PSCI PHARMACEUTICAL SUPPLY CHAIN INITIATIVE

Building responsible supply chains

PSCI Audit Update

Dr. Birgit Skuballa

Head of HSE Audits & Supplier Management

Bayer AG

Bio

Dr. Birgit Isabelle Skuballa

- **Current position** and responsibilities: Bayer AG, Corporate HSE, Head of HSE Audits & Supplier Management
- **Location:** based in Leverkusen, Germany
- **Background:** PhD in Organic Chemistry (University of Karlsruhe); post-doc at Nagoya University (Japan); ISO14001/OHSAS18001/17025 Lead Auditor; global Bayer HSE Audit Team Lead
- **Experience**: 24+ years within Pharma/Chemical Industry (Schering AG / Bayer); including 4+ years as Process Development Chemist at an API production site, 3 years HSE Management System Responsible and global Responsible Care Coordinator, short time assignment at a pharmaceutical finishing site in Italy, 5 years GMP/Quality Auditor for internal/external API sites and global HSE Auditor; after acquisition of Schering AG by Bayer HealthCare leading the HSE Audit and MS Group for the Healthcare Division for 7 years, including global HSE Data Management for the Bayer Annual Report; 3 years leading the global function for HSE MS, Audit Strategy & Planning for all Bayer Divisions (Pharma/ Consumer/ Animal Health/Crop) for 3 years; after acquisition of Monsanto by Bayer now leading the global function for HSE Audits and Supplier Management covering all divisions/businesses at Bayer.
- **Contact information:** birgit.skuballa@bayer.com

AGENDA

OVERVIEW ON PSCI AUDITS

PSCI SAQS AND AUDIT REPORT TEMPLATES UPDATE

GENERAL PSCI AUDIT PROCESS

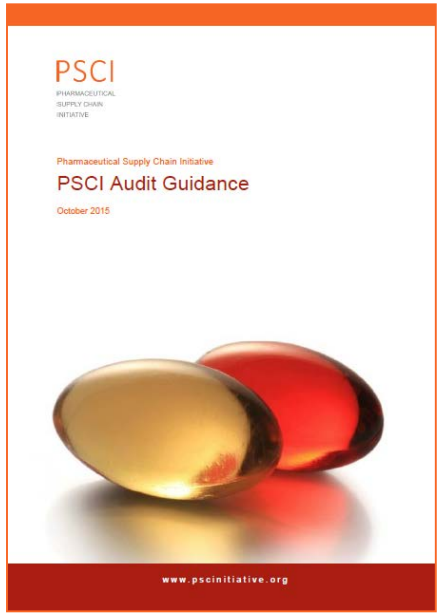
AUDIT REPORT WRITING

WHY DO WE AUDIT?

- PSCI Audits are designed to assess a supplier's performance against the PSCI Principles as well as against international standards and agreements, and local regulatory requirements in the areas of: Ethics, Labor, Health & Safety, Environmental Protection and Management Systems.
- The PSCI Shared Audit Program provides a framework and methodology to ensure PSCI Audits are carried out in accordance with PSCI Standards, thereby delivering a credible, transparent and consistent audit approach.
- Our goal is to ensure that the PSCI auditing model and tools become the norm for our industry.
- We encourage members to use the PSCI tools and their suppliers to share the results.

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

WHO CARRIES OUT PSCI AUDITS?

- In order to ensure the integrity of the audit process, PSCI Audits are carried out either by **professional and independent 3rd party audit firms incl. qualified auditors** or by PSCI member internal auditors.
- PSCI has currently approved **eleven professional, independent 3rd Party Audit firms** to conduct PSCI Audits, see https://pscinitiative.org/auditCollaboration
- On the contact details of the 3rd Party Audit firm it is indicated for which supplier categories and which audit type the firm is approved , e.g.:
  - Audit Firm 1 — Approved for: Type A, B & C Audits; All Audit Topics
  - Audit Firm 2 — Approved for: Type A, B & C Audits; Health & Safety; Environment; Management Systems
  - Audit Firm 3 — Approved for: PSCI Type A; All Audit Topics

EXPECTATIONS OF PSCI AND PSCI MEMBERS

A Standard Framework Agreement with each of our current and future 3rd party audit firms is in place, which outlines the PSCI expectations on conducting PSCI Audits, covering the following aspects:

- Audit performed according to latest audit program and documentation is complete with all required data in English
- Audit documentation does not contain customer-supplier relationship, competitive sensitive information, or personally sensitive data
- Audit firm pre-screens and proposes appropriate auditors per criteria for Supplier type A, B & C as per PSCI audit guidance document.
- Audit firm ensures that Auditors are familiar with and trained on Key PSCI Audit documents/webinars
- Audit firm conducts internal quality assurance review of audit reports
- Audit firm has feedback mechanism on auditors and take measures to ensure appropriate auditor conduct
- Escalation mechanism in place between PSCI (via PSCI Secretariat) & audit firm for issues
- Reasoning and method for audit firm removal from qualified PSCI Audit List (e.g. due to violations of agreement or guidance document)

PSCI GUIDANCE TOOLS FOR AUDITORS

Collaborative auditing embeds the PSCI Principles in our supply chain. The PSCI has developed guidance tools tailored for our industry for assessing performance and risk. These include:

- PSCI Principles
- PSCI Implementation Guidance
- PSCI Audit Guidance
- PSCI Introductory Training for Auditors - webinar
- Full PSCI SAQ & Audit Report Template for Core Suppliers, External Manufacturers, Component and Material Suppliers - word
- Full PSCI SAQ & Audit Report Template for Core Suppliers, External Manufacturers, Component and Material Suppliers - excel
- Abbreviated PSCI SAQ & Audit Report Template for Service Providers & General Manufacturers (word and excel)
- PSCI SAQ & Audit Report Template Update - 20th February 2019 - webinar
- Introduction presentation for PSCI audit opening meeting
- Pre-Audit Document Request List
- Corrective Action Plan – excel and word
- Data Sharing Agreement
- PSCI Audit Sharing Platform Supplier User Guide
- PSCI Auditor Evaluation Tool

NEW! chinese translations available

AGENDA

OVERVIEW ON PSCI AUDITS

PSCI SAQS AND AUDIT REPORT TEMPLATES UPDATES

GENERAL PSCI AUDIT PROCESS

AUDIT REPORT WRITING

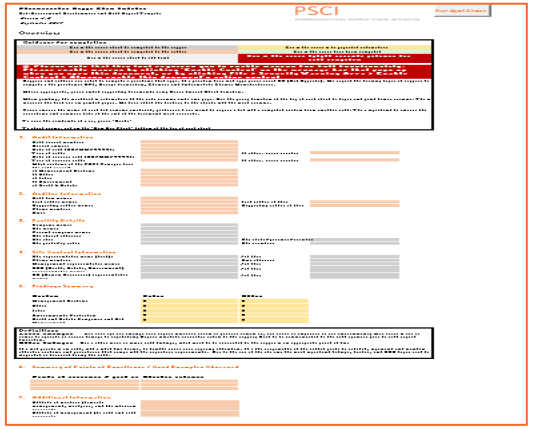
PSCI SUPPLIER CATEGORIES

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

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

PSCI SAQS & AUDIT REPORT PROTOCOLS

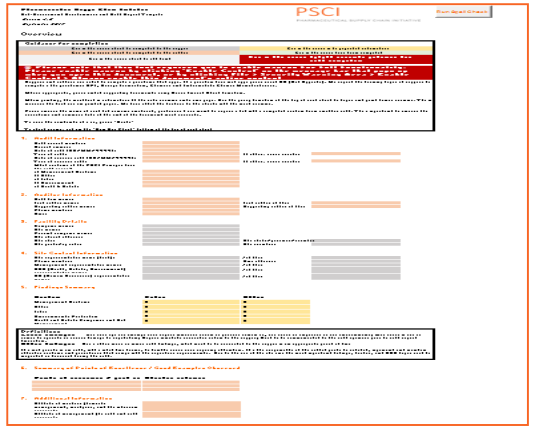
USE FOR "A" SUPPLIERS!!



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

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

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



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

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

PSCI SAQ/ AUDIT TEMPLATES (WORD AND EXCEL)

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

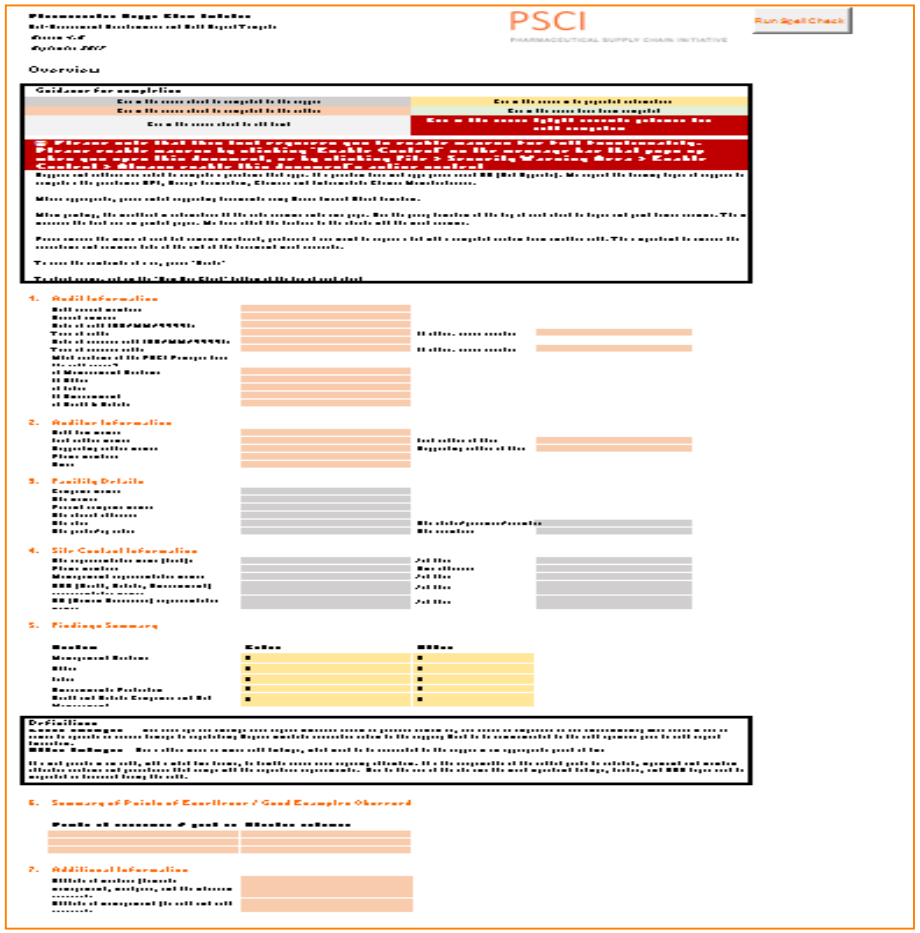
Report Number:			
Report Owner:	Note: this is the company paying for /sponsoring the audit. If a PSCI Member, the name should be removed before the report is uploaded to the PSCI audit sharing platform		
Date of Audit:	DD/MM/YYYY ☐ initial ☐ follow up ☐ other, please specify	**Date and Type of Previous 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):	

October 2016 *Version 4*

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



SAQ/ AUDIT TOOLS: OVERVIEW ON UPDATE

The SAQ/Audit tools (word and excel) have been updated from a few perspectives:

- New content
  - Now two methodologies for finding classification
    - Critical/"Others"
    - Critical/Major/Minor 

  - Revised questions
  - More auditor guidance

- New functionalities
  - Driven by revisions
  - Driven by feedback from member companies and approved auditors

WORD VERSIONS – Findings classifications

- **Findings classifications**, only the relevant executive summary should be filled in, depending on the findings classification required
  - Critical / Major / Minor
  - Critical / Other

Note:

for details on audit finding classification see section "Audit Report Writing"

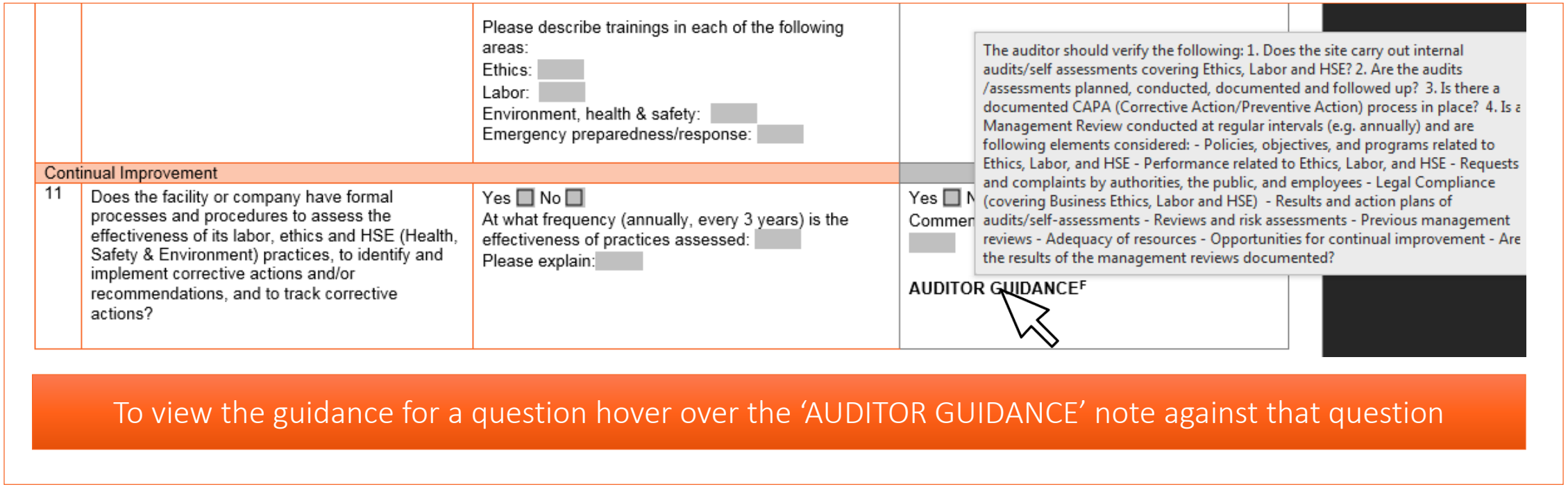
EXECUTIVE SUMMARY (FOR CRITICAL-OTHER)							
Overall findings		Please check applicable box(es) and indicate the number of findings					
		Critical	Number of Criticals	Other	Number of Others	No findings	Not reviewed
A	Management Systems	☐		☐		☐	☐
B	Ethics	☐		☐		☐	☐
C	Labor	☐		☐		☐	☐
D	Environmental Protection	☐		☐		☐	☐
E	Health & Safety Compliance and Risk Management	☐		☐		☐	☐

EXECUTIVE SUMMARY (FOR CRITICAL-MAJOR-MINOR)								
Overall findings		Please check applicable box(es) and indicate the number of findings						
		Critical	Number of Criticals	Major	Number of Major	Minor	Number of Minor	No findings	Not reviewed
A	Management Systems	☐		☐		☐		☐	☐
B	Ethics	☐		☐		☐		☐	☐
C	Labor	☐		☐		☐		☐	☐
D	Environmental Protection	☐		☐		☐		☐	☐
E	Health & Safety Compliance and Risk Management	☐		☐		☐		☐	☐

WORD VERSIONS – Auditor guidance (1)

Auditor guidance: the updated auditor guidance has been added to the tool using endnotes.

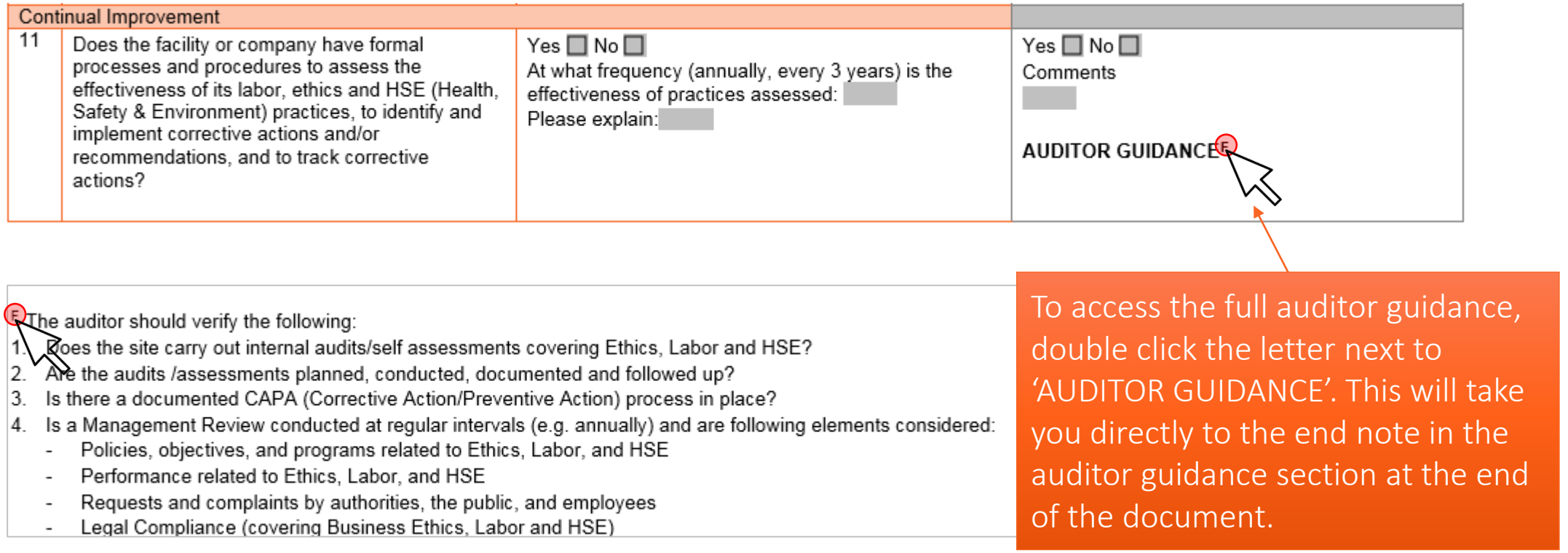
1) To view the guidance pop-up



To view the guidance for a question hover over the 'AUDITOR GUIDANCE' note against that question

WORD VERSIONS – Auditor guidance (2)

2) To view the full guidance text



Continual Improvement			
11	Does the facility or company have formal processes and procedures to assess the effectiveness of its labor, ethics and HSE (Health, Safety & Environment) practices, to identify and implement corrective actions and/or recommendations, and to track corrective actions?	Yes ☐ No ☐ At what frequency (annually, every 3 years) is the effectiveness of practices assessed: Please explain:	Yes ☐ No ☐ Comments AUDITOR GUIDANCE F

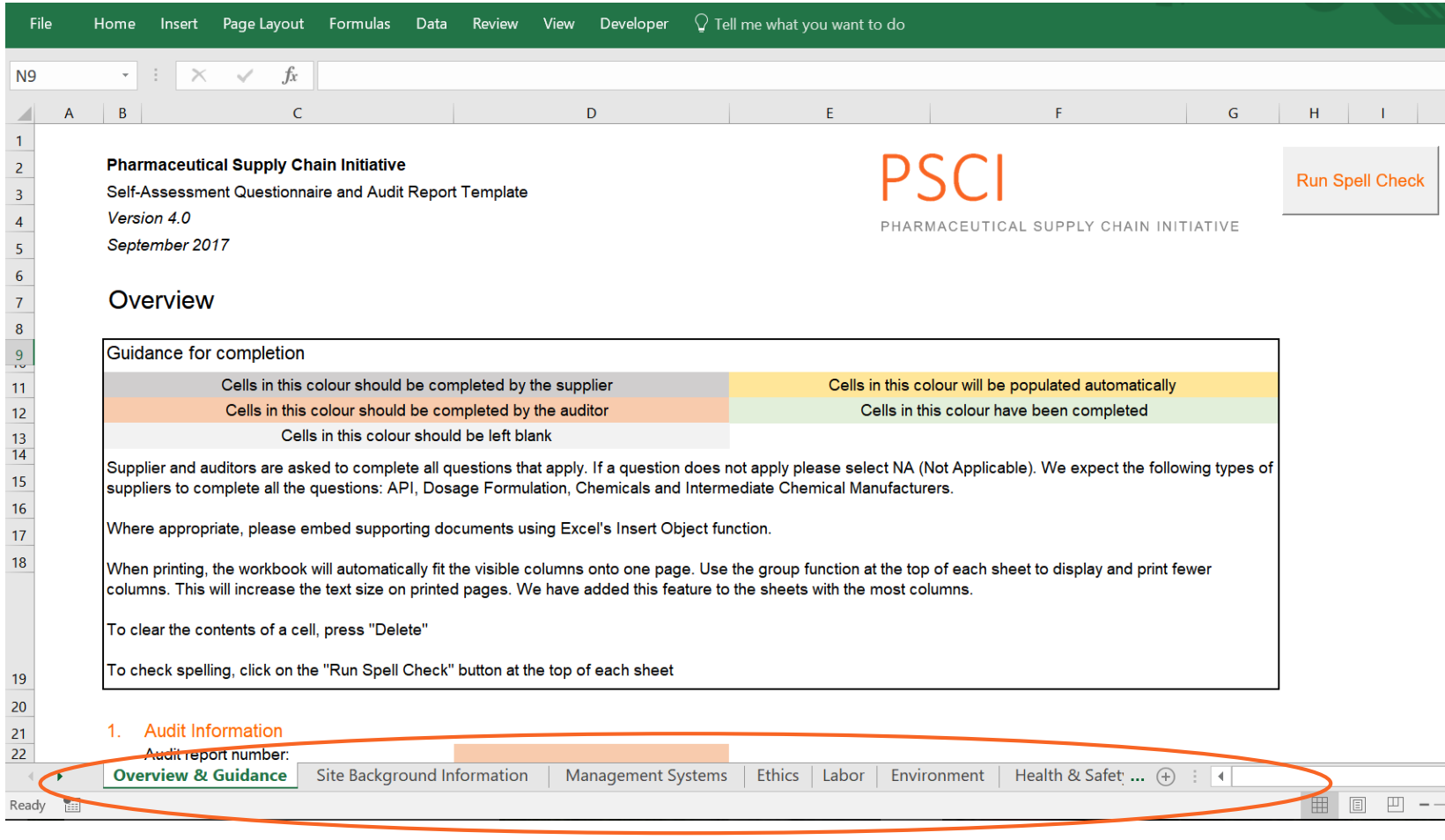
F The auditor should verify the following:

1. Does the site carry out internal audits/self assessments covering Ethics, Labor and HSE?
2. Are the audits /assessments planned, conducted, documented and followed up?
3. Is there a documented CAPA (Corrective Action/Preventive Action) process in place?
4. Is a Management Review conducted at regular intervals (e.g. annually) and are following elements considered:
   - Policies, objectives, and programs related to Ethics, Labor, and HSE
   - Performance related to Ethics, Labor, and HSE
   - Requests and complaints by authorities, the public, and employees
   - Legal Compliance (covering Business Ethics, Labor and HSE)

To access the full auditor guidance, double click the letter next to 'AUDITOR GUIDANCE'. This will take you directly to the end note in the auditor guidance section at the end of the document.

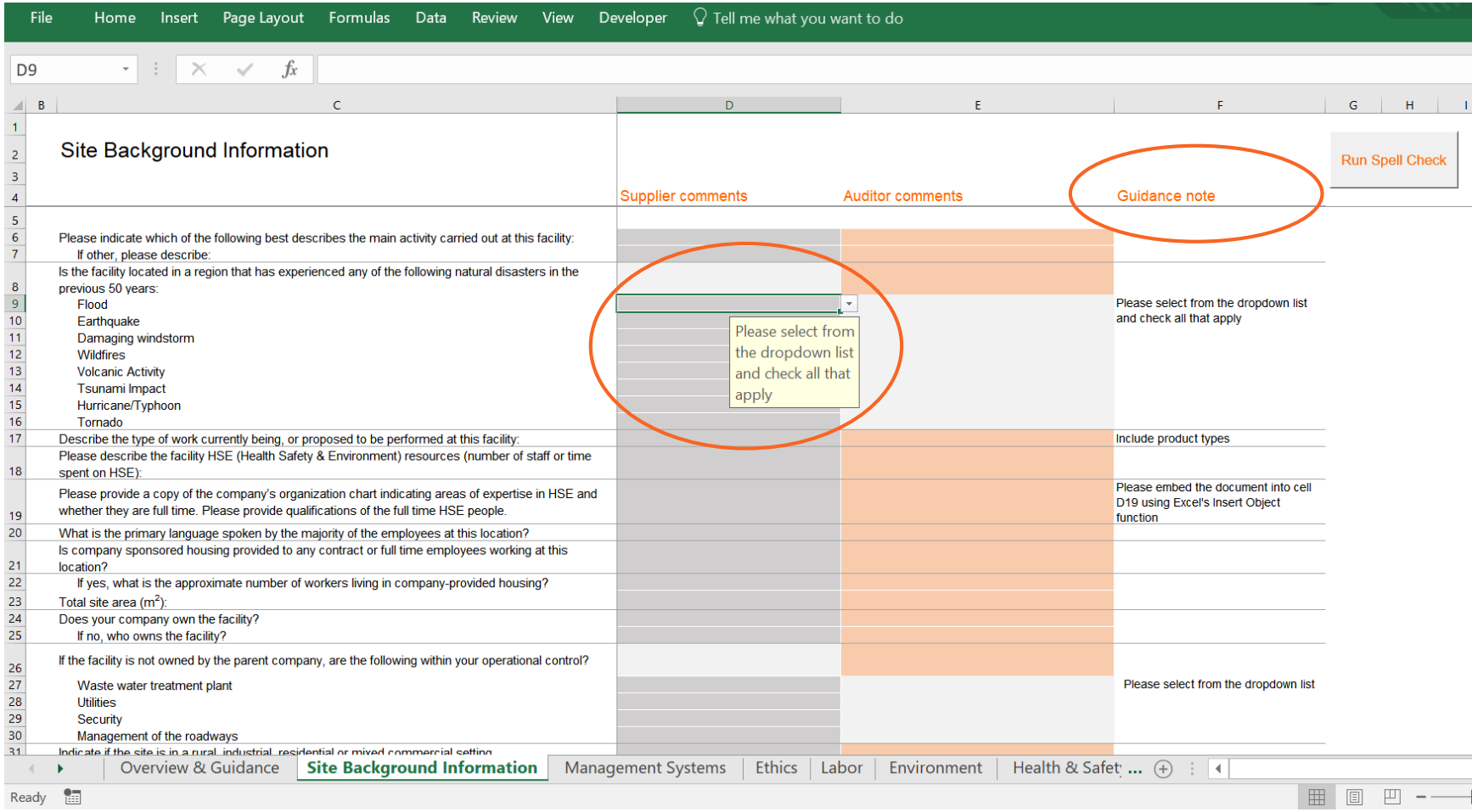
EXCEL TEMPLATE: KEY FEATURES (1)

- **Preferred tool** as we can drive overall evaluation of audit results better
- 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



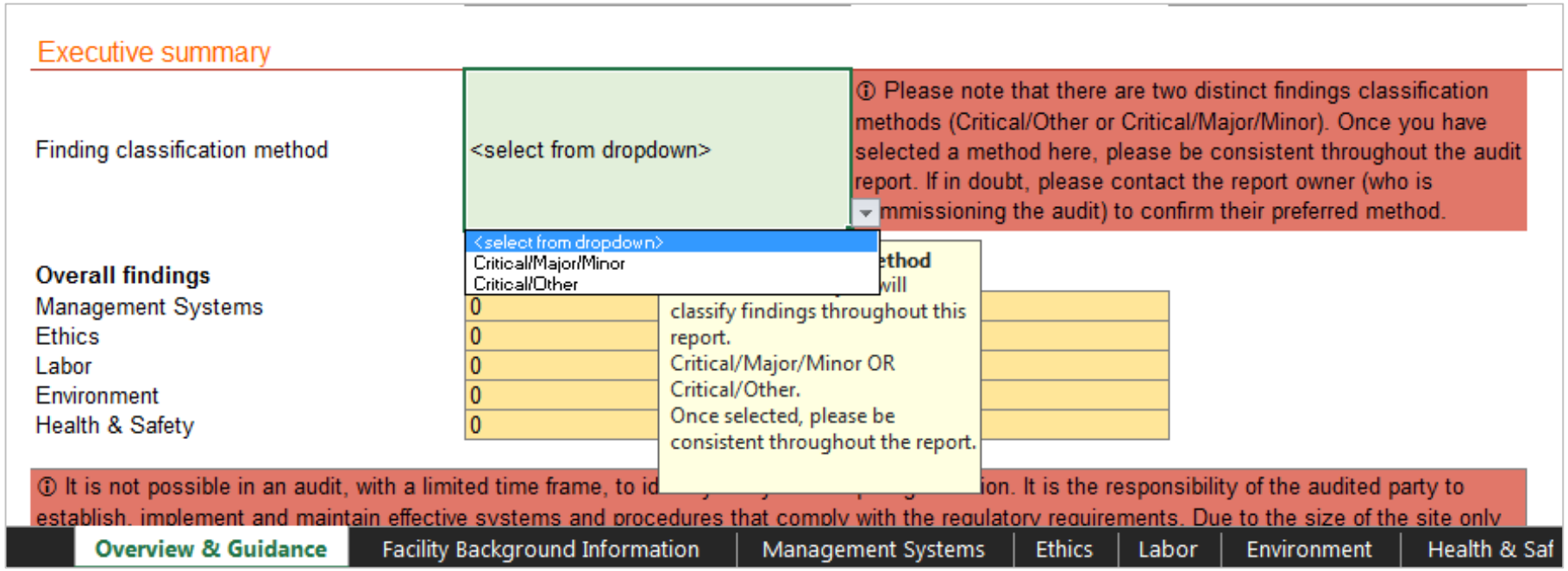
EXCEL TEMPLATE: KEY FEATURES (2)

- Detailed Auditor Guidance notes for questions covering higher risks
- Drop downs to standardise responses where appropriate



EXCEL VERSIONS –Findings classifications

- **Findings classifications**, in the excel version the classification method needs to be selected before starting the evaluation **and must not be changed in the process**. Select the findings classification required from the summary table on the 'Overview & Guidance' tab it will update automatically to:
  - Critical / Major / Minor
  - Critical / Other



EXCEL VERSIONS – Auditor guidance (2)

- **Auditor guidance**, the additional auditor guidance that has been added is included in an 'Additional Auditor Guidance' **column (K)** in the excel tool.

Pharmaceutical Supply Chain Initiative

Self-Assessment Questionnaire and Audit Report Template

ENVIRONMENT

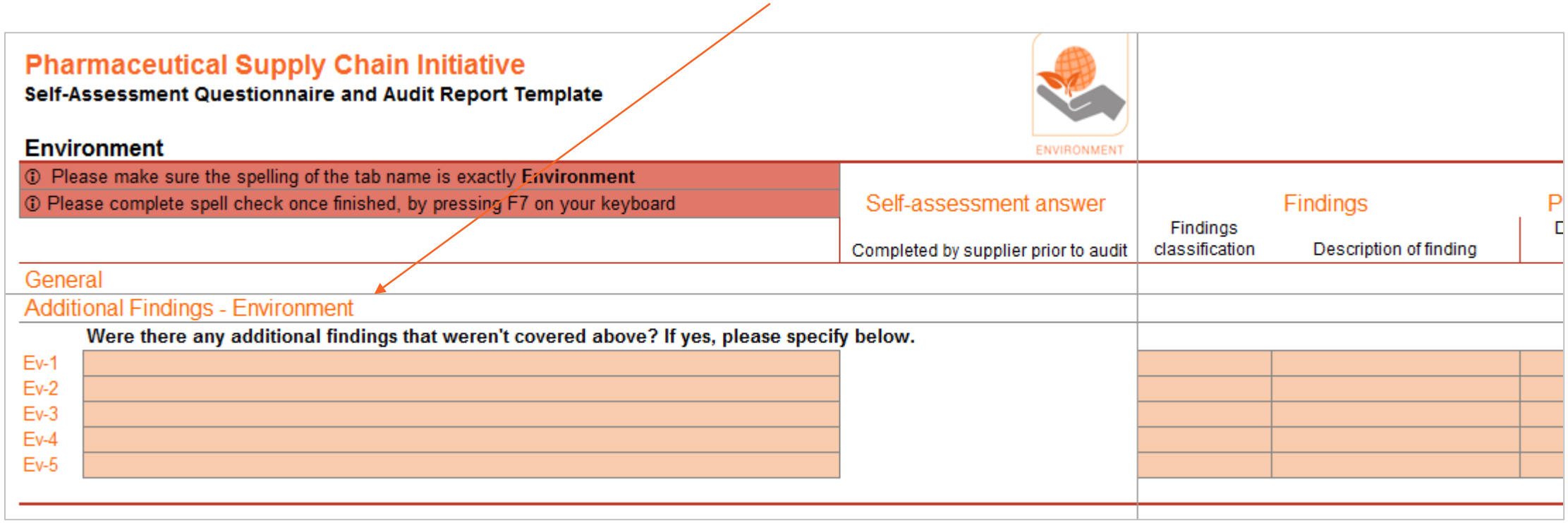
PSCI PHARMACEUTICAL SUPPLY CHAIN INITIATIVE
Building responsible supply chains

Environment

ⓘ Please make sure the spelling of the tab name is exactly **Environment** ⓘ Please complete spell check once finished, by pressing F7 on your keyboard		Self-assessment answer Completed by supplier prior to audit	Additional Auditor Guidance Where provided, it is mandatory to follow the guidance.
General			
31	**Does the facility have written environmental policy, procedures, and practices?**		
i.	Environmental policy?		
ii.	Environmental procedures?		
	Comments		
	If yes, please provide a copy of the policy and list of the procedure titles.		
32	**Does the facility have documented environmental objectives or goals for performance improvement, including metrics and targets?**		ⓘ Describe any formal or informal programs or procedures to reduce environmental impacts, noting any improvements made in recent (3) years. Does the supplier disclose environmental emissions and impacts to CDP?
	If yes, please describe goals, metrics, and/or targets and any improvements made in last 3 years		

EXCEL VERSIONS – Additional findings

- **Space for additional findings**, this is provided at the end of every section. This is aimed at including space for auditors to provide additional findings against a topic, like Environment that do not fit against a specific question.



Pharmaceutical Supply Chain Initiative

Self-Assessment Questionnaire and Audit Report Template

ENVIRONMENT

Environment

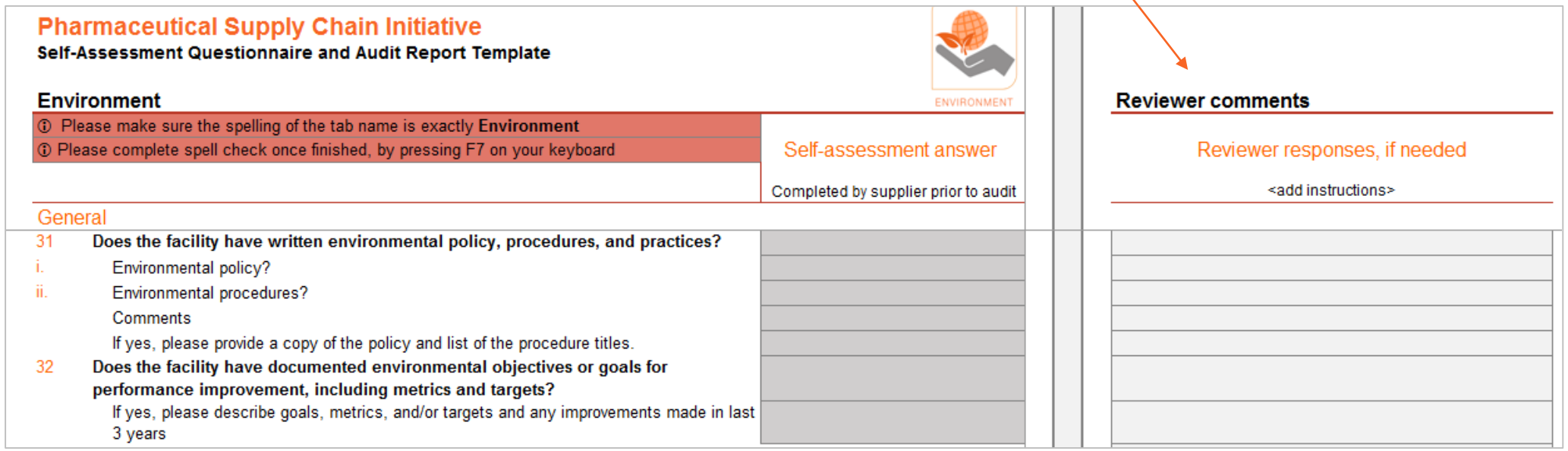
ⓘ Please make sure the spelling of the tab name is exactly **Environment**

ⓘ Please complete spell check once finished, by pressing F7 on your keyboard

	Self-assessment answer	Findings		P
	Completed by supplier prior to audit	Findings classification	Description of finding	D
General				
Additional Findings - Environment				
Were there any additional findings that weren't covered above? If yes, please specify below.				
Ev-1				
Ev-2				
Ev-3				
Ev-4				
Ev-5				

EXCEL VERSIONS – Reviewer comments

- **Reviewer comments**, we've included an additional column (O) at the very right of each form for reviewer responses. This is intended to be a column where a reviewer can comment against questions if they have comments.



Pharmaceutical Supply Chain Initiative

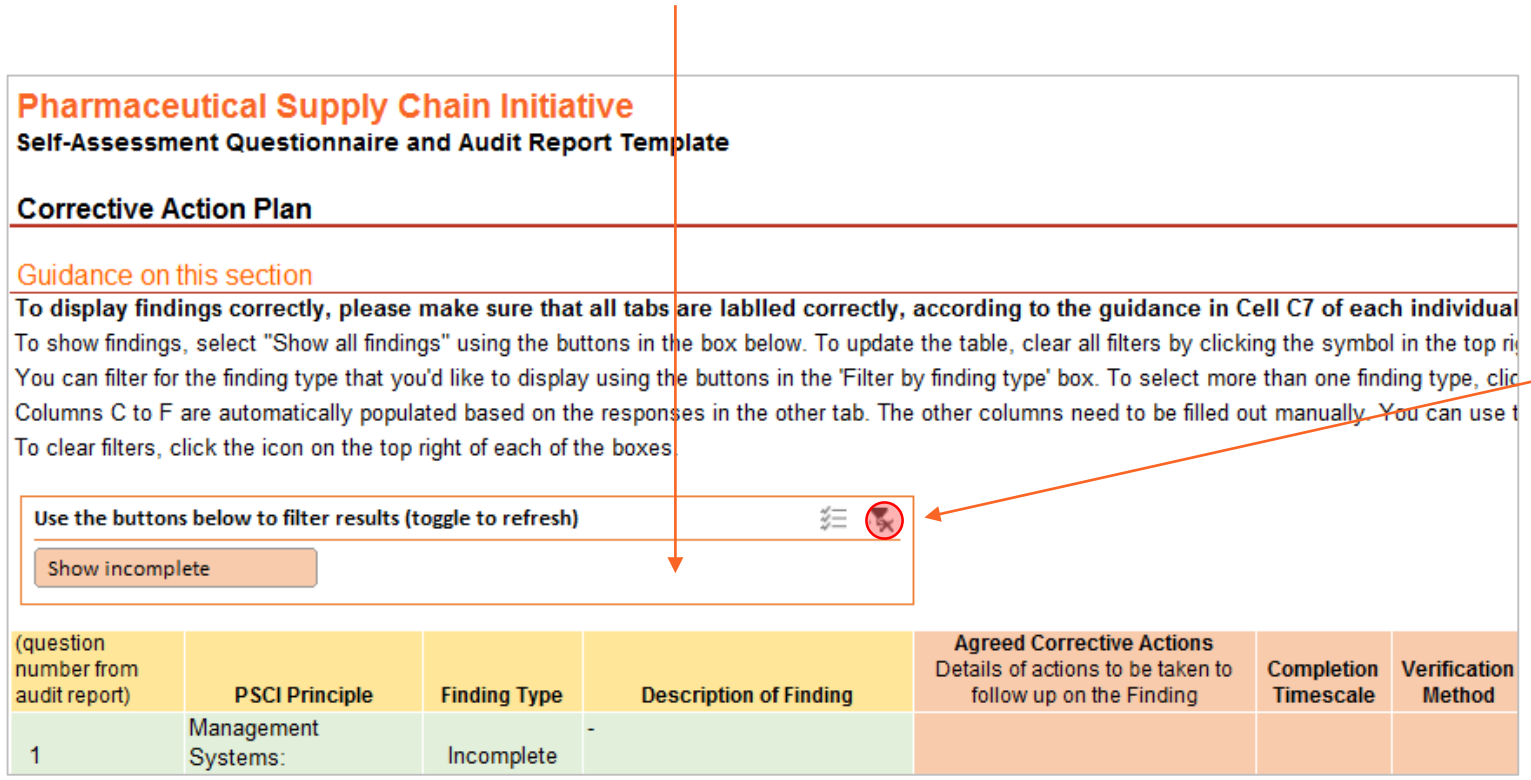
Self-Assessment Questionnaire and Audit Report Template

ENVIRONMENT

Environment			
ⓘ Please make sure the spelling of the tab name is exactly **Environment**			**Reviewer comments**
ⓘ Please complete spell check once finished, by pressing F7 on your keyboard		Self-assessment answer	Reviewer responses, if needed
		Completed by supplier prior to audit	<add instructions>
General			
31	**Does the facility have written environmental policy, procedures, and practices?**		
i.	Environmental policy?		
ii.	Environmental procedures?		
	Comments		
	If yes, please provide a copy of the policy and list of the procedure titles.		
32	**Does the facility have documented environmental objectives or goals for performance improvement, including metrics and targets?**		
	If yes, please describe goals, metrics, and/or targets and any improvements made in last 3 years		

EXCEL VERSIONS –CAP sheet updated

- **CAP sheet updated**, we've removed the Macro from the CAP sheet. The CAP sheet functionality is similar, but there are a few minor changes to how it works. Now findings can be filtered using the option menu at the top of the table.



Pharmaceutical Supply Chain Initiative

Self-Assessment Questionnaire and Audit Report Template

Corrective Action Plan

Guidance on this section

To display findings correctly, please make sure that all tabs are labllled correctly, according to the guidance in Cell C7 of each individual

To show findings, select "Show all findings" using the buttons in the box below. To update the table, clear all filters by clicking the symbol in the top ri

You can filter for the finding type that you'd like to display using the buttons in the 'Filter by finding type' box. To select more than one finding type, clic

Columns C to F are automatically populated based on the responses in the other tab. The other columns need to be filled out manually. You can use t

To clear filters, click the icon on the top right of each of the boxes.

Use the buttons below to filter results (toggle to refresh)

Show incomplete

(question number from audit report)	PSCI Principle	Finding Type	Description of Finding	Agreed Corrective Actions Details of actions to be taken to follow up on the Finding	Completion Timescale	Verification Method
1	Management Systems:	Incomplete	-			

In order to go back to reset the view, select this button

EXCEL VERSIONS –Other updates

- **Excel unlocked,** some of the restrictions caused issues when using it, so we've unlocked the excel sheets in order to make using them simpler.

  Please take care NOT to:

  - **Change any questions,** similarly to the word version
  - **If combining sheets keep to the original sheet names,** *or the CAP sheet won't work correctly*

- **Spell check updated,** we've removed the spell check Macro, as it was causing compatibility issues. Users now need to need to spell check using F7. This is clearly indicated at the top of each sheet where the spell check macro button used to be.

COMPLETING THE PSCI PROTOCOLS

TIPS/HINTS FOR AUDITORS

- Please do not change the report format and do not change the answers given by the supplier in the SAQ sections
- Auditors are generally asked to complete all questions that apply. If a question does not apply, please mark it NA (Not Applicable)
- If – e.g. in case of time constraints - some questions cannot be covered, this needs to be indicated as well.
- 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 audit
- Please insert photographs when applicable and feasible, following the instructions as mentioned in the audit protocols

AGENDA

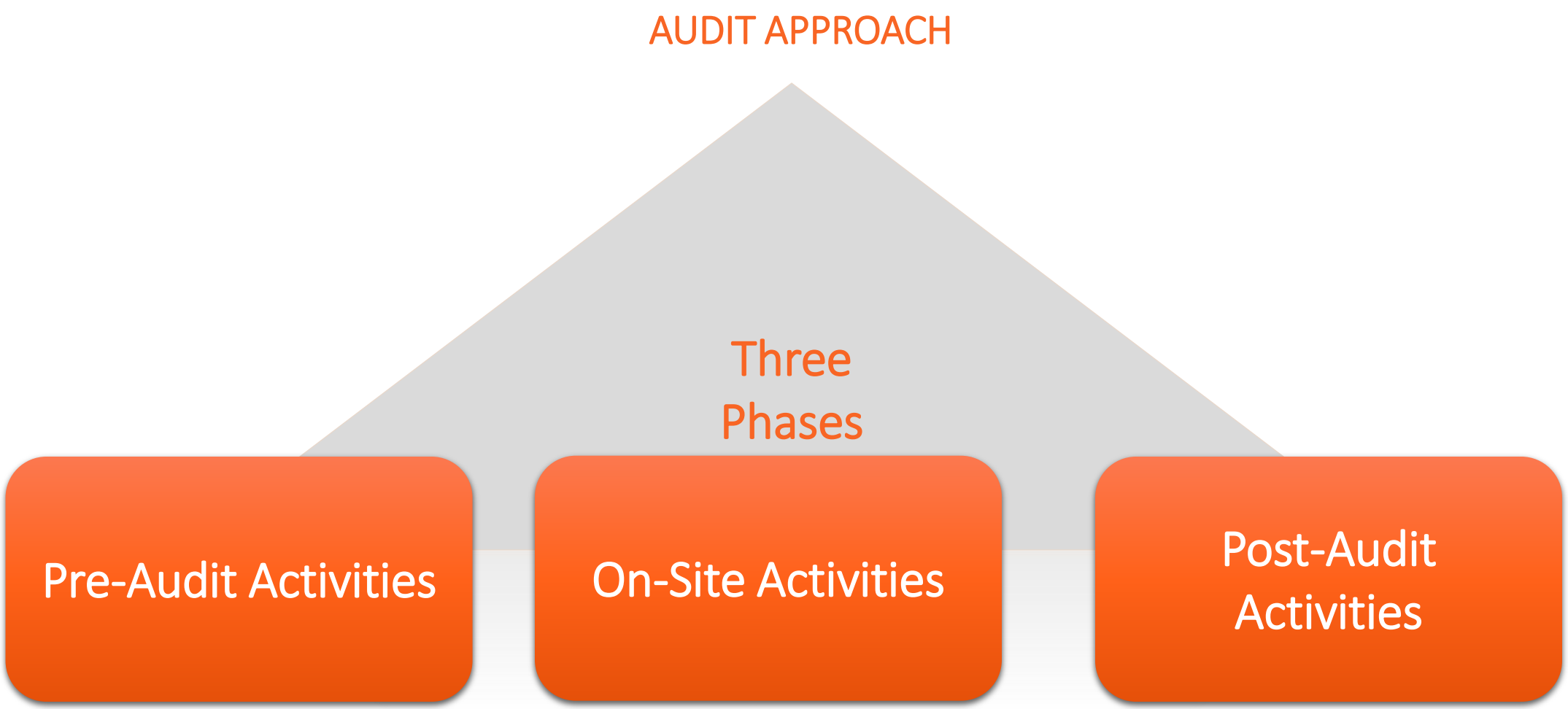
OVERVIEW ON PSCI AUDITS

PSCI SAQS AND AUDIT REPORT TEMPLATES UPDATE

GENERAL PSCI AUDIT PROCESS

AUDIT REPORT WRITING

GENERAL PSCI AUDIT PROCESS

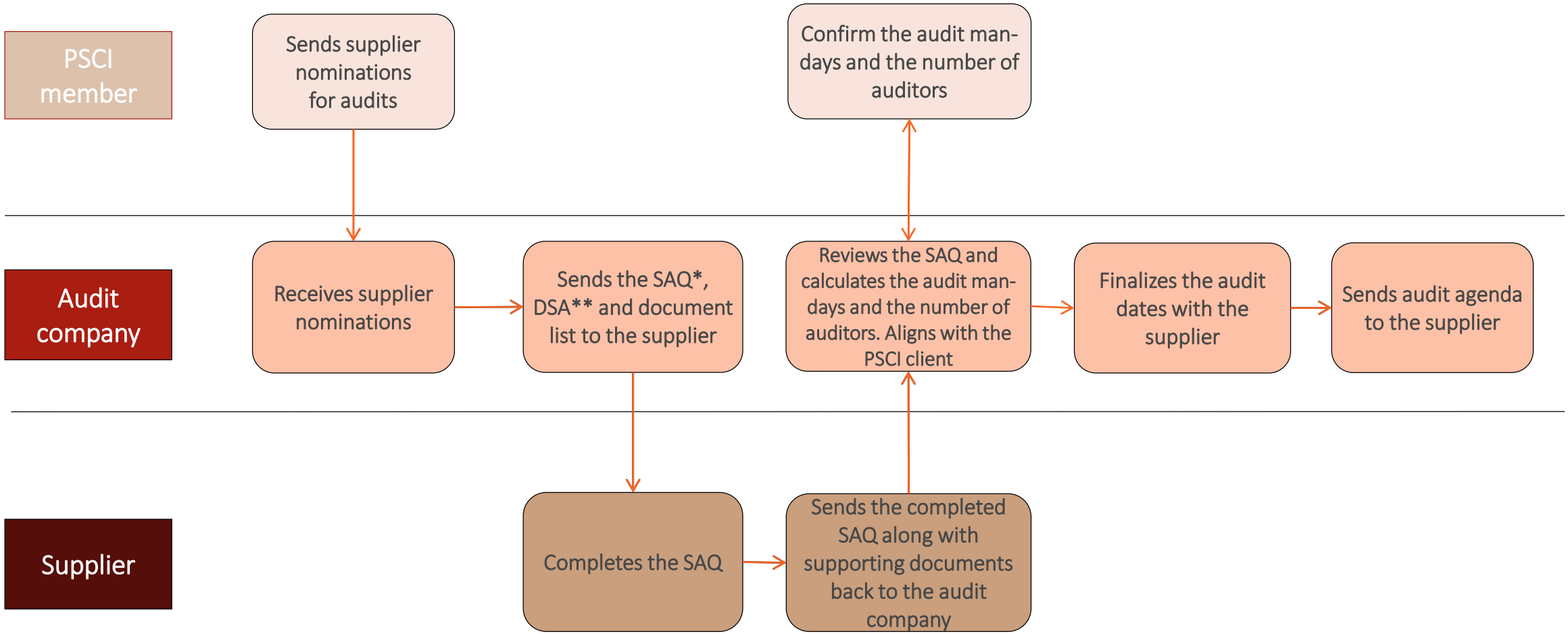


AUDIT PREPARATION

TIPS/HINTS FOR AUDITORS

- Study the PSCI SAQ (and the provided documents)
- 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
- Provide the supplier with an agenda and a tailored PSCI Pre-Audit Document checklist
- Check the website of the auditee
- Carry out background research about the auditee,
  e.g. media reports about environmental issues (for China: IPE database, relevant databases or reports about fatalities, accidents, incidents, loss of primary containments, news about legal issues etc.
- Check if there are any special instructions upon arrival
  (be prepared to show identification if required, ask where to sign in, who to ask for upon arrival…)
- Check if any special personal protective equipment is required

EXAMPLE PRE AUDIT ACTIVITIES



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

AUDITOR PREPARATION

TIPS/HINTS FOR AUDITORS

- Dress appropriately for the audit
  (e.g. no high heels or open toes shoes)
- Bring your own safety shoes (and other PPE if relevant)
- Respect company‘s opening and closing time/shift timings
- Most important: arrive on time!

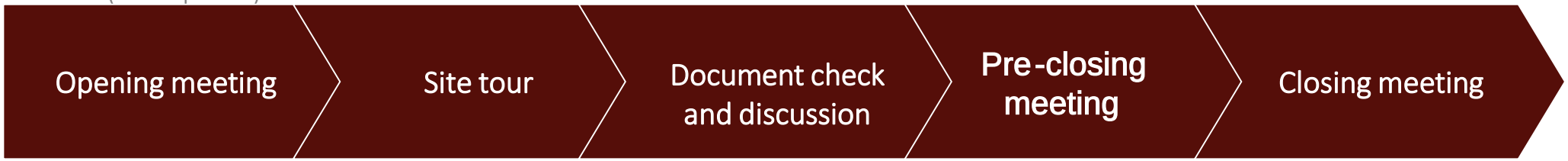
PSCI ONSITE AUDIT PROCESS (HSE PART)

Opening meeting

- includes a short introduction of the audit team by the lead auditor and the scope of the audit.
- Involved parties: site/plant management, HSE, engineering, production and others (as required)

Pre-closing meeting:

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



Site t our: 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

Discussions with technical experts and management (e.g. HSE, engineering, production)

Presentation

- of best practices and points for improvement
- summary of the CAP
- and as a sign of agreement signing it by both parties

OPENING MEETING

TIPS & HINTS FOR AUDITORS

- Be on time!
- Thank the management for hosting the audit
- Introduce yourself and audit team and ask the others participants to introduce themselves (facilitated by 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.

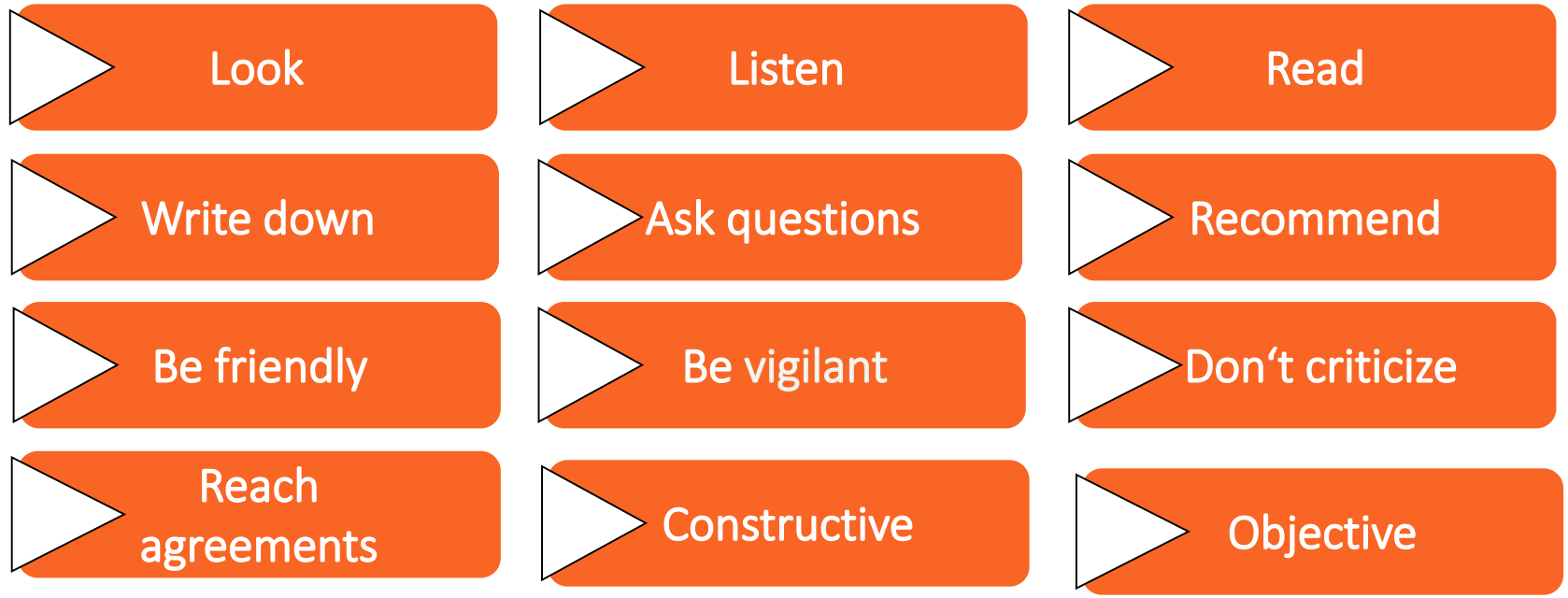
PHYSICAL INSPECTION OF THE FACILITY

TIPS & HINTS FOR AUDITORS

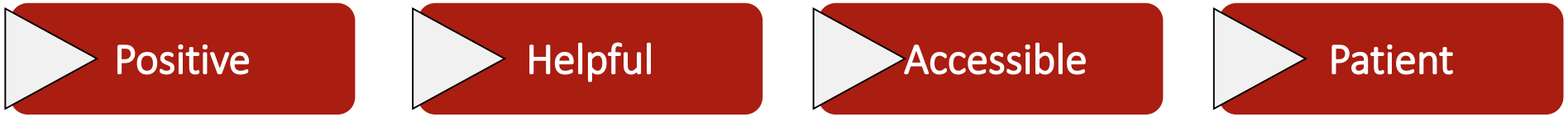
- Good time management is key, especially during site tours
- Allow for sufficient time for the site tour, do NOT spend the majority of time with document review in the office
- Ask for a site map for the tour to help you with the site orientation
- Keep in mind that gowning procedures in pharmaceutical finishing plant may require a significant amount of time
- Inspect main production areas, but be careful to reserve time for other areas (e.g. warehouses, waste storage/treatment, waste water treatment units and other utilities are also important to visit)
- Try to inspect critical activities especially those with high risk potential e.g. construction activities, inspection & sampling, loading/unloading, material handling and transfer, waste packing and pick-up, confined space entry
- Observe the facility also from the outside

BEHAVIOR DURING AN AUDIT

What an auditor should do:



How an auditor should behave:



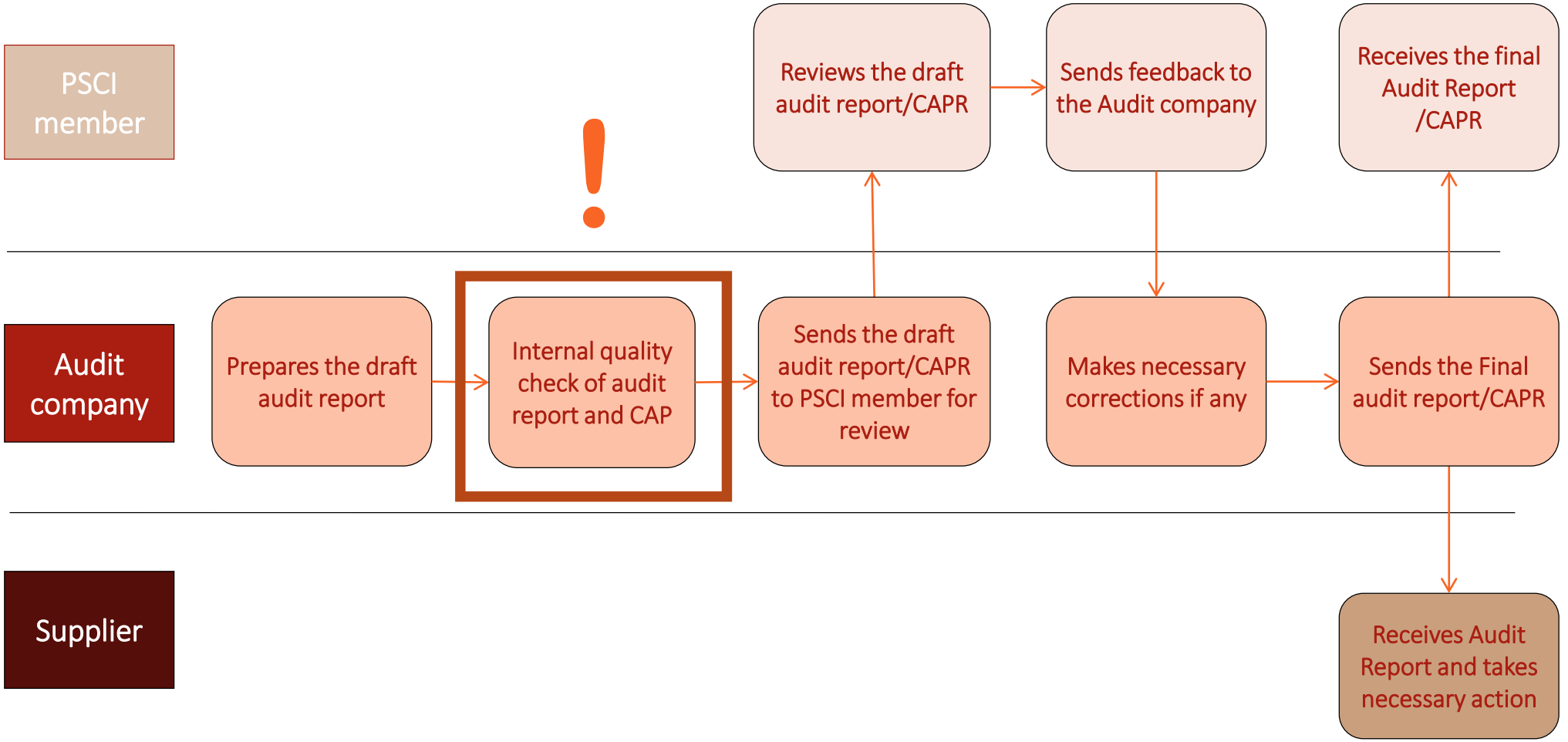
CLOSING MEETING (1)

- 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;

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 sharing of the PSCI Audit Report and Corrective Action Plan Report with other PSCI member companies
  (either by signing the PSCI Data Sharing Agreement or by sharing online via the PSCI audit sharing platform)

EXAMPLE POST AUDIT ACTIVITIES



AGENDA

OVERVIEW ON PSCI AUDITS

PSCI SAQS AND AUDIT REPORT TEMPLATES UPDATE

GENERAL PSCI AUDIT PROCESS

AUDIT REPORT WRITING

AUDIT REPORT WRITING

Note: Audit Report writing already starts during the audit!

- Ensure that notes are accurate (all are potentially “discoverable”)
- Document all evidence reviewed (even if it is not a finding)
- Take photos of documents & situations, if allowed
- Document where a photo was taken
- Note title/job description/area of interviewees
  (but never give names in the audit report)
- Note specific ID # for the SOP, other documents, equipment etc.
- Give # reviewed of total # available

WRITING AUDIT FINDINGS (1)

TIPS & HINTS FOR AUDITORS

- Use full sentences and keep them short, to the point
- Report facts, not opinions
- Define all acronyms when used the first time
- Do not make legal conclusions (e.g., “not compliant…”)
- Limit the use of adjectives (e.g. “always,” “every,” “any,” “none”)
- Do not exaggerate or overstate
- Use everyday language, avoid technical jargon
- Consider language like “was not available,” “no evidence of,” versus “there was no…”
- Use “active voice”
  OK: wastewater operator performs weekly wastewater sampling at the outfall point for criteria A, B, & C. The results are shared monthly with the local authority as per permit.
  Not OK: sampling was performed of the wastewater

WRITING AUDIT FINDINGS (2)

Following basic questions should be considered while writing a finding:

- **Who?** is involved in the finding
- **What?** is the subject of the finding
- **When?** did the finding take place
- **Where?** was the location of the finding
- **How?** did the finding come about and examples
- **How often?** does the finding happen: a single event/case or a systematic error

And: Challenge significance of each observation by asking **"So what?"**

WHAT´S WRONG WITH THESE AUDIT FINDINGS?

