PSCI PHARMACEUTICAL SUPPLY CHAIN INITIATIVE

Building responsible supply chains

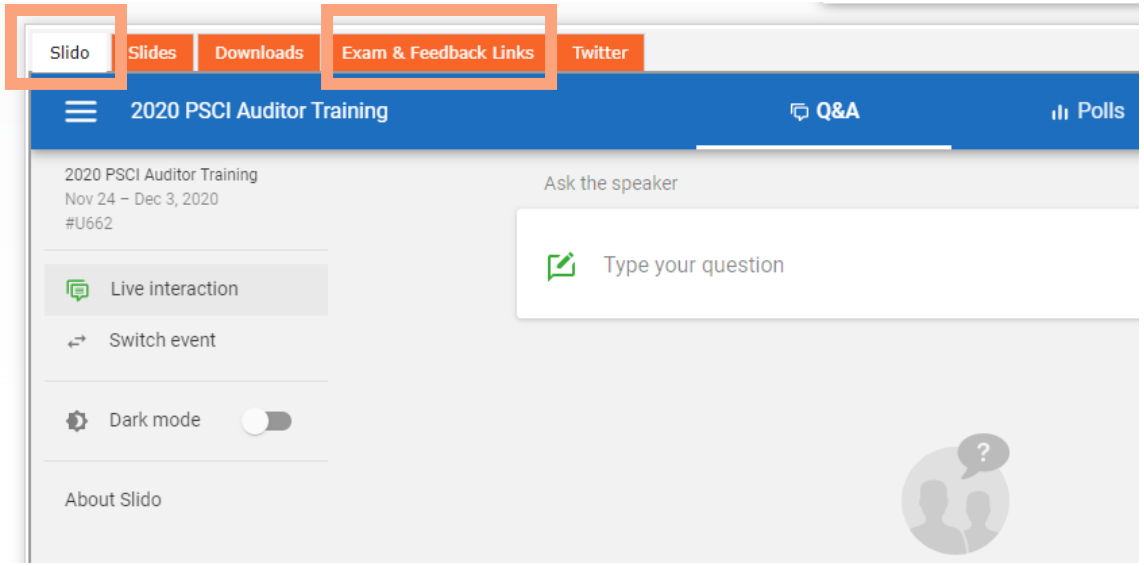
PSCI Auditor Training 2020

Day 3 Process Safety; Emergency Preparedness & Response

December 02, 2020

Practicalities

- Switch to audio feed only for better connection. Chinese attendees click at Live Stream (China)
- Break
- We'll be using Slido for Q&As, please click Slido tab to enter your questions or go to https://www.sli.do/ to pose questions with the code **#U662**
- Exam
- Certificates
- Feedback survey



Anti-Trust Statement

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

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

Topics of discussion that should be specifically avoided are:

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

Agenda

Process Safety; Emergency Preparedness & Response	
13:15 – 13:30	**Registration**
13:30 – 14:45	**Process safety risk – Identifying reactive hazards and powder processing hazard in pharmaceutical industry (1hr)** The presentation will help audiences to understand reactive hazards and powder processing hazard in pharmaceutical industry. It will also review PSCI questionnaires and typical observations related to process safety. **Kumarkrishna Bhattacharjee**, Head HS&E Supplier Assurance and Risk India Region, Novartis *Q&A (15 mins)*
14:45 – 14:55	**BREAK (10 mins)**
15:00 – 16:15	**Emergency preparedness & response (1hr)** Presentation on emergency response, fire protection basics, hazard information and an introduction to sprinkler protection. **Daniel Rehm**, HSE Advisor, External Manufacturing EMEA & API, Elanco *Q&A (15 mins)*
16:15 -16:45	**Exam (20 mins)** **Closing Comments / end of day 3**

PSCI PHARMACEUTICAL SUPPLY CHAIN INITIATIVE
Building responsible supply chains

Process safety risk – Identifying reactive hazards and powder processing hazard in pharmaceutical industry

Kumarkrishna Bhattacharjee

Head- Supplier HSE assurance and risk, India Region

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Speaker Bio

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- Chemical Engineer (B.E), PGCBM-XLRI
- 19+ years of diverse and multidisciplinary experience in field of manufacturing (API), process engineering, process development, technology transfer and Health, Safety and Environment.
- Previous experiences – Associate director, Process safety management – Corporate SH&E Drreddy's, Process engineer, AstraZeneca, Bangalore.
- PSCI Role : Process safety management subcommittee member, India Subcommittee member.

AGENDA

1. Process Safety management
2. Understanding process safety hazards
    - Process safety parameters
    - Essential information to chemical process
    - Critical interaction of materials
    - Exothermic and runaway reaction
    - Powder safety hazards
3. Review PSCI questionnaire
    - Expectation and intentions
    - Typical Gaps in process safety risk assessment
    - Typical observations

In this presentation we will understand reactive hazards and powder processing hazard in pharmaceutical industry. We will also review PSCI questionnaire and typical observation related to process safety

1. Process safety management

Some Recent Process Incidents

Date	Location	Incident	Consequences
07-May-2020	Vizag	Styrene Leak	12 citizens losing their lives and 585 citizens being hospitalized, causing loss of livestock and vegetation.
03-June-2020	Dahej, Bharuch	Boiler Explosion	8 dead, 50 injured
13-Jan-2020	Tarapur, Boisar	Explosion during testing of new reactor	8 killed & 6 injured
07-May-2020 01-July-2020	Cuddalore	Boiler Explosion	8 workers injured 6 losing their lives & 17 injured
30-June-2020	Parawada, Vizag	Gas leak	2 dead & 4 fall sick
13-Apr-2020	Tarapur, Boisar	Explosion	2 killed & 1 injured
17-Aug-2020	Tarapur, Boisar	Reactor Explosion	2 killed & 4 critically injured
12-June-2020	Ankleshwar	Reactor explosion	1 killed & 5 injured

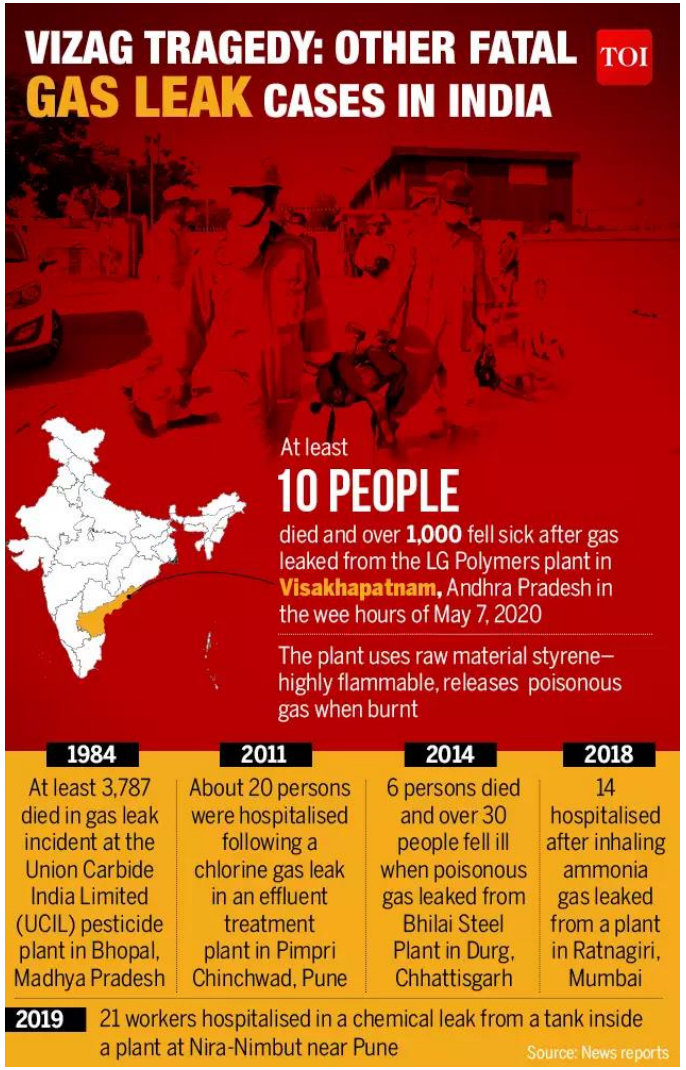
* Source: Collected recent accidents from internet

Process safety incident -LG Polymers

Description of the event:

- When: In the early hours of 7th May 2020, an accident of uncontrolled release of Styrene vapour occurred at LG Polymers India Pvt. Ltd. (LG Polymers) at Vizag from one of the Styrene storage tanks (M6).
- Type of industry: LG Polymers manufacturing of Polystyrene (General purpose PS & High impact PS), Expandable Polystyrene (EPS) & engineering plastic compounds -expanded the manufacturing capacities from time to time.
- Impact: The hazardous Styrene vapours spread beyond the factory premises, affecting the populace of five villages / habitations. This led to 12 citizens losing their lives and 585 citizens being hospitalized, besides causing loss of livestock and vegetation.

Source: High Power Committee Report



Process safety Management

- Process industries are vulnerable to the risk of Process safety incidents due to use of Hazardous chemicals and process conditions if not controlled suitably.
- Process safety incidents such as explosion, Fire, toxic release etc. results into loss of business,, Reputation loss and Regulatory violation
- It is very important that proper Management process is set to Prevent, Mitigate and Respond to such incidents.

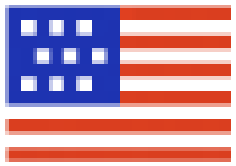
Application of management controls to a process to identify hazards, understand and control process risks so that serious process related-incidents can be eliminated is called Process Safety Management

Process safety Management

- Regulations around world to address process safety risk

- SEVESO III -Directive on the control of major-accident hazards involving dangerous substances

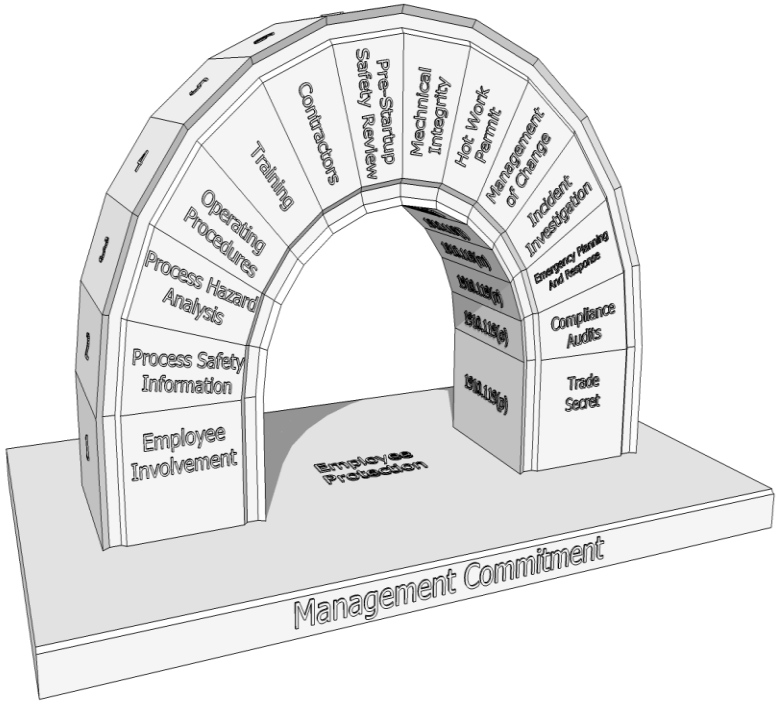
Council Directive 96/82/EC of 9 December 1996 on the control of major-accident hazards involving dangerous substances (as amended) is a European Union law aimed at improving the safety of sites containing large quantities of dangerous substances. It is also known as the **Seveso II Directive**, after the Seveso disaster. It replaced the Seveso Directive and was in turn modified by the Seveso III directive (2012/18/EU).



