PSCI

PHARMACEUTICAL SUPPLY CHAIN INITIATIVE

PSCI Board Welcome and Opening Address

Presented by

Dr. Birgit Skuballa

PSCI Vice Chair

Bayer AG, Head of HSE Management Systems, Audit Strategy & Planning

Bio

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

Dr Birgit Isabelle Skuballa
Bayer AG, Leverkusen, Germany
Head of HSE MS, Audit Strat. & Plan.
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Agenda

1. Anti-Trust Statement
2. Introduction
3. Joining forces for a sustainable supply chain
4. Who we are and what we do
5. Membership expectations
6. Benefits and how to get involved

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.“

Sustainability is expected of Us

Our stakeholders' expectations are changing:

- The global marketplace has created more complex supply chains, with increased social, economic and environmental risks

- The extent to which we manage our supply chains responsibly is becoming a key measure of our Corporate Social Responsibility competence

- Global companies are subject to increased scrutiny by NGOs, and the media in relation to their supply footprint

- Consumers increasingly expect to buy from companies who "purchase responsibly", respecting the rights of citizens in local communities

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Meeting the Sustainability Challenge

To increase the sustainability of our supply chains, we must understand:

- What impact our supply chain has in the communities where we buy
- The social, health, safety and environmental risks associated with our products and companies
- What we can do, either independently or in conjunction with our supply chain partners, to reduce or manage these risks cost effectively
- How we can use our collective influence to improve labor, health & safety, and other rights of workers across the pharmaceutical supply chain

Using our Collective Influence to Drive Change

Our ethos?

One company can't change the supply chain on its own

The member companies of the PSCI joined forces to address the issue of responsible supply chain management across the pharmaceutical industry

We believe that by sharing knowledge and expertise, the industry-wide PSCI can drive complex, global change more effectively than one organization alone

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What is the PSCI?

The Pharmaceutical Supply Chain Initiative

An industry body formed by the pharmaceutical sector whose members share a vision for responsible supply chain management, to deliver better social, health, safety and environmental outcomes in the communities where they buy

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The Board

Julie Brautigam, Chair
Head of Procurement, Risk and Corporate Social Responsibility
Takeda Pharmaceuticals

Birgit Skuballa, Vice Chair
Head of HSE Management Systems / Audits
Bayer

Steven Meszaros, Past Chair
Corporate Senior Director Business Resiliency & Business Development
Pfizer

Peter Etienne, Secretary
Senior Counsel Ethics & Compliance, Baxter

Sulaiman Hamidi, Treasurer
Director, Sustainability & Product Stewardship
Allergan

The PSCI Vision and Mission

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

Our vision is to establish and promote responsible practices that will continuously improve social, health, safety and environmentally sustainable outcomes for our supply chains.
This includes:

- Fair and safe work conditions and practices
- Responsible business practices
- Environmental sustainability and efficient use of resources

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

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The PSCI Principles

As a first step, the PSCI created the Pharmaceutical Industry Principles for Responsible Supply Chain Management ("the Principles")

These Principles address five areas of responsible business practices and the relevant standards any business operating within the pharmaceutical supply chain is expected to uphold

Implementing the PSCI Principles

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What

The PSCI Principles

Provides a descriptions of our expectations for pharmaceutical supply chain partners

How

Implementation Guidance

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

The PSCI Strategy Framework

PSCI Vision and Mission

Strategic Pillars
How we will influence

1 Driving leadership practices at member companies

2 Enabling suppliers to continuously improve

3 Improving engagement across the industry & with key stakeholders

Priority Issues
What we will influence

- Fair and Safe Work Places
- Responsible Business Practices
- Environmental Sustainability and Efficiency of Resources