FINDINGS	MISTAKES
There was minimal on-site compliance with Corporate or department contractor safety policy and procedures.	
Some of the air sources were being operated without proper permits and some are not adequately maintained.	
The facility's central SDS file was 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 SDSs reviewed appeared complete and contained the appropriate information.	
Bob Miller was neither familiar with the company's SOP on Hazardous materials nor could he identify where DSs were located.	

WHAT´S WRONG WITH THESE AUDIT FINDINGS?

FINDINGS	MISTAKES
There was minimal on-site compliance with Corporate or department contractor safety policy and procedures.	Not specific. Does not describe the problem in detail so that the factory can correct it.
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Bob Miller was neither familiar with the company's SOP on Hazardous materials nor could he identify where SDSs were located.	Avoid using names and personal accusations.

WHAT´S WRONG WITH THESE AUDIT FINDINGS?

FINDINGS	MISTAKES
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.	
It seemed that the emergency routes in the warehouse were too narrow.	
An operator reported work permits were not always issued when staff enter confined spaces. This violates the site´s confined space entry program.	
The chemical hygiene plan was found deficient and should be improved. This is a serious concern.	

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The chemical hygiene plan was found deficient and should be improved. This is a serious concern.	“Deficient” sounds opinionated; “serious” – avoid extreme wording

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 the audit sponsor prior to audit report finalization.
- Other Findings: Are all other major or minor audit findings, which need to be corrected by the supplier in an appropriate period of time.
  - Major Findings: Findings that may pose major impacts to workers, the community, or the environment. Findings that may pose major regulatory non-compliances or illustrate systemic program gaps.
  - Minor Findings: Findings that may pose minor impacts to workers, the community, the environment. Findings that may pose minor regulatory non-compliances.
- Non-Finding remarks: Are where the auditor wishes to raise an important comment, but this comment would not constitute any type of finding.
- **NOTE:** When writing the audit report, please choose **one** of the two classification methodologies (i.e. either critical/other OR critical/major/minor and consistently stay with it within the report.

CLASSIFICATION OF AUDIT FINDINGS (2)

Examples for Critical Findings:

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

Examples for Other Findings (Minor, Major - depending on further information provided)

- 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
- Safety training missing in a some cases and for some topics

EXCERSIZE: CLASSIFICATION OF AUDIT FINDINGS

Are these critical, other (major) or other (minor)?

- The safety data sheets for the cleaning agents 1273 and 1322 used in the production area were 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 were 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)

  OTHER (MAJOR)

THANK YOU!

CONTACT

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info@pscinitiative.org

Annabel Buchan:
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PSCI

@PSCInitiative

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About the Secretariat
Carnstone Partners Ltd is an independent management consultancy, specialising in corporate responsibility and sustainability, with a long track record in running industry groups.

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partners ltd

PSCI PHARMACEUTICAL SUPPLY CHAIN INITIATIVE
Building responsible supply chains

General Safety

DR. BIRGIT SKUBALLA
CORPORATE HSE - HEAD OF HSE AUDITS & SUPPLIER MANAGEMENT
BAYER

Bio

Dr. Birgit Isabelle Skuballa

- **Current position** and responsibilities: Bayer AG, Corporate HSE, Head of HSE Audits & Supplier Management
- **Location:** based in Leverkusen, Germany
- **Background:** PhD in Organic Chemistry (University of Karlsruhe); post-doc at Nagoya University (Japan); ISO14001/OHSAS18001/17025 Lead Auditor; global Bayer HSE Audit Team Lead
- **Experience**: 24+ years within Pharma/Chemical Industry (Schering AG / Bayer); including 4+ years as Process Development Chemist at an API production site, 3 years HSE Management System Responsible and global Responsible Care Coordinator, short time assignment at a pharmaceutical finishing site in Italy, 5 years GMP/Quality Auditor for internal/external API sites and global HSE Auditor; after acquisition of Schering AG by Bayer HealthCare leading the HSE Audit and MS Group for the Healthcare Division for 7 years, including global HSE Data Management for the Bayer Annual Report; 3 years leading the global function for HSE MS, Audit Strategy & Planning for all Bayer Divisions (Pharma/ Consumer/ Animal Health/Crop) for 3 years; after acquisition of Monsanto by Bayer now leading the global function for HSE Audits and Supplier Management covering all divisions/businesses at Bayer.
- **Contact information:** birgit.skuballa@bayer.com

AGENDA

Training / Competency

Incident Management

Machine Safety

Hazard Signage

Personal Protective Equipment

Circulation inside / outside of buildings

Training / Competency

«There is no formal evidence that H&S training to employees is provided»

«The company has not provided HSE training to their employees confirmed through management interview»

«Workers are not formally trained for emergency preparedness and response and for health & safety topics.»

Some findings from the shared reports...

Training / Competency

Training Program

- What to look for ?
  - SOP, concept (word or PowerPoint file)...
- When / how
  - During dedicated section
  - During review of high risk activities
- What good looks like
  - Topics mentioned in SAQ should be found in the training concept (see list on the right)
  - Strategy to capture new hires in the program

Emergency preparedness/response
New employee orientation (HSE)
Annual HSE refresher training
Pre-start up process HSE training
Hazard Communication
Process Safety Management
Health Practices
Environmental Practices

Training / Competency

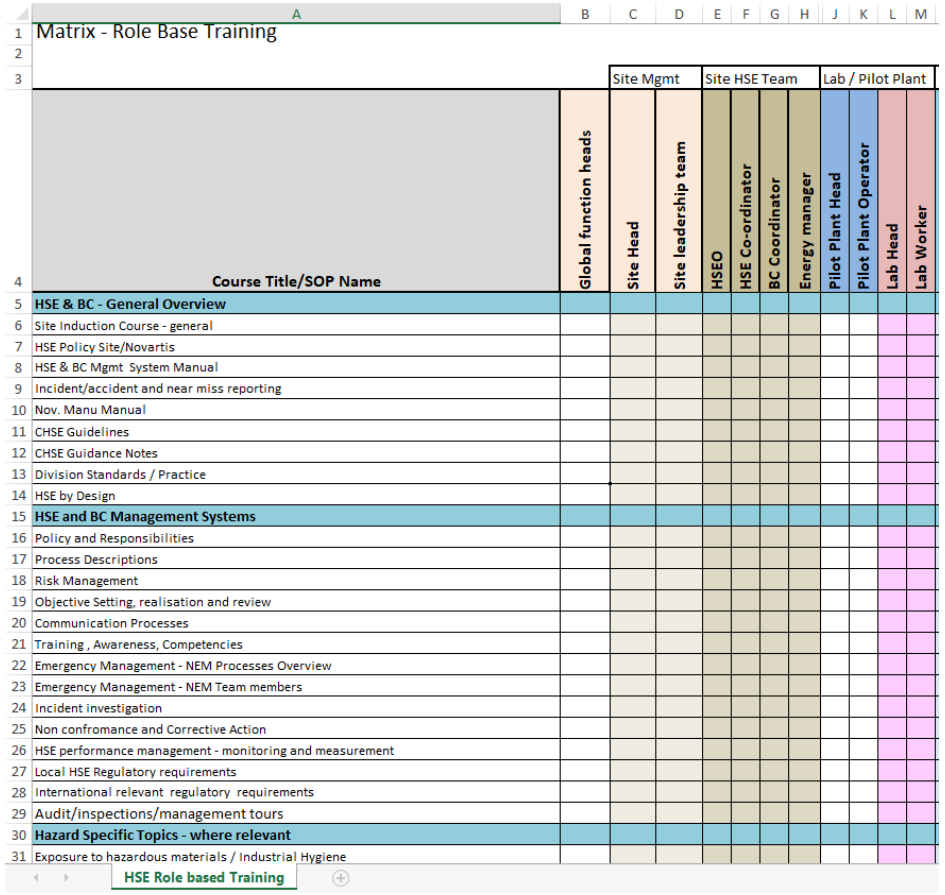
Training for activities with higher risks

- What to look for ?
  - Training regarding Risk Assessment and activities with higher risks like Working at Heights, Confined Space Entry, Working with Hazardous Energies...
- When / how
  - When reviewing a program dealing with higher risks, e.g. PHA (Process Hazard Analysis).
  - Check the training records of the team that perform the analysis
- What good looks like
  - Formal training took place
  - Enough opportunities to practice and get/keep proficiency

Training / Competency

Training Matrix

- What to look for ?
  - Description which roles get which trainings
- When / how
  - When reviewing the topic
- What good looks like
  - At role or individual level
  - Usually 0.5% of working time (10h for full FTE)
  - External audience (contractors) is captured



Matrix - Role Base Training

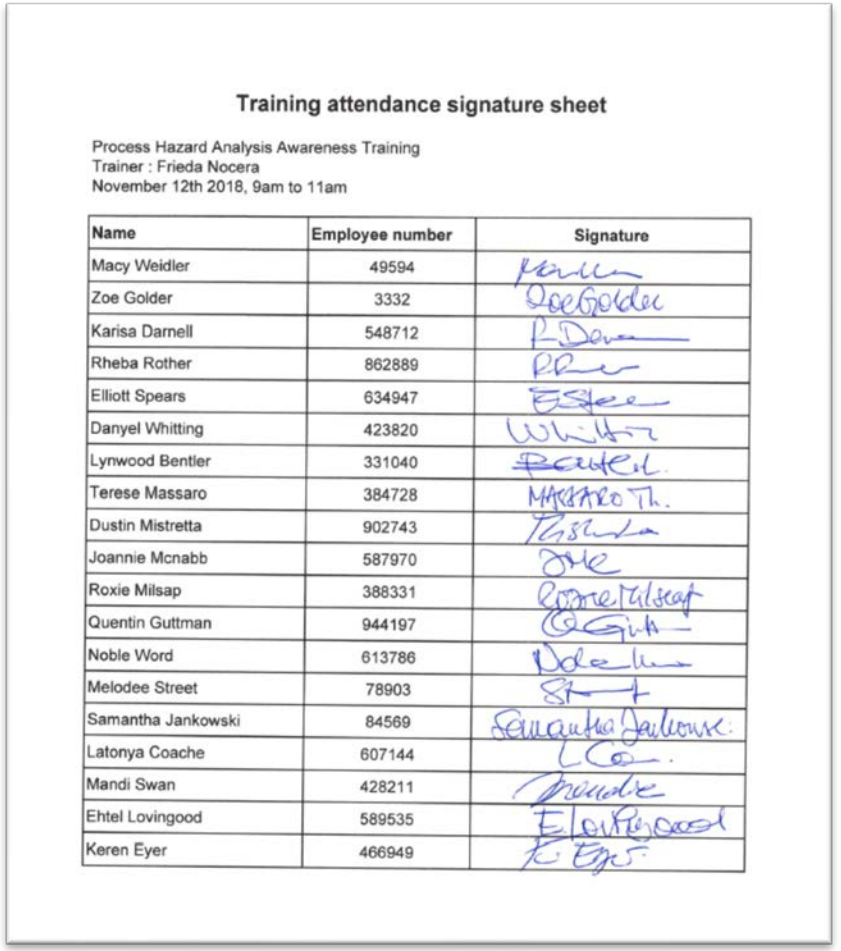
Course Title/SOP Name	Global function heads	Site Mgmt: Site Head	Site Mgmt: Site leadership team	Site HSE Team: HSEO	Site HSE Team: HSE Co-ordinator	Site HSE Team: BC Coordinator	Site HSE Team: Energy manager	Lab / Pilot Plant: Pilot Plant Head	Lab / Pilot Plant: Pilot Plant Operator	Lab / Pilot Plant: Lab Head	Lab / Pilot Plant: Lab Worker
HSE & BC - General Overview											
Site Induction Course - general											
HSE Policy Site/Novartis											
HSE & BC Mgmt System Manual											
Incident/accident and near miss reporting											
Nov. Manu Manual											
CHSE Guidelines											
CHSE Guidance Notes											
Division Standards / Practice											
HSE by Design											
HSE and BC Management Systems											
Policy and Responsibilities											
Process Descriptions											
Risk Management											
Objective Setting, realisation and review											
Communication Processes											
Training , Awareness, Competencies											
Emergency Management - NEM Processes Overview											
Emergency Management - NEM Team members											
Incident investigation											
Non confromance and Corrective Action											
HSE performance management - monitoring and measurement											
Local HSE Regulatory requirements											
International relevant regulatory requirements											
Audit/inspections/management tours											
Hazard Specific Topics - where relevant											
Exposure to hazardous materials / Industrial Hygiene											

HSE Role based Training

Training / Competency

Training Records

- What to look for ?
  - Attendance list, IT-system proof of attendance...
- When / how
  - When reviewing the topic
- What good looks like
  - Associate are identified by name or number
  - Associate have signed the sheet
  - IT-system is qualified for this task



Training attendance signature sheet

Process Hazard Analysis Awareness Training
Trainer : Frieda Nocera
November 12th 2018, 9am to 11am

Name	Employee number	Signature
Macy Weidler	49594	
Zoe Golder	3332	
Karisa Darnell	548712	
Rheba Rother	862889	
Elliott Spears	634947	
Danyel Whitting	423820	
Lynwood Bentler	331040	
Terese Massaro	384728	
Dustin Mistretta	902743	
Joannie Mcnabb	587970	
Roxie Milsap	388331	
Quentin Guttman	944197	
Noble Word	613786	
Melodee Street	78903	
Samantha Jankowski	84569	
Latonya Coache	607144	
Mandi Swan	428211	
Ehtel Lovingood	589535	
Keren Eyer	466949	

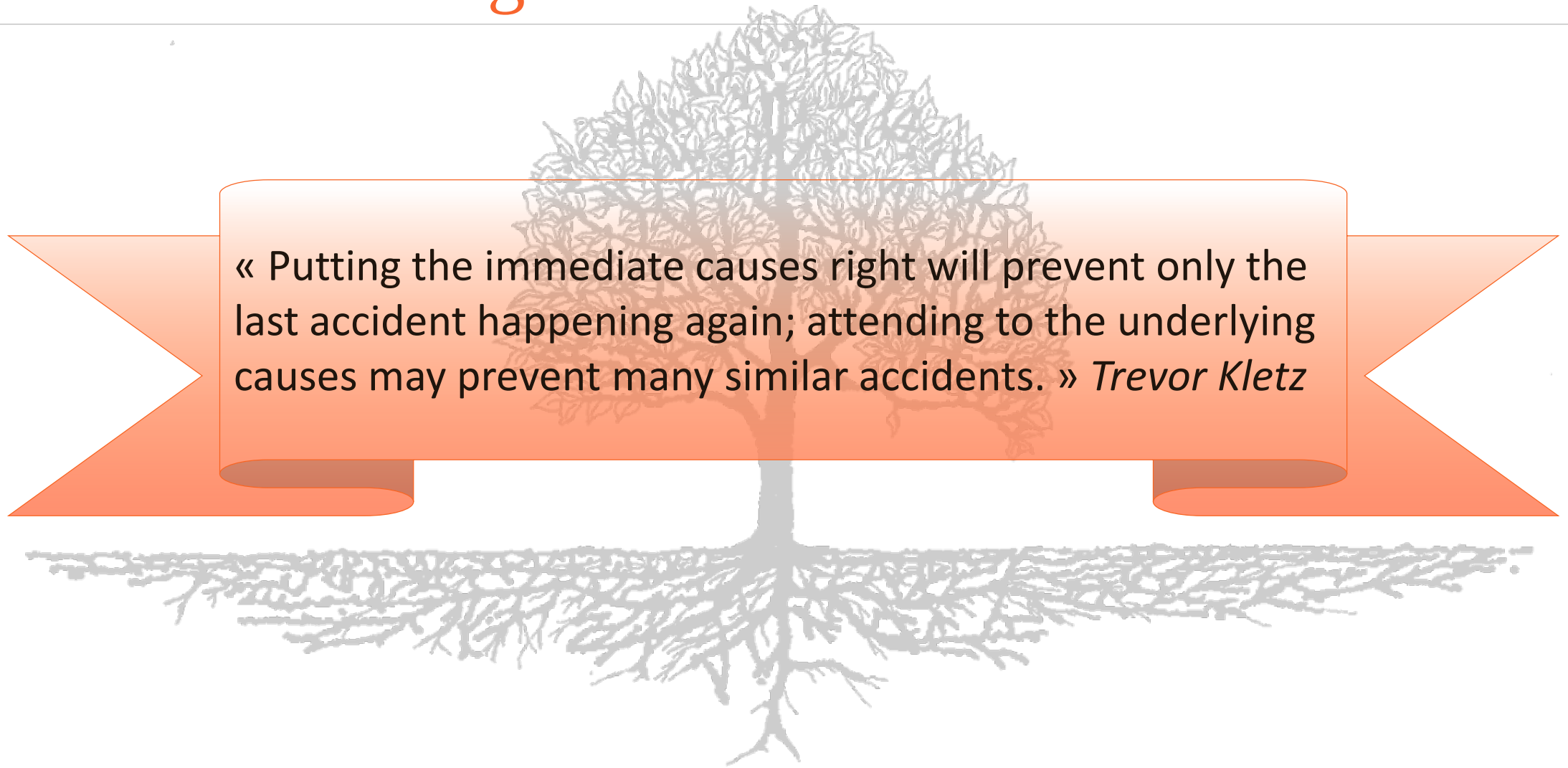
Incident Management

«Accident reporting of contractors is not mandatory as required by PSCI»

«Fire extinguisher is obstructed by the table in the kitchen during tour»

Some findings from the shared reports...

Incident Management



« Putting the immediate causes right will prevent only the last accident happening again; attending to the underlying causes may prevent many similar accidents. » *Trevor Kletz*

Incident Management

Reporting of accidents

- What to look for ?
  - Any kind of records ; could be paper based (cards, reports...) or through an IT-system
- When / how
  - During specific section or if an accident is mentioned then use this opportunity
- What good looks like
  - Check the number of reported events
  - Check the content's quality of a small sample

I was impressed when a voice on the office PA system announced, "This is a test of the PA system to ensure it will function correctly in case of emergency." My confidence faded when the voice added, "If you are unable to hear this announcement, please contact us."

How many ? (for a 500 FTE site)
TRCR of 1.0 = 5 cases per year
Near-Miss : 1 for 2 employees
250 per year = 20 per month

Incident Management

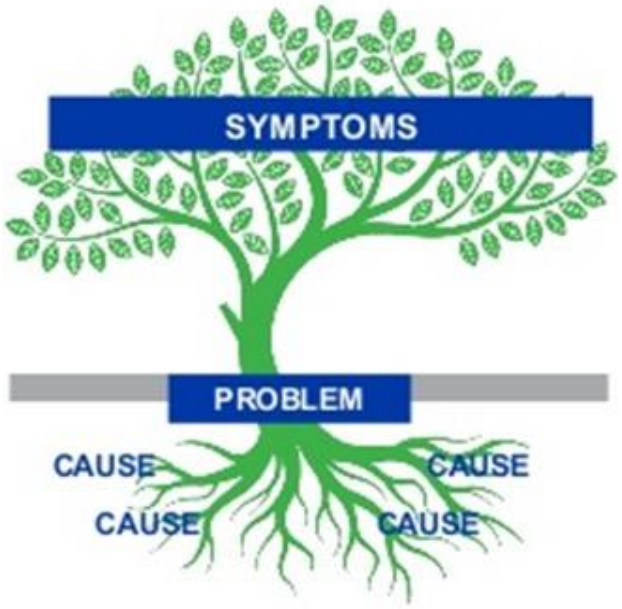
Near Miss

- What to look for ?
  - Same as for accidents : paper records or IT-system
- When / how
  - If a near miss is identified during site tour, use the opportunity
- What good looks like
  - Number (could indicate a good reporting culture), quality of content
  - Who exploits the near miss reports? are they tracked individually? any consolidation? any action plan derived from consolidated near miss?

Incident Management

Root-cause Analysis

- What to look for ?
  - Reports (root-cause analysis itself)
  - Trend analysis – systematic weaknesses ?
- When / how
  - During review of the topic
- What good looks like
  - Fitness of the used methodology
  - Adequate training of the team members
  - Root cause identified (no «human error»)



Incident Management

Action Plan and Follow-up

- What to look for ?
  - Action Plan itself
    paper, electronic document, IT-system
  - Any system to follow-up on actions
- When / how
  - During Incident Management or Risk assessment
  - Closure of actions can be checked during site tour
- What good looks like
  - Has to be effective : should be closed on time or escalated
  - Sufficiently large sample should be considered
  - System to make sure that individual Action Plans are not lost

Action Steps/ Tasks What will be done?	**Responsibility** Who will do it?	**Timeline** When will it begin and when will it be completed?	**Resources** What additional resources do you need?
Reserve two classrooms	**Michelé Robinson**	**Begin: 3/13 Completed: 3/13**	Rooms on campus
Schedule faculty for 'office hours' simulation	**Monica Edwards**	**Begin: 4/13 Completed: 5/13**	None
Schedule Library research visit	**Monica Edwards**	**Begin: 4/13 Completed: 5/13**	None
Schedule Financial Aid presentation	**Kris Hoffhines**	**Begin: 4/13 Completed: 6/13**	Financial aid representative commitment
Notify Success Services of student visits over a 2 week period	**Michelé Robinson**	**Begin: 4/13 Completed: 6/13**	None
Notify Career Center of student visits over a 2 week period	**Michelé Robinson**	**Begin: 4/13 Completed: 6/13**	None
Develop college readiness pre & post assessment	**Monica Edwards & Laura LaBauve**	**Begin: 5/13 Completed: 6/13**	Assessment tool

Machine Safety

«The worker protection for cone type rotary dryers was not effective. When it keeps rotating, operators can open the barrier door and approach it. [...] all the cone type rotary dryers were not equipped with interlock safety system for door barriers [...]»

«During facility tour it was noted that the machine does not have security device in danger zone»

Some findings from
the shared reports...

Machine Safety

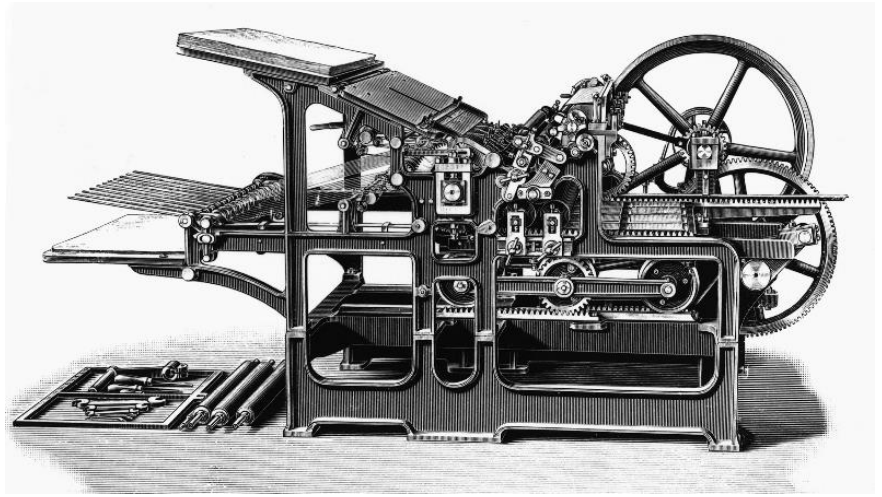
General

- What to look for ?
  - Adequate safety concept in place with regards to machinery-related hazards
- When / how
  - During site tour, check on general conditions/installation of machines.
  - Observe if controls and measures (e.g. necessary machine guarding in place) are in place and being adhered to during operation.
  - Pick one machine for review
- What good looks like
  - Declaration of Conformity available (for China: GB/T 15706).
  - All machines risk-assessed, appropriate risk reduction measures applied, tested prior to first use and maintained
  - Technical documentation available, including operating instructions in local language; machines operated by trained personnel
  - Periodic maintenance and inspections

Machine Safety

Risk Analysis for old equipment

- What to look for ?
  - «Old» machines should have been risked assessed and report should be available
- When / how
  - During site tour or after reviewing a new machine, ask «what about old ones?»
- What good looks like
  - Quality of risk assessment
  - Mitigation of identified risks implemented



Machine Safety

Modification of equipment

- What to look for ?
  - Obviously modified equipment
  - Machines / equipment trains
- When / how
  - Site tour
  - During review of documents related to risk assessment
- What good looks like
  - Quality of risk assessment

Hazard Signage

«The site has not displayed fire exit evacuation route map across the plant.»

«Site has not displayed chemical compatibility chart at warehouse»

Some findings from the shared reports...

Hazard Signage

Uniformity

- What to look for?
  - Any strategy for hazard signage, SOP
  - Example in the production / utilities area
- When / how
  - Ask question during site tour if issues are seen
- What good looks like
  - Same look and feel

Hazard Signage

Quality

- What to look for?
  - Signs in different languages, old, poorly visible
  - New machines might have signage in the language of the manufacturer, not the required local one!
- When / how
  - Ask question during site tour if issues are seen
- What good looks like
  - If associates are speaking different languages, pictures might be better compared to text
  - Signage needs to be visible and of good quality
  - Signage to be provided in local language

Hazard Signage

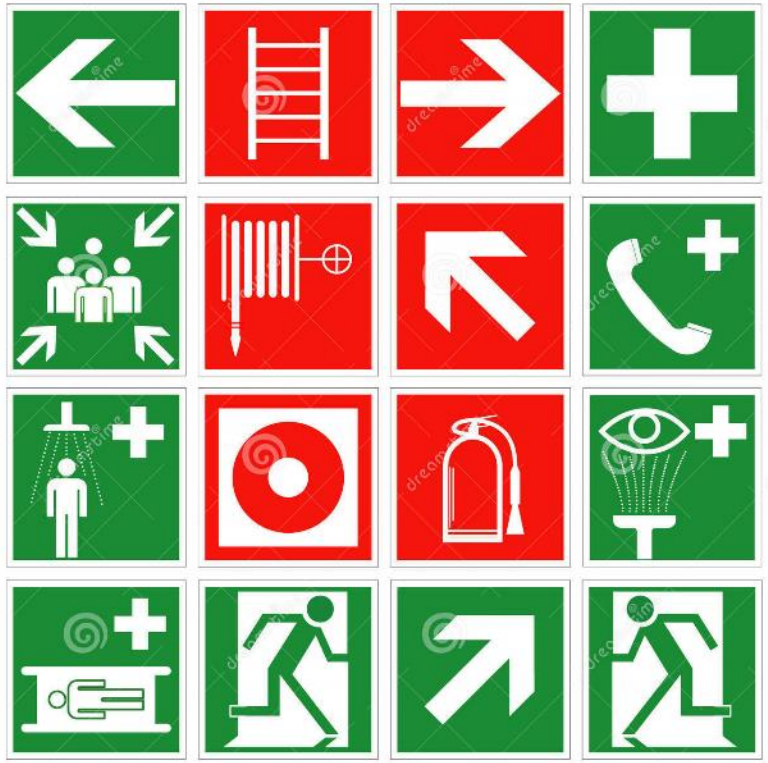
Quantity

- What to look for?
  - Situation during site tour with an excess of hazard signs
- When / how
  - Ask question during site tour if issues are seen
- What good looks like
  - Let to the judgement of the auditor based on experience

Hazard Signage

Emergency signage

- What to look for ?
  - Situation where emergency signage is missing or not appropriate
- When / how
  - During site tour
- What good looks like
  - Compliance with local / national legislation
  - Judgement of the auditor based on experience



Personal Protective Equipment

«Assignment of PPE in the production area is not clear to audit team.»

«Label points out gasmasks and other PPE are mandatory but they are only worn when it is necessary. Also safety glasses were not permanently worn in the production area.»

Some findings from the shared reports...

PPE

According to STOP principle, Personal Protective measures should be the last barrier but it is often used as the first and only one.

PPE

Adequacy of proposed PPE

- What to look for ?
  - Risk assessment defining PPE needs
  - Maintenance of some type of PPE
- When / how
  - During risk assessment review
  - During site tour, when seeing particular PPE in use
- What good looks like
  - PPE are defined based on risk assessment
  - Associate are not overprotected
  - Use of PPE is done correctly

Circulation in/ outside buildings

«One C[...] owned truck at a loading bay was observed not to be secured by safety wedges while being loaded by a fork lift truck [...]»

«It was observed that material was stored all around in the packaging room. There was no reflective strip pasted on the floors to maintain the walkway width»

Some findings from the shared reports...

Circulation in/outside of buildings

Segregation between walkers and traffic

- What to look for ?
  - Crowded areas with a lot of goods movements (not only in warehouses)
- When / how
  - During site tour
- What good looks like
  - Dedicated pathway
  - Markings on the grounds
  - Traffic lights...

Circulation in/outside of buildings

Forklift operations

- What to look for ?
  - Goods movements inside and outside of building
- When / how
  - Concept, SOP can be reviewed during desktop assessment
  - During site tour, good opportunity to observe behaviors
- What good looks like
  - Legal requirements vary but drivers should normally be officially trained

CONTACT

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About the Secretariat
Carnstone Partners Ltd is an independent management consultancy, specialising in corporate responsibility and sustainability, with a long track record in running industry groups.

carnstone
partners ltd

DAY 1 AGENDA

08:00 – 08:30	Registration, coffee/tea	
08:30 – 08:45	Welcome	Birgit Skuballa (Bayer)/ Maggie Zhang (Carnstone)
08:45 – 09:30	Introduction to PSCI Audit updates	Birgit Skuballa (Bayer)
09:30 – 10:45	General Safety	Birgit Skuballa (Bayer)
10:45 – 11:00	BREAK	
11:00 – 12:30	Process Safety 1	Li Liu (Boehringer Ingelheim)
12:30 – 13:30	LUNCH	
13:30 – 14:30	Process Safety 2	Li Liu (Boehringer Ingelheim)
14:30 – 15:30	General Environment	Daming Bai (Elanco)
15:30 – 15:45	BREAK	
15:45 – 17:00	PIE/AMR	Ken Sun (GSK)
17:00 – 17:30	EXAM Part 1	

DAY 2 AGENDA

08:00 – 08:30	Registration, coffee/tea	
08:30 – 10:30	Occupational Health and Industrial Hygiene	Wenjia Xu (J&J)
10:30 – 10:45	BREAK	
10:45 – 12:30	Emergency Preparedness and Response	Daniel Rehm (Elanco)
12:30 – 13:30	LUNCH	
13:30 – 15:00	High Risk work and red flags for dangerous working	Catherine Zhang (Bayer)
15:00 – 15:15	BREAK	
15:15 – 15:45	EXAM Part 2	
15:45 – 16:00	Training wrap up	Birgit Isabelle Skuballa (Bayer)

PSCI PHARMACEUTICAL SUPPLY CHAIN INITIATIVE
Building responsible supply chains

PSCI Auditor Training 2019

Environmental Protection

Barry Bai 白大明
HSE Manager, External Manufacturing China
ELANCO

Bio 个人简介

Company Role: HSE manager, ELANCO External Manufacturing
Tasks: Provide HSE support and oversight for external partners

2013-Present ELANCO
2005-2013 The Chemical company (CYTEC, 3M and BASF)

Master in Environment Engineering
Bachelor in Safety Engineering

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Bai_da_ming@elanco.com

AGENDA 大纲

1. **Auditor insights**
2. **Audit overview – SAQ/Audit tool questions review with auditor guidance**
3. **Deep dive – Pharmaceuticals in the Environment**
4. **Example audit findings**
5. **Audience questions**

1. AUDITOR INSIGHTS

Auditor Insights | Preparation for the Site Visit

Preparation is Key

- Supplier website & SAQ
- Internet
- Google satellite imagery

Auditor Insights | Background Information Review

Auditor Insights | Background Information Review

Auditor Insights | Opening Meeting

- Overview presentation – supplier
- Site tour expectations – be specific
- Documents
- Permission to photograph
- Neighbors

Auditor Insights | Tour of the Facility Exterior

First Impressions Count !!!

Auditor Insights | Tour of the Facility Exterior

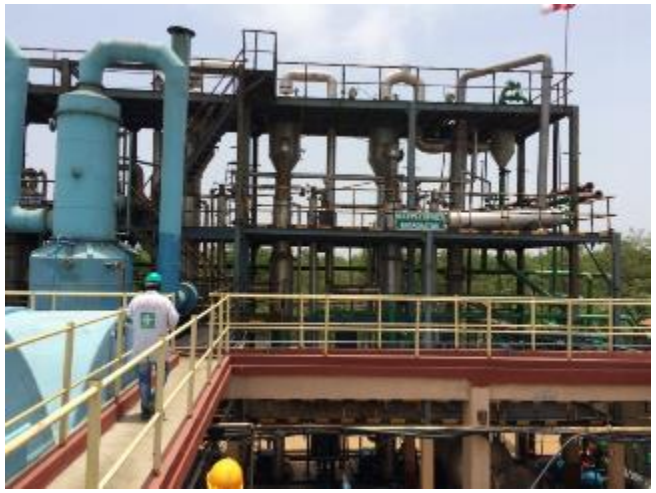
Particularly look for the following:

- Surface water
- Storm drains
- General housekeeping
- Excavations for construction
- Storage or placement of waste materials exterior to the facility
- Evidence of releases
- Visible emissions from air emission sources
- Significant dead vegetation (not seasonal)

Auditor Insights | Tour of the Facility Interior

Interior Tour should include:

- Boilers and Diesel Generators
- Fuel storage areas
- Wastewater collection and treatment systems
- Stormwater collection and discharge systems
- Waste storage areas



Auditor Insights | Tour of the Facility Interior

Interior Tour should also include:

- Process areas
- Water extraction wells
- Potable water delivery and storage systems
- Deep wells or borings for waste or wastewater disposal
- Underground storage tanks
- Air pollution control equipment for boilers and process emissions
- Solvent storage and recovery
- Incinerators

2. AUDIT OVERVIEW

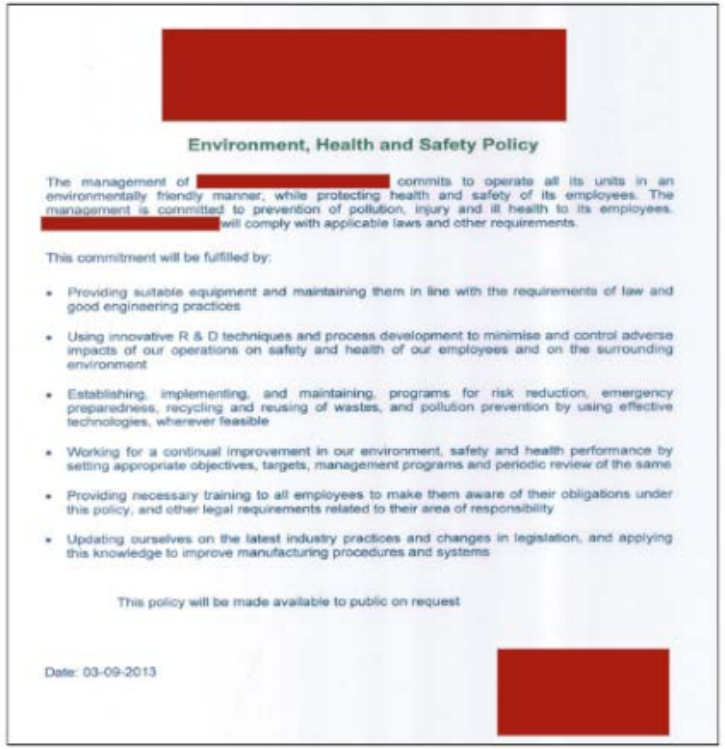
Audit Questions Summary – Environmental protection

Topic	Question summary
General	• Written environmental policy, procedures, and practices • Environmental objectives or goals for performance improvement, including metrics and targets • If in a water scarce region, is there a water strategy
Chemical registrations	• Is the site affected by any chemical registration program (REACH etc.)
Environmental Authorizations	• Environmental permits or authorization
Waste and Emissions	• Process to manage third-party waste treatment and disposal • Waste disposal methods & locations (explain as applicable) • Process wastewater management • Types of air emissions • Hazardous chemicals (including APIs) management program • Storm water management practices
Spills and releases	• Hazardous materials transportation • Soil, surface water or groundwater contamination • Potential environmental risks from hazardous substances

Audit Overview

General		
31	Does the facility have written environmental policy, procedures, and practices?	Policy: Yes No Procedure: Yes No Comments: Please provide a copy of the policy and a list of procedure titles.

- Ask for the supplier's environmental, health and safety policy.
- How are people trained in it?
- Are procedures in place for environmental activities?
- Do the operating procedures include environmental aspects?
- Is there clear evidence that the procedures are followed?
- During personnel interviews, are they familiar with the environmental policy, procedures & practices?



[redacted]

Environment, Health and Safety Policy

The management of [redacted] commits to operate all its units in an environmentally friendly manner, while protecting health and safety of its employees. The management is committed to prevention of pollution, injury and ill health to its employees. [redacted] will comply with applicable laws and other requirements.

This commitment will be fulfilled by:

- Providing suitable equipment and maintaining them in line with the requirements of law and good engineering practices
- Using innovative R & D techniques and process development to minimise and control adverse impacts of our operations on safety and health of our employees and on the surrounding environment
- Establishing, implementing, and maintaining, programs for risk reduction, emergency preparedness, recycling and reusing of wastes, and pollution prevention by using effective technologies, wherever feasible
- Working for a continual improvement in our environment, safety and health performance by setting appropriate objectives, targets, management programs and periodic review of the same
- Providing necessary training to all employees to make them aware of their obligations under this policy, and other legal requirements related to their area of responsibility
- Updating ourselves on the latest industry practices and changes in legislation, and applying this knowledge to improve manufacturing procedures and systems

This policy will be made available to public on request

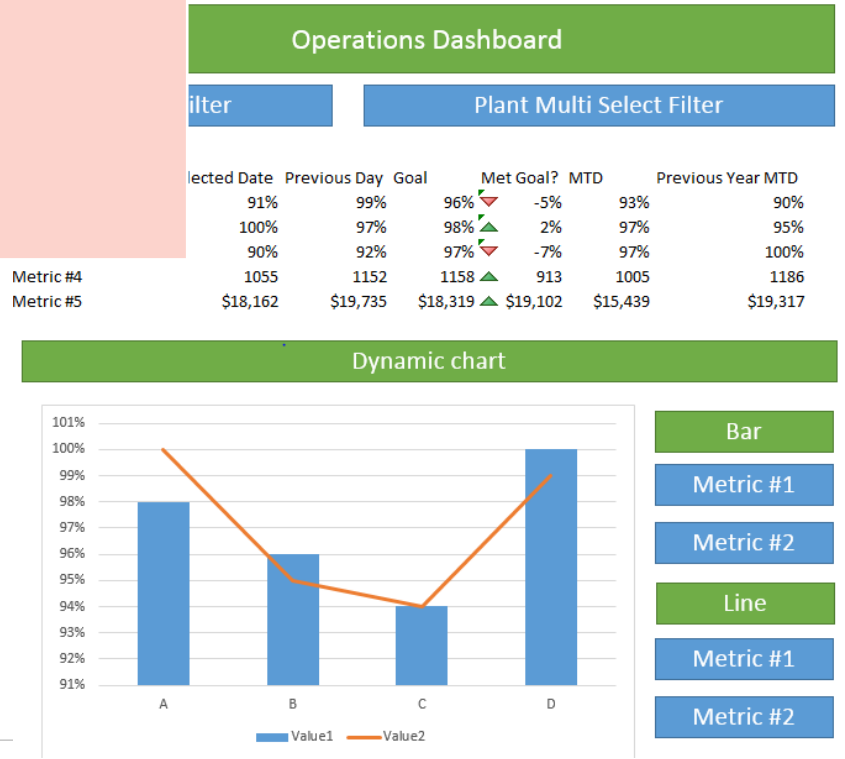
Date: 03-09-2013

[redacted]

Audit Overview

32	Does the facility have documented environmental objectives or goals for performance improvement, including metrics and targets?	Yes No If yes, please describe goals, metrics, and/or targets and any improvements made in last 3 years.: Do tracking and reduction programs exist for the following impacts: Energy consumption: Water consumption: Amount of hazardous waste: Amount of non-hazardous waste: Greenhouse gas emissions: Does the facility publicly report data? Yes No Program description: If yes, where can the information be found:

- Does the facility have clear environmental goals?
- Are they set locally or at the corporate level?
- Is there clear support for achieving the goals?
- Review the methods that facility has in place to measure key environmental impacts



Audit Overview

33	If the site operates in a water scarce region, has the facility developed a long-term strategy for future water sourcing and management?	Yes No NA Please explain: Is the long-term continuity for future water sourcing and management already covered in the site-based Business Continuity Management plan? Yes No NA Please explain: Does the facility have an authorisation/permit for water intake from groundwater, river or a public system? Yes No NA Please explain: Does this authorisation/permit have any requirements that will restrict or stop your ability to obtain water? Yes No NA Please explain:

- Describe any fresh water availability, access or infrastructure issues the site may be facing locally or regionally.
- Is the water withdrawal from groundwater from a renewable/sustainable source (not depleting the groundwater source)?
- If the site is reliant on a municipal water system, does the site know if the municipality will be unable to capture and distribute adequate supplies of water due to infrastructure development issues or lack of institutional capacity to maintain and manage them appropriately?

[1] Water scarcity is defined by the UN Food and Agriculture Organization as: (i) scarcity **in availability** of fresh water of acceptable quality with respect to aggregated demand, in the simple case of physical water shortage; (ii) scarcity **in access** to water services, because of the failure of institutions in place to ensure reliable supply of water to users; (iii) scarcity due to the **lack of adequate infrastructure**, irrespective of the level of water resources, due to financial constraints. In the last two cases, countries may have a relatively high level of water resources endowment but are unable to capture and distribute them because of limited financial resources for infrastructure development or lack of institutional capacity to maintain and manage them appropriately. (UN FAO, http://www.fao.org/nr/water/topics_scarcity.html)

Audit Overview

Chemical Registrations		
34	Is the site affected by a chemical registration program such as EU REACH (Registration, Evaluation; Assessment, Authorization and Restriction of Chemicals), China REACH, or TSCA (Toxic Substances Control Act) which requires registration or authorization to import or use a specific compound?	Yes No NA If yes, please identify the program: In case of yes, do you have a process in place to comply with the regulation? Yes No NA Which materials are applicable? • Finished Products produced in the site • Raw materials used for finished products • Other
35	Do you send materials to a region where REACH or similar regulations apply?	Yes No If yes, how do you ensure compliance in this region and what is your role in this case?

Audit Overview

Environmental Authorizations		
36	Does the facility have the required environmental permits or authorizations?	Yes No NA If yes, please list the permit type, the name of the permit, and the expiry date: NOTE: Please have all required environmental permits, licenses, information registrations and restrictions available for review including supporting compliance documentation.

Describe the permits and list the permit # or name, confirm expiry date and compliance conditions, if there were any non-compliances within last 3 years. Also add which data was reviewed for permits, for example, waste water sampling results for flow, BOD, pH, etc.

Confirm that all commercially manufactured products are endorsed in the site permits/permit applications.
For R&D suppliers in China, EIA permit at pilot scale does not need to specifically list the products.

What mechanisms does the site use to track compliance against the permit or authorisation conditions?

List all reportable and non-reportable non-compliance with permits (and parameters) within last 3 years.
Review compliance history via web search
Review compliance history with the site during the visit including:
Status of authorisations | Any notices of violation | Any fines or penalties for non-compliance | Any spills or unplanned releases

Describe any permits specifically regulate Active Pharmaceutical Ingredients (especially antibiotics)? For example, wastewater limits, waste disposal requirements).

If site handles antibiotics, indicate the applicability of any permit conditions for managing or controlling waste streams, wastewater or biosolids/biomass from that contain APIs.

Audit Overview

Waste and Emissions		
37	Does the facility have a process to select and manage third-party waste treatment and disposal facilities and service providers?	Yes No NA What records or documentations of waste disposal are maintained: Please provide specific details on land filling of waste (categories and volumes):

Check records/supporting documents such as manifests or shipping records, supplier selection procedure, contracts, audits of waste vendors, etc.
Indicate any non-compliance(s) for the site or contracted waste management supplier.
Describe assurances that waste disposal contractors possess authorizations /certifications from regulatory authorities to manage specific waste streams in accordance with local regulations and that containment and monitoring programs are in place.
Describe selection process review for the use of third-party waste facility or provider. Does it include considerations for staffing and API residual management?
Are the third-party waste treatment vendors used by the facility approved by regulatory authorities? How does the site know that they have valid Environmental permits?
How are third-party waste vendors reviewed periodically for their HSE performance/compliance?
How are waste manifest/transfer record systems followed and maintained for disposal of wastes as per applicable regulations?

More on Waste Management Disposal

- Waste must be disposed at authorized disposal facilities.
- Confirm locations of disposal
- Tracking system for waste shipments and shipment records retention
- Review hazardous waste manifests

More on Waste Management Vendor Considerations

- Does the facility audit their waste vendors?
- Do they have the right authorisations?
- Determine frequency, audit protocols, auditor qualification
- What is described in the contract?

Audit Overview

38	Does the facility use any of the following waste disposal methods & locations (explain as applicable)? Include explanation of how hazardous, including API containing waste (e.g. antibiotics), biohazardous, fermentation biomass, non-hazardous waste is disposed of.

Onsite vs. offsite disposal
Methods: Incineration (energy recovery?), landfill (hermetically sealed?), deep well, land application, other/reuse/recycling

Describe any criteria prescribed, established or referred to for determining the disposal pathway and whether compliance can be demonstrated

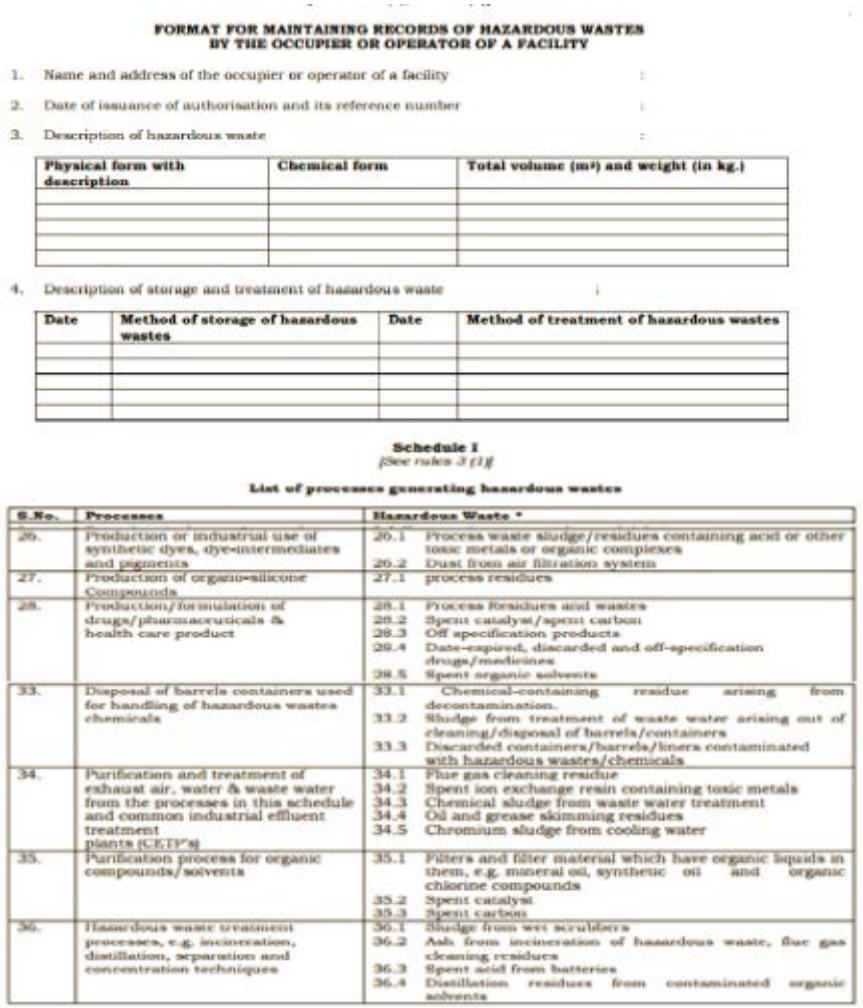
Comment on the appropriateness of waste disposal via methods reportedly used with focus on high risk disposal such as land application, deep well injection, or landfill of hazardous waste. Review in detail treated wastewater and/or sludge/fermentation biomass applied to land for irrigation and/or fertilizing purposes that might include API residual.

List any vendors or relevant authorities for disposal methods or records that were reviewed.

Does this disposal method cover any of the following?

- Branded materials
- API/drug product residuals
- Biosolids, biomass or sludge containing API
- Are environmental impacts from API residuals considered?

More on Waste Management Identification, Characterization, and Inventory



FORMAT FOR MAINTAINING RECORDS OF HAZARDOUS WASTES BY THE OCCUPIER OR OPERATOR OF A FACILITY

1. Name and address of the occupier or operator of a facility :
2. Date of issuance of authorisation and its reference number :
3. Description of hazardous waste :

Physical form with description	Chemical form	Total volume (m³) and weight (in kg.)

4. Description of storage and treatment of hazardous waste :

Date	Method of storage of hazardous wastes	Date	Method of treatment of hazardous wastes

Schedule I

[See rules 3 (1)]

List of processes generating hazardous wastes

S.No.	Processes	Hazardous Waste *	
26.	Production of industrial use of synthetic dyes, dye-intermediates and pigments	26.1 26.2	Process waste sludge/residues containing acid or other toxic metals or organic complexes Dust from air filtration system
27.	Production of organo-silicone Compounds	27.1	process residues
28.	Production/formulation of drugs/pharmaceuticals & health care product	28.1 28.2 28.3 28.4 28.5	Process Residues and wastes Spent catalyst/spent carbon Off specification products Date-expired, discarded and off-specification drugs/medicines Spent organic solvents
33.	Disposal of barrels containers used for handling of hazardous wastes chemicals	33.1 33.2 33.3	Chemical-containing residue arising from decontamination. Sludge from treatment of waste water arising out of cleaning/disposal of barrels/containers Discarded containers/barrels/liners contaminated with hazardous wastes/chemicals
34.	Purification and treatment of exhaust air, water & waste water from the processes in this schedule and common industrial effluent treatment plants (CETP's)	34.1 34.2 34.3 34.4 34.5	Flue gas cleaning residue Spent ion exchange resin containing toxic metals Chemical sludge from waste water treatment Oil and grease skimming residues Chromium sludge from cooling water
35.	Purification process for organic compounds/solvents	35.1 35.2 35.3	Filters and filter material which have organic liquids in them, e.g. mineral oil, synthetic oil and organic chlorine compounds Spent catalyst Spent carbon
36.	Hazardous waste treatment processes, e.g. incineration, distillation, separation and concentration techniques	36.1 36.2 36.3 36.4	Sludge from wet scrubbers Ash from incineration of hazardous waste, flue gas cleaning residues Spent acid from batteries Distillation residues from contaminated organic solvents

- The site should have a documented process to identify and properly characterize all of its waste streams
- An inventory of wastes generated should be available on site
- The inventory should include at a minimum:
  - Point of Generation (process generating the waste)
  - Hazardous characteristics and classification (corrosive, flammable, radioactive, etc.)
  - Annual Generation Rate

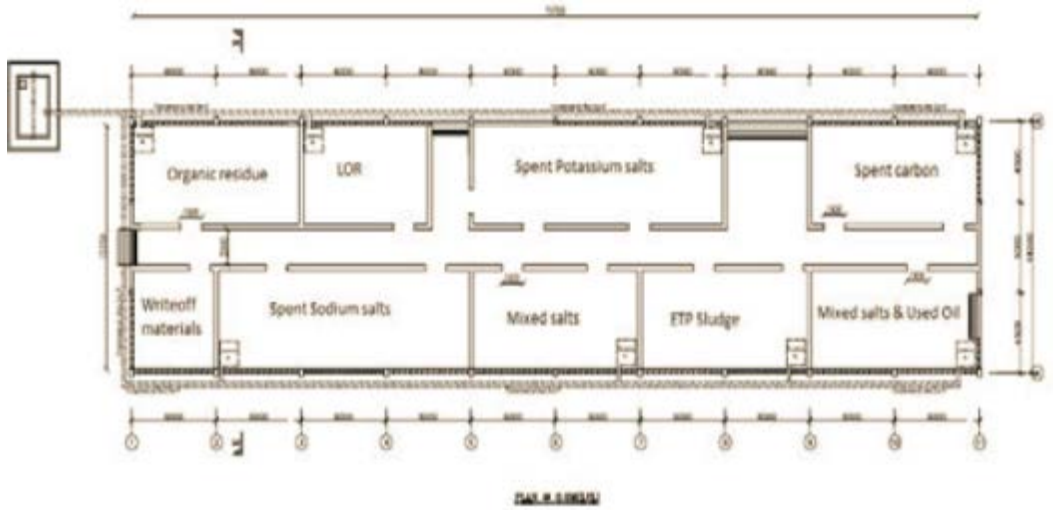
More on Hazardous Waste Management Storage and Handling

- Waste storage areas should be secured and managed
- Located indoors or in covered
- Impervious floors with secondary containment
- Storage areas clean and free of debris and accumulated liquids
- Sufficient aisle space

More on Hazardous Waste Management Storage and Handling

Review the following:

- Inspection program
- Separate storage for incompatible wastes
- Suitable emergency response equipment in place
- Suitable PPE available for personnel managing waste
- Proper security and signage



More on Waste Management Bio-Medical Waste

- Confirm with the site if they generate biohazardous wastes (e.g., microbiological testing wastes)
- Review storage and handling methods
- Must be managed appropriately while on site
- Segregated from other hazardous wastes
- Confirm disposal method and location
- Incinerated at an approved location

Audit Overview

39	Indicate which methods are used to manage process wastewater from this facility.	Check all that apply to treatment and disposal of wastewater: • Pretreatment of process water Yes No Please describe method(s) (example – hydrolysis with caustic or heat pre-treatment): • On-site wastewater treatment: Yes No Please describe: Does the facility collect, store, and analyze samples? Wastewater? Yes No Sludge? Yes No • Discharge to an offsite treatment facility: Yes No Please describe off-site treatment method (example - biological treatment followed by activated carbon filter): • Discharge to a settling/retention pond: Yes No Please describe: • Discharge to surface water (e.g., river, lake, ocean): Yes No Please describe: • Collection and transfer to an off-site wastewater management facility/company: Yes No Please describe: • Other, e.g. Zero liquid discharge, wastewater for irrigation, evaporation via cooling tower, incineration; deep well injection: Yes No Please describe: Are environmental impacts of API considered in disposal of: • Wastewater? Yes No • Sludge/biomass? Yes No

Audit Overview

Are wastewater discharges or practices in line with the permits issued by local agencies?

Describe how wastewater is managed (dedicated and sufficient staff, documented procedures, condition of facility). If an off-site wastewater treatment plant is used, describe selection/oversight by supplier in Question 50.

Assure that samples are collected, stored, and analyzed with results reported in accordance with local regulatory requirements.

Describe the wastewater treatment flow and treatment methods/treatment technologies used and surface water that receives wastewater effluent from the site. (Include all on-site plant discharges and any off-site treatment plant and the waterbody that receives the discharge).

Describe condition of monitoring equipment and effectiveness of controls. Water/wastewater monitoring devices and treatment systems are in good operating condition and appropriately maintained (e.g., in accordance with manufacturer's recommendations).

Describe best practices used by the site (treatment, capture, and containment or practices especially for highly potent API) to prevent or reduce API discharges in wastewater. Are these controls manually operated or proceduralized?

Describe how APIs are quantified in wastewater: mass balance, sampling with sufficiently sensitive method, etc. Describe risk assessment process and oversight such as procedure available, all APIs accounted for, toxicological info available, competent professional provides oversight, recommendations are incorporated, etc.

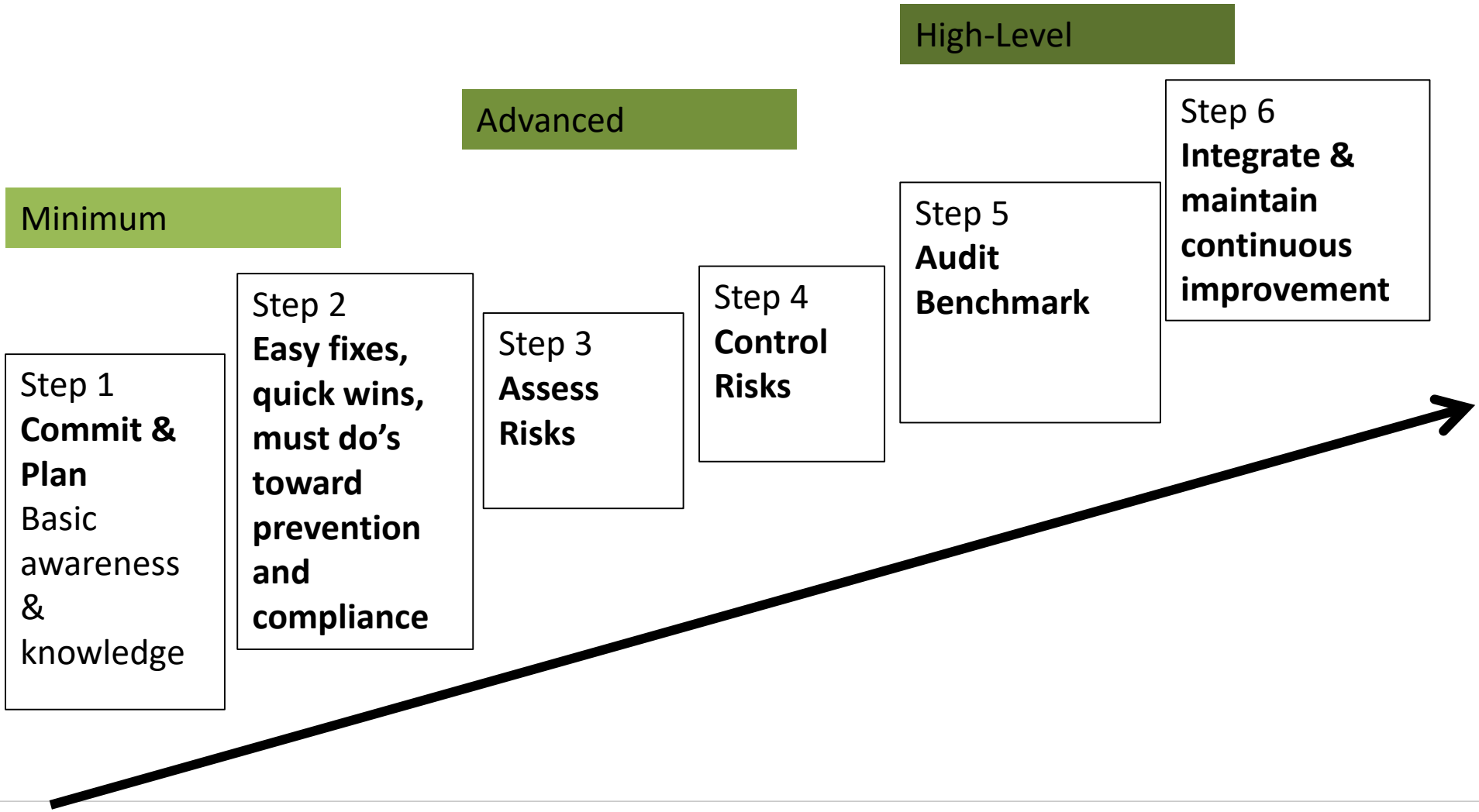
Review qualification for persons managing API emissions (i.e. knowledge of regulatory requirements and quantification of APIs in treated waste water)

More on Wastewater Treatment

- Treatment volume - Evidence of overspill
- Inspect Final Discharge Point
  - Where does it discharge to-standing waterbody, sewer, river, sea
  - Can you go to see the discharge point
  - What does the effluent look/smell like
    - Strong solvent odour
    - Visible contamination
- Permitted Volumes vs Daily Flows
  - What are they limited to
  - Compliance history
  - Specific parameters
- Treatment Capability
  - Do the know what the treatment type is

More on Wastewater Treatment

Wastewater Maturity Ladder



Audit Overview

40	Indicate which of the following types of air emissions are generated at the facility. Describe the types of pollution control activities if used.	Emission Type	Generated?
		Volatile organic chemicals	Yes No NA
		Corrosive vapors (e.g. acid, caustic)	Yes No NA
		Particulates or dusts	Yes No NA
		Ozone depleting substances	Yes No NA
		Combustion by-products	Yes No NA
		Other Pollutants (e.g., GHG, cyanides, sulfides, ammonias, bromines, phosgene)	Yes No NA

Are the air emissions/air quality monitored periodically as per local regulations?

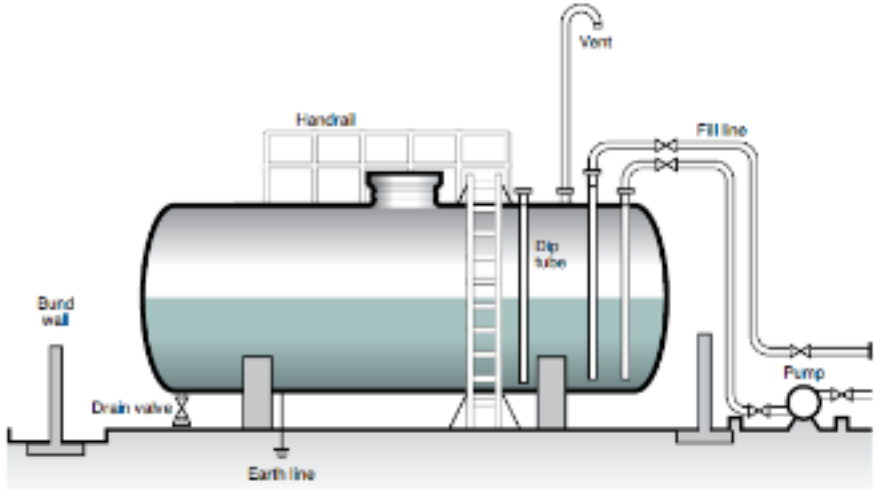
Are the monitoring reports maintained?
Were there any limit exceedances?

Is the air/emission monitoring carried out internally or a third-party?

Are third-party external labs approved for carrying out the tests?

More on Air emissions : Controls of Storage tanks

- Management and control of emissions from storage tanks
- Determine what controls are in place
- Look for controls (and emergency plans) in place for storage of bulk quantities of volatile toxic or highly flammable compounds
- Review Authorisations



More on Air emissions : Process emissions control

- Determine what controls are in place on process equipment
- Determine if the operating parameters and maintenance of the air pollution control equipment is understood and in place
- Review the Authorisation for any specific requirements for vent controls on process equipment

Requirements may include:
- Specific Limits on emissions
- Ambient air quality sampling and limits
- General conditions

More on Air emissions : Odor controls

- Note any odors on your interior and exterior tour
- Review odor control systems in place with facility staff
- Confirm operation and maintenance are adequate to prevent nuisance odors
- Confirm operation is in compliance with the Authorisation

Audit Overview

41	Has the facility developed and implemented a hazardous chemicals (including APIs) management program that includes development and maintenance of a current inventory of all hazardous chemicals (including APIs) used, manufactured or stored on-site, including those for production, maintenance, utilities, and laboratory purposes?	Yes No Please explain and list site hazardous substances:

Audit Overview

42	Has the facility established good storm water management practices?	Yes No Describe how the facility manages storm water and avoid contamination How has the retention volume been calculated? Does it take into account specific factors like rain, environmental hazards of substance stored/handled. Yes No Describe shortly any arrangements that are in place to treat / dispose of the water that would have been collected. Does the facility have a system for controlling and collecting water from fire-fighting to prevent off-site impacts? Yes No Please describe

Is there a dedicated storm water network inside the plant? Describe how the retention volume is calculated and if it takes into account specific factors like rain or environmental hazards of substance stored/handled. Briefly describe any arrangements that are in place to treat / dispose of the water that would have been collected.
If there is no dedicated network, how is storm water collected, measured/analyzed and discharged?