29 CFR 1910.119 - OSHA issued the Process Safety Management (PSM) of Highly Hazardous Chemicals standard 1 (29 CFR 1910.119) in 1992. This section contains requirements for preventing or minimizing the consequences of catastrophic releases of toxic, reactive, flammable, or explosive chemicals. These releases may result in toxic, fire or explosion hazards

Elements of Process Safety Management

- Process Safety Information
- Process Hazard Analysis
- Operating Procedures
- Training
- Contractors
- Mechanical Integrity
- Hot Work
- Management of Change
- Incident Investigation
- Compliance Audits
- Pre startup safety review
- Emergency planning & Respon
- Trade secrets
- Employee Participation



Ref.: OSHA PSM Regulation, 29CFR1910.119

PSM in India

- Legal Perspective
  - Environment protection Act (EPA) and rules under it such as
    - Manufacturing, storing, importing Hazardous chemical rule(MSIHC) – 1989
    - Chemical Accident (Emergency preparedness planning and response) CA(EPP&R) Rule – 1996
  - Section 41-B and 41-C of factories act – Safety audit by competent person.
- These rules do not detail out how the compliance can be achieved technically and hence requires technical competencies and guidance to achieve holistic fulfilment of regulation requirement at first place and people protection in all perspective.
- There lays business continuity risk if such process do not recognise technical knowhow and methods to identify hazard and then eliminate, control or mitigate it.

PSM elements in PSCI

Mechanical integrity - 80 **Describe how the facility ensures preventive maintenance of safety relevant equipment.**

PSI - 77. i. Collection of process information (process safety data, design information, operating parameters, and equipment specifications)
79. i. Assessment of the hazards (Minimum Ignition Energy, Kst classification rating, Impact sensitivity etc.) of the handled combustible dusts and powders

Emergency Preparedness and Response

Training -50 **Does the facility provide HSE (Health, Safety & Environment) training to employees (full-time, temporary, or contractor)?**

PHA -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).

II - 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

PSSR- 50. iii. Pre-start up process specific HSE training

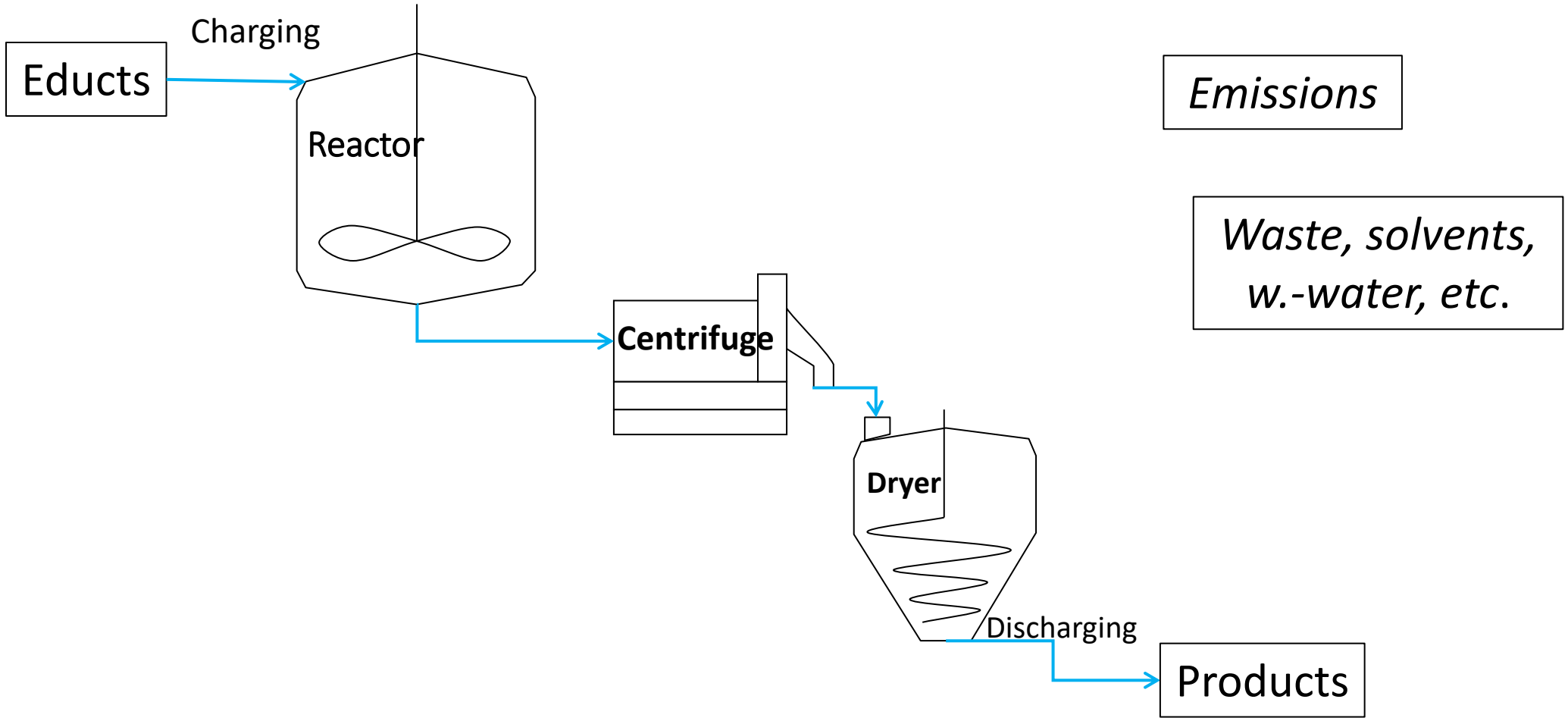
Hot work - 55 **Does the facility have a safe work permit system for the following?**

Contractor -58 **Does the facility use any of the following processes for managing risks related to contractor activity onsite?**

MOC- 6 **Does the facility or company have a process to manage all changes (e.g. raw materials, processes, personnel non-GMP, facilities, etc.)?**

2. Understanding process safety hazards

Chemical reaction in a production plant



Which information is necessary for a safe process?

1. Hazards of material
2. Process design basis
3. Equipment design Basis

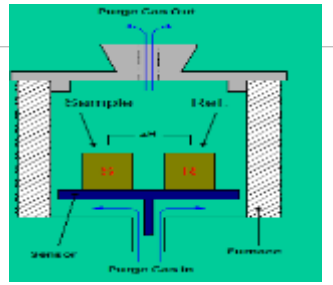
A safe chemical process is always an adequate combination of safe substance handling, known chemical process and adapted equipment.

What is necessary for a safe process?

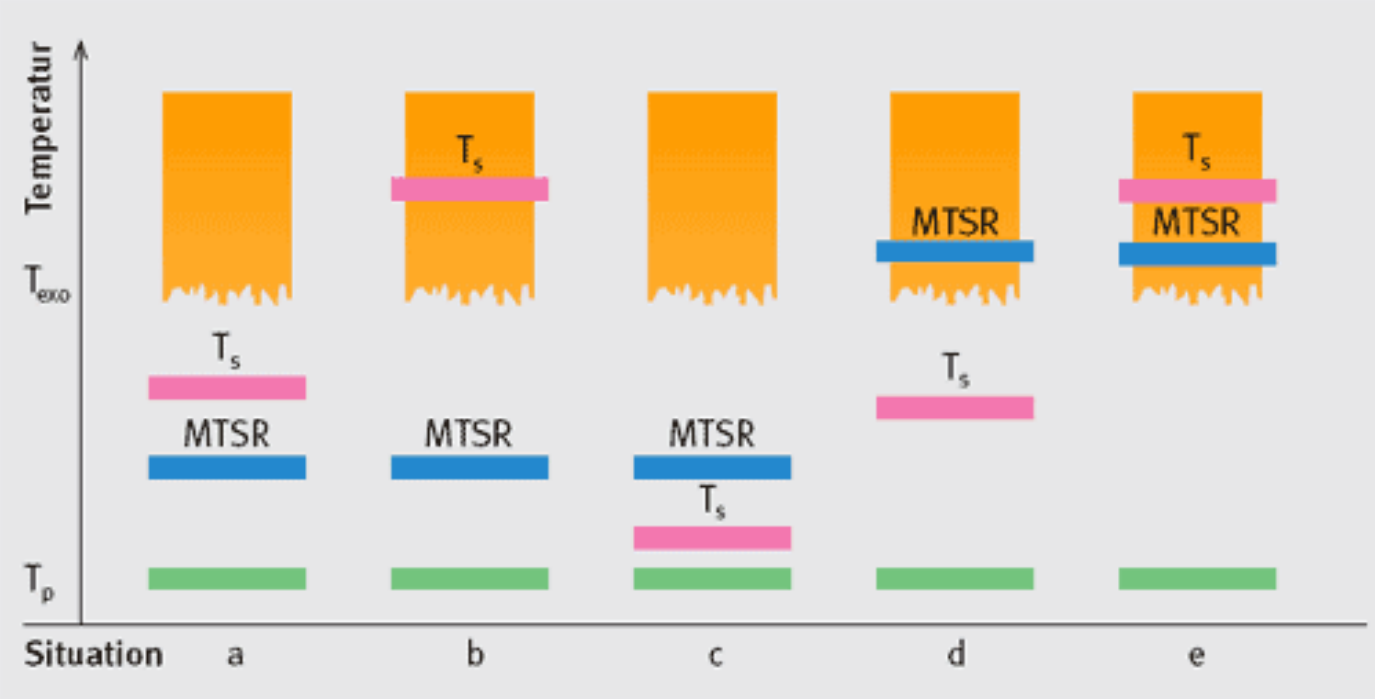
- Information required from Calorimetric data for chemical reaction (desired condition and undesired situation)
  - Whether heat is produced during reaction and if so what is quantity and rate of generation
  - Whether there is delay before reaction starts
  - Whether there is accumulation of reagent
  - Whether gas is evolved, if so total volume and rate of generation
  - Maximum temperature of reaction mass in adiabatic condition
  - Onset temperature (of desired and undesired reaction)
  - Energy of reaction / decomposition
  - Indication of gas generation
  - Maximum pressure (Pmax), pressure rise rate (dp/dt) and temperature rise rate (dT/dt)
  - Adiabatic temperature rise of secondary/decomposition reaction. ΔTad(decomp.)
  - Time for maximum rate at concerned temperature (TMRad)
  - Temperature at which time to maximum rate is sufficient to response

- Information on compatibility of chemicals with other material such as material of construction, solvents, auxiliaries materials etc.
  - Coupon study
  - Literature search

Hence reaction needs to be assessed and best would be with experimental data and data interpreted in a way that people doing the risk analysis understand. Auditor should check that there is a process for that.



