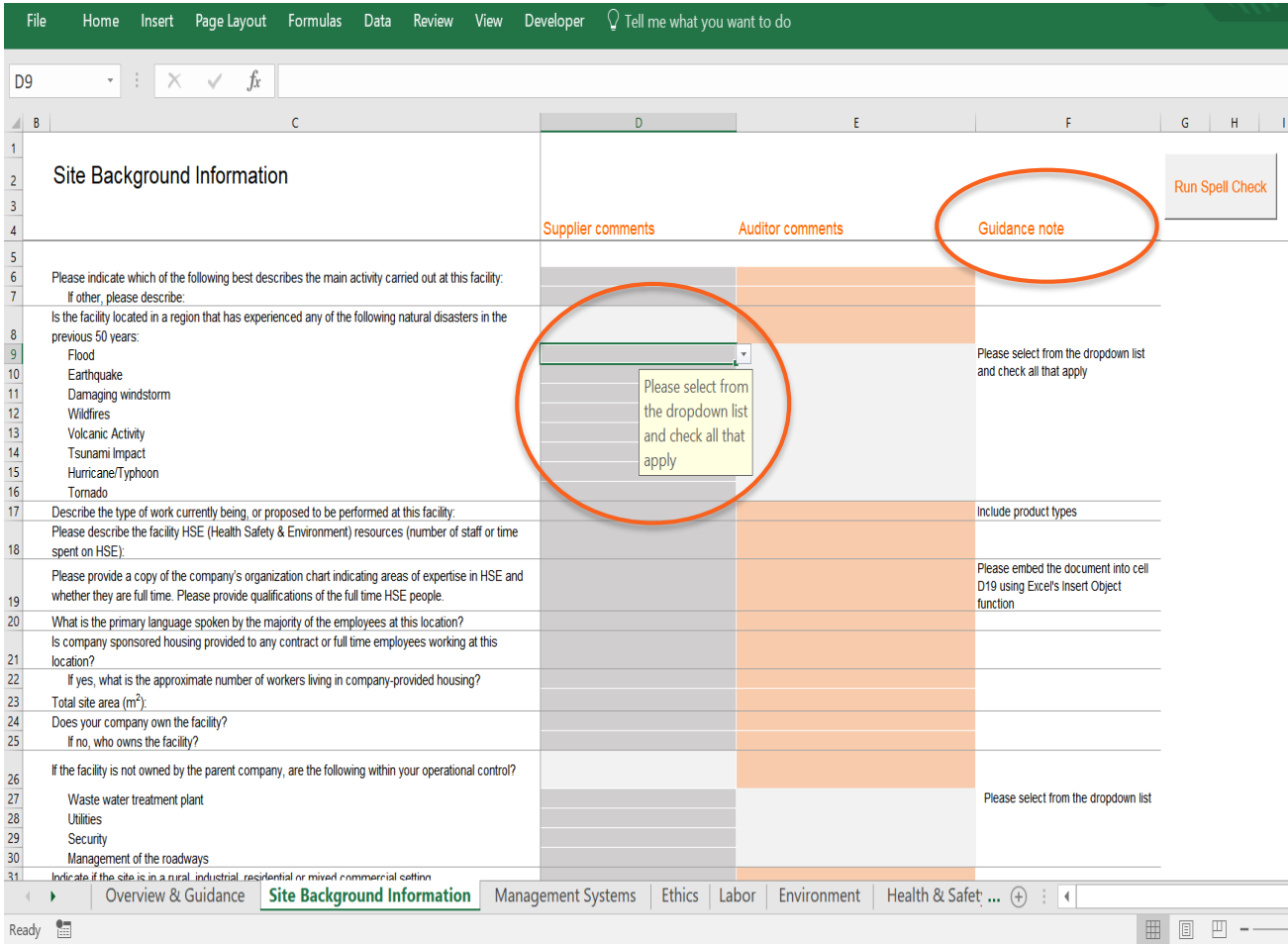
Excel templates: key features (2)

- Guidance notes
- Drop downs to standardise responses where appropriate



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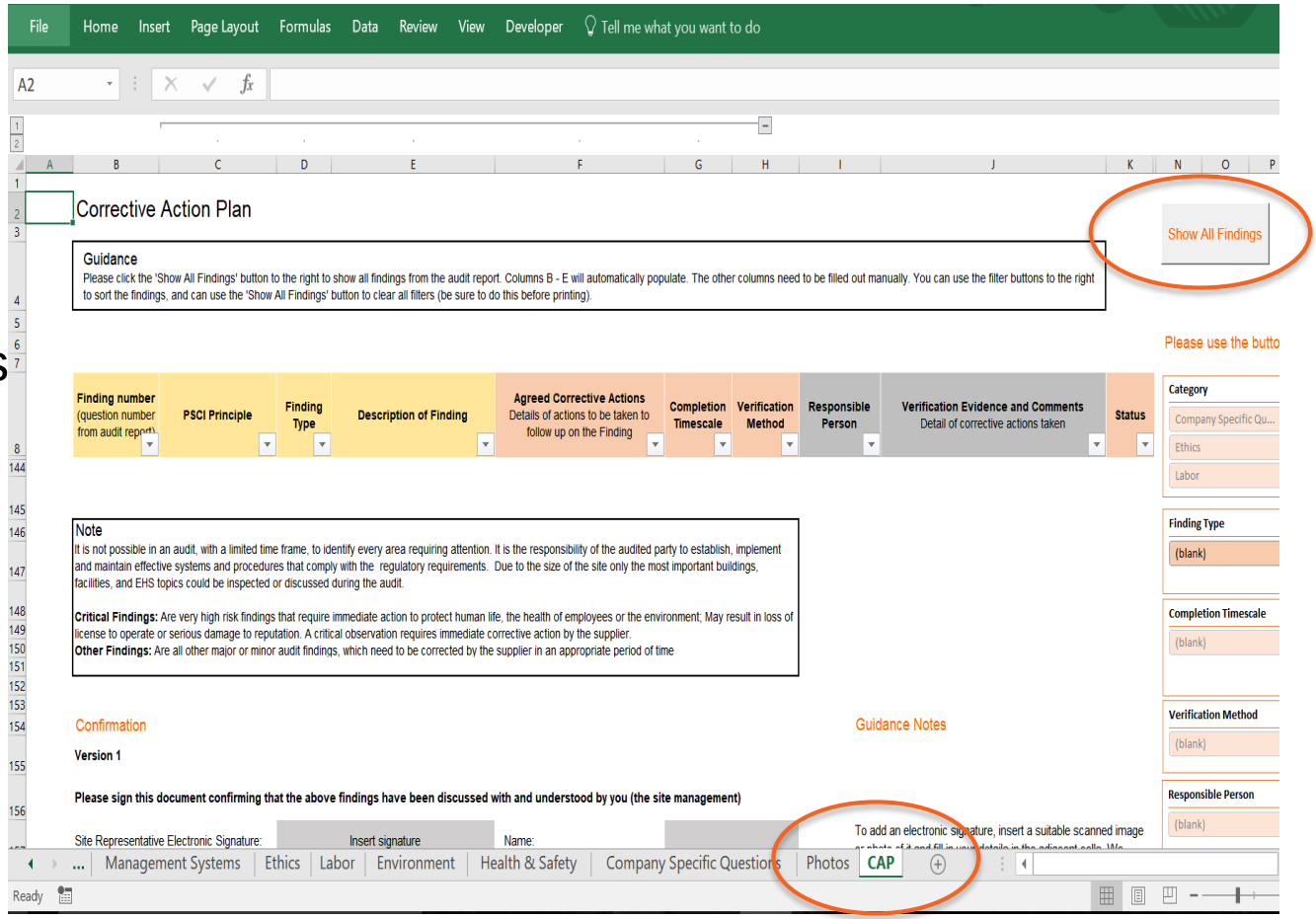
Excel templates: key features (3)

- One click automatic population of the Corrective Action Plan Report and summary findings table



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Excel templates: summary

- If you have suggestions on how to improve this template, or have questions, please send them to info@pscinitiative.org
- **Our long term goal is to move to Excel only. For now, both formats still can be used.**
- Please contact the sponsor of the audit (= the party who pays the audit) to confirm which version (excel or word) you are supposed to use for the audit.

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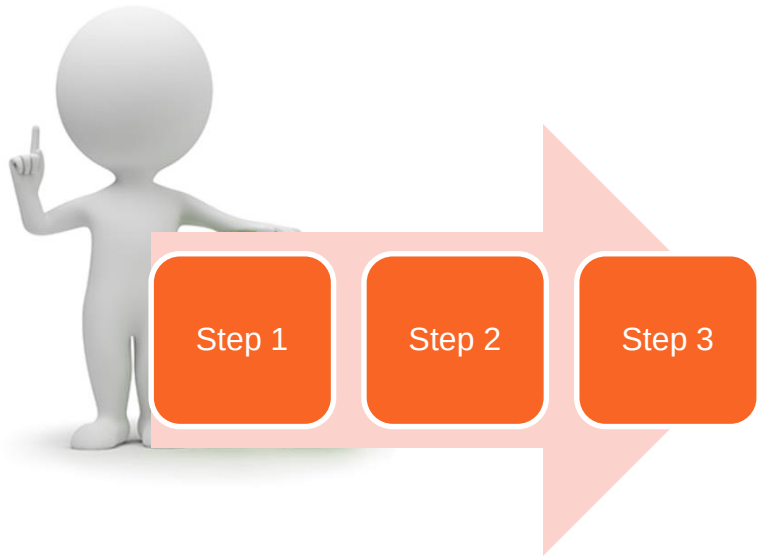
PSCI Audit Process



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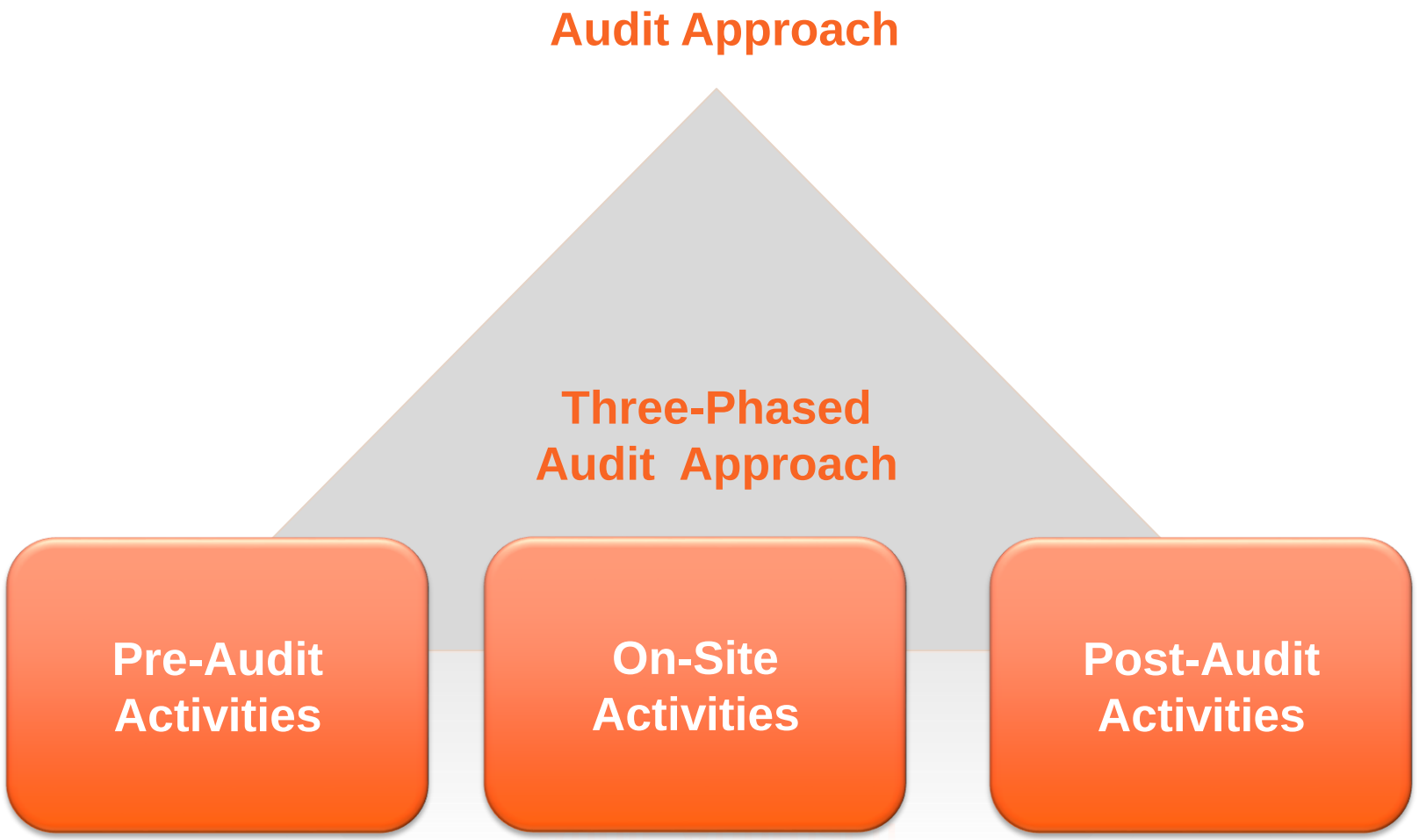
PSCI Audit Process



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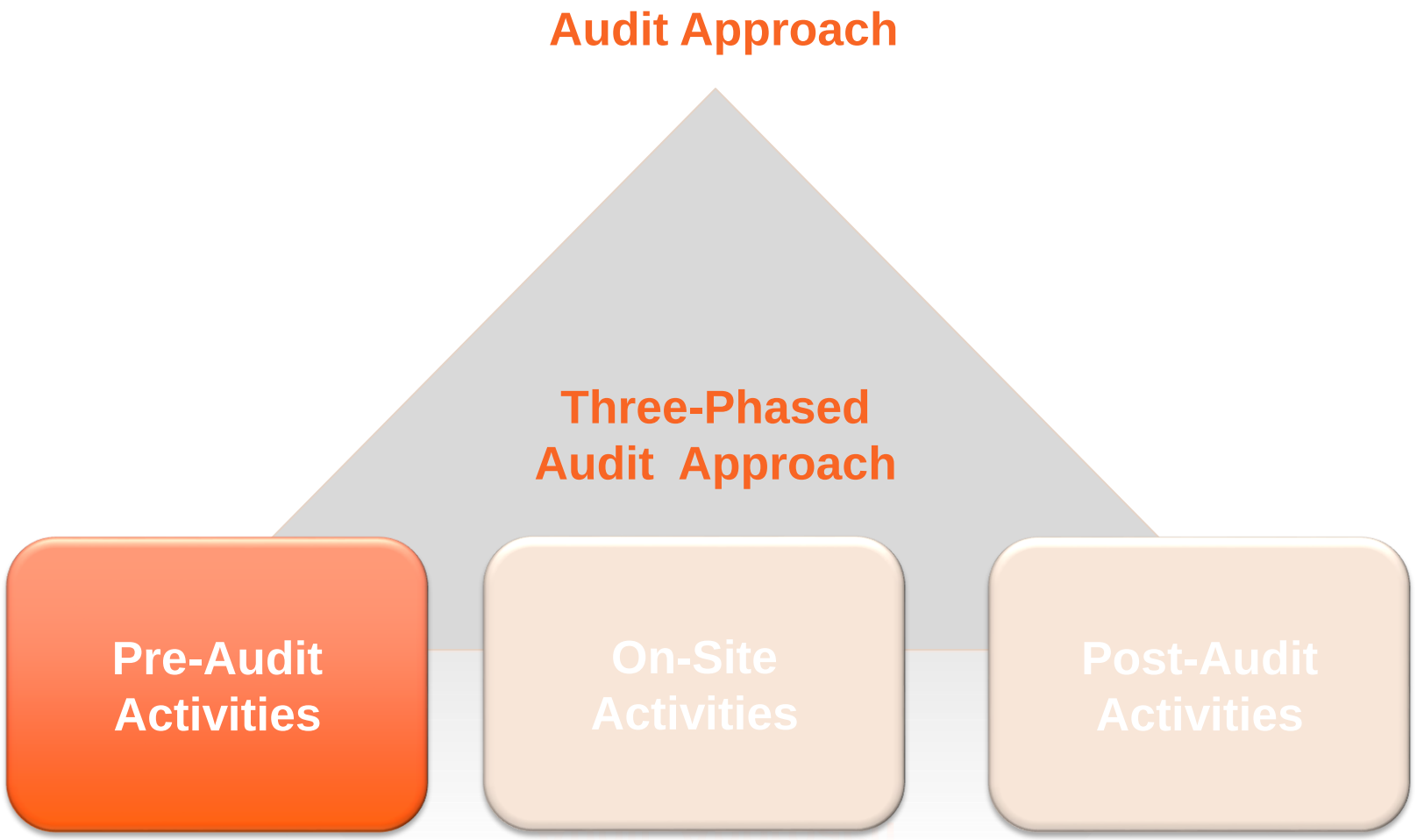
PSCI Audit Process



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Pre Audit Activities

Pre-Audit Activities

Administrative

- Schedule audit
- Contact & coordinate with the facility
- Distribute audit materials (SAQ, list of documents, audit plan)
- Arrange for travel

Planning

- Assemble & review background information & applicable regulations
- Develop audit assignments & areas to focus on
- Review & discuss audit team responsibilities

Goal
Hit the ground running

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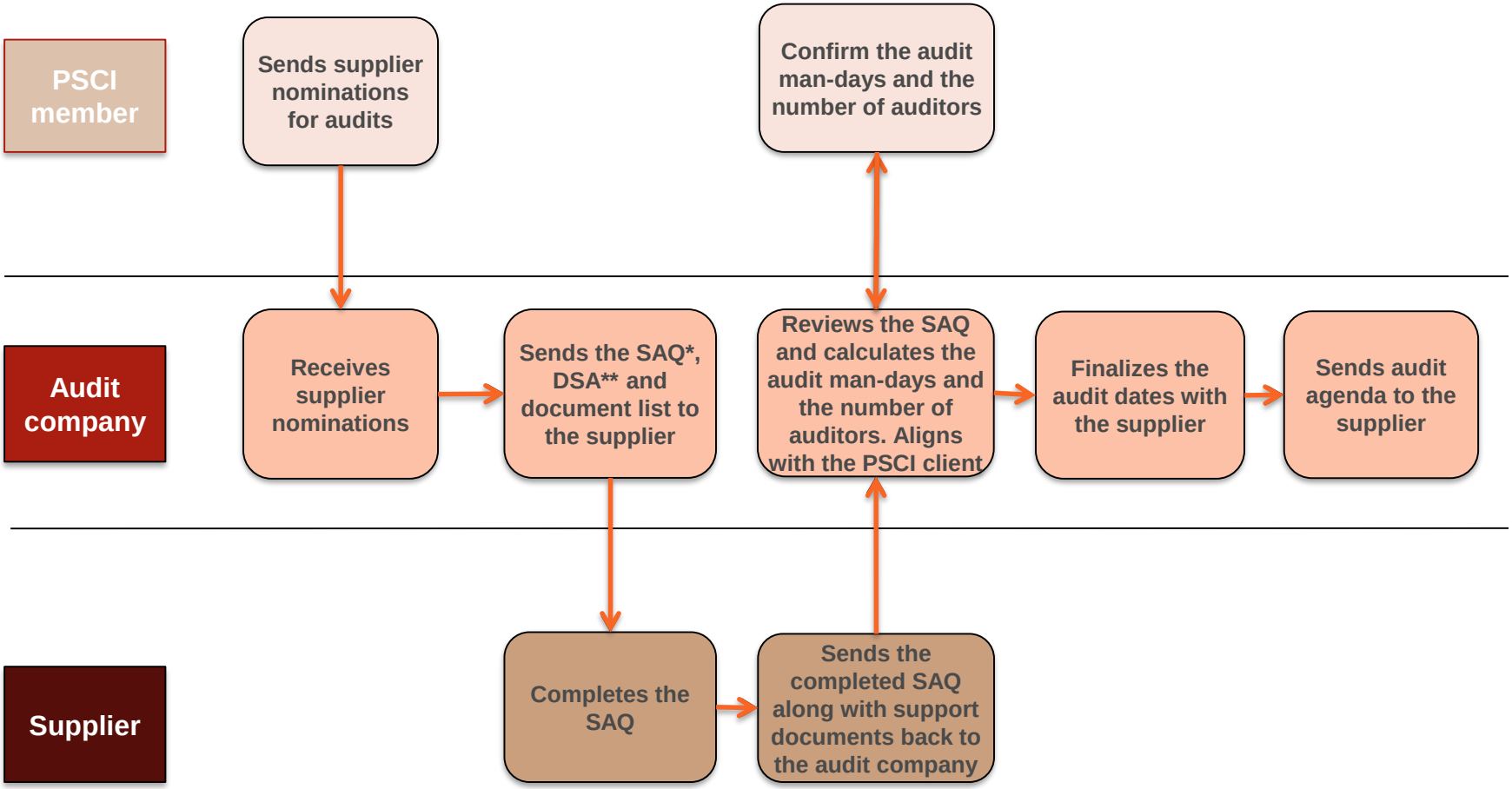
Pre Audit Activities



*SAQ – Self assessment questionnaire
**DSA – Data sharing agreement

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Pre-Audit Activities (1)

- Contact the supplier, provide information about the **audit team** and agree on the **audit date**
- Provide the **applicable PSCI Audit Report Template** to the supplier, so that they can fill out the **embedded Self-Assessment Questionnaire (SAQ)**; it is recommended to send the SAQ **at least four weeks prior to the audit date**.
- Provide the **PSCI Data Sharing Agreement** along with a short explanation.
- If requested by the supplier: sign a **confidentiality / data protection agreement** between the audit firm and supplier before any exchange of information takes place.

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Pre-Audit Activities (2)

- Check the **completed PSCI Self-Assessment Questionnaire** at least two weeks in advance to the audit
- Prior to the audit, provide the supplier with **an agenda** and a tailored **PSCI Pre-Audit Document checklist** which comprises documents/information which should be available during the audit
- Check the **website** of the auditee
- Carry out a **background research** about the auditee, e.g. media reports about environmental issues, reports about fatalities, accidents, incidents, loss of primary containments, news about legal issues etc.

Best Practice Example - Audit Announcement Letter (sample)

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Dear Mr./Ms

As a part of the (Name of the client) supplier sustainability evaluation process, you have been nominated to participate in a PSCI Supplier sustainability audit. (Name of the client) has designated (Name of the audit firm) to carry out this audit on their behalf. The purpose of this audit is to verify compliance with the PSCI (Pharmaceutical supply chain initiative) Principles. The Pharmaceutical supply chain initiative consists of a group of major pharmaceutical companies who share a vision of better social, economic and environmental outcomes for all those involved in the pharmaceutical supply chain. Please visit the PSCI website to find further information on the initiative.

Please find below the various steps involved:

Step 1: Announcement of the Audit and providing SAQ & DSA This is done by means of this e-mail and the attached information.

Step 2: Scheduling of the audit At this step the audit date and the length will be finalized.

Step 3: Sharing of the Audit plan Once the audit dates are finalized, we will share with you the detailed audit plan (agenda) along with the list of documents that would be reviewed during the audit.

Step 4: Onsite Audit
The onsite Audit would include the following:

- Opening Meeting with Senior Management and Middle Management
- Factory tour with Management
- Document Review
- Closing Meeting – Presentation of the audit results and agreement on a preliminary Corrective action plan (CAP)

Along with this email you will find the following documents attached:

- PSCI Audit protocol/SAQ (self-assessment questionnaire) – Please fill in the supplier section of this template and send it to us within **10 working days**. This SAQ covers the topics which will be addressed during the audit.
- Data sharing agreement template

As a starting point please provide us the following information at the earliest:

- No. of permanent and contract employees working at the site as on date
- Factory license copy
- Organization charts

The address of the site that will be audited is as follows:
Plot no xxxx, abc Industrial estate
City:
State:
Zip code:
Country:

Please feel free to contact us in case you have any queries on this topic. We look forward to your co-operation for a successful audit.