Are there documented programs to manage storm water and storm water contamination control?

Audit Overview

Spills and Releases		
43	Does the facility transport any hazardous materials that are subject to a regulatory authority that specifies transportation requirements? (including but not limited to the International Air Transportation Association (IATA), International Civil Aviation Organisation (ICAO), International Maritime Dangerous Goods (IMDG) Code, ADR (formally, the European Agreement concerning the International Carriage of Dangerous Goods by Road (ADR)), U.S. Department of Transportation (DOT).	Yes No Describe how the facility manages the transportation of hazardous materials and dangerous goods

Audit Overview

44	Does the facility or immediate surroundings external to the site have any known soil, surface water or groundwater contamination?	Yes No If yes, please provide a brief description of how this is being managed and whether it impacts surroundings of the site (e.g., neighboring facilities, companies), adjacent natural habitats:

Is any soil, surface water or groundwater testing carried out periodically?
Is it required by local regulations?
Are records maintained?

Audit Overview

45	Has the facility addressed potential environmental risks arising from storing and handling hazardous substances, including petroleum products and APIs, as follows:	Are there spill containment systems for hazardous substances (including petroleum products and APIs)? Yes No NA Please explain:

Drum storage, above ground tanks, in ground tanks

Secondary containment 110% volume of largest container/tank ?
Leak detection & overfill protection for tanks ?

Spill containment integrity is inspected, documented and maintained in satisfactory condition to prevent the discharge of waste materials into the environment.

Solid wastes are stored, protected from the elements and in a manner to prevent discharge as the result of rain/storm water runoff.

Are waste containers in good condition, compatible with the material being stored and maintained closed except during filling and emptying?

Are protocols or procedures for reporting leaks, spills and other abnormalities related to API waste handling in place and being followed?

Are potential emergency scenarios arising from storage of hazardous substances (including APIs) identified in the site Emergency Response Plan? Are controls and responses and detailed in the Emergency plan?

Have unpermitted releases been reported to the proper authorities and remedial measures instituted to prevent reoccurrence and address impacts associated with said release?

More on Material Storage Containers & Tanks

- Review storage of drummed and bagged materials
- Assess if warehouses are properly managed and have containment for potential releases
- Look for poor material storage practices
- Review the requirements of the Authorisation

- Look for appropriate maintenance on tanks
- Do the tanks have overflow and overfill protection?
- Fire detection and suppression
- Check for appropriate containment
- Review tank truck loading and unloading practices

More on Material Storage Underground Storage Tanks

- Where are they?
- Review construction and containment methods
- Review methods used to determine leaks
- Review tank truck loading and unloading practices

Audit Overview

46	Are tank truck, railcar, and other bulk transportation unit loading and unloading areas for hazardous substances provided with containment equivalent to at least 110% of the largest transportation unit handled in that area, or for compartmentalized transportation units, equivalent to at least 110% of the single largest compartment?	Yes No NA Please explain:

4. EXAMPLE AUDIT FINDINGS

- Paint a picture for reviewers in the report as if they have never been to the site
- Be specific where possible to provide context of scope of issue, impact to supply chain, depth of problem
- Accurate without overstating or understating issue

Case 1

Q39: Indicate which methods are used to manage process wastewater from this facility.

Real PSCI audit finding

The site has no evidence about the effectiveness of the private waste water treatment works.

What kinds of wastes are sent to the private waste water treatment works?
Is the site required to use this private waste water treatment works?
Does the site characterize waste water sent offsite?

Case 1 – Model finding

The site sends production wastewater to a private wastewater treatment plant via hired tanker truck daily.

The private wastewater treatment plant is the common local plant the site (and rest of industrial park) is required to use. The site characterizes the wastewater going offsite so quantity of API in discharge is known. The site has requested/been refused/not yet received information on treatment capability and effectiveness of the private wastewater treatment plant.

Case 2

Q45: Has the facility addressed potential environmental risks arising from storing and handling hazardous substances, including petroleum products as APIs, as follows: …
Does the site have protocols or procedures for storing and handling drums, providing containment for drums and managing spills from drums?

Real PSCI audit finding

Some hazardous wastes (empty chemical containers) stored in the open air.

Case 2 – Model finding

Approximately 40 empty 55 gallon metal drums (previously containing hazardous chemicals) were stored on loading dock of Building 16 with no protection from the elements.

Exercise 1

Q45: Has the facility addressed potential environmental risks arising from storing and handling hazardous substances, including petroleum products as APIs, as follows: … Does the site utilize Secondary containment in the form of double walled tank and piping or an external vault with a capacity equivalent to 110% of the largest tank or vessel in the containment area?

Real PSCI audit finding

Containment at tank farm is not adequate.

What kind of containment – double wall, vault…

What is the deficiency? Too small, breach, not compatible with material stored, doesn't exist…

How would you improve this finding?

Instructions

1. Use the audit finding sheet provided to write up the finding.
2. **Add details from your experience** not mentioned in the bad finding example.
3. You have 5 minutes (or less time if everyone is finished)
4. Afterwards we will discuss your answers

Exercise 1 - Sample finding

Tank farm storing solvents has concrete pad and berm surrounding tanks but 3 breaches have been cut into concrete to accommodate rain water removal, compromising the integrity of the berm.

Exercise 2

Practice writing 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

Exercise 2 - Sample finding

Behind the waste storage building, 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.

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About the Secretariat
Carnstone Partners Ltd is an independent management consultancy, specialising in corporate responsibility and sustainability, with a long track record in running industry groups.

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partners ltd

PSCI PHARMACEUTICAL SUPPLY CHAIN INITIATIVE

Building responsible supply chains

Pharmaceuticals in the Environment

Ken Sun

EHS&S Lead - Third Party

GSK

AGENDA

Pharmaceuticals in the Environment

Introduction

Risk assessment

PSCI tool

Mitigation strategy & example

Bio

Ken Sun

EHS&S Lead -Third Party, GSK

- Over 20 years multi-national pharmaceutical experience, covering whole site life cycle, from Green field site location selection & construction to site transition/close.
- Experienced for various roles, including mechanical engineer, Production Supervisor, Industry Facilitator, Project Regulatory Manager, Site Risk Champion, Site Transition Manager, Production Operation manager and Value Stream Head, EHS Manager and China Region EHS Lead
- Certified Safety Engineer. Mechanical & Electrical Bachelor degree. Quality management Master degree. Six-Sigma blackbelt

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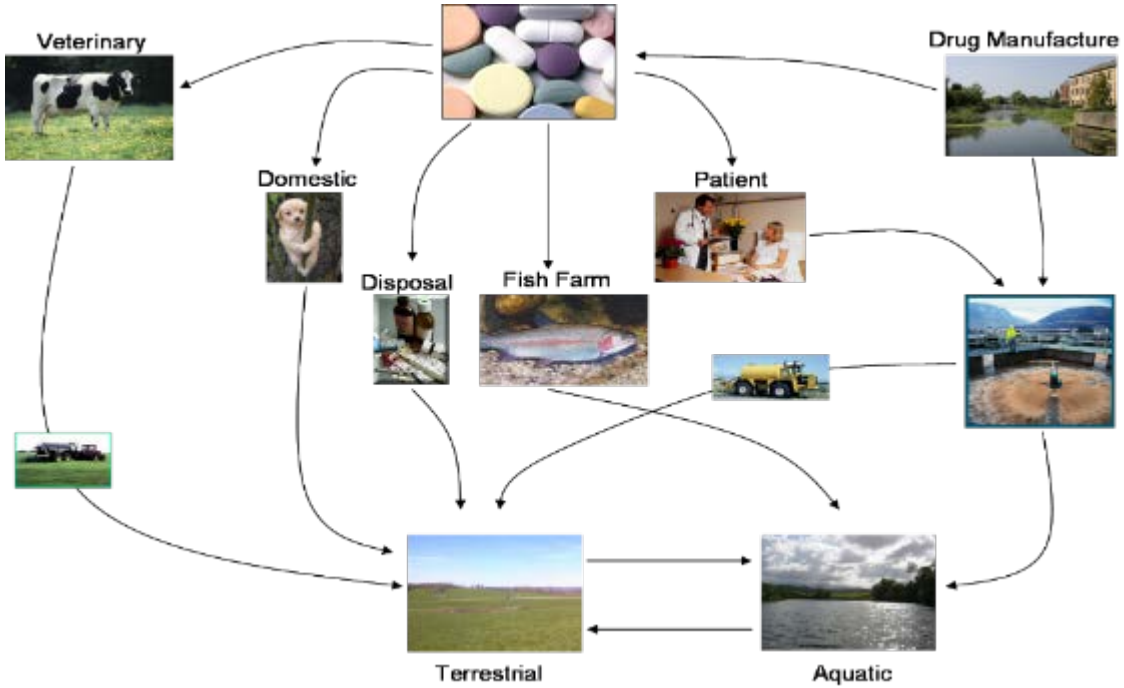
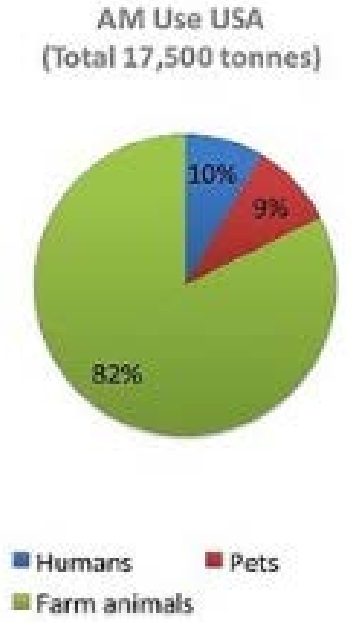
PIE Introduction

Sources of Pharmaceuticals in Surface Waters



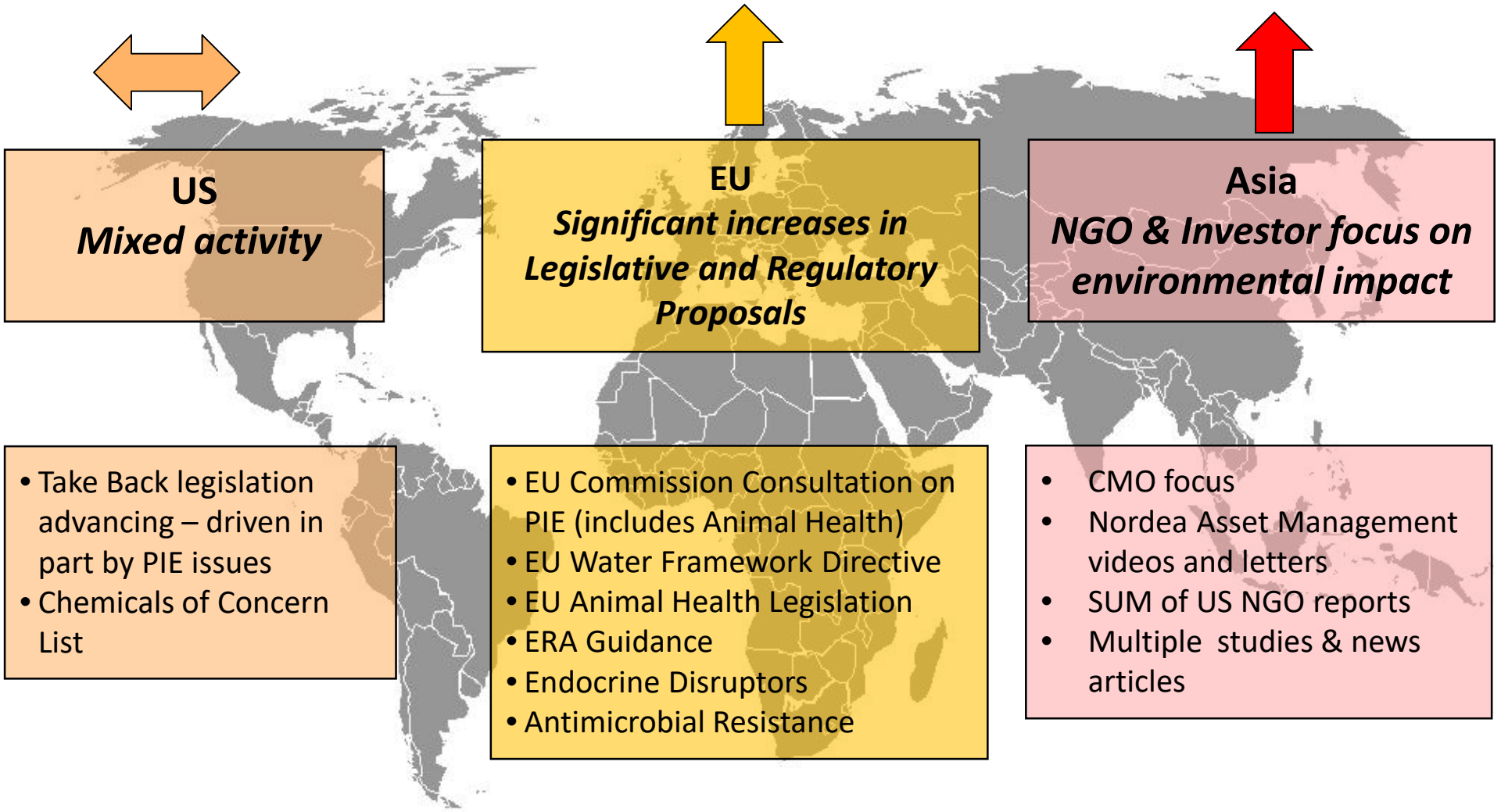


- Largest use of antibiotics globally is in animal production and human health. This is the largest source (98%) of antibiotics in the environment

- Manufacturing emissions to the environment are estimated <2% by mass.

HOWEVER this is a high profile area for pressure groups, media, NGOs etc

Global Perspective



US
Mixed activity

- Take Back legislation advancing – driven in part by PIE issues
- Chemicals of Concern List

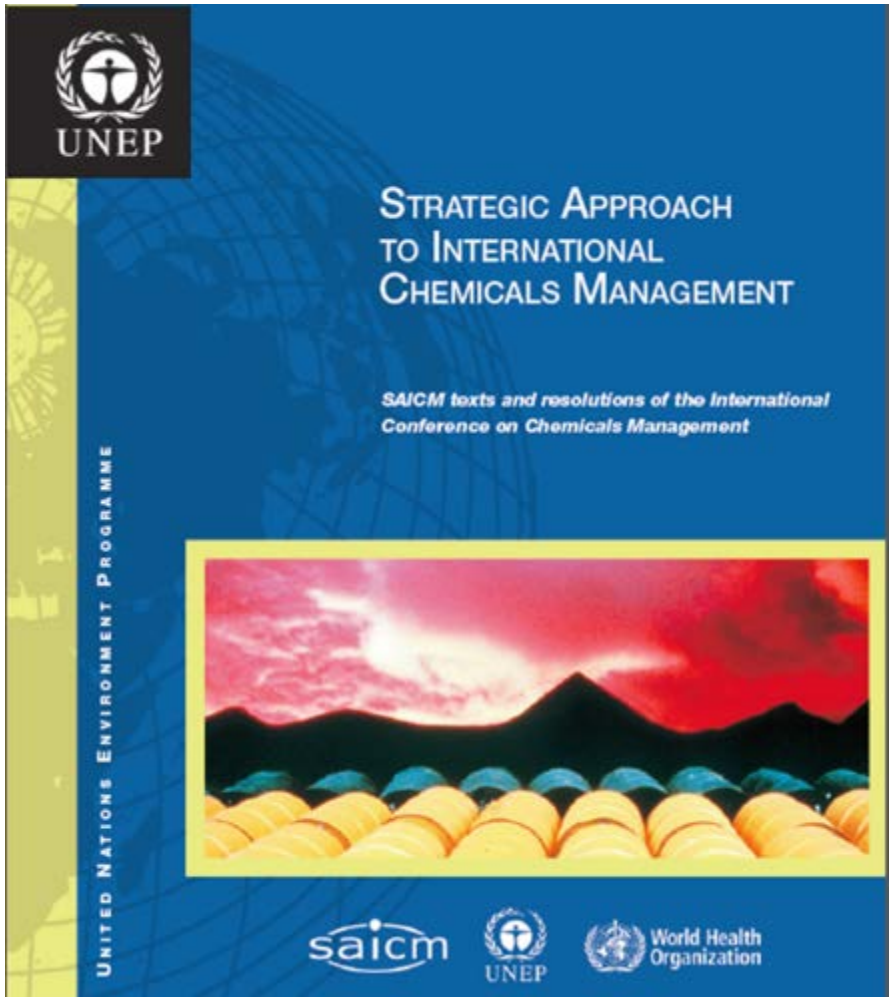
EU
Significant increases in Legislative and Regulatory Proposals

- EU Commission Consultation on PIE (includes Animal Health)
- EU Water Framework Directive
- EU Animal Health Legislation
- ERA Guidance
- Endocrine Disruptors
- Antimicrobial Resistance

Asia
NGO & Investor focus on environmental impact

- CMO focus
- Nordea Asset Management videos and letters
- SUM of US NGO reports
- Multiple studies & news articles

Stakeholders voicing their concerns



At its first session, held in Dubai, United Arab Emirates, from 4 to 6 February 2006, the International Conference on Chemicals Management adopted the Dubai Declaration on International Chemicals Management and the Overarching Policy Strategy. The Conference also recommended the use and further development of the Global Plan of Action as a working tool and guidance document. Together these three documents constitute the Strategic Approach to International Chemicals Management.

Emerging Policy Issues:

- Lead in Paint
- Chemicals in Products
- Endocrine Disrupting Chemicals
- Hazardous substances in electrical and electronic products
- Nanotechnology and manufactured nanomaterials
- Environmentally Persistent Pharmaceutical Products*

*Added October, 2015

Drug Resistance Research

- Harvard Medical School and Technion Institute of Technology demonstrate how bacteria move as they become immune to antibiotics, supported by grants from the NIH and European Health Council*

- Cinematic Approach to Drug Resistance
- **https://www.youtube.com/watch?feature=player_embedded&v=plVk4NVIUh8**

*A Cinematic Approach to Drug Resistance", Harvard Gazette, September 8, 2016

Drug Resistance Research

Global Response on AMR

- WHO Health Assembly 2015
- UK-One Health Report
- UK- O'Neil Report 2016
- UN General Assembly 2016
- International Federation of Pharmaceutical Manufacturer's and Associations 2016-Davos Declaration

Reduce Environmental pollution

ESTABLISH MINIMUM STANDARDS TARGETING THE EMISSION OF MANUFACTURING WASTE CONTAINING APIs

ENCOURAGE THE PHARMACEUTICAL INDUSTRY TO DRIVE HIGHER STANDARDS THROUGHOUT THEIR SUPPLY CHAINS

Review on Antimicrobial Resistance

Tackling drug-resistant infections globally

O'Neill Final Report - 2016

World Health Organization

GLOBAL ACTION PLAN ON ANTIMICROBIAL RESISTANCE

SIGNATORY COMPANIES

Allergan (NYSE: AGN)
AstraZeneca (NYSE: AZN)
Cipla (NSE: CIPLA)
DSM Sinochem Pharmaceuticals (Euronext: DSM)
F. Hoffman-La Roche Ltd., Switzerland (VTX: ROG)
GSK (NYSE: GSK)
Johnson & Johnson (NYSE: JNJ)
Merck & Co., Inc., Kenilworth, New Jersey, U.S.A. (NYSE: MRK)
Novartis (NYSE: NVS)
Pfizer (NYSE: PFE)
Sanofi (EURONEXT:SAN, NYSE: SNY)
Shionogi & Co., Ltd. (TYO: 4507)
Wockhardt (NSE: WOCKPHARMA)

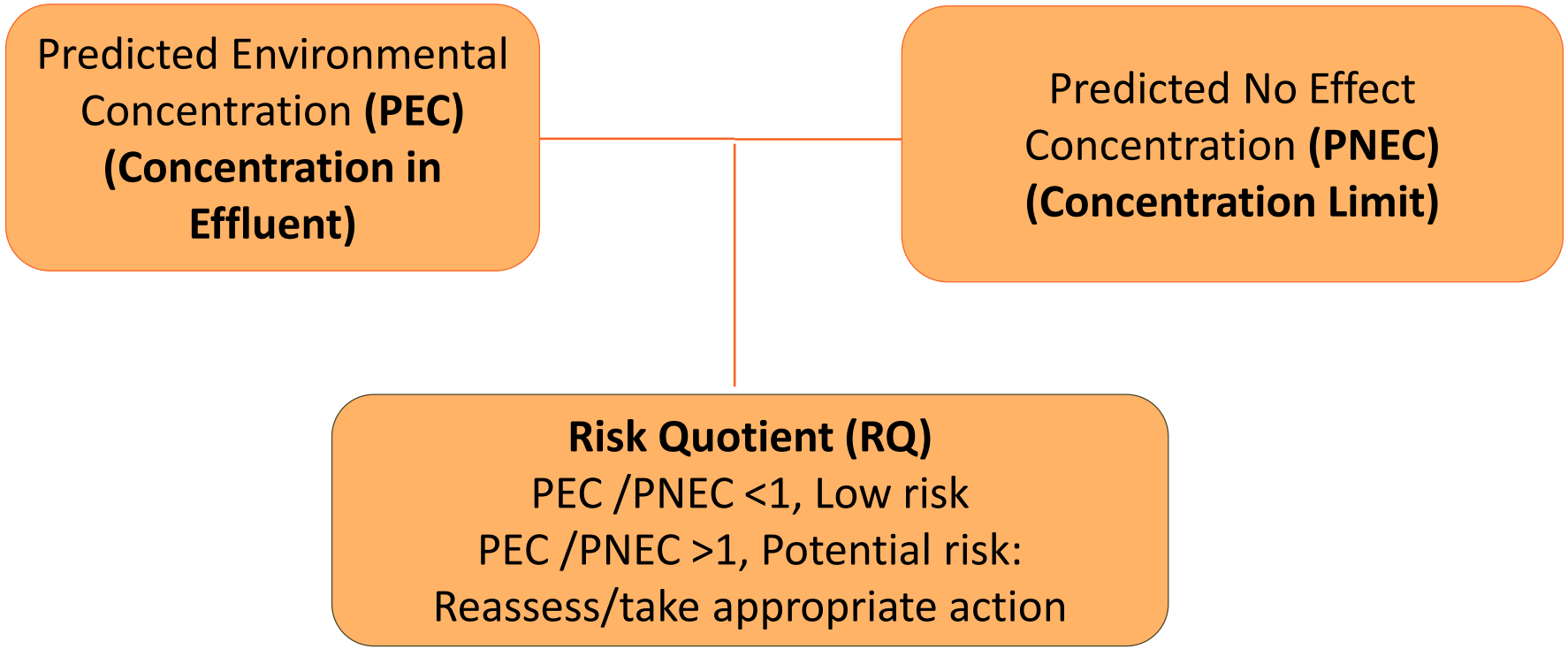
PIE Risk assessment

Pre Assessment Information

- What information can you gather in advance:
  - What APIs do they handle
  - Safety Data Sheets (SDS)-Example
  - Is there any guidance available for the limit to water (PNEC)
  - Where is the nearest water body-receiving water
  - Flow rates of receiving water bodies

API Environmental Risk Assessment

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



PEC Data Collection & Analysis

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

Examples

On-Site

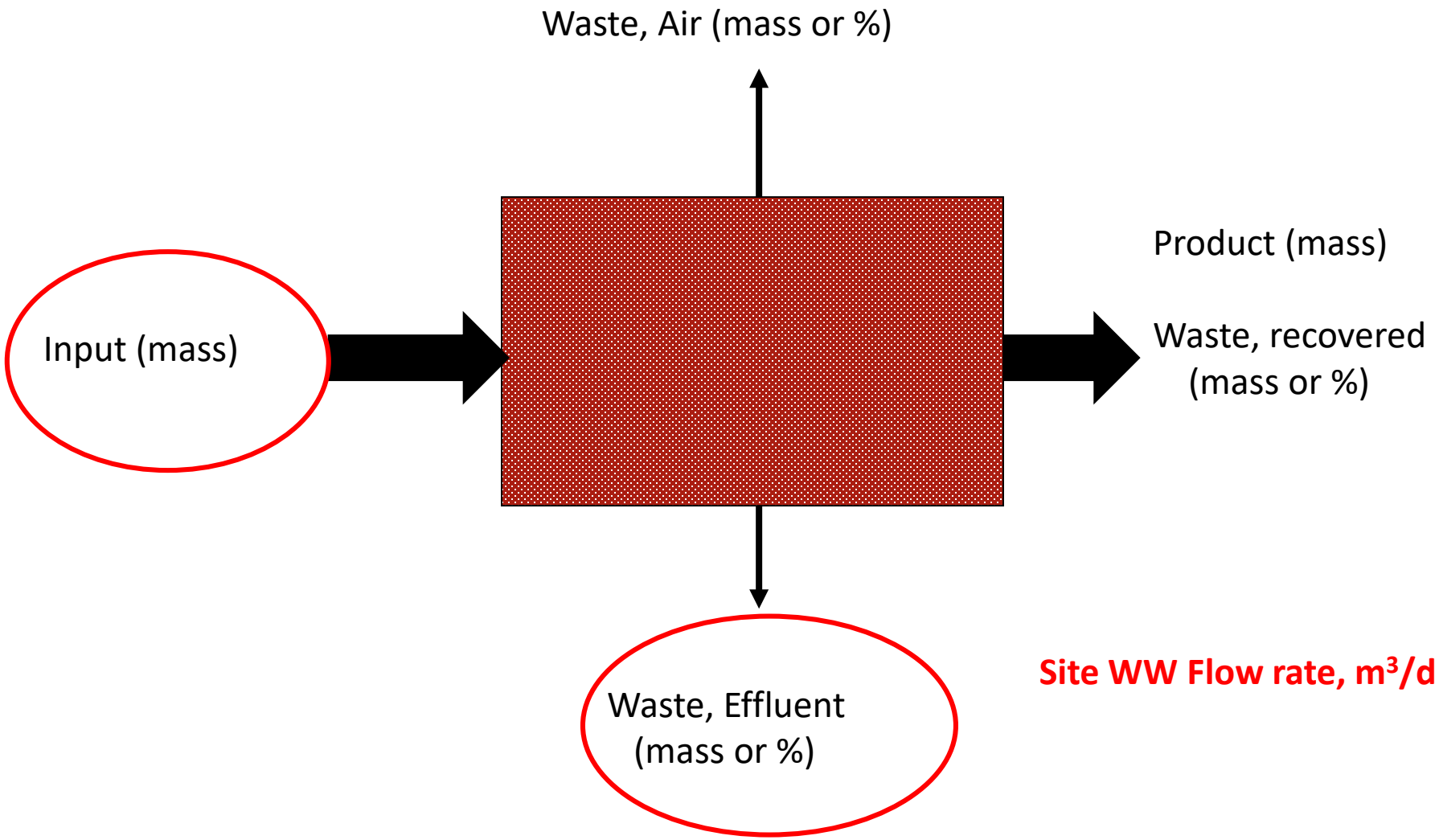
batch records	wastewater POG[1]
product yield	wastewater flows
batch/year	WWTP unit ops
cleaning cycles	API analyses[2]

Off-Site

POTW flow
POTW unit ops
receiving water flow

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

API Mass Balance



API Mass Balance Loss - Example

Using mass balance values

1. Must be representative of the process
2. Consider control chart for calculated losses

Date of Manufacture	Item Code	# of vials filled	Amount of API in vials (kg), (calculated)	Amount of API not in vials (kg), (calculated)	Daily sum of amount not in vials
04-JAN-2011 14:13:03	000000000000	15767	18.037448	0.095552	0.216272
04-JAN-2011 14:18:08	000000000000	15745	18.01228	0.12072	
11-JAN-2011 14:12:12	000000000000	15740	18.00656	0.12644	0.332416
11-JAN-2011 14:09:54	000000000000	15765	18.03516	0.09784	
11-JAN-2011 14:24:55	000000000000	15756	18.024864	0.108136	
18-JAN-2011 10:52:49	000000000000	15723	17.987112	0.145888	0.283768
18-JAN-2011 10:46:36	000000000000	15730	17.99512	0.13788	
25-JAN-2011 16:24:28	000000000000	15534	17.770896	0.362104	0.491976
25-JAN-2011 16:22:15	000000000000	15737	18.003128	0.129872	
	Avg Number of vials filled	Avg Amount of API in vials (kg)	Avg Amount of API not in vials (kg)	Worst Case API in Wastewater (kg)	Limit API in Wastewater (kg/day)
	15721.89	17.99	0.15	0.29	0.65
				Cumulative Daily Worst Case (kg)	
				0.49	

Calculating the Risk Quotient

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

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

Permits

- Most discharge permits will address established parameters, e.g., control of pH, biological oxygen demand, chemical oxygen demand, etc.
- Some discharge permits include periodic general toxicity testing, i.e., whole effluent toxicity
- Most discharge permits will NOT directly address active pharmaceutical ingredients (APIs) but DO include a 'general duty' clause, i.e., "No toxics in toxic amounts".

Guidance

SETAC PRESS

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Hazard/Risk Assessment

A RISK-BASED APPROACH TO MANAGING ACTIVE PHARMACEUTICAL INGREDIENTS IN MANUFACTURING EFFLUENT

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Caldwell et al Paper

PNEC Resources

Webinar series:

Part 1

Part 2

Part 3

Part 4

PSCI tool

Audit Overview | Wastewater question

39	Indicate which methods are used to manage process wastewater from this facility.	Check all that apply to treatment and disposal of wastewater: • Pretreatment of process water Yes No Please describe method(s) (example – hydrolysis with caustic or heat pre-treatment): • On-site wastewater treatment: Yes No Please describe: Does the facility collect, store, and analyze samples? Wastewater? Yes No Sludge? Yes No • Discharge to an offsite treatment facility: Yes No Please describe off-site treatment method (example - biological treatment followed by activated carbon filter): • Discharge to a settling/retention pond: Yes No Please describe: • Discharge to surface water (e.g., river, lake, ocean): Yes No Please describe: • Collection and transfer to an off-site wastewater management facility/company: Yes No Please describe: • Other, e.g. Zero liquid discharge, wastewater for irrigation, evaporation via cooling tower, incineration; deep well injection: Yes No Please describe: Are environmental impacts of API considered in disposal of: • Wastewater? Yes No • Sludge/biomass? Yes No

Audit Overview | Auditor guidance for wastewater

Are wastewater discharges or practices in line with the permits issued by local agencies?

Describe how wastewater is managed (dedicated and sufficient staff, documented procedures, condition of facility). If an off-site wastewater treatment plant is used, describe selection/oversight by supplier in Question 50.

Assure that samples are collected, stored, and analyzed with results reported in accordance with local regulatory requirements.

Describe the wastewater treatment flow and treatment methods/treatment technologies used and surface water that receives wastewater effluent from the site. (Include all on-site plant discharges and any off-site treatment plant and the waterbody that receives the discharge).

Describe condition of monitoring equipment and effectiveness of controls. Water/wastewater monitoring devices and treatment systems are in good operating condition and appropriately maintained (e.g., in accordance with manufacturer's recommendations).

Describe best practices used by the site (treatment, capture, and containment or practices especially for highly potent API) to prevent or reduce API discharges in wastewater. Are these controls manually operated or proceduralized?

Describe how APIs are quantified in wastewater: mass balance, sampling with sufficiently sensitive method, etc. Describe risk assessment process and oversight such as procedure available, all APIs accounted for, toxicological info available, competent professional provides oversight, recommendations are incorporated, etc.

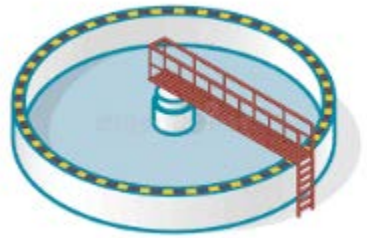
Review qualification for persons managing API emissions (i.e. knowledge of regulatory requirements and quantification of APIs in treated waste water)

PIE mitigation Strategy & Examples

Strategy

Type of mitigation strategy depends on local specs :

- Waste water flow on site/WWTP configutation
- Type & number of 'problematic' APIs



At source mitigation

- Targeted waste stream with highest API load
- Single API mitigation
- GMP consideration (inside plant)
- $

Pre-treatment

- Treat multiple waste streams, multiple API mitigation
- Avoid full flow of Waste Water treatment
- No GMP (outside plant)
- $$

End of pipe treatment

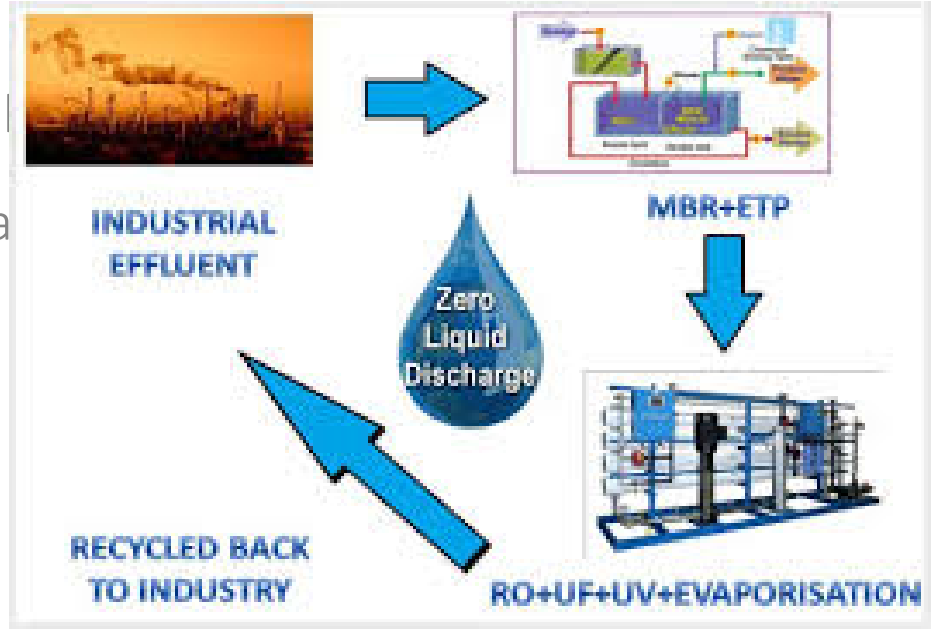
- 'Polishing' step after WWTP
- 'All inclusive'
- No GMP (outside plant)
- $$$

EXAMPLE
Zero Liquid Discharge

- Zero Discharge-Reuse of treated effluent

- Check the mass balance volumes-
  - e.g. is the daily amount of effluent the same as the input to the cooling towers
  - is the volume far greater than irrigation use

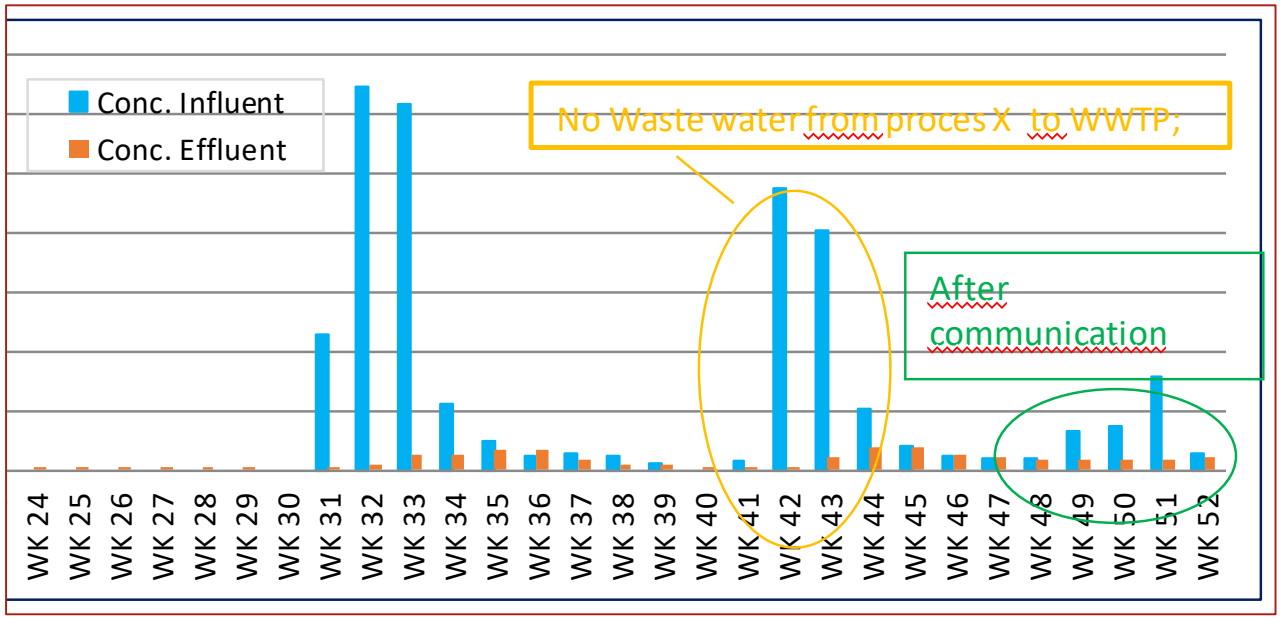
- ZLD Doesn't always equal 'zero risk'. Ground dispersion may resul in:
  - Dermal/inhalation exposure to applicator and/or recreationa users
  - Edible vegetation and/or groundwater users
  - Terrestrial organisms
  - Mist inhalation from opened cooling uses



Zero Liquid Discharge

EXAMPLE
At source mitigation @ API chemcial manufacturing plant

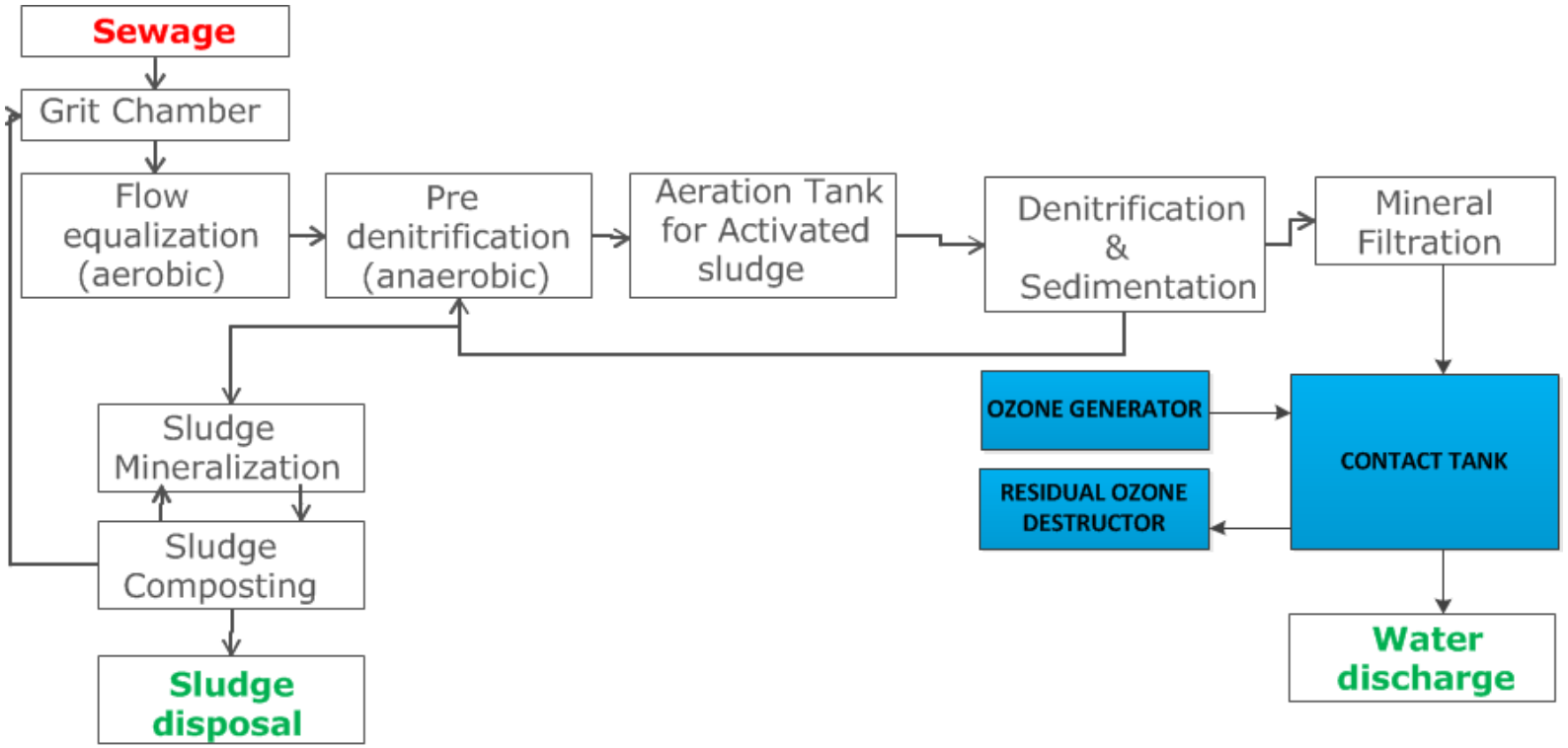
- Discard process wastewater with ‘problematic compound X’ to incineration instead of WWTP
- Investigation with procesmanager → during emptying of centrifuge, some product falls on floor and is flushed to sewer → include good practice in SOP to avoid flushing residual powders in sewer



EXAMPLE
Pre treatment @ API chemcial manufacturing plant : mobile equipment to treat process streams

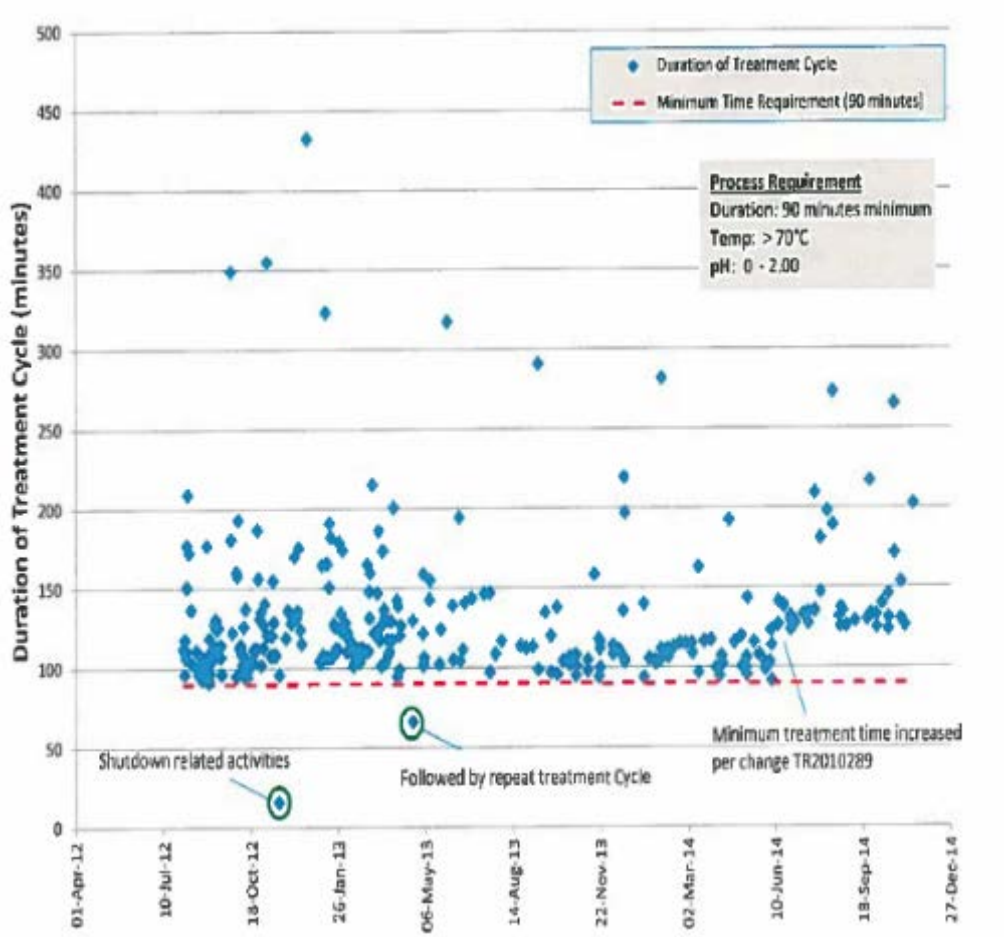
- Remove API from production wastewaters with modular technology (advanced oxidation/adsorption/etc.)
- Pre-treated water can furter be treated in on site water treatment plant
- Equipment can be trucked to other locations (other plants e.g.)

EXAMPLE
End of pipe MBR + ozone treatment @ fill&finish Pharma plant



EXAMPLE
On-site Treatment Removal Performance of API

- Batch wastewater Fill/Finish API collection and treatment system
- Performance testing of acid plus high temperature treatment showed 95% API destruction
- Process requirements
  - Temperature >70°C
  - pH 0 – 2.00 s.u.
  - ≥ 90 minutes

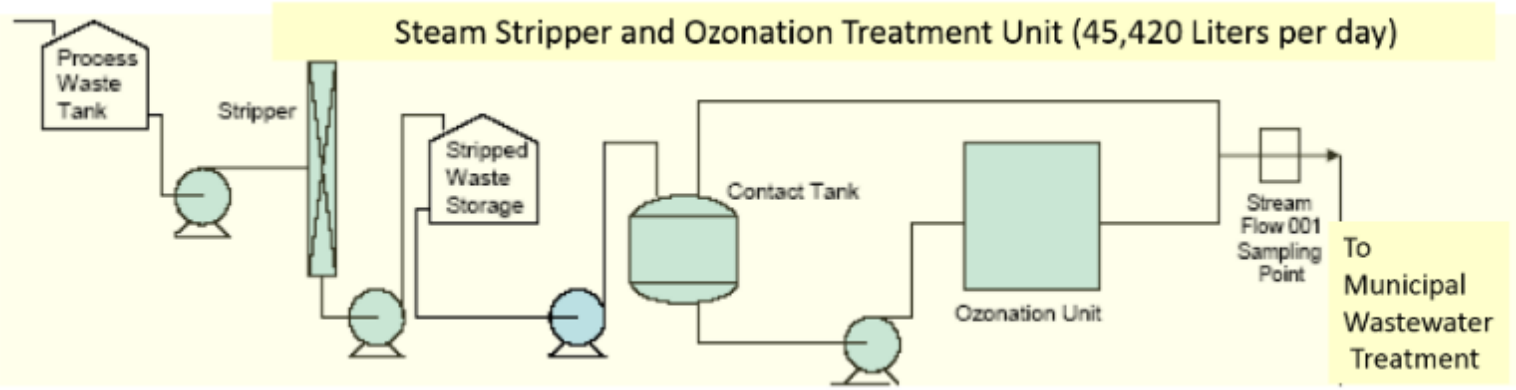


EXAMPLE Audit Questions to Consider:

1. Is appropriate staffing provided to manage and implement programs to control emissions of active ingredients?
2. What are the business area's written qualifications for persons performing and reviewing environmental calculations.
3. How were the process requirements for temperature plus time and pH determined? How does the site ensure that the wastewater content has not changed to impact treatability?
4. Is the treatment system manually operated systems
5. Are other physical barriers (plugged floor drains) in place and do all API containing wastewaters go to this treatment system?
6. Are appropriate systems in place to control the loss of active ingredient to wastewater from production (i.e. to ensure we do not have treatment breakthrough)?

EXAMPLE
On-site Treatment and Control of API Discharge

- 2 Bulk chemically synthesized APIs manufactured at this site
  - Product A – All waste streams collected for off-site incineration -system cannot physically discharge to the wastewater sewer system
  - Product B - Batch Wastewater Collection and Treatment System



EXAMPLE Audit Questions/Actions to Consider:

For Product A

1. Field verify that system is not physically connected to the sewer system
2. Verify that wastewater is sent to an incineration system

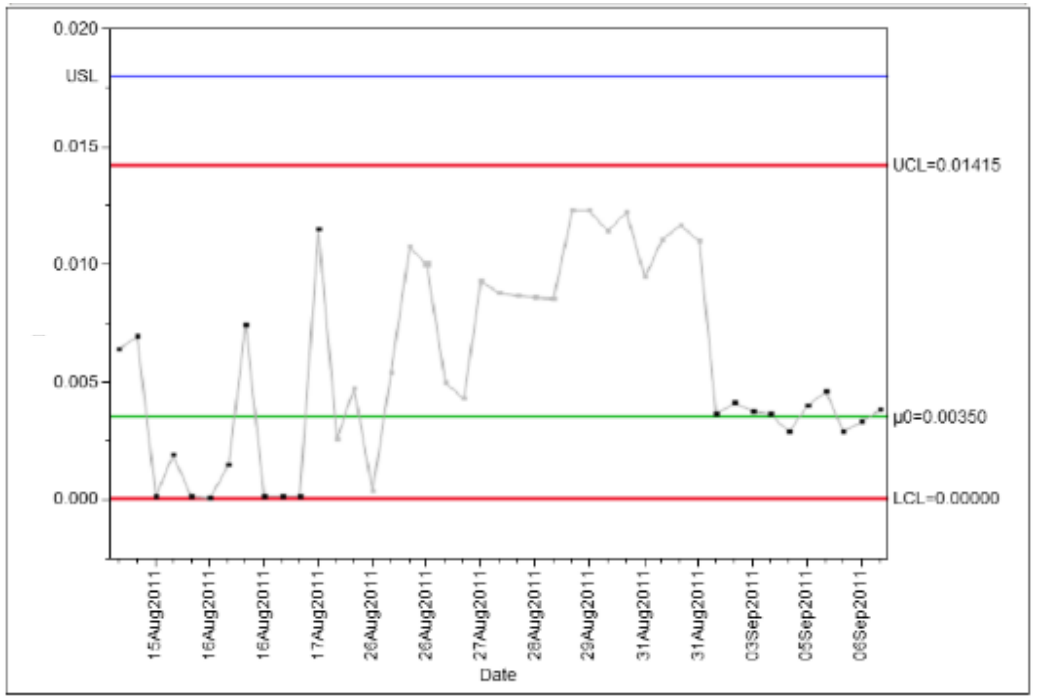
For Product B

1. Review the treatment design studies to verify the assumptions that went into designing the treatment system
2. What are the critical process variables for the ozonation system used to ensure that it routinely achieves API removal credit
3. Verify that the assumptions used for using the municipal treatment system are adequate (i.e. size, treatment provided, location of discharge)

EXAMPLE
On-site Treatment and Control of API Discharge

- Large Scale Batch Ozonation
- Greater than 93% API destruction
- Batch processing

Risk Quotient at site final discharge – PNEC $_{acute}$	Risk Quotient at site final discharge – PNEC $_{chronic}$
< 0.211	<0.762



EXAMPLE Audit Questions/Actions to Consider:

1. What were the PNEC values used in these calculations? Were the PNEC values developed by the site or provided by another source? Check the source and background values behind setting the PNEC values.
2. Is appropriate staffing provided to manage and implement programs to control emissions of active ingredients?
3. What are the business area's written qualifications for persons performing and reviewing environmental calculations and running the treatment system.
4. How were the process requirements for ozonation system (ozone concentration and reaction time) determined? How does the site ensure that the wastewater content is not changed to impact treatability?
5. Is the treatment system manually operated?
6. Are other physical barriers (plugged floor drains) in place and do all API containing wastewaters go to this ?

EXAMPLE
Results of Refined PEC Estimates

CASE EXAMPLE Assumptions:

Maximum API loss rate: 0.5 kg/day API
Municipal discharge flow rate: 10,000 m^3/day
River low flow rate: 20,000 m^3/day
Fraction of river allowed for mixing: 0.5
Drinking water Intake flow: 100,000 m^3/day

PEC at Point of Application	PEC – No Removal	PEC – After On-Site Treatment	PEC – After On-site and Municipal Removal
PEC_{acute}	50 ug/L	2.5 ug/L	1.4 ug/L
$PEC_{chronic}$	25 ug/L	1.25 ug/L	0.7 ug/L
$PEC_{drinking\ water}$	0.02 ug/L	0.001 ug/L	0.0006 ug/L

EXAMPLE Audit Questions/Actions to Consider:

1. What were the PNEC values used in these calculations? Were the NEC values developed by the site or provided by another source? Check the source and background values behind setting the PNEC values.
2. Is appropriate staffing provided to manage and implement programs to control emissions of active ingredients?
3. What are the business area's written qualifications for persons performing and reviewing environmental calculations.
4. How were the process requirements for temperature plus time and pH determined? How does the site ensure that the wastewater content is not changed to impact treatability?
5. Is the treatment system a manually operated system?
6. Are other physical barriers (plugged floor drains) in place and do all API containing wastewaters go to this ?

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About the Secretariat
Carnstone Partners Ltd is an independent management consultancy, specialising in corporate responsibility and sustainability, with a long track record in running industry groups.

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PSCI PHARMACEUTICAL SUPPLY CHAIN INITIATIVE
Building responsible supply chains

Chemical Process Safety: Which parameters are important to perform a chemical reaction in a safe way?

(Presentation by Dr Stefan Gries, Boehringer Ingelheim Corporate Center)

Speaker : Liu Li (刘立)
EHS&S China, Boehringer Ingelheim

AGENDA 大纲

1. **Session 1**

- **Process safety parameters**
- **Essential information to chemical processes**
- **Critical interactions of material**
- **Exothermic and run-away reaction**
- **Scale up**

2. **Session 2**

- **Runaway reaction**
- **PSCI Questionnaire & Typical Observations**

3. **Audience questions & discussions**

SPEAKER BIO

Mr. Liu Li

- Chemist
- 13 years in Pharam Industry
- 8 years with Boehringer Ingelheim China
- Current position: EHS & S Manager

- Former positions in
  - Medicinal Chemsitry
  - Chemcial Process Research and Development
  - EHS&S

SPEAKER BIO

Dr. Stefan Gries

- Chemist
- More than 25 years with Boehringer Ingelheim
- Current position: Corp. EHS & S
  (occupational health, exposure control, soil and groundwater protection, EHS auditor)
- Former positions in
  - Local EHS (Safety Engineer)
  - Research & Development (Head of pilot plant)
  - Chemical Production (Head of production plant)

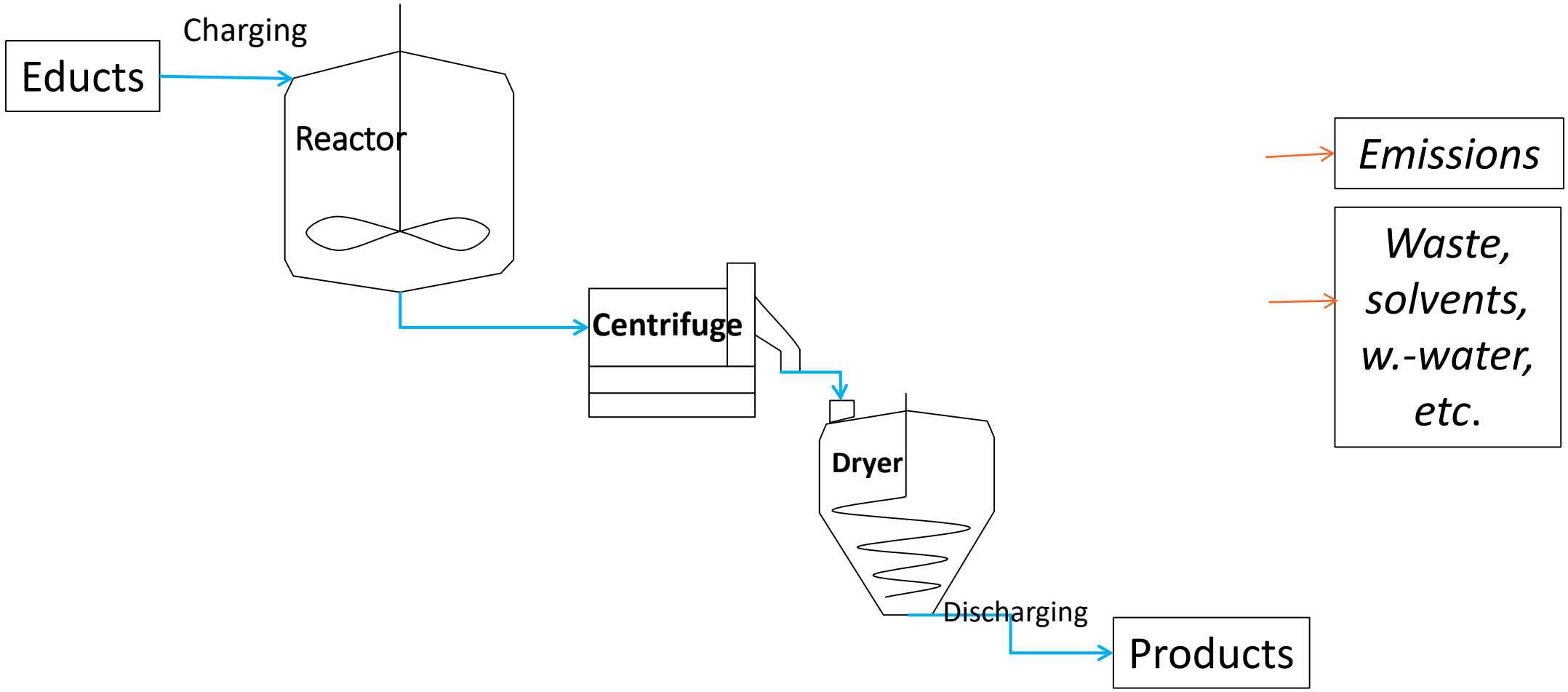
TRAINING STRUCTURE

1. **Session 1**
- **Process safety parameters**
- **Essential information to chemical processes**
- **Critical interactions of material**
- **Exothermic and run-away reaction**
- **Scale up**

2. **Session 2**
- **Runaway reaction**
- **PSCI Questionnaire & Typical Observations**

3. **Audience questions & discussions**

Chemical reaction in a production plant



Which information is necessary for a safe process?

- Knowledge about the used chemicals regarding thermal stability, physical safety parameters and toxicology
  - Educts
  - Products (incl. side products)
  - Reagents
  - Solvents & Auxiliaries
- Knowledge about the chemistry
  - Main reaction and side reactions
  - Waste streams (gas release, liquids and solids)
  - Consecutive reaction, decomposition?
- Reaction type
  - Batch reaction
  - Semi-batch reaction
  - Continuous flow reaction

What is necessary for a safe process?

- Calorimetric data of the chemical reaction
  - Adiabatic temperature rise
  - Gas evolution rate (→ reactor venting sufficiant?)
  - precipitation of solids (→ reduction of heat transfer, stirrer blocking?)
  - Accumulation of reactants, thermal output/time
  - Stability of reaction mixtures, distillation residues, etc.
  - Potential for runaway reaction, abnormal operating conditions
  - If necessary: investigation of the runaway reaction

- Knowledge about critical interaction between the used chemicals and other material
  - Material resistance of reactor & other equipment
  - Possible material contact (e.g. media supply)

What is necessary for a safe process?

- Plant equipment “state of the art”
  - Materials of the equipment = > material tests, corrosive data, etc.
  - Inertisation of equipment
  - Earthing of the equipment, explosion-proof equipment
  - Blow-down system, pressure relief valve, rupture disc,
  - Heating and cooling medium & capacity
  - Safety concept e. g. for electrical shut down

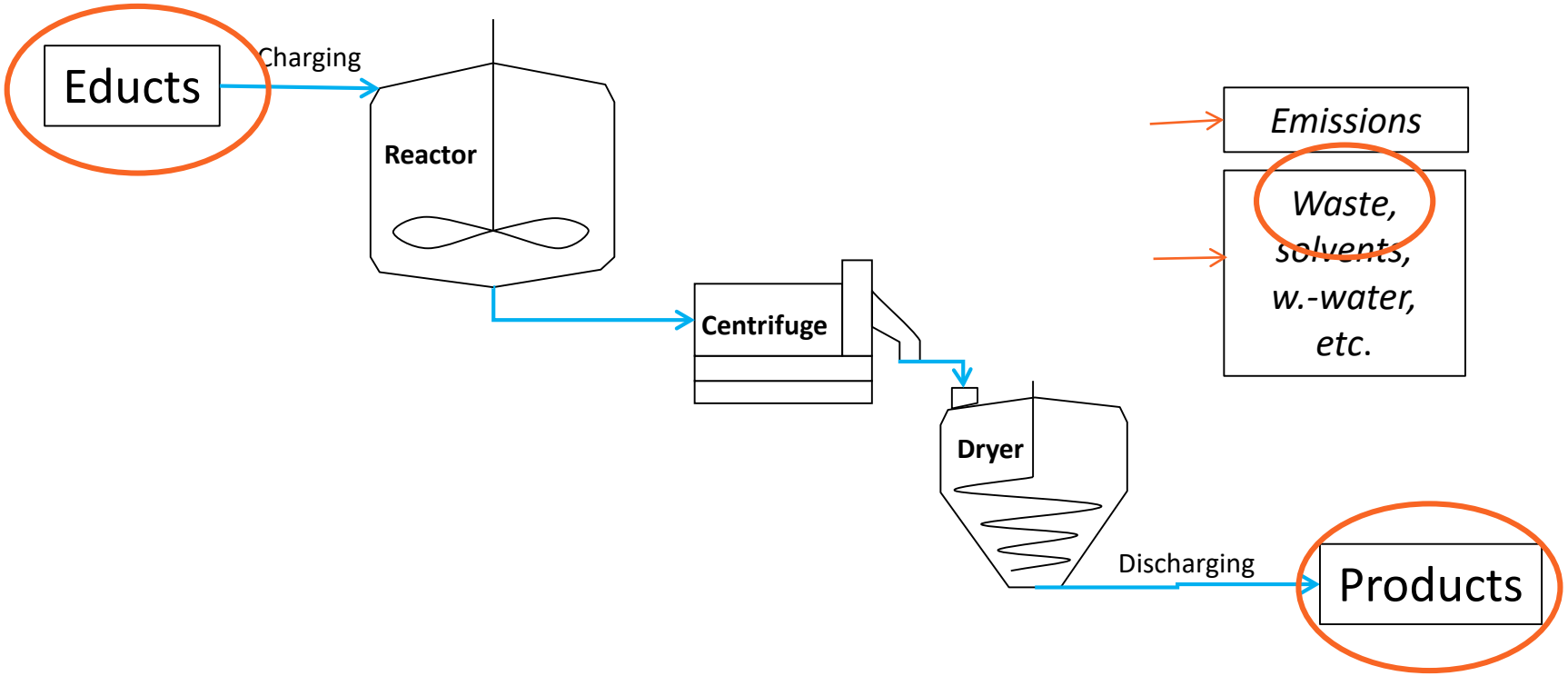
→ Process Hazard Analysis

Examination of the chemical properties and chemical process safety data together with the technical installation of the plant.