Governance
How we will manage

- Governing with Transparency and Managing with Accountability

Strategy Framework: **Priority Issues**

Priority Issues
What we will influence

ETHICS

LABOR

HEALTH & SAFETY

ENVIRONMENT

MANAGEMENT SYSTEMS

Fair and Safe Work Places

1. Worker protection
2. Process safety
3. Fair treatment and labor practices
4. Wages, benefits and working hours

Responsible Business Practices

1. Business integrity and fair competition
2. Data privacy and security

Environmental Sustainability and Efficiency of Resources

1. Water use and management
2. Waste management
3. Pharmaceuticals in the environment
4. Drive reductions in carbon footprint

PSCI Work Streams

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- Audit Collaboration
- Capability Building
- Communications
- Governance

Audit Collaboration

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- Leads: Kelly Kappler (JnJ), Rachel Rae (Lilly)
- Board Liaison: Birgit Skuballa (Bayer)
- Areas of Focus
  - Self-Assessment Questionnaires & Audit Report Protocols
  - Updating Audit Guidance documents
  - Audit models (e.g. shared audits sponsored by PSCI members, supplier self-audits)
  - Audit sharing process and data platform
  - Qualifying 3rd party auditors for PSCI audits
  - Reporting audit findings and trends
  - Auditor training (together with Capability Committee)

Capability Building

- Lead: Ingrid Vande Velde (Johnson & Johnson)
- Board Liaison: Steven Meszaros (Pfizer)
- Areas of Focus
  - Seminars: 3-4 day events with member and outside presenters usually held in developing regions
  - Webinars: Current topics of interest with subject matter experts from member companies
  - Resource Library: Best practice documents from member companies on topics related to PSCI Principles
  - Auditor training (together with Audit Committee)

Communications

- Lead: Andy Rayment (Astra Zeneca)
- Board Liaison: Julie Brautigam (Takeda)
- Areas of Focus
  - Building visibility and influence across the pharma industry
  - Enhancing the reputation of PSCI
  - Strengthening partnerships with other organisations
  - Membership engagement and growth

Governance

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- Lead: Kevin Borud (Roche)
- Board Liaison: Peter Etienne (Baxter)
- Areas of Focus
  - Establishing a strong, transparent governance process
  - Defining and implementing a performance management system
  - Defining membership requirements for new and existing members to PSCI
  - Updating the Bylaws

PSCI Special Projects

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Sustainability data collection

Aligning members on how they collect sustainability information from suppliers – the questions they ask and platform they use

APIs in wastewater

Defining a PSCI response to the high profile issue of API release into the environment from manufacturing sites (particularly in India and China)

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Two Membership Levels

- **Full membership** is designed for companies that wish to actively participate and demonstrate leadership

- **Associate membership** allows companies to take a less active role; for example, those just starting their responsible sourcing programmes or those that do not have the time to participate fully

Member Responsibilities

The general membership has two primary responsibilities:

- electing the Board of Directors
- voting to amend governance documents as needed

Members are invited and encouraged to join working groups, attend biannual in-person meetings, and run for a seat on the Board.

Membership Expectations

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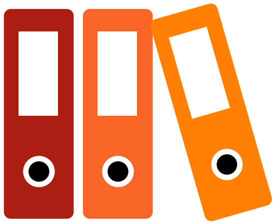
Full Members	Associate Members
Commit to the Bylaws and adhere to the Articles of Incorporation, Bylaws, Principles, Membership Agreement and Anti-Trust Policy	
Put the PSCI Principles on their website	
Pay annual membership fees according to the PSCI Membership Fee Structure	
Must share five supplier audits or alternative expectation as determined by the PSCI Board	**May** share supplier audits / audits of own sites
Must join a working group	**May** join a working group
Must attend Annual General Meeting	

Benefits of PSCI

1. Using common standards across the supply chain
2. Benchmarking and sharing best practices with other pharma companies, and other sectors
3. Being recognized as a supporter and advocate of responsible procurement
4. Suppliers gain a more in-depth understanding of customers' expectations for responsible business practices and raise their profile as a high-performing supplier for current and future customers
5. Suppliers have the opportunity to collaborate with customers to build the sustainability capability at the facilities
6. Members and suppliers can reduce duplication (and make savings) through the audit sharing program