Best Practice Example: Pre-Audit Document Request List

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Pharmaceutical Supply Chain Initiative (PSCI)

PRE-AUDIT DOCUMENT REQUEST LIST

	Available	Not Available	Not Applicable
1 General Management Systems			
Organization chart			
Site drawings showing: ❒ property borders, ❒ tanks, ❒ detailed building layouts ❒ hazardous chemicals, solvents, oils and wastes storage, ❒ stacks and vents ❒ buried services (pipes, drains, sewers) ❒ buried tanks ❒ sumps, pits, oil separators ❒ lagoons and any points of discharge to local watercourses ❒ on site waste disposal areas (used and abandoned and disused)			
Site HSE policies and programs			
Management of change documentation			
Inspection and follow-up records			
Compliance self-assessment reports			
HSE training records			
Incident and Emergency Response Plans.			
Roles and responsibilities matrix			
Previous audit reports			
Reports of regulatory agency inspections and enforcement actions			
Regulatory agency correspondence			
Copies of previous social and HSE audits/review reports			
Details and outcome of complaints if any (plus			

	Available	Not Available	Not Applicable
correspondence).			
Government Inspection reports, e.g. sanitation, fire safety, structural safety, environmental compliance, etc			
2 ENVIRONMENT – General			
Correspondence with authorities relating to any environmental violations and pollution incidents (air, water, effluent, wastes, odor and noise).			
Emission Reduction Plan			
Waste reduction plan			
Spill, incident and upset reports			
Documented procedures and operating manuals relating to environmental matters (e.g. emergency response, spill containment, waste handling and disposal).			
3 AIR EMISSIONS			
All current air permits			
Air monitoring data for the past 36 months			
Air emissions inventory			
Air emissions reports submitted to regulatory agencies			
Copies of any violation notices received in the past three years			
Copies of any federal/national, state/provincial and/or local emissions standards			
Chlorofluorocarbon compounds (CFC) equipment maintenance records			
Air pollution abatement equipment maintenance records			
4 WATER SUPPLY, STORMWATER, AND WASTEWATER			
Wastewater discharge permits			
Wastewater discharge inventory			
Wastewater sewer drawings			
Wastewater treatment permits			
Wastewater discharge monitoring data/reports for flow and permit parameters for last 36 months			
Wastewater treatment plant maintenance records and as-built drawings			
Site's water balance			
Water abstraction permits			

https://pscinitiative.org/resource?resource=282

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Audit preparation tips and hints

- Study the SAQ (and the provided documents) carefully and prepare a plan on the topics that need more attention
- Ask for any additional information if needed from the supplier
- Check with the client if there are any special topics that need to be considered
- Dress up appropriately for the audit (e.g. business/casual attire, no high heels for ladies)
- Bring your own safety shoes
- Respect company‘s opening and closing time/shift timings
- Most important: arrive on time!

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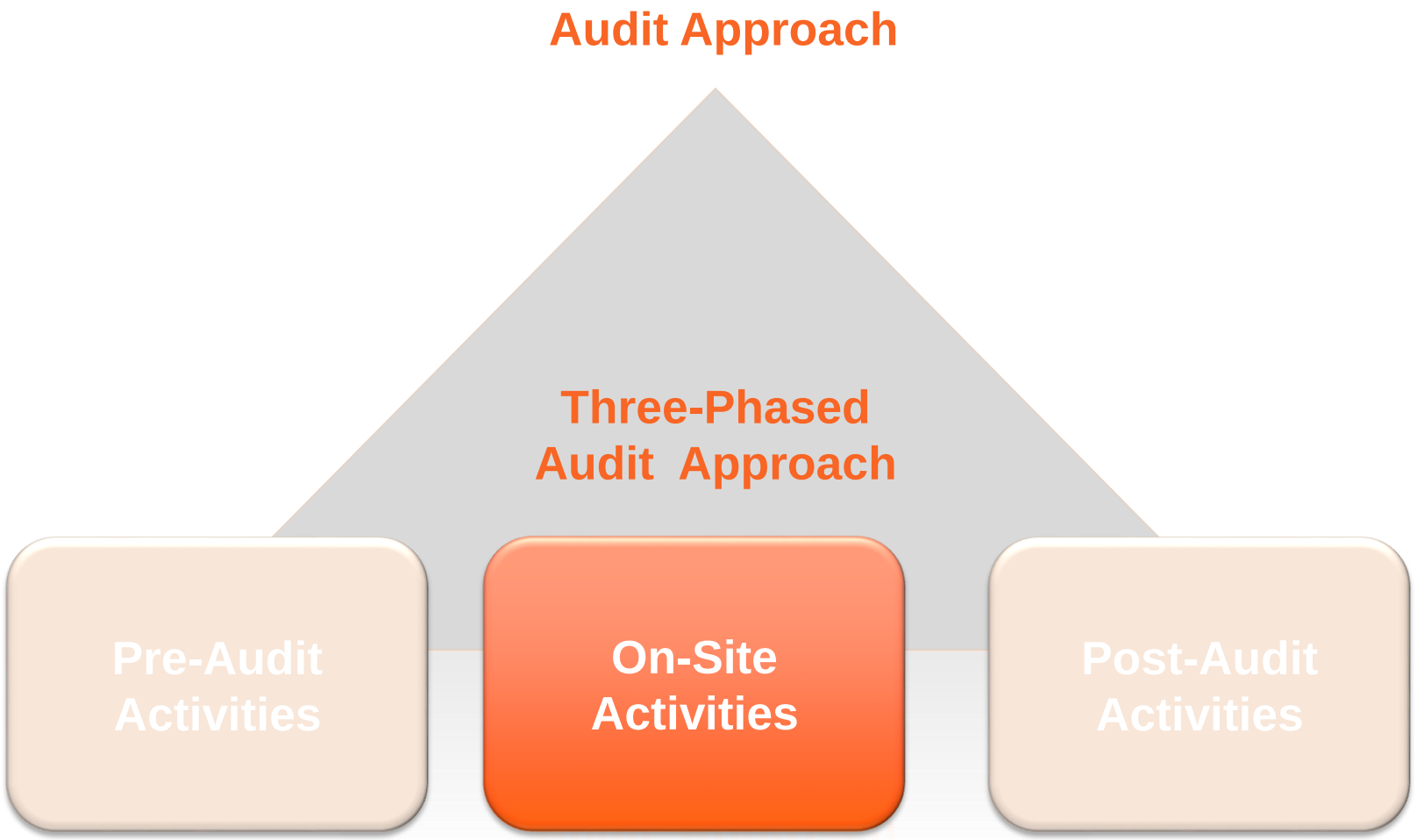
PSCI Audit Process



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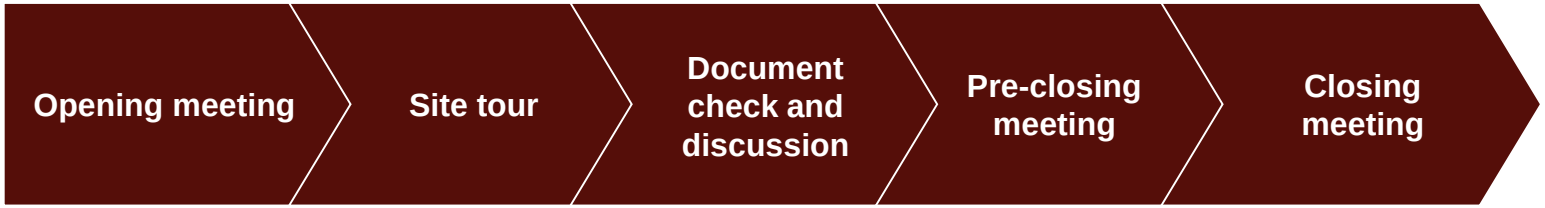
PSCI On-Site Audit Process (HSE Part)

Opening meeting by the auditor which would include the introduction of the auditor and the scope of the audit.

Involved parties: site/plant management, HSE(Q), engineering, production and others (as required)

Internal discussion among the auditors and **preparation of the CAP** (Corrective Action Plan)



Covers **production and other relevant infrastructure areas** e.g. waste, waste water, technical areas, utilities.

Exchange/discussions with employees and management

Document review e.g. as listed in the in the PSCI document list and **discussions** with technical experts and management (e.g. HSE(Q), engineering, production)

Presentation of best practices and points for improvement

Summary of the CAP and as a sign of agreement signing by both parties

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Opening Meeting

- Be **on time**!
- **Thank** the management for hosting the audit
- **Introduce** yourself and audit team and ask the others participants to introduce themselves (business cards; list of attendees)
- Provide a brief **background** about PSCI in case the company is unaware
- Explain the **purpose** and the benefits of the PSCI Audit
- Explain the **audit plan** (including areas to be inspected); be flexible if needed
- Ask the auditee to provide an **overview of their facility and processes**
- Ask if you **may take photographs** of selected areas (do not insist taking photographs if the auditee denies it)
- Ask for **safety instructions** and **evacuation plan** if not provided by the company.

Physical inspection of the facility – points to consider (1)

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- **Good time management** is key, especially during site tours
- Allow for **sufficient time for the site tour**, do not spend the majority of time with document review in the office
- Ask for a **site map** for the tour to help you with the site orientation
- Keep in mind that **gowning procedures** in pharmaceutical finishing plant may require a significant amount of time
- Inspect **main production areas**, but be careful not to spend too much time there (other areas like warehouses, waste storage/treatment, waste water treatment units and other utilities are also important to visit)

Physical inspection of the facility – points to consider (2)

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- Try to inspect **critical activities** e.g.
  - construction activities
  - drills,
  - inspection & sampling,
  - loading/unloading
  - Material handling and transfer
  - Waste packing and pick-up
  - Confined space entry
- Also inspect **remote areas, trailers, buildings** etc.
  - Are they truly free from hazardous materials?
  - Do employees work in this building?
  - Is there a ventilation system?
  - Are there items like fire extinguishers, emergency showers etc. which need to be inspected?
  - What about asbestos?
- Observe the facility also from the **outside**

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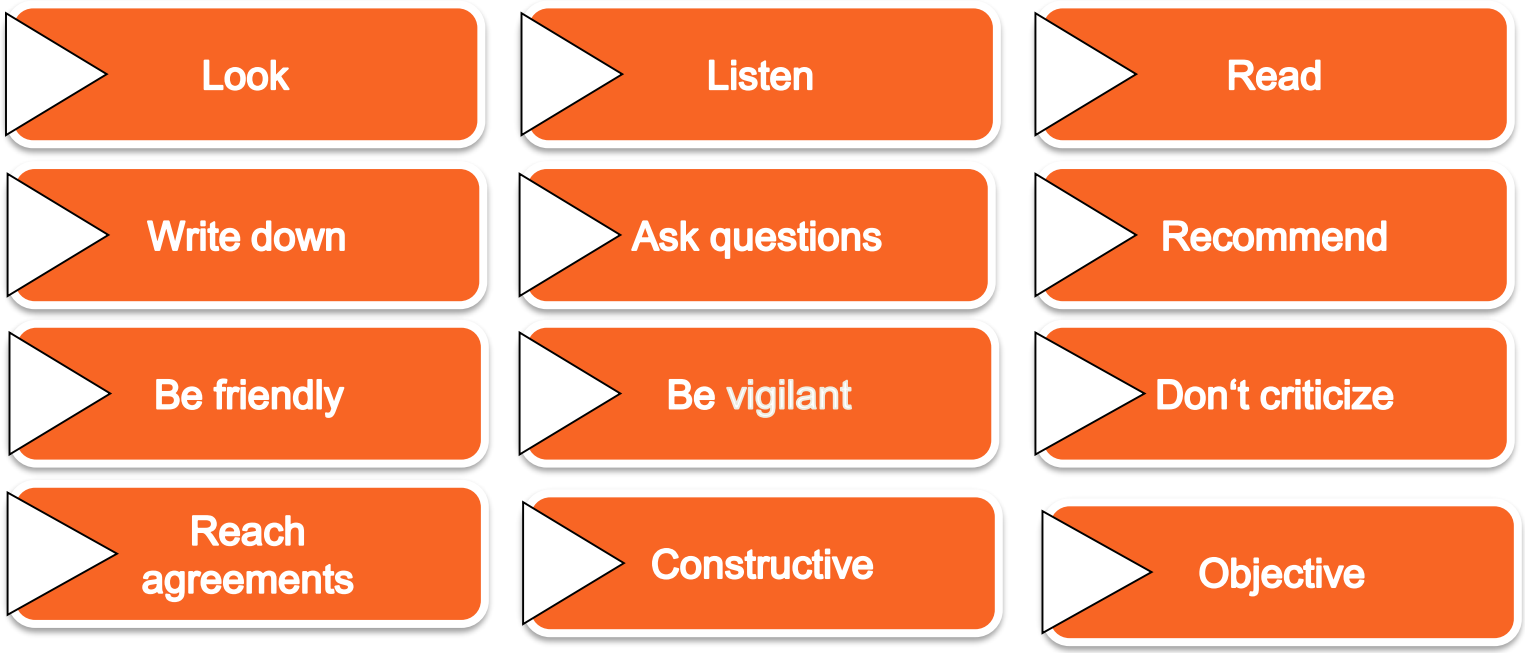
Behaviour During an Audit

- What an auditor should do:



- How an auditor should behave:

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Closing Meeting (1)

- **Thank** the management for their time, patience and openness and indicate how this contributes to fostering the mutual relationship and building trust;
- **Re-confirm** the purpose of the audit;
- Mention **good working practices** that have been observed during the audit;
- Explain that the audit was based on a **sample examination** of their site and that it is the site's responsibility to conduct a deeper investigation into their programs;
- Explain which **findings and improvement potentials** have been observed during the audit, and discuss possible corrective actions;
- Remind the supplier that they may **challenge/discuss findings** (or provide factual evidence that a finding was incorrect) in this meeting, but any issues they have agreed to will not be changed later;
- Besides listing the findings, ensure that any **agreements or disagreements** are clearly **recorded** on the Preliminary Corrective Action Plan;

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Closing Meeting (2)

- If possible: **Obtain the signature** of the site management on this Preliminary Corrective Action Plan Report;
- **Explain the next steps**; Drafting of PSCI Audit Report and PSCI Corrective Action Plan, Quality control of the audit report, finalization of the PSCI Audit Report and Corrective Action Plan Report and distribution to supplier and to the respective PSCI member;
- Encourage the management of the site to **allow for PSCI Audit Report and Corrective Action Plan Report Sharing** with other PSCI member companies (either by signing the PSCI Data Sharing Agreement or by **sharing online via the PSCI audit sharing platform**)

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Closing Meeting – Don´ts

- Never start with **negative observations**
- No **blame game**
- **Do not point out or name an employee** concerning a finding in the presence of management or his/her superior
- Never use **names or ID numbers** or any other identification of employees while presenting findings
- Avoid lengthy discussions with the management/other representatives in case of **disagreement on findings**, rather **document** the disagreement in the audit report/CAPR

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Encouraging Suppliers to share audits

Two ways of sharing PSCI Audit Reports:


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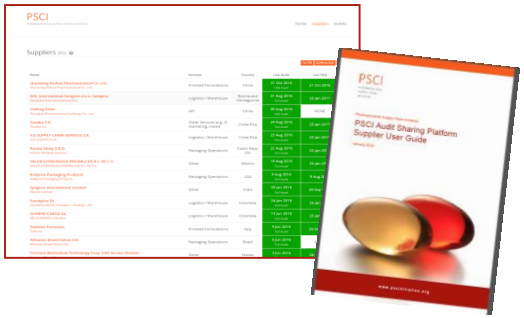
DATA SHARING AGREEMENT



PSCI Data Sharing Agreement

- Available on the PSCI website

  https://pscinitiative.org/resource?resource=283

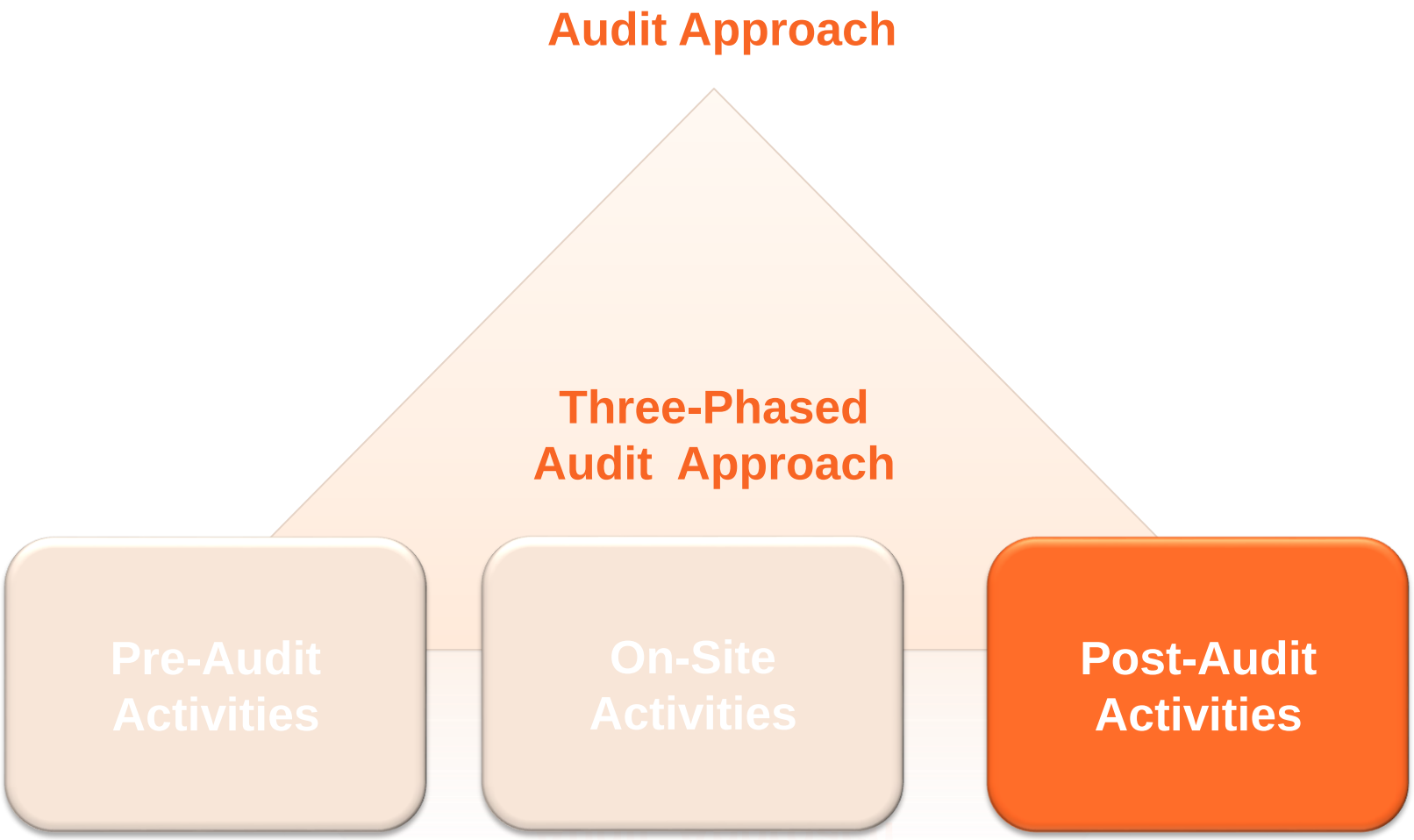
- To be physically signed by the supplier at the end of the audit or at a later stage
- A scanned copy to be provided to the PSCI Secretariat along with the audit documents

PSCI Audit Sharing Online Platform

- Suppliers can directly share the audit documents/SAQ by registering and logging into the PSCI audit platform
- A Supplier User Guide on how to share audit reports is available on the PSCI audit sharing platform

https://pscinitiative.org/resource?resource=290

PSCI Audit Process



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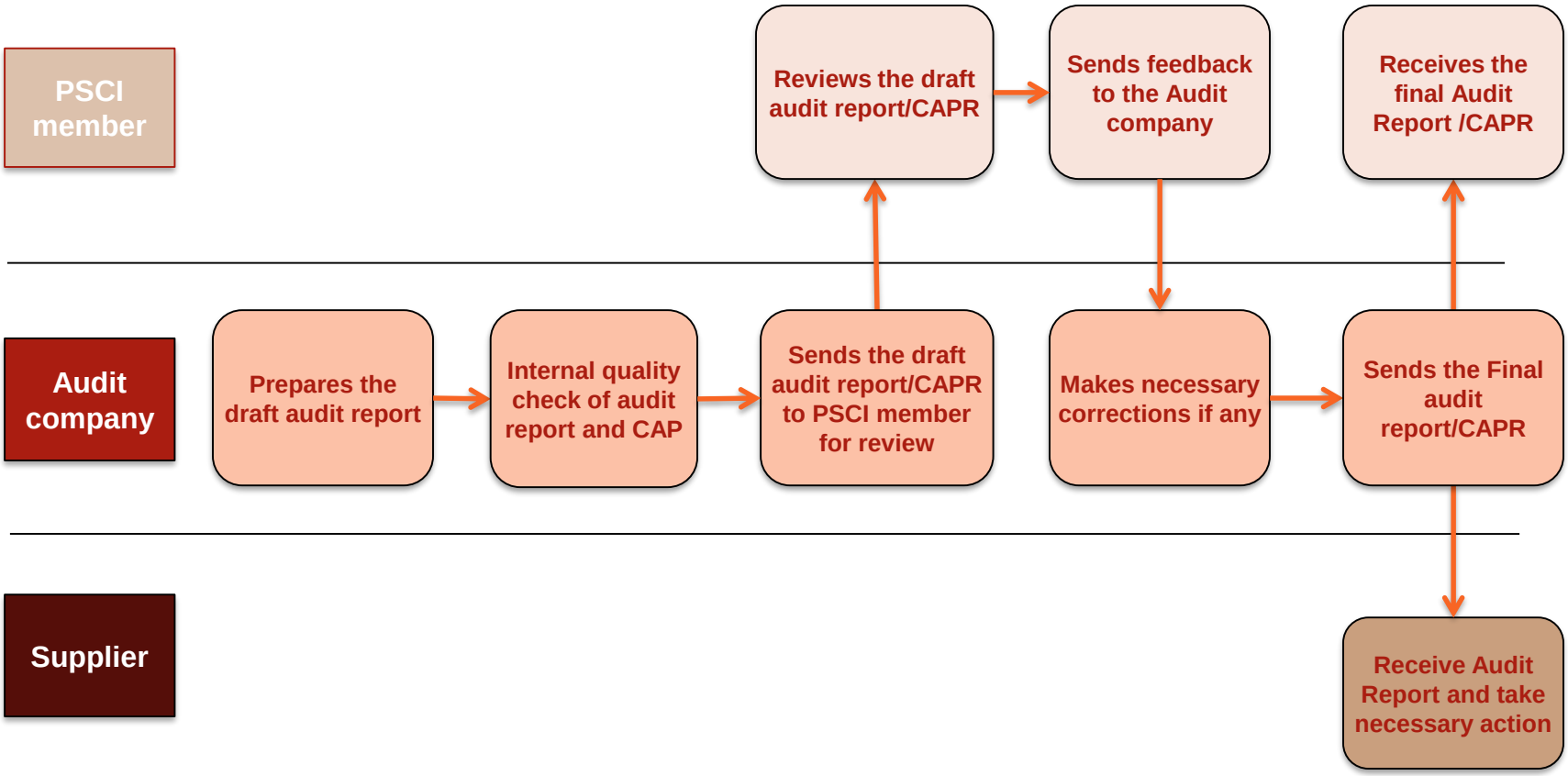
Post Audit Activities



** In general, the auditor **should not send** the draft audit report directly to the supplier without **prior internal quality review** and **approval** by the PSCI member

Post Audit Activities

Describing an Audit Finding

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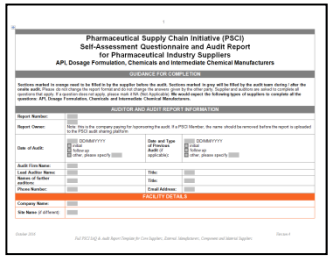
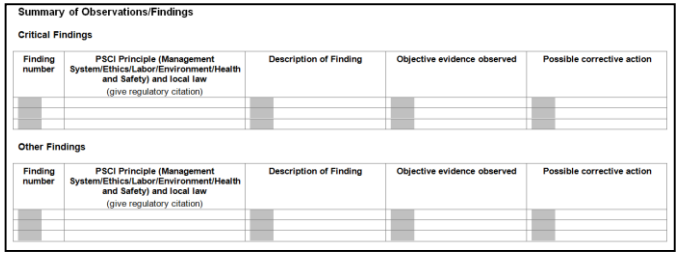
For each finding, the following is provided in the audit report / corrective action plan:

- Finding number
- Reference to the related PSCI Principle and if applicable also local law
- A description of the observation in a simple, clear and unambiguous language so that that the issue could be understood also by others not present in the audit
- Classification (critical or others, as described in the PSCI Audit Guidance)
- Objective evidence to substantiate the finding (e.g. site tour, checked documents, workers interview)
- A suggestion for a corrective action
- In the CAP additionally method of verification, responsibilities, timelines and status.