A safe chemical process is always an adequate combination of safe substance handling, known chemical process and adapted equipment.

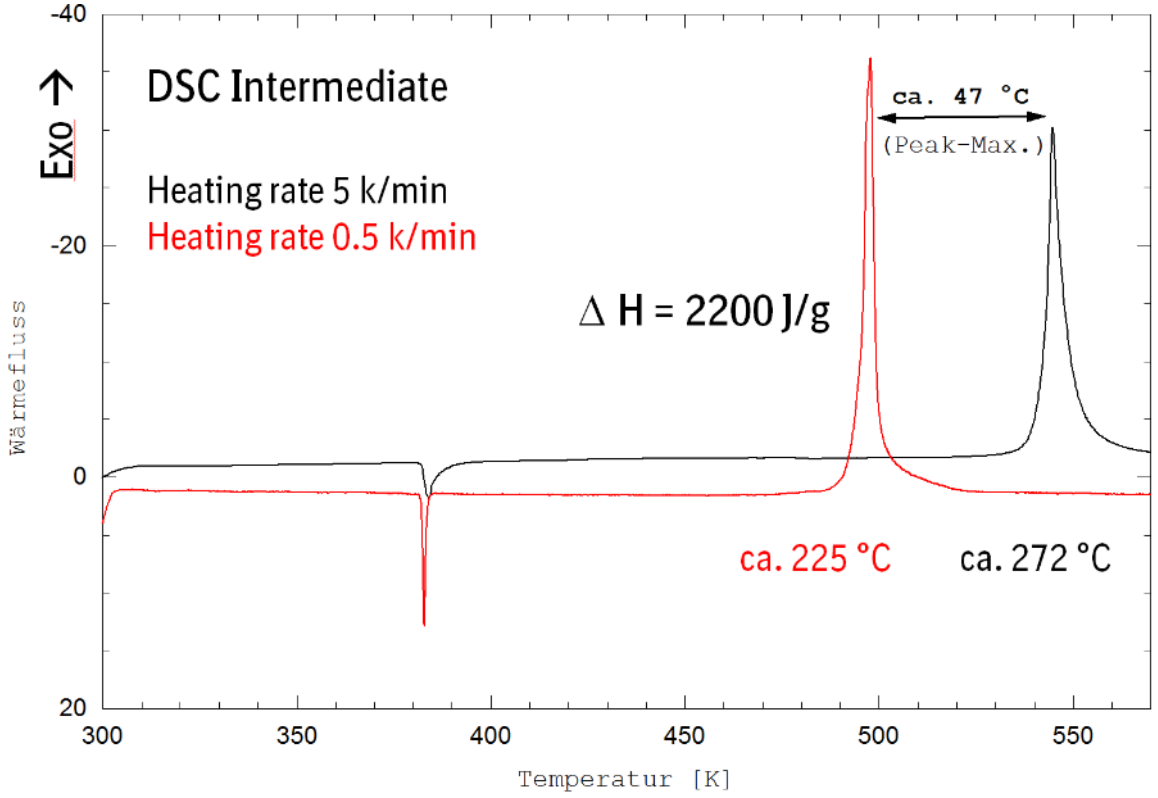
What is necessary for a safe process?

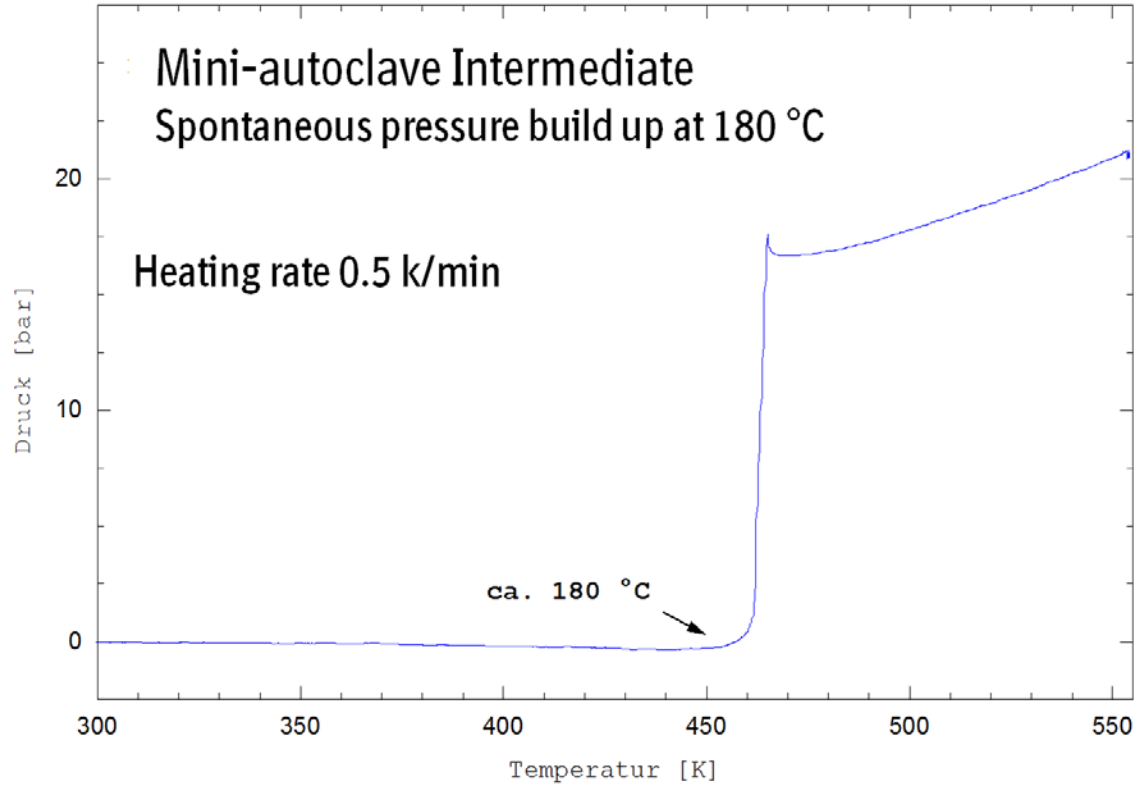
Thermal stability of chemical substances and reaction mixtures



Thermal stability of chemical substances and reaction mixtures

- Thermal stability:
  - Differential Scanning Calorimetry (DSC) or Differential Thermo Analyses (DTA)
- Decomposition test closed vessel (pressure build-up):
  - e.g. in a mini-autoclave





Known hazardous substances

- Typical chemical functions in thermodynamically unstable compounds:

-C≡C-	acetylene and acetylide
$-N_3$	azide and hydrogen azide
$-N{\equiv}N^+$	diazonium salts, triazene, tetrazene
-N=N-	azo compounds
-HN-NH-	hydrazide
>C=N=O	fulminates, oximates
>N-X	halogene nitrogene compounds
$-NO_x$	nitrites, nitrates, nitro- and nitroso compounds
-O-O-	peroxides, peroxy acids, ozonids
$-O-ClO_x$	(per-)chlorate, (hypo-)chlorite

Known highly reactive substances

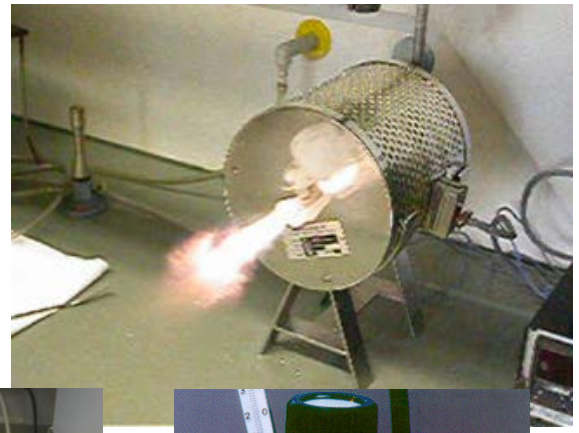
- Typical compounds or chemical functions:

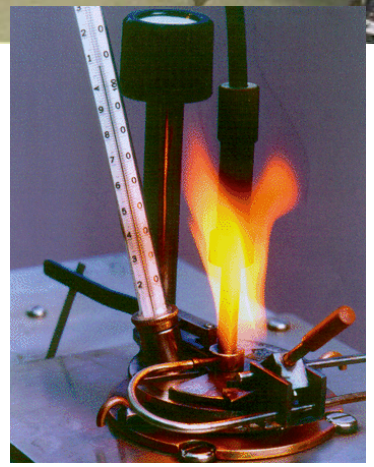
R-Mg-X	Grignard reagents
R-Li	organic lithium compounds
-COCl	acid cloride
-CO-O-OC-	acid anhydride
Na-, K-OR	Sodium-, Potassium alkoholate
$POCl_3$, $SOCL_2$	inorganic anhydride
„H_2SO_4“	conc. acids, lyes
NaH, $LiAlH_4$	hydride
Na, K, Mg, Li …	metals
O_2, H_2	gases
F_2, Cl_2, Br_2	halogen

General handling characteristic of substances

- Additional test for thermal stability
  - Thermogravimetry (TG) or combination TG/DSC; TG/DTA
  - Quasi-adiabatic heat aging in a Dewar flask (or an adiabatic calorimeter)
  - Time Pressure Test

- Flammability of solids or liquids
  - Combustion test
  - Flammability of solids
  - Smoldering temperature; minimum ignition temperature of a dust layer
  - (minimum) dust cloud ignition temperature
  - Ignition temperature of liquids
  - Flash point (of liquids)





General handling characteristic of substances

- Dust explosibility:
  - Dust explosion test
  - Dust explosion characteristics (p_{max}; $(dp/dt)_{max}$; K_{St}; explosion limits
  - Minimum ignition energy (MIE)

- Mechanical sensitivity, further safety characteristics
  - Sensitivity to impact
  - Sensitivity to friction
  - Self-ignition test
  - Conductivity

Details to: Dust stability/explosibility

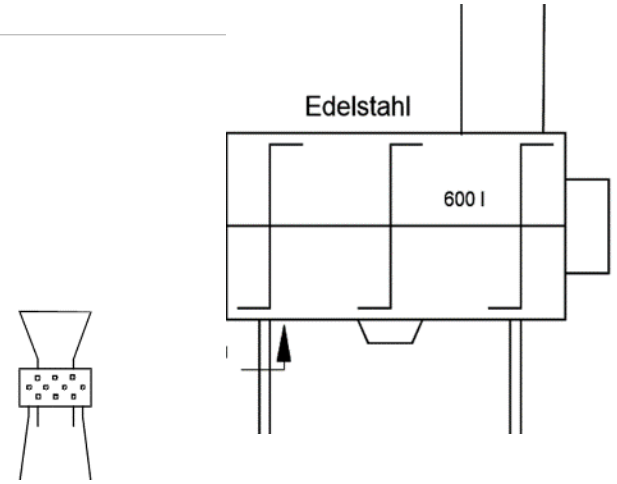
- Mechanical sensitivity: Sensitivity to impact / friction

➢ Important for mechanical actions
(e.g. transport systems, in dryer with agitator, in a pin mill,)
→ maximum temperature & agitation time

- Maximum explosions pressure p_{max}

For most of the organic gases and vapors in mixture with air p_{max} is between 8 bar to 10 bar under initial atmospheric conditions.

➢ Important for e.g. venting pipes/filter units, for mills, dryers („dust containing air“)
→ explosion-resistant design



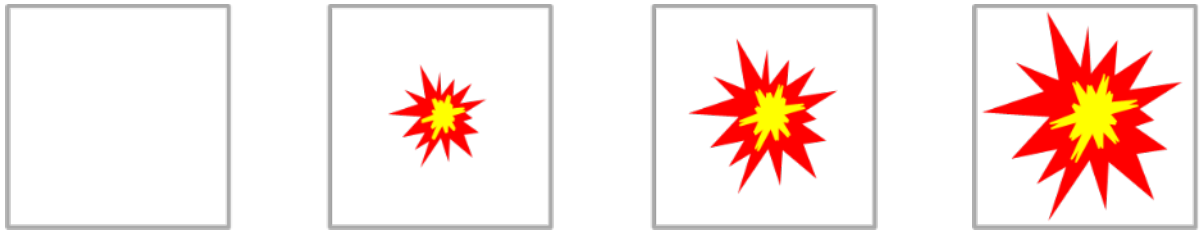
Details to: Flammability of solids or liquids

- Ignition temperature

Auto-ignition temperature (according to EN 14 522)	Temperature class	Maximum surface temperature
> 450 °C	T 1	450 °C
> 300 °C to 450 °C	T 2	300 °C
> 200 °C to 300 °C	T 3	200 °C
> 135 °C to 200 °C	T 4	135 °C
> 100 °C to 135 °C	T 5	100 °C
> 85 °C to 100 °C	T 6	85 °C

Details to: Dust explosibility

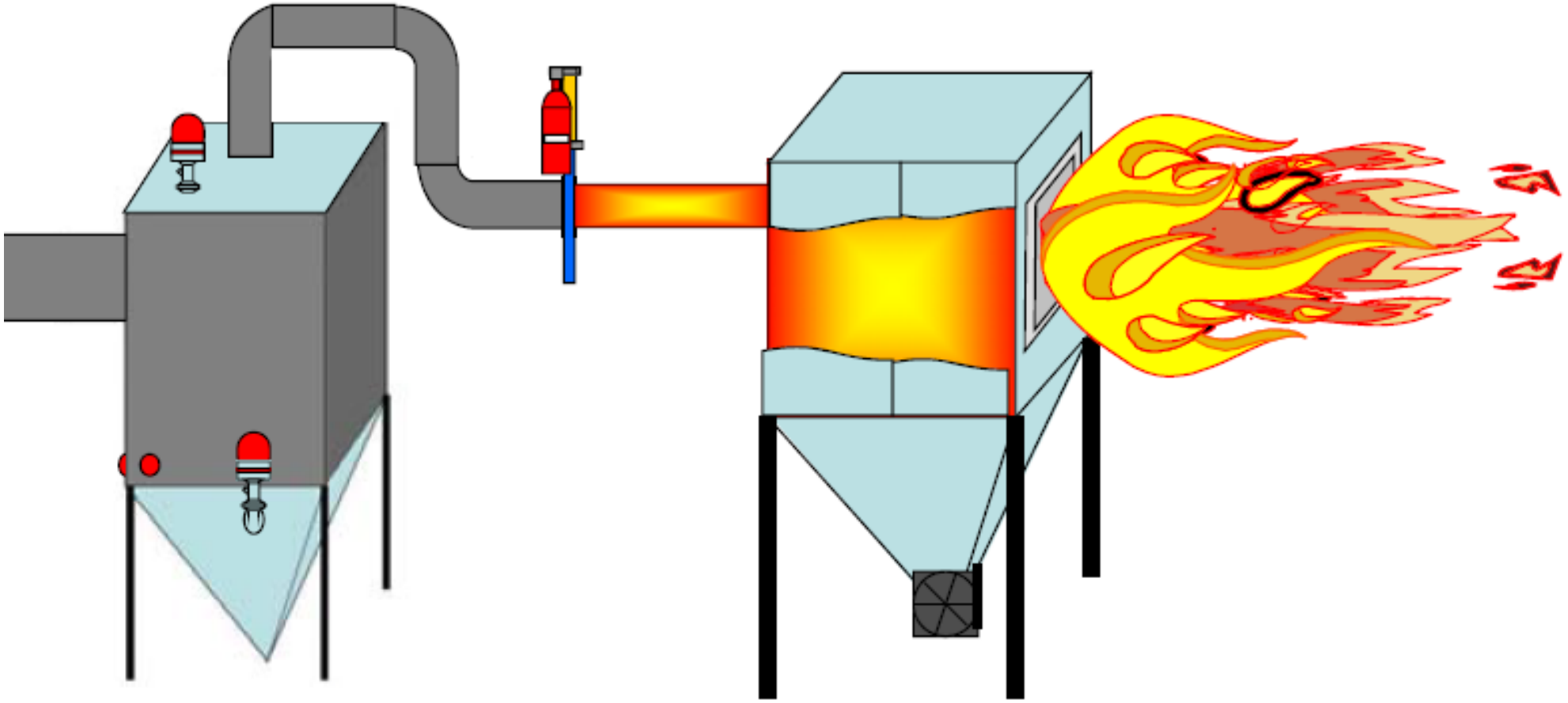
- Maximum explosion pressure rise $(dp/dt)_{max}$ and K_{St}



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

➢ Important for design of “explosion relief“, “explosion suppression” system

Examples of Process Equipment

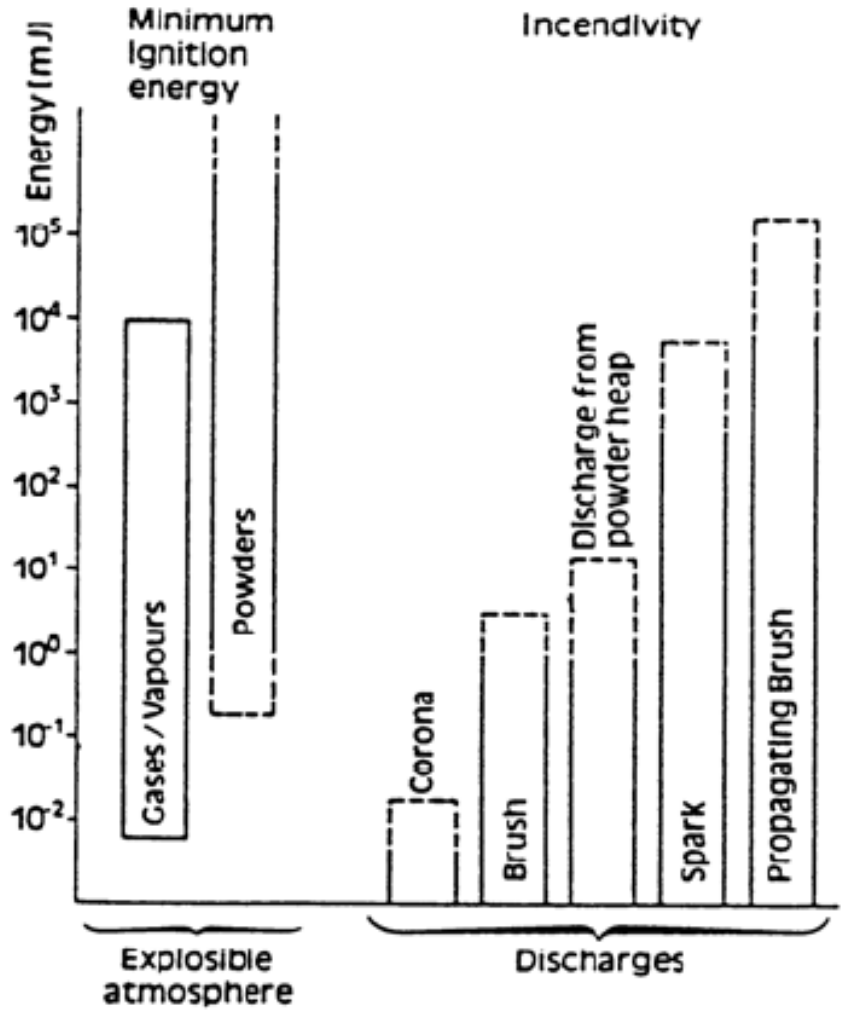


- If the K_{st} is above 300 bar m/s, the valve would not work

Details to: Dust explosibility

- Minimum ignition energy (MIE)

Risk	Substance Name	MIE in air
High risk < 25 mJ	Hydrogen	0.01mJ
	Methanol	0.14 mJ
	n-HeptanE	0.24 mJ
	Acetone	1.15 mJ
	“Normal organic" dust	>10 mJ
	Paracetamol	<10 mJ
Medium risk 25 – 100 mJ	Wheat flour	~50 mJ
	Sugar powder	30-100 mJ
	Coal	30-100 mJ
Low risk >100 mJ	PVC	1500 mJ



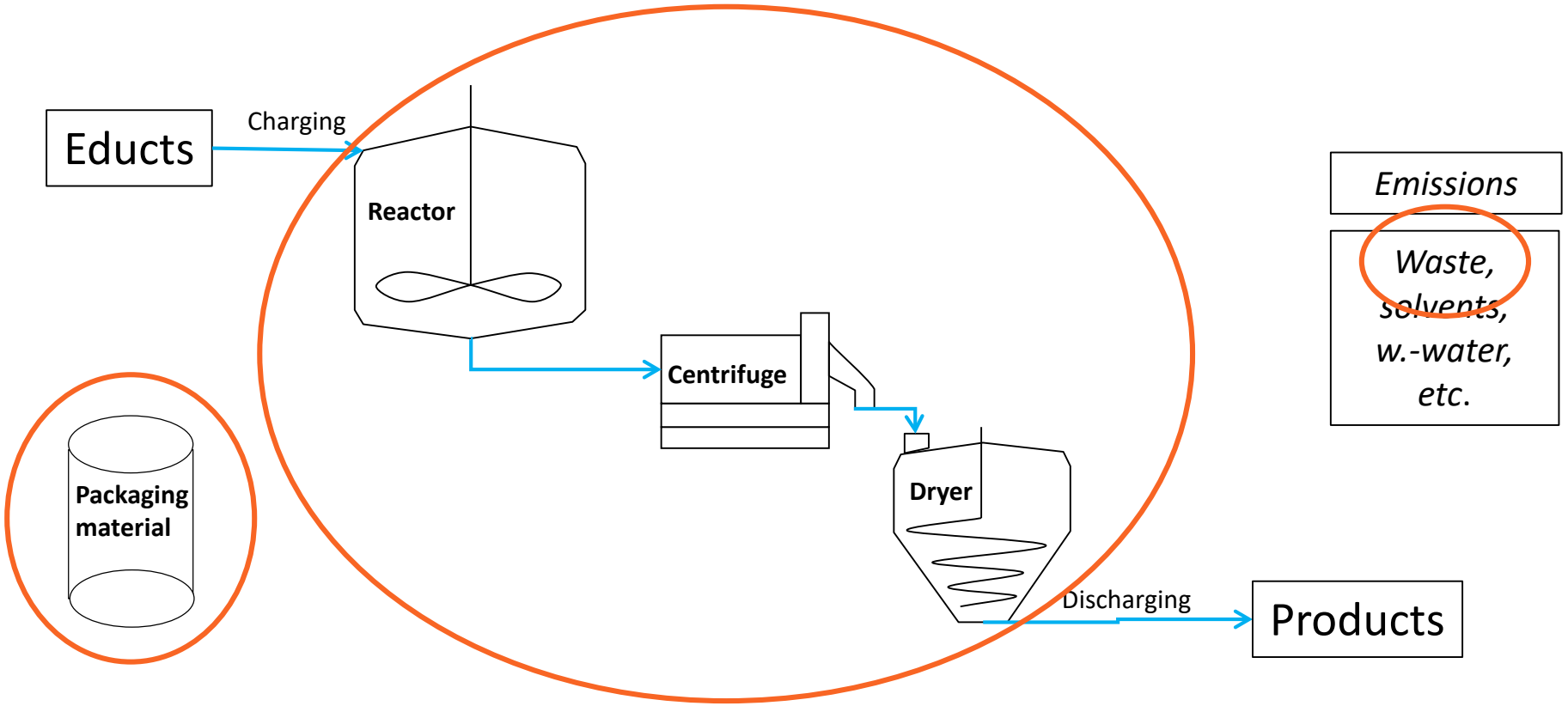
Resulting technical requirements of equipment

Temperatur Class						
Explosion Group	T1 (> 450°C)	T2 (> 300°C)	T3 (> 200°C)	T4 (> 145°C)	T5 (> 100°C)	T6 (> 85°C)
IIA	Acetone Acetic acid Methane Propane Ammonia Benzene Toluene	Fuel Methanol Butan	Hexane Diesel Fuel oil	Acetal-dehyde		
IIB	Hydrogen cyanide	Ethanol Ethane	Hydrogen sulfide			
IIC	Hydrogen					Carbon disulfide

MIE

What is necessary for a safe process?

Critical interaction between the used chemicals and between chemicals and materials



Critical interaction between chemicals and materials

- Incident in a chemical production plant
- Due to an operational error a mixture of thionyl chloride, ethyl acetate and acetyl chloride have to be disposed of. For disposal the worker used the empty thionyl chloride drum. Short time later the drum exploded.

- Result of safety examination in laboratory
- No critical reaction between thionyl chloride, ethyl acetate and acetyl chloride.

- But, the used drum was zinc-coated
  ➔ critical reaction under pressure build-up between ethyl acetate, thionyl chloride and zinc !

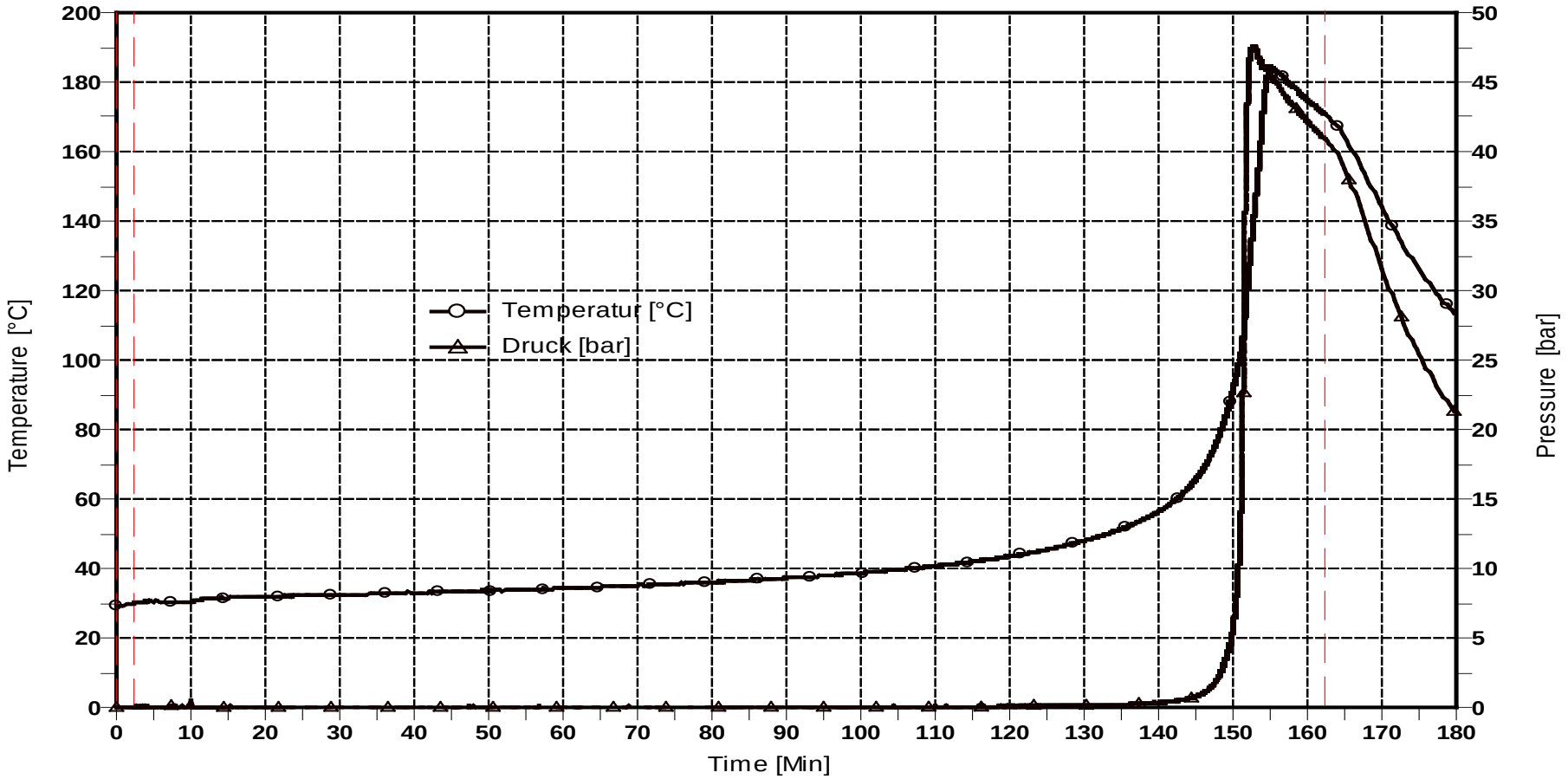
Critical interaction between chemicals and materials

- Incident in a chemical production plant B:
- In a process the excess of $POCl_3$ is distilled off and purged into a 200 l steel drum with a PE-inliner. Approx. 10 h later the drum burst.
- Between the batches the pipes were washed with acetone. Residual quantities of acetone remained in the pipes.

- Result of safety examination in laboratory:
- Retarded critical reaction between acetone and $POCl_3$.

Critical interaction between chemicals and materials

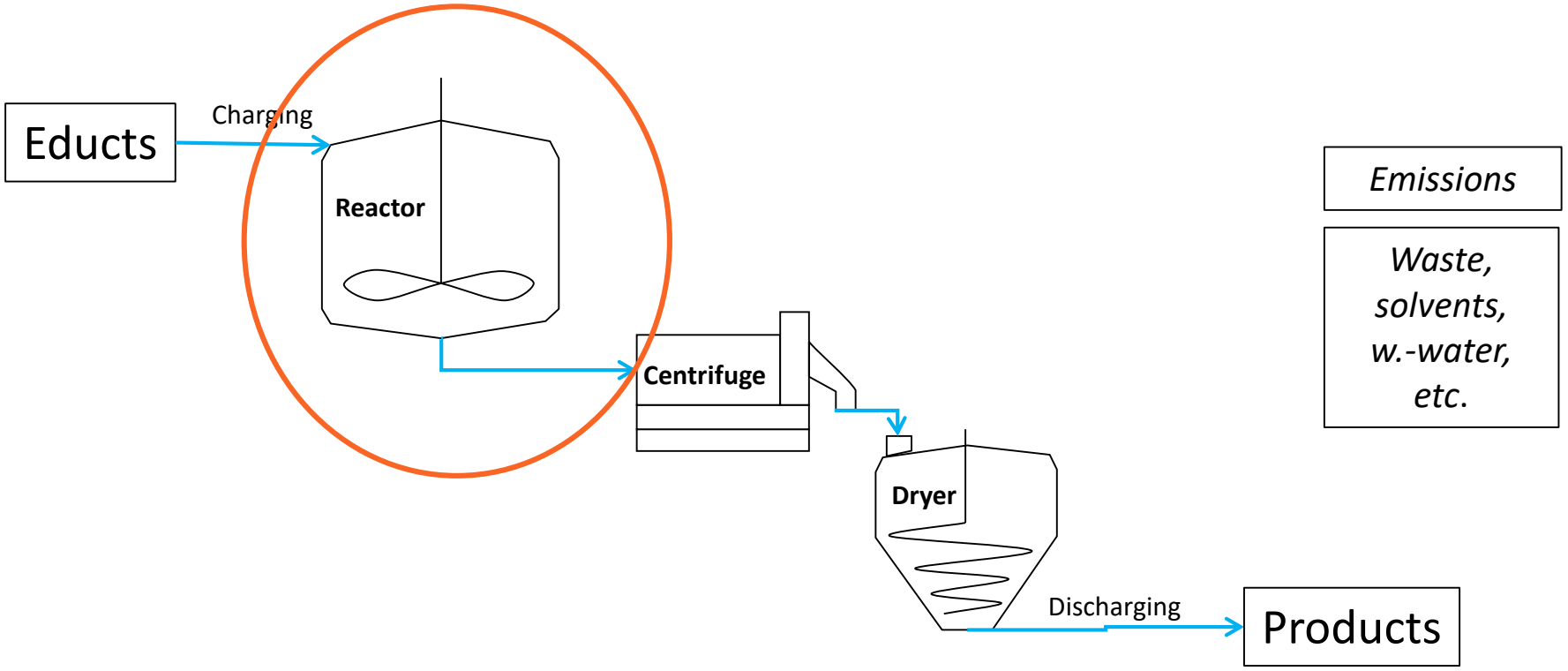
- Reaction experiment
- closed cell test, $POCl_3$ overlay with ca. 5.8 weight-% acetone



What is necessary for a safe process?

Chemistry – chemical reaction

Calorimetric measurements for chemical reactions



Chemistry – chemical reaction

- The chemical reaction should be known, including side reactions and consecutive reaction. The chemical reaction can depend on the reaction temperature or the working procedure.
- Mass balance of the whole reaction is very useful
- Side products can have a big influence on process safety
- Are decomposition reactions known?
- Waste streams can contain highly reactive compounds or unstable substances (e. g. slow gas generation leading to a pressure build up in waste containers)

Working procedure for chemical reaction

- Batch reaction:

All reagents are charged to the reactor.
Then the content is heated to the reaction temperature.

- The accumulation of reaction partners is at the beginning 100 %.
- For an exothermic reaction, if the cooling capacity is not sufficient, an uncontrolled temperature rise occurs and a run away reaction is possible.
- Batch reactions should only be applied with endothermic or very slow reaction with smooth exothermic behavior.

What is in general the best temperature for running a exothermic batch reaction?

The lowest possible reaction temperature is in general the safest temperature!

Working procedure for chemical reaction

- Semi-batch reaction

One reaction compound (including solvent) is charged to the reactor.
The other compound is added over a defined time at the reaction temperature.

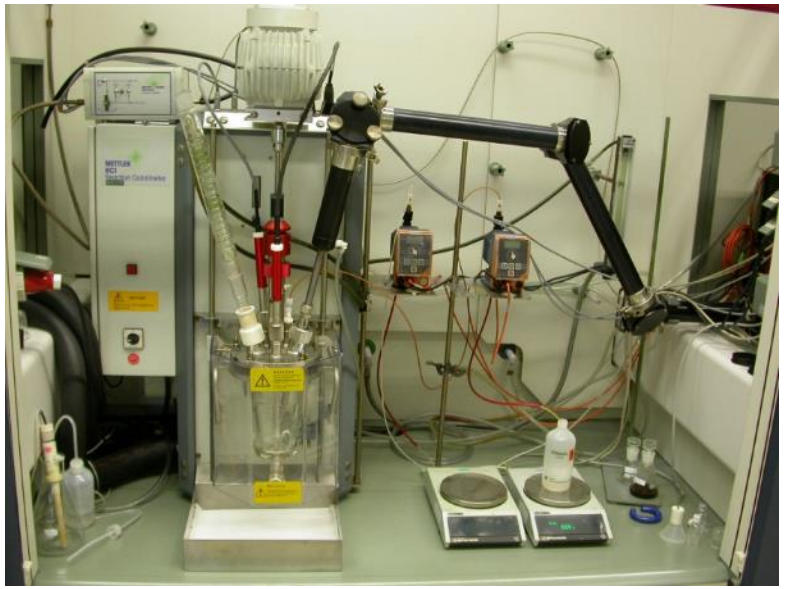
- The accumulation of reaction partners is at the beginning 0 %.
  Across the whole addition time the accumulation should be small.
- Always add the reactive compound.
  (Adding a catalyst or a compound in a huge excess is not a semi-batch process!)
- A stop of the addition stops further heat generation (if low accumulation).

What is in general the best temperature for running a exothermic semi-batch reaction?

The highest possible temperature is the best! -> fast reaction -> less accumulation

Chemical reaction parameters, calorimetric measurements

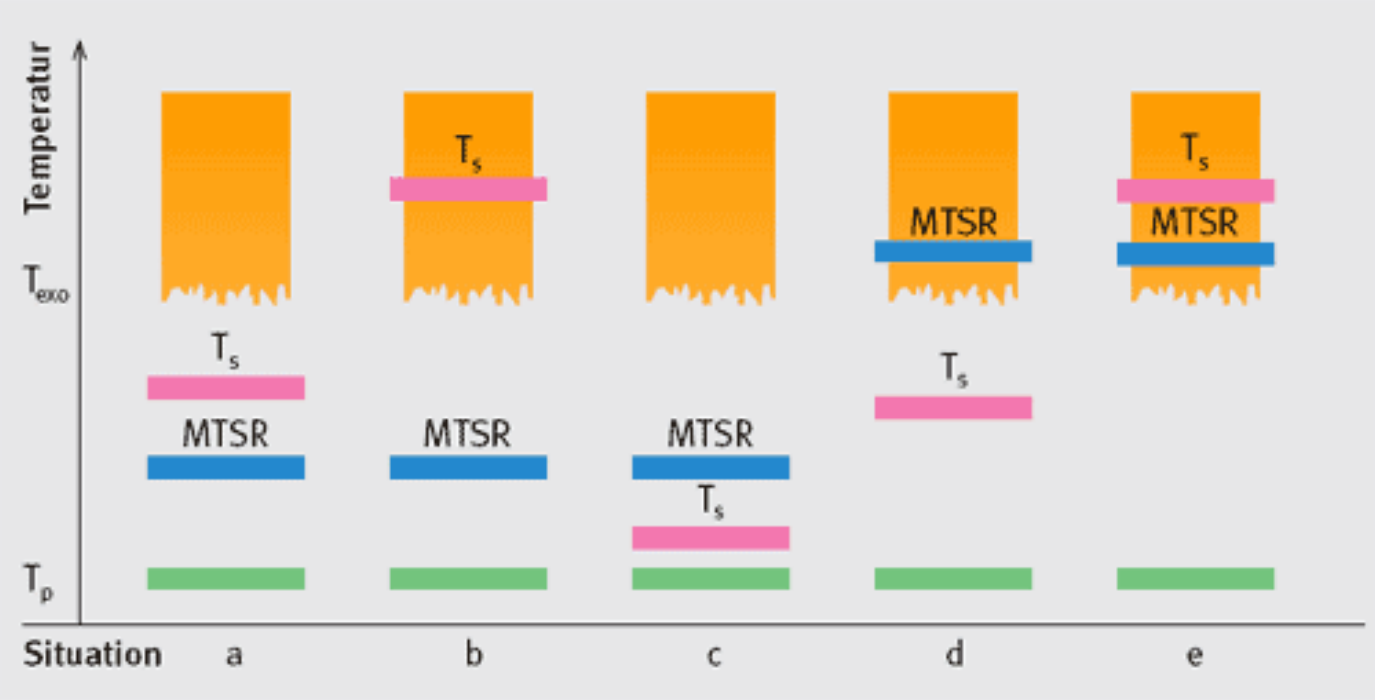
- Safety investigation of reaction under process like conditions:
- Reaction calorimeter (e.g. Mettler RC1) with dosing, gas measurement etc.



- Determination of:
- Heat of reaction ΔH_R [J/g] or [J/mol]
- Heat capacity c_p [J/g K]
- Adiabatic temperature rise ΔT_{ad} [K] or [°C]
- Degree of accumulation [%]
- Gas release [l/min]

- Adiabatic investigation of abnormal operating conditions:
- Determination of thermal stability under adiabatic conditions (no heat exchange, like DTA)

Thermal hazard potential of chemical reactions



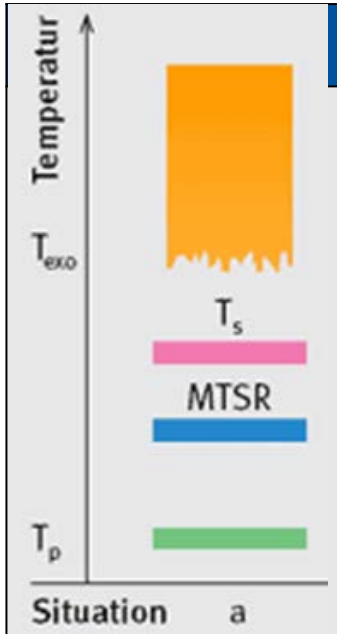
T_p : process temperature at the start of the deviation

MTSR: maximum temperature of the synthesis reaction; $MTSR = T_p + \Delta T_{ad} \cdot \alpha_{accu}$

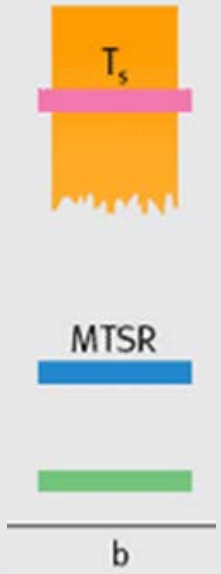
T_{exo}: the maximum temperature at which a substance or reaction mixture can just be handled safely

T_s: (=T_b) the boiling point in an open system

Thermal hazard potential of chemical reactions

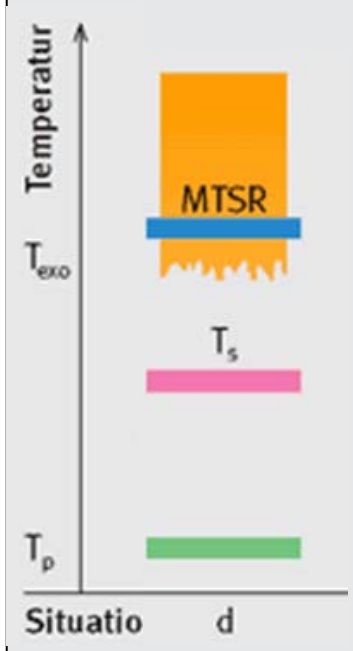


Description - criticality
The boiling point of the mixture and the maximum reaction temperature stay below T_{exo}. Such processes may be regarded as inherently safe with respect to the process deviation evaluated.

Case	Description - criticality
	Absence of the boiling point barrier, but maximum reaction temperature below T_{exo}. The process may be regarded as safe.

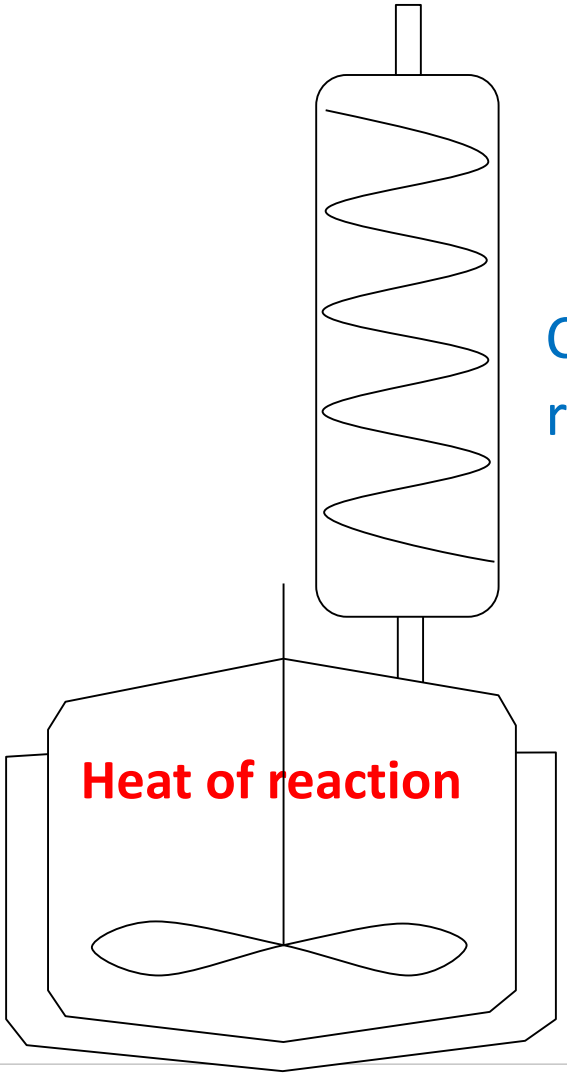
Case	Description - criticality
	The boiling point with its latent heat of evaporation may be considered as a safety barrier (adquate condenser!) In a closed system, the reactor must be designed for the maximum expected overpressure or be equipped with a pressure relief device. It would be better to reduce the accumulation so that the boiling point could not be reached.

Thermal hazard potential of chemical reactions

Case	Description - criticality
	It must be evaluated if the evaporation capacity provides sufficient safety. If not, additional organizational or technical measures have to be implemented. If the operation is performed in a closed system, the temperature corresponding to the relief valve's set pressure may not be too high.

Case	Description - criticality
	This case must be rated as problematic. In case of a (simple) cooling failure, the reaction can pass over the safe temperature range. Plant and/or process modifications should be evaluated in such situations.

Temperature control of chemical reaction



Cooling by
reflux condension

Cooling jacket

Heat balance of exothermic reactions

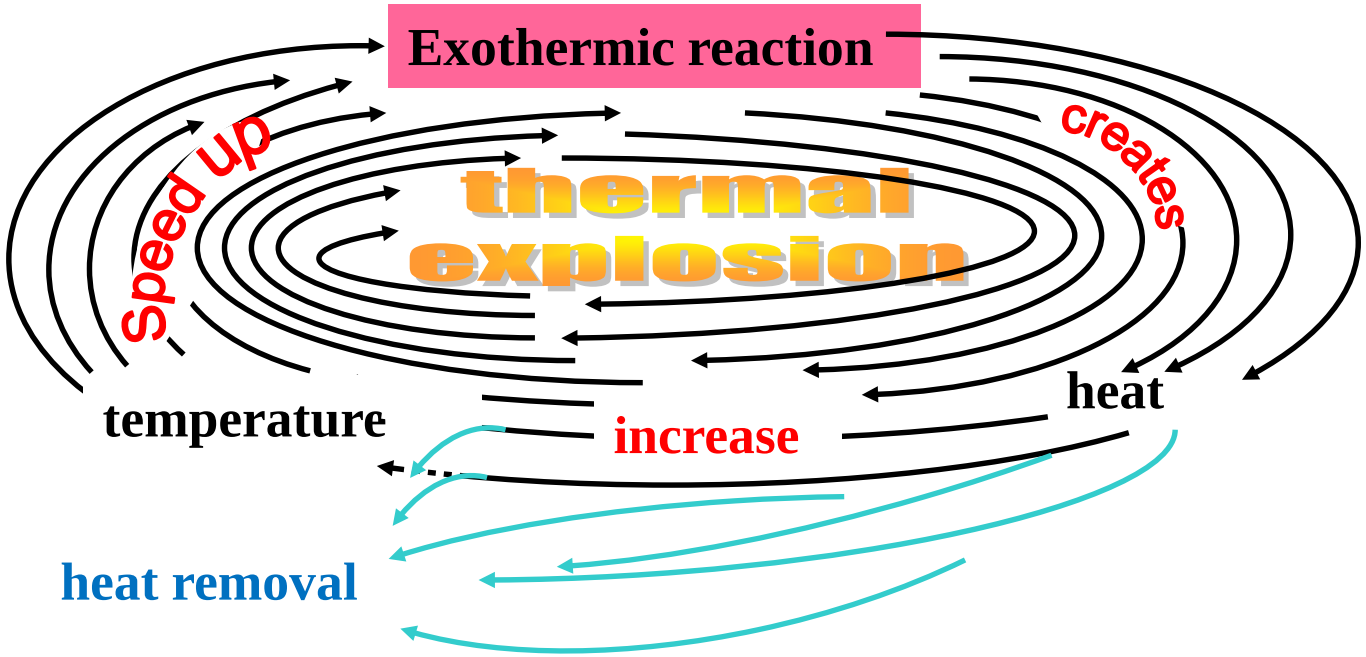
heat production

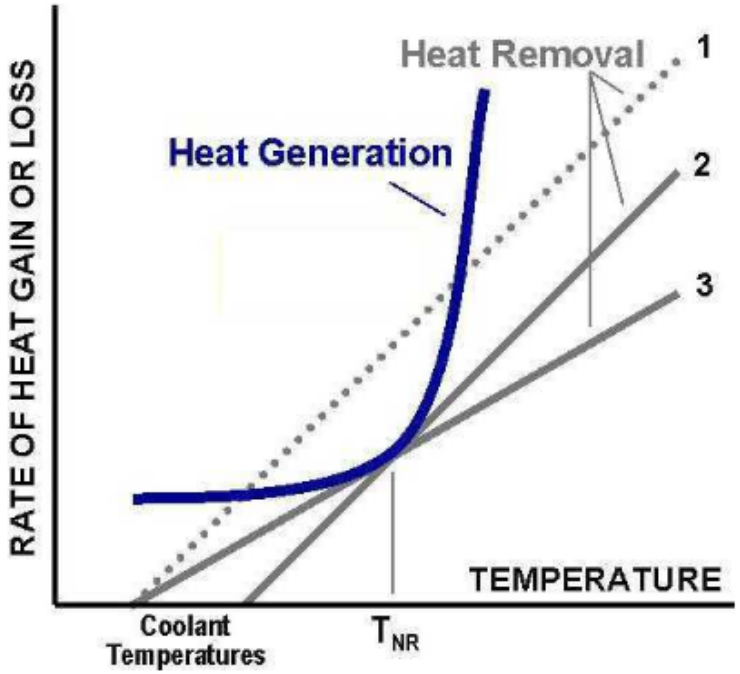
heat removal

Increased heat production	Decreased heat removal
• Additional energy supply (e.g. heating, stirring, pumping) • Higher concentration of reactants (e. g. missing solvent) • Presence of a catalyst (e.g. rust, nonferrous metals) • Initiation of other exothermic processes (e.g. side reaction, decomposition)	• Loss of cooling (e.g. pump failure, solvent evaporated) • Degrade heat transfer (e.g. fouling, adhesion) • Increase of viscosity (e.g. higher degree of polymerization) • Inadequate mixing (e.g. pump failure, solvent evaporated, stirrer failure)

Exothermic and run-away reaction

- An exothermic reaction produces heat which leads to an increase of the reaction temperature if the cooling capacity is not sufficient.
- A runaway reaction is an exothermic chemical process, which leads to uncontrollable reaction conditions due to an uncontrolled rise of the reaction speed.

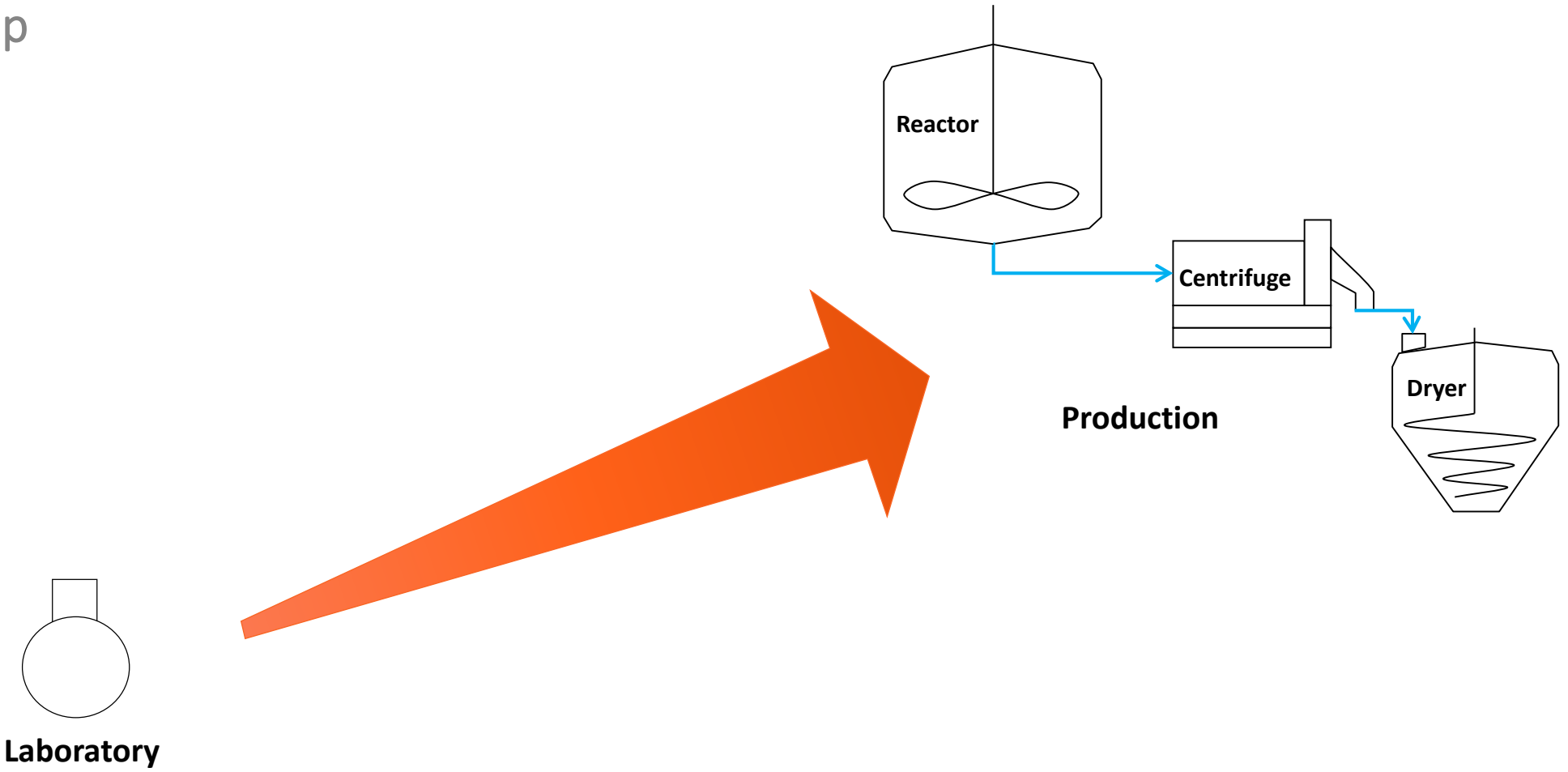




Exothermic reaction and run-away reaction

What is necessary for a safe process?

Scale up



Scale up laboratory → (pilot) plant

- Example of a heat balance change during the scale up

- From laboratory (1 l) to pilot plant (1 m^3).
- Dosing controlled reaction
- Exothermic reaction
- Reaction heat of 360 kJ kg^{-1} (= 0,1 kWh kg^{-1})
- Density of reaction mass is 1 g cm^{-3}
- Reaction temperature 80 °C
- Filling degree is 100 %
- Heat transmission of both apparatus are 500 W m^{-2} K^{-1}
- Effective temperature difference for cooling is 30 K

Scale up – laboratory – (pilot) plant

	Laboratory	Pilot or production plant
Reactor size	1 l	1 m^3
Cooling surface	0,046 m^2	4,4 m^2
Specific cooling power	15 kW m^{-2} (= 500 W m^{-2} K^{-1} * 30 K)	
Cooling power	**0,69 kW** (= 15 kW m^{-2} * 0,046 m^2)	**66 kW** (= 15 kW m^{-2} * 4,4 m^2)
Reaction power with 3 h dosing time	0,03 kW (= 0,1 kWh kg^{-1} * 1 kg /3h) *heating required*	33 kW (= 0,1 kWh kg^{-1} * 1000 kg /3h) cooling sufficient
Reaction power with 2 h dosing time	0,05 kW (= 0,1 kWh kg^{-1} * 1 kg /2h) *no cooling required*	50 kW (= 0,1 kWh kg^{-1} * 1000 kg /2h) cooling sufficient
Reaction power with 1 h dosing time	0,1 kW (= 0,1 kWh kg^{-1} * 1 kg /2h) cooling sufficient	**100 kW** (= 0,1 kWh kg^{-1} * 1000 kg /1h) **cooling insufficient**

Factor 1000

Factor ~100

Factor ~100

Expectation of an EHS auditor

R&D → scale up → production

Amounts of substances	Location	Working documents	Guidance documents
miligrams to grams	Research & Development Laboratory	- Lab documentation - First observations to process safety	- Policy „Safe Research & Development“ - Lab safety SOPs
grams to kilograms	Transfer from tab to kilolab / pilot plant	- Basic safety report - Transfer report	- Regulation to „Basic safety examinations“ - Transfer protokoll
kilograms	kilolab / pilot plant	- Batch records - Safety assessments - Process safety examinations	- Guidelines for safety examinations - SOPs to substance handling etc.

Expectation of an EHS auditor

R&D → scale up → production

Amounts of substances	Location	Working documents	Guidance documents
kilograms to tons	Transfer from pilot plant to production	- Transfer report - Risk assessment - Technical measures	- Transfer protokoll - SOP „Risk assessement/ HAZOP“
kilograms to tons	Production plant	- Batch records - Change Control documents - Maintenance of technical installation	- SOP „ CC“ - SOPs „Maintanance“
kilograms to tons	Transfer to other plants	- Transfer report - Risk assessment - Technical measures	- Transfer protokoll

Usefull Links/ Infos

- https://www.bgrci.de/fachwissen-portal/topic-list/hazardous-substances/
- https://downloadcenter.bgrci.de/resource/downloadcenter/downloads/R003e_Gesamtdokument.pdf

Accident Prevention & Insurance Association - data sheets
[BG-Merkblätter R 001-007]

PSCI PHARMACEUTICAL SUPPLY CHAIN INITIATIVE
Building responsible supply chains

PSCI Auditor Training 2019

Runaway Reaction Explosion

(taken from a presentation by Lamy Bao)

PSCI Questionnaire &observations

(Presentation from Dr. Stefan Gries Boehringer Ingelheim Corporate Center, Corp. EHS&S)

Speaker: Mr. Li Liu Boehringer Ingelheim Corporate China. EHS&S

TRAINING STRUCTURE

1. Session 1
- Process safety parameters
- Essential information to chemical processes
- Critical interactions of material
- Exothermic and run-away reaction
- Scale up

2. Session 2
- Runaway reaction
- PSCI Questionnaire & Typical Observations

3. Audience questions & discussions

Investigation Report - Explosion in T-2 Labs

- **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 (≈ 635 kg TNT)**
- **Causes:**
  - **Company did not recognize the worst credible scenario**
  - **No redundancy in cooling system**
  - **Inadequate pressure relief device**

Reaction Hazards - Historical Data of Incidents

(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 – Incidents by Causes

(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%)**

PSCI Questionnaire and Typical observations

Audit Questions Summary – Process Safety

Topic	Question summary
Process Safety	76: Top 3 most hazardous process activities conducted at this facility 77: Process hazard assessment 78: Evaluated the impact of its operation on the community Evaluated the impact from the activities of neighboring businesses 79: Risk assessment for explosion of flammable liquids, vapors, powders, and gases 80: Preventive maintenance of safety relevant equipment. 81: Handling compressed gases safely 82: Bulk chemical handling procedures 83: Safety measures around direct fire equipment (e.g. boiler, incinerators, ovens etc.)

Process Safety - Typical Observations

77	Does the facility perform Process Hazard Assessment (PHA)? *Aim is to identify processes or operations that could present significant risks in case of deviation (exothermic reactions, use of flammable, combustible or toxic materials, processes involving extreme temperatures or pressures).*	… • Collection of process information (process safety data, design information, operating parameters, and equipment specifications) • Hazard evaluations capturing significant risks during process development, preliminary engineering, and upon completion of process design? • Sizing of pressure vessels and relief devices according to appropriate codes and standards? • Flammable storage areas separate from production and well managed?

No safety data for any chemical reaction are available (example: heat of reaction, adiabatic temperature rise, decomposition temperature,…)
The auditee has made some improvement to collect process safety data and to conduct PHA for high sophisticated chemical reaction (nitration, oxidization, hydrogenation etc.) running at site. Nevertheless the interpretation of this data and the transfer into safety measures for the production is not always reliable.
Basic safety data for chemical processes are available from the Development report. However data are archived and in case of changes these data are not any more reconsidered, since there is no systematic approach in place to cover chemical safety data in a change control system.

Process Safety - Typical Observations

Most of the vent pipes coming from safety valves or rupture disks have at least 3 ninety degree angles. Therefore there is no evidence about the pressure profile inside the venting pipe. This leads to back pressure build up in case of activation with a certain risk for pipe bursting.
The reactor where the bromination takes place misses a safety valve or rupture disc respectively. Furthermore the adiabatic reaction heat is not known.
The explosion vent of the fluid bed dryer in the Bromhexine clean rooms is venting into the cleanroom.
In the chemical production building, the venting pipes of the safety valves end close to the floor in the production room. Taking into consideration the highly hazardous nature of the ingredients (e.g. Oleum, CO, SO_3) this may lead to fatal accidents in case of a pressure relief.

Process Safety - Typical Observations

79	Does the facility perform risk assessment related to the explosion of flammable liquids, vapors, powders, and gases in processing operations (including storage, transfer and charging)? Does it include the following steps?	• Assessment of the hazards (Minimum Ignition Energy, Kst classification rating, Impact sensitivity etc.) of the handled combustible dusts and powders • Hazardous area classification (zones according EU-ATEX and Classes according to US-NFPA) … • Installation of special electrical equipment for flammable vapors, gases, combustible dusts, … • Periodic testing of grounding and bonding circuits, lightning arresters, and electrical distribution equipment? • Maintenance/calibration done for critical safety equipment (e.g. sensors, instruments, valves, interlocks, reactors, condenser etc.) at suitable intervals. • Assessment of the hazards due to mechanical ignition sources? • Installation of special electrical equipment for flammable vapors, gases, combustible dusts, and wet areas? • Periodic testing of grounding and bonding circuits, lightning arresters, and electrical distribution equipment? • Maintenance/calibration done for critical safety equipment (e.g. sensors, instruments, valves, interlocks, reactors, condenser etc.) at suitable intervals. • Assessment of the hazards due to mechanical ignition sources?

Process Safety - Typical Observations

Safety data like MIE, St Class etc. are available for most of the finished products (API). No data is available for isolated intermediates. Hence it could not be proven if the Fluid Bed Drying of intermediates can be done safely.
The company has not assessed the hazards (Minimum Ignition Energy, K_{st} classification rating, Impact sensitivity etc.) associated with combustible dusts and powders being handled in various operations at site.
At the installations in the production area stainless steel clamps were installed instead of using copper wires for grounding and bounding. No evidence was provided showing that this type of bounding grounding is as safe and effective as copper wires.

Process Safety - Typical Observations

The Customer product is received in packaging, treated in anti-static agents and the specifications for the finished product require it to be packaged in liners that are treated with anti-static agents. However, the material handled in the intermediate steps is not treated with anti-static agents. Site personnel assume that the minimum ignition energy is low enough to warrant this type of packaging if the incoming and finished product are packaged in anti-static treated liners.
There is no gas detector near the ethanol recovery device at VB1 workshop, no O2 detector at centrifuges which used N2.
In the production plant, grounding points and grounded piping are installed. A detailed SOP for working in Ex-zones is available and trained. But an instruction, how to ground mobile equipment (e.g. solvent drums) is not included in this SOP.
An Ex light in the hydrogenation room was labeled as “Ex ed IIB T4”, which was not the proper type for hydrogen environment.

Process Safety - Typical Observations

80	Describe how the facility ensures preventive maintenance of safety relevant equipment.	• Pressure safety relief valves/rupture disks • Bonding/earthing systems • Mass transfer systems (e.g. piping systems) • Pressurized vessels • Explosion prevention system (e.g., prevention of static electrical discharge) • Is there emergency power supply for relevant equipment?

Anti-static bridge connection of pipes for transporting flammable chemicals is very rusty in Building A-6.
Most of the P+IDs presented during the audit where not up to date. Furthermore the guidelines of ISO14617 regarding the symbols are not followed. P+IDs should always be up to date, showing the "as build" situation to avoid any risk due to mistaken identity of any component of an equipment.