Thermal hazard potential of chemical reactions



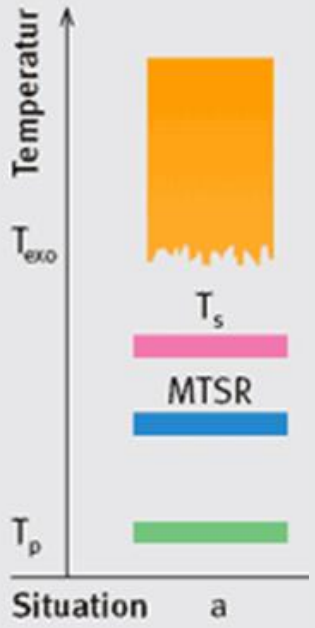
T_p : process temperature at the start of the deviation

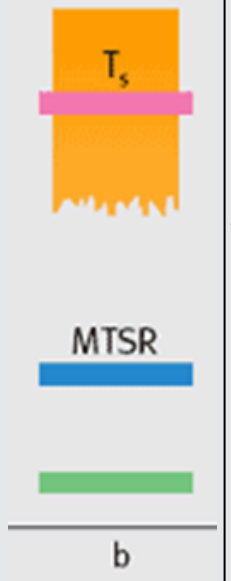
MTSR: maximum temperature of the synthesis reaction; $MTSR = T_p + \Delta T_{ad} \cdot \alpha_{accu}$

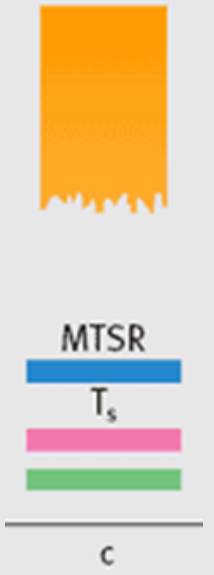
T_{exo}: the maximum temperature at which a substance or reaction mixture can just be handled safely

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

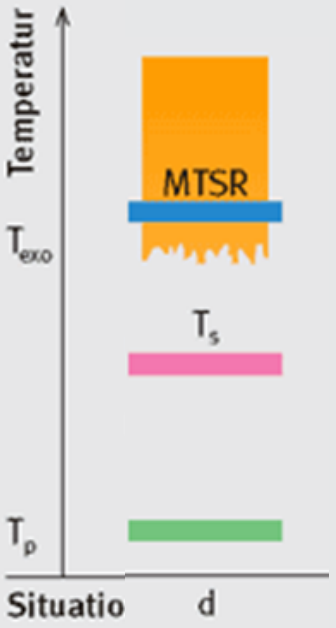
Thermal hazard potential of chemical reactions

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.

Thermal hazard potential of chemical reactions

1.On December 19th 2007, an explosion at T2 laboratories Inc. killed four, injured 32 and destroyed multiple business.

2.The explosion was due to runaway exothermic reaction in batch reactor during first step of metalation process during cooling system **failure**, leading to a **second (undesired) exothermic** reaction.

3.Cooling system lacked design redundancy and was susceptible to single-point failure – No emergency source of cooling existed.

4.The pressure relieve system was designed for normal operating conditions and it was unable to relieve the second exothermic reaction.

5.Root cause – T2 did not recognize the runaway reaction hazard associated with MCMT it was producing.

Powder processing hazards

- There is a risk of powder safety hazard like fire and dust cloud explosion due to handling and processing of powder in bulk quantity in formulation process.

- Due to presence of ignition source such as static current discharge, hot surface, friction, impact etc powder processing is susceptible to dust cloud explosion/fire risk.

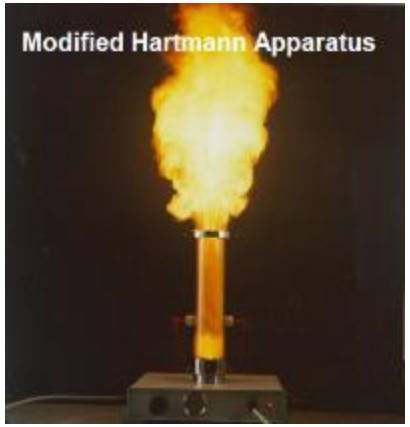
- First recorded dust explosion – Turin, Italy 1785
  - Ignition of flour dust by lamp in bakery storeroom

- In US, up to 1980 - 2005, total of 281 major dust explosions
- 119 fatalities and > 720 worker injuries
- Millions of $ in property damage
- Litigation and prosecutions
- Damage to reputations

Ref: Combustible Dust Hazard Investigation – US Chemical Safety Board (CSB) Final Report – http://www.csb.gov/combustible-dust-hazard-investigation

Powder processing hazards in formulations

- Dust explosibility:
  - Dust explosion test
  - Dust explosion characteristics (pmax; (dp/dt)max; KSt; explosion limits
- Flammability and ignition sensitivity of solids
  - Burning behavior test
  - Minimum ignition energy (MIE)
  - Minimum ignition temperature of a dust layer
  - Minimum ignition temperature of layer
- Mechanical sensitivity, further safety characteristics
  - Sensitivity to impact
  - Sensitivity to friction
  - Self-ignition test
  - Conductivity

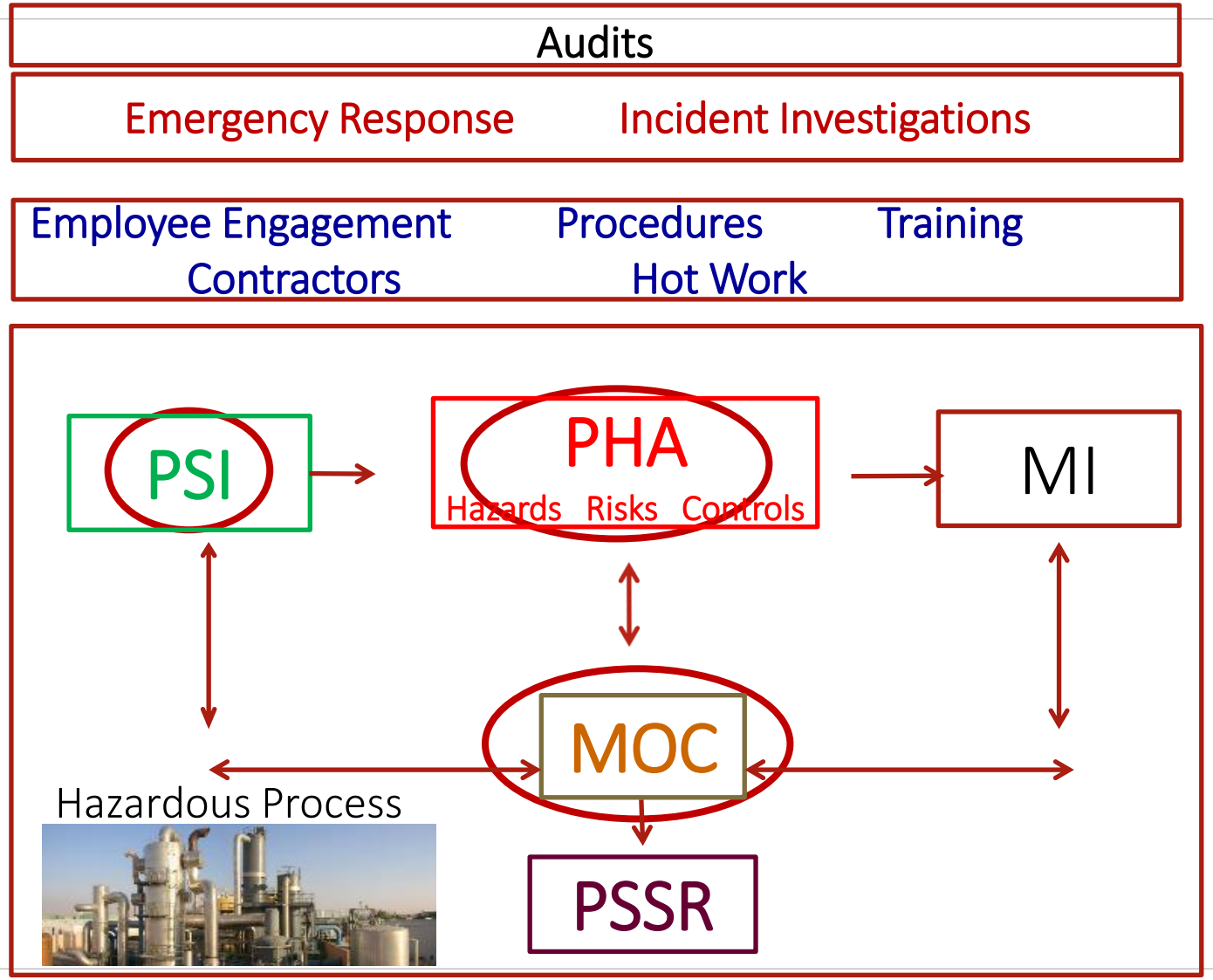


Risk assessment

The plant hence shall conduct Process Hazard analysis which is

“Examination of the chemical/material properties and chemical process/powder safety data together with the technical installation of the plant”

All elements of process safety management



3. Review PSCI questionnaire

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.)

PSCI Questionnaire – local regulation and beyond

Audit Questions Summary – Process Safety

Q. No	Question Summary	Corresponding Indian regulation	PSCI Expectation/intention
76	Report top 3 hazardous process activities conducted at this facility	---	This question is to understand the hazardous process conducted at site and hence check if site is aware of risk. For auditor to probe further on type of hazards
77	Process Hazard assessment	The Manufacture, Storage and Import of Hazardous Chemical Rules, 1989. Rule 10 &11; Schedule-8	Determine if the methodology used is internationally recognized, a national standard / best practice or in-house. Use sub-questions to determine – based on a couple of examples – if the major steps of a risk assessment are covered by the used methodology. This includes and not limited to availability of process safety data, Equipment limitations, venting capability assessment etc.
78	Evaluated the impact of its operations on the community & Evaluated the impact from the activities of neighboring business	The Manufacture, Storage and Import of Hazardous Chemical Rules, 1989. Rule 15 FA -41B	This question is to understand if company is aware about risk of its operation to neighboring community and has proactively taken action to inform them on do's and don't during emergency. Also to check if company is aware of risk from neigbouring operation and have addressed protection and emergency preparedness for same

PSCI Questionnaire – local regulation and beyond

Audit Questions Summary – Process Safety

Q. No	Question Summary	Corresponding indian regulation	PSCI Expectation/intention
79	Risk assessment for explosion of flammable liquids, vapors, powder and gases	The Manufacture, Storage and Import of Hazardous Chemical Rules, 1989. Rule 10 &11; Schedule-8 Petroleum Rules 2002 rule 114, 106, 107 Petroleum Rules 2002 rule 127 Petroleum Rules 2002, Rule 7, 8(1), 111, 119, Rule 4(1),9, 10, 11, 117, 120, 121, 123, 125, 129, 133	Process safety risk such as fire, explosion due to processing of flammable solvents, its vapors, powder and gases with data on ignitions risk and explosion potential vis-a-vis verification of protection and basis of safety on plant.
80	Preventive maintenance of safety relevant equipment	Factories Act 7A 2 (a), 31 & 40	Program should cover the following elements: criteria for inclusion, equipment list, control and maintenance measures, frequency and handling of deviations (planned / unexpected). Check a couple “classical” piece of equipment that should be in such a program (rupture disc,...). Quality critical equipment shall not be considered as also and only process safety critical equipment.