Pharmaceutical Supply Chain Initiative (PSCI)
Self-Assessment Questionnaire and Audit Report
for Pharmaceutical Industry Suppliers
API, Dosage Formulation, Chemicals and Intermediate Chemical Manufacturers

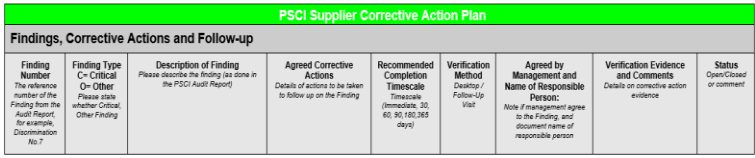

Summary of Observations/Findings

Critical Findings

Finding number	PSCI Principle (Management System/Ethics/Labor/Environment/Health and Safety) and local law (give regulatory citation)	Description of Finding	Objective evidence observed	Possible corrective action

Other Findings

Finding number	PSCI Principle (Management System/Ethics/Labor/Environment/Health and Safety) and local law (give regulatory citation)	Description of Finding	Objective evidence observed	Possible corrective action


PSCI Supplier Corrective Action Plan

Findings, Corrective Actions and Follow-up

Finding Number *The reference number of the Finding from the Audit Report, for example, Discrimination No.7*	Finding Type C= Critical O= Other *Please state whether Critical, Other Finding*	Description of Finding *Please describe the finding (as done in the PSCI Audit Report)*	Agreed Corrective Actions *Details of actions to be taken to follow up on the Finding*	Recommended Completion Timescale *Timescale (Immediate, 30, 60, 90,180,365 days)*	Verification Method *Desktop / Follow-Up Visit*	Agreed by Management and Name of Responsible Person: *Note if management agree to the Finding, and document name of responsible person*	Verification Evidence and Comments *Details on corrective action evidence*	Status *Open/Closed or comment*

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Audit Report Writing

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Writing Audit Findings (1)

Audit findings are a particularly challenging form of writing. They

- usually involve **technical points** describing a **discrepancy from requirements**
- must accurately communicate **factual information**
- must be in an **unambiguous language** to state - as **simply as possible** - what was found.
- should be **understandable to any reader**. Specifically, they must **be clearly understood by the supplier** responsible for corrective actions.

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Writing Audit Findings (2)

Following basic questions should be considered while writing a finding:

- **Who?** defines who is involved in the finding
- **What?** defines the subject of the finding
- **When?** defines the timeframe for the finding
- **Where?** describes where the finding took place
- **How?** describes the nature of the discrepancy including examples
- **How often?** describes whether the finding is a single event/case or a systematic error

And: Challenge each observation by **asking ``So what?´´** (regarding significance)

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Audit Report Writing (1)

Write facts

- Base your audit report entirely on the **evidence** you have gathered. **Avoid** any statement of **opinion**.

Examples

Opinionated statement

The facility's contingency plan is **inadequate**.

Replaced with factual statement

The facility's contingency plan lacks the following elements: agreement with local authorities, types and locations of fire protection equipment and up-to-date listing of emergency telephone numbers

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Audit Report Writing (2)

Use evidence

- Be **specific** in the evidence that you present. Consider whether you have answered key questions such as **when, where, how many, by whom** and **how** and, if you have not, add further detail.

Examples:

Too general

- Emergency exit signs are missing.
- Three fire extinguishers at the site did not have the required inspection tags.
- Employees have not received safety training.

Improved by adding precise details

- Two emergency exit signs were missing in the following areas:
  - in an unused warehouse and
  - in the QC laboratory (room No 512)
- The team inspected 10 of 80 fire extinguishers at the site. Three fire extinguishers in the QC laboratory did not have inspection tags.
- Based on a review of the training records, four of 30 maintenance employees have not received safety training.

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Audit Report Writing (3)

Avoid extreme language and speculations

- **Refrain** from using words like **dangerous, severe, terrible** etc. as they are not helpful in communicating of the exact nature of the problem.

Examples:

Extreme language

- The lack of documented confined space entry procedures for the manufacturing operations may lead to dangerous situations.

Speculation

- The site does not have a secondary containment for Nitric acid. Any releases would spill onto soil and enter the groundwater.

Better wording

- The manufacturing operations do not have written confined space entry procedures.

Just the fact

- The site stores two 100 liter drums of Nitric acid without secondary containment.

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Audit Report Writing (4)

Only factual conclusions

- Provide statement of requirements (e.g. legal reference) where possible but **do not draw legal conclusions**.

Example:

Legal conclusion

- The company does not have a Fire safety authorization in place (No-Objection Certificate), this is not in compliance with the Shanghai State Fire Services Act 1999.

Factual conclusion

- The company does not have a Fire safety authorization in place. As per the Shanghai State Fire Services Act 1999 a Fire safety authorization (No-Objection Certificate) is required.

Audit Report Writing (5)

No overstatement of conclusions

- Clearly state the nature of the problem; **do not overstate conclusions**

Example:

Too general

- Instruments are not being calibrated.

Overstated conclusion

- The facility has no respiratory protection program.

More detailed and exact information

- The sampling and analytical instruments in the wastewater treatment plant are not part of the calibration program.

Exact observation

- The facility's respiratory protection program does not include fit testing, routine inspection and maintenance of respirators.

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Audit Report Writing (6)

Avoid relying on hearsay evidence alone

Statement based on Hearsay

An operator mentioned that 2 fatalities occurred in Production Block H during 2016.

Statement based on evidence

The Incident investigation report no. xxx dated xx.xx.2016 indicated that 2 fatalities occurred due to a fire in Production Block H.

Avoid indirect expressions

Statement using the word 'Appear'

It appears that the air monitoring equipment is not calibrated.

Statement mentioning what was observed

The facility does not calibrate air monitoring equipment annually.

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Audit Report Writing (7)

No criticism of individuals or their mistakes

- Do **not criticize individuals** or highlight their mistakes in an audit report. **Ensure privacy** of individuals is maintained. **Never use unique identifiers** in audit reports e.g. names, Company ID numbers.

Example:

Pinpointing individuals

Mr. Jing and Mr. Xu were observed ……

Improved by removing the names of individuals

The team observed two maintenance personnel……

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Audit Report Writing (8)

Avoid Abbreviations

- Not all recipients of the report will be involved in health, safety and environmental activities on a daily basis and, thus, they may not be as familiar with the health, safety and environmental acronyms, abbreviations, and regulatory jargon as the auditors are.

Example:

Using abbreviations

There is no evidence showing that the facility measures TSS, BOD, and oil and grease in its discharges to the CETP.

Improved by including full forms

There is no evidence showing that the facility measures total suspended solids (TSS), biochemical oxygen demand (BOD), and oil and grease in its discharges to the common effluent treatment plant (CETP).

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Audit Report Writing (9)

- In general be careful with / avoid using the following wording:
  - Is inadequate…not adequate
  - Is inappropriate…not appropriate
  - Is unclear …not clearly defined
  - Seems to…
  - Is likely /probably
  - There is a risk…
  - This is a violation of…
  - Is not in compliance with….

- Improved wording:
  - Is incomplete /missing as e.g. …..
  - Lacks the following details as e.g.
  - Is deficient in that e.g….

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Audit Report Writing - Summary

- Writing of findings is an **integral part of the audit process**.
- **Do not wait until the audit is over to start thinking about writing the report!**
- **Gather all details** and investigate links when possible.
- Answer basic questions: **Who ? What?, When?, Where?, How?, How many** and **So what?**
- Build on findings by asking **"Why?"** for possible root causes.
- Ask yourself "**What corrective actions will result from the observation?**" "Will the actions improve one document/record or will the entire process/system be improved?" What is the goal? Write accordingly.
- Keep the written observations **simple, clear, objective, and factual.**

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Some Examples…

Incomplete Information

Example 1

Has the facility developed and implemented a waste and wastewater management practices?	Yes ☐ No ☐ N/A ☒ Do the practices cover: Characterization of all wastes generated at the facility, including returned products, with regard to regulatory classification (e.g. hazardous waste, special waste, infectious waste, non-regulated solid waste, low-level radioactive waste) and hazardous properties (e.g. flammability, corrosiveness, toxicity)? Yes ☐ No ☒ Are wastes that contain Active Pharmaceutical Ingredients (APIs) managed in such a way that the API is destroyed via that waste management method? Yes ☐ No ☒ Are there measures in place to ensure that API, drug product, and branded materials are not diverted from the intended waste treatment/disposal method/facility? Yes ☐ No ☒ Does the facility evaluate the discharge of wastewater to surface waters, onsite treatment works or offsite treatment to determine potential Active Pharmaceutical Ingredient (API) impact? Yes ☐ No ☒ *(considerations include: treatability, bioaccumulation potential, bio-toxicity potential, and the capacity and capability of on-site treatment works, off-site treatment works, or Publicly Owned Treatment Works (POTWs) receiving the wastewater discharges to effectively perform treatment)* Are potential APIs in wastewater subject to treatment, capture, and containment practices to reduce API levels to no effect levels when practical? Yes ☐ No ☒ Comments:	Yes ☒ No ☐ Comments Only domestic waste is treated whereas process waste is transported to authorized treatment facility.

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Some Examples…

Incomplete Information Continued…

Example 2

Does the facility provide sufficient portable fire extinguishing equipment for the hazards present?	Yes ☒ No ☐ Please explain: 175 fire extinguishers provised at designated locations	Yes ☒ No ☐ Comments Total present as on date 158

Example 3

Are regular emergency evacuation drills conducted, and what is the frequency? Are employees trained in the use of the Emergency Response equipment?	Yes ☒ No ☐ Please explain: Once in 6 months	Yes ☒ No ☐ Comments Verified during interview with security guard and ERT team memebers

Example 4

Is the facility emergency response equipment visually inspected monthly, comprehensively inspected annually, and documentation maintained for all inspections?	Yes ☒ No ☐ Please explain: Inspecting Internally and by external agency	Yes ☒ No ☐ Comments Maintenance records

Example 5

Does the facility rely primarily on respiratory protective devices and/or engineering controls to protect employees who handle chemicals to achieve exposure levels below the exposure limit?	Respiratory protective devices Yes ☒ No ☐ Engineering controls Yes ☒ No ☐ Both Yes ☒ No ☐ Please explain: PPE, LEV's	Yes ☒ No ☐ Comments Verified at process area and found satisfactory

Some Examples…

Unclear/Unspecific Information

Example 1

Does the facility provide a means for handling compressed gases safely that includes:	Yes ☐ No ☒ Inspection and approval before acceptance of delivery? Yes ☐ No ☐ Storage in a segregated area designed for compressed gases? Yes ☐ No ☒ Separation or barriers to manage compatibility issues? Yes ☐ No ☒ Gas classification labeling? Yes ☐ No ☒ Regulator, hose and flexible connection inspections? Yes ☐ No ☒ Please explain:	Yes ☐ No ☒ Comments Only Compressed gas used in process and no storage.

Example 2

Is there a site procedure to inform employees of the results of exposure evaluations and monitoring results?	Yes ☒ No ☐ Not applicable ☐ Comments:	Yes ☒ No ☐ Comments Medical check up

Example 3

Is the facility emergency response equipment visually inspected monthly, comprehensively inspected annually, and documentation maintained for all inspections?	Yes ☒ No ☐ Please explain: Inspecting Internally and by external agency	Yes ☒ No ☐ Comments Maintenance records

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Classification of Audit Findings (1)

Critical Findings:

- Are **very high risk findings** that require immediate action to protect human life, the health of employees or the environment;
- May **result in loss of license to operate or serious damage to reputation**;
- Require **immediate corrective action** by the supplier;
- Need to be communicated to PSCI member or PSCI secretariat prior to audit report finalization.

Examples for Critical Findings:

- Operation of a solvent storage facility without legally required permit
- Intentional shut-down or bypassing of important safety installations

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Classification of Audit Findings (2)

Other Findings:

- Are all other **major or minor** audit findings*, which need to be corrected by the supplier in an appropriate period of time

Examples of Other Findings:

- Inspection of portable fire extinguishers not carried out monthly
- Not all safety data sheets are available in local language
- Hazard communication labeling missing on some bottles and drums
- Facilities respirator protection program lacks fit testing
- Inspection intervals of respirators exceeded in some cases
- Safety training missing in a some cases and for some topics

All findings need to be summarized in the PSCI Corrective Action Plan

*Please align with the client regarding further sub classification of the `other´ findings

Proposing Recommendations for Corrective Actions (1)

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Ensure that recommendations are written in a way to convey ***what* should be done**, without dictating to the auditee ***how* it is to be done**.

Don´t tell them "How" tell them "What"

Example 1:

How

Description of finding	Local law (give regulatory citation) or PSCI Principles	Objective evidence observed:	Possible corrective action
The company does not have sufficient resources to carry out personnel dust exposure assessment and process hazards analysis	PSCI	Review of documents, discussion with concerned personnel	The facility should hire an industrial hygienist and two additional process safety engineers.

Better: What

The company does not have sufficient resources to carry out personnel dust exposure assessment and process hazards analysis	PSCI	Review of documents, discussion with concerned personnel	The facility should assess the need for additional industrial hygiene and process safety resources to perform personnel dust exposure assessment and process hazards analysis in units A, B, and C.

Proposing Recommendations for Corrective Actions (2)

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Don´t tell them **“How”** tell them **“What”**

Example 2:

	Description of finding	**Local law (give regulatory citation) or PSCI Principles**	**Objective evidence observed:**	**Possible corrective action**
How	The Company has only installed 2 portable fire extinguishers in the flammable goods warehouse	PSCI & Local law	Review of documents, discussion with concerned personnel & facility visit	The company shall install 10 more fire estinguishers in the flamable goods warehouse.
Better: What	The Company has only installed 2 portable fire extinguishers in the flammable goods warehouse	PSCI & Local law	Review of documents, discussion with concerned personnel & facility visit	The company should review its fire protection plan in the flammable goods warehouse to ensure that sufficient fire extinguishers are in place.

Post PSCI Audit Activities: Detailed Corrective Action Plan Report by the Supplier

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After receiving the PSCI Audit Report and the Corrective Action Plan (CAP), the supplier should provide an updated version of the CAP within 30 days:

- Confirming or adjusting/detailing the proposed corrective actions;
- Confirming or adjusting the time scales;
- Indicating the individuals/functions responsible for the implementation of the corrective actions;
- Providing a short description regarding the evidence of the corrective actions;
- Providing a status definition (open/closed) of the individual findings.

Post PSCI Audit Activities: Regular status updates by the supplier

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- A regular status report (e.g. every 3 months) should be submitted by the supplier to the PSCI member until all audit findings are closed.
- In case the verification methods were defined as “follow up visit” or the corrective action evidence cannot be effectively verified by a desk top review, a follow-up audit needs to be scheduled.
- Ideally the follow up audit should be carried out by the same audit team which carried out the previous audit

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Verification of Corrective Action Implementation

- A desk top review may be used to verify and remotely approve corrective actions. This can be done e.g. by submitting photographs, copies of policies, records or certificates

- A follow up audit is required for critical findings or when corrective actions can only be verified by comprehensive document review, interviews and/or on-site tours. Typical examples would be:
  - Most of the findings related to working hours and wages
  - Buildings lacking structural safety or require significant repairs
  - Deficiencies /systematic failures in the fire fighting system
  - Unsafe and poorly/not maintained technical installations that could cause serious injuries

- The follow up audit report is issued as an updated version of the original report with all new elements highlighted. Comments should include evidence reviewed, effectiveness of corrective actions and status of the findings (open or closed). Any new finding must be included in the report.

- New CAP to be issued and tracked accordingly.

Questions

Coffee Break
(15 mins)

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Group Exercise

Exercise: What´s wrong with the wording of following audit findings?

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There is minimal on-site compliance with Corporate or department contractor safety policy and procedures.	Not specific.Does not describe the problem it detail so that the auditee can correct it.
Some of the air sources are being operated without proper permits and some are not adequately maintained.	Do not use words like some, proper or adequately. Which sources? How many?
The facility's central MSDS file is very neat and accessible to those employees who should see it. Not all materials used or stored by the facility have MSDSs in the central file. Those MSDSs reviewed appeared complete and contained the appropriate information.	What does MSDS mean? Audit findings and good observations are combined here. Do not use words like "not all" and "appears".
Bob Miller was neither familiar with the company's SOP on Hazardous materials nor could he identify where MSDSs were located.	Avoid using names and personal accusations.
The audit team was told that there have been a number of spills of hazardous materials by the maintenance staff. The audit team recommends that these individuals be disciplined and retrained.	Be precise and avoid including hearsay. Don´t put recommendations into findings. Don´t recommend disciplinary measures
It seems that the emergency routes in the warehouse are too narrow.	Avoid including "seems" and "too".
An operator reported that work permits were not always issued when staff enters into confined spaces. This violates the site´s confined space entry program.	Hearsay (no real factual evidence); "violates"– avoid extreme language
The chemical hygiene plan was found deficient and should be improved. This is a serious concern.	"Deficient" sounds opinionated; "serious" – avoid extreme wording

Exercise: Classification of Audit Findings (1) – 10 minutes

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- The Streba 30 Fluid Bed Granulator used for substances (containing micronized active pharmaceutical ingredients) with dust explosion properties was run without any pressure relief device (pressure relief flaps had been set out of function). During the audit, the pressure relief flaps were set into operation again, but the proper function in case of dust explosion is not ensured. The pressure relief is directed into the working room.
  - **Critical**

- The natural gas pipe from the gas transfer station to the boiler house is not identified / labeled.
  - **Other (Minor)**

- Eight 100 l drums containing used organic solvents – waiting for distillation – are stored in the outside distillation area without any retention basin and next to the rainwater drainage which runs to the river.
  - **Other (Major)**

Exercise: Classification of Audit Findings (2) - Solution

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- The safety data sheets for the cleaning agents 1273 and 1322 used in the production area are only available in English and not in the local language. -
  - **Other (Minor)**

- 4 out of 5 emergency exit doors in the raw material warehouse and 4 out of 7 emergency exit doors in the canteen were found locked by padlocks.
  - **Critical**

- Eye showers and/or eye wash bottles are not available in the following areas where corrosive liquids are handled: Cleaning room of Quality Control Laboratories and Microbiological Laboratory (corrosive cleaning liquids)
  - Cleaning room of non-hormonal production building A100 (corrosive cleaning liquid)
  - Battery charging rooms in warehouse A, B and C (acids)
  - Water treatment plant in technical area for QC laboratory (sodium hydroxide)
  - **Other (Major)**

Exercise: Classification of Audit Findings (3) - Solution

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- Ear protection is worn in the areas for which protection is required, but there are no signs posted on wearing ear protection in 2 areas (packaging area in ground floor, mill room in waste area).
  - **Other (Minor)**

- No documented risk assessment on handling biological substances in the Microbiological laboratory has been performed and the handled biological substances have not been classified into biological risk groups or to safety levels.
  - **Other (Major)**

- Two containers of liquid/solvent waste (1 and 2 liters) were stored in the paint shop without a retention basin, and they were not labeled with regard to waste type and hazard symbol.
  - **Other (Minor)**

Exercise: Classification of Audit Findings (4) - Solution

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- In the finished goods warehouse there are three fire resisting compartments. Ten openings for cables to pass through the walls were seen which were not fire-stopped /sealed.
  - **Other (Major)**

- 23 out of 25 hoods in the research & development (R&D) and 12 out of 15 hoods in the Quality control (QC) laboratories of an API site have measured air flow rates below 0,25 m/s. Standard NFX XXX requires a minimum air flow rate of 0,5 m/s.
  - **Other (Major)**

- In the warehouse for flammable liquids (stored in closed containers) two LP (liquid propane) – certified trucks are used which are not approved for this service.
  - **Other (Major)**

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Group Exercises – Writing an audit finding

Writing an audit finding (10 minutes)

- Please divide into 7 groups
- Each group writes ONE audit finding based on the provided picture and the gathered information.

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Group Exercise 1 – Writing an audit finding

Write an audit finding based on the below gathered information:

- During the site tour, these 4 gas cylinders were seen in a small unidentified room.
- Last inspection date was either not visible on the cylinder or more than 10 years ago.
- Windows in the room were closed.
- Besides these gas cylinders 4 other types of gases were also stored in a similar manner in this room e.g. flammable gases (acetylene) and oxygen.

Group Exercise 2 – Writing an audit finding

Write an audit finding based on the below gathered information:

- Company manufactures API intermediates in an industrial zone
- No other source of drinking water is provided by the company e.g. bottled water, water purifier/cooler

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Group Exercise 3 – Writing an audit finding

Write an audit finding based on the below gathered information:

Gathered information:

- This grinder was seen in the workshop at a site.
- The audit team was told that this equipment was still in use.

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Group Exercise 4 – Writing an audit finding

Write an audit finding based on the below gathered information:

- Site manufactures intermediates and active ingredients
- The water seen in the picture is the outcome from the washings of the empty reaction vessels and reaction room
- This is the general practice at the facility
- This was repeatedly observed also in follow-up audit

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Group Exercise 4 – Writing an audit finding

Write an audit finding based on the below gathered information:

- This picture was taken at a manufacturing block where about 30 employees are working on each floor
- The building had 4 floors in total
- This picture is from the second floor
- The stair case is also a part of the emergency exit route.

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Group Exercise 6 – Writing an audit finding

Write an audit finding based on the below gathered information:

- These drums were stored at the backyard of a site that manufactures API intermediates
- 3 out of 5 drums were empty, 2 were half-full (content unknown, strong odor of organic solvents noticed)
- The site also handles hazardous materials

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Group Exercise 7 – Writing an audit finding

Write an audit finding based on the below gathered information:

- This emergency body and eye wash shower was seen when touring an API manufacturing site (close to an area where corrosives were handled)
- This type of emergency shower was observed in similar conditions at various locations during the site tour

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Possible solution to Group Exercise 1

During the site tour it was noted that room 3 in building 2 (ground floor) was used as a storage room for gas cylinders.

- The purpose of this room was not identified (warning label missing), and no assessment had been done to ensure that this room was suitable for the storage of gas cylinders
- All windows were closed and the was also no other means of ventilation
- There is no inspection and approval before acceptance of gas cylinder delivery in place.
- Periodic inspection and testing of the gas cylinders could not be verified since last inspection dates were either not visible on the cylinder or more than 10 years ago.
- All eight cylinders stored in this room were neither capped nor fixed (e.g. by chaining) against fall
- Full and empty cylinders were not stored separately, and there was no segregation done by the properties of the gas (flammable, inert, oxidizing etc.)

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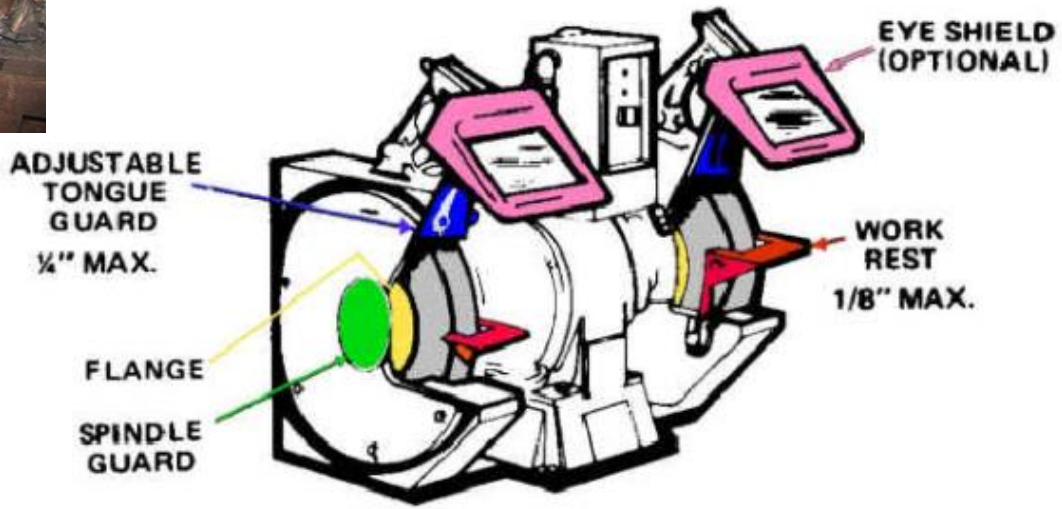
Possible solution to Group Exercise 2

Following was found related to the drinking water dispenser in building 1, ground floor:

- The area around the drinking water tap was unclean and muddy
- Water logging was observed near the water tap
- There was no evidence (e.g. test results) to ensure the that the water provided to the employees meets (applicable) drinking water standards.