Process Safety - Typical Observations

81	Does the facility provide a means for handling compressed gases safely that includes:	Inspection and approval before acceptance of delivery? Storage in a segregated area designed for compressed gases? Separation or barriers to manage compatibility issues? Gas classification labeling? Regulator, hose and flexible connection inspections?

PSCI Questionnaire

82	Has the facility developed and implemented bulk chemical handling procedures that include:	Not applicable Specific unloading and loading procedures? Identification sampling before unloading? Hose inspection? Fire protection? Spill control measures (dike or bund area)?

Storage of Oxalyl Chloride is done under “normal” conditions (Hyderabad room temperature in the warehouse).
As of the “Tech Pack” information, the storage temperature should not exceed -10°C.
Even if there are some newer SDS available that storage at middle European room temperature range (max. 25°C) might be sufficient, the company could not show evidence that the change of storage conditions was assessed.

The bulk unloading process needs improvement. The unloading area is asphalt but no defined retaining volume in case of any spillage is provided.

Process Safety - Typical Observations

83	What are the safety measures around direct fire equipment (e. g. boiler, incinerators, ovens etc.)? *Consider gas accumulation, steam overpressure...*	

In the Building B, Water For Injection (WFI) system, the clean steam generator operates at 65 psig with a safety relief valve venting directly to the room. In the case of activation, 155°C steam would be released and fill the room.

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About the Secretariat
Carnstone Partners Ltd is an independent management consultancy, specialising in corporate responsibility and sustainability, with a long track record in running industry groups.

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PSCI PHARMACEUTICAL SUPPLY CHAIN INITIATIVE
Building responsible supply chains

Chemical Process Safety: Which parameters are important to perform a chemical reaction in a safe way?

Dr. Daniel Rehm
HSE Advisor Elanco External Manufacturing EMEA & API
由Daniel Rehm博士来演讲
HSE顾问，礼来动物保健外部制造，欧洲 & 原料药

Bio

- Daniel is HSE Advisor in the Elanco External Manufacturing EMEA & API Hub Basel, Switzerland
- PhD in Chemistry from Humboldt University in Berlin, Germany with 19 years of experience in Chemical Industry, Insurance and Pharmaceutical Industry. Functional experience in Process Development, HSE, Engineering and Manufacturing
- Working in Elanco for 3.5 year.
- Additional qualification as Fire Protection Manager CFPA-E

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AGENDA 大纲

Session 1

Session 2

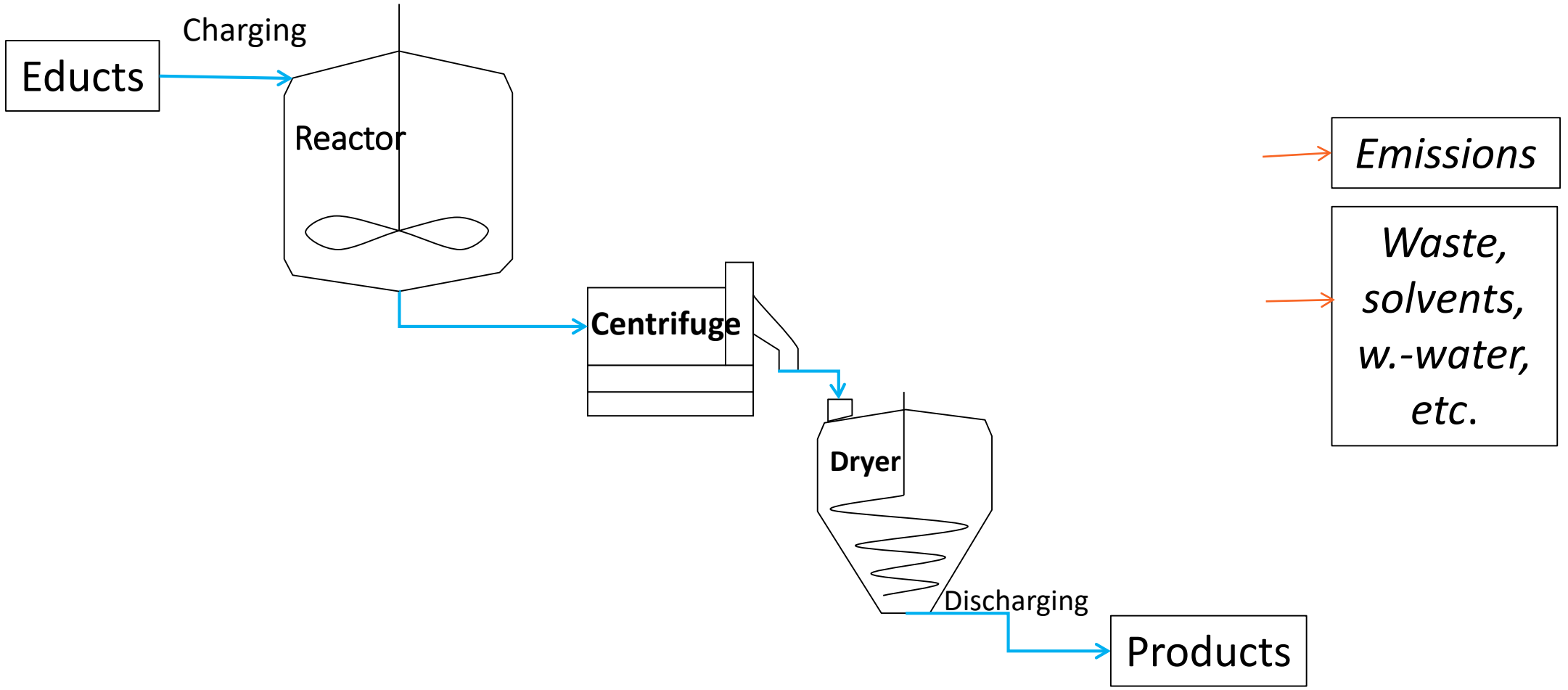
TRAINING STRUCTURE

1. Session 1
   - Process safety parameters
   - Essential information to chemical processes
   - Critical interactions of material
   - Exothermic and run-away reaction
   - Scale up

2. Session 2
   - Runaway reaction
   - PSCI Questionnaire & Typical Observations

3. Audience questions & discussions

Chemical reaction in a production plant



Which information is necessary for a safe process?

- Knowledge about the used chemicals regarding thermal stability, physical safety parameters and toxicology
  - Educts
  - Products (incl. side products)
  - Reagents
  - Solvents & Auxiliaries

- Knowledge about the chemistry
  - Main reaction and side reactions
  - Waste streams (gas release, liquids and solids)
  - Consecutive reaction, decomposition?

- Reaction type
  - Batch reaction
  - Semi-batch reaction
  - Continuous flow reaction

What is necessary for a safe process?

- Calorimetric data of the chemical reaction
  - Adiabatic temperature rise
  - Gas evolution rate (→ reactor venting sufficiant?)
  - precipitation of solids (→ reduction of heat transfer, stirrer blocking?)
  - Accumulation of reactants, thermal output/time
  - Stability of reaction mixtures, distillation residues, etc.
  - Potential for runaway reaction, abnormal operating conditions
  - If necessary: investigation of the runaway reaction

- Knowledge about critical interaction between the used chemicals and other material
  - Material resistance of reactor & other equipment
  - Possible material contact (e.g. media supply)

What is necessary for a safe process?

- Plant equipment “state of the art”
  - Materials of the equipment = > material tests, corrosive data, etc.
  - Inertisation of equipment
  - Earthing of the equipment, explosion-proof equipment
  - Blow-down system, pressure relief valve, rupture disc,
  - Heating and cooling medium & capacity
  - Safety concept e. g. for electrical shut down

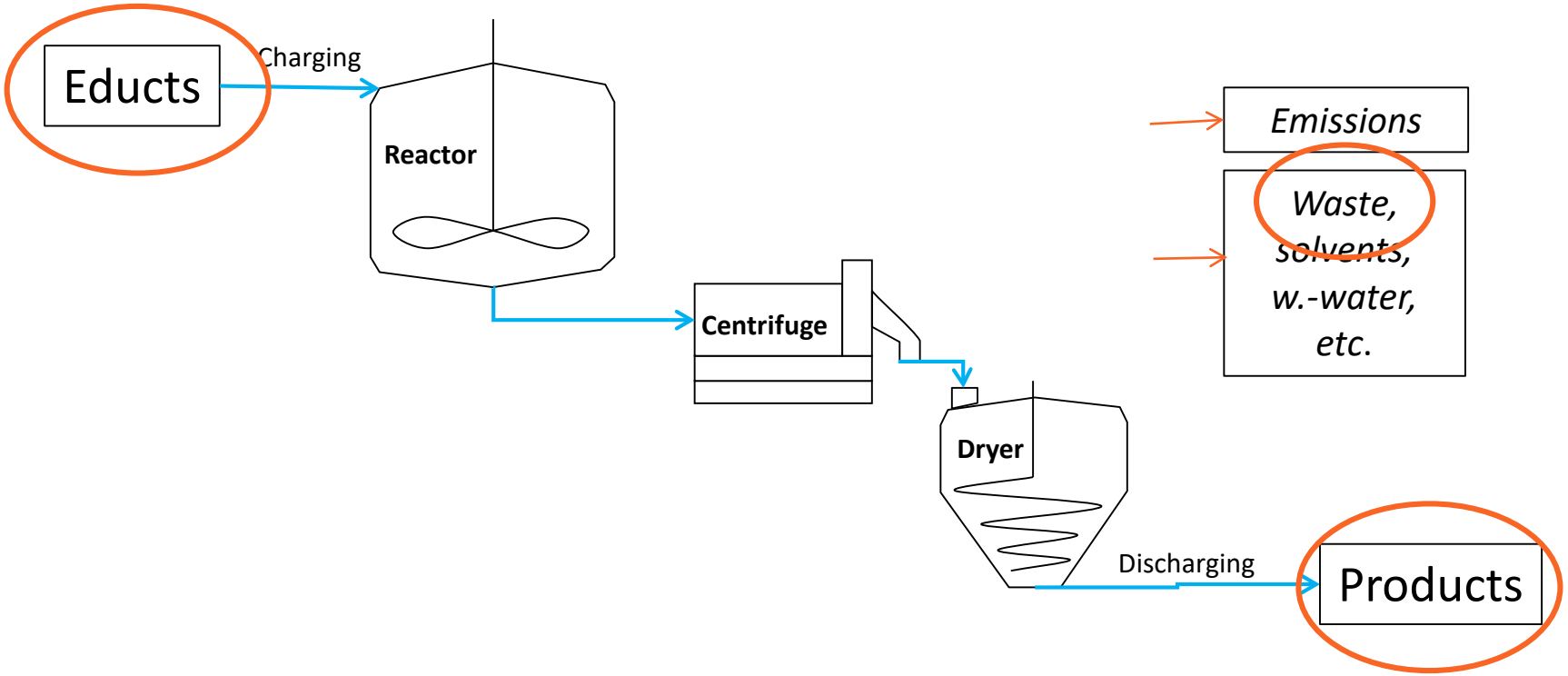
→ Process Hazard Analysis

Examination of the chemical properties and chemical process safety data together with the technical installation of the plant.

A safe chemical process is always an adequate combination of safe substance handling, known chemical process and adapted equipment.

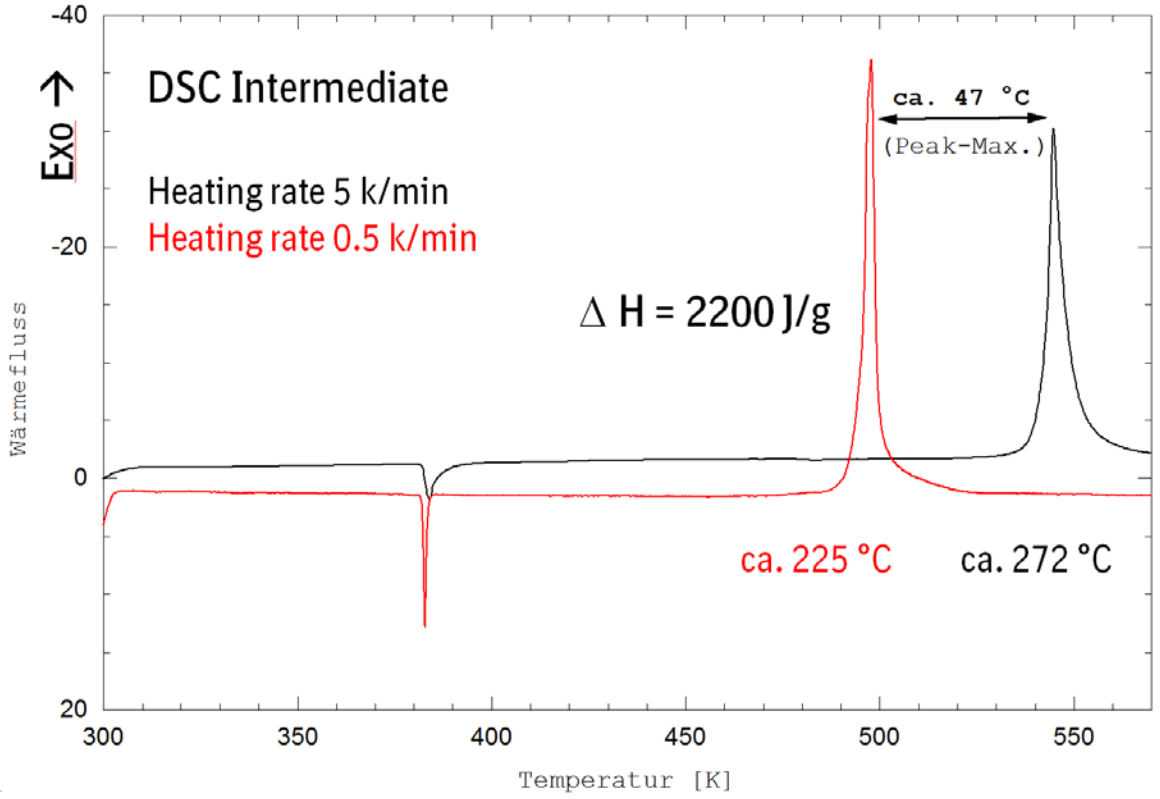
What is necessary for a safe process?

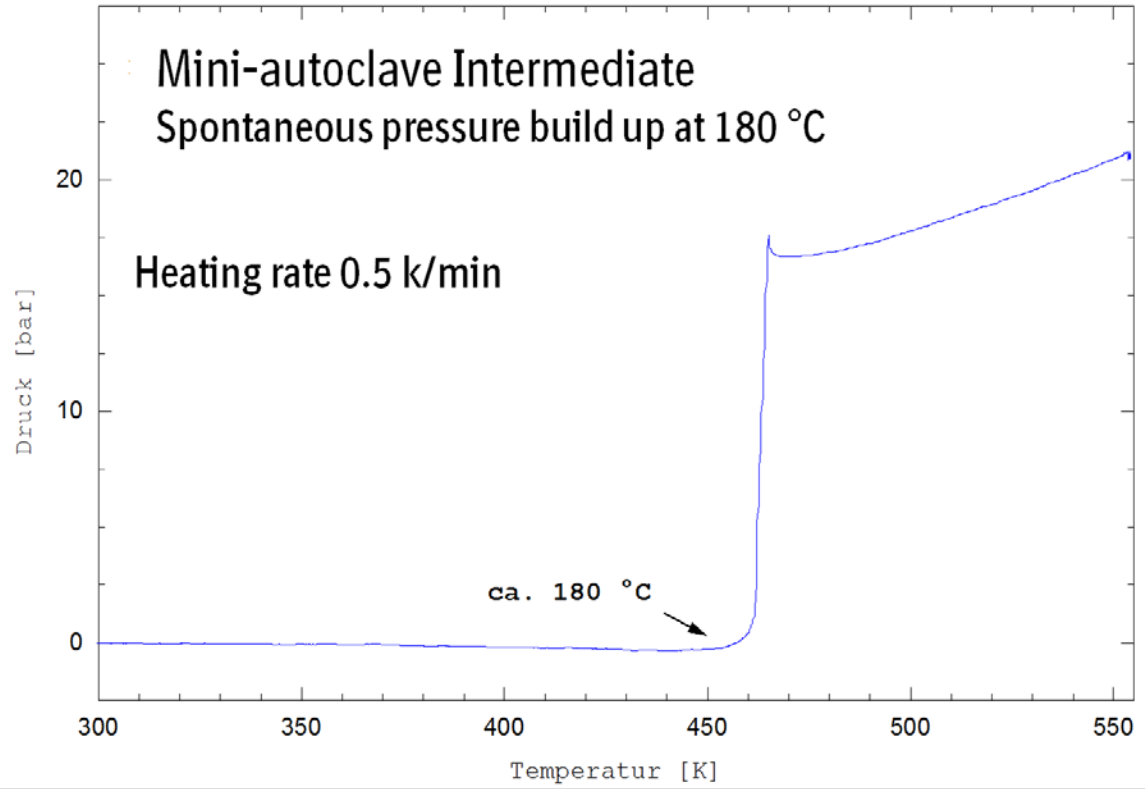
Thermal stability of chemical substances and reaction mixtures



Thermal stability of chemical substances and reaction mixtures

- Thermal stability:
  - Differential Scanning Calorimetry (DSC) or Differential Thermo Analyses (DTA)
- **Decomposition** test closed vessel (pressure build-up):
  - e.g. in a mini-autoclave





Known hazardous substances

- Typical chemical functions in thermodynamically unstable compounds:

-C≡C-	acetylene and acetylide
$-N_3$	azide and hydrogen azide
$-N{\equiv}N^+$	diazonium salts, triazene, tetrazene
-N=N-	azo compounds
-HN-NH-	hydrazide
>C=N=O	fulminates, oximates
>N-X	halogene nitrogene compounds
$-NO_x$	nitrites, nitrates, nitro- and nitroso compounds
-O-O-	peroxides, peroxy acids, ozonids
$-O-ClO_x$	(per-)chlorate, (hypo-)chlorite

Known highly reactive substances

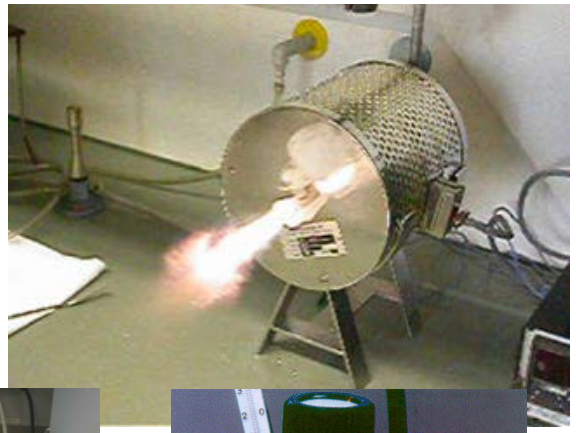
- Typical compounds or chemical functions:

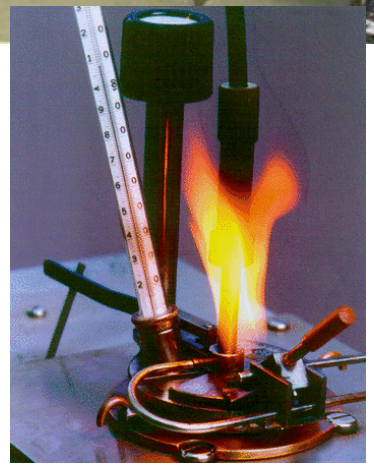
R-Mg-X	Grignard reagents
R-Li	organic lithium compounds
-COCl	acid cloride
-CO-O-OC-	acid anhydride
Na-, K-OR	Sodium-, Potassium alkoholate
$POCl_3$, $SOCL_2$	inorganic anhydride
„H_2SO_4“	conc. acids, lyes
NaH, $LiAlH_4$	hydride
Na, K, Mg, Li …	metals
O_2, H_2	gases
F_2, Cl_2, Br_2	halogen

General handling characteristic of substances

- Additional test for thermal stability
  - Thermogravimetry (TG) or combination TG/DSC; TG/DTA
  - Quasi-adiabatic heat aging in a Dewar flask (or an adiabatic calorimeter)
  - Time Pressure Test

- Flammability of solids or liquids
  - Combustion test
  - Flammability of solids
  - Smoldering temperature; minimum ignition temperature of a dust layer
  - (minimum) dust cloud ignition temperature
  - Ignition temperature of liquids
  - Flash point (of liquids)





General handling characteristic of substances

- Dust explosibility:
  - Dust explosion test
  - Dust explosion characteristics (pmax; (dp/dt)max; KSt; explosion limits
  - Minimum ignition energy (MIE)

- Mechanical sensitivity, further safety characteristics
  - Sensitivity to impact
  - Sensitivity to friction
  - Self-ignition test
  - Conductivity

Details to: Dust stability/explosibility

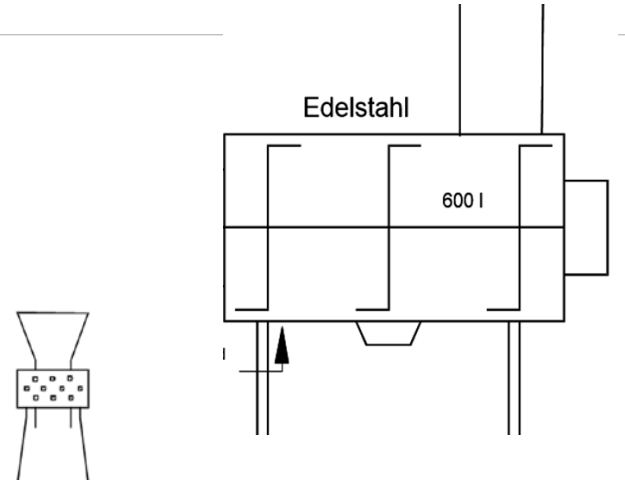
- Mechanical sensitivity: Sensitivity to impact / friction

➢ Important for mechanical actions
(e.g. transport systems, in dryer with agitator, in a pin mill,)
→ maximum temperature & agitation time

- Maximum explosions pressure p_{max}

For most of the organic gases and vapors in mixture with air p_{max} is between 8 bar to 10 bar under initial atmospheric conditions.

➢ Important for e.g. venting pipes/filter units, for mills, dryers („dust containing air“)
→ explosion-resistant design



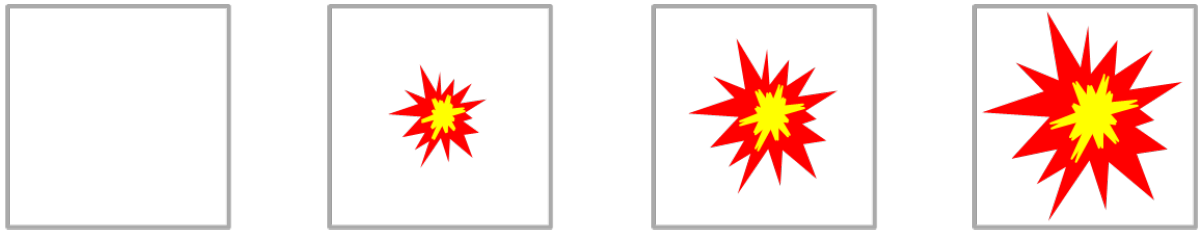
Details to: Flammability of solids or liquids

- Ignition temperature

Auto-ignition temperature (according to EN 14 522)	Temperature class	Maximum surface temperature
> 450 °C	T 1	450 °C
> 300 °C to 450 °C	T 2	300 °C
> 200 °C to 300 °C	T 3	200 °C
> 135 °C to 200 °C	T 4	135 °C
> 100 °C to 135 °C	T 5	100 °C
> 85 °C to 100 °C	T 6	85 °C

Details to: Dust explosibility

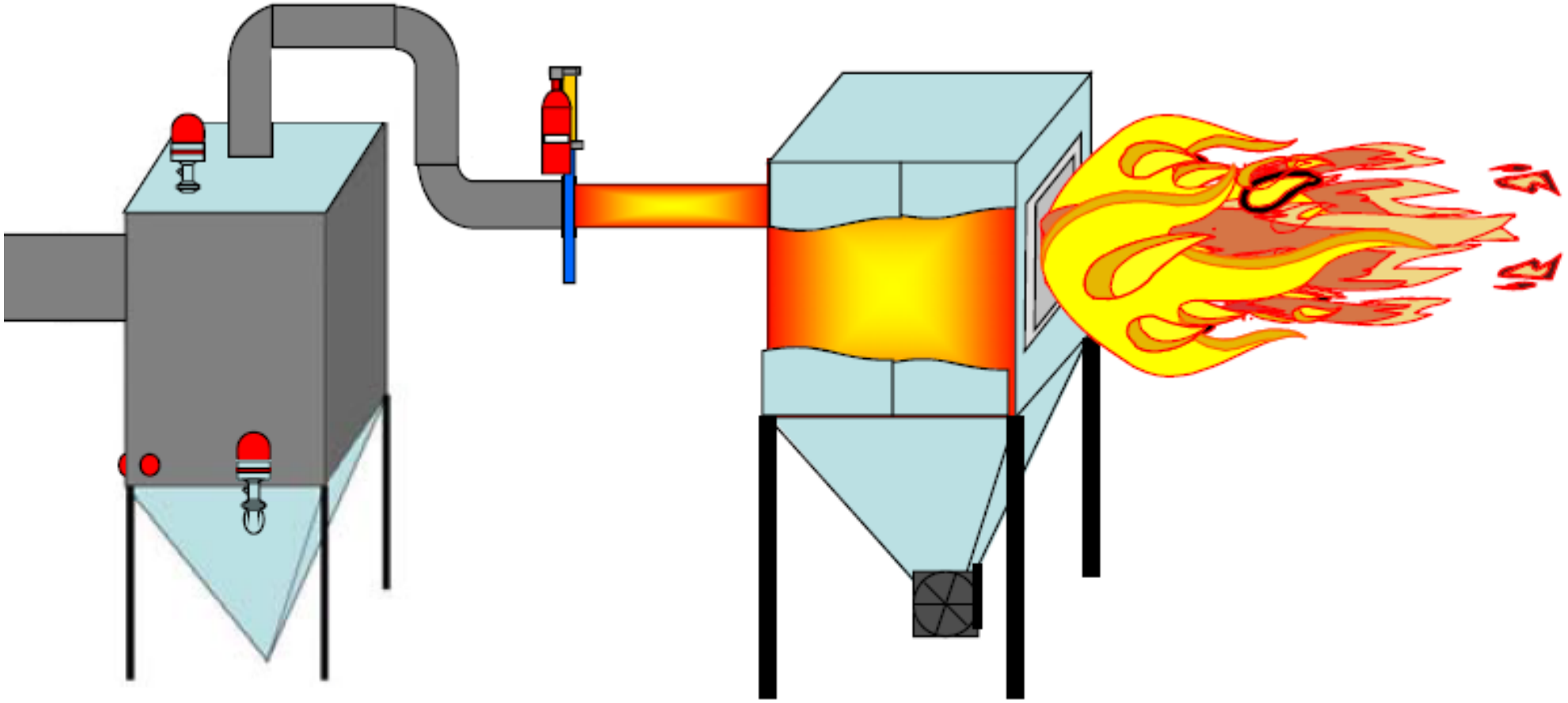
- Maximum explosion pressure rise $(dp/dt)_{max}$ and K_{St}



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

➢ Important for design of “explosion relief“, “explosion suppression” system

Examples of Process Equipment

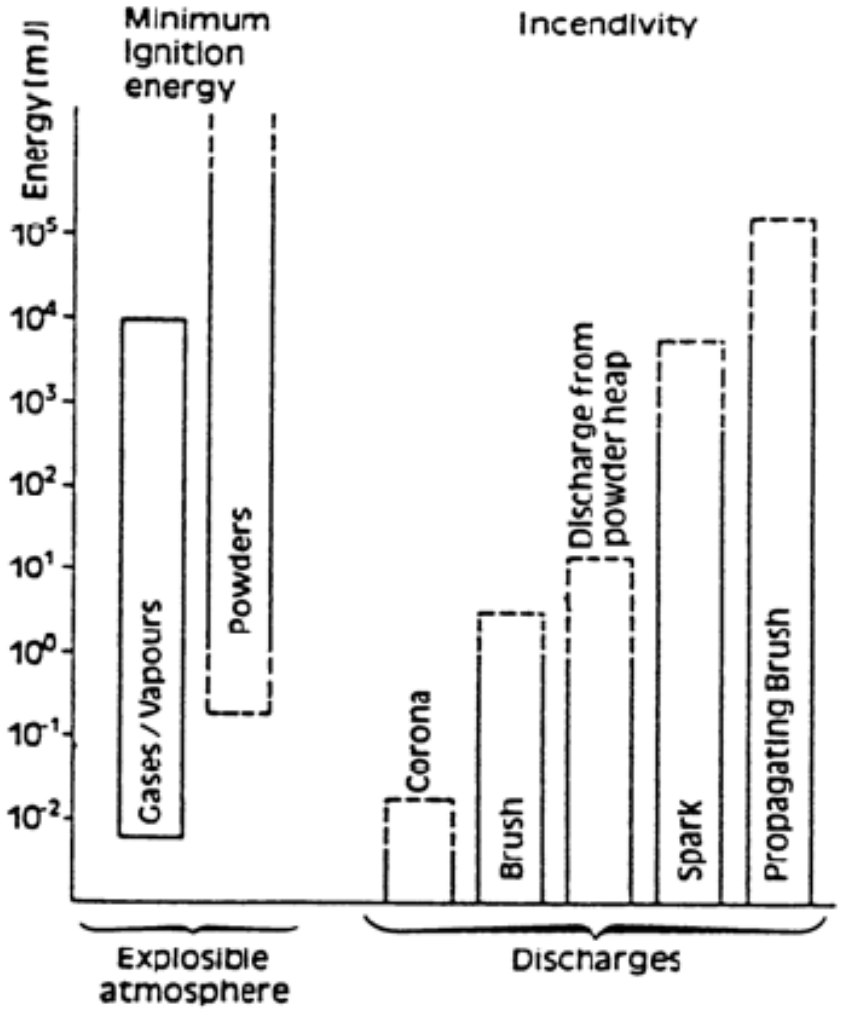


- If the K_{st} is above 300 bar m/s, the valve would not work

Details to: Dust explosibility

- Minimum ignition energy (MIE)

Risk	Substance Name	MIE in air
High risk < 25 mJ	Hydrogen	0.01mJ
	Methanol	0.14 mJ
	n-HeptanE	0.24 mJ
	Acetone	1.15 mJ
	“Normal organic" dust	>10 mJ
	Paracetamol	<10 mJ
Medium risk 25 – 100 mJ	Wheat flour	~50 mJ
	Sugar powder	30-100 mJ
	Coal	30-100 mJ
Low risk >100 mJ	PVC	1500 mJ



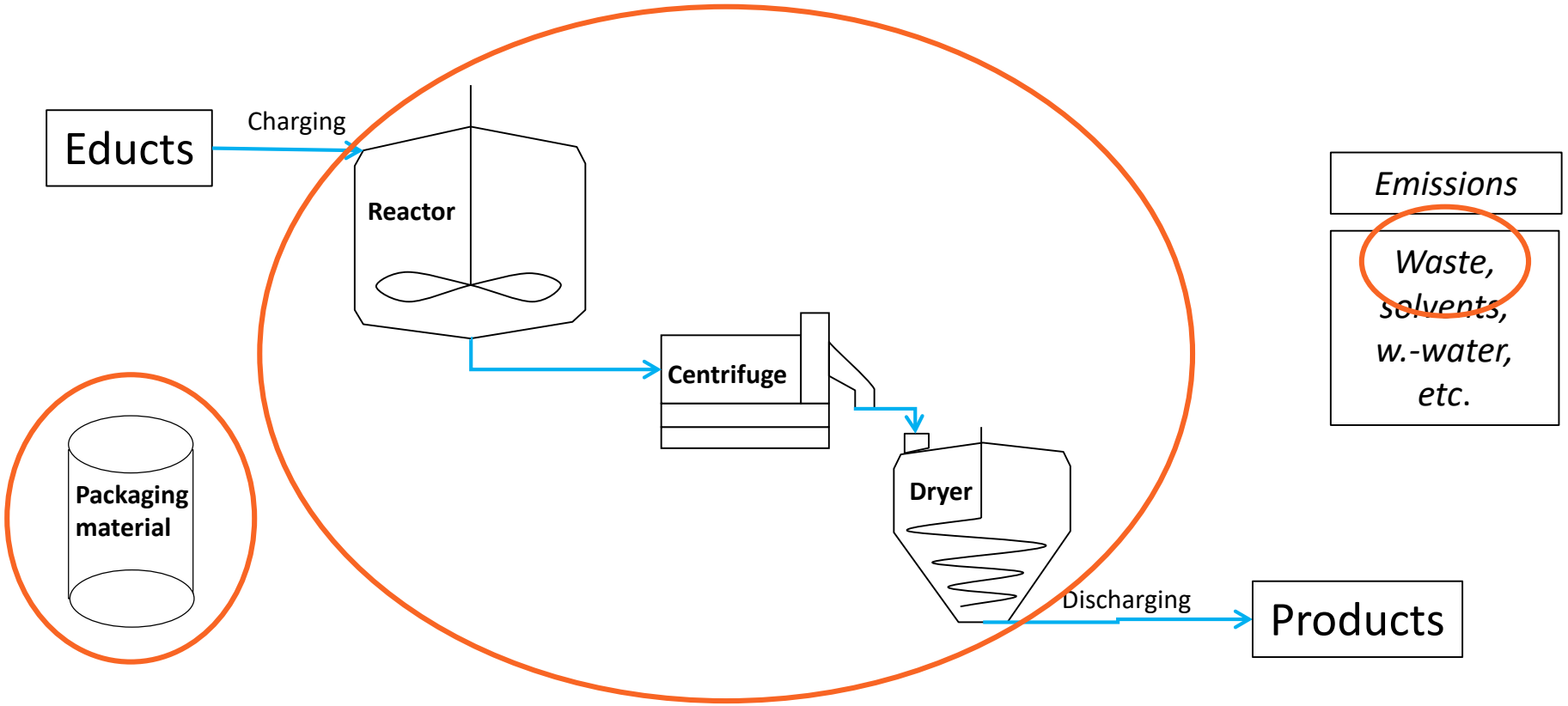
Resulting technical requirements of equipment

Temperatur Class						
Explosion Group	T1 (> 450°C)	T2 (> 300°C)	T3 (> 200°C)	T4 (> 145°C)	T5 (> 100°C)	T6 (> 85°C)
IIA	Acetone Acetic acid Methane Propane Ammonia Benzene Toluene	Fuel Methanol Butan	Hexane Diesel Fuel oil	Acetal-dehyde		
IIB	Hydrogen cyanide	Ethanol Ethane	Hydrogen sulfide			
IIC	Hydrogen					Carbon disulfide

MIE

What is necessary for a safe process?

Critical interaction between the used chemicals and between chemicals and materials



Critical interaction between chemicals and materials

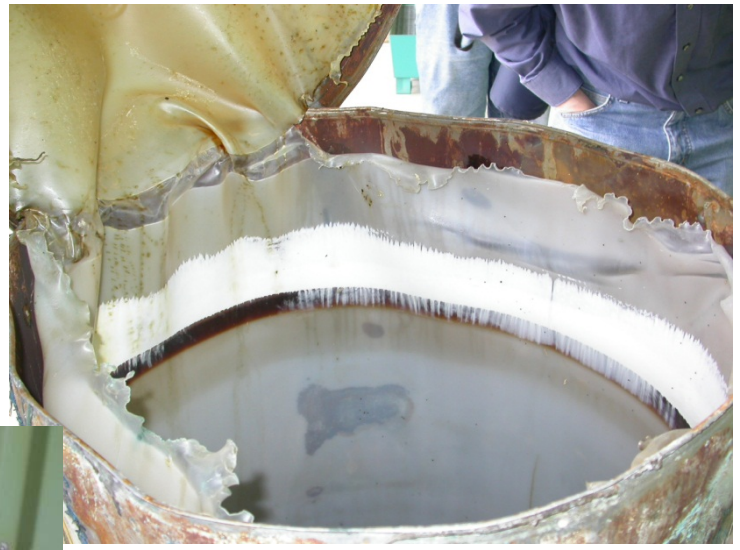
- Incident in a chemical production plant
  - Due to an operational error a mixture of thionyl chloride, ethyl acetate and acetyl chloride have to be disposed of. For disposal the worker used the empty thionyl chloride drum. Short time later the drum exploded

- Result of safety examination in laboratory
  - No critical reaction between thionyl chloride, ethyl acetate and acetyl chloride.

  - But, the used drum was zinc-coated
    ➔ critical reaction under pressure build-up between ethyl acetate, thionyl chloride and zinc !

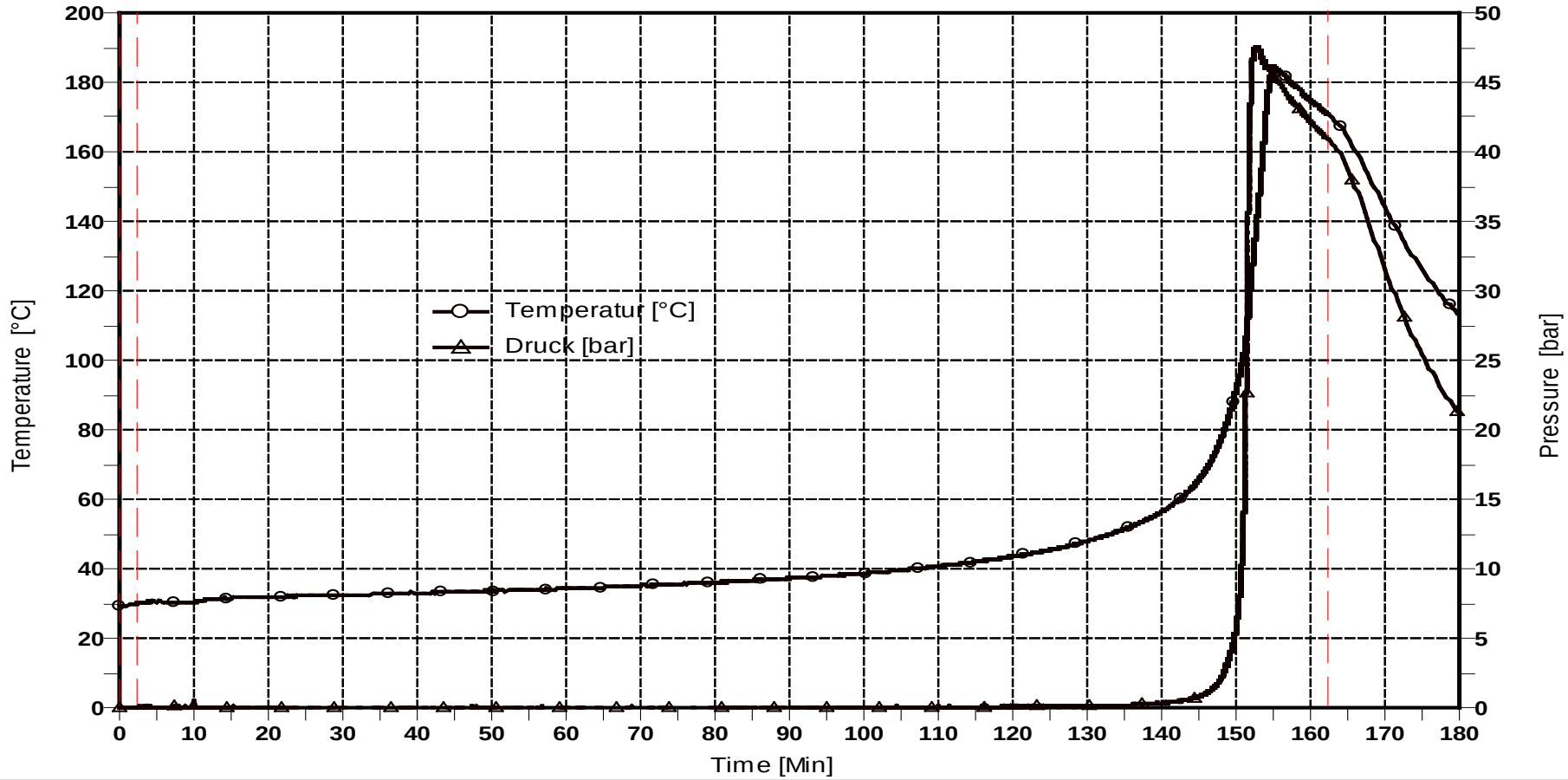
Critical interaction between chemicals and materials

- Incident in a chemical production plant B:
  - In a process the excess of POCl3 is distilled off and purged into a 200 l steel drum with a PE-inliner. Approx. 10 h later the drum burst.
  - Between the batches the pipes were washed with acetone. Residual quantities of acetone remained in the pipes.
  - Result of safety examination in laboratory:
  - Retarded critical reaction between acetone and POCl3.



Critical interaction between chemicals and materials

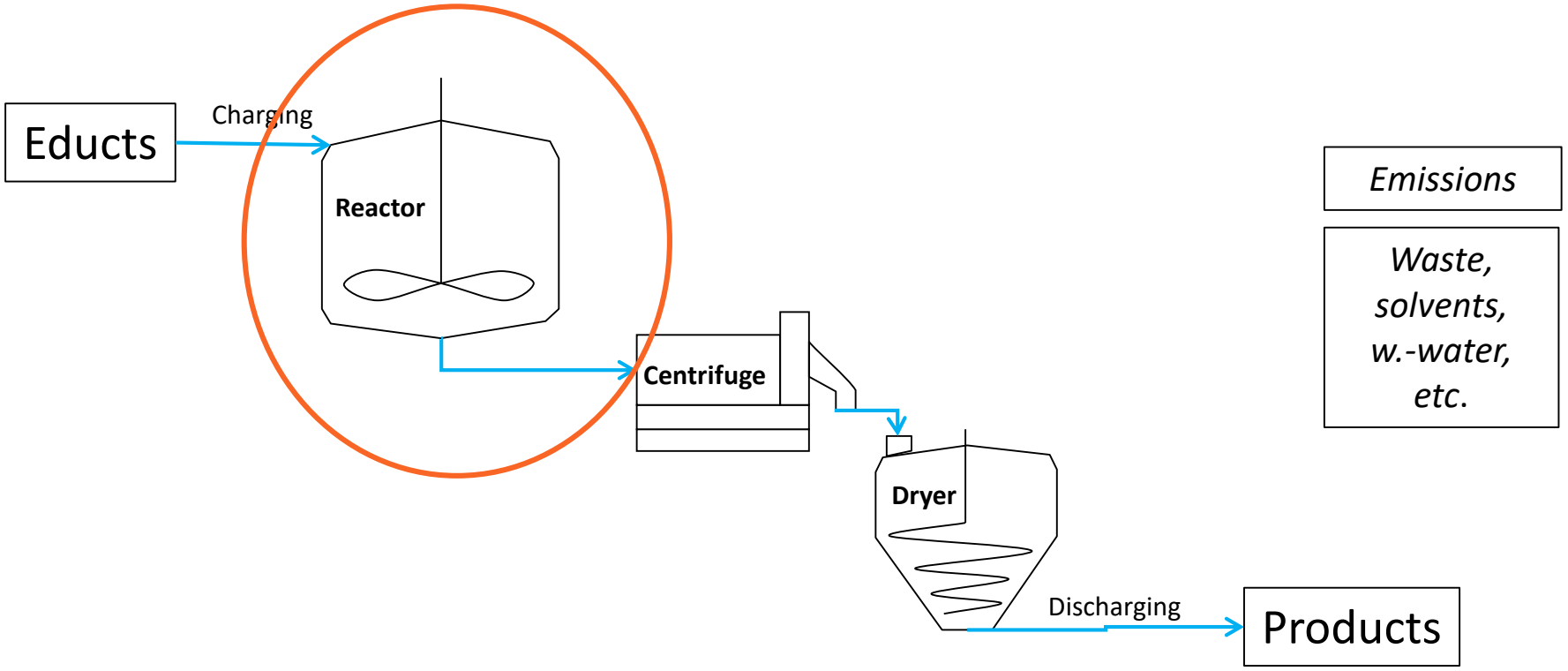
- Reaction experiment
  - closed cell test, POCl3 overlay with ca. 5.8 weight-% acetone



What is necessary for a safe process?

Chemistry – chemical reaction

Calorimetric measurements for chemical reactions



Chemistry – chemical reaction

- The chemical reaction should be known, including side reactions and consecutive reaction. The chemical reaction can depend on the reaction temperature or the working procedure.
- Mass balance of the whole reaction is very useful
- Side products can have a big influence on process safety
- Are decomposition reactions known?
- Waste streams can contain highly reactive compounds or unstable substances (e. g. slow gas generation leading to a pressure build up in waste containers)

Working procedure for chemical reaction

- Batch reaction:
  - All reagents are charged to the reactor.
    Then the content is heated to the reaction temperature.

The accumulation of reaction partners is at the beginning 100 %.

For an exothermic reaction, if the cooling capacity is not sufficient, an uncontrolled temperature rise occurs and a run away reaction is possible.

Batch reactions should only be applied with endothermic or very slow reaction with smooth exothermic behavior.

- What is in general the best temperature for running a exothermic batch reaction?
- The lowest possible reaction temperature is in general the safest temperature!

Working procedure for chemical reaction

- Semi-batch reaction

One reaction compound (including solvent) is charged to the reactor.
The other compound is added over a defined time at the reaction temperature.

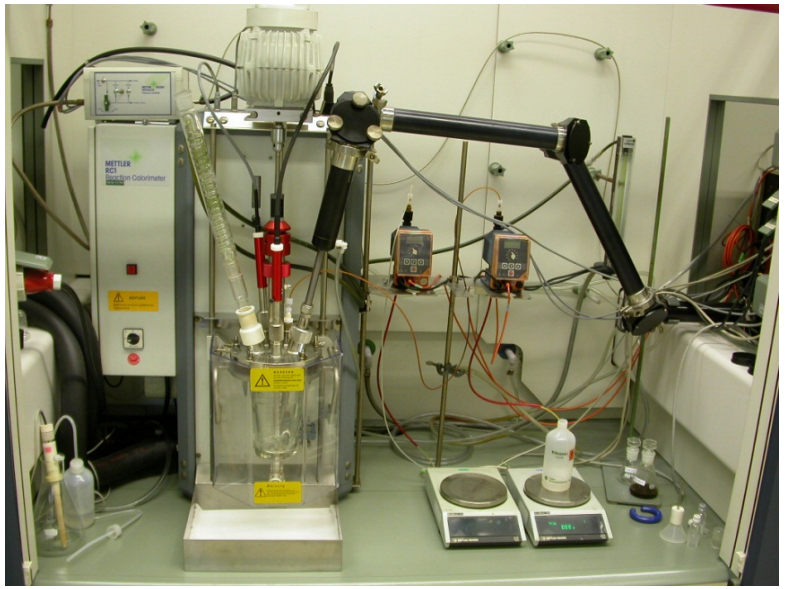
- The accumulation of reaction partners is at the beginning 0 %.
  Across the whole addition time the accumulation should be small.
- Always add the reactive compound.
  (Adding a catalyst or a compound in a huge excess is not a semi-batch process!)
- A stop of the addition stops further heat generation (if low accumulation).

What is in general the best temperature for running a exothermic semi-batch reaction?

The highest possible temperature is the best! -> fast reaction -> less accumulation

Chemical reaction parameters, calorimetric measurements

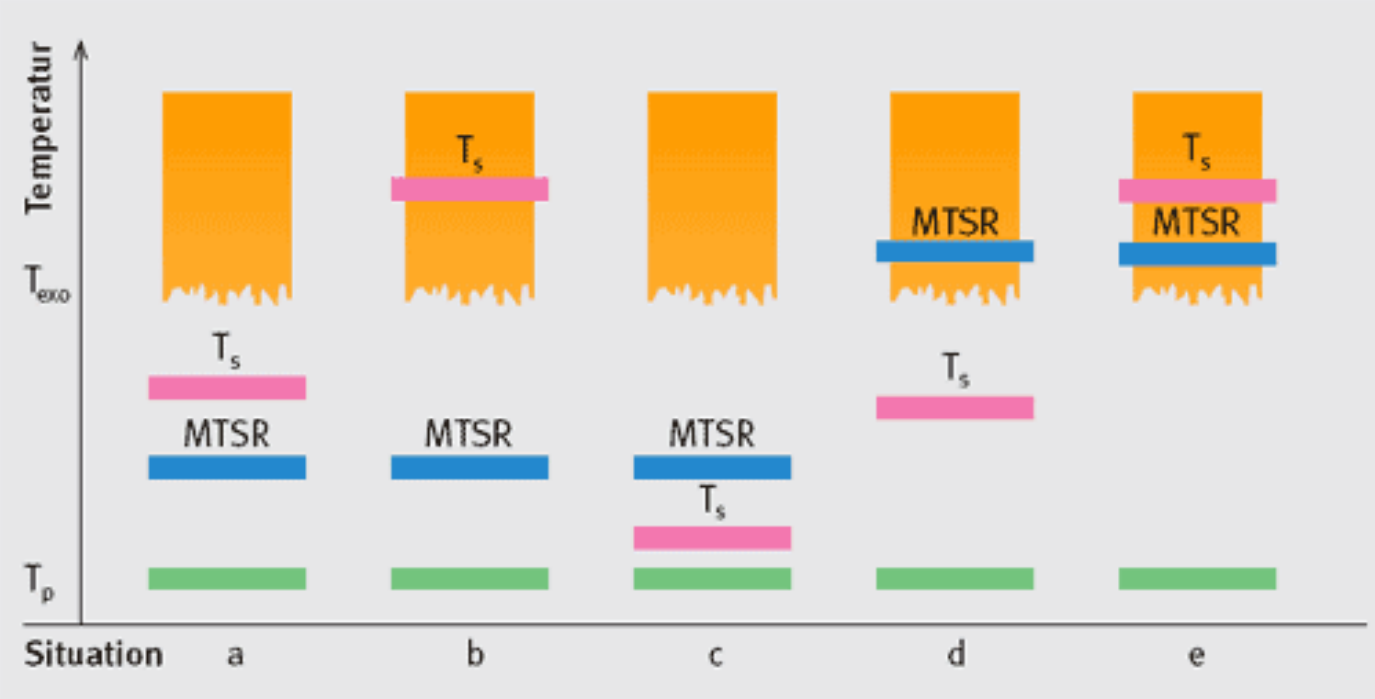
- Safety investigation of reaction under process like conditions:
- Reaction calorimeter (e.g. Mettler RC1) with dosing, gas measurement etc.



- Determination of:
  - Heat of reaction ΔHR [J/g] or [J/mol]
  - Heat capacity cp [J/g K]
  - Adiabatic temperature rise ΔTad [K] or [°C]
  - Degree of accumulation [%]
  - Gas release [l/min]

- Adiabatic investigation of abnormal operating conditions:
- Determination of thermal stability under adiabatic conditions (no heat exchange, like DTA)

Thermal hazard potential of chemical reactions



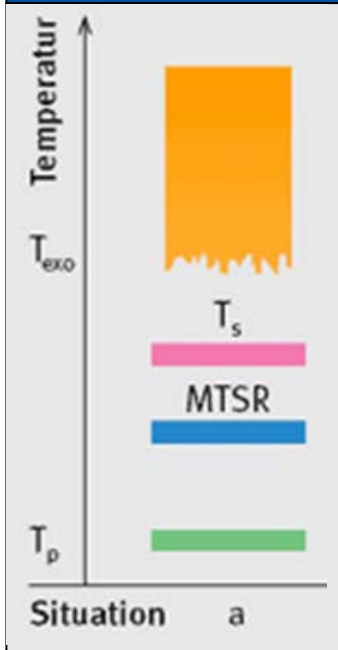
T_p : process temperature at the start of the deviation

MTSR: maximum temperature of the synthesis reaction; $MTSR = T_p + \Delta T_{ad} \cdot \alpha_{accu}$

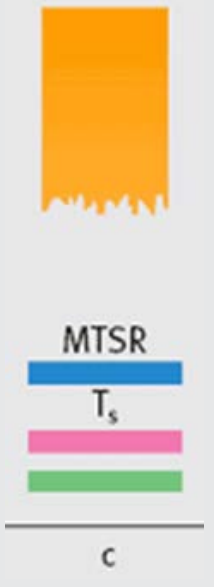
T_{exo}: the maximum temperature at which a substance or reaction mixture can just be handled safely

T_s: (=T_b) the boiling point in an open system

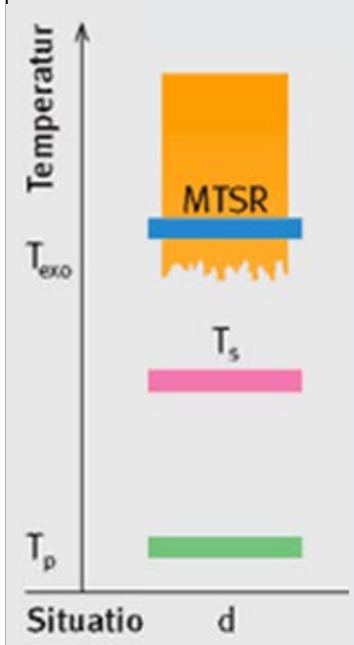
Thermal hazard potential of chemical reactions

Case	Description - criticality
	The boiling point of the mixture and the maximum reaction temperature stay below T_{exo}. Such processes may be regarded as inherently safe with respect to the process deviation evaluated.

Case	Description - criticality
	Absence of the boiling point barrier, but maximum reaction temperature below T_{exo}. The process may be regarded as safe.

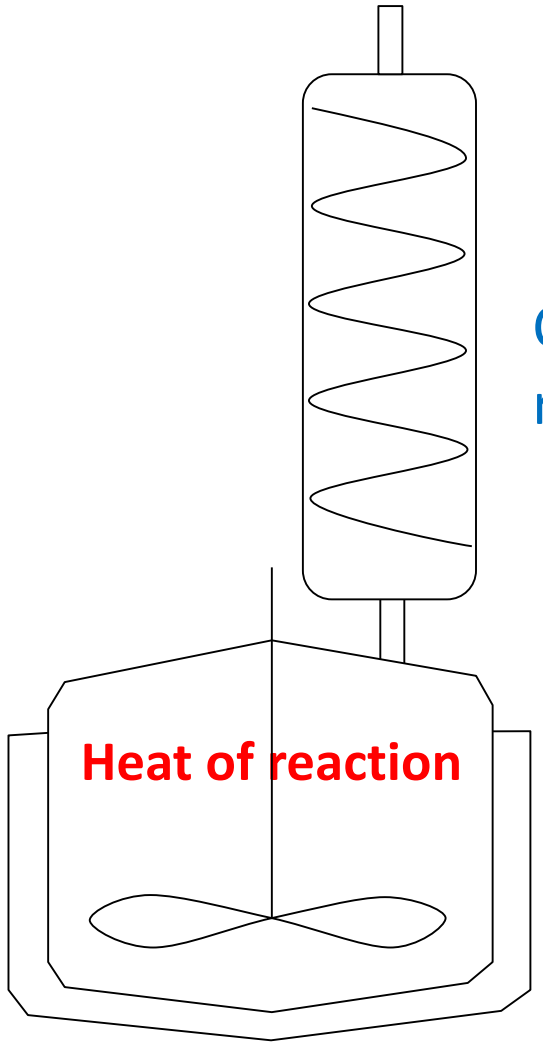
Case	Description - criticality
	The boiling point with its latent heat of evaporation may be considered as a safety barrier (adquate condenser!) In a closed system, the reactor must be designed for the maximum expected overpressure or be equipped with a pressure relief device. It would be better to reduce the accumulation so that the boiling point could not be reached.

Thermal hazard potential of chemical reactions

Case	Description - criticality
	It must be evaluated if the evaporation capacity provides sufficient safety. If not, additional organizational or technical measures have to be implemented. If the operation is performed in a closed system, the temperature corresponding to the relief valve's set pressure may not be too high.

Case	Description - criticality
	This case must be rated as problematic. In case of a (simple) cooling failure, the reaction can pass over the safe temperature range. Plant and/or process modifications should be evaluated in such situations.

Temperature control of chemical reaction



Cooling by
reflux condension

Cooling jacket

Heat balance of exothermic reactions

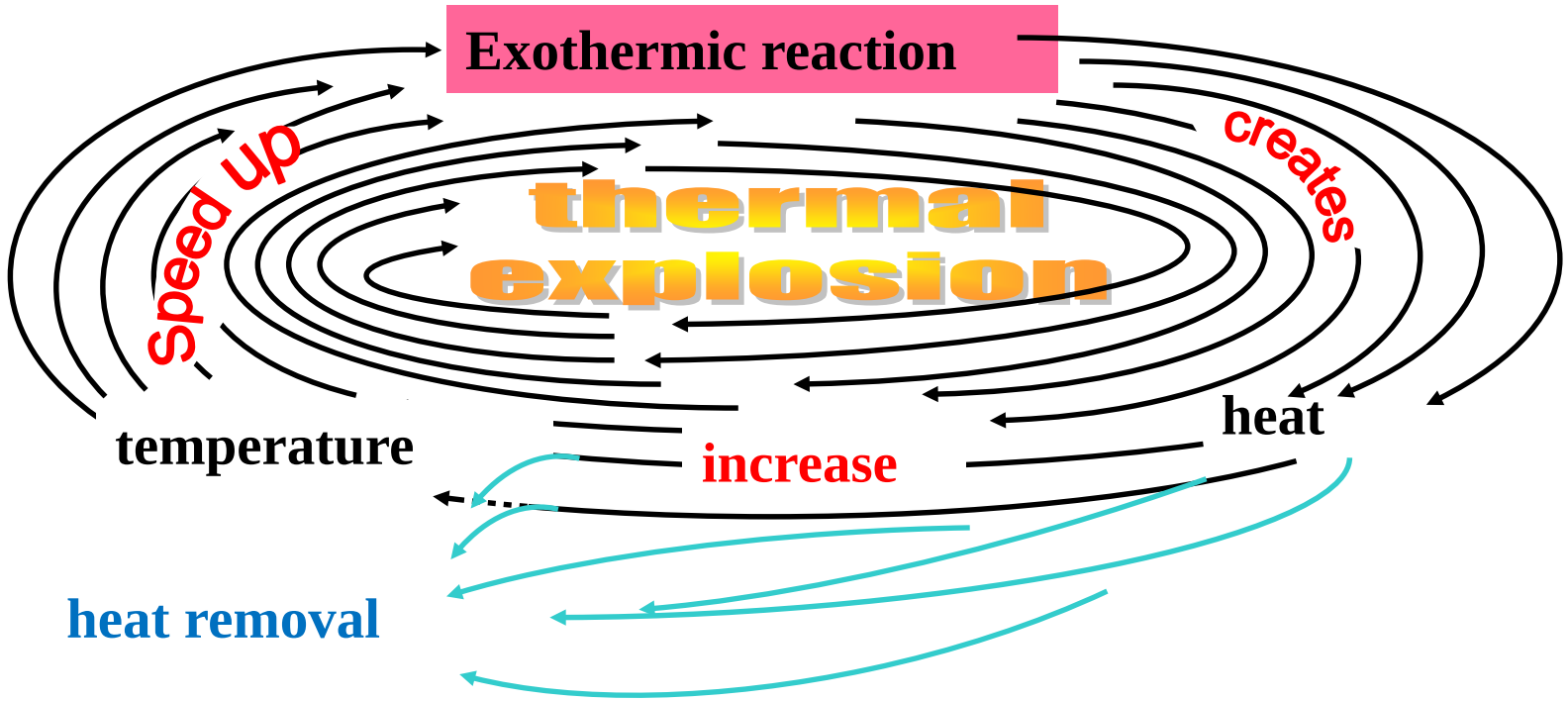
heat production

heat removal

Increased heat production	Decreased heat removal
• Additional energy supply (e.g. heating, stirring, pumping) • Higher concentration of reactants (e. g. missing solvent) • Presence of a catalyst (e.g. rust, nonferrous metals) • Initiation of other exothermic processes (e.g. side reaction, decomposition)	• Loss of cooling (e.g. pump failure, solvent evaporated) • Degrade heat transfer (e.g. fouling, adhesion) • Increase of viscosity (e.g. higher degree of polymerization) • Inadequate mixing (e.g. pump failure, solvent evaporated, stirrer failure)

Exothermic and run-away reaction

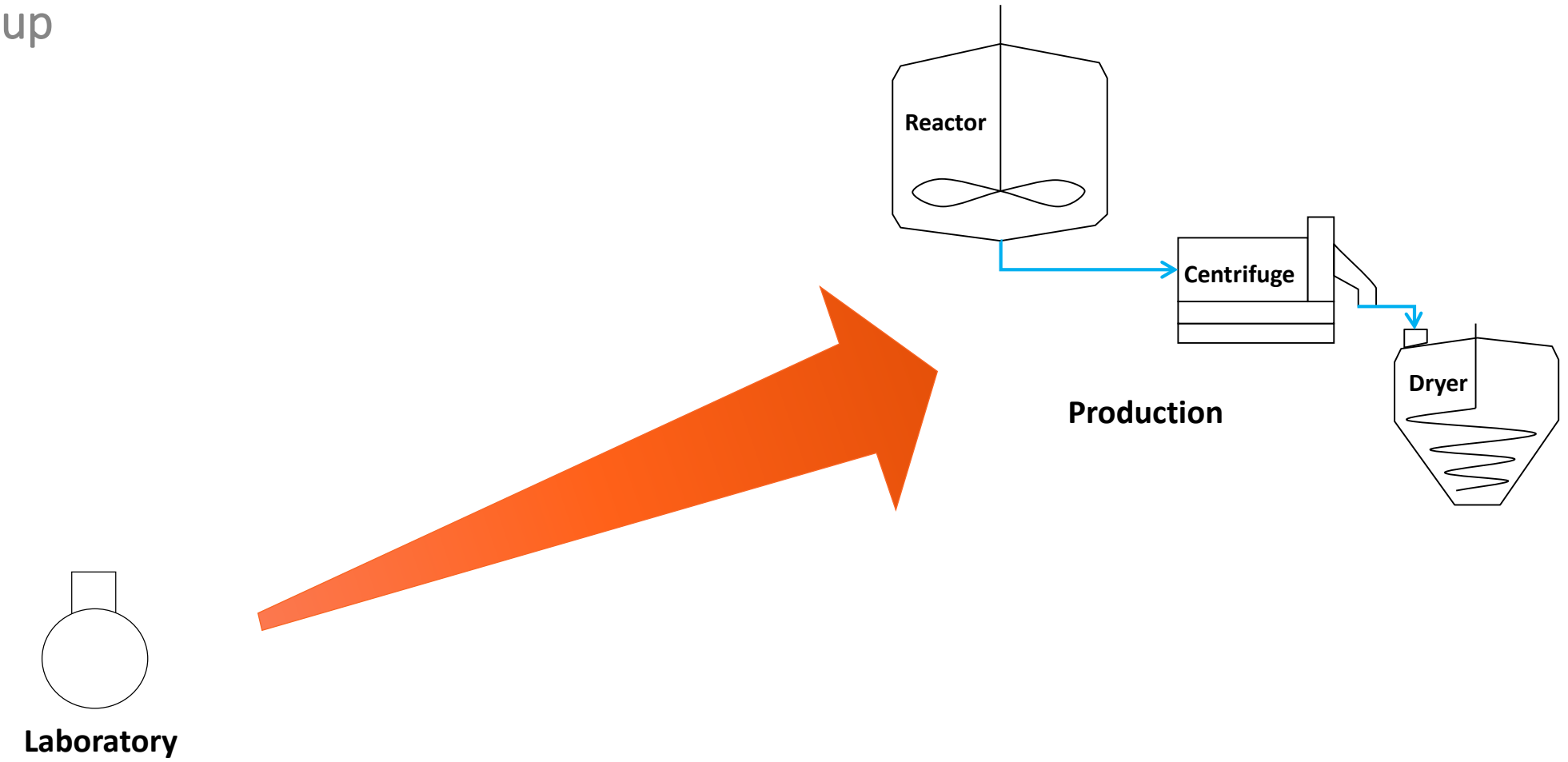
- An exothermic reaction produces heat which leads to an increase of the reaction temperature if the cooling capacity is not sufficient.
- A runaway reaction is an exothermic chemical process, which leads to uncontrollable reaction conditions due to an uncontrolled rise of the reaction speed.