PSCI Questionnaire – local regulation and beyond

Audit Questions Summary – Process Safety

Q. No	Question Summary	Corresponding indian regulation	PSCI Expectation/intentions
81	Handling compressed gas safely	1. Gas Cylinder Rules 2016 2. Indian Explosives Act, 1884 and Static and Mobile Pressure Vessels (Unfired) Rules, 2016	Program to safely receive, store and use compressed gas cylinders and other storage.
82	Bulk chemical handling procedure	1. Petroleum Rules 2002 Rule 76 (1) and (2), 79, 81, 83 and 108 (3) (4) 2. Indian Explosives Act, 1884 and Static and Mobile Pressure Vessels (Unfired) Rules, 2016 Rule 27 3. OSID114	Established process to safely unload, store, transfer and process bulk chemicals including flammable solvents.
83	Safety measure around direct fire equipment (e.g boiler, incinerator, ovens etc)	1. Indian Boilers Act, 1923 and Indian Boiler Regulations, 1950Regulation 377, 379 (a)(i), Section 7 and Regulation 530, Section 4E, 7 and Regulation 394(a), 6 (d)	Determine which prevention measures are in place to avoid boiler feed water low level. Check which routine testing, in line with regulatory and/or insurance requirements, is in place.

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?

Cylinders are stored in weather shed protection however multiple cylinders are secured with single chain. Also some of the cylinders do not have nozzle guards.
Cylinder storage is not segregated and fenced. It was found stored till outside on road. Chance of vehicle hitting cannot be ruled out. Labeling as gas classification and segregation is not followed. QC lab gas bank regulator and hose pipe inspection is not done

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.

Typical gaps in process safety risk assessment

- Risk assessment with out process safety information

- No/inadequate information on Hazards of material (in normal and challenged condition), process technology and equipment results in incomplete risk analysis and Risk assessment
- This in turn fails to identify potential risk and hence right control in place

- Risk assessments focusing only on work place safety (e.g. Personal injuries like trip, falls, cuts etc.)

- Wrong impression to management that process risk assessments are identified and addressed.
- Organization is exposed to probability of process safety incidents.

- Inadequate identification of risk

- Due to lack of understanding of Hazardous event and process safety information, which in turn is due to inadequate skills, expertise and insufficient resource allocation, results in incomplete risk assessment.
- E.g. 1. unable to identify risk of decomposition of reaction mass near operating temperature, risk of non-sequential addition of chemicals or reagent can result in fire/explosion. 2. ignition sensitivity and dust cloud explosion risk of formulation mixture etc.

Typical gaps in process safety risk assessment

- Inadequate identification of controls commensurate with risk

- Risk identified having high consequences and probability with weak controls implemented such as only training & administrative control like instruction in SOP etc., may result in incidents.
- Right control/s based on risk shall be implemented, for example passive controls, active controls, redundant controls etc, based on risk.

- Inadequate system to implement identified recommendations or controls

- Failure of management to allocate budget and resource to implement recommendations like engineering controls can result in incident when event occurs without preventive and mitigation system in place

- Inadequate or improper upkeep of controls over life cycle of process

- Not identifying list of process safety critical equipment and absence of robust preventive maintenance program can result in failure of control and resulting in incident.

Typical gaps in process safety risk assessment

- Outsourcing risk assessment and considering it as one time activity

- Conducting risk assessment as one time activity just to meet requirement of audit clearance and not making as part of management system can result in process safety incident during such time such as implementation of change , introduction of new process and modification of facility etc.

- Risk assessment without considering risk to/from neighbouring industry

- Incidents at neighbouring industry impacts operations of site at close vicinity and vice-versa
- Risk assessment if do not identify such risk result into shut down and loss of life. For example risk assessment considering facility siting identifying largely populated office near fire zone of risky process of neighbouring site and impact of site on nearby population (temporary/permanent)

- Not making risk assessment as part of input to Onsite emergency plan

- Hazardous event scenario identified during risk assessment shall become part of onsite emergency plan and drill. During real event absence of such drill results into large scale damage

Final thought and approach to verify PSM

- ✓ Management system in place
- ✓ Responsible team identified and integrated with line function
- ✓ Process in place to review process safety risk from development to scale up to commercial production and product discontinuation.
- ✓ Risk assessment is detailed and informed risk assessment by relevant data made available on table to identify dangerous situations.
- ✓ Management of change in place for process safety review.
- ✓ Procedures, work instructions highlights and covers process risk and controls.
- ✓ Basis of safety is identified in plant and implemented for the process.
- ✓ Basic infrastructure set up identifies safe handling of process – Fire protection, safety relieve valves, redundant controls etc in place supported by documents – multiproduct facility
- ✓ Mechanical integrity (preventive maintenance programs) and Quality assurance (RAGAGEP) for equipment (process safety equipments)
- ✓ Lead and Lag indicators monitoring to continuously Run and improve Process safety management program.

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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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BREAK

It is break now. Please come back in 10 minutes.

PSCI PHARMACEUTICAL SUPPLY CHAIN INITIATIVE
Building responsible supply chains

1) Emergency Preparedness and Response
2) Hazard Information

Dr. Daniel Rehm

Lead HSE Advisor Elanco External Manufacturing EMEA & API

Speaker Bio

- Daniel is Lead HSE Advisor in the Elanco External Manufacturing EMEA &API Hub Basel, Switzerland
- PhD in Chemistry from Humboldt University in Berlin, Germany with 16 years of experience in Chemical Industry, Insurance and Pharmaceutical Industry. Functional experience in R&D, HSE, Engineering and Manufacturing
- Working in Elanco for 5 year.
- Additional work as Loss Prevention Manager and Tech Transfer Project Lead
- Team lead of the PSM sub-team of the PSCI Capability Committee

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AGENDA

Emergency Preparedness and Response

Hazard Information

1 – AUDIT OVERVIEW

Audit Questions Summary – Emergency Preparedness 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
Hazard Informat	

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

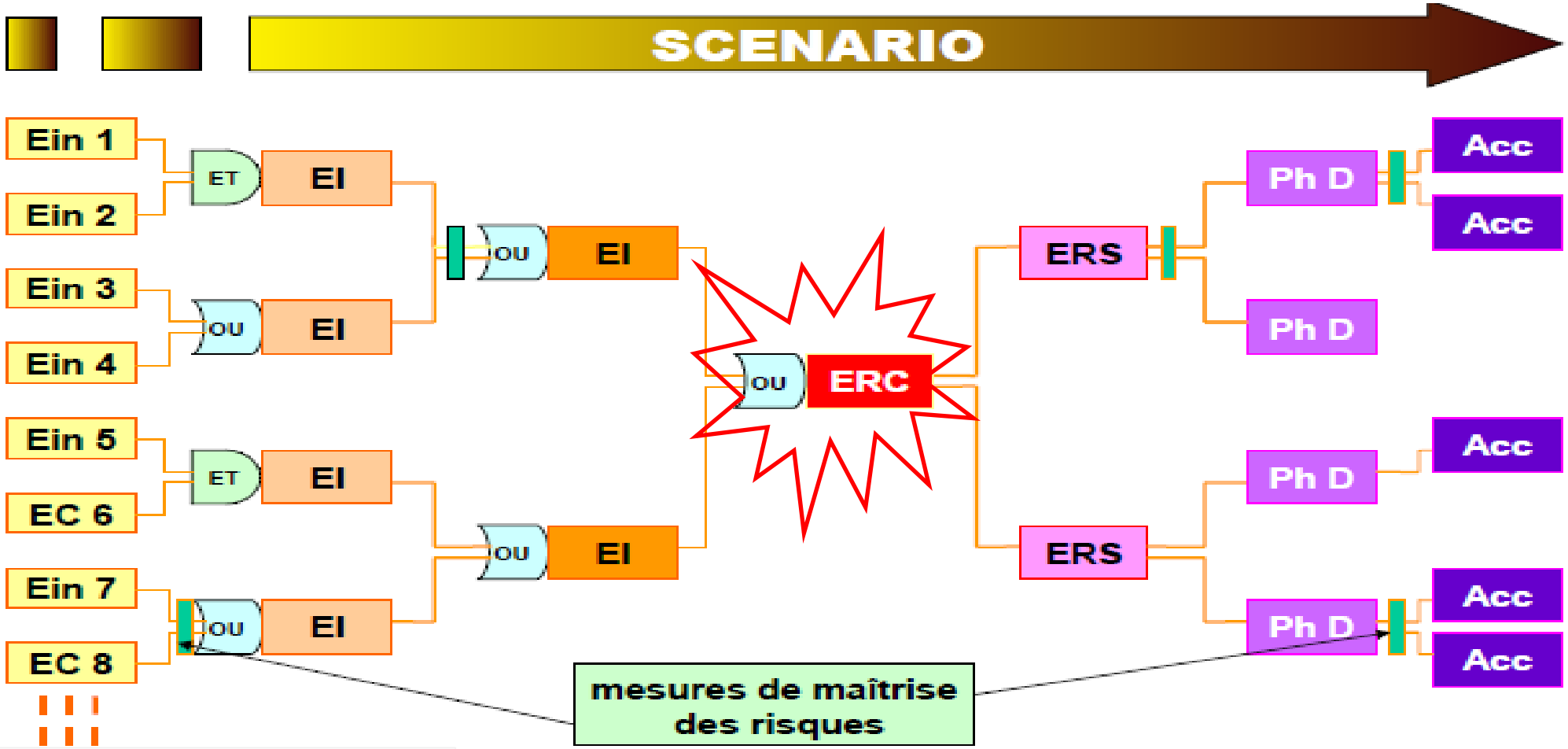
Topic	Question summary
Process Safety	• Impact of its operation on the community • Safety measures around direct fire equipment (e. G. Boiler, incinerators, ovens etc.)