Further points to consider: who is responsible for the installation…

Possible solution to Group Exercise 3



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Possible solution to Group Exercise 3

In the maintenance workshop following deficiencies were seen related to grinding activities:

- Cleanliness and clearance around the grinder is not maintained
- There is not sign posted indicating that goggles or face shields have to be worn when grinding
- There is neither a work rest nor an adjustable tongue guard available on the grinder, and no side guards are installed to cover the spindle, nut, flange and wheel
- The manufacturer´s label is not legible.

Further points to consider: risk assessment of the workplace, grounding of the equipment, exhaust ventilation….

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Possible solution to Group Exercise 4

Following practice was observed during the site tour:

- All water coming from cleaning of the reaction vessels and the reaction rooms used for the production of intermediates and active ingredients at the site is not further treated but discharged directly to the soil around the site.
- This finding was also addressed during the initial audit but no corrective actions have been implemented so far.

Further points to consider: waste water procedure at the site, batch records, CAPA system (corrective & preventive actions)…

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Possible solution to Group Exercise 5

The emergency escape route at the staircase on the second floor of the manufacturing block 1 was obstructed with plastic trays and carton boxes.

Further points to consider: internal management walk through and self-inspections, housekeeping, training of employees on topics like waste management, emergency preparedness

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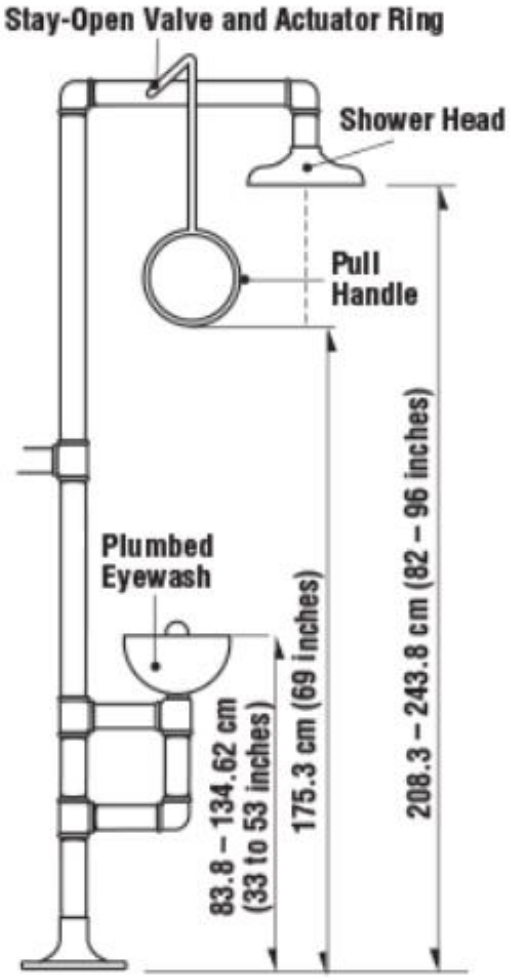
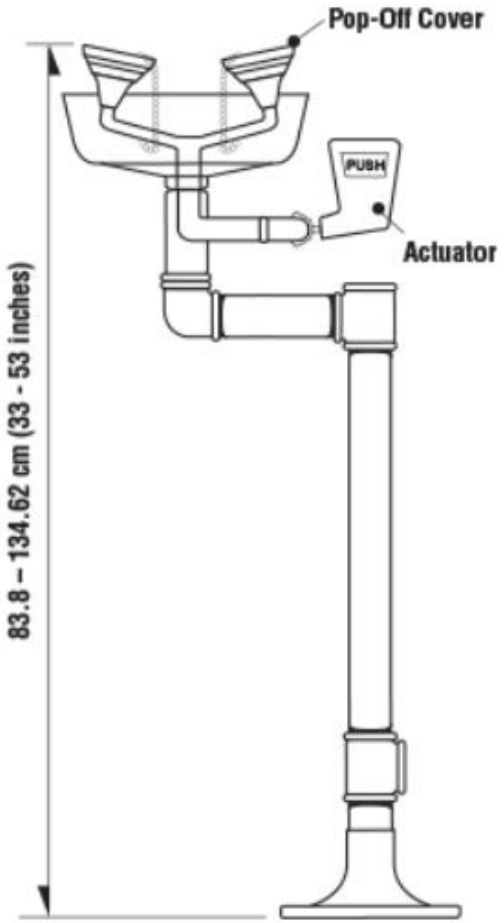
Possible solution to Group Exercise 6

- At the backyard of the site 5 rusty drums were stored directly on the soil without any further labeling or protection against the environment.
- Three out of five drums were empty, two were half-full with an unknown content, a strong odor of organic solvents was noticed.
- Furthermore other trash including other glass pieces, plastic boxes as well as cleaning equipment was found nearby these drums.

Possible solution to Group Exercise 7





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Possible solution to Group Exercise 7 (2)

Emergency eye wash stations and body showers are in place at locations where corrosives are handled.

- The installations are self-designed and as demonstrated during the audit not suitable for immediate use in case of an emergency.
- The locations of each emergency body shower and eye wash station are not identified by sign.

- Further considerations: regular testing, training of employee, protection against freezing….

Questions

Thank you very much for your attention!

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Process Safety

Presented by

Wenjia Xu

Manager, EHS&S External Supply

JnJ

PSCI Audit Questionnaire "Process Safety Section"

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This presentation will give the Auditors the training and guidelines to collect the right information for "Questions No. 93 to 106" in the PSCI Audit Questionnaire, Version 4, Oct.2016.

Topics covered in this presentation

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1. Process Safety Elements & Regulations
2. Storage & Handling of Hazardous & Flammable Chemicals Including Electrostatic Hazards
3. Centrifuge Safety Controls
4. Reaction Thermal Hazards & Relief Vent Sizing
5. Dust Hazards & Explosion Protection

Bio

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PSCI Role:

Company Role: Manager, EHS&S External Supply

Tasks: Provides EHS oversight and support all external suppliers and manufactures of JnJ.

2017 – present	Johnson & Johnson
2014-2017	Roche Pharmaceutical Shanghai, Asso. EHS Manager
2009-2013	BASF Polyurethane Shanghai, Sr. EHS Engineer
2005-2009	Shanghai Chlorine-Alkali Chemical Ltd. EHS Engineer

BS Degree Safety Engineering, Nanjing University of Sci. & Tech.

Wenjia Xu, CIH
Manager, EHS&S Ext. Supply, JnJ
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Process Safety Elements & Regulations

Wenjia Xu – Manager, EHS&S External Supply , JnJ

Definition of PSM

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Process Safety Management

Application of management controls to a process to identify hazards, understand and control process risks so that serious process related-incidents can be eliminated.

Process Safety Management

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What is the objective or purpose of PSM?

The prevention or the reduction of the consequences of disasters such as releases of toxic, active, flammable, explosive or chemical products.

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(AP PHOTO)

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Partial List of Accidents in Pharma Industry (Global)

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Date	Location	Incident	Casualties
2009-Mar	China	Accident in HBr Recovery System	Huge amount of water source contaminated
2010-Jan	USA	Phosgene Leak	62 hospitalized
2010-April	China	Centrifuge Fire	None
2010-Sep	Italy	Gas Poisoning	
2010-Dec	India	Asphyxiation	2 killed
2011-Jan	China	Solvent Fire	None
2011-Jan	China	Phosgene Leak	62 hospitalized
2011-Mar	India	Bromine Leak	120 hospitalized
2011-May	China	Dust Explosion	2 killed
2012	USA	Dust Explosion	7 suffered severe burns
2013-Jan	India	Reactor Explosion	2 killed
2016-Feb	USA	Feed Mill Dust Explosion	7 killed, 1 severe burns
2016-Oct	China	Explosion in WW Recovery System	None

Managing Process Safety Is Good Business!

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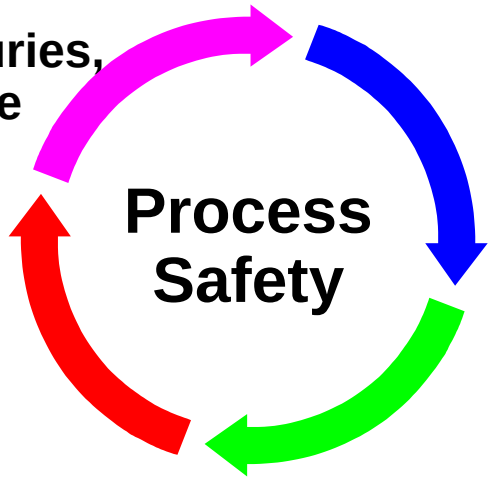
(1) Loss avoidance

to save lives, reduce injuries, limit property damage

(2) Protect

and maintain the business; to enable growth and success



(3) Creating Value

For employees, customers, shareholders, the community and the industry

(4) Corporate responsibility

to employees, shareholders, the community, and the public

National Regulations – China

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Regulations and codes related to Process Safety have been increasing in the latest 10 years. PSM is more and more addressed.

Title	Year	Description
Guidelines for PSM of petrochemical corporations	2010	12 elements
Hazardous process inventory under key supervision	2013	Hazardous process inventory and engineering measures
Guidelines for layer of protection analysis	2015	
Safety design management guidelines for chemical construction project	2010	New project design code
Technical specification for dust explosion hazardous areas	2016	Dedust
…		

Elements of Process Safety Management

- Employee Participation
- Process Safety Information
- Process Hazard Analysis
- Management of Change
- Pre-Startup Safety Review
- Operating Procedures
- Hot Work/Safe Work Permits
- Employee Training
- Incident Investigation
- Mechanical Integrity
- Emergency Planning & Response
- Contractor Safety

Ref.: OSHA PSM Regulation, 29CFR1910.119

Employee Participation

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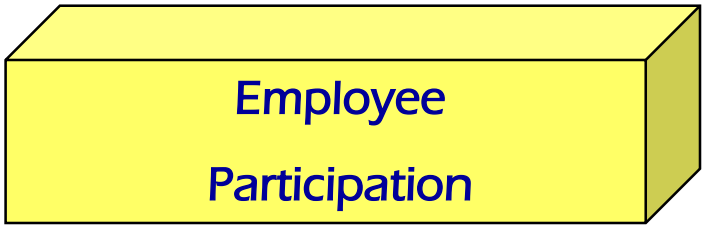
- Employers shall develop a written plan of action regarding the implementation of employee participation.
- Employers shall consult with employees on the conduct and development of process hazards analysis and on the development of the other elements of process safety management.
- Employers shall provide to employees access to process hazard analysis and to all other information required to be developed under the standard.



Employee Participation

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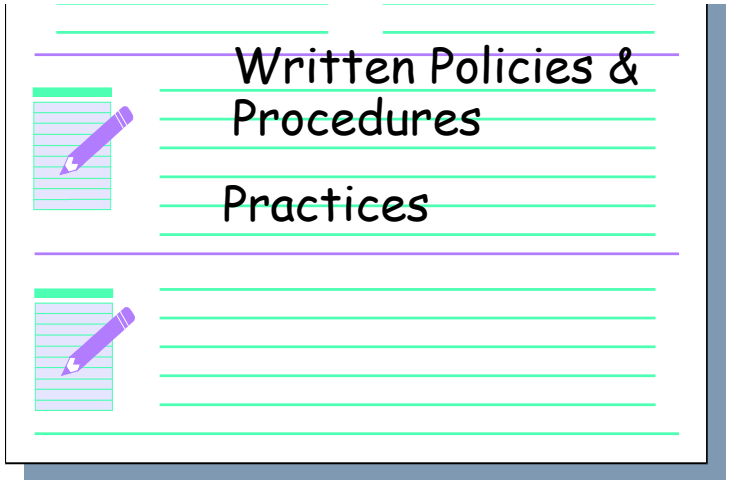
Employee participation is a key component of the process safety program.

- **Information for all employees should include:**



- **Employee tools**
  - Experience/knowledge
  - Observations
  - Ability to make suggestions

Process Safety Information

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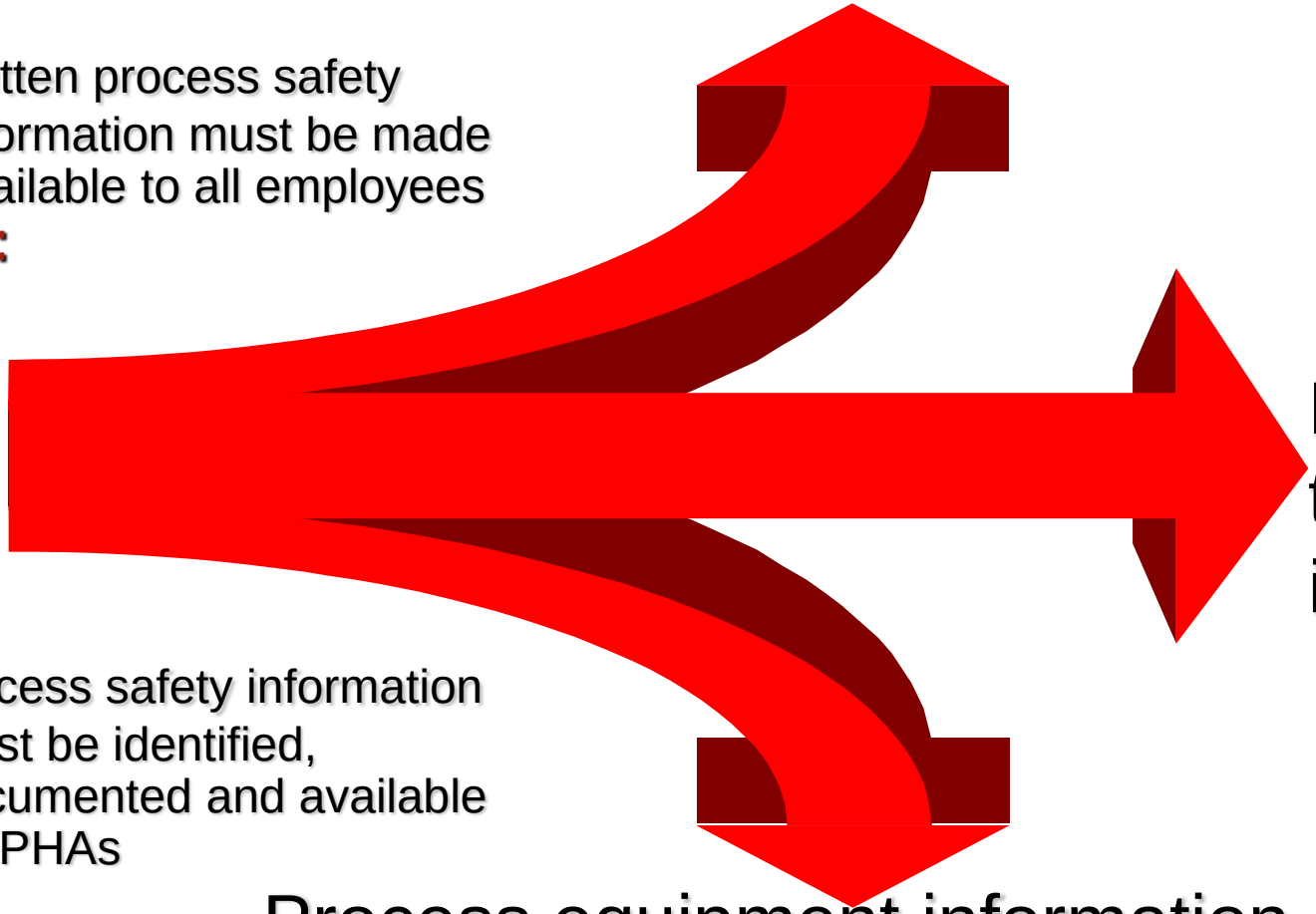
Process chemical information

Written process safety information must be made available to all employees on:



Process technology information

Process safety information must be identified, documented and available for PHAs

Process equipment information

Process Safety Information

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- **What**: Complete and accurately written information concerning the safety characteristics of *process chemicals*, *process technology* and *process equipment*

- **Why**: It is the information necessary for implementation of all other aspects of PSM, for example:
  - Process Hazards Analysis
  - Mechanical Integrity
  - Emergency Planning & Response
  - Incident Investigations

Process Safety Information

- Process Chemical Characteristics

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Chemical Characteristics

- Compound identification
- Physical properties
- Health characteristics (toxicity - exposure limits)
- Safety characteristics (flammability – thermal stability – explosive properties – dust explosion)
- Environmental/Ecological characteristics

Chemical Interactions

- Chemical compatibility (or incompatibility)
  - other chemicals
  - materials of construction
- Hazardous effects of inadvertent mixing

Note to Auditors: It is not enough to verify that the facility has the Safety Data Sheet (SDS) for each chemical. The information about some components on the above list may not be in the SDS sheets. Therefore, you should verify that the above information is documented for each hazardous chemical in a central file.

Process Safety Information

- Process Technology Characteristics

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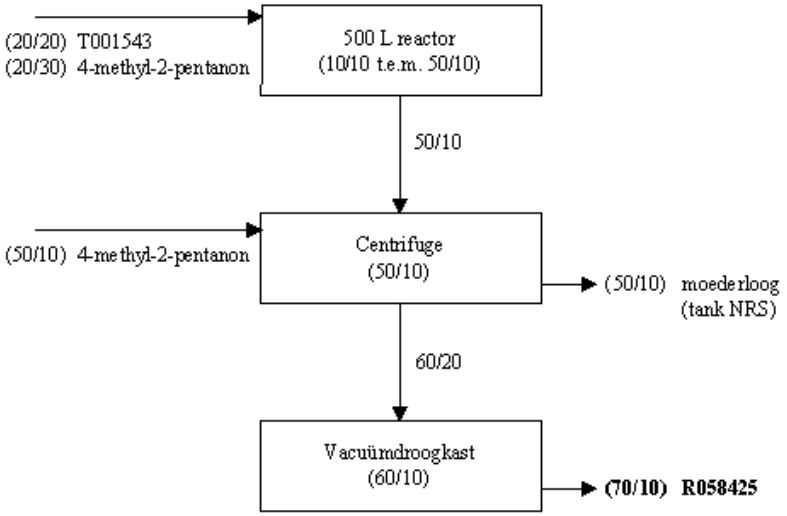

- Block flow diagrams
- Process chemistry (desired/side)
- Balances (Material / Energy)
- Heat of reaction (Calorimetry)
- Gas generation rate
- Safe upper and lower limits (operating parameters)
- Evaluation of consequences of deviations (What if)

Where the original technical information no longer exists, such information may be developed in conjunction with the process hazard analysis in sufficient detail to support the analysis.

Process Safety Information

- Equipment Characteristics

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- Material of construction
- Electrical classifications
- Design codes and standards
- Piping and instrument diagrams (P&ID)
- Relief system design
- Ventilation system design
- Specifications (P, T, flow, special conditions)
- Safety systems (e.g. Interlocks, detections or suppression systems)
- Emergency shutdown systems

❖**Note for the Auditors:** **Accurate P& I drawings are very critical for conducting the Haz-Op reviews, preparing operating instructions and to provide training. These drawings also allow the Auditors to verify the design of the key process safety elements.**

Process Hazards Analysis

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A process hazard analysis must be performed, by a knowledgeable team, to prevent a catastrophic Incident.

1. Identify all possible hazards
2. Assess human factors and safer system designs
3. Analyze possible causes and consequences (include previous incidents which had likely potential for catastrophic consequences)
4. Develop prevention techniques
5. Evaluate the current operation and revalidate every **5** years
6. Solicit feedback from employees and provide communication

Operating Procedures

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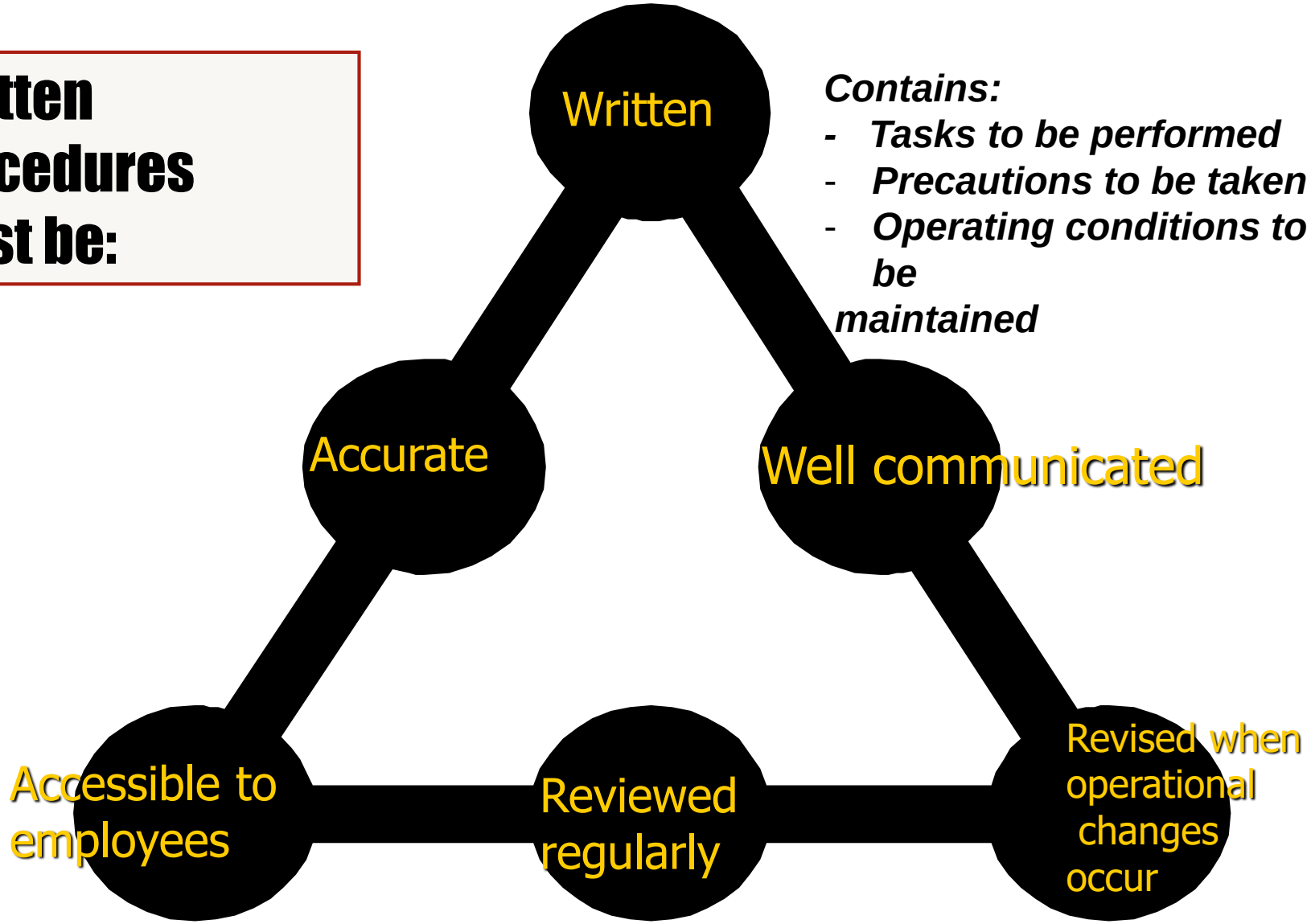
Written procedures must be:



Contains:

- ***Tasks to be performed***
- ***Precautions to be taken***
- ***Operating conditions to be maintained***

Training

- Employee should be trained initially and receive overview training at least every 3 years.

- Training should consist of:
  - Written objectives
  - Overview of each process
  - Operating procedures
  - Emergency operations & procedures
  - Health considerations
  - Safety control systems
  - Hazard communications
  - Rules for contract employees
  - Documentation of understanding

Management of Change

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Procedures to manage process technology safety and process hazard changes

- When changes occur in process chemicals, technology, equipment, procedures, headcount and facilities, an MOC must be completed.

Pre-Startup Safety Review

A pre-start up safety review is required when there is a change in the process or equipment.

This review shall include:

1. Safety training for employees involved in operating a process.
2. Design requirements must be met for Construction and equipment.
3. Safety operating maintenance and emergency procedures must be in place.
4. Ensure a PHA has been performed and all recommendations resolved.

Mechanical Integrity

The mechanical integrity program must ensure the process equipment and safeguards operate the way they are designed to.