Exothermic reaction and run-away reaction

What is necessary for a safe process?

Scale up



Scale up laboratory → (pilot) plant

- Example of a heat balance change during the scale up
  - From laboratory (1 l) to pilot plant (1 m^3).
  - Dosing controlled reaction
  - Exothermic reaction
  - Reaction heat of 360 kJ kg–1 (= 0,1 kWh kg-1)
  - Density of reaction mass is 1 g cm–3
  - Reaction temperature 80 °C
  - Filling degree is 100 %
  - Heat transmission of both apparatus are 500 W m–2 K–1
  - Effective temperature difference for cooling is 30 K

Scale up – laboratory – (pilot) plant

	Laboratory	Pilot or production plant	
Reactor size	1 l	1 m^3	Factor 1000
Cooling surface	0,046 m^2	4,4 m^2	Factor ~100
Specific cooling power	15 kW m^{-2} (= 500 W m^{-2} K^{-1} * 30 K)		
Cooling power	**0,69 kW** (= 15 kW m^{-2} * 0,046 m^2)	**66 kW** (= 15 kW m^{-2} * 4,4 m^2)	Factor ~100
Reaction power with 3 h dosing time	0,03 kW (= 0,1 kWh kg^{-1} * 1 kg /3h) *heating required*	33 kW (= 0,1 kWh kg^{-1} * 1000 kg /3h) cooling sufficient	
Reaction power with 2 h dosing time	0,05 kW (= 0,1 kWh kg^{-1} * 1 kg /2h) *no cooling required*	50 kW (= 0,1 kWh kg^{-1} * 1000 kg /2h) cooling sufficient	
Reaction power with 1 h dosing time	0,1 kW (= 0,1 kWh kg^{-1} * 1 kg /2h) cooling sufficient	**100 kW** (= 0,1 kWh kg^{-1} * 1000 kg /1h) **cooling insufficient**	

Expectation of an EHS auditor

R&D → scale up → production

Amounts of substances	Location	Working documents	Guidance documents
miligrams to grams	Research & Development Laboratory	- Lab documentation - First observations to process safety	- Policy „Safe Research & Development“ - Lab safety SOPs
grams to kilograms	Transfer from tab to kilolab / pilot plant	- Basic safety report - Transfer report	- Regulation to „Basic safety examinations“ - Transfer protokoll
kilograms	kilolab / pilot plant	- Batch records - Safety assessments - Process safety examinations	- Guidelines for safety examinations - SOPs to substance handling etc.

Expectation of an EHS auditor

R&D → scale up → production

Amounts of substances	Location	Working documents	Guidance documents
kilograms to tons	Transfer from pilot plant to production	- Transfer report - Risk assessment - Technical measures	- Transfer protokoll - SOP „Risk assessement/ HAZOP“
kilograms to tons	Production plant	- Batch records - Change Control documents - Maintenance of technical installation	- SOP „ CC“ - SOPs „Maintanance“
kilograms to tons	Transfer to other plants	- Transfer report - Risk assessment - Technical measures	- Transfer protokoll

Usefull Links/ Infos

- https://www.bgrci.de/fachwissen-portal/topic-list/hazardous-substances/
- https://downloadcenter.bgrci.de/resource/downloadcenter/downloads/R003e_Gesamtdokument.pdf

Accident Prevention & Insurance Association - data sheets
[BG-Merkblätter R 001-007]

AGENDA 大纲

Session 1

Session 2

TRAINING STRUCTURE

1. Session 1
   - Process safety parameters
   - Essential information to chemical processes
   - Critical interactions of material
   - Exothermic and run-away reaction
   - Scale up

2. **Session 2**
   - **Runaway reaction**
   - **PSCI Questionnaire & Typical Observations**

3. **Audience questions & discussions**

TRAINING STRUCTURE

1. Session 1
- Process safety parameters
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2. Session 2
- Runaway reaction
- PSCI Questionnaire & Typical Observations

3. Audience questions & discussions

Investigation Video

Runaway Reaction Explosion

- **T-2 Labs , Jacksonville, Florida (USA)**
- **Video 1**
- **Video 2**

Investigation Report - Explosion in T-2 Labs

- 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 (≈ 635 kg TNT)

Causes:

- Company did not recognize the worst credible scenario
- No redundancy in cooling system
- Inadequate pressure relief device

Reaction Hazards - Historical Data of Incidents

(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 – Incidents by Causes

(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%)

PSCI Questionnaire and Typical observations

Audit Questions Summary – Process Safety

Topic	Question summary
Process Safety	76: Top 3 most hazardous process activities conducted at this facility 77: Process hazard assessment 78: Evaluated the impact of its operation on the community Evaluated the impact from the activities of neighboring businesses 79: Risk assessment for explosion of flammable liquids, vapors, powders, and gases 80: Preventive maintenance of safety relevant equipment. 81: Handling compressed gases safely 82: Bulk chemical handling procedures 83: Safety measures around direct fire equipment (e. g. boiler, incinerators, ovens etc.)

Process Safety - Typical Observations

77	Does the facility perform Process Hazard Assessment (PHA)? *Aim is to identify processes or operations that could present significant risks in case of deviation (exothermic reactions, use of flammable, combustible or toxic materials, processes involving extreme temperatures or pressures).*	… • Collection of process information (process safety data, design information, operating parameters, and equipment specifications) • Hazard evaluations capturing significant risks during process development, preliminary engineering, and upon completion of process design? • Sizing of pressure vessels and relief devices according to appropriate codes and standards? • Flammable storage areas separate from production and well managed?

No safety data for any chemical reaction are available (example: heat of reaction, adiabatic temperature rise, decomposition temperature,…)
The auditee has made some improvement to collect process safety data and to conduct PHA for high sophisticated chemical reaction (nitration, oxidization, hydrogenation etc.) running at site. Nevertheless the interpretation of this data and the transfer into safety measures for the production is not always reliable.
Basic safety data for chemical processes are available from the Development report. However data are archived and in case of changes these data are not any more reconsidered, since there is no systematic approach in place to cover chemical safety data in a change control system.

Process Safety - Typical Observations

Most of the vent pipes coming from safety valves or rupture disks have at least 3 ninety degree angles. Therefore there is no evidence about the pressure profile inside the venting pipe. This leads to back pressure build up in case of activation with a certain risk for pipe bursting.
The reactor where the bromination takes place misses a safety valve or rupture disc respectively. Furthermore the adiabatic reaction heat is not known.
The explosion vent of the fluid bed dryer in the Bromhexine clean rooms is venting into the cleanroom.
In the chemical production building, the venting pipes of the safety valves end close to the floor in the production room. Taking into consideration the highly hazardous nature of the ingredients (e.g. Oleum, CO, SO_3) this may lead to fatal accidents in case of a pressure relief.

Process Safety - Typical Observations

79	Does the facility perform risk assessment related to the explosion of flammable liquids, vapors, powders, and gases in processing operations (including storage, transfer and charging)? Does it include the following steps?	• Assessment of the hazards (Minimum Ignition Energy, Kst classification rating, Impact sensitivity etc.) of the handled combustible dusts and powders • Hazardous area classification (zones according EU-ATEX and Classes according to US-NFPA) … • Installation of special electrical equipment for flammable vapors, gases, combustible dusts, … • Periodic testing of grounding and bonding circuits, lightning arresters, and electrical distribution equipment? • Maintenance/calibration done for critical safety equipment (e.g. sensors, instruments, valves, interlocks, reactors, condenser etc.) at suitable intervals. • Assessment of the hazards due to mechanical ignition sources? • Installation of special electrical equipment for flammable vapors, gases, combustible dusts, and wet areas? • Periodic testing of grounding and bonding circuits, lightning arresters, and electrical distribution equipment? • Maintenance/calibration done for critical safety equipment (e.g. sensors, instruments, valves, interlocks, reactors, condenser etc.) at suitable intervals. • Assessment of the hazards due to mechanical ignition sources?

Process Safety - Typical Observations

Safety data like MIE, St Class etc. are available for most of the finished products (API). No data is available for isolated intermediates. Hence it could not be proven if the Fluid Bed Drying of intermediates can be done safely.
The company has not assessed the hazards (Minimum Ignition Energy, K_{st} classification rating, Impact sensitivity etc.) associated with combustible dusts and powders being handled in various operations at site.
At the installations in the production area stainless steel clamps were installed instead of using copper wires for grounding and bounding. No evidence was provided showing that this type of bounding grounding is as safe and effective as copper wires.

Process Safety - Typical Observations

The Customer product is received in packaging, treated in anti-static agents and the specifications for the finished product require it to be packaged in liners that are treated with anti-static agents. However, the material handled in the intermediate steps is not treated with anti-static agents. Site personnel assume that the minimum ignition energy is low enough to warrant this type of packaging if the incoming and finished product are packaged in anti-static treated liners.
There is no gas detector near the ethanol recovery device at VB1 workshop, no O2 detector at centrifuges which used N2.
In the production plant, grounding points and grounded piping are installed. A detailed SOP for working in Ex-zones is available and trained. But an instruction, how to ground mobile equipment (e.g. solvent drums) is not included in this SOP.
An Ex light in the hydrogenation room was labeled as “Ex ed IIB T4”, which was not the proper type for hydrogen environment.

Process Safety - Typical Observations

80	Describe how the facility ensures preventive maintenance of safety relevant equipment.	• Pressure safety relief valves/rupture disks • Bonding/earthing systems • Mass transfer systems (e.g. piping systems) • Pressurized vessels • Explosion prevention system (e.g., prevention of static electrical discharge) • Is there emergency power supply for relevant equipment?

Anti-static bridge connection of pipes for transporting flammable chemicals is very rusty in Building A-6.
Most of the P+IDs presented during the audit where not up to date. Furthermore the guidelines of ISO14617 regarding the symbols are not followed. P+IDs should always be up to date, showing the "as build" situation to avoid any risk due to mistaken identity of any component of an equipment.

Process Safety - Typical Observations

81	Does the facility provide a means for handling compressed gases safely that includes:	Inspection and approval before acceptance of delivery? Storage in a segregated area designed for compressed gases? Separation or barriers to manage compatibility issues? Gas classification labeling? Regulator, hose and flexible connection inspections?

Video – Gas bottles transporter

(optional: Video gas transporter)

PSCI Questionnaire

82	Has the facility developed and implemented bulk chemical handling procedures that include:	Not applicable Specific unloading and loading procedures? Identification sampling before unloading? Hose inspection? Fire protection? Spill control measures (dike or bund area)?

Storage of Oxalyl Chloride is done under “normal” conditions (Hyderabad room temperature in the warehouse). As of the “Tech Pack” information, the storage temperature should not exceed -10°C. Even if there are some newer SDS available that storage at middle European room temperature range (max. 25°C) might be sufficient, the company could not show evidence that the change of storage conditions was assessed.
The bulk unloading process needs improvement. The unloading area is asphalt but no defined retaining volume in case of any spillage is provided.

Process Safety - Typical Observations

83	What are the safety measures around direct fire equipment (e. g. boiler, incinerators, ovens etc.)? *Consider gas accumulation, steam overpressure...*	

In the Building B, Water For Injection (WFI) system, the clean steam generator operates at 65 psig with a safety relief valve venting directly to the room. In the case of activation, 155°C steam would be released and fill the room.

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About the Secretariat
Carnstone Partners Ltd is an independent management consultancy, specialising in corporate responsibility and sustainability, with a long track record in running industry groups.

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partners ltd

PSCI PHARMACEUTICAL SUPPLY CHAIN INITIATIVE
Building responsible supply chains

1) Emergency Preparedness and Response
2) Hazard Information

Dr. Daniel Rehm
HSE Advisor Elanco External Manufacturing EMEA & API
由Daniel Rehm博士来演讲
HSE顾问，礼来动物保健外部制造，欧洲 & 原料药

Bio

- Daniel is HSE Advisor in the Elanco External Manufacturing EMEA & API Hub Basel, Switzerland
- PhD in Chemistry from Humboldt University in Berlin, Germany with 19 years of experience in Chemical Industry, Insurance and Pharmaceutical Industry. Functional experience in Process Development, HSE, Engineering and Manufacturing
- Working in Elanco for 3.5 year.
- Additional qualification as Fire Protection Manager CFPA-E

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AGENDA 大纲

Emergency Preparedness and Response

Hazard Information

1 – AUDIT OVERVIEW

Audit Questions Summary – Emergency Prepardness and Response / Hazard Information

Topic	Question summary
Emergency Preparedness and Response	• Fire detection/protection systems • Emergency response equipment inspection • Fire alarm system monitoring and notification to emergency services • Fire water for fire protection • Emergency exits and evacuation routes clearly marked, kept free of obstructions • Emergency exit signs illuminated with emergency backup power • Regular emergency evacuation drills • Emergency response plans • On-site emergency response team that is trained for fire or other emergencies

Topic	Question summary
Hazard Informatic	
Worker protection	• Does the facility have a safe work permit system **(Hot Work Permit)**

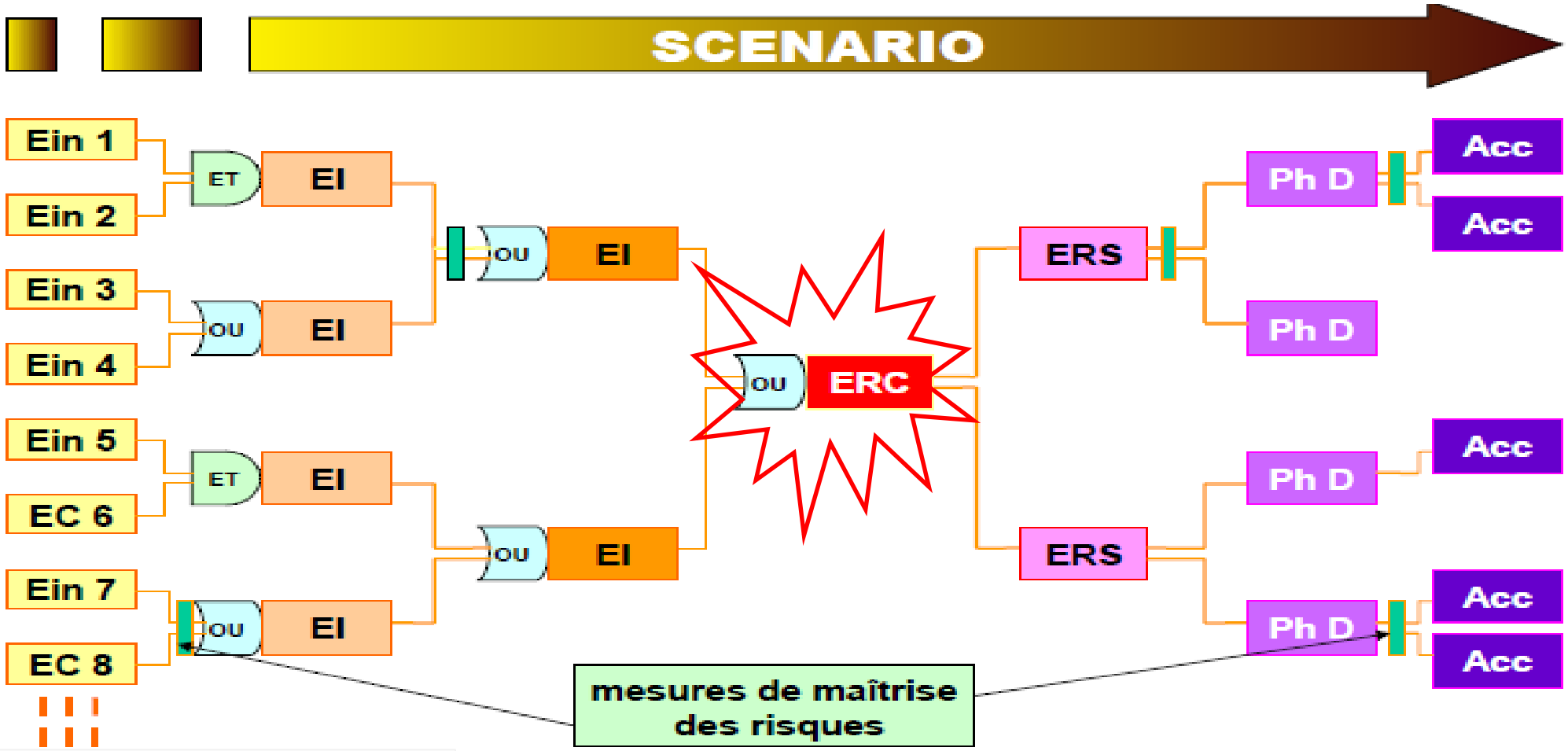
Topic	Question summary
Process Safety	• Impact of its operation on the community • Safety measures around direct fire equipment (e. G. Boiler, incinerators, ovens etc.)

1 – AUDIT OVERVIEW

Topic	Question summary
Process Safety	• Impact of its operation on the community • Safety measures around direct fire equipment (e. G. Boiler, incinerators, ovens etc.)

78	Has the facility evaluated the impact of its operation on the community? Has the facility evaluated the impact from the activities of neighboring businesses?	Yes No NA Yes No NA	Yes No NA Comments
83	What are the safety measures around direct fire equipment (e. g. boiler, incinerators, ovens etc.)? *Consider gas accumulation, steam overpressure...*	Please describe:	Yes No NA Comments

1 – AUDIT OVERVIEW



Emergency scenario: 3 types of effects

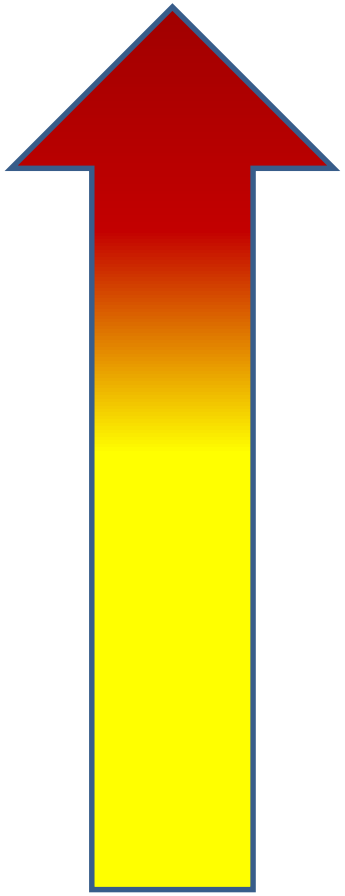
1 – Thermal effects : burns, suffocation

2 – Toxic effects: inhalation, intoxication

3 – Overpressure direct effets : Explosion of lungs or eardrums, Projection against an obstacle, …
Or indirect (missile effect): breaking of windows, moving objects…

1 – AUDIT OVERVIEW

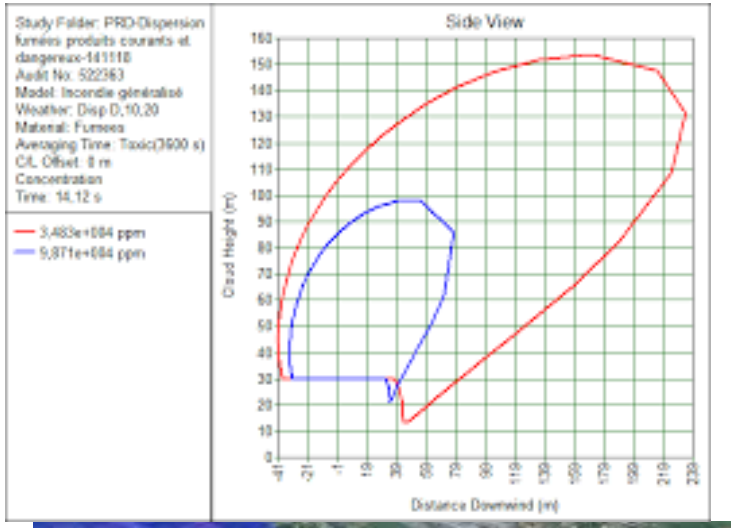
4 thresholds of effects on the people

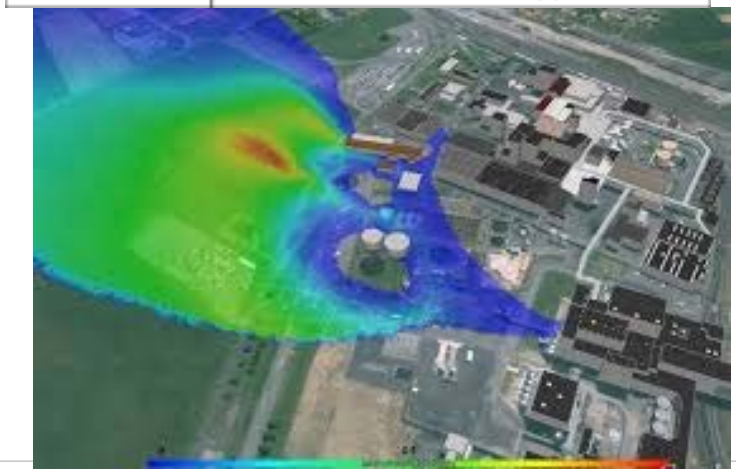


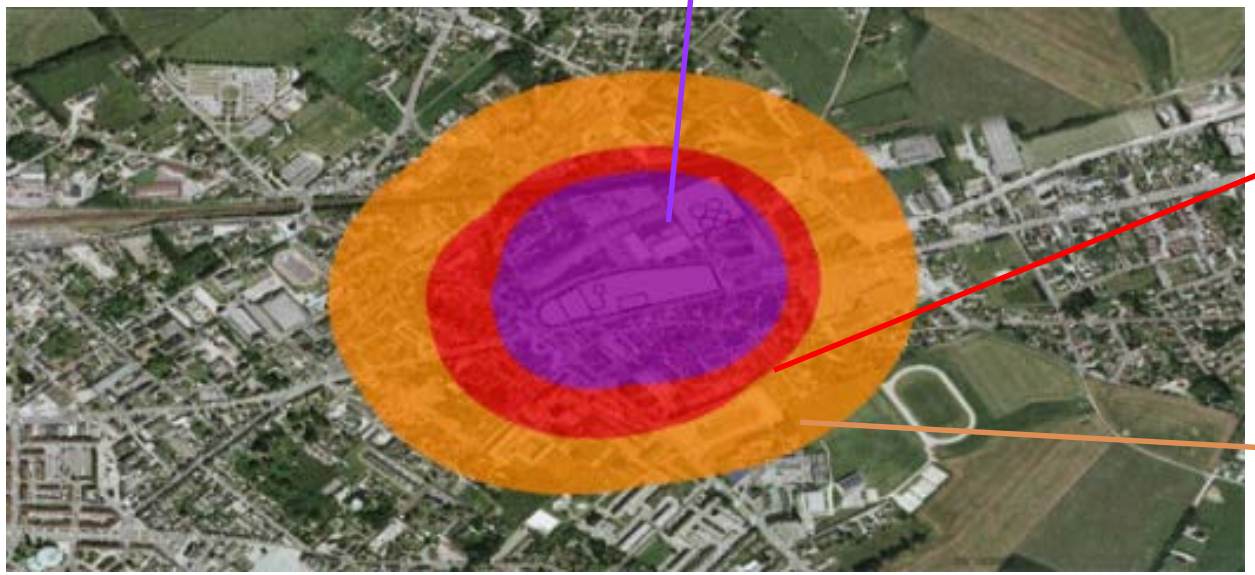
Treshold of effects on human	TYPES OF EFFECTS		
	Thermal	Toxic	Overpressure
LETHAL SIGNIFICANT (SELS)	8kW/m²	CL 8%	200 mbar
LETHAL (SEL)	5kW/m²	CL 1%	140 mbar
IRREVERSIBLE (SEI)	3kW/m²	SEI	50 mbar
INDIRECT (Breaking of windows)			20 mbar

1 – AUDIT OVERVIEW

Specific softwar calculation and graphic representation







1 – AUDIT OVERVIEW

Topic	Question summary
Worker protection	• Does the facility have a safe work permit system **(Hot Work Permit)**

55	Does the facility have a safe work permit system for the following?	**Hot Work: Yes No NA** Confined Space Work: Yes No NA Energy Isolation or Lock Out/Tag Out: Yes No NA Line Breaking: Yes No NA Work at Height: Yes No NA General Permit Yes No NA Other: Yes No Please describe:	Yes No Comments **AUDITOR GUIDANCE:** Provide the procedure title or # as reference and comment on the applicability at the site.

1 – AUDIT OVERVIEW

Topic	Question summary
Emergency Preparedness and Response	• Fire detection/protection systems • Emergency response equipment inspection • Fire alarm system monitoring and notification to emergency services • Fire water for fire protection • Emergency exits and evacuation routes clearly marked, kept free of obstructions • Emergency exit signs illuminated with emergency backup power • Regular emergency evacuation drills • Emergency response plans • On-site emergency response team that is trained for fire or other emergencies
Hazard Information	• Safety Data Sheets (SDSs) for all hazardous substances

1 – AUDIT OVERVIEW

84	Are the following areas of the facility equipped **with fire detection/protection** systems?	Site areas	Fire/smoke detectors	*Sprinkler or suppression* systems	Comments AUDITOR GUIDANCE Briefly describe the site's fire protection program and to what extent it has been implemented. Describe any observations that could impair a normally acceptable fire protection plan in terms of building construction, fire load, general state sprinkler system, smoke detectors, alarm system, inclusion of key equipment in preventive maintenance program etc. Check for stored materials that could create a fire hazard, such as idle pallets.
		Raw material storage areas	Yes No	Yes No	Yes No Comments
		Flammable liquid storage tanks	Yes No	Yes No	Yes No Comments
		Process areas	Yes No	Yes No	Yes No Comments
		Finished product warehouse	Yes No	Yes No	Yes No Comments
		Hazardous waste storage area	Yes No	Yes No	Yes No Comments

1 – AUDIT OVERVIEW

85	Is the facility emergency response equipment **(fire extinguisher, fire pumps, sprinkler systems) visually inspected monthly,** comprehensively inspected annually, and documentation maintained for all inspections?	Yes No Please explain:	Yes No Comments
86	Is the **fire alarm system monitored 24 hours** a day (including weekends and holidays) with prompt notification to emergency services (within 5 minutes)?	Yes No Please explain:	Yes No Comments
87	Does the facility ensure that an adequate amount of fire **water is maintained for fire protection**?	How many cubic meters of fire water is maintained for fire protection? How was it determined to be sufficient? Can the capacity of the pumps meet the requirements of NFPA (sufficient water flow?) Yes No Please explain if No:	Yes No Comments

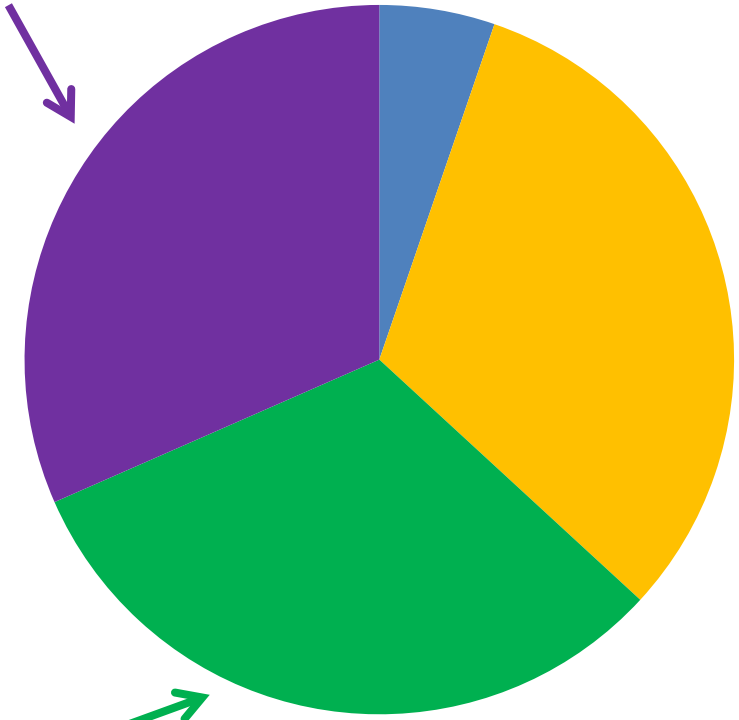
2 – SUBJECT OVERVIEW : FIRE SOURCES

SMOKING

>> Smoking policy

ELECTRICITY

>> Electrical inspection
>> Electrical rooms
>> Infra red – Thermography
>> Lightning protection



HOT WORK

>> Hot work Permit

PROCESS

>> Chemical : process safety
>> Other activities : ??

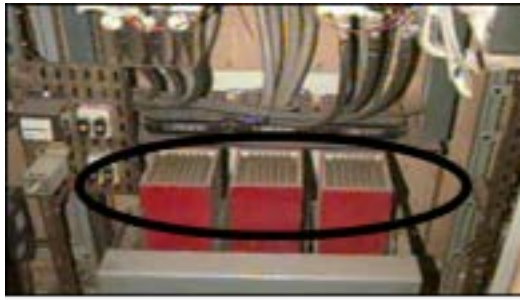
2 – SUBJECT OVERVIEW : FIRE PREVENTION

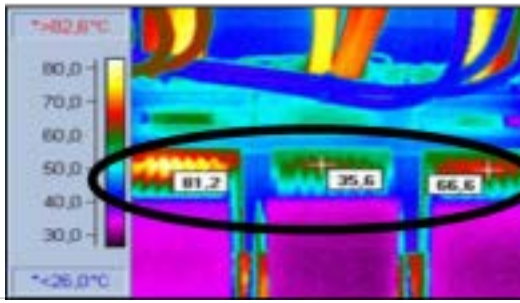
SMOKING

- Smoking policy specifies at the site entrance / visitor training ?
- Clear signs/ limits ?? To see during the site tour
- Do you find cigarette end during your site tour ?

ELECTRICITY

- Electrical inspection >> Maintenance / regular check
- Electrical rooms >> Visit electrical room, transformers PSCI 56
- Infra red – Thermography
  PSCI 56
- Lightning arresters
  PSCI 79
- Location of electrical equipments near combustible material ???





2 – SUBJECT OVERVIEW : FIRE PREVENTION

PROCESS

- **Chemical/Pharmaceutical : process safety chapter PSCI 76-82**
- **Warehouse:**
  - **Where are located the battery chargers ?**
  - **Lights above the storage /aisle ?**
  - **Stability chamber in Polyurethane / cooling system ?**
- **Pharmaceutical processes**
  - **Milling ,** Sieving**, Micronization** (see process safety / powder data)
  - **Granulation** (Use of solvant: see process safety)
  - **Electrical dryer**
  - **Equipment running 24/7**
- **Laboratories:**
  - **Oven (24/7) CPLG: H2 ?**
  - **Mixing of waste …**
- **Technical area**
  - **Filters, Heater, Electricity**

2 – SUBJECT OVERVIEW : FIRE PREVENTION

HOT WORK

during the documentation review :

- Check the Hot work Permit
- Procedures / SOP (link with HW Permit)
- Who signs hot work permit ?
- What if : Fire detection above the hot work permit ????
- Hot work permit in ATEX Areas >> LEL

- NO Fire detection >> Visit 1 to 3 hour after the end of the work
- Permanently present for 1 hour.
- Patrols every hour for 3 hours

Hot Works

Check the fire systems

Visit the location and neighbouring vicinity

Combustible load

Extinguishers

Protect and cover up

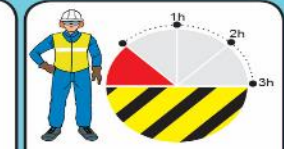
≥10m (33ft)

Equipment Conformity

Qualified & protected operators


Specific 1 day permit


Alarm/Emergency



Safety visit after work


Explosimeter control

Before starting the work...

➔ Study the possibility of doing the work in the maintenance shed or in another zone specially designed to avoid fire or explosions.

➔ Visit the location and neighbouring vicinity:
Look for links with neighbouring installations (pipes, casings, gutters, false-ceilings, openings…).

Specific permit

➔ Draft a specific 1 day permit .

Yellow Tag

Combustible material

➔ Displace combustible material beyond 10 m (33ft).

Protection

➔ Protect exposed areas and block openings though which incandescent particles could pass.

➔ Cordon off the area

➔ Wet floor

Explosion control

➔ Take specific measures for zones with a risk of explosion

As a minimum scan explosimetre monitoring (before and during).

➔ ATEX areas, flammable liq tank / waste water network …..

Fire fighting

➔ Be prepared for fire fighting.

As a minimum have extinguishers at hand.

Fire systems

➔ Depending on work in progress and the difficulties encountered (false alarms) decide whether to impair

Equipment Conformity

Check the equipment (pipes, gas cylinders secured ..)

Qualified and protected operators

Post work fire watch

➔ Permanently present for 1 hour.

➔ Patrols every hour for 3 hours

Alert / Help

➔Define the means of alerting help
➔Check the work
➔In the case of a problem or unexpected event:
Stop the work, alert and call a supervisor

Hot works

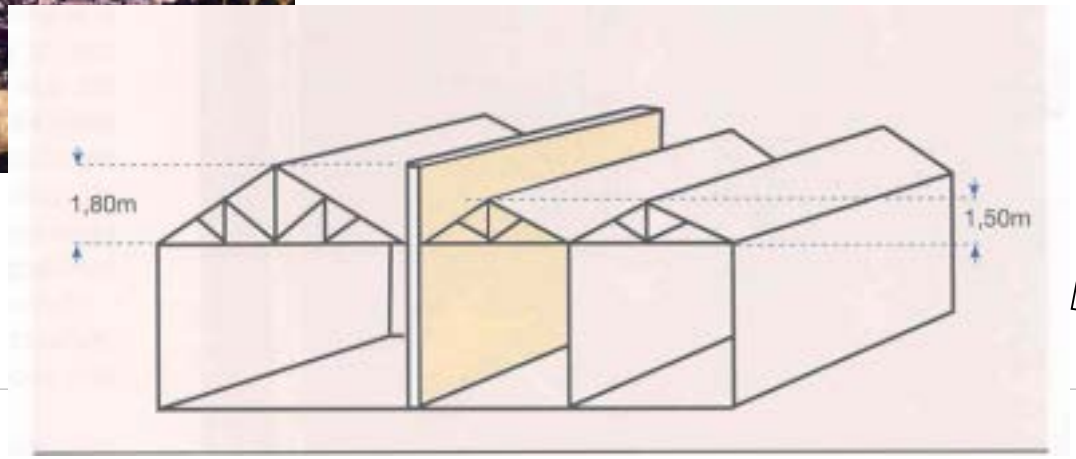
HSE SANOFI

2 – SUBJECT OVERVIEW : FIRE PROTECTION

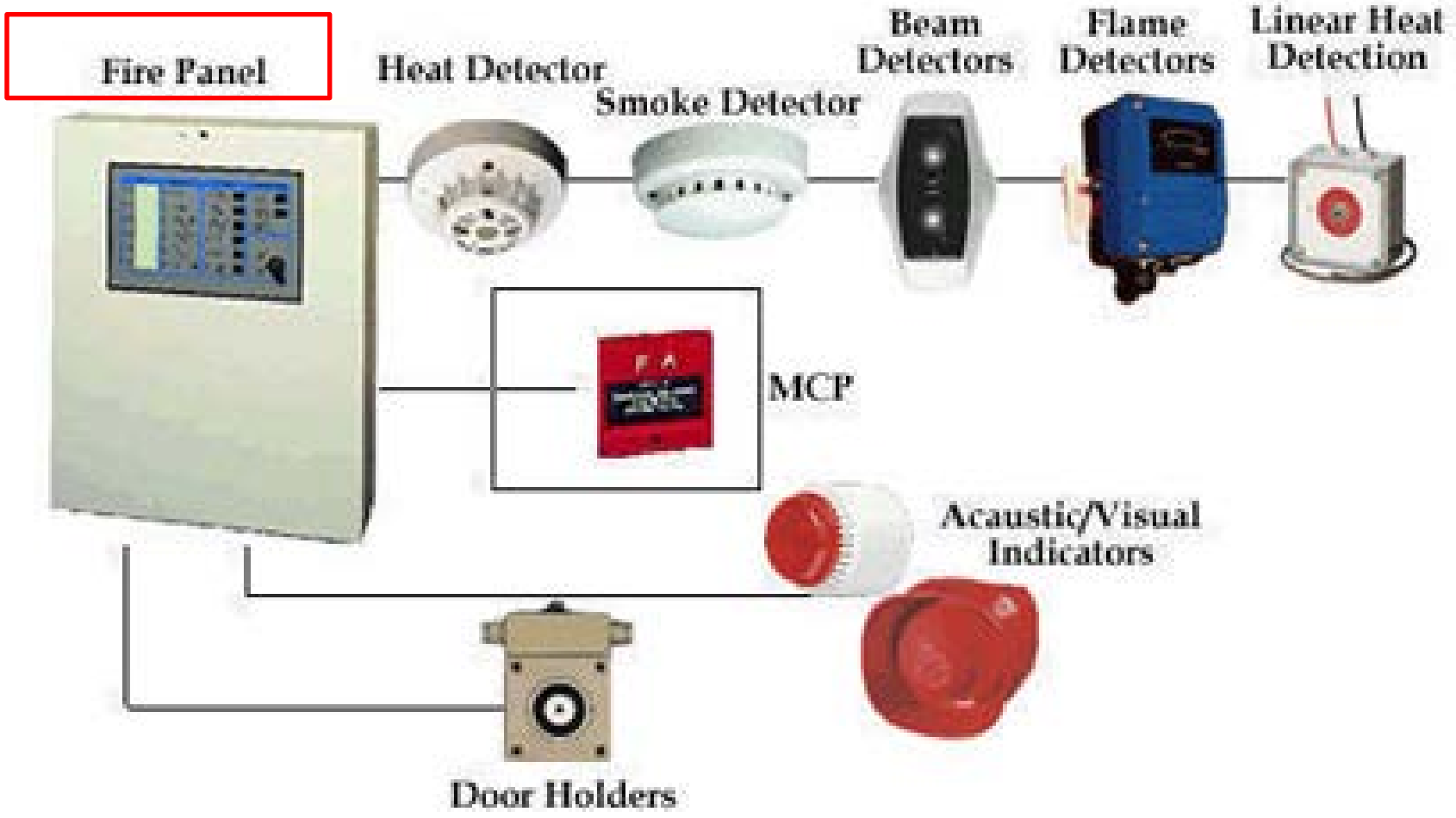
FIRE PARTIONING ASSESSMENT

- One block ?
- Many buildings/workshop ?
- Fire wall + door ?

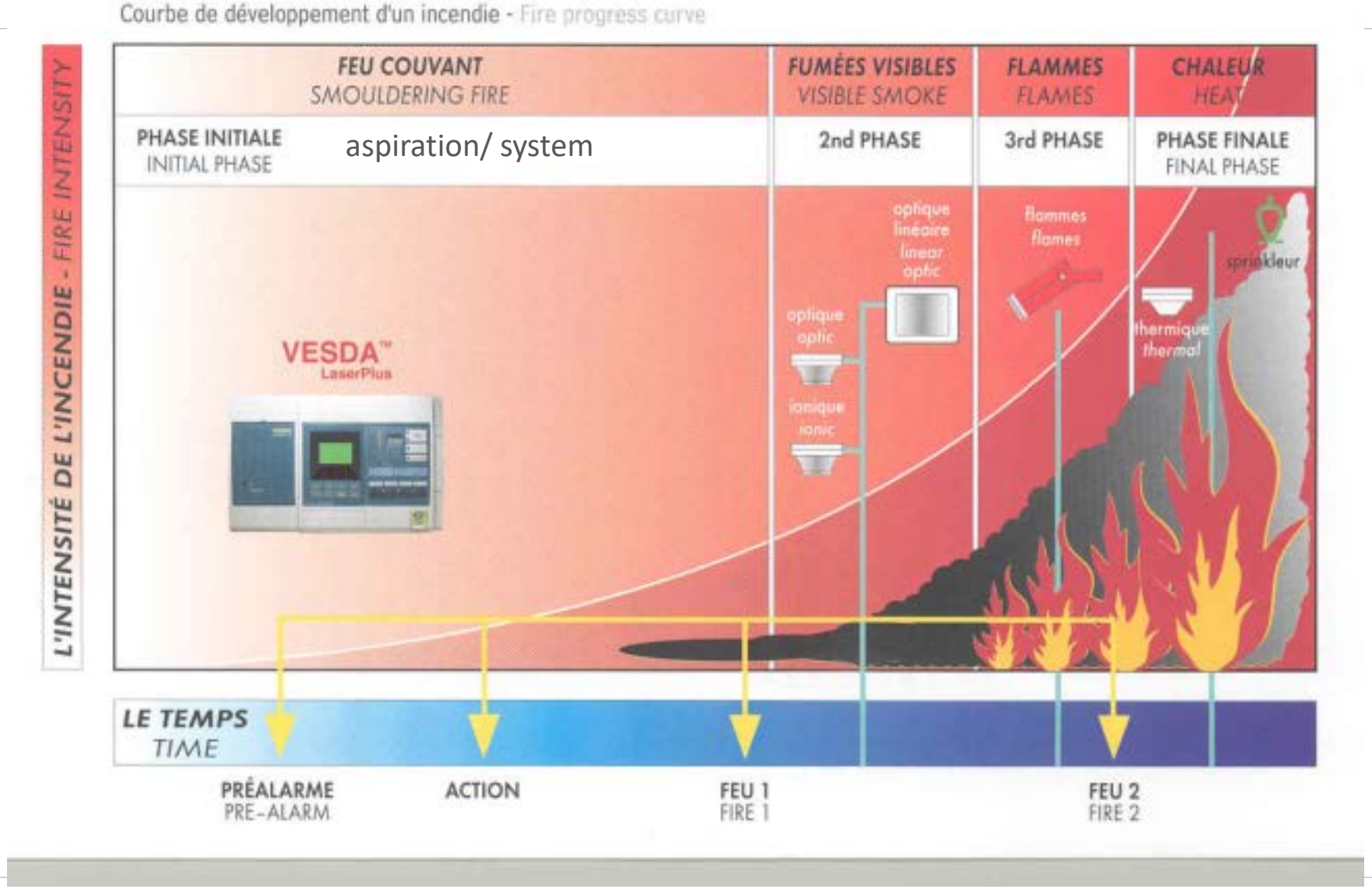
2 x 2 hours fire doors



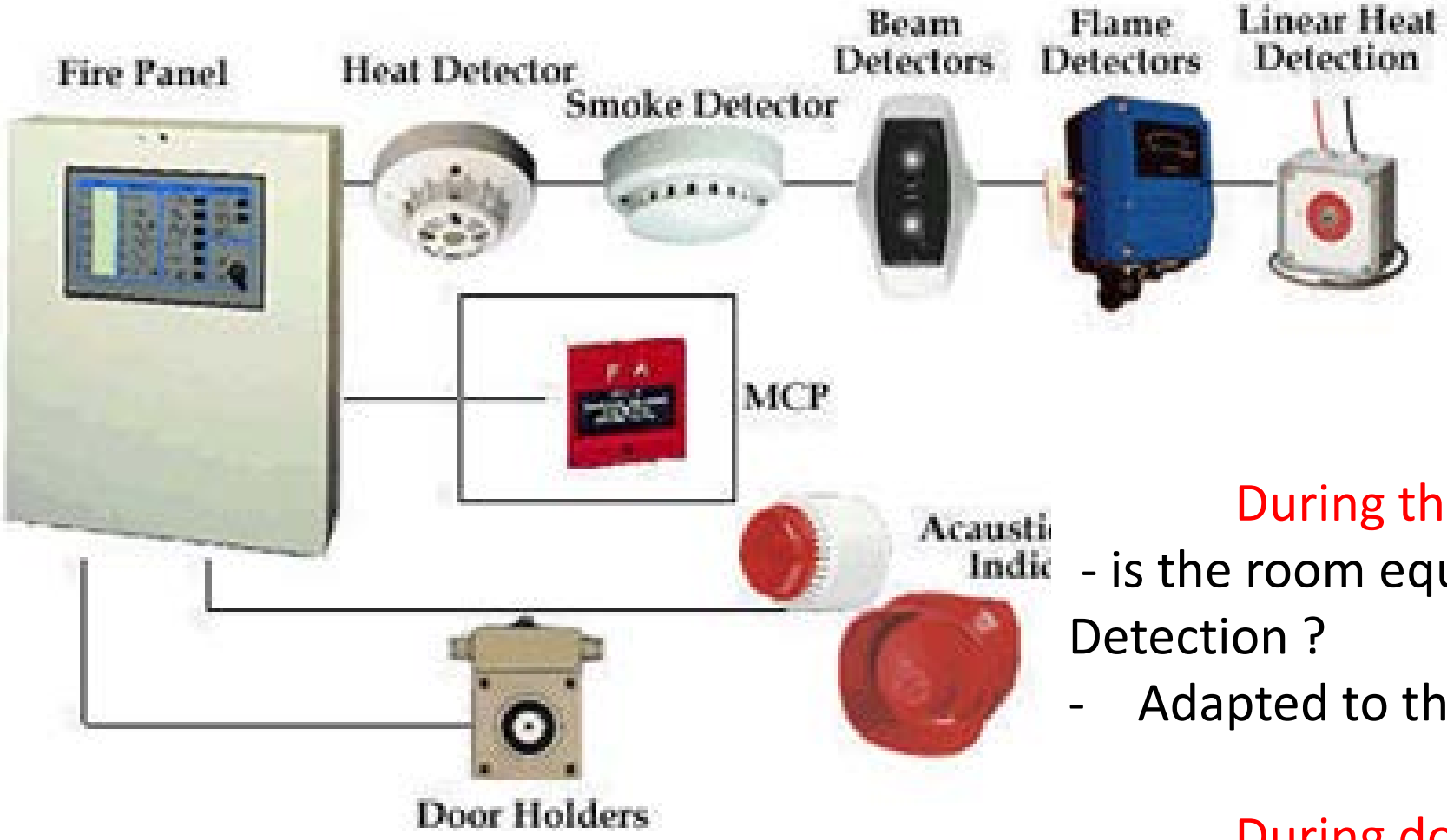
2 – SUBJECT OVERVIEW : FIRE DETECTION



2 – SUBJECT OVERVIEW : FIRE SOURCES



2 – SUBJECT OVERVIEW : FIRE DETECTION



Smoke removal

During the visit:

- is the room equiped with Fire Detection ?
- Adapted to the risk ?

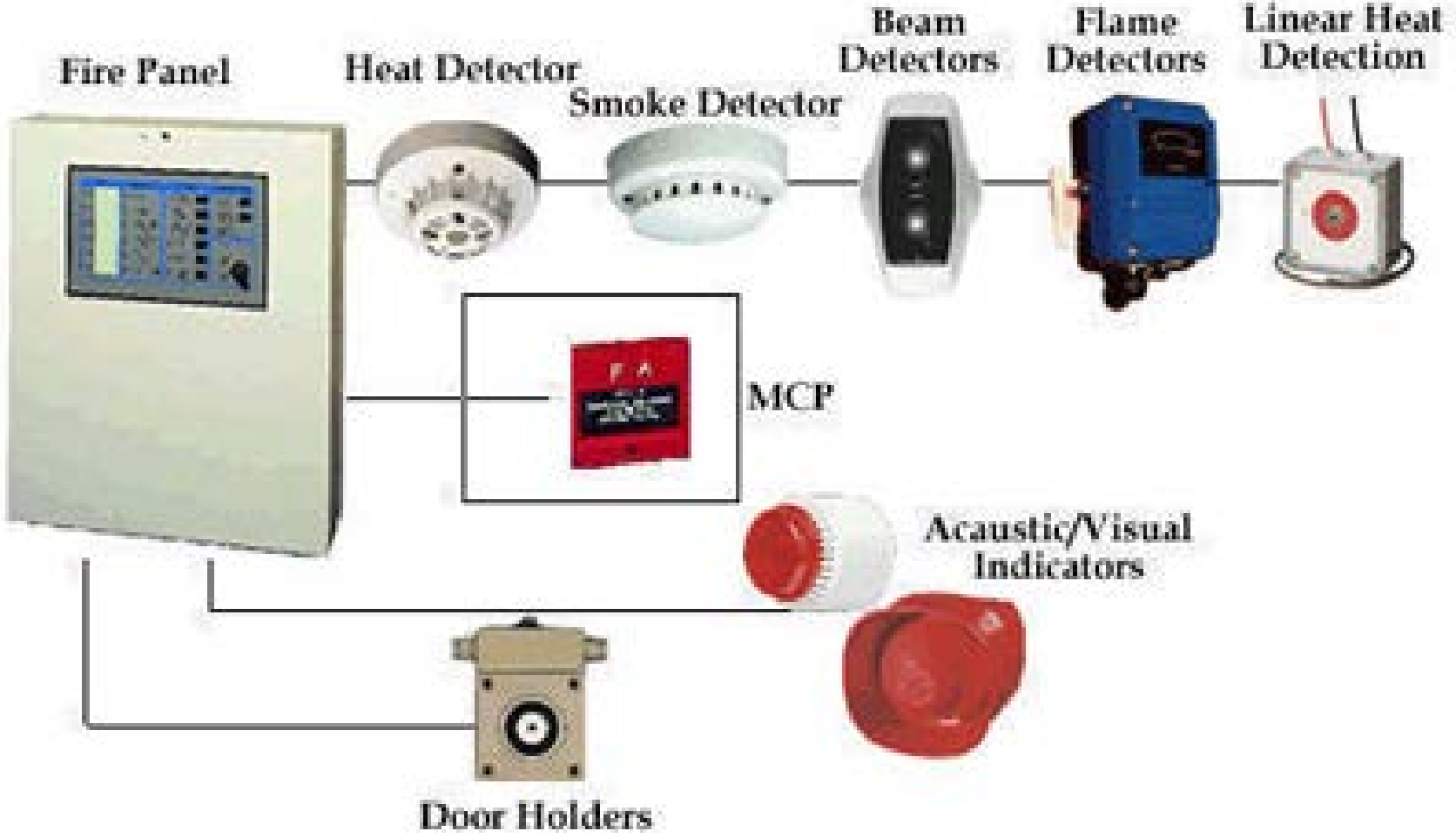
During documention review:

- Maintenance / inspection ?

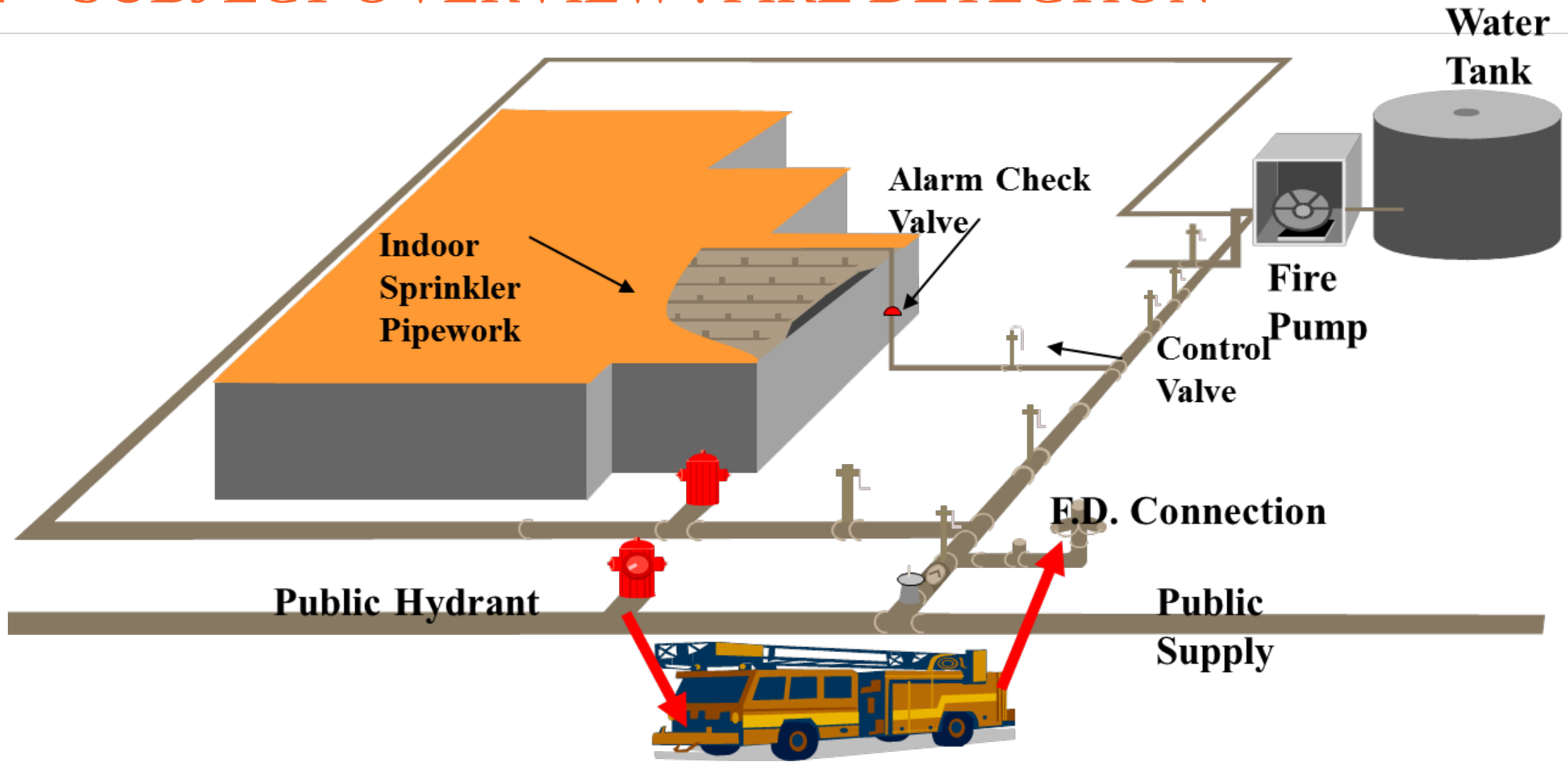
2 – SUBJECT OVERVIEW : FIRE DETECTION

24h/7 ?

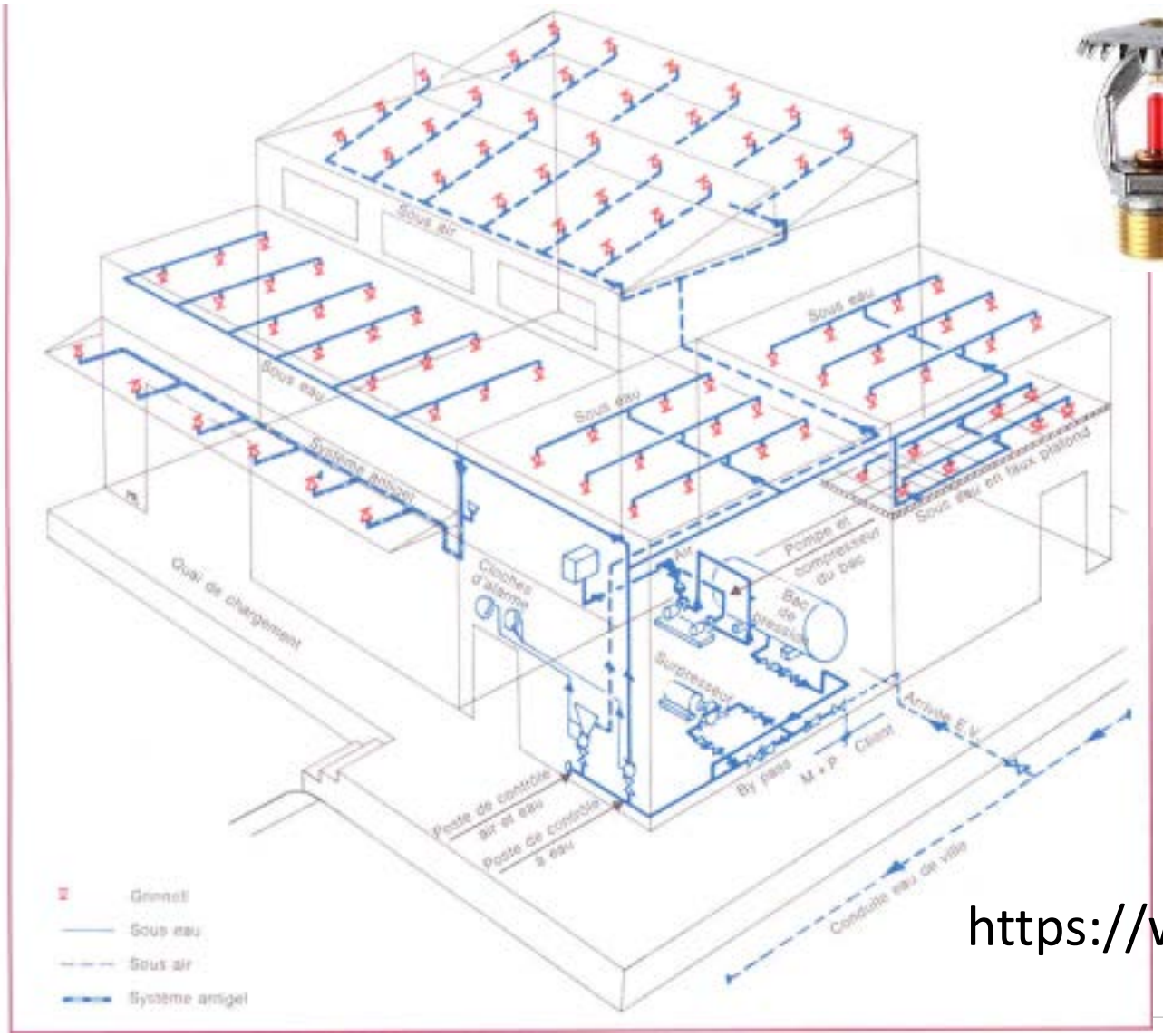
Distance to the fire brigade ?



2 – SUBJECT OVERVIEW : FIRE DETECTION



2 – SUBJECT OVERVIEW : SPINKLER Network



Extinguishing activation:

- By sprinkler network
- By dry sprinkler network
- By fire detection
- Manually (?)

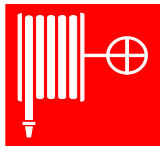
During the visit:

- Is the workshop covered by Sprinkler?
- Adapted to the risk ?

https://www.youtube.com/watch?v=o-ylvugYc0w

2 – SUBJECT OVERVIEW : SPINKLER

(Sprinkler System Demand + Hose Stream Demand) x Required Duration = Water Supply Demand

( + ) x 3 hours =

- Total capacity ?
- Anti-freezing system ?
- Low level alarm ?

- Sprinklers: 12.2 l/min/m². over 278 m²
- Hose stream demand: 2840 l/min
- Required duration: 3 hours

EXAMPLE :

(12.2 l/min/m²) (278.8 m²) (110%) = 3741 l/min

Hose demand = 2840 l/min

3741 l/min + 2840 l/min = 6581 l/min

(6581 l/min) (60 min/hr.) (3 hrs.) = 1185 m³

2 – SUBJECT OVERVIEW : SPINKLER PUMP

During the visit: at sprinkler pump station

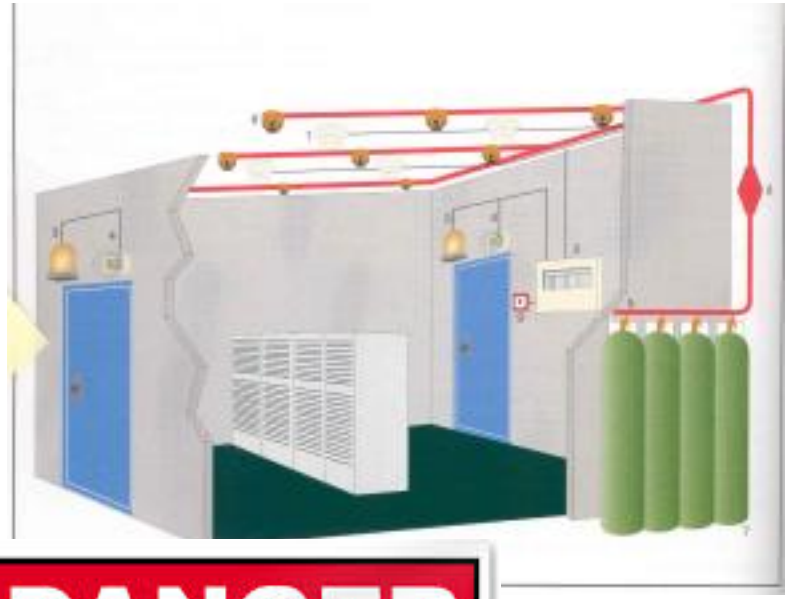
- 1,2,3 pumps ?
- Diesel ? Electrical pumps ? (generator)
- Flow m3/h
- Fuel storage /Battery / Oil
- Lamps / Key of the control panel
- Safe conditions: fire proof, locked, order
- Maintenance

During documention review:

- Sprinkler certificat
- Maintenance / inspection

2 – SUBJECT OVERVIEW : FIRE Protection

Other extinguishing systems



2 – SUBJECT OVERVIEW : Fire extinguishers

Industrial Activity

1 extinguisher 9 l of water or 9 kg of powder by 200 m2 or
1 extinguisher 6 l of water or 6 kg of powder by 150 m2 or
3 extinguisher 5 kg CO2 by 200 m2

Additional subsidy

Localized hazard (electric cupboard, transformer, compress
generator, electric engine, special machine):
An adapted fire extinguisher has to be unless 5 m of the danger

Storage (height > 3 m)

1 extinguisher on wheel of 50 kg (water or powder) by 100 m2, from 400 m2 of storage

This *subsidy is useless on the storage witch is provided with RIA*

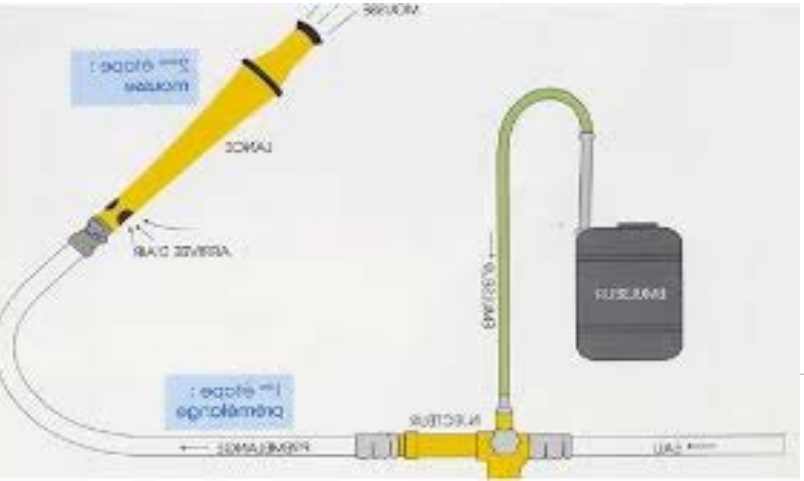
During the visit

Clear access + Labelling + check inspection label

During documentation review

Training + inspection

2 – SUBJECT OVERVIEW : Fire reels and hose



- A specific fire hose network should supply fire fighting points with a fire reels and hose (FPHS).
- The location of the FPHS's should make it possible to sprinkle one point of the building with 2 FPHSs.