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



Failure Tree

Risk control / Barries

Events tree

Emergency scenario: 3 types of effects

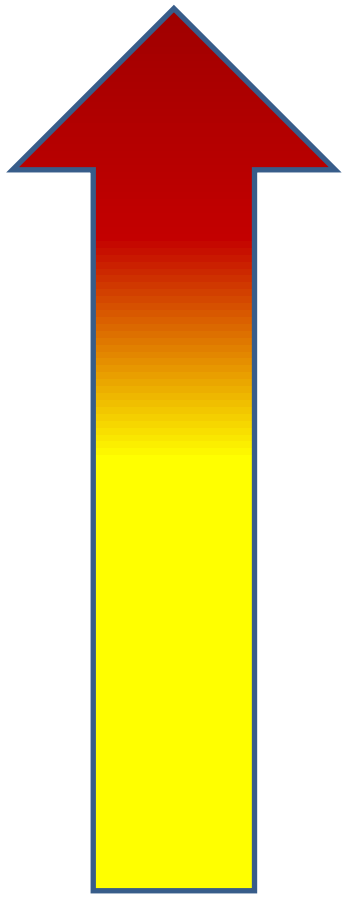
1 – Thermal effects : burns, suffocation

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

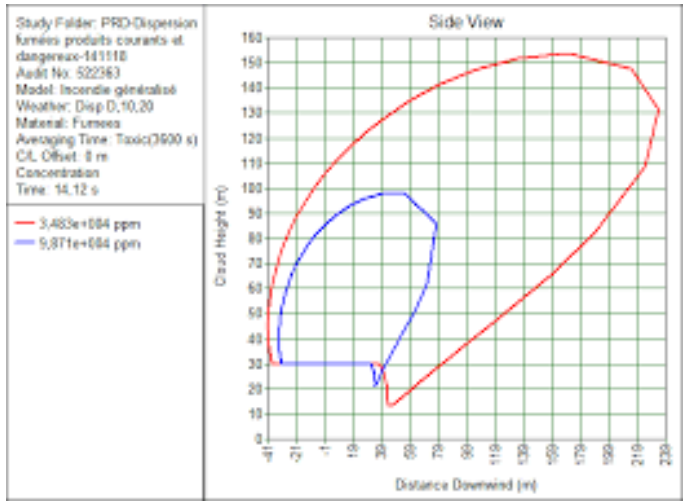
4 thresholds of effects on the people

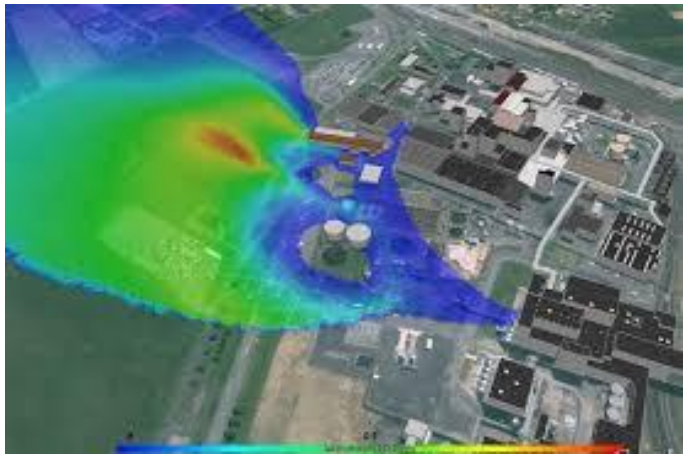


Threshold of effects on human	TYPES OF EFFECTS		
	Thermal	Toxic	Overpressure
LETHAL SIGNIFICANT (SELS)	8kW/m²	CL 8%	200 mbar
LETHAL (SEL)	5kW/m²	CL 1%	140 mbar
IRREVERSIBLE (SEI)	3kW/m²	SEI	50 mbar
INDIRECT (Breaking of windows)			20 mbar

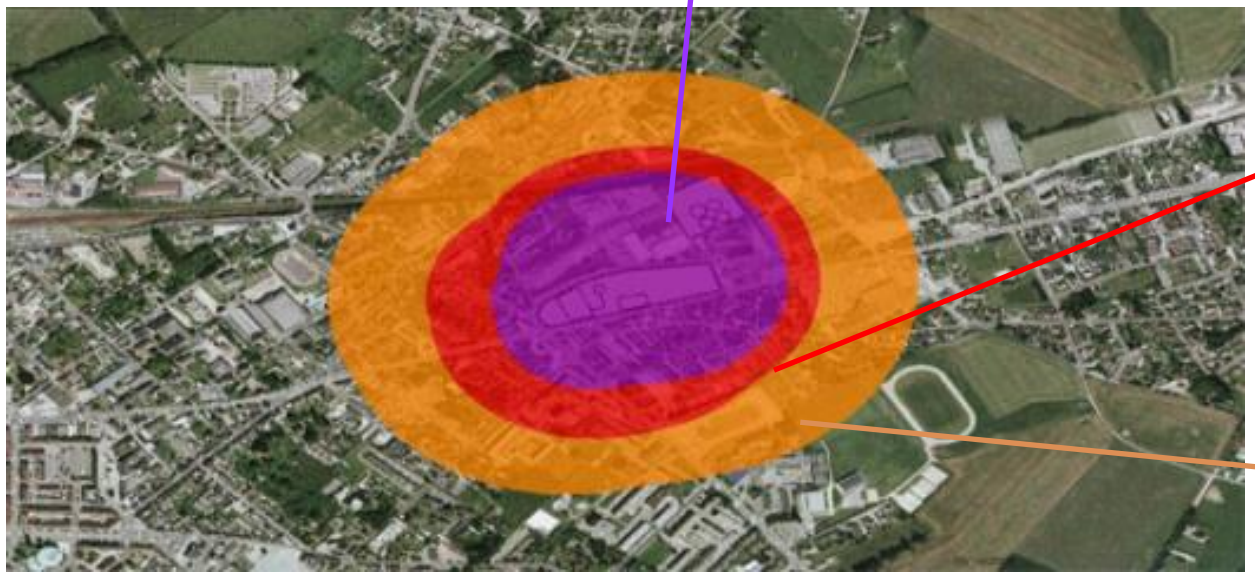
1 – AUDIT OVERVIEW

Specific software calculation and graphic representation





Zone of lethal significant effects



Zone of lethal effects

Zone of irreversible effects

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

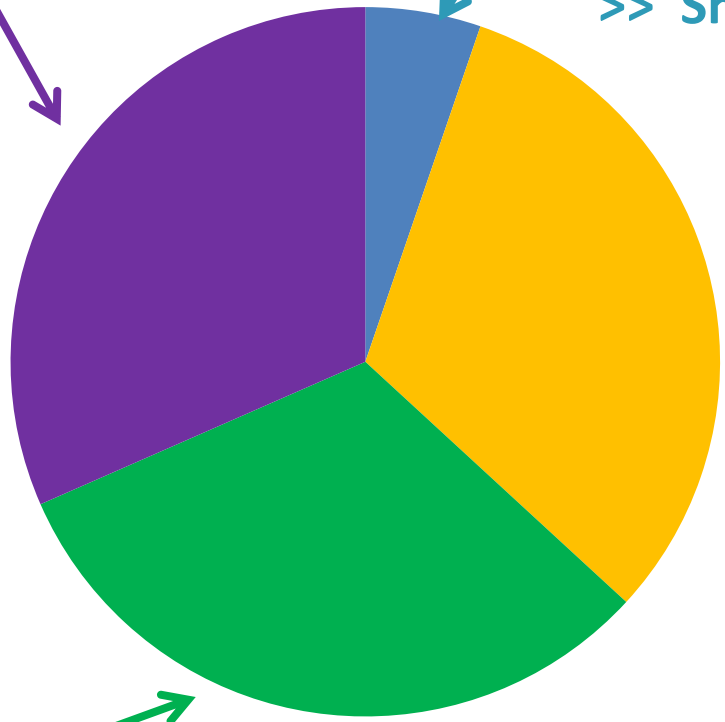
2 – SUBJECT OVERVIEW : FIRE SOURCES

ELECTRICITY

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

SMOKING

>> Smoking policy



HOT WORK

>> Hot work Permit

PROCESS

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

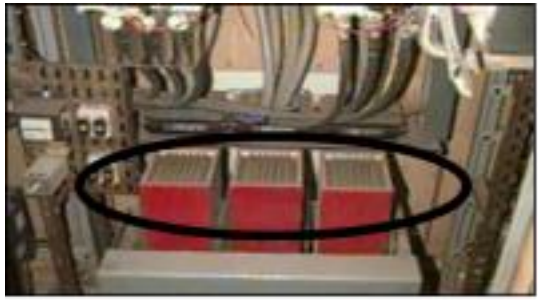
2 – SUBJECT OVERVIEW : FIRE PREVENTION

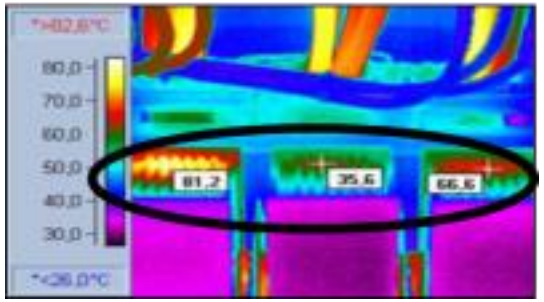
SMOKING

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

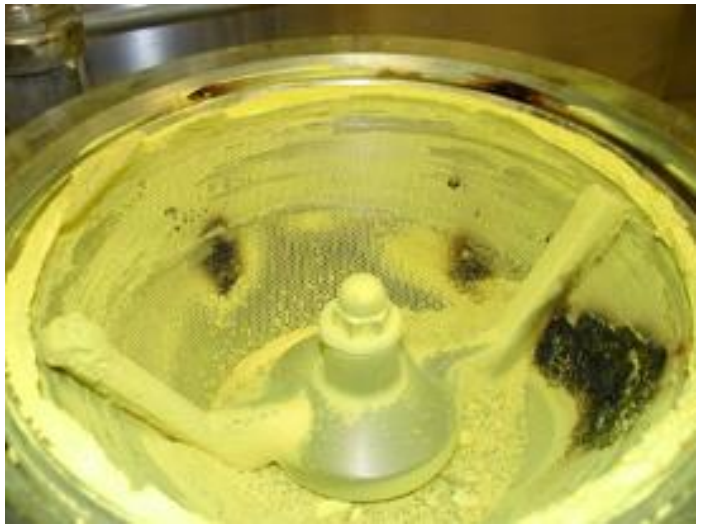




2 – SUBJECT OVERVIEW : FIRE PREVENTION

PROCESS

- **Chemical/Pharmaceutical : process safety chapter PSCI 76-82**
- **Warehouse:**
  - **Where are the battery chargers located?**
  - **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...

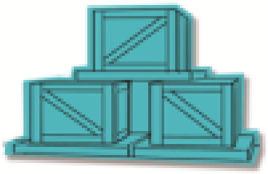
➔ Study the possibility of doing the work in the maintenance shed or in another zone specially designed to avoid fire or explosions.

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

Specific permit

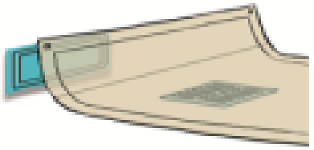
➔ Draft a specific 1 day permit .

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

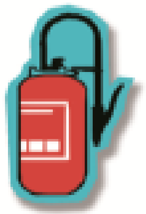
➔ Wet floor

Explosion control

➔ Take specific measures for zones with a risk of explosion

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

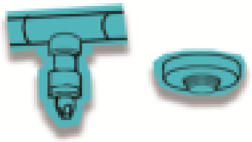
➔ ATEX areas, flammable liq tank / waste water network …..



Fire fighting

➔ Be prepared for fire fighting.

As a minimum have extinguishers at hand.