- Train personnel
- Equipment should be kept in good operating condition and proper procedures should be followed
- Development and use of maintenance procedures
- Testing and inspection procedures
- Correct equipment defects

Hot Work

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Permit required for hot work jobs carried out on or near a covered process. This includes:

- **Safe Work Practices**
- **Fire prevention and protection measures**
- **Fire watch personnel**

Incident Investigation

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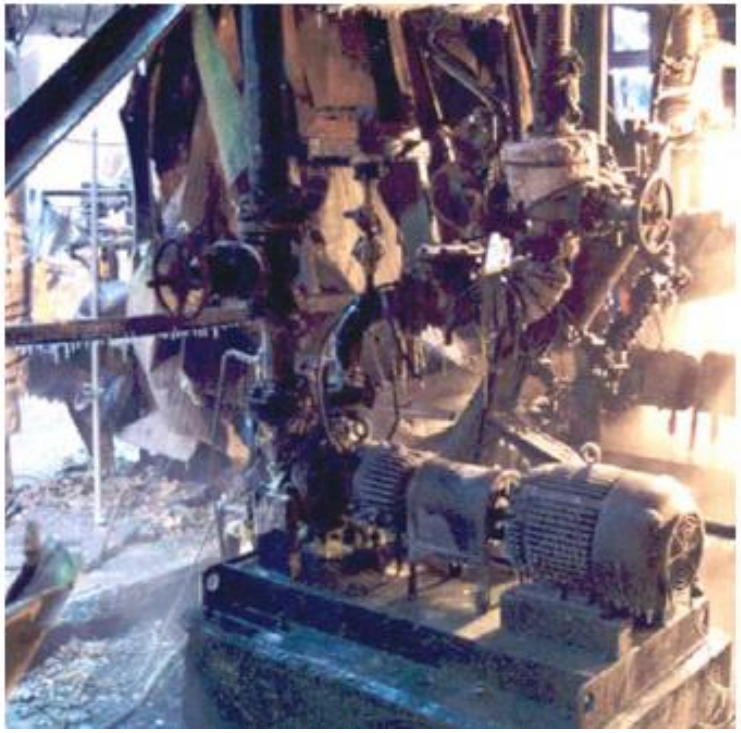
- A Process Safety incident investigation must be conducted following an incident or near miss.
- Analyze all possible causes of the incident.



Incident: explosion of pumps as a result of overheating

Emergency Planning & Response

The Plan must include:

Warning and clearing of personnel if a major accident release of highly hazardous chemicals happens.

An Evacuation Plan.

Emergency Procedures.

Spill Team - Training for hazardous chemicals cleanup and disposal.

Contractor Safety

- All contractors must receive training before beginning work.
- All contractors must ensure that their employees follow all safety rules, procedures, work practices and be aware of possible hazards.

All contractor employees must be aware of the site Emergency Action Plan

Putting All Elements Together

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Audits

Emergency Response **Incident Investigations**

Employee Engagement **Procedures** **Training**
Contractors **Hot Work**

PSI

PHA
Hazards Risks Controls

MI

MOC

Hazardous Process

PSSR

Q&A

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Storage & Handling of Hazardous & Flammable Chemicals Including Electrostatic Hazards

Wenjia Xu – Manager, EHS&S External Supply , JnJ

Guidelines for Storage of Hazardous Chemicals in Bulk Storage Tanks 1 of 4

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- Tanks should have labels indicating name of chemical and hazmat risks. Labels are critical for:
  - Information for employees
  - Loading/Unloading Operations
  - Emergency Responders
  - Community Right to Know
  - Regulatory Compliance
- Safety Data Sheets (SDS) of each chemical should be available to personnel involved in the operation

Guidelines for Storage of Hazardous Chemicals in Bulk Storage Tanks 2 of 4

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- Containment dike for spill control. Minimum volume of dike = 110% of largest tank. Material - impervious
- Incompatible materials should not be in a common dike
- Instruments to monitor level, pressure and temperature (it should preferably be remote and have alarms in control room/process area)

Guidelines for Storage of Hazardous Chemicals in Bulk Storage Tanks 3 of 4

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- Suitable fire protection/fire fighting at tanks
- Tanks are designed to prevent ignition (dip pipes, tangential splash legs, N2 blanketing)
- Dedicated hoses for transfer of each chemical & properly labled
- Use of appropriate PPE and Respiratory Equipment
- Leak detectors and alarms for gases

Guidelines for Storage of Hazardous Chemicals in Bulk Storage Tanks 4 of 4

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- Written procedure for unloading from tankers including inspection of tankers for leaks, quality and identity check and transfer to process before unloading
- Written procedure for grounding and bonding of tankers and hoses prior to unloading
- Written procedure for transfer from bulk tanks to process
- Current list of chemicals and inventories should be reviewed with local authorities, fire department and emergency responders.

Best Practice Example - Design of Bulk Stg Tank

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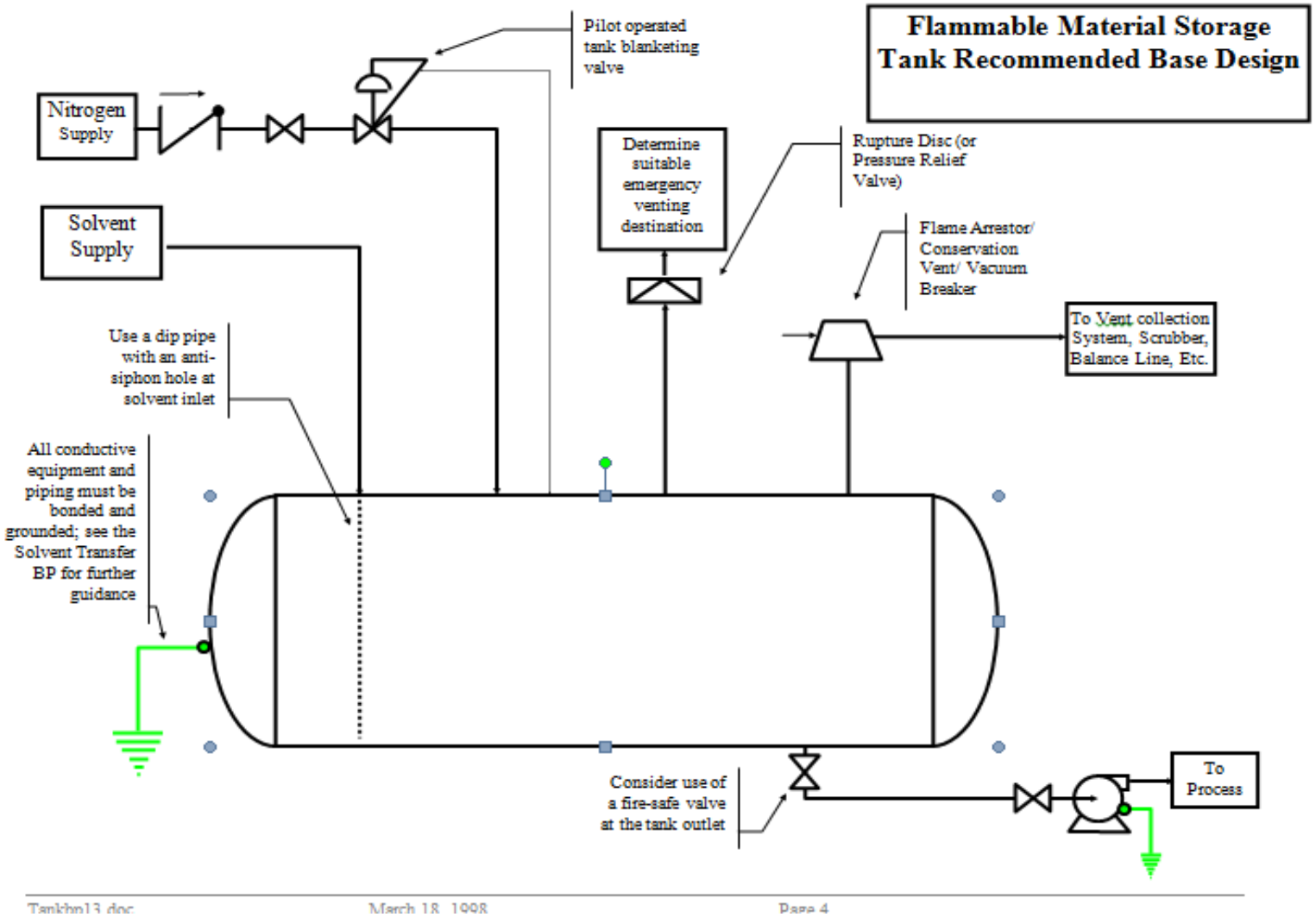

Storage of Hazardous Chemicals in Drums & Gas Cylinders- 1 of 3

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- All drums, containers and cylinders should have labels indicating name of chemical and warnings of hazmat risks
- SDS for each chemical should be available to personnel involved in the operation
- Materials should be stored as per instructions in Safety Data Sheets
- Storage area should be curbed for spill control. Material of floor and curb should be impervious

Storage of Hazardous Chemicals in Drums & Gas Cylinders- 2 of 3

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- Storage areas should be segregated and partitioned based on compatibility of materials.
- Water reactive materials should not be stored in areas where water flooding from pipe leaks or roofs can occur
- Leak detectors and alarms for toxic gas cylinders (Cl2, H2, HCl, NH3, etc)
- Dispensing of flammable chemicals should not be done in the storage area.

Storage of Hazardous Chemicals in Drums & Gas Cylinders- 3 of 3

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- Periodic inspection of stored drums and gas cylinders
- The site should have a written emergency evacuation plan based on dispersion modeling for highly toxic vapors and gases such as Cl2, NH3, Phosgene, etc.
- Current list of chemicals and inventories should be reviewed with local fire department and emergency responders.
- Suitable fire protection/fire fighting of building/area.

Electrostatic Hazards in Storage & Handling of Flammable Solvents

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Risk of Electrostatic Hazards

- Numerous fire and explosion incidents in the Pharma industry have occurred from electrostatic charges.
- If static charge is not eliminated rapidly, arc charge is built up
- It will build enough energy to jump as a spark to nearby ground or a less charged object.

Examples of Sources of Static

- Liquid flowing through a hose
- Spraying or coating
- Blending or mixing
- Filling tanks, drums, cans or pails
- Dry powders through chutes or pneumatic conveying
- Belts that are moving.
- Human body (can pass on 75-100 mJ of energy)

Grounding, Bonding & Inerting

- All equipment handling flammable liquids and powders must be grounded & bonded.
- In addition, proper measures should be taken to eliminate all sources of ignition, including electro-static.

Bonding: Process of connecting 2 or more conductive objects together with a conductor to equalize their electrical potential.

Grounding: Process of bonding 1 or more conductive objects to the ground, so that all objects achieve zero potential

Inerting: Protection method based on reduction of O2 concentration of a flammable mixture by the addition of an inert gas, such as N2, CO2.

Inert gas: A non-flammable, non reactive gas that renders the combustible material in a system incapable of supporting combustion

Control of electrostatic hazards

Control of electrostatic hazards from conductive (metal) items

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Items that require grounding:

- Fixed and portable equipment, containers (drums, IBCs, FIBCs):
  - Grounding connections should be routed to protect them from accidental damage.
  - Resistance to ground should be checked. If R>10 ohm, direct ground connection is required.
  - Their purpose should be known to operators.
  - Fixings for ground connections should be clearly visible.
  - Ground connections should be checked regularly.

Common grounding point
Grounded portable equipment

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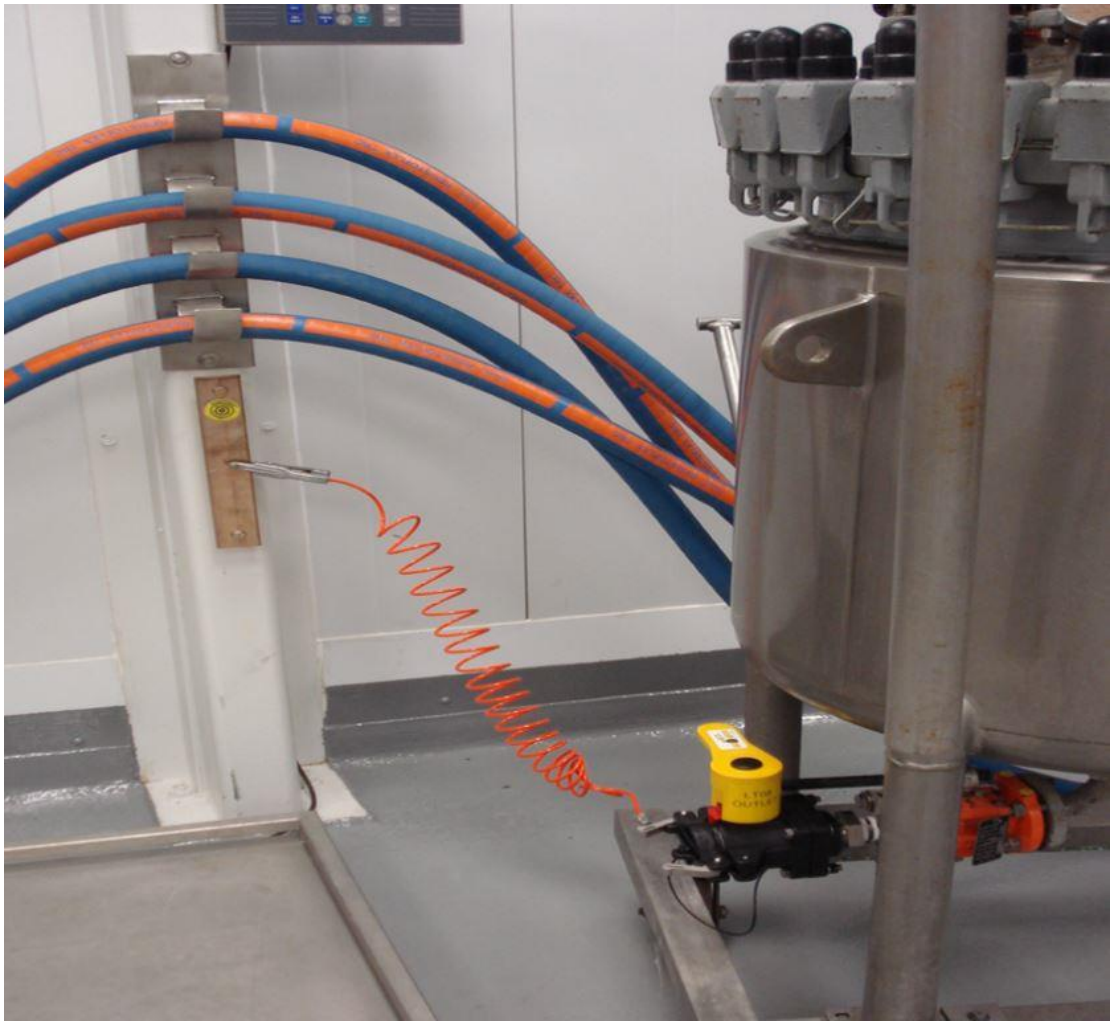

Jumper wire for bonding of flanges isolated with nonconductive gasket

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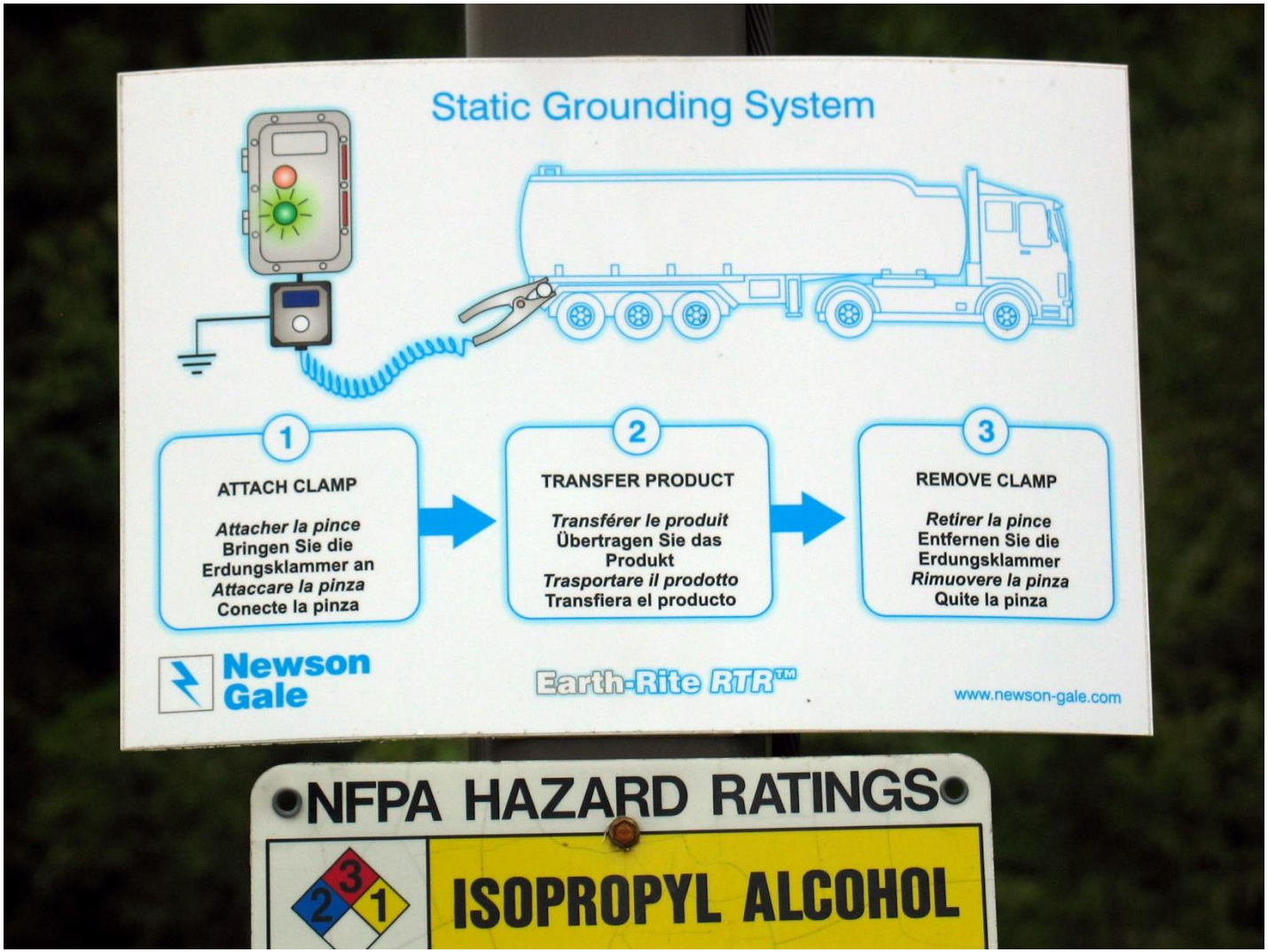
Verification of Static Grounding System



Verification of Static Grounding System

- Used to determine continuity of unique bonding and grounding applications
- Very common ground point effectiveness
- Verify jumpers on pipe, pumps etc.

Continuity testing device

Control of electrostatic hazards

Control of electrostatic hazards from liquids

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Static electricity hazards can arise in various liquid handling operations including filling, sampling, filtration and mixing. The following suggestions can reduce the electrostatic ignition hazards.

- Control of flow velocity
  - Liquids with conductivities > 100 pS/m, no flow velocity restrictions.
  - Liquids with conductivities < 100 pS/m and no immiscible components, flow velocity should be less than 7 m/s.
  - Liquids with conductivities < 100 pS/m and containing immiscible components, flow velocity should be less than 1 m/s.

Investigation Video

Explosion From Electrostatic Charge (Barton)

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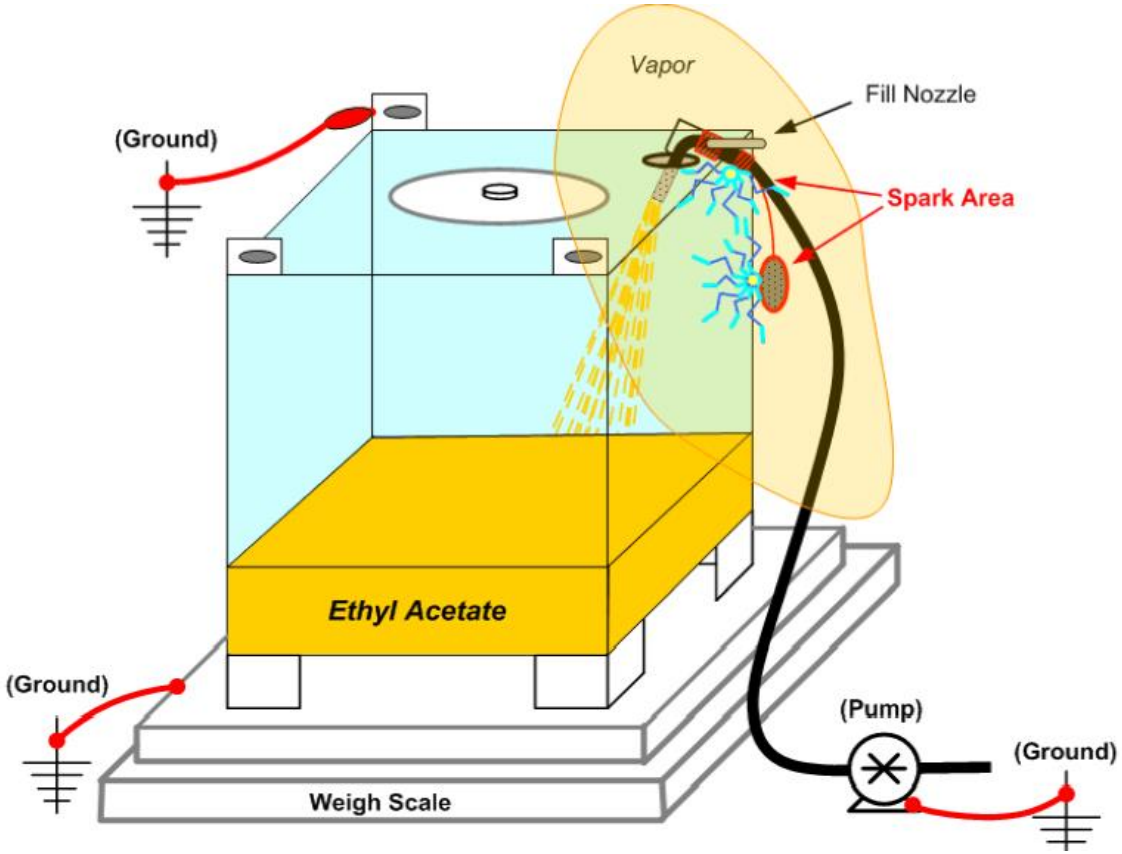
Static_Explosion_in_Kansa



Conclusions from Explosion in Barton Solvents Co- Kansas

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- Location: Portable Tote Tank Filling Operation in Warehouse
- Injuries: 2 (1 employee & 1 fire fighter)
- Damage: Warehouse completely destroyed
- Cause: Ignitable vapor formed at the nozzle opening. Lack of proper bonding and grounding
- Static discharge between tote body & metal components on the fill nozzle created a static discharge
- This company had a similar incident of a fire in a flammable storage tank due to static discharge 3 months prior to this incident.