- + FOAM << Quantity / time limit use

<u>During the visit</u>

Clear access + Labelling + check inspection label

<u>During documentation review</u>

Training + inspection

2 – SUBJECT OVERVIEW : FIRE STRATEGY???

What is the site fire prevention and protection strategy ??? Human/Organizational or Technical

EXAMPLES	Solution 1 (-)	Solution 2 (+)
Chemical site	Fire or gas detection and on site fire brigade	Automatic sprinkler system with foam
Chemical workshop with sodium handling	Clear sign: No water! / No connections of water pipe in the process	Gas extinguishing system / special powder
Warehouse	Fire detection and on site fire brigade Fire hoses /	Automatic sprinkler
Sterile Pharmaceutical class A	Fire detection and on site fire brigade Gas extinguihers Contamination by smoke ????	*Sprinkler with preaction ????* *Sometimes water and smoke can cause more damages ?????*
Packaging	Fire detection and on site fire brigade Fire hoses /	Automatic sprinkler
OEB5 workshop	Fire detection and on site fire brigade Gas extinguiher / Water polution	(sometimes sprinkler can create more dammages ?????)
Biological agent workshop	Fire detection and on site fire brigade Gas extinguiher / Water polution	(sometimes sprinkler can create more dammages ?????)
Technical areas (Electrical / Dust collector/Filters ….)	Fire detection and on site fire brigade Gas extinguiher	Automatic sprinkler

1 – AUDIT OVERVIEW

88	Are **emergency exits and evacuation** routes clearly marked, kept free of obstructions (unlocked)? Are emergency exit signs illuminated with emergency backup power?	Yes No Please explain: Yes No Please explain:	Yes No Comments
89	Are regular **emergency evacuation drills** conducted, and what is the frequency?	Yes No Frequency:	Yes No Comment
90	Are **emergency response** plans in place?	Yes No Please explain the key points of the emergency response plan: Indicate when the plan was last revised:	**AUDITOR GUIDANCE:** Describe if the relevant emergency scenarios been addressed in the emergency response plan - Natural: Earthquake, flood, tornado, hurricane, drought, etc. - Chemical: Spill, fire, wastewater treatment plant upset, - Human: Evacuation, first aid, medical emergency, civil unrest, active shooter/security threat, Does the facility have a communication system to alert the local community of impacts in the event of major emergency?
91	Does the site have an o**n-site emergency response team that is trained for fire or other emergencies?**	Yes No NA If yes, please explain:	Yes No NA Comments

2 – SUBJECT OVERVIEW : EVACUATION

<u>During site visit: In each workshops/room:</u>

- are the evacuation ways clear and easy access?
- with emergency light?
- evacuation plan ?
- siren ?

<u>During the documentation review</u>

- Date of evacuation drill + report
- Emergency Siren/light suply power ?
- Who gives alarm?
- Training ?
- Including in emergency plan or in a SOP ?

2 – SUBJECT OVERVIEW : FIRE SOURCES

During the visit

- Equipment for Fire / Environment / Chemical Risk ….
- PPE

During documentation review :

- Number of emergency team?
- Shift 24/7/365 ?
- Distance of fire-brigade ?
- Check emergency plan : Roles and responsabilties / Alert to the authorities




3 – PROBLEM TOPICS: FLOOD

Historical data

On live data and alert network

3 – PROBLEM TOPICS: FLOOD

Prevention /Protection measures

<u>Before the flood</u>

- **Evacuate the raw material/ finished product**
- **Protect equipment**
- **Anti-flooding system**

<u>During the flood</u>

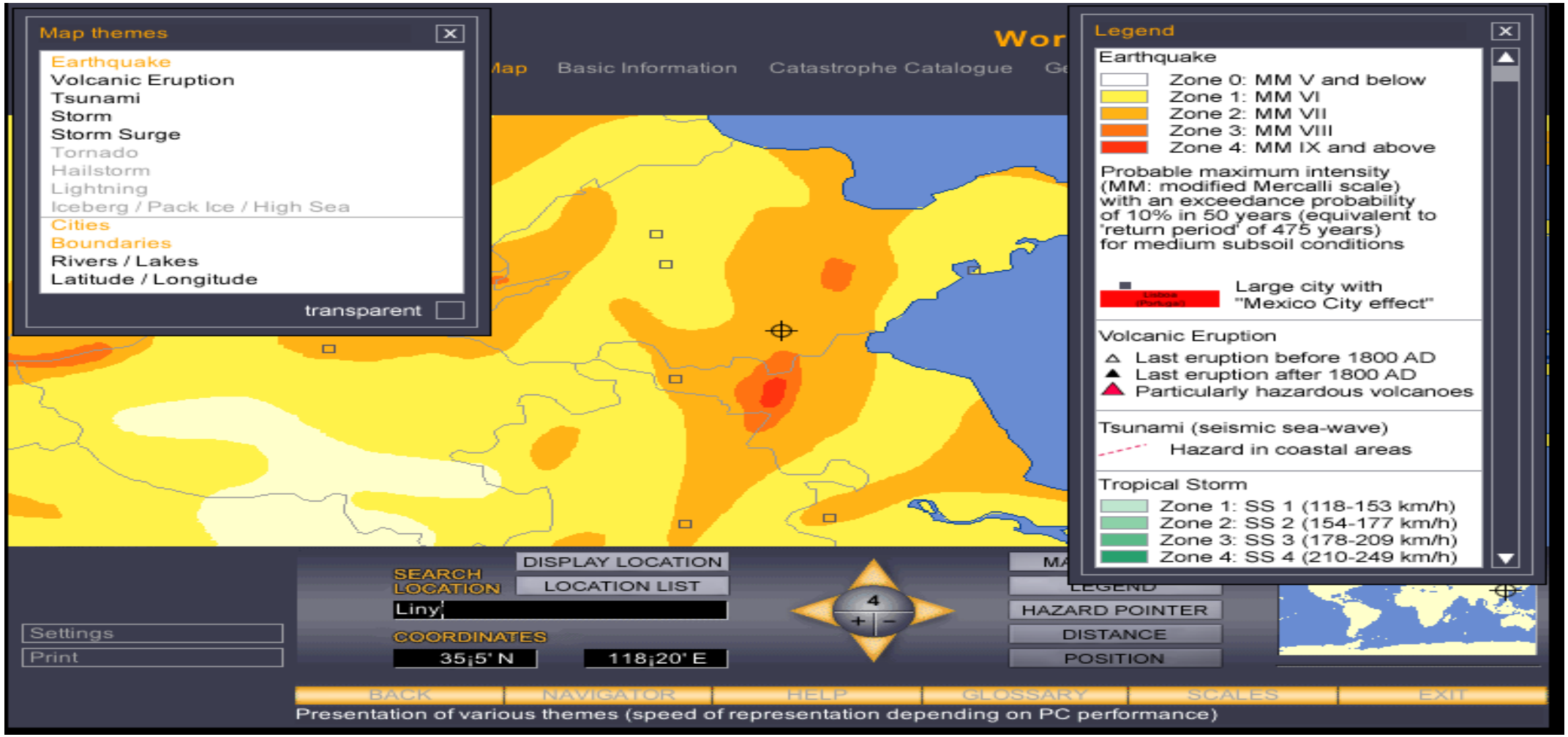
- Inspection

<u>After the flood</u>

- **Pumping / Cleaning**
- **Ventilation/ Drying**

Natural Hazards

Munich Re Nathan Natural Hazard Database: Earthquake



3 – PROBLEM TOPICS

- Eartquake resistant building
- Specific Storage
- Automatic seismic gas shutoff valv
- Specific sprinkler design
- Training

AGENDA 大纲

Emergency Preparedness and Response

Hazard Information

1 – AUDIT OVERVIEW

Topic	Question summary
Hazard Information	• Safety Data Sheets (SDSs) for all hazardous substances

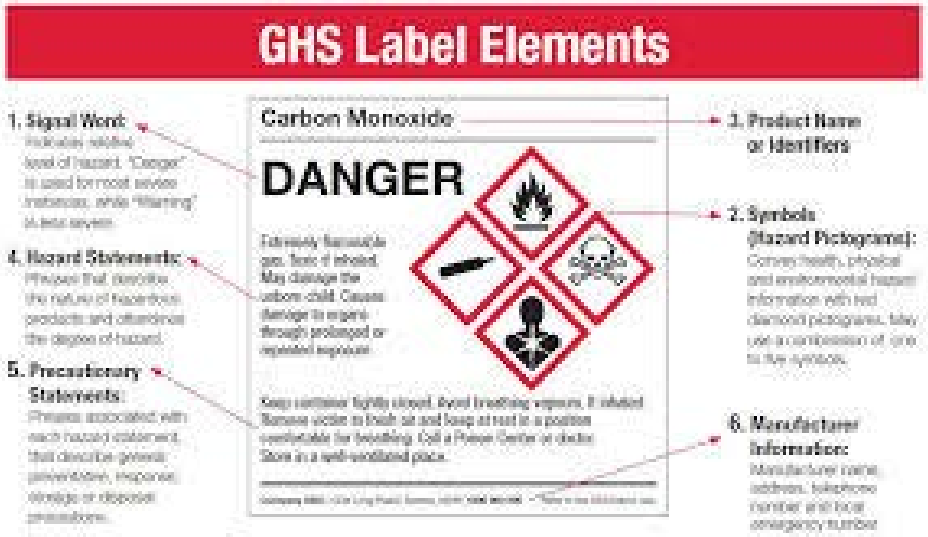
92	Does the facility maintain Safety Data Sheets (SDSs) for all hazardous substances?	Yes No Please explain:	AUDITOR GUIDANCE **WHO** edit/valid MSDS of your products ? **HOW** do you collect MSDS from your suppliers? Local **LANGUAGES** ? **ACCESS** for your operators/occu physician …? **ACCESS** for your clients ? TRAINING program covering the properties and health effects of the hazardous substances, use of and access to SDSs, container labeling and safe handling procedures?

1 – AUDIT OVERVIEW

During the site visit:

- Ask for a SDS to an operator
- Check labelling of raw, material, INTERMEDIARE, finish product

- During the documentation review:
  - WHO edit/valid SDS or labels of your products (16 chapters)?
  - HOW do you collect SDS from your suppliers?
  - Local LANGUAGES ?
  - ACCESS for your operators/occu physician …?
  - ACCESS for your clients ?
  - TRAINING program?



4 – EXAMPLE AUDIT FINDINGS

- No exit doors in the raw material warehouse W2 and finished goods warehouse W6
- Emergency light in the workshop B56 are not available.
- There are no smoke detectors, nor sprinkler, nor permanent presence on the site. Fire water storage is not available
- All emergencies doors are not identified
- The liquid substance Trimethylchlorosilane (CAS-# 75-77-4), which is violently reacting with water under formation of massive amounts of gaseous HCl, is stored in 200 L steel drums (in total about 4-5 to) together with all other flammable liquid drums in the area W34. There is no warning signs “no extinguishing with water” .
- Emergency evacuation drill are not conducted regularly , the latest drill was conducted in September 2014 . (we were in 2018 !!)
- Emergency response team responsibilities are not defined in the emergency plan
- Occupational physician has no access to the SDS database

EXAMPLE What is wrong?

84	Are the following areas of the facility equipped with fire detection/protection systems?	Site areas	Fire/smoke detectors	*Sprinkler or suppression* systems	Comments The site is partialy covered by sprinkler and fire detection.
		Raw material storage areas	Yes	No	Yes
		Flammable liquid storage tanks	Yes	Yes	Yes
		Process areas	Yes	Yes No	Yes
		Finished product warehouse	Yes	Yes No	Yes No
		Hazardous waste storage area	No		No

EXAMPLE

84	Are the following areas of the facility equipped with fire detection/protection systems?	Site areas	Fire/smoke detectors	Sprinkler or suppression systems	Comments Sprinkler is designed according NFPA rules. 2 diesel pumps (350m3/h) and a sprinkler tank 500m3 The site is partialy covered by sprinkler and fire detection.
		Raw material storage areas	Yes	No	Fire detection / fire hoses at all gates of the buildings
		Flammable liquid storage tanks	Yes	Yes	Manual foam canons in place
		Process areas	Yes	Yes No	Process areas are all equiped with fire detection Worshop A B are sprinkled Whorshop C is not covered by Sprinkler
		Finished product warehouse	Yes	Yes No	There is no sprinkler in FP warehouse
		Hazardous waste storage area	No	No	No

4 – EXAMPLE AUDIT FINDINGS

What is wrong ?

118	Does the site have an on-site emergency response team that is trained for fire or other emergencies?	Yes If yes, please explain: Team in place for spills.	No Comments Site leadership team provided documentation about spillage training

4 – EXAMPLE AUDIT FINDINGS

118	Does the site have an on-site emergency response team that is trained for fire or other emergencies?	Yes If yes, please explain: Team in place for spills.	No Comments Site leadership team provided documentation about spillage training

4 – EXAMPLE AUDIT FINDINGS

What is wrong ?

120	Does the facility maintain Safety Data Sheets (SDSs) for all hazardous substances?	Yes Please explain: Training session	No Comments Site leadership team provided details and documentation for Haz Comm training to site personnel.

4 – EXAMPLE AUDIT FINDINGS

What is wrong ?

120	Does the facility maintain Safety Data Sheets (SDSs) for all hazardous substances?	Yes Please explain: Training session	No Comments SDS access trough Online system. XYZ SDS are not in local langage.

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About the Secretariat
Carnstone Partners Ltd is an independent management consultancy, specialising in corporate responsibility and sustainability, with a long track record in running industry groups.

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PSCI PHARMACEUTICAL SUPPLY CHAIN INITIATIVE
Building responsible supply chains

Sprinkler Protection 喷淋防护
From basics to special applications
从基础到特殊应用

Presented by
Dr. Daniel Rehm
HSE Advisor Elanco External Manufacturing EMEA & API
由Daniel Rehm博士来演讲
HSE顾问，礼来动物保健外部制造，欧洲 & 原料药

Agenda 议题

Sprinkler Systems Basics 喷淋系统基础

Sprinkler Systems in Production 生产车间的喷淋系统

Sprinkler Systems in Warehouses 仓库的喷淋系统

Sprinkler Systems: History 喷淋系统：历史

- **Leonardo da Vinci** designed a sprinkler system in the **15th century**. Leonardo automated his patron's kitchen with a super-oven and a system of conveyor belts. In a comedy of errors, everything went wrong during a huge banquet, and a fire broke out. "The sprinkler system worked all too well, causing a flood that washed away all the food and a good part of the kitchen."
- 莱昂纳多·达·芬奇在15世纪设计了一套喷淋系统。莱昂纳多用一个特大号的烤箱和传送带在他顾客的厨房设计了一套自动化（喷淋系统）。在一次盛大的宴会上，大家都犯了戏剧性的错误，这些错误导致了火灾的发生。“喷淋系统运行的非常好，大量的水清洗了食物和厨房”。
- Ambrose Godfrey created the first successful automated sprinkler system in **1723**. He used gunpowder to release a tank of extinguishing fluid.
- 1723年，安布罗斯·戈弗雷成功的建立了第一套自动化喷淋系统。他使用黑火药将一储罐的灭火剂释放出来。
- The world's first modern recognizable sprinkler system was installed in the Theatre Royal, Drury Lane in the United Kingdom in **1812** by its architect, William Congreve, and was covered by patent No. 3606 dated the same year
- 1812年，在英国德鲁里巷的皇家剧院，建筑师威廉·康格里夫安装了世界认可的第一套现代化喷淋系统，同年包括在他的专利号3606里面。
- Sprinklers have been in use in the United States since **1874**, and were used in factory applications where fires at the turn of the century were often catastrophic in terms of both human and property losses.
- 自1874年，美国使用喷淋系统来保护工厂设施。在世纪之交，喷淋系统被用于保护灾难性的火灾导致的人员（受伤）和财产损失。

Sprinkler Systems: Design of sprinklers
喷淋系统：喷淋头设计

- Determination of fire hazard by building use and contents
- 通过建筑物用途和存放物料来确定火灾危害
- Hazard groups: 危害分组
  - Light hazard: offices, dwellings, church seating areas
  - 轻微危害：办公室，民居，教堂休息区域
  - Ordinary hazard group 1: parking garages, kitchens
  - 普通危害组1：汽车停车场，厨房
  - Ordinary hazard group 2: retail stores, warehouses
  - 普通危害组2：零售商店，仓库
  - Extra hazard group 1: saw mills, plywood manufacturing
  - 严重危害组1：锯木厂，胶合板制造
  - Extra hazard group 2: chemical manufacturing
  - 严重危害组2：化学品制造

HAZARD CLASSIFICATION	QUANTITY OF COMBUSTIBLES	COMBUSTIBILITY	RATE OF HEAT RELEASE
LIGHT	Low	Low	Low
ORD., GROUP 1	Moderate	Low	Moderate
ORD., GROUP 2	Moderate/High	Moderate/High	Moderate/High
EXTRA, GROUP 1	Very High	Very High	High
EXTRA, GROUP 2	Very High	Very High	High

Sprinkler Systems: Design of sprinklers
喷淋系统：喷淋头设计

- Density of sprinklers is defined per hazard group
- 基于危害组别来决定喷淋头的密度。
- Design area: worst case area of a fire in a building
- 设计区域：建筑里面，火灾发生的最糟糕情况的区域。
- Example: office (light hazard) 举例：办公室 （轻微危害）
  - Design area: 1500 ft^2 = 140 m^2 设计区域：1500平方英尺=140平方米
  - Design density: 0. 1 gal/min per ft^2 = 0.38L/min per 0.093 m^2
    设计密度：0.1加仑/分钟每平方英尺=0.38升/分钟每0.093平方米
  - Sprinkler system design: 570 L/min over 140 m^2
  - 喷淋系统设计：570升/分钟，覆盖140平方米
- Example: manufacturing facility (ordinary hazard group 2)举例：制造类工厂（普通危害组2）
  - Design area: 140 m^2 设计区域：140平方米
  - Design density: 0. 2 gal/min per ft^2 = 0.76L/min per 0.093 m^2
  - 设计密度：0.2加仑/分钟每平方英尺=0.76升/分钟每0.093平方米
  - Sprinkler system design: 1100 L/min over 140 m^2
  - 喷淋系统设计：1100升/分钟，覆盖140平方米

Sprinkler Systems: Design of sprinklers
喷淋系统：喷淋头设计

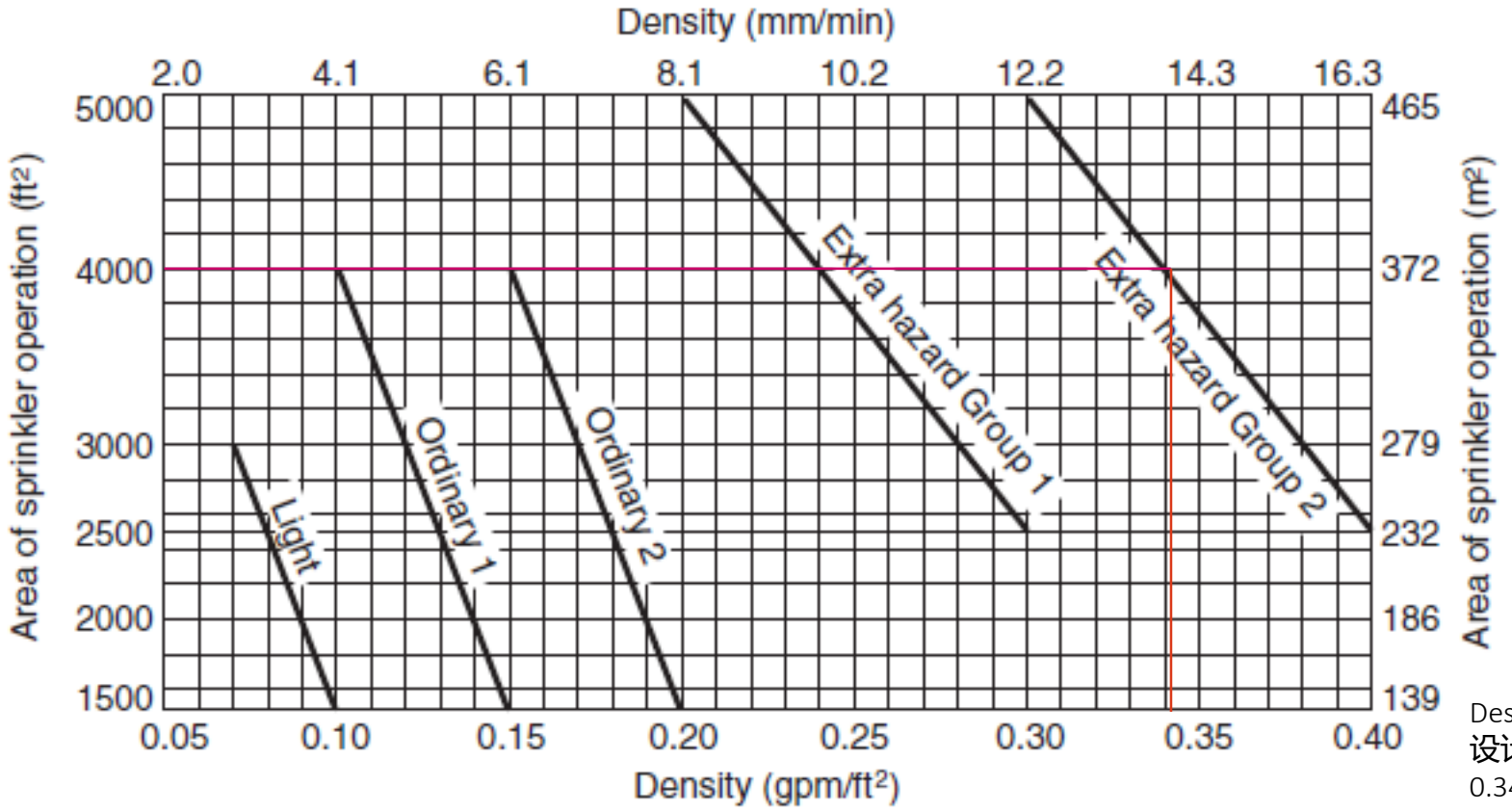

FIGURE 11.2.3.1.1 Density/Area Curves.

Occupancy	Inside Hose		Total Combined Inside and Outside Hose		Duration (minutes)
	gpm	L/min	gpm	L/min	
Light hazard	0, 50, or 100	0, 189, or 379	100	379	30
Ordinary hazard	0, 50, or 100	0, 189, or 379	250	946	60–90
Extra hazard	0, 50, or 100	0, 189, or 379	500	1893	90–120

Design area 4000 ft2 at extra hazard group 2:
设计区域 4000平方英尺，严重危害组2
0.34 gal/min/ft2 over 4000 ft2 for 90 – 120 min
0.34加仑/分钟每平方英尺，覆盖4000平方英尺，90-120分钟
→ 5168 L/min over 372 m2
→ 5168升/分钟，覆盖372平方米

Sprinkler Systems: meaning of the colors?
喷淋系统：颜色的含义

- The bulb color specifies the temperature the bulb breaks
- 玻璃管颜色代表玻璃管破裂的温度
- The bulb breaks as a result of the thermal expansion of the liquid inside the bulb
- 玻璃管内部液体的温度膨胀导致了玻璃管的破裂
- Under standard testing procedures, a 68 °C sprinkler bulb (RED) will break within 7 to 33 seconds
- 按照标准测试程序，达到68度时，喷淋头玻璃管（红色）应该在7-33秒内破裂。

Temperature		Color of liquid alcohol inside bulb
°C	°F	
57	135	Orange
68	155	Red
79	174	Yellow
93	200	Green
141	286	Blue
182	360	Purple
227 260	440 500	Black

Agenda 议题

Sprinkler Systems Basics 喷淋系统基础

Sprinkler Systems in Production 生产车间的喷淋系统

Sprinkler Systems in Warehouses 仓库的喷淋系统

Sprinkler systems in production
生产车间的喷淋系统

- Design of sprinkler systems in production units depends on use
- 生产单元喷淋系统的设计依赖于用途
- Sprinkler design needs to be re-visited after every change of installation and use
- 在每次变更安装和用途之后，喷淋系统设计需要再次评估。
- Placement of sprinkler heads needs to be done very carefully
- 喷淋头的布置需要非常认真仔细
  - Sprinkler heads should be below reaction vessels at outlet valve
  - 喷淋头应该位于排水阀反应器的下方
  - Sprinkler heads should not be obstructed by piping and other equipment
  - **喷淋头不能被管道和其它设备阻挡**

Sprinkler systems in production
生产车间的喷淋系统

- For production units with solvent handling the installation of foam systems is recommended
- 在生产单元内有溶剂处理的操作，推荐安装泡沫系统
- Available foam qualities: 可选的泡沫种类：
  - Alcohol Resistant Film-Forming FluoroProtein (AR-FFFP) 抗酒精型成膜氟蛋白泡沫
  - Film-Forming FluoroProtein (FFFP) 成膜氟蛋白泡沫
- Foam needs to be tested annually for degradation and is replaced every 5 years
- 每年测试泡沫的降解情况，每5年更换

Agenda 议题

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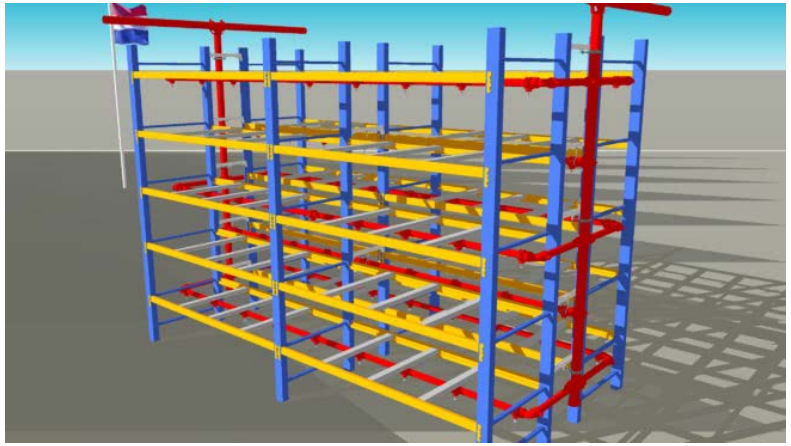
Sprinkler systems in warehouses
仓库的喷淋系统

- Sprinkler protection in warehouses:仓库内的喷淋保护：
  - Sprinkler systems protect buildings not stored goods
  - 喷淋保护建筑，不保护储存的货物
  - Water and smoke damage render goods unusable
  - 水和烟气损害致使货物不稳定
  - Loss for electronics and pharmaceuticals: 100%
  - 电子（设备）和药物损失率：100%
- Maintaining small fire areas is crucial to limit loss of product
  为了减少产品损失，维持小范围过火区域至关重要

	Structural damage **结构毁坏**	Damage to stored goods **储存的货物毁坏**
No sprinkler protection **无喷淋保护**	100%	100%
Sprinkler protection **喷淋保护**	<10%	50 to 100%

Sprinkler systems in warehouses
仓库的喷淋系统

- To protect stored goods it is important that the fire is extinguished at a very early stage
  为了保护储存的货物，在火灾初期扑灭是非常重要的
- Two systems are suitable: 两种可行的系统
  - Ceiling mounted sprinklers plus in-rack sprinkler heads (every 2.5 m)
  - 安装在顶部的喷头加上货架内喷头（每2.5米）
  - ESFR (Early Suppression Fast Response Fire Sprinkler Systems)
  - ESFR （早期抑制快速响应消防喷淋系统）



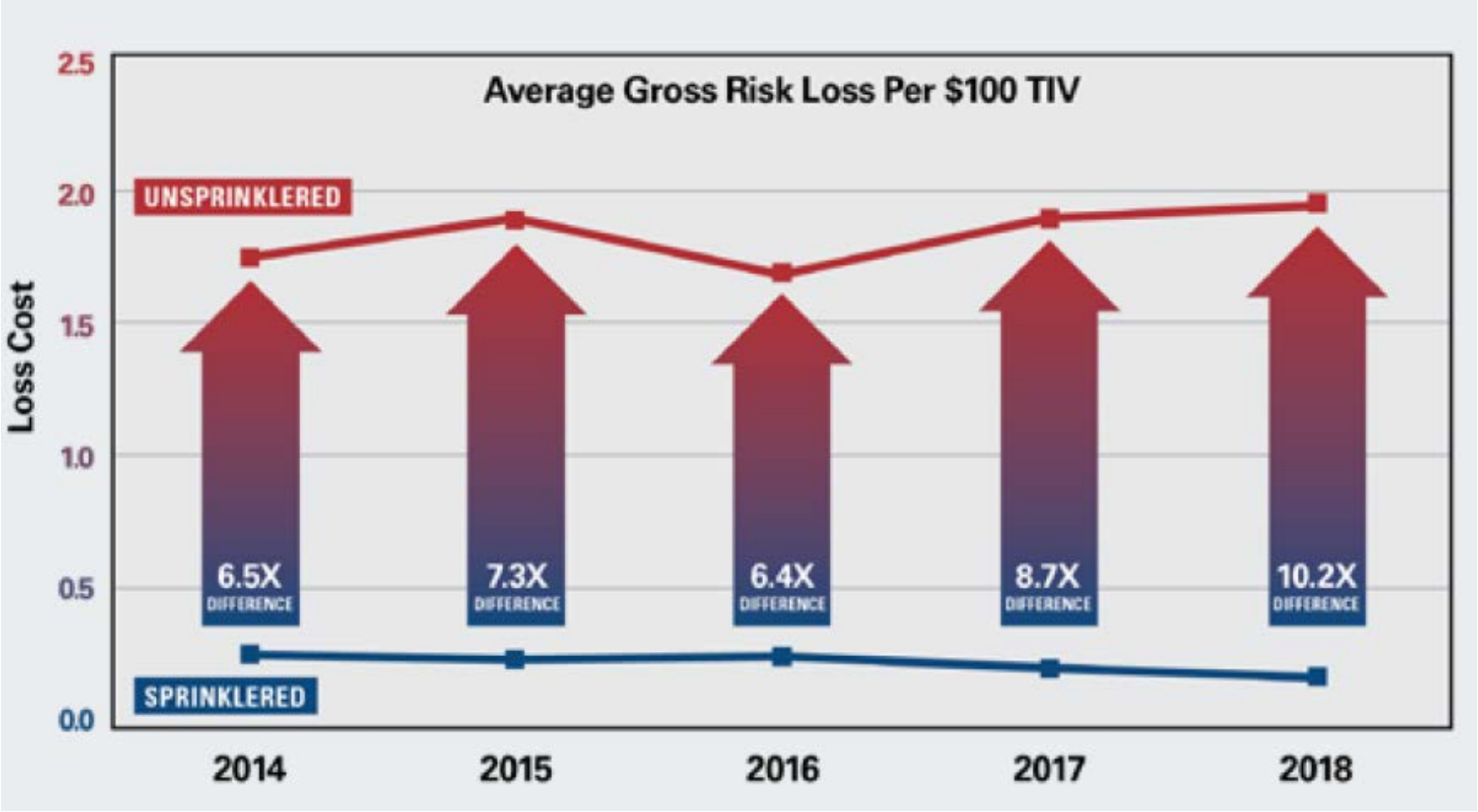
Sprinkler systems in warehouses
仓库的喷淋系统

- Stacked IBCs with flammable/combustible liquids: max height 2 when foam is available
- 叠放的IBCs内装有易燃/可燃液体：最大高度是2层IBCs（叠放）的情况下，泡沫系统才能正常工作。

Sprinkler Systems: Costs vs benefits
喷淋系统：成本 vs 收益

- Costs 成本
  - Average costs of sprinkler installation: US$ 3.3 – 38.7 per m^2
  - 喷淋安装的平均成本： 3.3-38.7美金 每平方米
  - Sprinkler protection installation as retrofit is generally more expensive
  - 改造时安装喷淋防护常常要更贵一些
- Benefits 收益
  - Fires in hotels with sprinklers averaged 78% less damage than fires in hotels without them (1983–1987).
  - 安装有喷淋系统的酒店，比没有安装喷淋系统的酒店，发生火灾时伤害损失平均减少78% （1983-1987）。
  - Average loss per fire in buildings with sprinklers was $2,300, compared to an average loss of $10,300 in unsprinklered buildings
  - 安装有喷淋系统的建筑，每次火灾的平均损失是2,300美金。作为对比，没有安装喷淋系统的建筑，每次火灾的平均损失是10,300美金。

Sprinkler Systems: Costs vs benefits
喷淋系统：成本 vs 收益



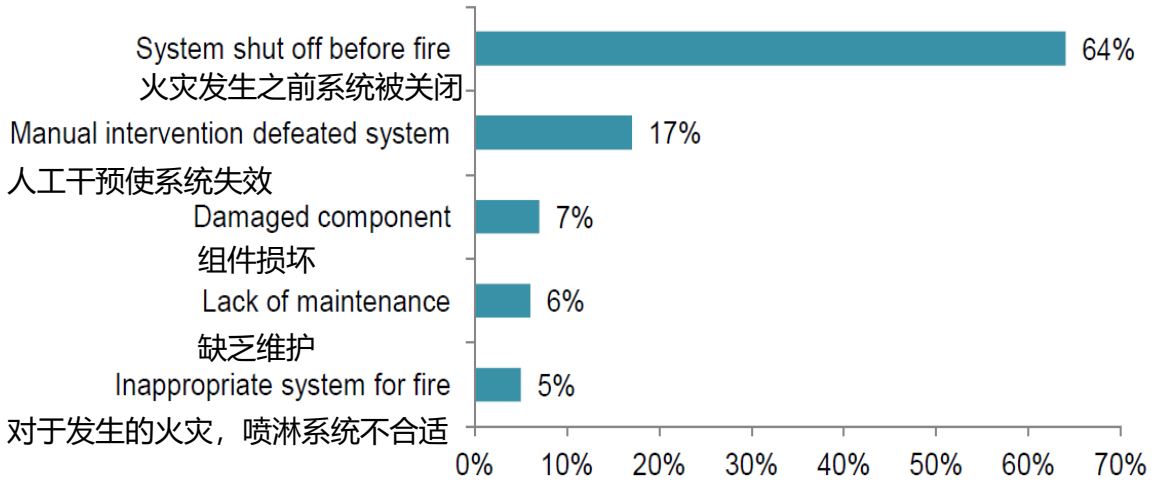
Why sprinklers fail to operate
喷淋系统无法正常启动的原因

In 2007-2011 fires large enough to activate them, sprinklers operated in 91% of fires in sprinklered properties. The graph below is based on the other 9% in which sprinklers should have operated but did not.

2007-2011年，发生火灾启动喷淋系统，正常启动的概率是91%。下图统计了另外9%的情况下，喷淋系统应该启动却没有启动的原因。

Reasons When Sprinklers Fail to Operate, 2007-2011

喷淋系统没有正常启动的原因，2007-2011



What to look for
需要注意什么

- Correct system? 系统是否正确
  - Foam system for flammable liquids? / Alcohol resistant foam needed? 针对易燃液体的泡沫系统/是否需要抗酒精型泡沫?
  - Automatic or manual? (sprinkler or deluge system?) 自动还是手动 （喷淋还是雨淋系统）？
  - In-rack sprinkler (every 2.5 m in high rack storage) 货架内喷淋（每2.5米，高层货架储存）
- Regular testing and Maintenance by qualified 3rd party 有资质的第三方进行常规的测试和维护
  - Flow test: 1/a, valve check 1/month/ visual check 1/week
  - 流量测试：1年1次，阀体检查：1月1次，目视检查：1周1次
- Protection against freezing? 防冻保护
  - Anti-freeze can lead to leakage during summer 未做好防冻保护，在夏季时会导致泄漏。
- Closed valves at foam tanks and headers! 泡沫罐和顶部的阀门被关闭
- Design documentation 设计文件
  - Correct occupancy 是否正确应用
- Fire load below sprinklers 喷头下方的火灾负荷
  - <1.8 m wooden pallets 木质托盘，小于1.8米
  - < 2.5 m empty plastic container 空的塑料容器，小于2.5米
  - <2 IBCs with flammable liquids 装有易燃液体的IBCs，不超过2层
- MOC! 变更控制
  - Change of sprinkler design in case of change in occupancy
  - 一旦用途变更，喷淋设计也要变更

Sprinkler systems: Standards
喷淋系统：标准

- NPFA 13: Standard for the Installation of Sprinkler Systems 喷淋系统安装标准
- CEA 4001
- NFPA 2001: Standard on Clean Agent Fire Extinguishing Systems (CO_2, Foam, FM200 etc.) 清洁剂灭火系统标准（二氧化碳，泡沫，FM200等）

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About the Secretariat
Carnstone Partners Ltd is an independent management consultancy, specialising in corporate responsibility and sustainability, with a long track record in running industry groups.

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PSCI PHARMACEUTICAL SUPPLY CHAIN INITIATIVE
Building responsible supply chains

High Risk work and red flags for dangerous working

Catherine Zhang
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Bio 个人简介

Catherine Zhang 张晓花

- Head of HSE Expert, APAC Based in Singapore
- Master in Environmental Engineering, Certified Safety Engineer in China, Certified Industrial Hygienist (ABIH)
- 10+ years within HSE, including 4+ years in Consumer Health production site, 6 months short time assignment in Germany, 3 years leading HSE Integration projects supporting 5 sites in China, after that move to regional HSE function covering all divisions in Pharmaceutical/ Consumer Health/ Animal Health/Crop science businesses at Bayer. Now Leading HSE Expert Team with subject matter experts and supplier management in the region of APAC.
- Contact information : Catherine.zhang1@bayer.com

Introduction

Traditional programs like Process Safety Management only indirectly protect employees health and life.

More people targeted programs are required !

Programs are called :

- High Risk Work Programs
- Prevention of Serious Injuries or Fatality (SIF)

Most of the requirements are legal obligation in Europe / USA

3.Work with hazardous energies

2.Confined space entry

4.Lifting operations

5.Working at height

10. Manual handling

6.High risk contractor and construction work

AGENDA

1 What is SIF

2 Confined Space Entry (CSE)

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Serious Incident, Impact or Fatality -Definitions

Fatality: a case that has caused the death of one or more individuals.

Serious Injury: life-threatening / life-altering, permanent, work-related injury;

- **Life-threatening:** a case that requires immediate life-preserving rescue action and that, if not applied in an immediate fashion, would likely have resulted in the death of that person. (Usually requires the intervention of emergency response personnel to provide life-saving support).
  - Examples include: significant blood loss, damage to the brain or spinal cord, use of CPR or AED, chest or abdominal trauma affecting vital organs or serious burns.

- **Life-altering:** a case that resulted in a permanent and significant loss or use of a major body part or organ function that permanently changes or disables that person's normal life activity.
  - Examples include: significant head injuries, spinal cord injuries, paralysis, major amputations, catastrophic fractured bones, and serious burns.

SIF Approach – High Level

- Determined the old methods were not accurate
- Treating all events equally to drive the triangle down
- Studies show ~21% of less serious events have SIF potential
- That does not mean we can ignore the lesser events but we must concentrate more closely on those with SIF Potential (the 21%).

15 SIF Categories

Mobile Equipment / Vehicles

Used in regular operation and interaction with pedestrians, structures etc.;

Confined Space Entry

As part of regular maintenance or repair being the cause of entry etc.;

Work with Hazardous Energies

Including moving or rotating machine parts, electricity, pressure, steam systems, line breaking, tasks requiring Lock-out / Tag-out procedures etc.;

Lifting Operations

Including use of cranes, fork lift trucks, lifting beams, block and tackle etc. to physically lift an object;

Working at Height

Use of scaffolds, ladders, MEWPs or fall arrest systems etc.;

High Risk Contractor & Construction Work

Such as excavations, demolitions, removal of contaminated materials etc.;

Exposure to or Release of Hazardous Material

Including APIs, intermediates or other materials that can result in asphyxiation, IDLH conditions or irreversible health effects etc.;

Release of Flammable Liquids or Gases

Including the quantity of release / exposure that must be considered in research, operation or maintenance or repair etc.;

Release of an environmental pollutant

A release of any substance to air, ground or water that may be beyond set limits or which may have a detrimental effect on the environment;

Corrosive Liquid Handling

Used in regular operation, maintenance or repair activities;

Manual Handling

Involving items of considerable weight or highly repetitive movements etc.;

Significant Process Upsets or Instability

During regular operation, maintenance or repair activities;

Unexpected Maintenance

Includes plant and equipment or systems where urgent maintenance is required etc.;

Unexpected Changes

In items of plant and equipment or processes etc.; and

Hot Work

Activities or operations that may generate sufficient heat, sparks or flame to cause a fire Includes welding,flame cutting, soldering, brazing, grinding and other equipment incorporating a flame.

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PSCI Questionnaire – High Hazard General

Worker Protection			
55	Does the facility have a safe work permit system for the following?	Hot Work: Yes No NA Confined Space Work: Yes No NA Energy Isolation or Lock Out/Tag Out: Yes No NA Line Breaking: Yes No NA Work at Height: Yes No NA General Permit Yes No NA Other: Yes No Please describe:	Yes No Comments **AUDITOR GUIDANCE:** For small size operations, a general permit might be sufficient provided it covers all relevant risks identified at that location. Asses the permit and determine if sufficient.

Confined Space Entry

This is an operation that takes often place although common thinking is that it's only related to entering in small vessels.

Typical activities :

- Manual charging of reactors
- Visual inspection
- Cleaning of equipment
- Inspection and maintenance

Confined Space Entry - Risks

- Asphyxing atmosphere
- Moving parts
  (hazardous energies)
- Exposure to chemicals
- Injuries / accident
- Difficulties during rescue

Confined Space Entry - Criteria

- No harmonized definition between companies, authorities, experts
- Usually related to a dimension (volume, length), difficulty of access, potential hazardous atmosphere / energies present
- Need to make sense, be consistent with other programs
- Need to be enforced !

Confined Space Entry – Program Elements

- Definition of Confined Space
- Inventory of Confined Space
- Permit system
- Atmosphere monitoring
- Planning of rescue operations
- Maintenance of equipment (oxygen monitoring, rescue equipment,...)

Work at heights

- All operations that are above ground ; where a fall is possible.
- Access to remote places (inspections, reparations, cleaning, maintenance)
- Access to roofs
- Access to underground or excavated areas

Work at heights - Risks

- Fall
- Fall of objects
- Impact due to moving parts (scissor lift, MEWP)
- Failure of equipment (Lack of maintenance of the ladder, platform,...)

Work at heights - Criteria

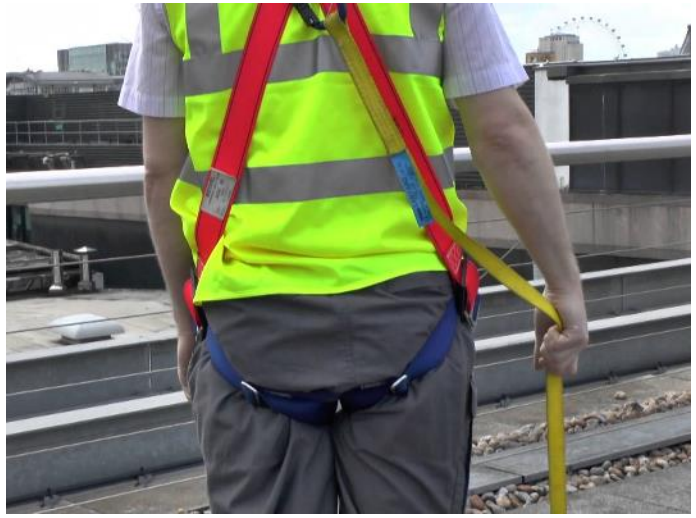
- Definition of height
  - 0 meter
  - 1.8 – 2 meters

Mobile Elevated Work Platform (MEWP)

Scissor lift

Work at heights – Program Elements

- Definition
- Risk assessment
- PPE – Fall protection system
- Rescue
- Permit system
- Maintenance program
- Safety perimeter during operation



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Working at Heights

- What is right ?
- What is wrong ?

- What are doing when
  you see such a situation during the audit ?

- Which documents are you checking after the visit ?

- What will be the finding(s) ?

Confined Space Entry

- What is right ?
- What is wrong ?

- What are doing when you see such a situation during the audit ?
- Which documents are you checking after the visit ?
- What will be the finding(s)?

Working at Heights

- What is right ?
- What is wrong ?

- What are doing when you see such a situation during the audit ?

- Which documents are you checking after the visit ?

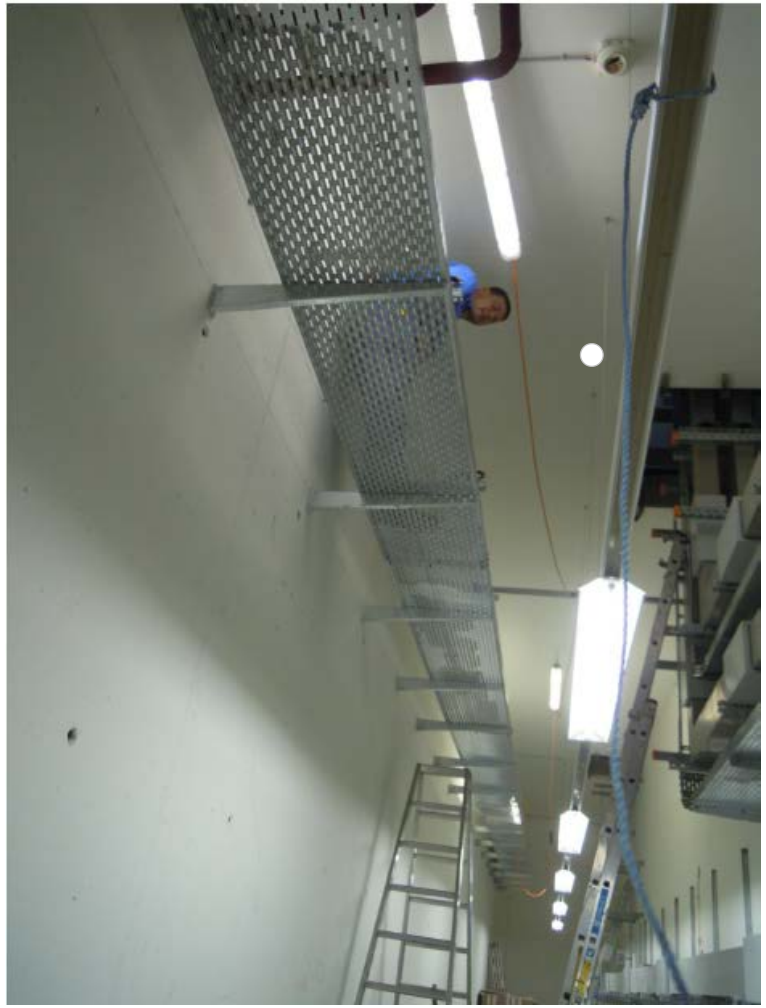
- What will be the finding(s)?

Challenging situation

During your visit, no operation like entry in a Confined Space Entry or Working at Heights take place...

What do you do to get an idea of the efficiency of their programs?

Some wrong behaviors…



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PSCI Questionnaire – High Hazard Energies, Electrical, Machine Guarding

Worker Protection			
55	Does the facility have a safe work permit system for the following?	Hot Work: Yes No NA Confined Space Work: Yes No NA Energy Isolation or Lock Out/Tag Out: Yes No NA Line Breaking: Yes No NA Work at Height: Yes No NA General Permit Yes No NA Other: Yes No Please describe:	Yes No Comments **AUDITOR GUIDANCE:** For small size operations, a general permit might be sufficient provided it covers all relevant risks identified at that location. Asses the permit and determine if sufficient.
56	Has the facility developed and implemented an Electrical Safety Program that includes:	Installation of lockable disconnects interlocks, and emergency stop devices? Yes No Labeling of switches, outlets, breakers, panels, and disconnects? Yes No Designating keep clear areas around electrical equipment for safe work practices? Yes No Electrical cabinets are locked? Yes No Arc Flash Analysis? Yes No	Yes No Comments
57	Has the facility developed and implemented machine guarding procedures (including conveyor systems or other overhead equipment conveying materials (side rails, netting, etc.)) with proper hazard symbols?	Yes No NA Comments:	Yes No NA Comments

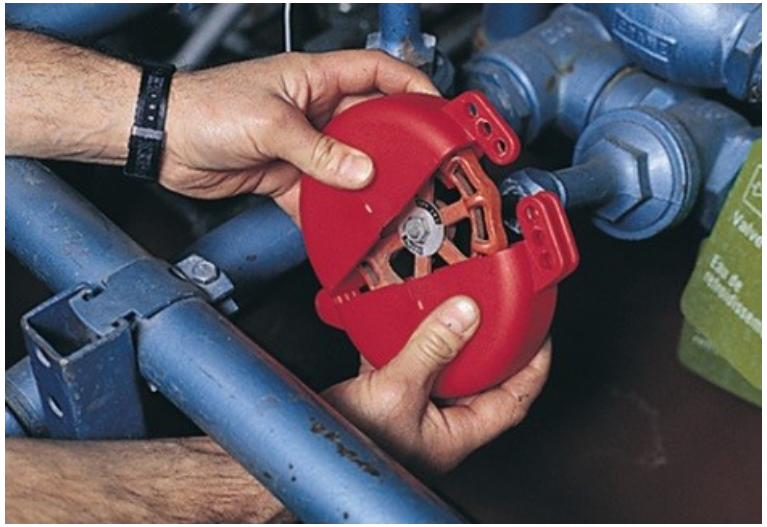
Working with Hazardous Energies - Sources

Hazardous energies sources include electrical, mechanical, hydraulic, pneumatic, chemical, thermal, or other sources in machines and equipment can be hazardous to workers.

- Moving or rotating machine parts (Mechanical)
- Pressure or steam systems
- Hazardous materials
  (e.g., chemicals, solvents, toxic gases, asphyxiants gases etc.)
- Gravity & stored energy
  (e.g., springs, potential energy which would cause equipment to move or rotate, explosion suppression systems, etc.)
- Electricity
  (mains and stored e.g., capacitors)
- Pneumatic valves
- Extreme temperatures
- Ionizing and non-ionizing energy sources
  (e.g., nuclear, x-ray, lasers, UV, etc.)

Working with Hazardous Energies Program Elements

- Definition
- Permit system
- Lock-out tools
- Tag-out tools
- Procedure for special cases
- Possibility of locking out
  (can be checked during visit also if there is no LOTO currently taking place)



Working with hazardous Energies

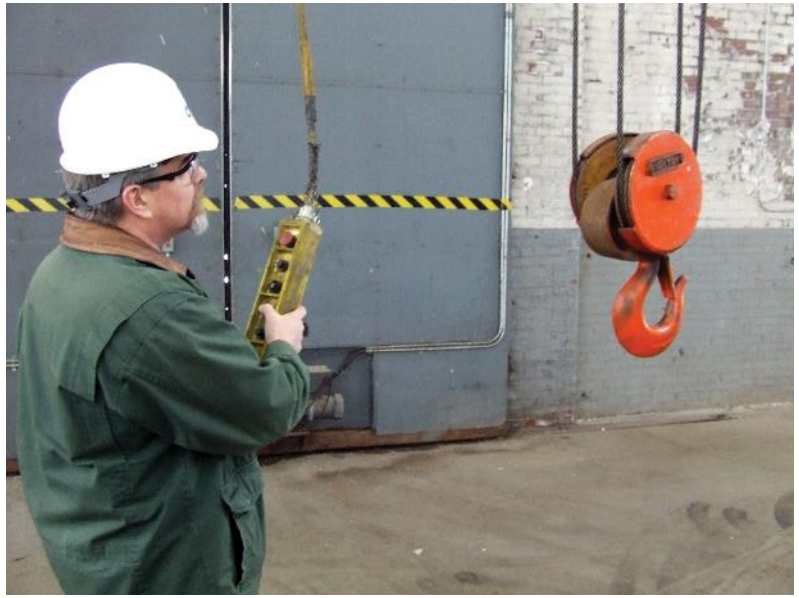
- Any work done on an equipment that can release energy and harm people
- Working on a packaging line that is switched on by someone else
- Retained energy like compressed air, spring...
- Work on electrical equipment

PSCI Questionnaire – Material Handling

59	Are the facility's pedestrian and material handling equipment aisles marked or designated?	Yes No Please explain:	Yes No Comments
60	Has the facility developed and implemented a formal program to provide for the selection and maintenance of Material Handling Equipment?	Yes No Does it include: Operation by trained persons? Yes No Periodic inspection and preventive maintenance by qualified personnel? Yes No If elevated work devices are used is appropriate fall protection equipment in place and is a rescue plan in place? Yes No Please explain:	Yes No Comments
61	Are the facility receiving and/or shipping docks equipped with wheel chocks, dock locking systems or other means of trailer restraint to prevent trailers from moving during loading/unloading?	Yes No Please explain:	Yes No Comments
62	Is product stored overhead in pallet racking stretch wrapped or secured by some means to prevent it from falling?	Yes No Please explain:	Yes No Comments
63	Does the facility have practices to ensure pallet racking is maintained in good condition and regularly inspected (no obvious damages to components – especially uprights – cross beams locked in place, foot plates secured to floor, and capacity posted)?	Yes No Please explain:	Yes No Comments

Lifting Operations

- Moving goods and materials using dedicated equipment
- Lifting of equipment for maintenance or repairs



Lifting Operations - Risks

- Fall of transported goods
- Failure of lifting equipment
- Injury of persons nearby
- Damage to nearby installation (→ chain reaction)

Lifting Operations– Program Elements

- Task assessment
- Equipment clearly and visibly labeled with appropriate information
- Inspection of the equipment prior to use
- Respect of limitations
- Maintenance program

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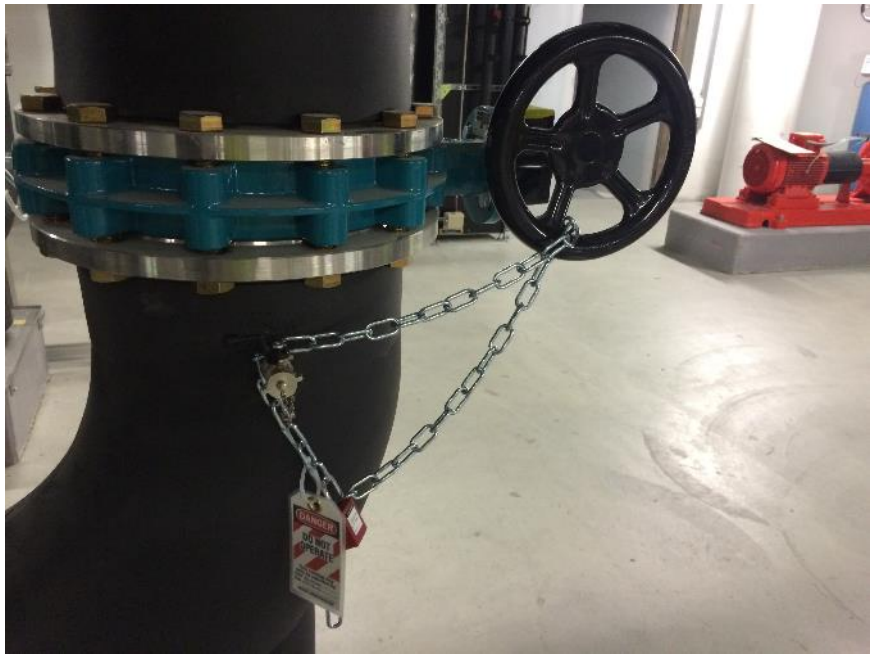
Is this a proper Lock-out ?



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PSCI Questionnaire – High Risk Contractors

58	Does the facility use any of the following processes for managing risks related to contractor activity onsite?	Contractor pre-approval: Yes No Training/orientation before entry: Yes No Electronic access control: Yes No Drug/alcohol testing: Yes No On-going recurrent safety training: Yes No Mandatory accident reporting: Yes No Other: Yes No If yes, please describe:	Yes No Comments AUDITOR GUIDNACE: Describe how you reviewed each program including details during tour, interviews and document review.

High Risk Contractors - Purpose

- Works that are not routine (= complex and high risk) are usually realised by specialised, external companies
- Includes Construction workers
- Trend in Europe/USA to have also routine work being done by external companies

High Risk Contractors - Risks

- Activity in itself
- Contractors lacking training / experience
- Not familiar with the facility
- Discrepancy between industry and «local» way of working
- Impact on adjacent / remote operations

High Risk Contractors - Criteria

Contractors performing high risk activities → definition, see ex. SIF activities

Resident contractors vs. one time contractors

High Risk Contractors – Program Elements

- Pre-selection of contractors
- On-boarding orientation (know the site)
- Need to use the Permit to Work system
- PPE / approved tools
- Checks during works
- Assessment of performance

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Short Case Study

- What is right ?
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Short Case Study

- What is right ?
- What is wrong ?
- What are doing when you see such a situation during the audit ?
- Which documents are you checking after the visit ?
- What will be the finding(s)?

Short Case Study

Besides usual risks of getting injured (trips, falls...) :

Important fire load

Programs

When you review those programs...

- Make sure that the program makes sense
- Make sure that what is written in a SOP is implemented
- Look for proofs of efficiency of those programs
- Look for consistency of those programs
- Look for interdependency

Conclusion

Those High Risk Work or SIF Programs are very important.

They might be seen as low priority because they impact only one person at a time...

but those operations takes place several time a day therefore *they make a difference* !

General Safety Questions

HEALTH & SAFETY COMPLIANCE AND RISK MANAGEMENT Self-Assessment Questionnaire			Auditor Verification Please provide observations, details, comments and any supporting documents
General			
47	Does the facility have a written Health & Safety policy, procedures, and practices?	Policy: Yes ☐ No ☐ Procedures: Yes ☐ No ☐ If yes, provide a copy of the policy and list the procedure titles:	Yes ☐ No ☐ Comments Link or policy provided: Yes ☐ No ☐ List of procedures provided: Yes ☐ No ☐
48	Does the facility have any documented Health & Safety objectives and targets or goals for performance improvement, including metrics?	Yes ☐ No ☐ Please describe:	Yes ☐ No ☐ Comments
49	Indicate the number of significant Health & Safety incidents that occurred at this facility over the past three years? *(Significant incidents are defined as: causing serious injuries or fatalities; a fire resulting in damage to process equipment, building, storage areas; physical explosions, fines or violations.)* *If any of these incidents were or are not being tracked, please indicate this by adding "not tracked" to the appropriate cell*	Three years ago / Two years ago / Last year Serious injuries Fatalities Fire Explosions Fines or violations	Yes ☐ No ☐ Comments **AUDITOR GUIDANCE:** Please note that deficiencies in this question do not necessarily result in a finding.
50	Does the facility provide HSE (Health, Safety & Environment) training to employees (full-time, temporary, or contractor)?	New employee orientation and HSE training: Yes ☐ No ☐ Periodic refresher training: Yes ☐ No ☐ Pre-start up process specific HSE training: Yes ☐ No ☐ Employee emergency response action training: Yes ☐ No ☐ Hazard Communication, Yes ☐ No ☐ Process Safety Management, Yes ☐ No ☐ Environmental Practices: Yes ☐ No ☐ Comments:	Yes ☐ No ☐ Comments **AUDITOR GUIDANCE:** Review qualification for persons managing API emissions (i.e. knowledge of regulatory requirements and quantification of APIs in treated waste water) Review the business area's written qualifications for persons performing and reviewing environmental calculations and sampling. Ensure that the qualifications address knowledge of the process and applicable regulatory requirements. Are employees responsible for active ingredient wastewater control practices provided suitable and sufficient information, instruction and training to be able to understand the hazards associated with environmental releases of those active ingredients and isolated intermediates?

General Safety Questions - Continued

51	Does the site have a program for improving safe behaviors?	Yes ☐ No ☐ If yes, please describe:	Yes ☐ No ☐ Comments
52	Does the facility ensure the provision of safe and potable drinking water and hygienic facilities to all employees?	Yes ☐ No ☐ Please explain:	Yes ☐ No ☐ Comments **AUDITOR GUIDANCE:** Water systems that could be impacted by contamination are tested for compounds of concern.
53	Does the company provide adequate sanitary facilities (e.g. clean toilets, possibilities for hand-washing).	Yes ☐ No ☐ Please explain:	Yes ☐ No ☐ Comments
54	If living accommodation (e.g. dormitories) are provided to employees or contractors, are they safe and clean, and do they meet the relevant basic requirements (e.g. fire protection and emergency)?	Yes ☐ No ☐ Please explain: If housing is provided, who has responsibility for maintenance and general HSE? Please explain: Is it ensured that housing for workers and families is not in the vicinity of production areas or with uncontrolled access to operational facility? Yes ☐ No ☐	Yes ☐ No ☐ Comments

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About the Secretariat
Carnstone Partners Ltd is an independent management consultancy, specialising in corporate responsibility and sustainability, with a long track record in running industry groups.

carnstone
partners ltd

PSCI PHARMACEUTICAL SUPPLY CHAIN INITIATIVE
Building responsible supply chains

Occupational Health and Industrial Hygiene

Wenjia Xu/徐文嘉
EHS&S Manager, External Supply/EHS&S经理，外部供应链
Johnson & Johnson/强生公司

AGENDA 大纲

1. Audit overview – 10 mins
2. Subject overview –40 mins
3. Example audit findings – 30 mins
4. Audience questions – 10 mins

Bio 个人简介

15 years in Pharma & Chemical

PSCI Role: IH sub team member

Company Job Title: Manager, External Supply EHS&S, J&J

Previously working as

- Associate EHS Manager at Roche
- EHS Supervisor at BASF
- EHS Engineer at Shanghai chlorine-alkline chemical

BS in Safety Engineering

Certified Industrial Hygienist

AGENDA 大纲

1. **Audit overview – 10 mins**
2. **Subject overview –40 mins**
3. **Example audit findings – 30 mins**
4. **Audience questions – 10 mins**

1 – AUDIT OVERVIEW

Audit Questions Summary – Occupational Health and Industrial Hygiene

Topic	Question summary
Occupational Health and Industrial Hygiene	• Risk assessments for chemicals handled • Occupational exposure level (OEL) values for APIs and hazardous substances • Exposure control capabilities for pharmaceutical compounds • Risk-based medical monitoring or employee health surveillance • Plan to protect First Aid Responders and Medical Professionals from body fluids • Exposure monitoring for the following health and safety risks • Site procedure to inform employees of the results of exposure evaluations and monitoring • Personal Protective Equipment (PPE) for face, eye, foot, head, body and hand protection • Respiratory protective devices and/or engineering controls • Respiratory protection equipment program appropriateness • Fit testing, training, use, cleaning, inspecting, storing, and maintenance of respirators
Hazard Information	• Safety Data Sheets (SDSs) for all hazardous substances
Biosafety	• Does the site handle Risk Group 2 – 4 organizations and have a Biosafety Program

2 – SUBJECT OVERVIEW

What are the PSCI Health & Safety Principles applicable to IH?