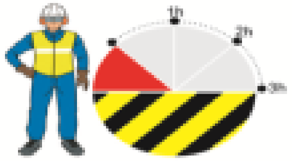
Fire systems

➔ 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

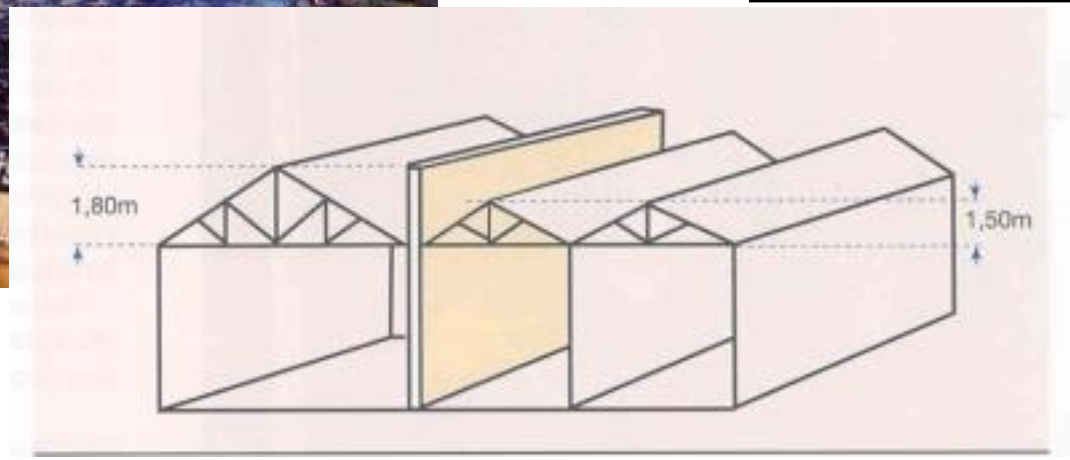
➔Define the means of alerting help
➔Check the work
➔In the case of a problem or unexpected event:
Stop the work, alert and call a supervisor

Hot works

2 – SUBJECT OVERVIEW : FIRE PROTECTION

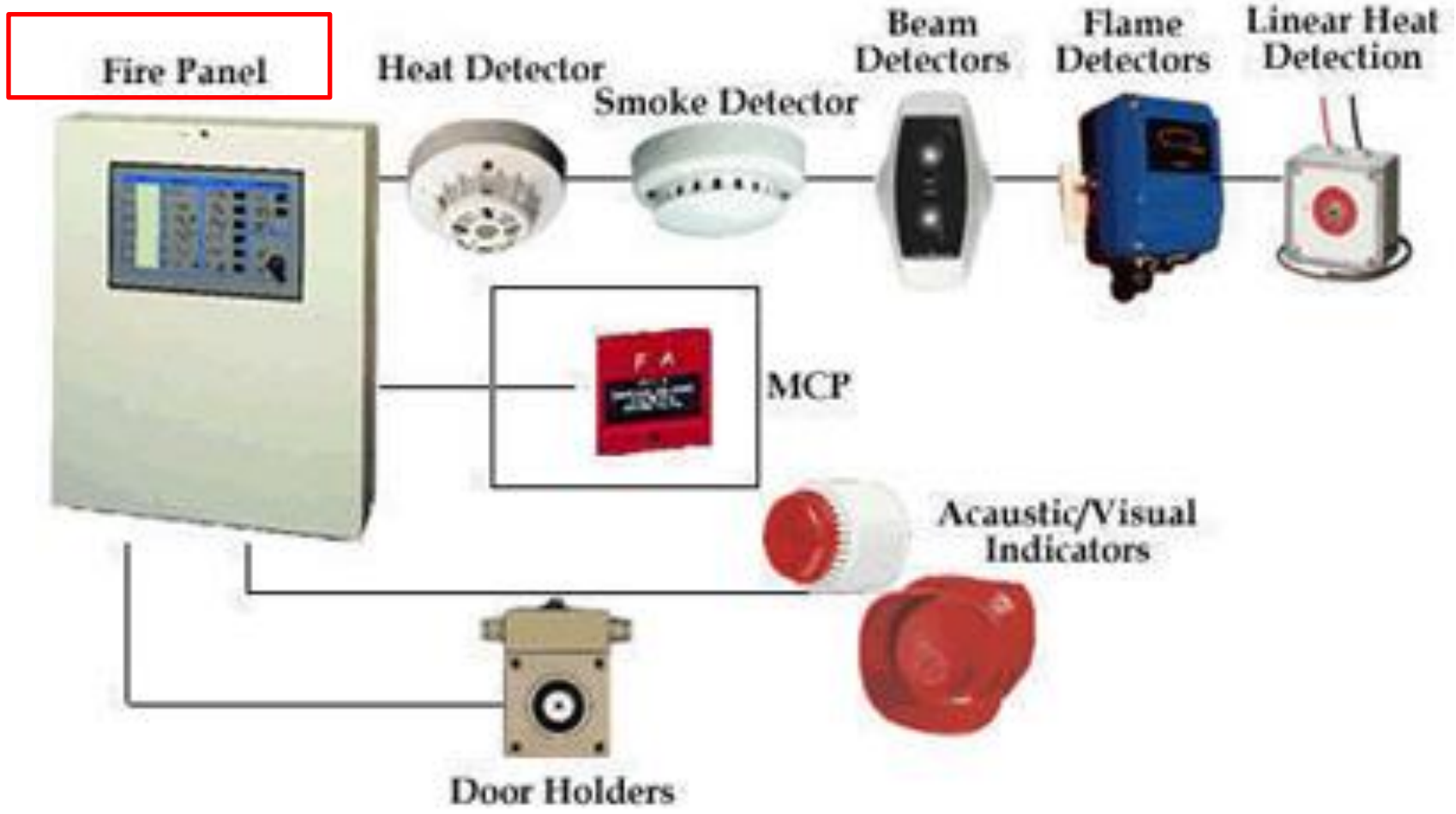
FIRE PARTIONING ASSESSMENT

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



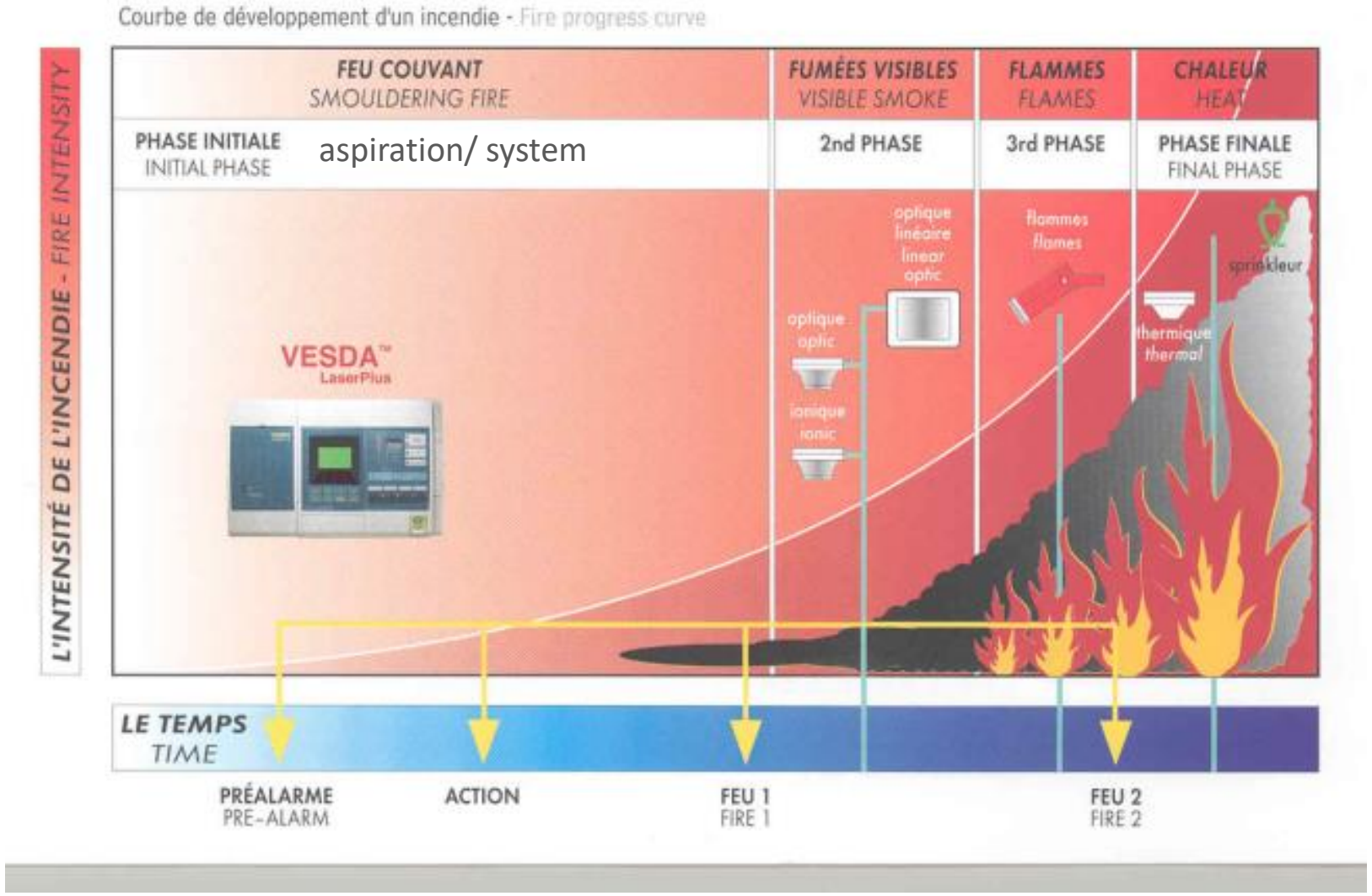
2 x 2 hours fire doors

2 – SUBJECT OVERVIEW : FIRE DETECTION



Smoke removal

2 – SUBJECT OVERVIEW : FIRE SOURCES



2 – SUBJECT OVERVIEW : FIRE DETECTION

Smoke removal

During the visit:

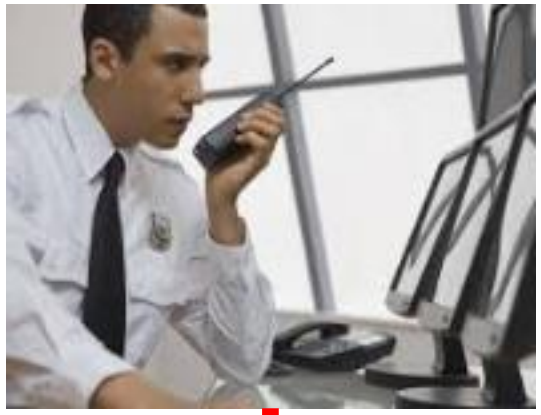
- Is the room equiped with Fire Detection ?
- Adapted to the risk ?