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Centrifuge Safety Controls

Wenjia Xu – Manager, EHS&S External Supply , JnJ

Centrifuge Safety – 1 of 4
Risk Analysis

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- **Risk of fire & explosion in centrifuges using flammable solvents is much greater than other equipment.**
  - ➢ **Ignition sources are frequently present.**
  - ➢ **Centrifuges operate like a fan and draw air into the equipment**
  - ➢ **They have inherent sources of ignition such as:**

- **Risk Levels:**

- **High: Centrifuges containing liquids at or above flash point**
- **Medium: Liquids below flash point that are opened frequently**
- **Low: Liquids below flash point that are opened infrequently**

- **Guidelines for Safe Operation of Centrifuges:**

Centrifuge Guidelines

Centrifuge Safety – 2 of 4

Inerting System – Option No. 1

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Flow Monitored System:

- **Recommended for low risk operation**

Advantages:

Simple, inexpensive

Disadvantages:

- **Least reliable.**
- **Unexpected leaks of air will not detect unsafe condition**

Methodology:

- **Two N2 supply lines (1 for high purge rate and 1 for continuous purge)**
- **Regular O2 monitoring, min. one per shift**

Centrifuge Safety – 2 of 4

Inerting System – Option No. 1

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PHARMACEUTICAL SUPPLY CHAIN INITIATIVE

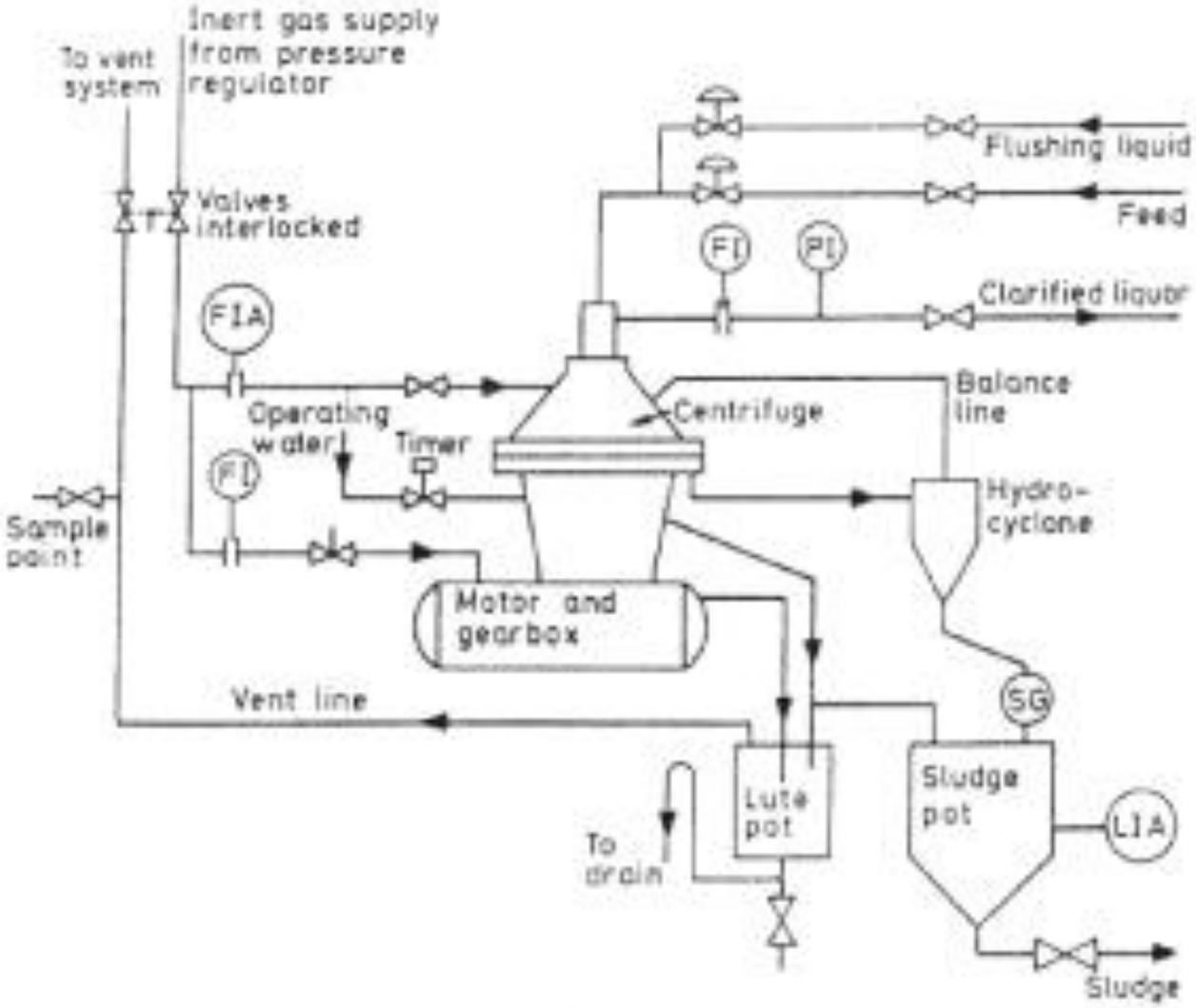

Figure 1. Schematic drawing of flow-monitored inerting system (for opening bowl clarifier centrifuge).

Centrifuge Safety – 3 of 4

Inerting System – Option No. 2

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Pressure Monitored System:

- **Recommended for medium risk operation**

Benefits:

- **Moderately expensive, more reliable, uses less N2**

Requirements:

- **Design of equipment should be able to withstand 6”wc (0.22 psig) pressure**
- **Interlocks for lid, valves, N2 pressure and vent line**
- **Pressure relief in case pressure exceeds 6”wc or goes below 1” with automatic shutdown of centrifuge and closure of feed line, wash line and introduction of high N2 flow.**

Centrifuge Safety – 3 of 4

Inerting System – Option No. 2

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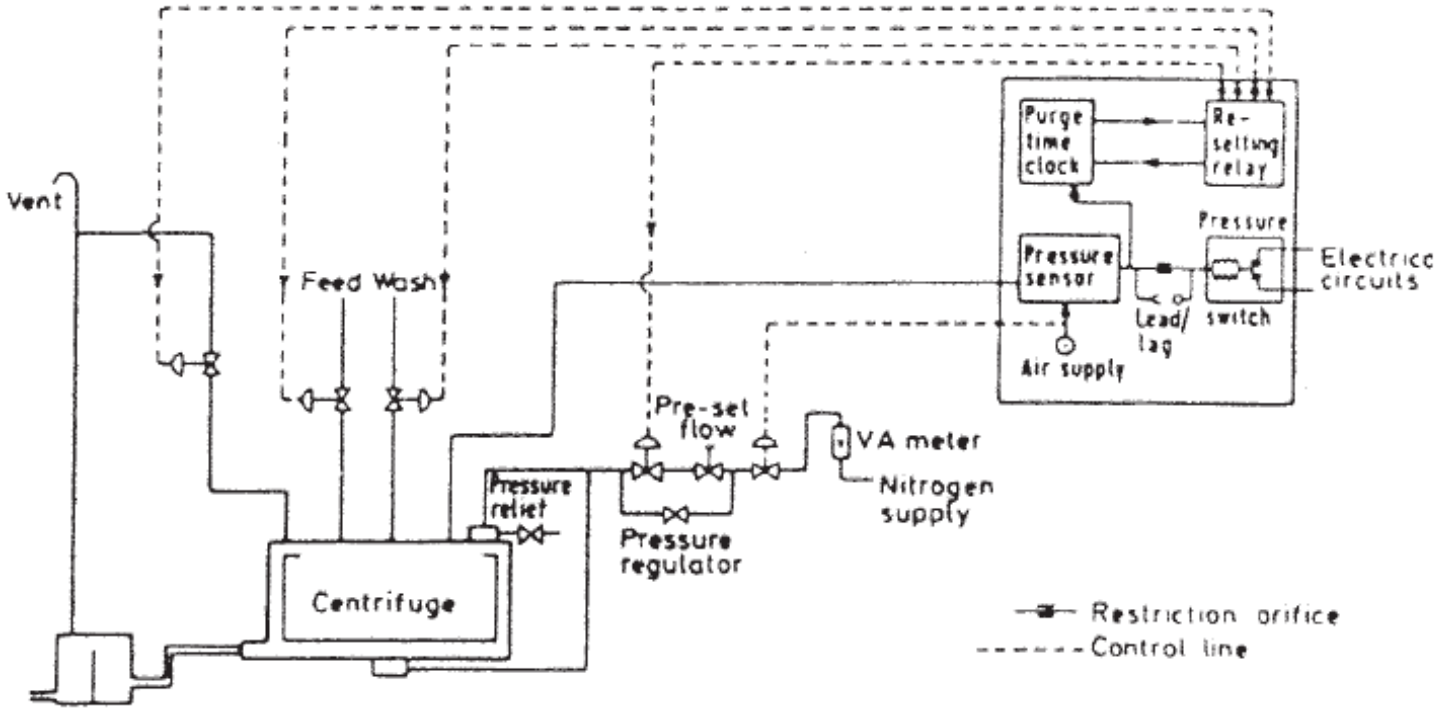

Figure 2. Schematic drawing of pressure-monitored inerting system (for batch centrifuge).

Centrifuge Safety – 4 of 4

Inerting System – Option No. 3

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O2 Monitored System:

- **Recommended for high risk operation**

Advantages:

- **Most reliable and fail safe**

Disadvantages:

- **Most expensive**
- **O2 analyzer needs to be checked daily**

Methodology:

- **O2 is measured continuously**
- **Automatic N2 feed**
- **N2 feed stops when safe O2 level is reaches acceptable pre-set value.**

Centrifuge Safety – 4 of 4

Inerting System – Option No. 3

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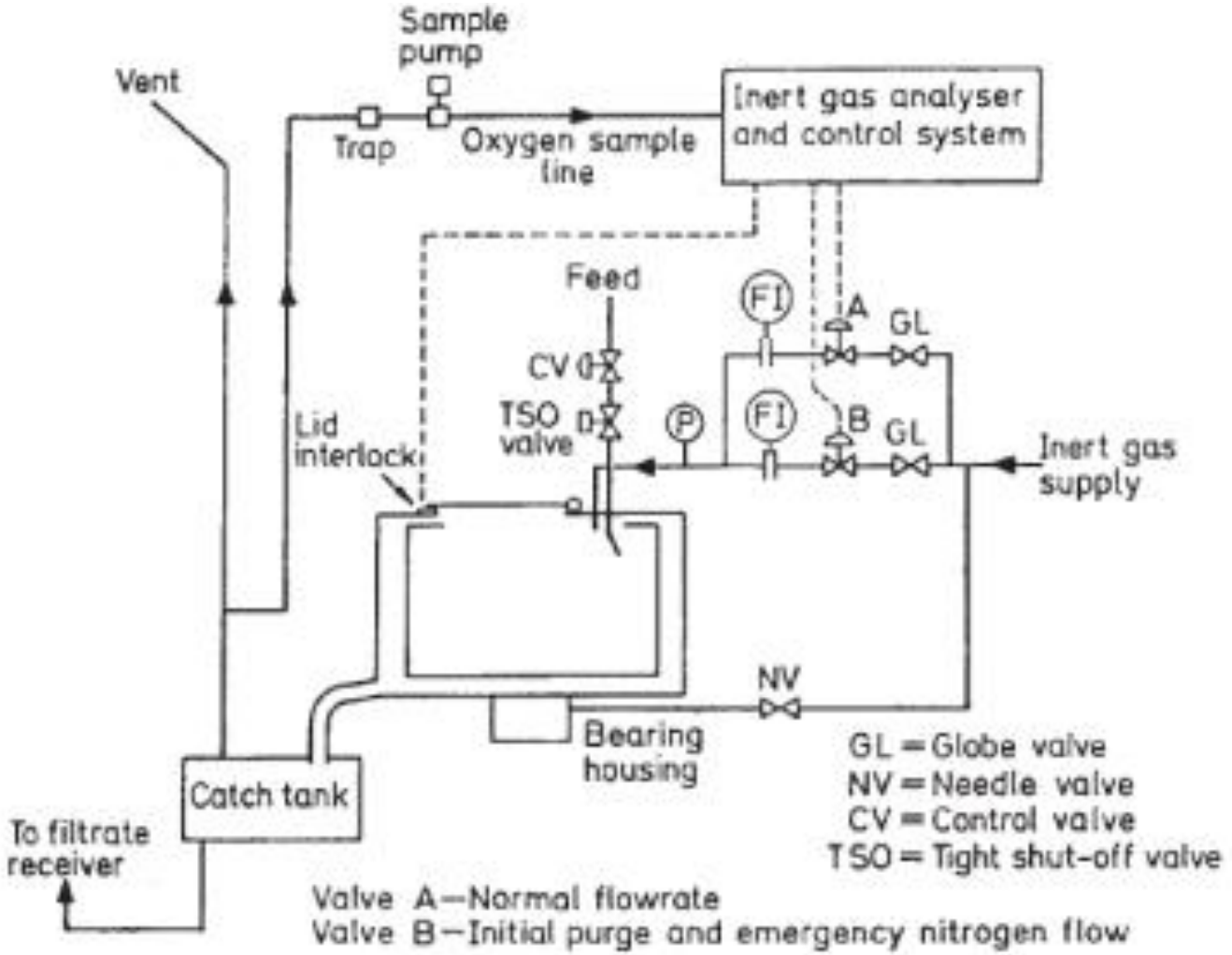

Figure 3. Schematic drawing of oxygen-monitored inerting system (for batch centrifuge).

Q&A

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Reaction Thermal Hazards and Emergency Vent Sizing

Lamy Bao – External Manufacturing EHS Associate Director, Bristol-Myers Squibb

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Bio

- **Master Degree in Safety Engineering from East China University of Science and Technology**
- **Have over 17 years EHS experience, Registered Certified Safety Engineer of China**
- **Worked in Pfizer, Trane and FedEx prior to BMS**
- **Had been with BMS for 3 years in Min Hang, Shanghai Plant as EHS Manager.**
- **Transfer internally to a position of External Manufacturing EHS Associate Director in 2014**

Lamy Bao
External Manufacturing EHS Associate Director

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Investigation Video
Runaway Reaction Explosion

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- **T-2 Labs , Jacksonville, Florida (USA)**

Reactor_T2_Laboratories_Runaway Explosion.mov

Investigation Report
Explosion in T-2 Labs

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- **Location: Jacksonville, Florida (USA)**
- **Incident: Explosion in Reactor due to runaway reaction**
- **4 employees killed, 32 injured (including 28 from surrounding community**
- **Explosion force: Equivalent to 1,400 lbs of TNT**
- **Causes:**
  - **Company did not recognize the worst credible scenario**
  - **No redundancy in cooling system**
  - **Inadequate pressure relief device**

Reaction Hazards – 1 of 7

Historical Data of Incidents

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- **(Ref. Book: Chemical Reaction hazards by John Barton)**

Following data was collected for 189 industrial incidents in UK involving thermal runaway reactions:

- **134 incidents were classified by processes, key ones are:**
  - **Polymerization (condensation): 64 (48%)**
  - **Nitration: 15 (11 %)**
  - **Sulphonation: 13 (10%)**
  - **Hydrolysis: 10 (7%)**
  - **Raw Materials Quality: 15 (11%)**
  - **Others: 13%**

- **34 incidents were caused because there was no study done for reaction hazards**

Reaction Hazards – 2 of 7

Incidents by Causes

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(Ref: Book: Chemical Reaction hazards by John Barton)

- **35 incidents were caused by mischarging of reactants or catalysts (29%)**
- **32 incidents were caused by temperature control (27%)**
- **25 incidents were caused by maintenance (21%)**
- **17 incidents were caused by agitation (14%)**
- **11 incidents were caused by human error (9%)**

Reaction Hazards – 3 of 7

CRH vs Process Lifecycle

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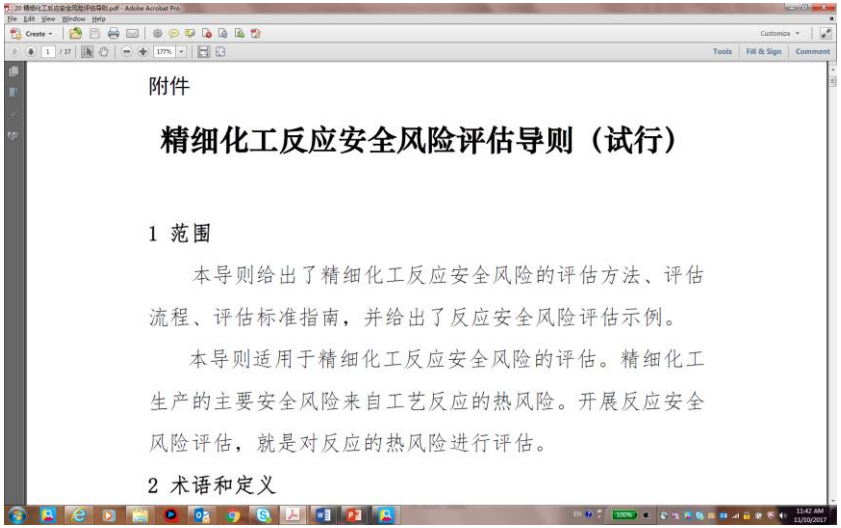
Product Identified → **Synthetic Routes Identified** → **Chosen Synthetic Route Optimised** → **Scale-Up to Pilot Plant Scale** → **Scale-Up to Production Scale**

- Literature / Calculation
- Thermal Screening
- Reaction Calorimetry
- "Minor" Hazard Assessment
- "Major" Hazard Assessment
- Adiabatic Calorimetry
- Basis of Safety Specification



附件

精细化工反应安全风险评估导则（试行）

1 范围

本导则给出了精细化工反应安全风险的评估方法、评估流程、评估标准指南，并给出了反应安全风险评估示例。

本导则适用于精细化工反应安全风险的评估。精细化工生产的主要安全风险来自工艺反应的热风险。开展反应安全风险评估，就是对反应的热风险进行评估。

2 术语和定义

Reaction Hazards – 4 of 7

Thermal Hazards Testing – Heat of Reaction

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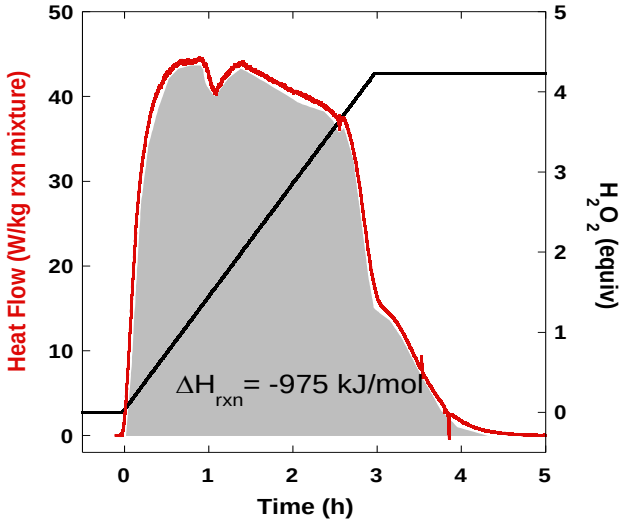
- **RC1 Calorimeter is used to measure heat of reaction.**
- **If RC-1 data is not available and if the chemistry is known, the heat of reaction can also be estimated from heats of formation.**



Typical Graph of RC1 Experiment

Reaction Hazards – 5 of 7

Thermal Hazards Testing – Thermal Stability (DSC)

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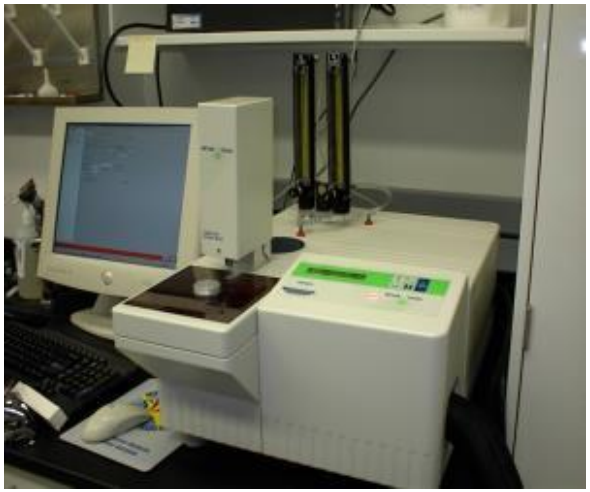
- **Differential Scanning Calorimeter (DSC) is used to give an indication of thermal stability of a reaction.**
- **Detects exothermic/endothermic activity.**

Advantages:

- **Small sample size (5 -10 mg)**
- **Rapid testing time (can be done in 2 hours)**

Disadvantages:

- **No information about pressure**



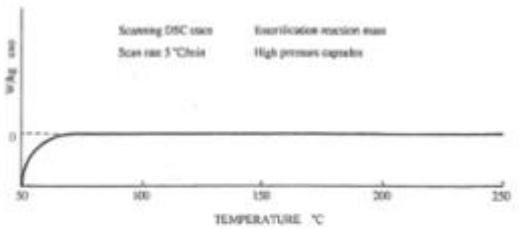


Figure 4.4 DSC trace — no thermal events.

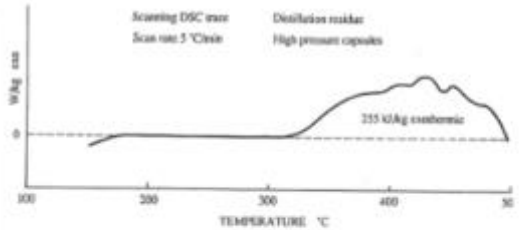


Figure 4.5 DSC trace — mild exothermic activity.

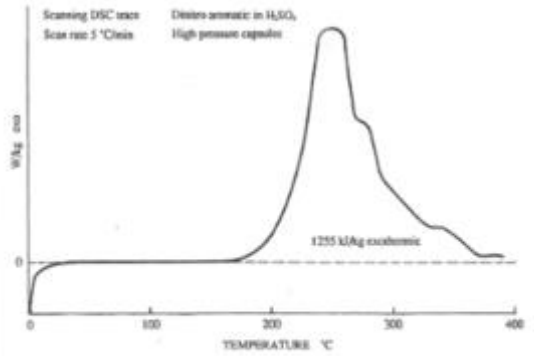


Figure 4.6 DSC trace — strong exothermic activity.

Reaction Hazards – 6 of 7

Thermal Hazards Testing for Runaway Reactions (ARC)

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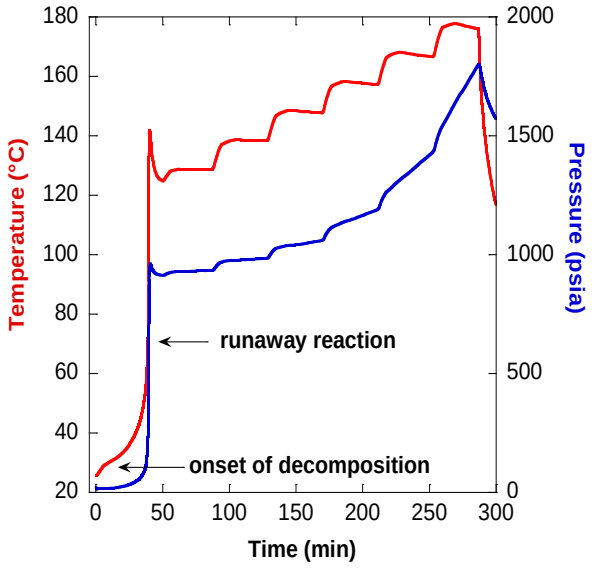
- **Accelerated Rate Calorimeter (ARC) is used to study the characteristics of a runaway reaction.**
- **Rate of pressure & temperature rise from this test can be used for vent sizing for runaway reactions.**

Advantages:

- **Larger sample size (2-5 g)**
- **More accurate onset temperature**
- **Pressure information**

Disadvantages:

- **1-3 days per sample**



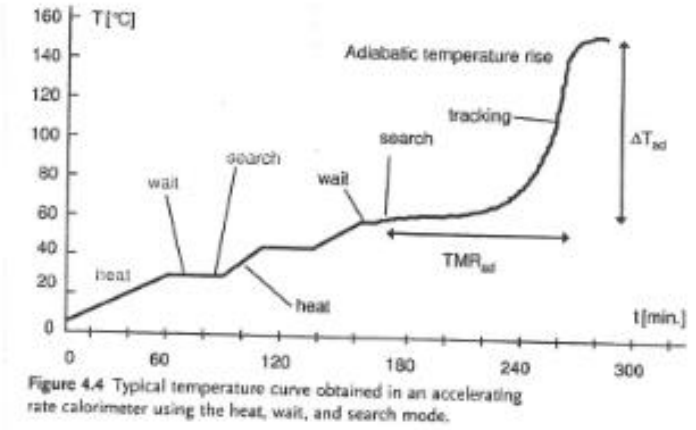


Figure 4.4 Typical temperature curve obtained in an accelerating rate calorimeter using the heat, wait, and search mode.

Reaction Hazards – 7 of 7

Thermal Hazards Testing – Vent Sizing (VSP)

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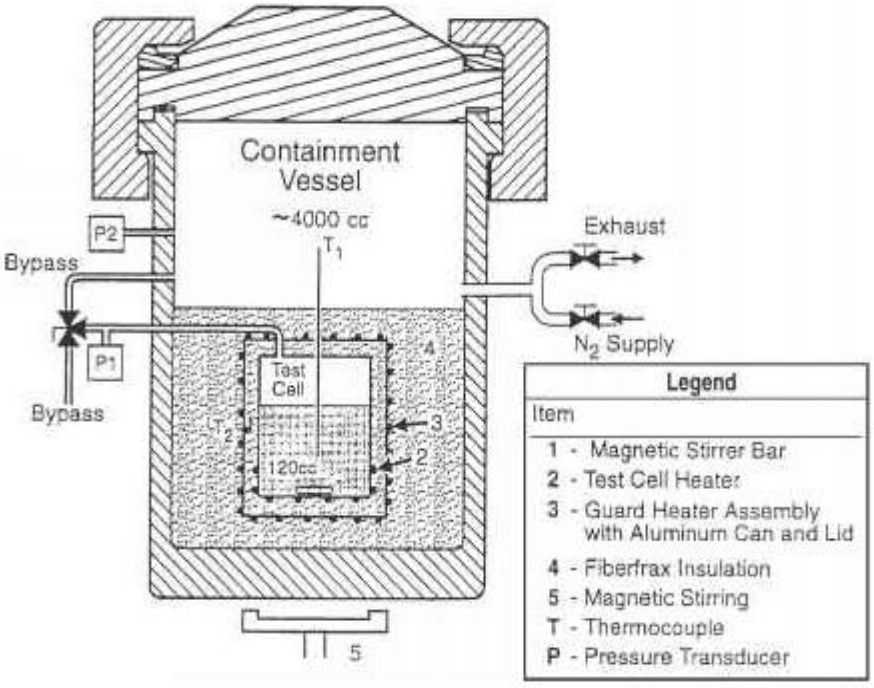
Vent Sizing Package (VSP):

This test uses a 120 ml heated test cell with pressure control system. The test yield data on vapor behavior and the information is used for the sizing of emergency relief vents on the reactors.