1. Worker Protection
Suppliers shall protect workers from over exposure to chemical, biological, physical hazards and physically demanding tasks in the work place and in any company provided living quarters.

3. Emergency Preparedness and Response
Suppliers shall identify and assess emergency situations in the workplace and any company provided living quarters, and to minimize their impact by implementing emergency plans and response procedures.

4. Hazard Information
Safety information relating to hazardous materials - including pharmaceutical compounds and pharmaceutical intermediate materials - shall be available to educate, train, and protect workers from hazards.

Using the PSCI Questionnaire for IH

- Don't just answer yes/no. If you did not evaluate that question – type in Not Evaluated.
- Identify what they do and let the PSCI company understand ANY concerns with the approach you see.
- Ultimately place in your conclusions about acceptability for the Supplier to be CAPABLE and EFFECTIVE at handling the APIs they are under contract to handle. Be sure in question 66 to document whether the OEL handling approach aligns between the companies. Also document whether in question 67 whether the capability they say they have is there and if it is appropriate for what they are actually handling.
- One of the most common findings is the Supplier doesn't really know whether exposure control is acceptable as there is no monitoring– write the finding "Company has monitoring data for employees but it is limited to (or does not exist) and thus the exposure control strategy cannot be confirmed as adequate. The recommendation might be "secure the exposure assessment data to confirm the existing control strategy of engineering and PPE controls is sufficiently protective.
- ALWAYS – reference what you SAW in the field, not what you read just in a SOP. Be sure to document what you did or did not see on your tour! The actual SCOPE toured is very important for possible sharing of future audit reports between PSCI members. For example we did not see the highly potent handling area or we did not tour buildings 1,2,3.

Using the PSCI Questionnaire for IH

Management System Questions for IH

- 6. Does the facility or company have a process to manage all changes (e.g. chemicals)?
- 9. Does the facility or company maintain documentation for : Injury/Illness logs
- 11. Does the facility have formal processes to assess effectiveness of it's HSE programs?

Safety/Risk Management Questions – for IH

- 49. Indicate the number of significant Health & Safety incidents occurred at this facility over the past three years? if yes – look for evidence of tracking actions.

Some Ideas/Considerations

- Be sure to understand how new unit operations and/or new chemicals are introduced to the facility and if there is a formal change control process for that and for conducting baseline risk assessments.
- Explore how new chemical regulations (vs process) changes are managed – e.g. a new REACH like ban on a chemical.
- Ask about the last 5 years and any chemical exposure events or ergonomic events. If there are none- investigate into reporting of first aids and near misses as this would be somewhat unusual.
- For the self auditing program – confirm that the company is including worker safety / PPE type programs. You don't want centrally written programs by a corporate group that are not verified on the floor at the plant that you are doing business.

Some Ideas/Considerations

- Be sure to cover Chemical exposure to workers or contractors in the scope of this question.

Using the PSCI Questionnaire for IH

Safety/Risk Management Questions – for IH

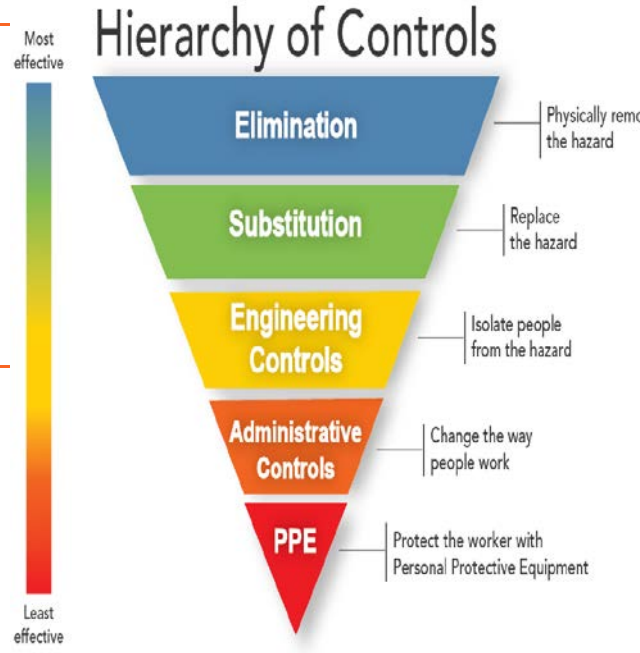
- 50. Does the facility provide HSE training to employees (full time, part time and contract)?

Some Ideas/Considerations

- The only IH specific question is Hazard Communication. There are many other IH related trainings – such as respirator, noise, PPE, asbestos, ergonomics. If you find a significant gap in training for IH be sure to include it either here or in the IH set of questions.

1 – Actual IH Questionnaire questions..

Occupational Health and Industrial Hygiene			
65	Does the facility perform risk assessments for chemicals handled?	Yes ☐ No ☐ Please explain: Do they consider pregnant women?	Yes ☐ No ☐ Comments
66	Has the facility occupational exposure level (OEL) values for all Active Pharmaceutical Ingredients (API) and hazardous substances (including intermediates and solvents)?	Yes ☐ No ☐ NA ☐ If yes, please explain how the OEL values are obtained:	
67	Has the facility established exposure control capabilities for handling pharmaceutical compounds? Please specify the lowest control range of containment for dust/powder handling that has been achieved.	Yes ☐ No ☐ NA ☐ ☐ <1µg/m³ ☐ 1-10 µg/m³ ☐ 10-100 µg/m³ ☐ >100 µg/m³ Comments:	
68	Does the facility perform risk-based medical monitoring or employee health surveillance which includes recording, investigation and follow-up?	Pre-employment physicals: Yes ☐ No ☐ Routine blood monitoring: Yes ☐ No ☐ Routine urinalysis: Yes ☐ No ☐ Lung function testing: Yes ☐ No ☐ Hearing test: Yes ☐ No ☐ Other: Yes ☐ No ☐ If yes, please describe:	



1 – AUDIT OVERVIEW

69¶	Has·the·facility·developed·and·implemented·a·plan·to·protect·First·Aid·Responders·and·Medical·Professionals·from·exposure·to·body·fluids?¤	Yes·☐·No·☐·Please·explain:·°°°°°¶ Does·the·program·include:¶ Training?·Yes·☐·No·☐¶ Exposure·response·kits·regularly·checked?·Yes·☐·No·☐¶ The·offer·of·Hepatitis·B·vaccinations?·¶ Yes·☐·No·☐¤
70¶	Does·the·facility·perform·exposure·monitoring·for·the·following·health·and·safety·risks?¤	Solvent·vapors:·Yes·☐·No·☐·NA·☐¶ Workplace·noise·levels:·Yes·☐·No·☐·NA·☐¶ Pharmaceutical·powders:·Yes·☐·No·☐··NA·☐¶ Radiation·levels:·Yes·☐·No·☐·NA·☐¶ Oxygen-deficient·atmospheres·(e.g.·nitrogen,·inert·gases):·Yes·☐·No·☐·NA·☐¶ Ergonomics·(height·lifting,·clima,·illumination,·vibrations,·...):·Yes·☐·No·☐·NA·☐¶ Other:·Yes·☐·No·☐·¶ If·yes,·please·describe:·°°°°°¤
71¶	Is·there·a·site·procedure·to·inform·employees·of·the·results·of·exposure·evaluations·and·monitoring·results?¤	Yes·☐·No·☐·NA·☐¶ Comments:·°°°°°¤
72¶	Does·the·site·provide·Personal·Protective·Equipment·(PPE)·for·face,·eye,·foot,·head,·body·and·hand·protection?¤	Yes·☐·No·☐¶ Please·explain:·°°°°°¤

1 – AUDIT OVERVIEW

73¶ ¤	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·☐¶ ¶ Please·specify·the·types·of·engineering·controls·used·to·manage·identified·chemical·exposure·risks:¶ ¶ Laminar·flow·hoods:·☐·¶ Down·flow·booths:·☐¶ Powder·transfer·systems:·☐¶ Alpha-beta·valves:·☐¶ Split·butterfly·valve:·☐¶ Soft·or·hard·wall·isolators:·☐¶ Local·exhaust·ventilation:·☐¶ Closed·processes:·☐¤
74¶ ¤	Does·the·facility·use·any·of·the·following·respiratory·protection·equipment·for·worker·protection·against·exposure·to·chemicals·or·pharmaceutical·compounds?¤	Supplied·air·breathing·systems·Yes·☐·No·☐¶ Powered·air·purifying·respirators·Yes·☐·No·☐¶ Full·face·respirators·Yes·☐·No·☐¶ Half·face·respirators·Yes·☐·No·☐¶
		Filtering·face·masks·Yes·☐·No·☐¶ Other·Yes·☐·No·☐·-If·yes,·describe:·°°°°°¶ What·criteria·are·used·to·select·respirator·protection·devices?·°°°°°¶ Respiratory·Protection·is·not·used?·☐·¶ Please·explain·if·not·applicable:·°°°°°¤
75¶ ¤	Are·there·provisions·for·fit·testing,·training,·use,·cleaning,·inspecting,·storing,·and·maintenance·of·respirators?¤	Yes·☐·No·☐·NA·☐¶ Please·explain:·°°°°°¤

AGENDA 大纲

1. Audit overview – 10 mins
2. Subject overview –40 mins
3. Example audit findings – 30 mins
4. Audience questions – 10 mins

Potent and Sensitizing API Compounds

What is a Good IH Program?

- An onsite person who has had training in control of hazardous agents.
- Access to an expert (e.g. certified industrial hygienist, qualified consultant).
- Inventory of hazardous chemicals, in particular potent materials, sensitizers, carcinogens and reproductive hazards.
- Information on chemical agents from customers and suppliers, occupational exposure limits or use of a banding system.
- Access to SDS and communication of risks, procedures and controls to staff using the hazardous chemicals.
- Risk assessments:
  - chemicals used, operations performed, assessment of control measures (including non-production tasks such as maintenance of equipment, handling of waste).
  - physical hazards and exposure controls methods in place.
- PPE Procedures and training on use, storage, and cleaning.
- Exposure sampling and monitoring data as appropriate.
- Risk based health surveillance.
- Incident/exposure records & strong accident investigations.
- Company has default program rules for handling unknown characterized chemicals.
- Worst case scenarios are understood for off-site consequences with training and emergency plans that are practiced….e.g. Ammonia cloud going off site.

WHY is this so critical in Pharma? Because APIs are not Nuisance Dust!!

INDUSTRIAL HYGIENE / WORKER EXPOSURE RED FLAGS

- We know APIs typically do not have regulatory exposure limits – PSCI companies DO NOT treat APIs as NUISANCE DUST. Agree on the required exposure limit and control banding. If none exists – Red Flag.
- Look at SDS between companies – do they agree on OEL and classifications? Differences >20X may be of concern.
- Bulk API /DP (drug product) companies for Pharma MUST have internal processes for setting final API and intermediate control banding and implementing those practices – especially in development and for intermediates.
- Industrial hygiene workplace monitoring needs to CONFIRM their strategy is working, especially when exposure limits are low (< 10 micrograms/m3) and respirator in use is very minimal. No data is a RED FLAG if handling highly potent materials.
- IH Capability in some parts of the world is a challenge. We typically encourage our partners to hire consultants.

First Question to prepare before audit –
Do we agree on Hazards of API?
Do we agree on the Controls Needed?

- API Supplier – Generic
- API Supplier – Proprietary Chemistry as Contract Manufacturer
- Pharma Drug Product site acting as Contract Manufacturing Company

Some Ideas/Considerations

- Review SDSs available– Do they agree on Hazard Classification and Occupational exposure limit?
  - If there is different classification or different OELs, Are the implemented exposure control methods based on the most conservative/lowest OEL?

- In your field visit, verify which are the exposure controls in place. Do they match with the described in the Risk Assessment?
- Request results of IH monitoring data collected.
  - If monitoring has not been conducted, verify exposure control/containment capabilities in your field visit.

A few foundational basics….

- **Occupational Exposure Limit (OELs)**
  - A numerical air concentration limit expressed as PPM or mg/m3 over a stated time duration (8hr, 12hr, 15 min, Ceiling) which nearly all adult workers may be exposed to during their working lifetime without adverse effects. These may be set by a government or a company.
  - Thousands of chemical do NOT have OELs.
  - Can be found on a SDS.

- **Occupational Exposure Banding** – Pharmaceutical Industry Method
  - Classify the Hazard Bands and pick your Default Band: The method a company establishes to setup rules for identifying a control strategy for handling materials with limited toxicology data for safe handling. The bands may be created using rule sets, limited toxicology, and Risk Phrases from the Global Harmonization Standard. Typically found on a SDS.
  - An established set of recommended ENGINEERING and CONTROL strategies for handling chemicals within a chemical exposure band. Companies who set OELs generally have these. NOT typically found on a SDS. You should ask to see this.

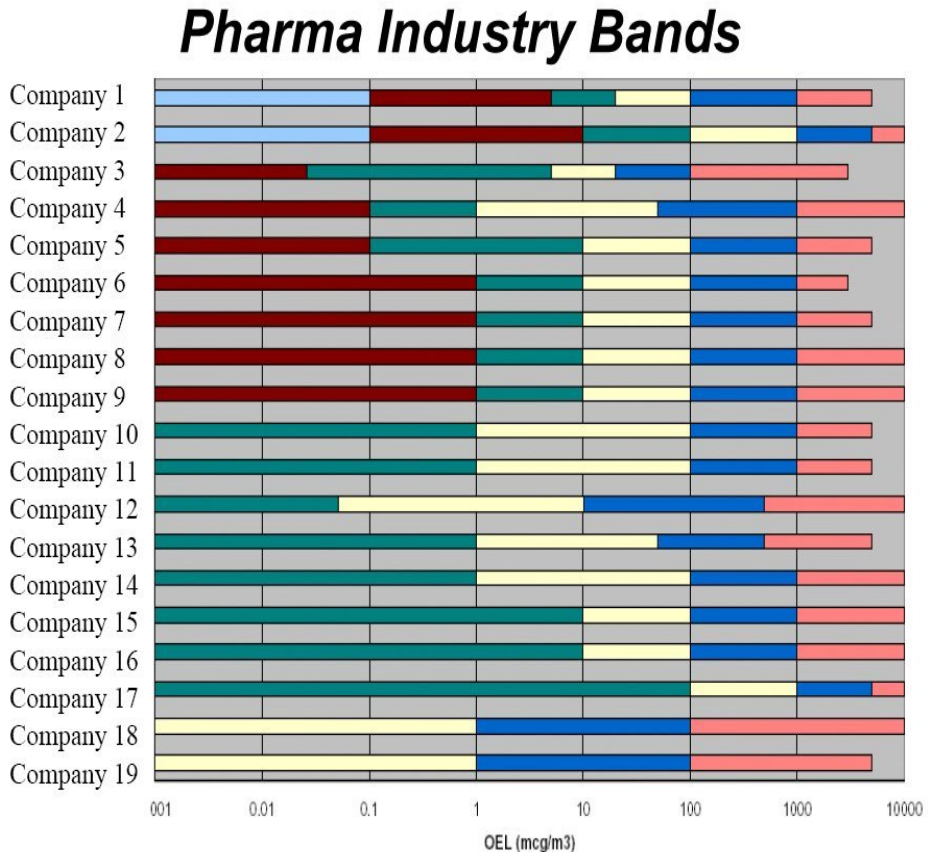
$$\text{OEL } (mg/m^3) = \frac{\text{NOEL } (mg/kg/day) \times \text{BW } (kg)}{V\ (m^3/day) \times S \times UF \times \alpha}$$

- NOEL = the no-observable-effect-level (mg/kg/day)
- BW = average human body weight (50 kg)
- V = volume of air breathed in an 8-hr work day (10 m^3/day)
- S = time, in days, to achieve a plasma steady state
- UF = uncertainty factors
- α (alpha) = % absorbed through inhalation

Managing Potent and Sensitizing Compounds Exposure Control Banding

- Example of exposure control banding:
  - OEB 1 (>1000 ug/m3)
  - OEB 2 (100-1000 ug/m3)
  - OEB 3 (10-100 ug/m3)
  - **OEB 4 (1-10 ug/m3)**
  - **OEB 5 (<1 ug/m3)**
  - **OEB 6 (<0.1 ug/m3)**

Highly Potent Categories



Yes –variation and nomenclature does exist among companies.

Banding Exercise
What OEL Band mass can your eyes no longer see?

Average worker breathes about 17 m^3 in a workday

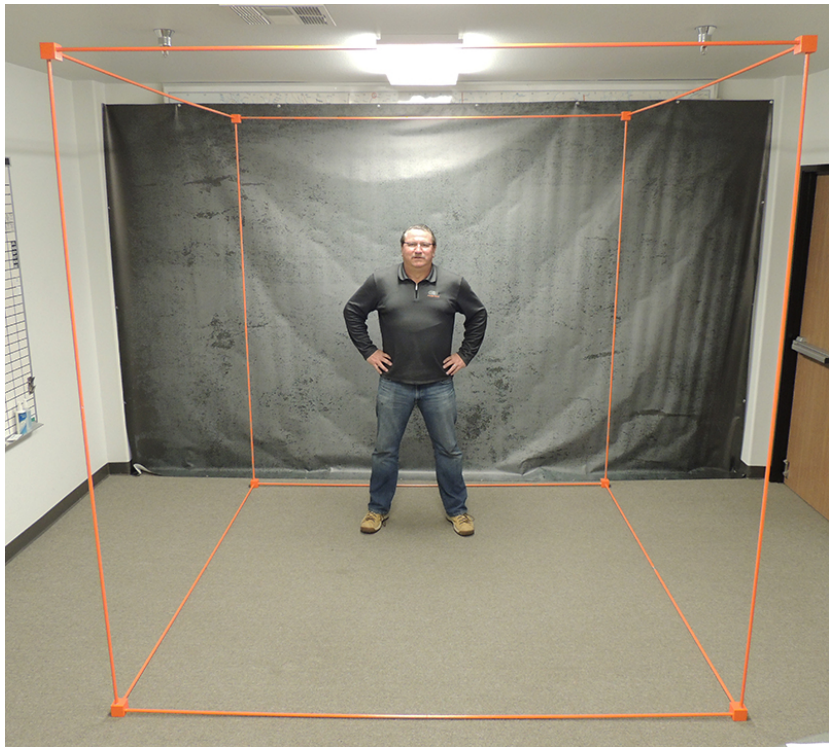
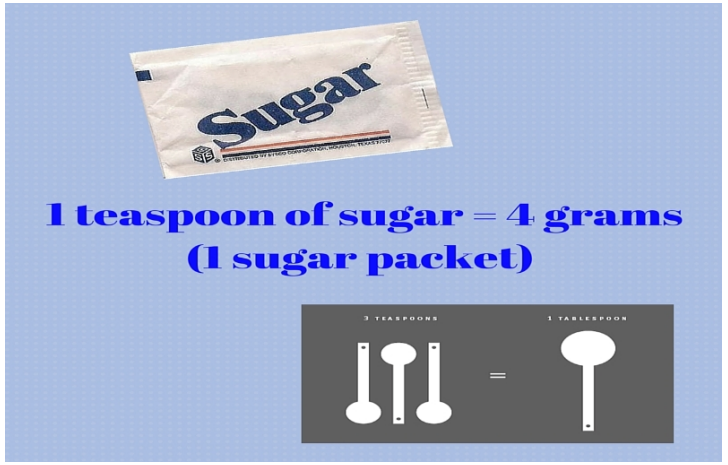


Photo from web reference "IP Powertools – Understanding the OSHA Silica PEL"



Band Range	Mass inhaled over 8hr day
10,000 µg/m^3	4% sugar pack
1,00 µg/m^3	0.4% sugar pack
100 µg/m^3	0.04% sugar pack
10 µg/m^3	0.004% sugar pack
1 µg/m^3	0.0004% sugar pack
0.1 µg/m^3	0.00004% sugar pack

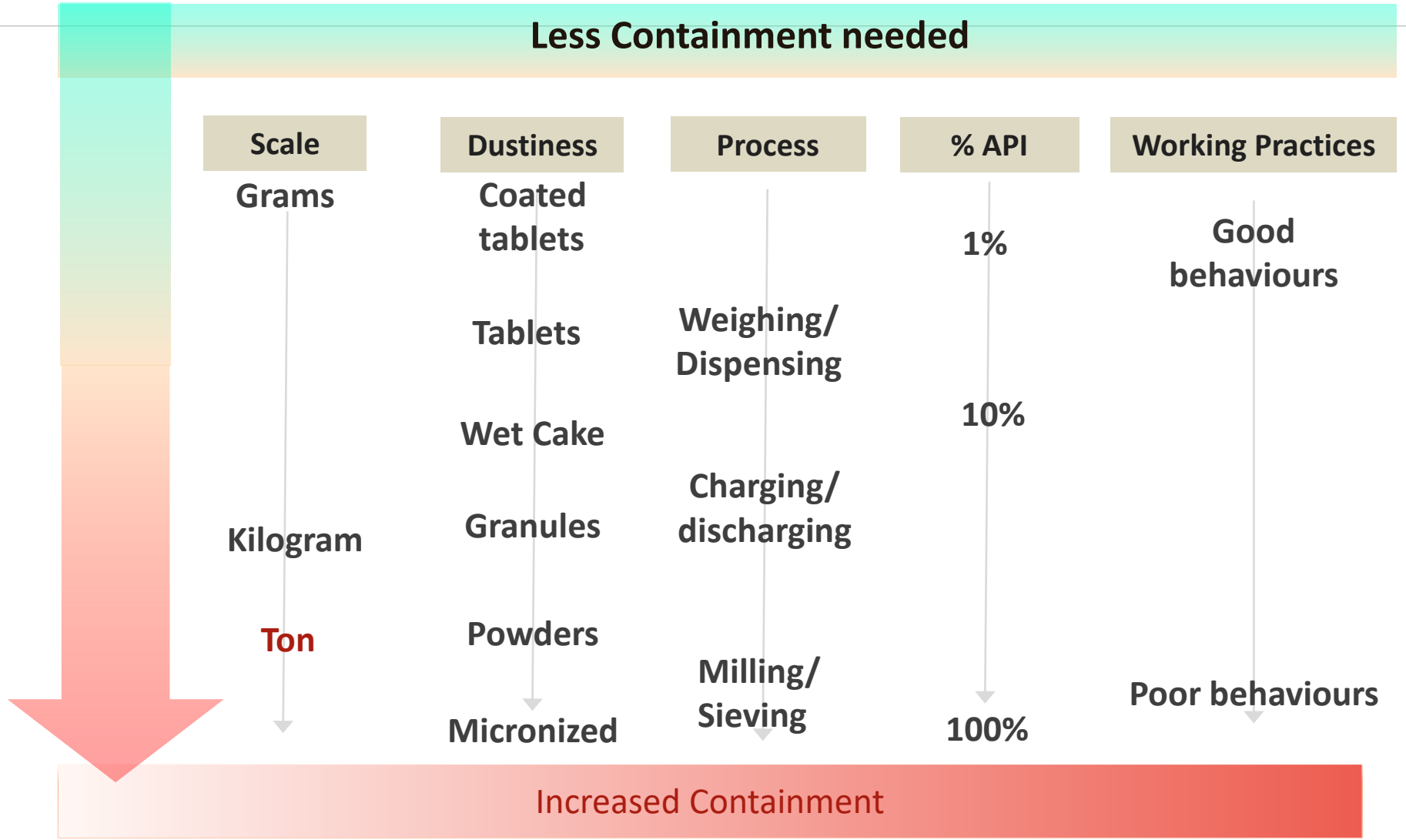
You can't see this exposure

Managing Potent and Sensitizing Compounds Factors Influencing Exposure

If you are Auditing a Supplier making products with an OEL <1 ug/m3 you really need an auditor experienced with exposure control concepts.

It is recommended even for OEL <10 ug/m3.

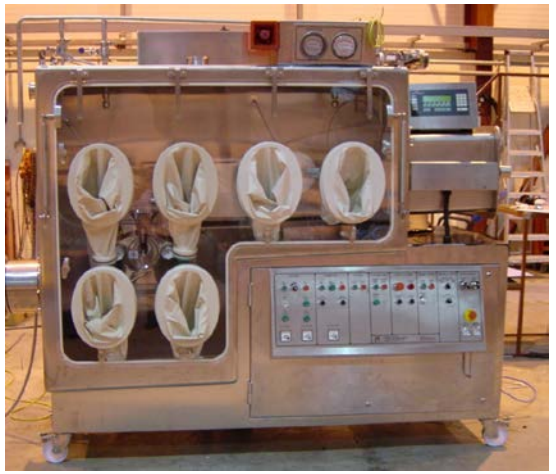
Managing Potent and Sensitizing Compounds Factors Influencing Exposure



Are the controls identified in the Risk Assessment appropriate for the substance OEL or Band and the operation or task observed in your Field visit?

Engineering Control Capabilities from PSCI website

Engineering Control	OEL Capability (µg/m3)*
Walk-in fume hood	< 5000
Laminar flow booth (horiz)	< 500
Laminar flow w/ continuous liner	< 100
Downflow booth	< 100
Downflow booth w/ screen	< 25
Split butterfly valve (SBV)	< 10
Single chamber glovebox (GB)	< 1
SBV w/ purge capability	< 0.5
Glovebox isolator around continuous liner	< 0.1
GB w/ RTP (rapid transfer port)	< 0.05
Multi-chamber GB w/ RTP/ESBV	< 0.01



** operator exposure during unit operation*

When doing a PSCI audit for a member company – Request their banding categories and tools up front to compare supplier actual handling….

Example: Control Banding Implementation

Band	PPE	Facility Design	Engineering Controls	Equipment Cleaning and Maintenance
Level 1	•Gloves •uniforms	•General Ventilation •Shared HVAC •General Filtered Exhaust •Recirculate Permitted •Common Gowning & De-gowning	•Passive Ventilation/Dilution •Open Mat'l Conveying and/or Mat'l Transfers •Open Process Equipment	•Open Process Equipment Transport to Cleaning Area •Manual Cleaning
Level 2	•Respirators •Tyvek coveralls	•Pressure Differential To Selected Adjacencies •Open Process Area •Closed Building •Process segregation with doors •Gowning/De-gowning Room	•Standard Equipment Design (Normally Closed) •Local Exhaust Ventilation •Mat'l Conveying Essentially Open with Hardware Remediation •Pressure Convey •Laminar flow	•Open Process Equipment Cleaned In-Situ
Level 3	•Maximum PF respirator	•HEPA Filtration •Room Finishes & Surface MOC's and Utilities Are Designed for Ease of Cleaning •Process segregation with airlocks •Decon Shower	•Standard Equipment Design with Separate Mechanical Space •Glovebox or Glovebag •Closed Material Conveying •Minimize Make/Break Connections •Split butterfly valves (SBV)	•Provide CIP with Rinse Water Capture •Closed equipment maintenance capability
Level 4	•Seek expert assistance •Respirators not adequate for "open" processing •Redundant PPE with engineering controls	•Seek expert assistance •Dedicated HVAC •HEPA Filtration w/Safe Change •No Exhaust Return •Closed Process Area •Closed Building •Separate Gowning & De-gowning •Automation	•Seek expert assistance •Process Equipment is Designed for Total Containment •Closed Mat'l Transfers with Barrier Add-ons •Vacuum Convey •Minimize Mat'l Conveying Steps •Minimize Material Transfer Connections •Isolator with continuous liner •Enhanced/purgeable SBV	•Seek expert assistance •Minimize Waste via Process and Formula Optimization •Protective barriers for laptops, paperwork, documents

what are your PSCI member company's band cut-off points?

Isolators

High Containment Capability for Potent Substances/APIs.

Flexible- glovebag or room enclosures

Rigid- glovebox

Laminar Flow Booths

When working on Laminar Flow Booths, additional control measures are usually needed to handle potent APIs.

Another important aspect is to ask how filters are changed/replaced? Is it performed in a way that minimizes exposure potential ?

Material Transfers

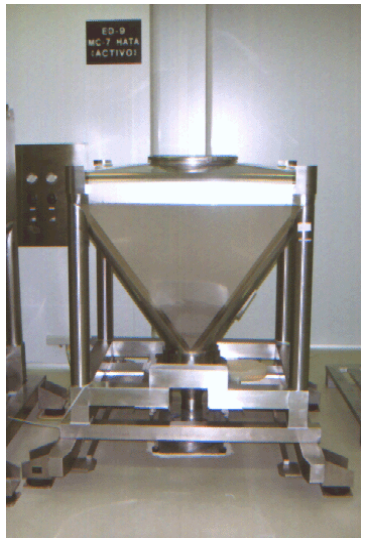
Active- open

Might be acceptable for substances with high OELs, non Potent.

VS

Active- closed

Appropriate for potent substances or substances with low OELs.



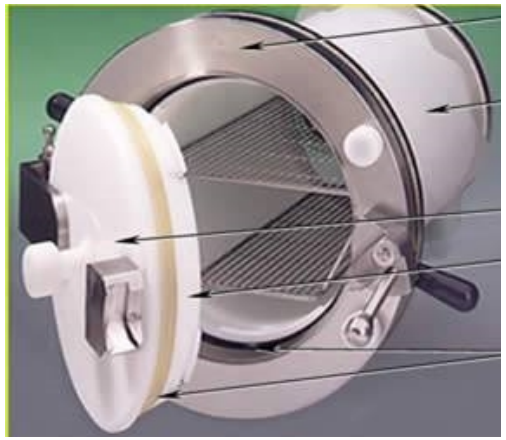
IBC

High containment design but transfer mechanism has to be set in place according to the substance containment level.

FIBC

High containment design for potent and low OELs substances.

Containment Transfer Mechanisms



Alpha/beta flange

Cone valve

Split Butterfly Valve

Containment flap

Continuous liner

Cut & tape bag

Local Exhaust Ventilation (LEV) Case Study

Good vs BAD Design?

- Is it appropriate for the type of operation or substance containment level?
- Does it has the appropriate duct and face velocity?

Request duct and face velocity and compare with industry standard (eg. Industrial Ventilation Manual).

Caution:
When handling Potent APIs, this would not be acceptable. Usually the human eye can not see dusts levels < 10 ug/m3.
Therefore, IH monitoring is necessary to assess containment capability and exposure potential – even on what you think might be well contained

› **Request IH monitoring studies.**

Laboratory Controls

Fume Hood

- Average face velocity 100 fpm
- Max sash height should be demarked
- Alarm (face velocity loss)

Biological Safety Cabinet

- Face velocity varies between 75-100 fpm depending of the cabinet type.
- Alarm (face velocity loss).
- HEPA filtration or ducted models available.
- Filter integrity testing.

Ventilated Enclosure Cabinet for Weighing

Employees must be Trained on how to appropriately use these equipment.

Request performance testing and compare results with industry standard or manufacturer recommendations.

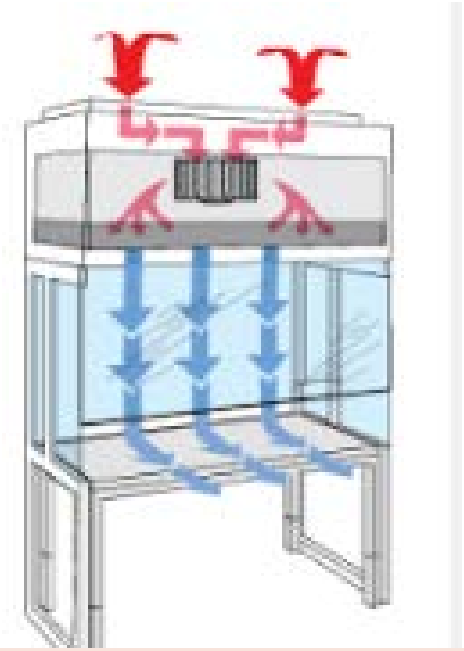
Laboratory Controls

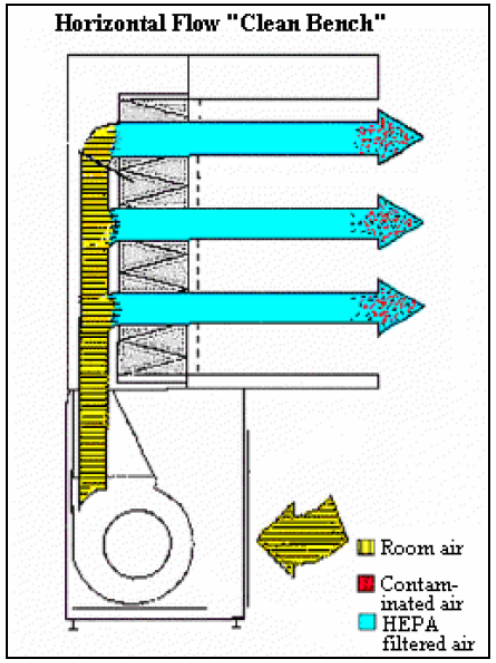
Glove Box

- Provides High Containment capability
- Requires detailed procedure to describe
  - Pre inspection verification
  - Practices for removing API and material (reusable and no reusable) after its use.
- Requires routine maintenance (gloves replacement, filter, pressure test).

Laboratory Controls

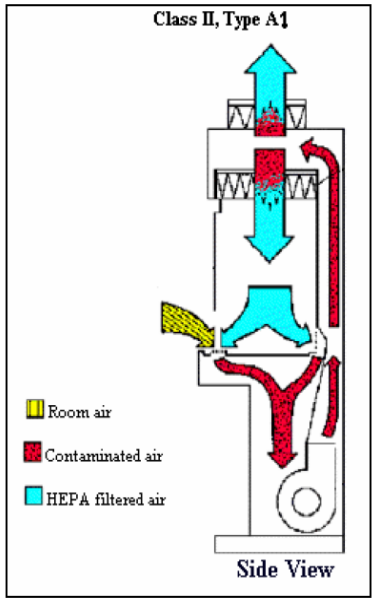
Laminar Airflow Bench





Caution:
Laminar Airflow Workbenches does not provides worker protection. Do not sure for chemicals or Biosafety Level 2 – 4 materials.

Biological Safety Cabinets



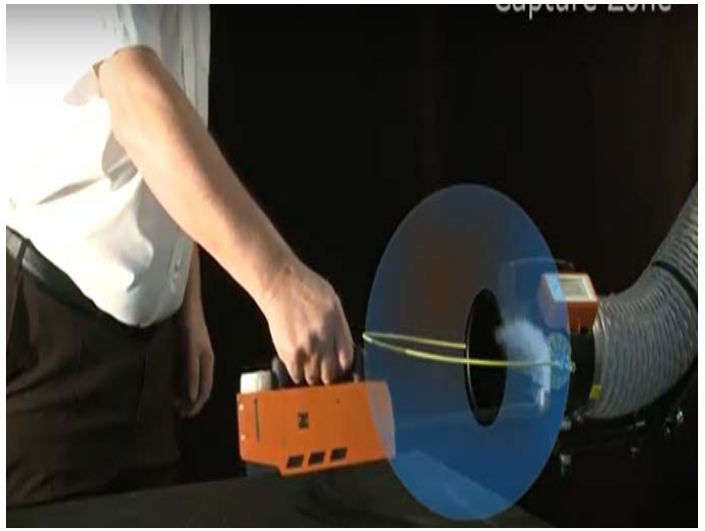
Biological Safety Cabinets Type I or II provides personnel protection. HEPA filters must be tested for efficiency and integrity.

http://www2.tulane.edu/oehs/safety/upload/BSCFactSheet-2.pdf

Engineering Controls Performance Testing

- Proper function of engineering controls depends on adequate maintenance.

Request maintenance records for all engineering control methods and check equipment are being tested in a regular basis and results are compared with industrial standard parameters or manufacturer design parameters.



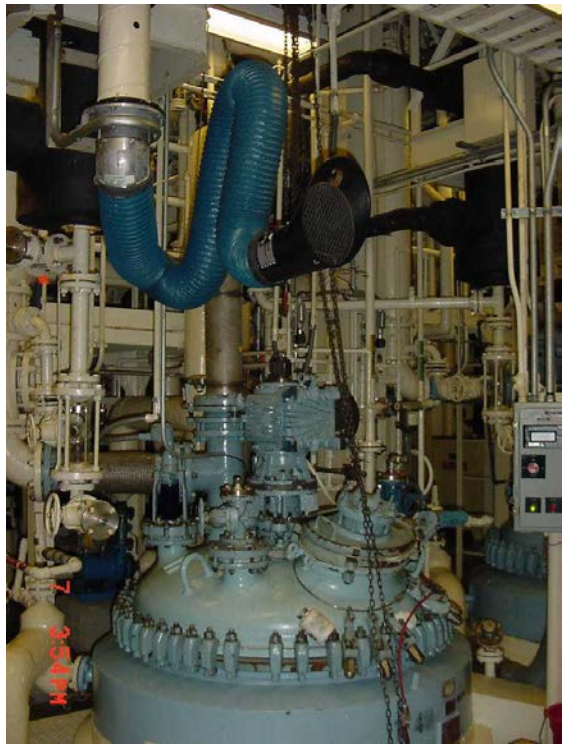
Other IH Considerations in Laboratories

- Chemical Storage by Compatibility (Acids, Bases, Oxidizers, Flammables, Health)
- Flammable Cabinet Storage

- Availability of Eye Wash Safety Showers

Pharma Unit Operations with High Potential for Exposure if not contained

- Reactor charge/material transfer
- Centrifuge unloading of solvent wetcakes
- Unloading Dryers
- Granulation/mixing
- Milling/de-lumping
- Compression
- Dispensing/weighing/repackaging
- Maintenance activities
- Cleaning / Manual Vessel Heel Removal
- Process upsets/spills
- Weighing/Dispensing chemicals



OR

Focus your tour to see these things

IH Monitoring Basics

Does the facility perform exposure monitoring for the following health and safety risks? Mark per category.
Is there a site procedure to inform employees of the results of exposure evaluations and monitoring results?

- Do data/studies ONLY focus on API and not on solvent/gases – Can be BIG issue for wet cakes in API plants.
- Evaluate:
  - # of samples, # of days sampled to understand exposure profile distribution
  - Total Dust vs API dusts at Drug Product Sites – if they are estimating are they using math?
  - Personal Breathing Zone Samples vs Area Samples
  - Short tasks data versus full shift data
  - Training or Technical expertise of the person that
    - collected the samples
    - make study exposure conclusions, and
    - report writer
  - Verify the Math on protection factors
  - No data – they use company's commissioning data on their web site.
- Employees should be informed of monitoring results.

Is it well managed?

Does it seem appropriate?

Most important, use the information to qualify the scope of the data you did see.

Reviewing IH Monitoring Data

During the review of the IH Information and Monitoring Data:

- Be very careful of Units of Measure:
  - mg/m3
  - mcg/m3=µg/m3
  - µg/m3
  - ng/m3

Example:
API Manufacturer Limit : 0.1 mg/m3

PSCI Member Limit: 0.1 mcg/m3

This can be a MAJOR data interpretation mistake on acceptable exposures…it is a 1,000 fold difference.

2nd question – based on controls in place, are people protected?

- If what you saw didn't use the Hierarchy of Engineering Controls, but was more heavily reliant on PPE or work procedures….
- ARE THEY ADEQUATELY PROTECTIVE?

72. Does the site provide Personal Protective Equipment (PPE) for face, eye, foot, head, and hand protection?

- Do PPE and Containment designation comes from a risk or hazard assessment?
- Are PPE and Containment requirements documented in the manufacturing batch record or are employees aware of the requirements by any other formal process?
- Are personnel wearing the correct/required PPE?
- Does the site's Respirator Program appear to be adequately managed?
- If the site is handling highly potent API powders or drug products, have they implemented containment measures to avoid "open handling"? Is there an actual engineering improvement plan? Does the engineering/containment plan comes from a risk assessment or IH monitoring results?
- If the site is handling potent API powders or drug products, have they implemented a comprehensive Industrial Hygiene Monitoring Program (i.e. more than just cursory area samples or particle counting)?

PPE Program should cover the following elements:

- Hazards and PPE types:
  - Head Protection
  - Eye Protection
  - Hearing Protection
  - Respiratory Protection
    - Fit Testing
    - Filters/Cartridges (Use and Replacement)
  - Hands Protection
    - Based on Compatibility Data (Breakthrough time)
  - Body Protection
  - Fee

- Inspection of PPE
- Use of PPE
- Maintenance
- Cleaning
- Storage
- Training

Respirators

- There are two types of Respiratory Protection:
  1. Negative Pressure
  2. Positive Pressure

Negative Pressure

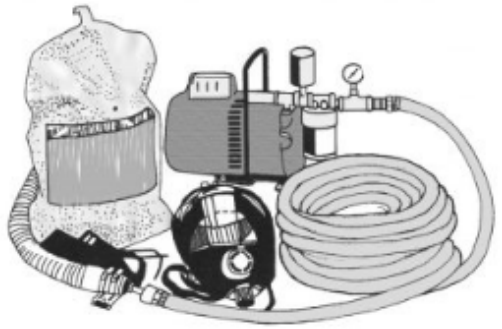
Half Mask Tight Fitting

Medical surgical mask is not a respirator

Full Face Mask Tight Fitting

Positive Pressure

Powered Air Purifying Respirator (PAPR)
Supplied Air Respirator
Self Contained Breathing Apparatus



Respirators

Negative Pressure	Positive Pressure
• Fit Test is conducted prior to assign. 	• Fit Test is not needed.
• Fit Check is conducted prior to use. Explained in Training. • Can not be use with beard or other interferences on the respirator seal. • Training is needed.	• Prior to use inspection is required (physical, battery, airflow, filtration media) • Training is needed.

Use of appropriate filtration media according to the chemicals present.

3rd Question – do we have adequate Respiratory Protection?

The values of the APF in EU and other countries [edit]

Studies of respirator's performance was carried out not very often, and almost all of these studies were conducted in USA (and UK). It is possible that the lack of information about the RPD efficiency in the workplaces, was the reason behind developing these assigned PF in several European countries, whose values differ significantly from the evidence-based values of APFs in the US and UK.

The Assigned Protection Factors for some main RPD types, developed in several EU countries[2] [hide]

RPD type	APF in several EU countries			
	Finland	Germany	Italy	Sweden
FFP2 filtering facepices	10	10	10	10
Elastomeric half masks with P2 filters	10	10	10	10
FFP3 filtering facepices	20	30	30	20
Elastomeric half masks with P3 filters	-	30	30	-
Negative pressure air-purifying respirators with full face mask and P2 filters	15	15	15	15
Negative pressure air-purifying respirators with full face mask and P3 filters	500	400	400	500
Powered Air-Purifying Respirators (PAPRs) with loose-fitting hood or helmet, and THP3 filters	200	100	200	200
PAPRs with full face mask, and TMP3 filters	1000	500	400	1000
SARs with full facepiece and negative pressure demand air supply	500	1000	400	500
Supplied Air Respirators (SARs) with full facepiece and positive pressure demand air supply	1000	1000	400	1000
SCBAs with full facepiece and positive pressure demand air supply	-	≥ 1000	1000	-

If you see dust masks with open handling tasks this could be a red flag…

What is the Level of Protection

- The level of protection for Respirators is defined by the Assigned Protection Factor or Nominal Protection Factor.
- Usually, each Country has established their APF or NPF.
  - APF or NPF x OEL substance= Max Use Concentration

Application:

- Sampling results show a TWA exposure of 350 ug/m3 in 8 hrs
- Respirator being used has a NPF of 10
- OEL for the API is 8 ug/m3 TWA 8 hrs

Is the Respirator appropriate?
> 8 ug/m3 x 10=80 ug/m3 (maximum use concentration).

No, Sampling results (350 ug/m3 TWA) are higher than respirator maximum use concentration. Evidence of employee over-exposure.

Medical Surveillance

68. Does the facility perform risk-based medical monitoring or employee health surveillance which includes recording, investigation and follow-up?

- Regulations can vary on formality of program and scope – know your local countries requirements
- Generally – programs globally exist for respirator protection, noise, some vaccines.
- Is there an occupational physician for the site who understands and sees the workers IH profiles and establishes the medical surveillance program?
- For highly potent compounds – does the site have any special medical surveillance programs, including biological monitoring?
- Has the site experienced high blood results / occupational health events – what is their response action?
- If the material is a sensitizer, has the site established processes to protect people with known allergies?
- How is the site managing reproductive hazards for both men and women?
- What is the frequency of IH Health type events at the site?
- How does the site investigate workplace exposure events?




Is it well managed?

Does it seem appropriate?

Does it cover all hazards that were identified in the visit?

Case Study....potent steroid

- API manufacturer of Generic material did not set their own limits but found a limit on the web from another company and used it.
- **PSCI Member** limit was 500X times lower. Data exchange revealed similar thought process on setting limits but different toxicology data was being used.
  - End Result – companies aligned within 5X on OEL accounting for different safety margin practices.
- Company had no workplace monitoring data to verify they were meeting their previous limit or the new limit. They were in a dedicated suite.
  - API company asked to immediately upgrade from dust masks to PAPR respirators and install better controls.
  - API manufacturer collected IH data to verify that their final PPE/engineering was protective.
  - Engineering controls were implemented in a very focused way reducing costs. Best practice ideas shared between member company and manufacturer.
  - Company applying same approach to all their chemical manufacturing where OELs are not yet established.
  - After visit, manufacture developed a comprehensive banding approach using a consultant.
- DATA IS YOUR FRIEND. In absence – default to more protective PPE & SOPs.

AGENDA 大纲

1. Audit overview – 10 mins
2. Subject overview – 40 mins
3. Example audit findings – 30 mins
4. Audience questions – 10 mins

Industrial Hygiene – What are we after?

PSCI Audit Findings Definitions

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 the audit sponsor prior to audit report finalization.

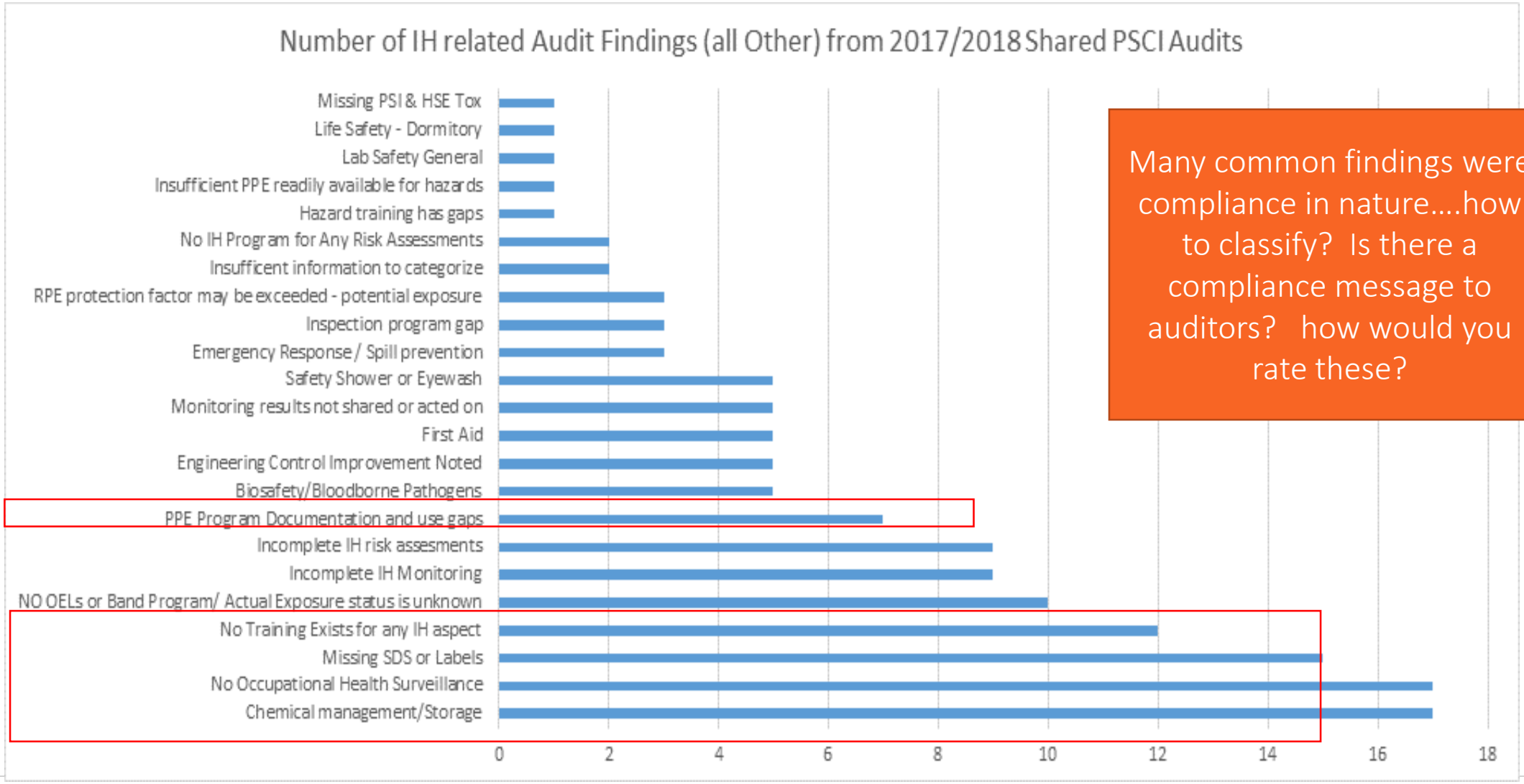
Examples for critical findings:

- Severe violations of human rights or labor rights (e.g. presence of child labor in a facility or forced labor, over-excessive working hours);
- Health and safety issues that can cause immediate life threatening situation or serious injuries to employees and other individuals on site;
- Environmental or safety issues that could result in serious and immediate harm to the community.

Other findings:

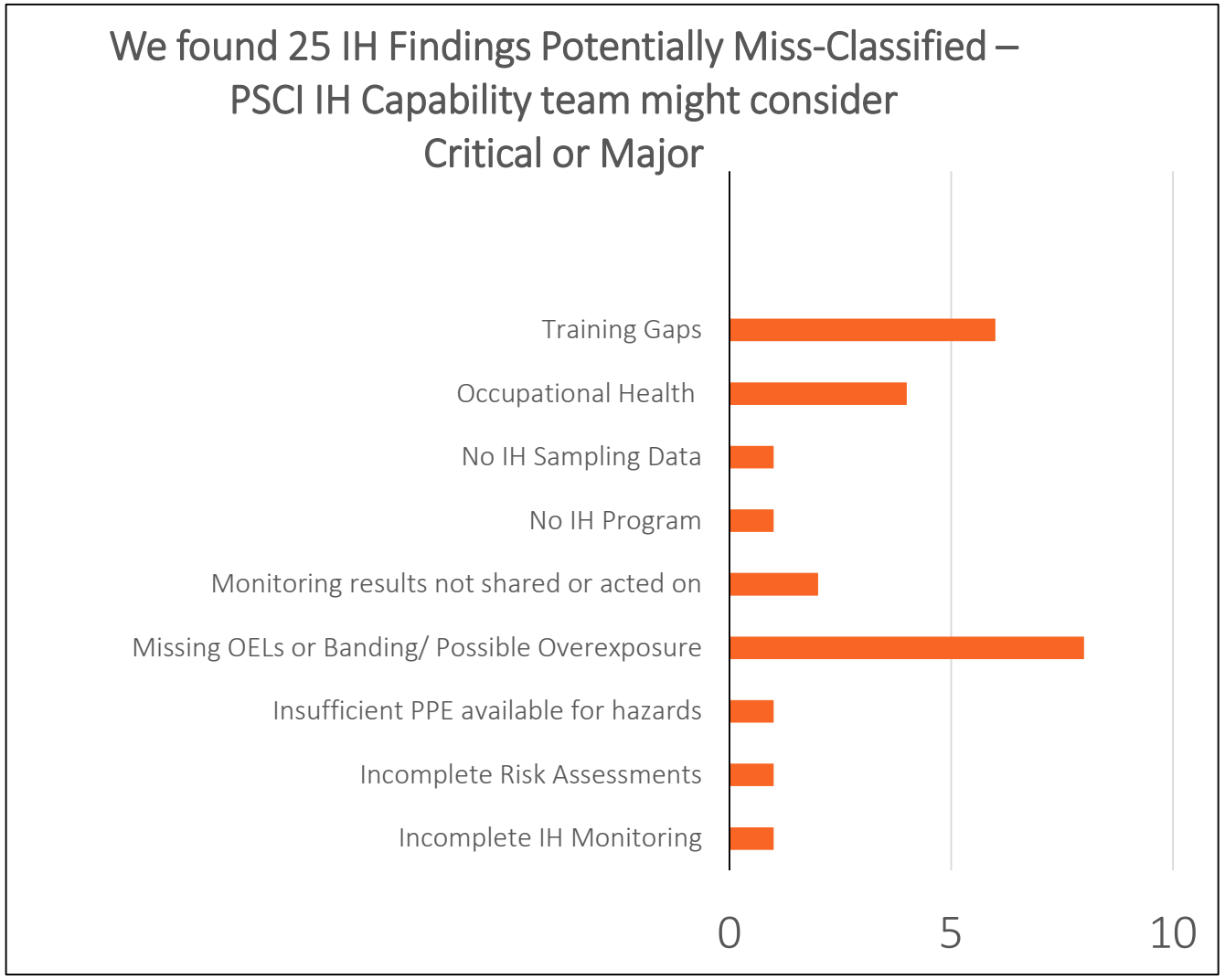
- Are all other major or minor audit findings, which need to be corrected by the supplier in an appropriate period of time?

What do we see with Shared PSCI Audits?

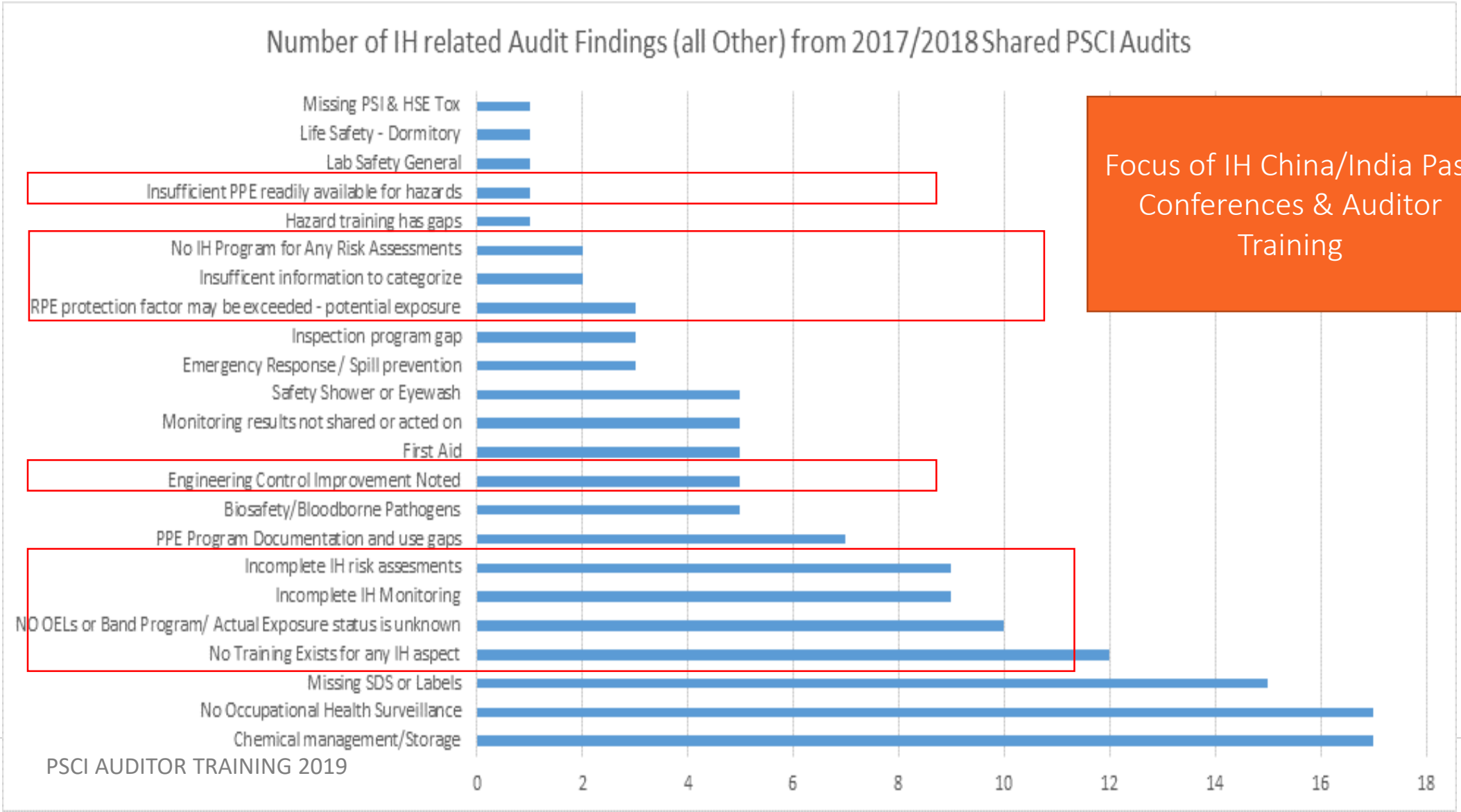


Many common findings were compliance in nature….how to classify? Is there a compliance message to auditors? how would you rate these?

In 587 Findings in 2017/2018 PSCI shared audits – there were no CRITICAL IH findings



What might be serious concerns misclassified?



Focus of IH China/India Past Conferences & Auditor Training

Common Possible Critical Findings - Examples

- The site lacks any data to justify that they know their workers are protected i.e. There is no IH qualitative & quantitative risk assessment is in place where facilities handling multiple API's & chemicals including potent compounds. This combines with limited or no Hazard communication information and observed inadequate PPE/RPE practices- Basic IH program not in place.
- Site handling their API as NUSIANCE DUST 10 mg/m3 because no regulatory limit. No banding approach exists for products without limits. Site has never seen the API – OEL from the PSCI member company SDS. When you compare SDSs available, there is a major difference in classifications, OEL band, and handling. No engineering control or RPE exist.
- Highly potent pharmaceutical being handled (<10 mcg/m3), operation is OPEN , respirator required by SOP but is NOT on the site or completely wrong for the hazard class (e.g. not a respirator or respirator protection factor too low). No segregation and unsure if nearby personnel are also overexposed.
- Observed strong odors during site tour and also observed inadequate knowledge (Adequate training not provided on usage of respiratory protective equipment's) on RPE Selection, storage, cleaning, disposal. e.g. Wearing surgical mask for handling solvents & dust and no other masks available. Also training, use, cleaning, inspection, storage and maintenance of respirators not in place.

Common Possible Critical Findings - Examples

- During tour of area with highly toxic gases and/or solvents – you smell strong odors, experience irritation, see wrong PPE and RPE, and no alarm or shut-offs. Dust masks being used on solvents/gases. Process venting is directed into the room where people work.
- There is no LEV in the centrifuge unloading or dryer loading rooms where wet cakes are being handled. Limited PPE and RPE are being worn.
- IH monitoring (if collected) has had faulty interpretation – there are clear overexposures and no action.
- Limited knowledge on handling of hazardous chemicals like Carcinogens, Teratogens, Mutagens –No program in place.
- Improper chemical storage at many locations & observed chemical spills at many locations.

IH–Common "Other" Findings- Examples

- Combination of all controls appear to be protecting workers but process is HIGHLY dependent on PPE and administrative controls. Engineering improvements to improve control are strongly recommended.
- No marking on the fume hood to demarcate safe working level and also fume hood performance details not available & no place available to handle liquids in the fume hood (placed other equipment's in the fume hood).
- Working cloths not provided/half sleeve aprons provided to all the company employees/visitors however same carry back to home for washing and no working cloths provided to workers.
- Hazard labels not available for all the containers and also provided training on SDS/ Missing Safety Data Sheets
- Site has not assessed exposure risk and potential in lab areas handling materials.
- Site performs QC sampling in warehouse on the open floor for ALL chemicals – regardless of banding
- PPE and IH Program are written centrally by Supplier corporate HSE office – instructions on posters, SOPs, etc., do not match what is available at the actual site. Need confirmation of all SOPs and PPE actual requirements so workers can be protected. No evidence of immediate overexposure concerns.
- Site not doing respirator fit testing.
- Site has not linked occupational workplace exposure to their health surveillance program fully
- IH data collected exists but is very limited, all area samples (no personal results) – data does not show a major issue
- LEV exists, but designs and photos show it is most likely highly ineffective to control risks and no (or very minimal) PPE is being used. The site needs a review of its engineering control strategy and data collected on LEV/exposure performance…no potent compounds.
- Noise data exists but not covered all the process areas of the site.

On Line Control Banding Information and Tools

- COSHH (Control of Substances Hazardous to Health) Essentials (UK HSE, 2006)
  http://www.coshh-essentials.org.uk/
- ILO (International Labour Organization) International Chemical Control Kit (ILO, 2006)
  http://www.ilo.org/public/english/protection/safework/ctrl_banding/index.htm
- AIHA Control Banding Working Group
  http://www.aiha.org/content/insideaiha/volunteer+groups/controlbanding.htm
- NIOSH Control Banding
  http://www.cdc.gov/niosh/topics/ctrlbanding/
- ISPE Volume 7 (2010) “Risk Based Manufacture of Pharmaceutical Products”
- PSCI website – Type in “IH, Banding, or Containment” on the resource link.

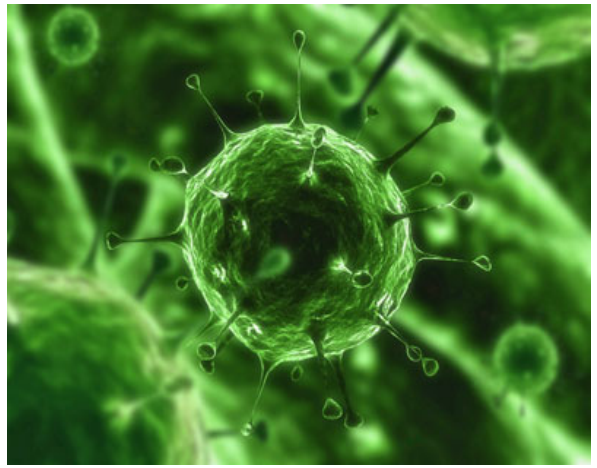
Other SDS Classification Potential Issues you may find

- Material is a Dangerous Good for Shipping and API company is not aware of the toxicology data driving this decision.
- Packaging, Shipping, and handling practices need awareness
- Combustible Dust Classification
- Process Safety Data may not may not be on the SDS depending on the company philosophy.
- Labeling for shipping country does not match the labeling for the receiving country requirements.

Biosafety & Radiation Safety

- Just as there are Control Bands for Chemicals, there are Risk Groups for Biosafety Hazards and the establishment of Biosafety Control Bands (1-4) for Biologicals. Do the companies agree?

- If sites have products with ionizing radiation and/or BSL 3 or 4 operations be sure the correct expert is part of the evaluation. Generally special government licenses may be required.



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About the Secretariat
Carnstone Partners Ltd is an independent management consultancy, specialising in corporate responsibility and sustainability, with a long track record in running industry groups.

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