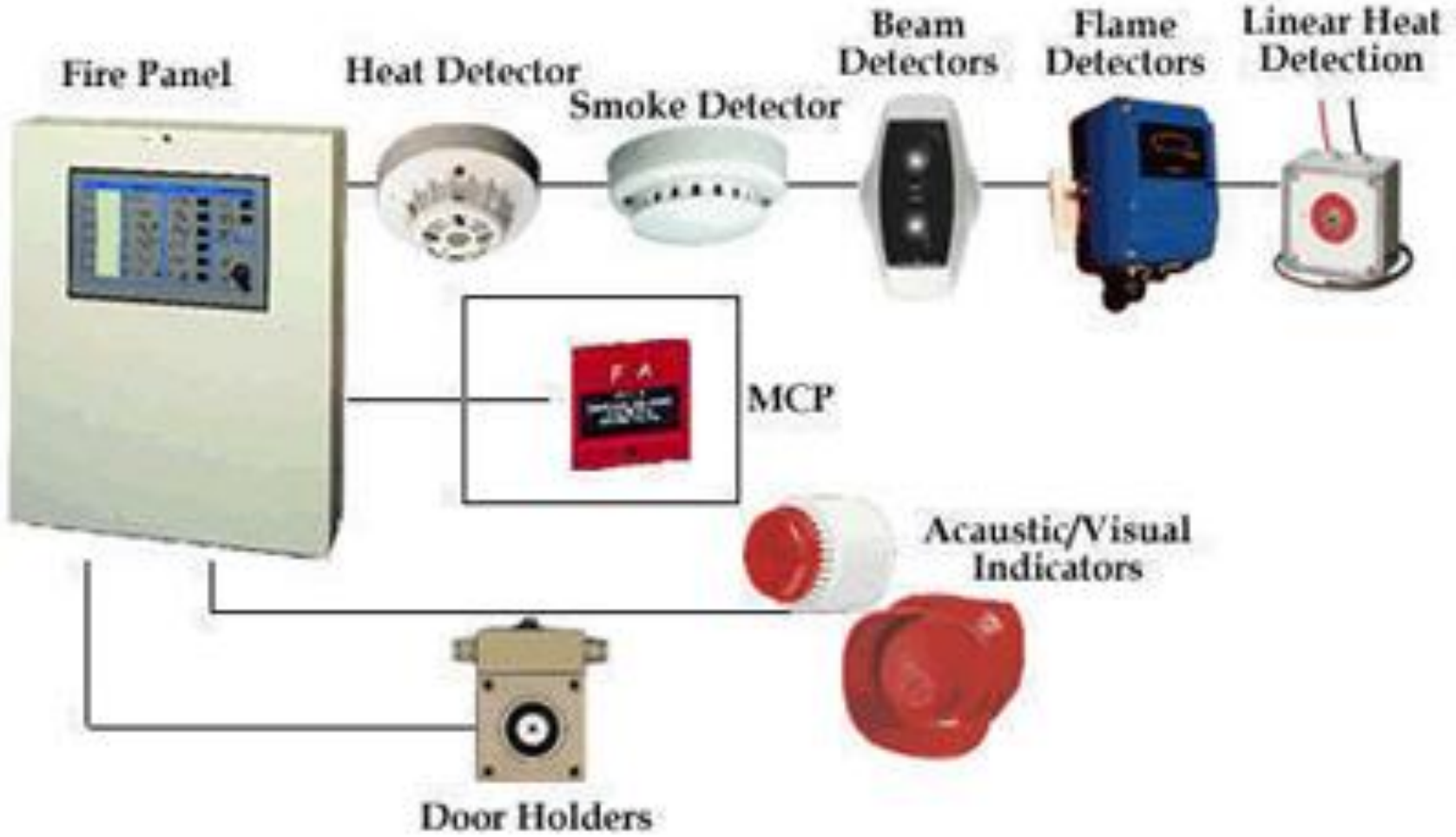
During documention review:

- Maintenance / inspection ?

2 – SUBJECT OVERVIEW : FIRE DETECTION

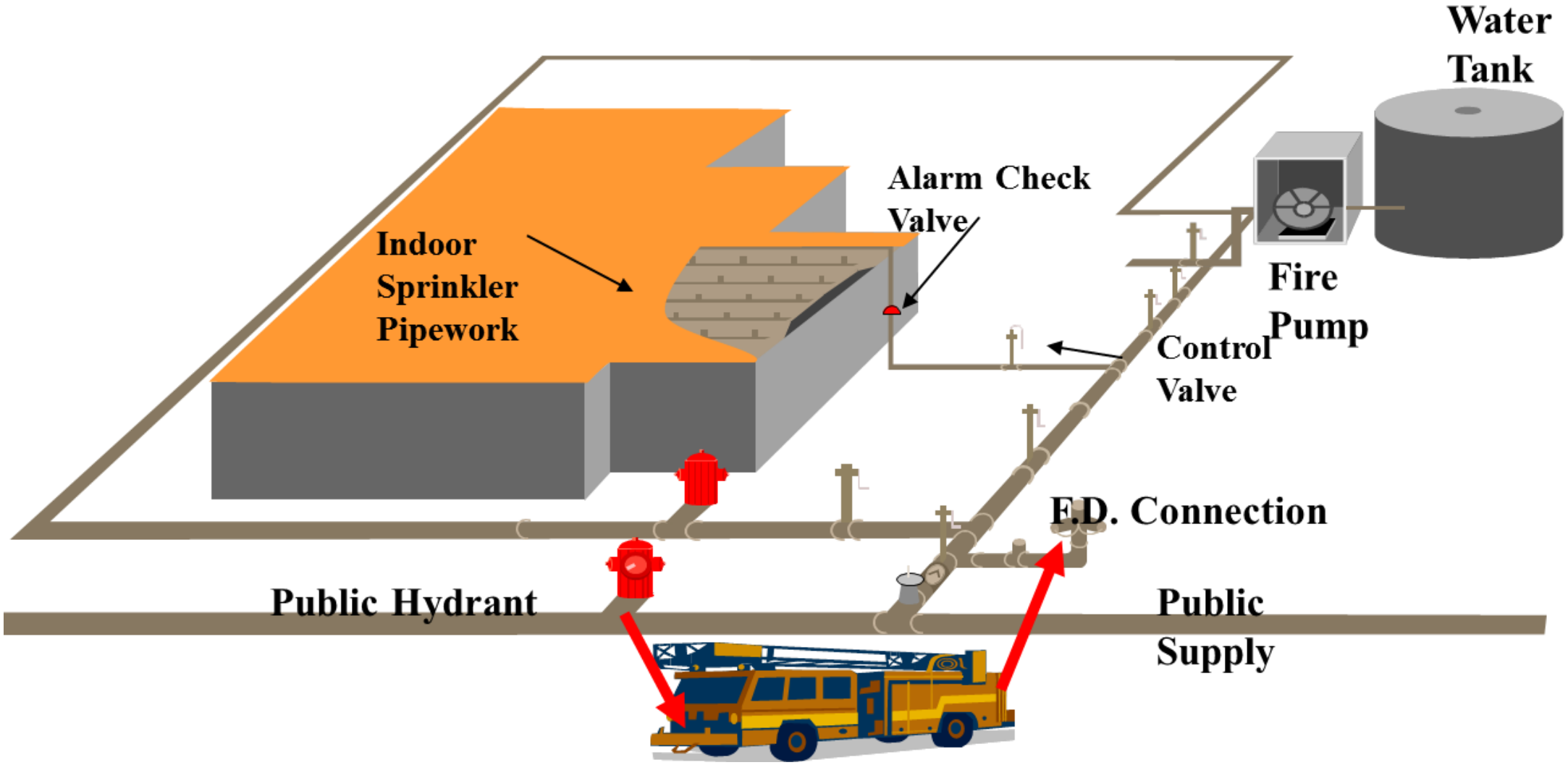
24h/7 ?



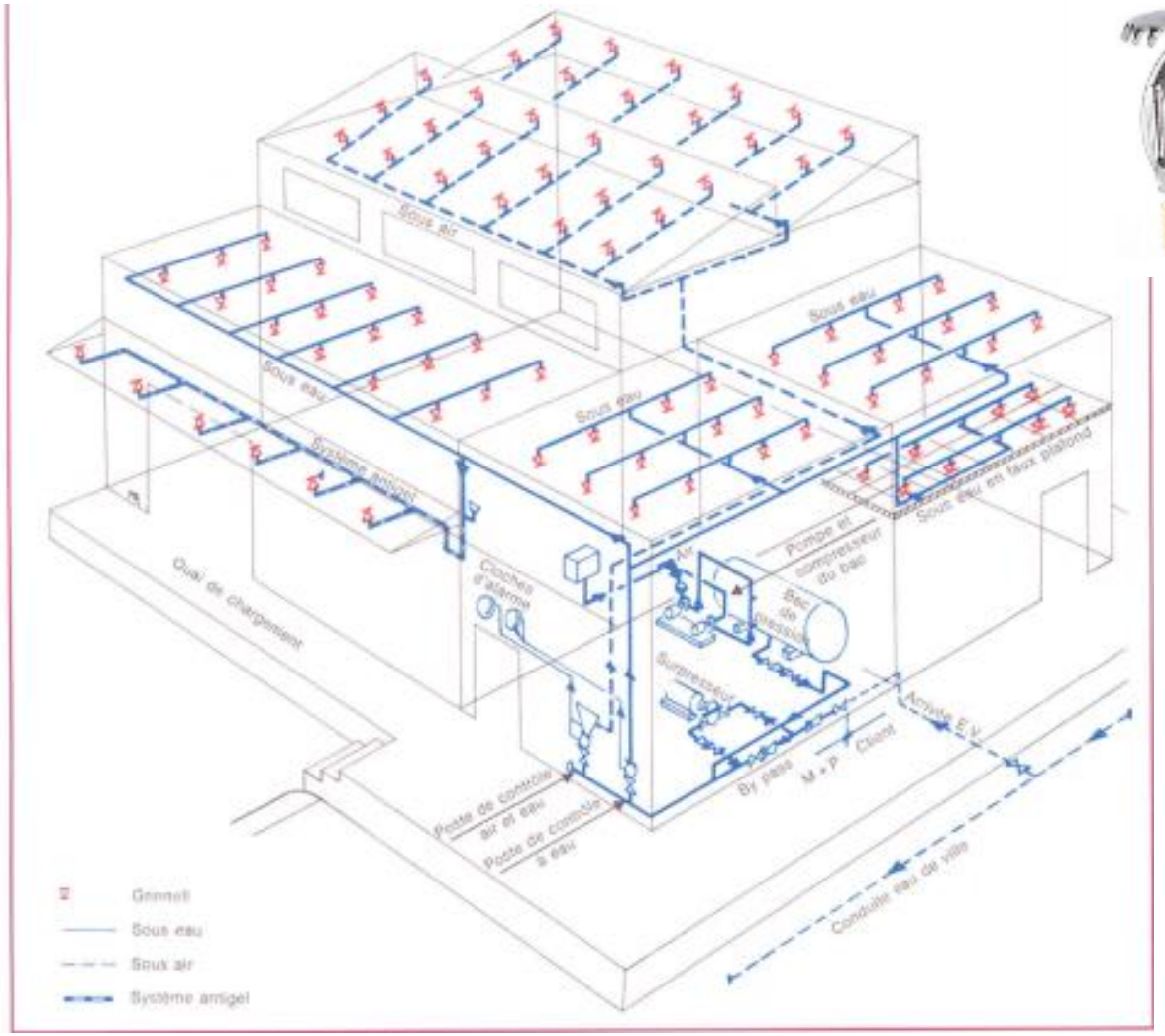


Distance to the fire brigade?