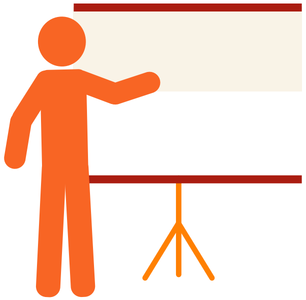
Benefits for Suppliers



Resource library

Our supplier resource library is available at

www.pscinitiative.org/resources



Training / capacity building events

We will be posting information about training/capacity building events on key issues for suppliers

Webinars

- On current topics impacting our industry

Supplier Conferences

- To support technical capacity building

How Can You Get Involved?

- Join PSCI and collaborate with us to further improve the pharmaceutical supply chain (for more information contact info@pscinitiative.org)
- Go to the PSCI website and use the tools in the Resource Library to make improvements
- Participate in upcoming supplier capability building events

The Pharmaceutical Supply Chain Initiative

Need more information?

Visit: www.pscinitiative.org

Email: the PSCI Secretariat at info@pscinitiative.org

@pscinitiative

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Responsible Procurement

Wolfgang Rauch
Chief Procurement Officer, Novartis

Novartis Procurement

Novartis, PSCI & You

Wolfgang Rauch, Chief Procurement Officer Novartis
Hyderabad, India
May 2017

NOVARTIS

In 2016, Novartis products reached nearly 1 billion patients

Our mission and vision for sustainable growth

Mission

Discover new ways to improve and extend people's lives

- Using science-based innovation
- Delivering breakthrough treatments to as many people as possible
- Aim to provide shareholder return

Vision

Be a trusted leader in changing the practice of medicine

A world-leading healthcare company

Our strategy is to use science-based innovation to deliver better patient outcomes. We aim to lead in growing areas of healthcare.

We focus where our skills can help address great medical need:

Oncology

Cardiovascular

Respiratory

Neuroscience

Immunology and dermatology

Eye care

Our innovation engine sustains an industry-leading pipeline

$9bn

Invested in research and development

200+

R&D projects underway

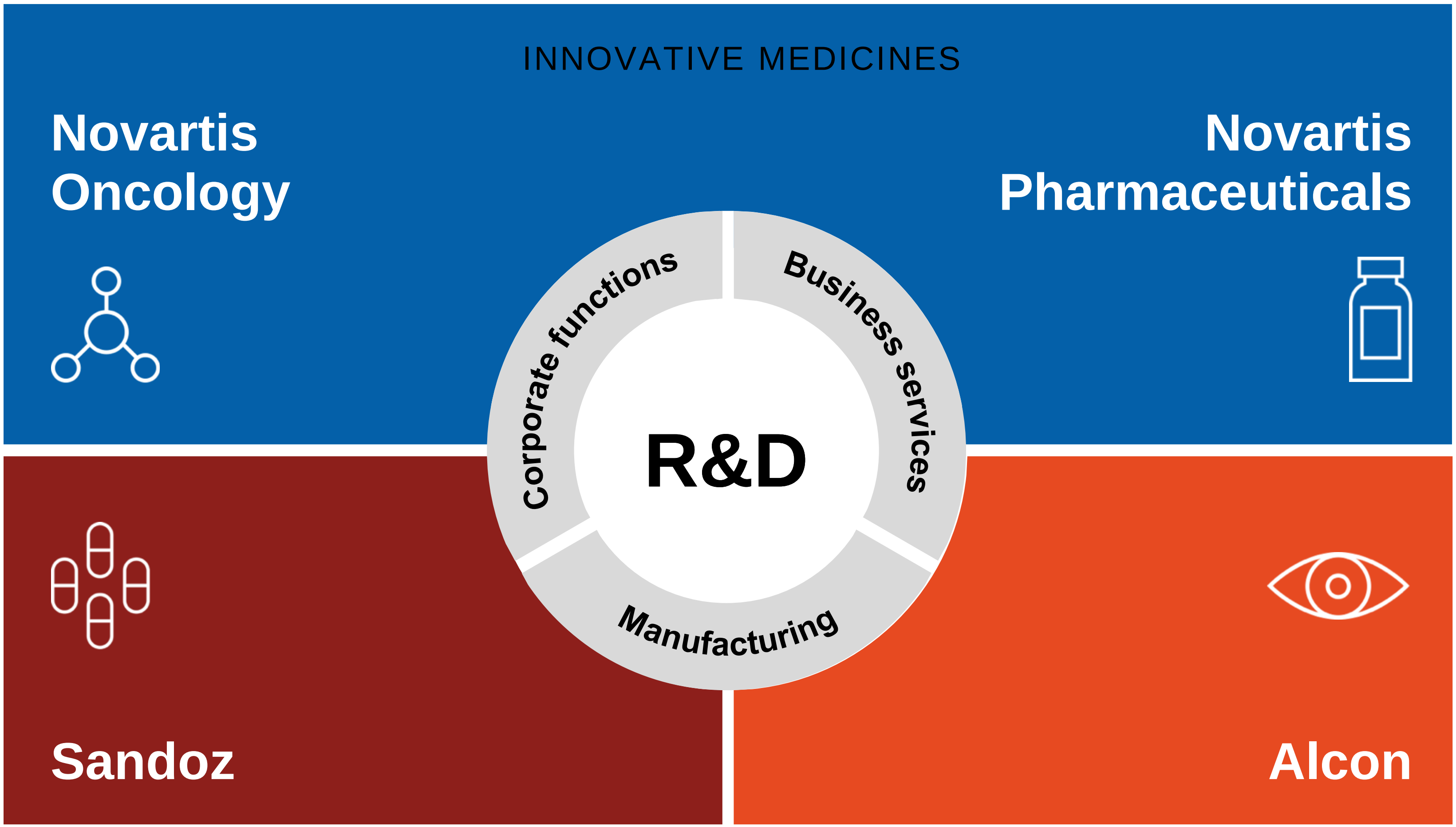
23,000

People working in research and development worldwide

16

Major regulatory approvals in 2016 (US, EU and Japan)

Focused businesses fueled by innovation and functional excellence



The Novartis Global Service Centers are a key enabler of the NBS strategy …

Vision of a globalized network, allowing 24/7 operations...	... in 5 locations chosen based on multiple criteria

- **Interconnected** network
- **Standardized**, effective, efficient
- **High-quality** service delivery
- **Agile** to meet evolving customer needs
- **Innovative** and continuously improved

- **Large talent pool**, attractive to many global companies
- **Complementary attributes** for business (language, time zone)
- Well established **Novartis presence**
- Favorable **business conditions**
- Good **infrastructure**

… and so is Procurement

Procurement at a glance

Providing Procurement services cross-divisionally for all of Novartis

Approx. 1,100 associates

Covering 77 countries

With approx 132,000 active suppliers

And a spend of USD18bn in 2016

Ratio of indirect to direct spend is 70:30

With savings in 2016 of USD 1.66 bn (8.5%)

How we work

Partnering with the business to deliver value for Novartis		
Spend categories	We are organized based on the products and services the business needs	Everything we purchase is in a category of spend, e.g. advertising, chemicals, IT, travel, marketing, packaging etc.
Buying strategies	We develop buying strategies with the business	We have product and market experts in our teams. Both globally and in the countries, they work with the business to create buying strategies depending on the category of spend and the market.
From source to contract	We find the best suppliers and sign them up	With our business partners, we identify appropriate suppliers, manage negotiations and award contracts.
Purchasing process	We manage the purchasing process	At a local level, in-country, we manage the process to meet the purchasing requirements and ensure compliance to contracts
Enablement	We make sure we have the processes and skills to make buying easy	Our enablement teams support the business by: • providing end to end process simplification • defining standards, processes and solutions • delivering training and development
Value	Together we monitor the suppliers performance and we search for ways to innovate and improve	Our goal is to deliver the best for Novartis by: • ensuring there is no risk to business continuity • innovating with suppliers and the business, • identifying opportunities to improve performance and unlock value