Reference Book for Understanding Reaction Hazards

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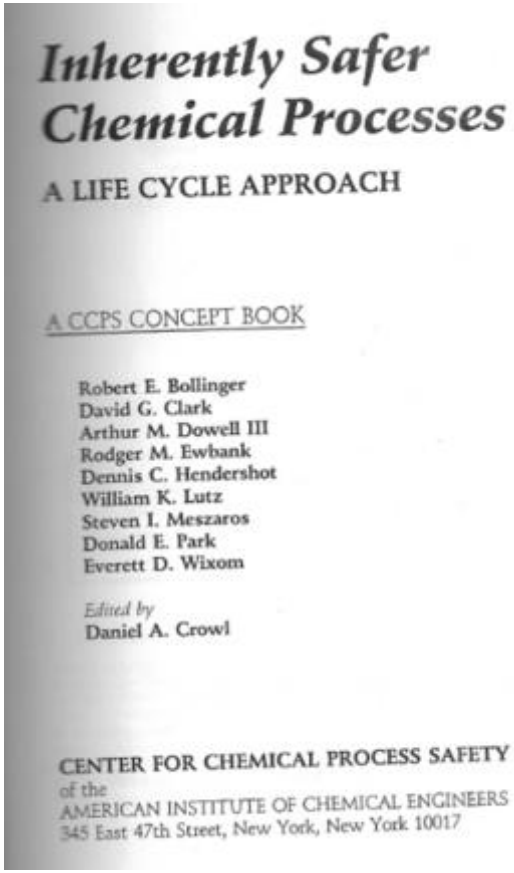
- **This book provides very good material for the design & understanding of inherently safer processes**



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Summary on Process Safety Management

Lamy Bao – External Manufacturing EHS Associate Director, Bristol-Myers Squibb

OSHA PSM Elements

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- **Commit to Process Safety**
  - Employee Participation
- **Understanding Hazards and Risks**
  - **Process Safety Information**
  - **Process Hazards Analysis**
- **Learning from Experience**
  - **Incident Investigations**
  - **Compliance Audits**
- **Manage Risk**
  - **Operating Procedures**
  - **Hot work permits**
  - **Mechanical integrity**
  - **Contractors**
  - **Training**
  - **Management of Change**
  - **Pre-startup safety review**
  - **Emergency Procedures**
- Trade Secrets

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Understanding Hazards - Question 93

- **Do you as a auditor understand the site's hazards?**
- **Does the site employee (leaders, operators, functional personnel) understand the hazards?**
- **What methods does site personnel to cascade the information to other shareholders in the site?**
- **Does the site have a procedure to maintain the process safety information?**

Understanding Risk – Questions 94, 99 & 100

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- **How does the site manage the risks? Whether are they giving it enough consideration?**
- **Who participated in the hazard review program? What is the frequency? Has the review identified any issues that need to be addressed?**
- **Do the site assess the miscellaneous failure conditions in batch processes including chemical reaction, equipment, utility and batch scale up?**
- **Does the site manage all process hazards (Dust fires, reactive chemicals, High temperature and/or high pressure operations, Toxic materials)?**

Management Risks - Questions 95 – 98, 101 - 106

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- **Does the site have proper engineering control in place to manage the risks associated with ignition resources, compressed gas, bulk chemical storage, combustible dusts, and direct fire equipment?**
- **Is the engineering control adequately to protect the site's employee?**
- **Can the site provide technical evaluation, certification, calculation and verification documentation to ensure the effectiveness of engineering control?**

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Questions and Answers

- **Thanks for your attention**
- **Time for Questions???**

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Dust hazards and explosion protection

Ivy Shang
Elanco
Nov 2017

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Agenda

1. 粉尘爆炸的危害和特点Dust Explosion Hazards
2. 识别粉尘爆炸的危害 Hazard Identification
3. 影响粉尘爆炸的参数 Dust Explosion Parameters
4. 常见粉尘爆炸控制措施Preventive/ Mitigation Strategies

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Major Combustible Dust Accidents

2002 Jan, US
5 persons killed
Rubber powder explosion

2003 Jan, US
6 persons killed
Plastic powder explosion
West Pharmaceutical
Services plant

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Major Combustible Dust Accidents

2003 Jan, US
6 persons killed
Plastic powder explosion

2003 Feb, US
7 persons killed
Resin powder explosion

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Major Combustible Dust Accidents

2008 Feb, US
14 persons killed
Sugar powder explosion

2011 Feb, Qinhuangdao, China
19 persons killed
Flour powder explosion

Kunshan Zhongrong Explosion incident
昆山中荣粉尘爆炸特大事故

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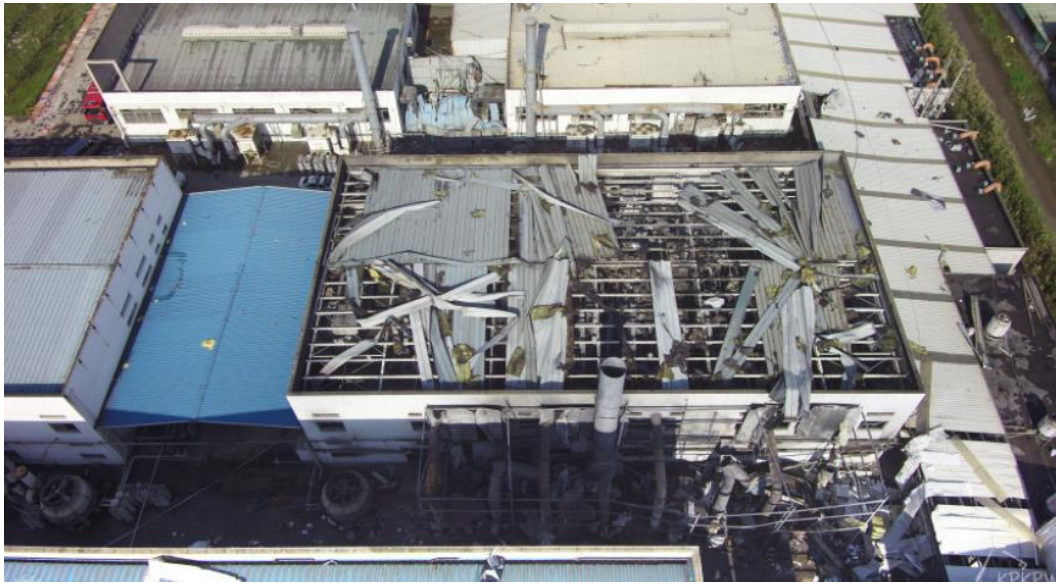

2014 Aug, Kunshan, China
97 persons killed
Aluminum powder explosion

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Agenda

- 粉尘爆炸的危害和特点Dust Explosion Hazards
- **识别粉尘爆炸的危害 Hazard Identification**
- 影响粉尘爆炸的参数 Dust Explosion Parameters
- 常见粉尘爆炸控制措施Preventive/ Mitigation Strategies

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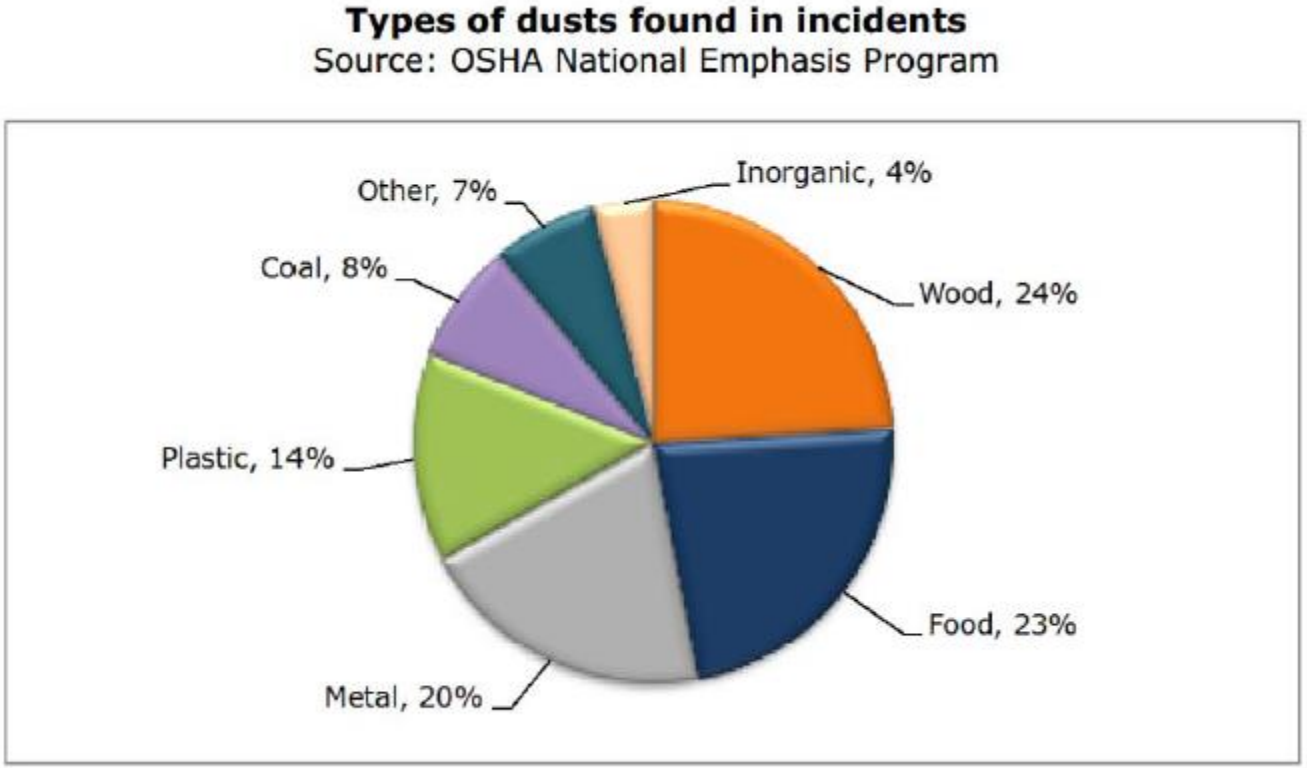
Types of dusts found in incidents



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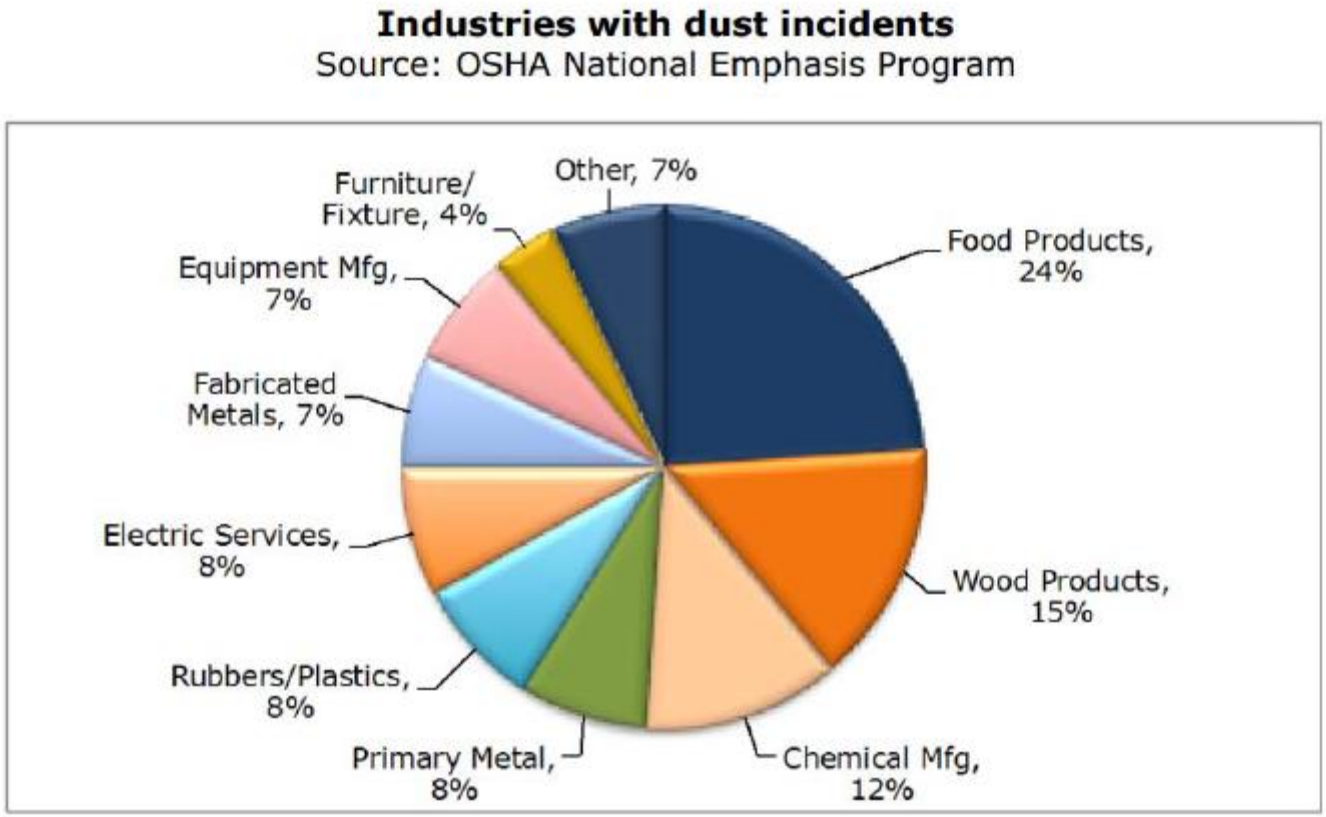
Industries with dust incidents



Most frequent dust explosion areas
容易发生粉尘爆炸的区域

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Table 1. Equipment involved in dust explosions in the U.S. (1975–2001), U.K. (1979–1988), and Germany (1965–1985).

Equipment	Number of Incidents	Percent of Total
Dust Collectors	284	26†
Grinders/Pulverizers	142	13
Silos/Bunkers	132	12
Conveying Systems*	108	10
Dryers/Ovens	99	9
Mixers/Blenders	39	4
Others/Unknown	293	27
Total	1,101	

* Conveying systems include conveyors, ducts and elevators.

† The percentage of all explosions occurring in dust collectors in the U.S. was much higher — 42% — but this was masked by the lower percentages in the U.K. and Germany when the data were combined.

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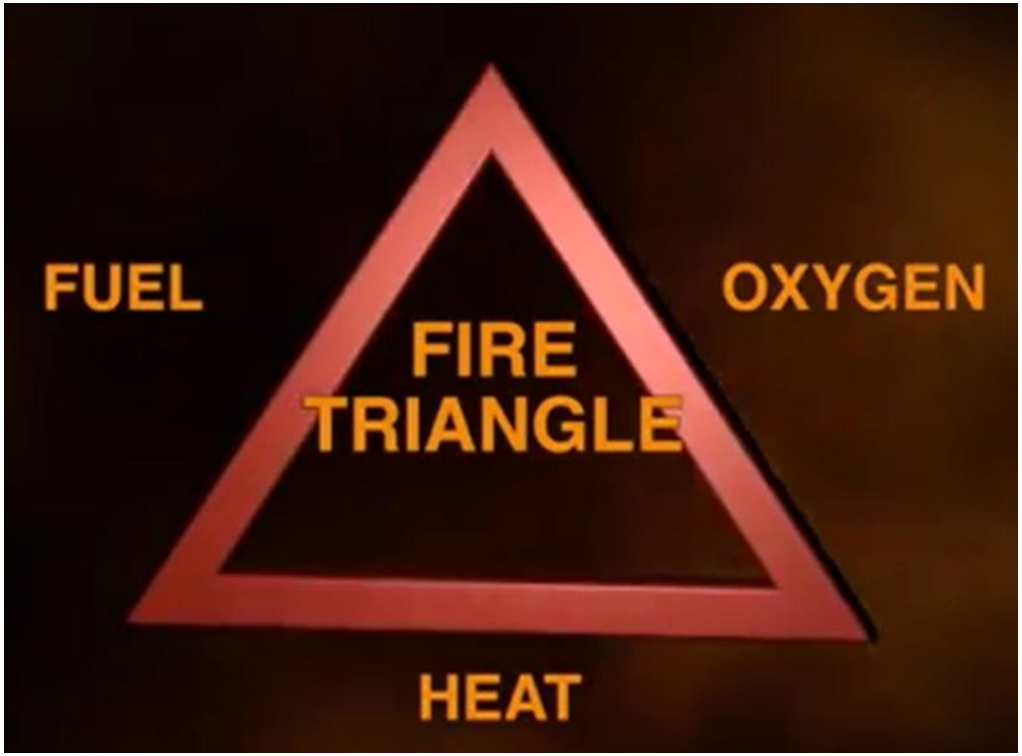
Fire Triangle火灾三角形



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Dust Explosion Pentagon粉尘爆炸五边形

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Agenda

- 粉尘爆炸的危害和特点Dust Explosion Hazards
- 识别粉尘爆炸的危害 Hazard Identification
- **影响粉尘爆炸的参数 Dust Explosion Parameters**
- 常见粉尘爆炸控制措施Preventive/ Mitigation Strategies

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Data for Dust Hazards Evaluation

Property	Definition	ASTM Test Method	Application
Kst	Dust deflagration index	ASTM E 1226	Measures the relative explosion severity compared to other dusts
Pmax	Maximum explosion overpressure generated in the test chamber	ASTM E 1226	Used to design enclosures and predict the severity of the consequence
(dp/dt) max	Maximum rate of pressure rise	ASTM E 1226	Predicts the violence of an explosion; used to calculate Kst.
MIE	Minimum ignition energy	ASTM E 2019	Predicts the ease and likelihood of ignition of a dispersed dust cloud

Data for Dust Hazards Evaluation

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Property	Definition	ASTM Test Method	Application
MEC	Minimum explosible concentration	ASTM E 1515	Measures the minimum amount of dust, dispensed in air, required to spread an explosion; analogous to the lower flammability limit (LFL) for gas/air mixtures
LOC	Limiting oxygen concentration	ASTM standard under development	Determines the least amount of oxygen required for explosion propagation through the dust cloud
ECT	Electrostatic charging tendency	No ASTM standard	Predicts the likelihood of the material to develop and discharge sufficient static electricity to ignite a dispensed dust cloud

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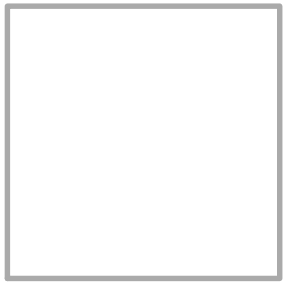
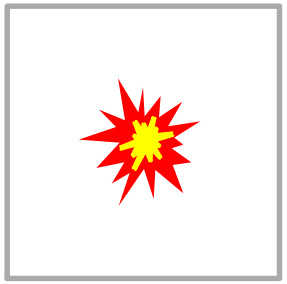
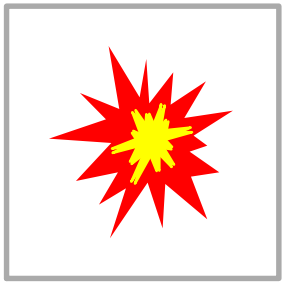
Explosion Severity


Dust explosion group	St 0	St 1	St 2	St 3
Kst bar.m.s^{-1}	0	> 0 ≤ 200	> 200 ≤ 300	> 300
Explosion characteristics	no explosion	weak/ moderate	strong	very strong

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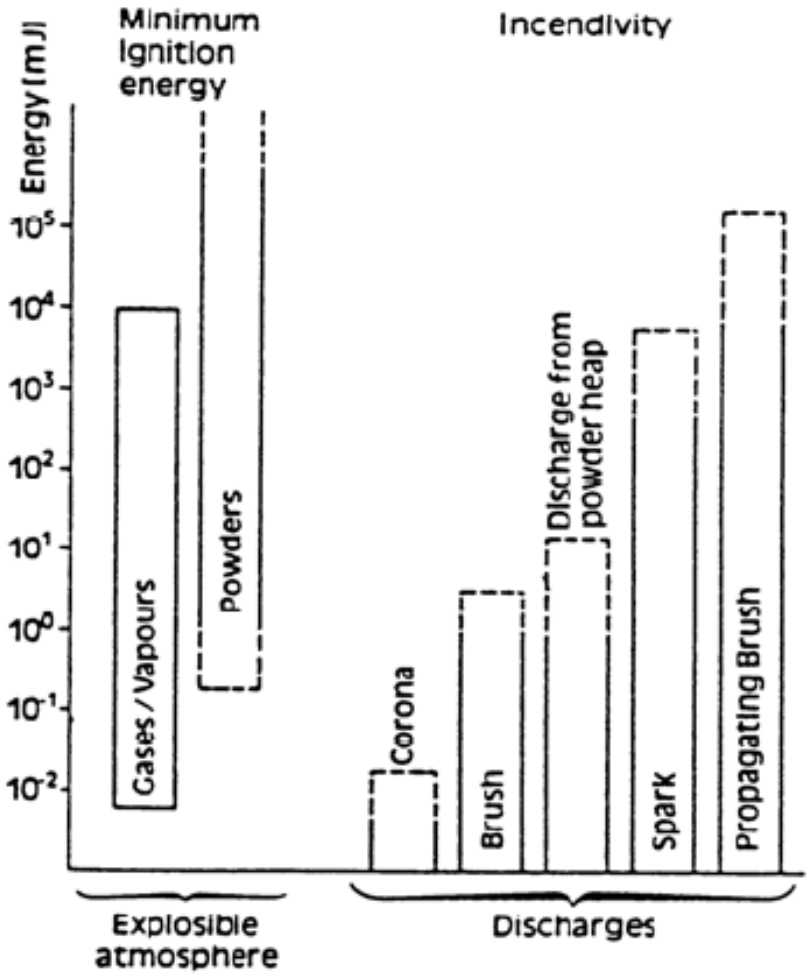
Minimum Ignition Energy



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Minimum Ignition Energy In Air

Product Name	MIE in air
Hydrogen 氢气	0.01mJ
Methanol 甲醇	0.14 mJ
n-Heptane庚烷	0.24 mJ
Acetone 丙酮	1.15 mJ
“Normal” Dust 普通粉尘	>10 mJ
Sugar powder 糖粉	30-100 mJ
Wheat flour 面粉	~50 mJ
Coal 煤粉	30-100 mJ
Paracetamol扑热息痛	<10 mJ
PVC 聚氯乙烯	1500 mJ

Dust Explosion Incident

(West Pharmaceutical, Jan, 2003)

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- West Pharmaceuticals Plant, North Carolina
- Manufacturing plant for rubber stoppers for pharma industry
- Powder in a mixing step created a cloud which ignited
- The fire spread into other areas and propagated in the ceiling above the equipment where a dust layer ignited and caused a major secondary explosion.
- Explosion destroyed 50% of the plant.
- 6 persons killed, 38 injured
- Damage: $150 million
  Fire raged for 2 days
- Shock wave from explosion broke windows 1,000 feet away
- Propelled debris was found about 2 miles away

Photos of Damage from West Pharma Explosion

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Photos of Damage from West Pharma Explosion