2 – SUBJECT OVERVIEW : FIRE DETECTION



2 – SUBJECT OVERVIEW : SPINKLER Network



Extinguishing activation:

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

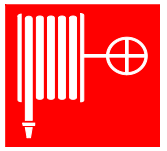
During the visit:

- 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

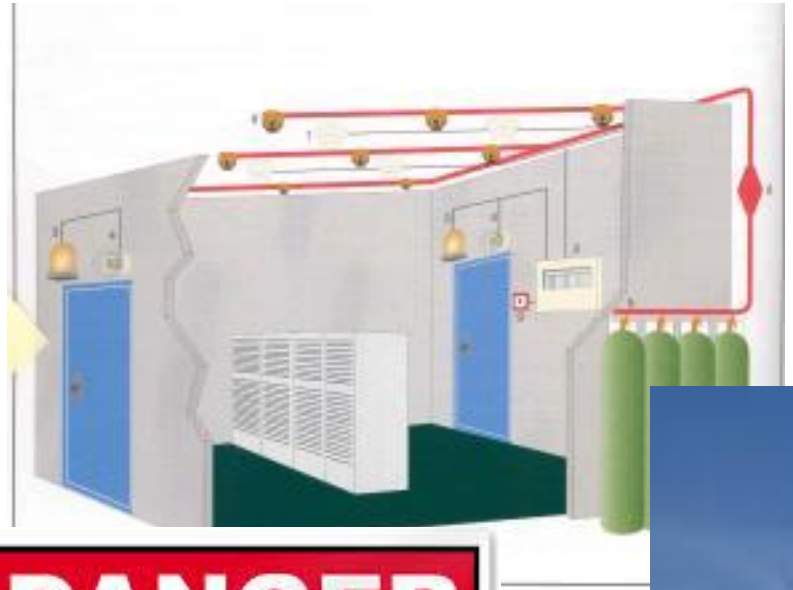
- 1,2,3 pumps ?
- Diesel ? Electrical pumps ? (generator)
- Flow m3/h
- Fuel storage /Battery / Oil
- Lamps / Key of the control panel
- Safe conditions: fire proof, locked, order
- Maintenance

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, compressor, 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*

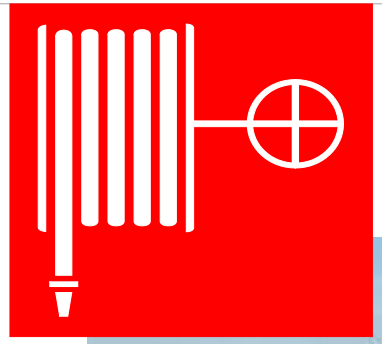
During the visit

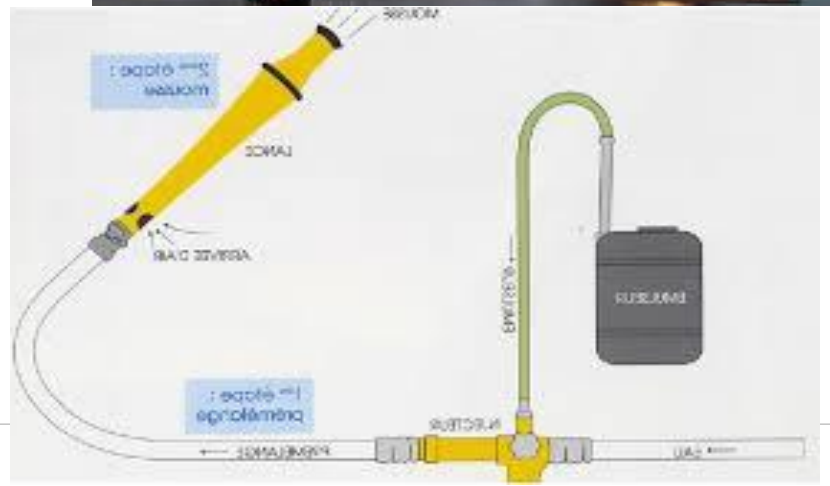
Clear access + Labelling + check inspection label

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 supply 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>

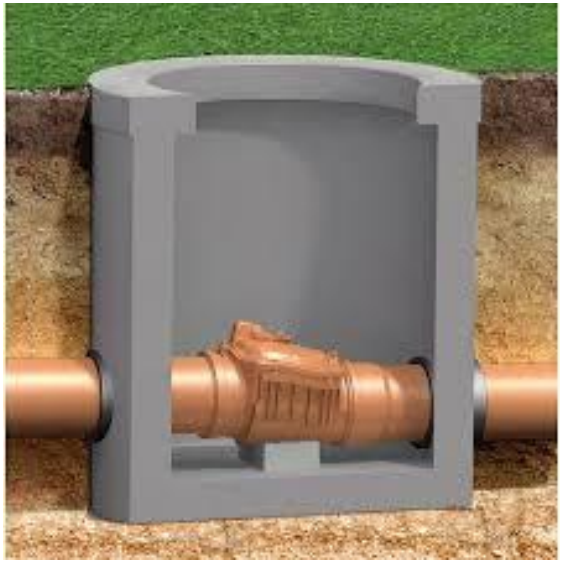
- **Evacuate the raw material/ finished product**
- **Protect equipment**
- **Anti-flooding system**

<u>During the flood</u>

- Inspection

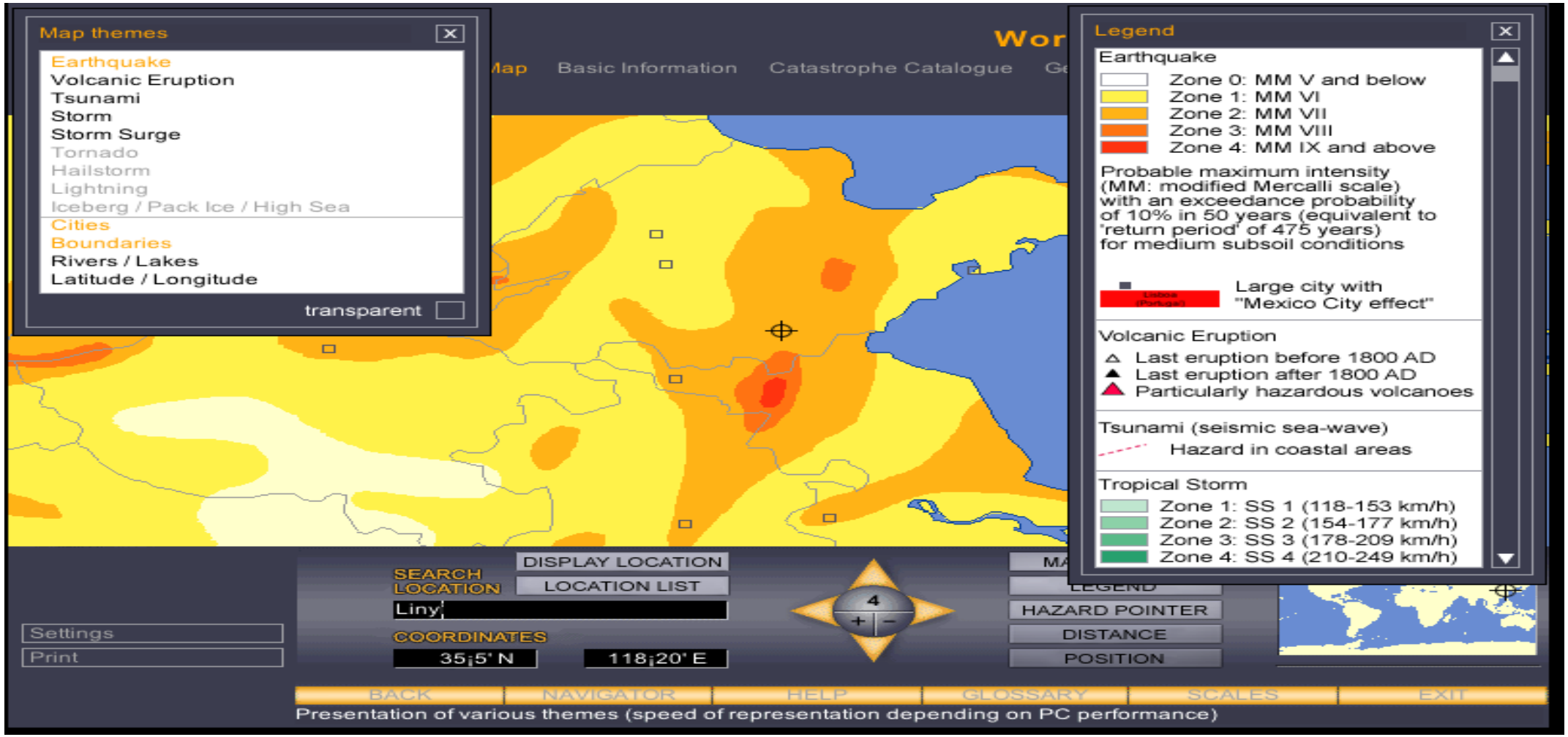
<u>After the flood</u>

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



Natural Hazards

Munich Re Nathan Natural Hazard Database: Earthquake



3 – PROBLEM TOPICS

- Earthquake resistant building
- Specific Storage
- Automatic seismic gas shutoff valve
- Specific sprinkler design
- Training

AGENDA

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?

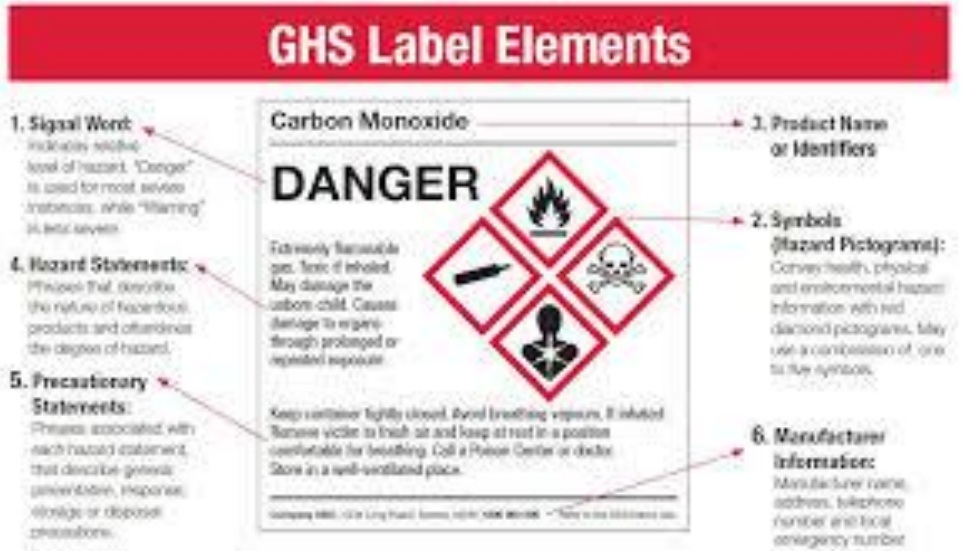
1 – AUDIT OVERVIEW

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 through 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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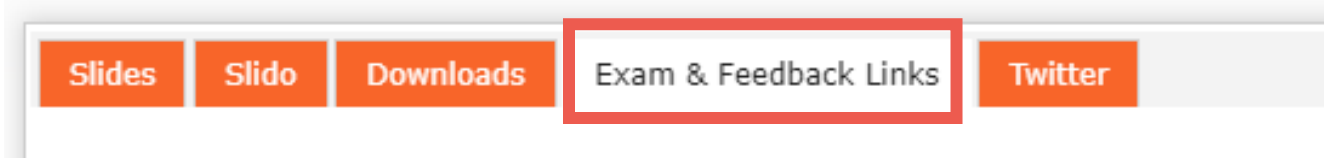
Exam (20 mins) & Feedback survey

Please **scan below QR Code** OR click at links under "**Exam & Feedback Links**" tab on Live Stream page to access exam & feedback survey.



Exam QR Code

Feedback survey QR Code

We recommend everyone to take the exam. Only auditors joining all the sessions and exams will receive certificates of participation. Thanks for your participation!

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