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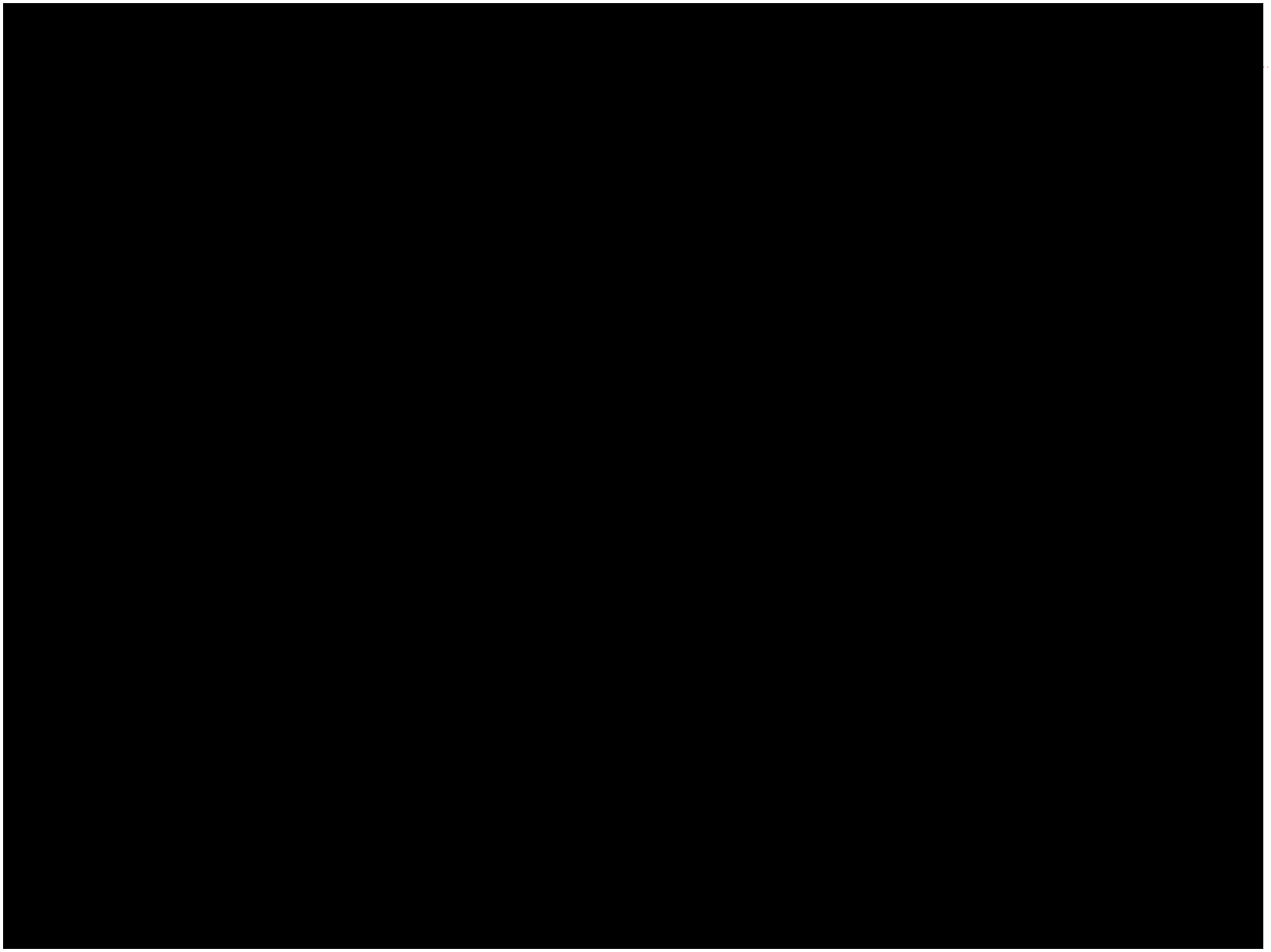

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Agenda

- 粉尘爆炸的危害和特点Dust Explosion Hazards
- 识别粉尘爆炸的危害 Hazard Identification
- 影响粉尘爆炸的参数 Dust Explosion Parameters
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Preventive/ Mitigation Strategies for Dust Explosions

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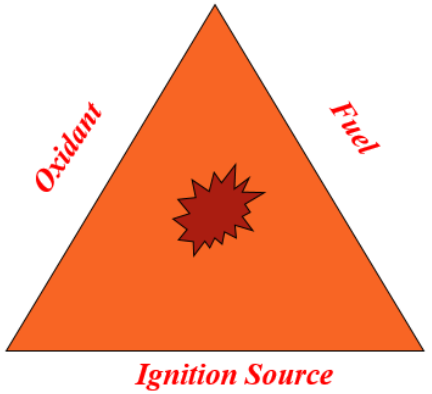
- **Preventive :**
  - Remove any leg of the fire triangle to prevent combustion,
    - Remove ignition source
    - Innertting
    - Operate below the minimum explosion concentration
  - If this is not possible, then mitigation steps are needed.

- **Mitigative:**
  - Accept that an explosion may occur and institute measures that will eliminate the potential for injury to personnel or damage to equipment.. This can be by the following methods:

    - Option - 1: Venting
    - Option - 2: Containment
    - Option – 3: Suppression
    - Option – 4: Isolation



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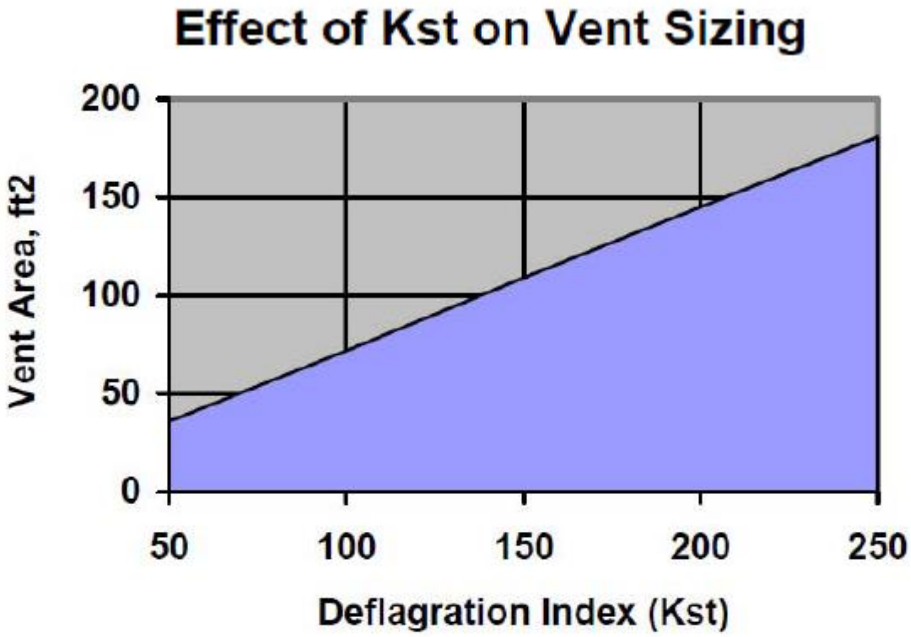
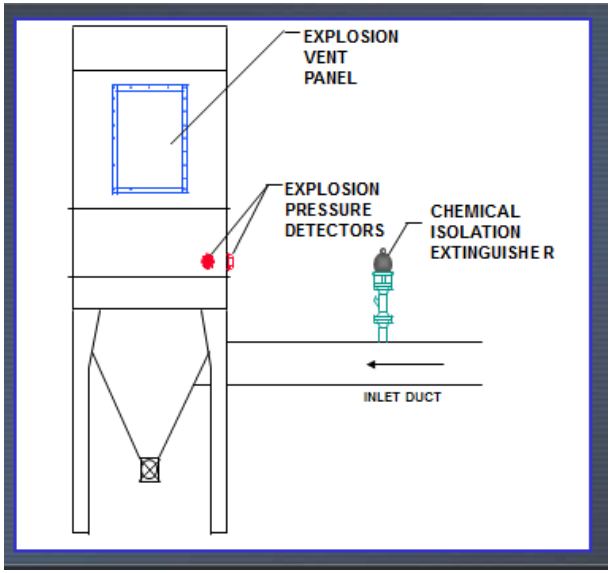
Option – 1 - Explosion Venting

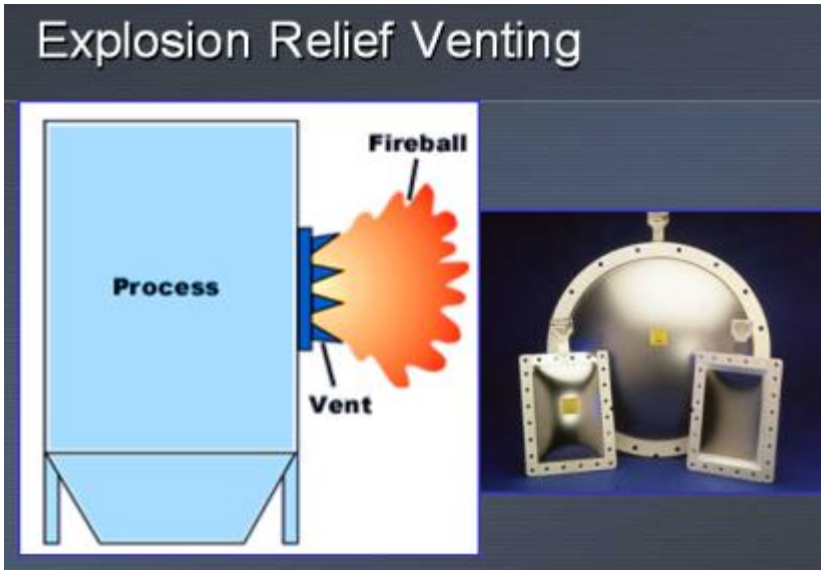
- **This is the most commonly used method**
- **Use intentionally 'weak' elements to relieve the pressure & vent combustion event to a safe location to prevent catastrophic equipment damage or personnel injury**
- **Use value of K_{st} along with appropriate nomographs and/or equations to size vent of proper area**



Calculations based on NFPA 68, 2002 Edition:
Pstat = 0.1 barg
Pred = 0.25 barg
L/D = 3
Volume = 200 m^3

Explosion Venting





$$A_v = \left(8.535 \times 10^{-5}\right)\left(1 + 1.75 P_{stat}\right) K_{St} V^{0.75} \sqrt{\frac{(1-\Pi)}{\Pi}} \qquad (7.1)$$

where:

A_v = vent area (m^2)
P_{stat} = static burst pressure of the vent (bar)
K_{St} = deflagration index (bar-m/sec)
V = hazard volume (m^3)
Π = P_{red}/P_{max}
P_{red} = reduced pressure after deflagration venting (bar)
P_{max} = maximum pressure of a deflagration (bar)

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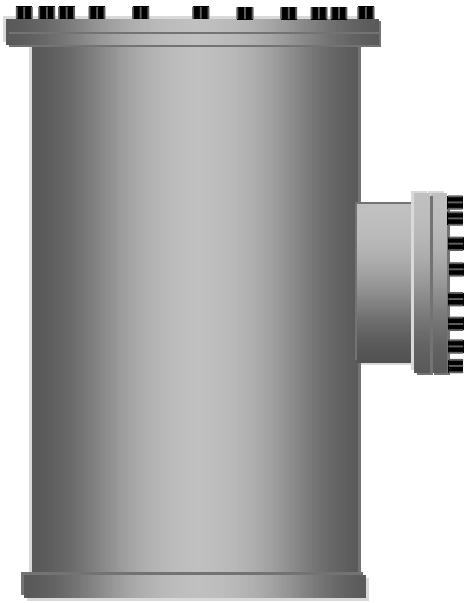
Option -2: Containment

- **Design the equipment to withstand internal explosion without catastrophic failure. Maximum pressure from a dust explosion can be up to 12 bars.**
- **The maximum pressure is determined from the Explosion Severity Test (Kst)**
- **Generally limited to smaller volume equipment due to cost**



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Option-3: Explosion Suppression – 1 of 2

- **This system uses fast-responding system to detect incipient explosion and releases extinguishing agent to terminate the combustion (typically detection in <10 msec, suppression in <100 msec)**
- **Either presence of flame and/or pressure rise can be detected**
- **Extinguishing agent may be extinguishing powder (e.g., sodium bicarbonate), water or inert gas**
- **Design of the system is generally vendor-specific but the value of K_{st} is needed**
- **Suppression systems must be periodically inspected to ensure operational integrity**
- **Suppression systems only operate once; process must be interlocked to shut down upon activation**

Explosion Suppression System – 2 of 2

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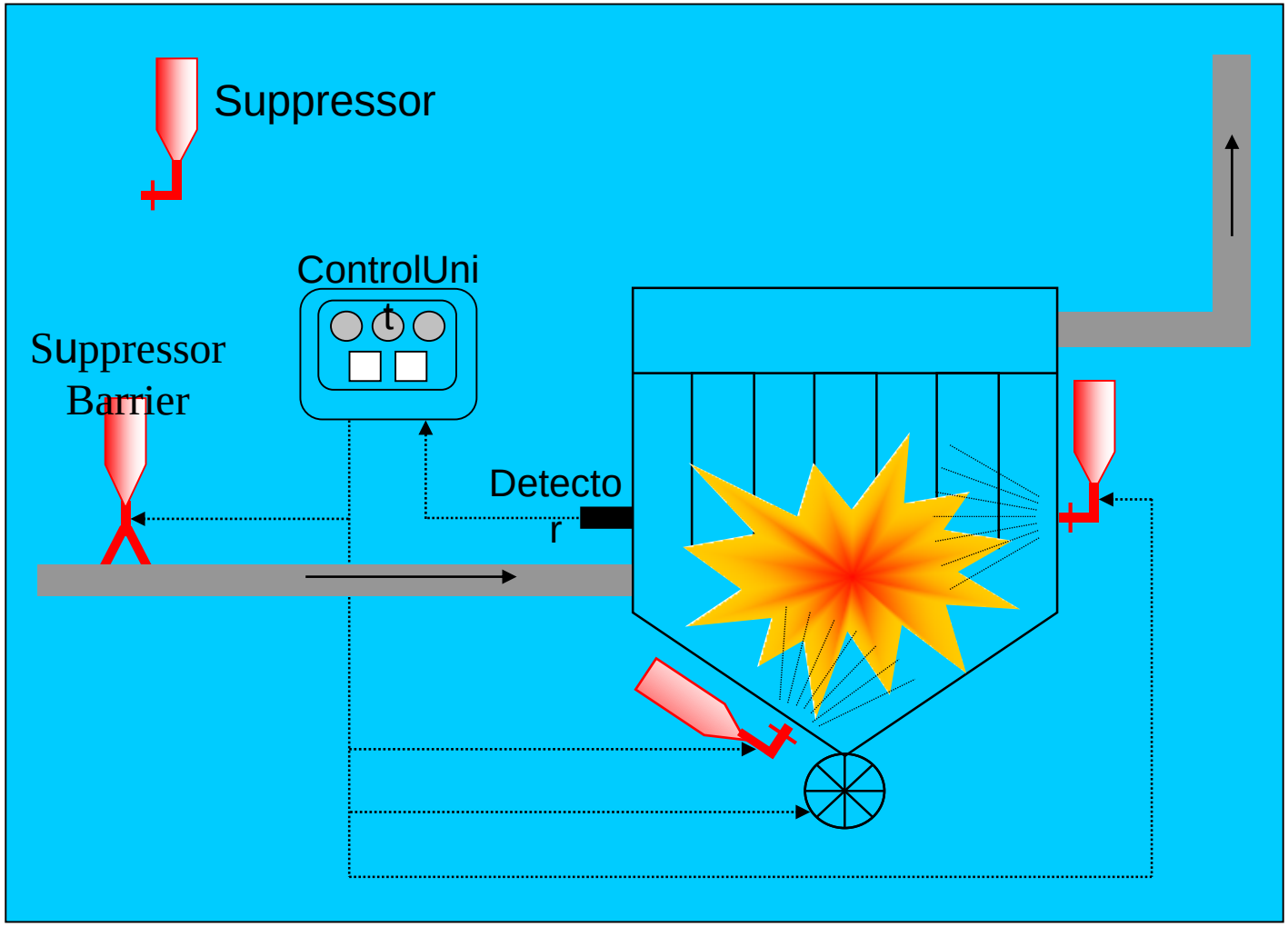

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Option - 4: Isolation

- **This is required to prevent propagation of an event in one vessel to other attached pieces of equipment**
- **Quick acting isolation valves on the inlet and/or the outlet of the equipment are used when explosion is vented**
- **Either passive or active methods may be used to prevent an explosion from propagating from its point of origin to other pieces of equipment**
- **Process elements or dedicated special devices can also be used to isolate the event**

Examples of Process Equipment Used for Isolation

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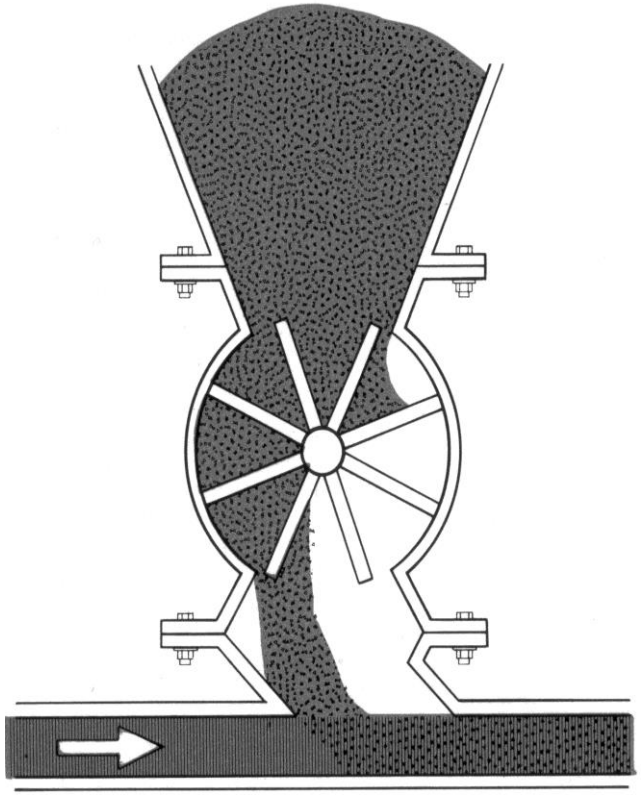
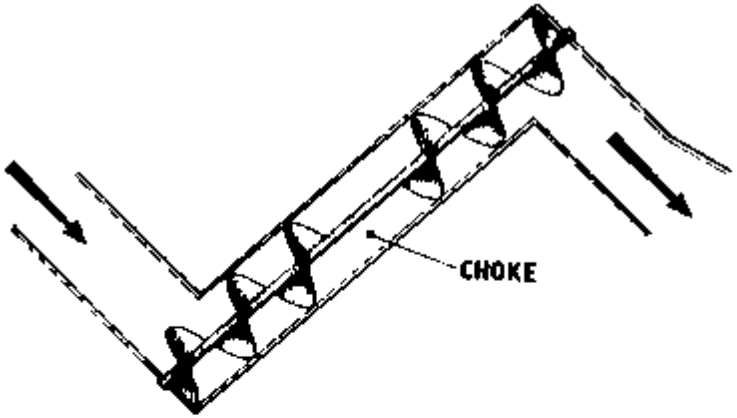
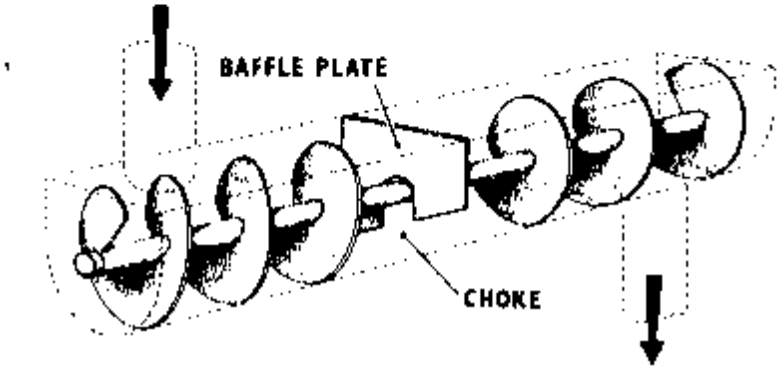
Rotary Valve



Screw Feeder





Examples of Process Equipment Used for Isolation

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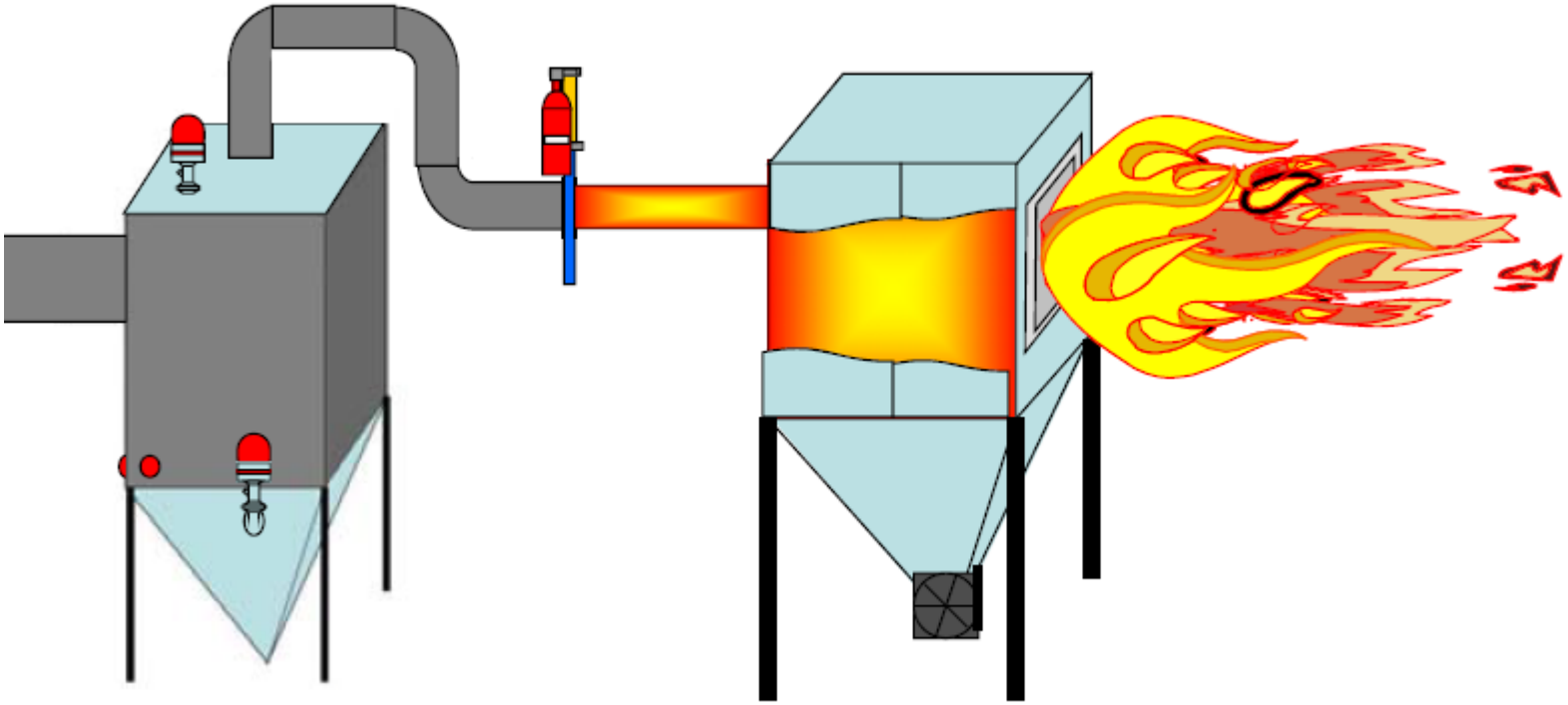
Automatic Explosion isolation Valve



If the Kst is above 300 bar.m/s, the valve would not work

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Dust Hazards Assessment Guide

This paper was presented by Steve Meszaros and Ron Sethi at the NFPA Symposium in Baltimore in May, 2009. It offers guidance for the following topics:

- **Assessment of dust explosivity hazards**
- **Testing of powders**
- **Layers of protection based on MIE for different types of equipment**
- **Special considerations for aqueous formulations and those containing flammable solvents**
- **Design of explosion protection equipment**

Dust Hazards
Assessment Guide

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Dust explosion related regulations
粉尘爆炸相关法规

Chinese Regulations

- 粉尘防爆术语 GB/T 15604-2008
- 粉尘爆炸泄压指南 GB/T 15605-2008
- 粉尘防爆安全规程 GB15577-2007
- 粮食加工、储运系统粉尘防爆安全规程 GB17440-2008
- 粉尘爆炸危险场所用收尘器防爆导则 GB/T17919-2008

International Regulations

- Dust Explosion Venting Protective System, BS EN 14491:2006
- Standard for the prevention of Fire and Dust Explosions from the Manufacturing, Processing, and Handling of Combustible Particulate Solids, NFPA 654-2006
- Standard for Combustible Metals, NFPA 484-2009
- VDI 3673-2002 粉尘爆炸泄压

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