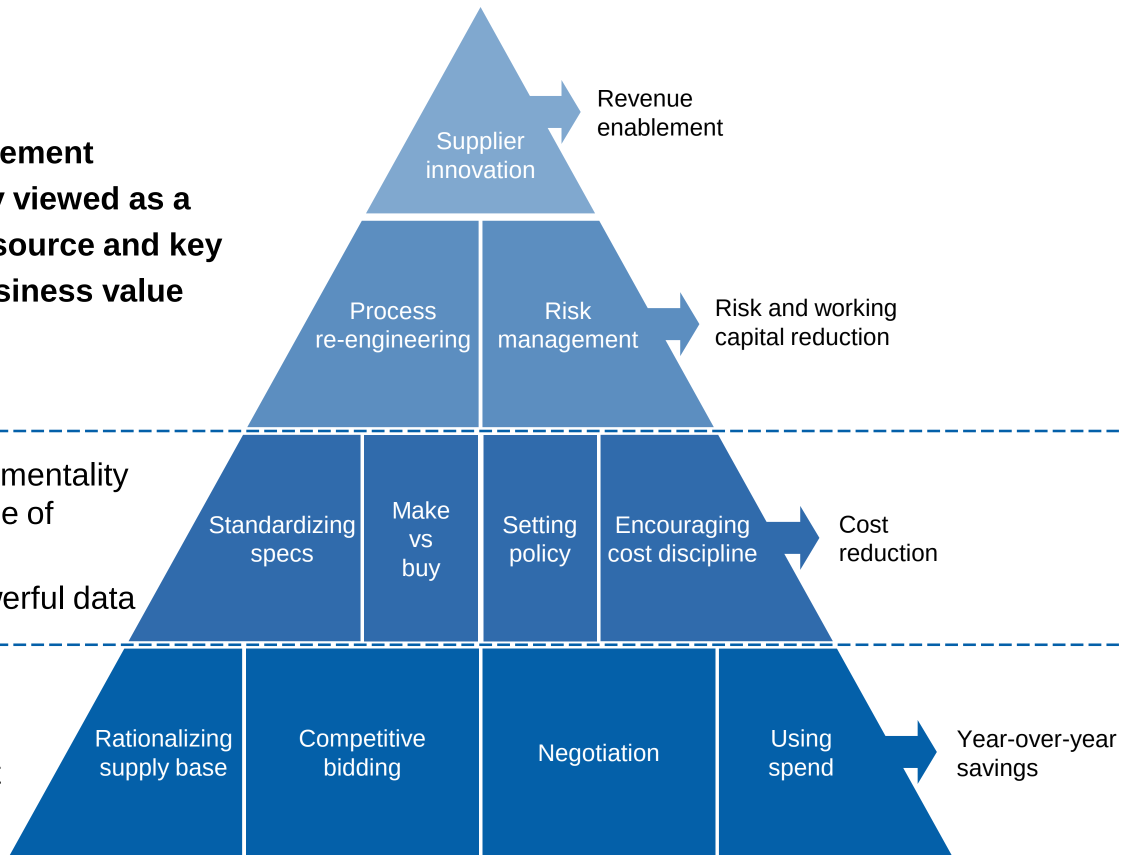
Our evolution to business partner and innovation

Business Value-Enabler Pyramid

ONE Procurement increasingly viewed as a strategic resource and key driver of business value

New partner mentality
Increased use of technology
Trusted, powerful data

Traditional Procurement



Organization

ONE Procurement "all in"

Categories / Countries / NGSCs / Operations Excellence

Cross-divisional operating model and category organizations

Growth of SCP

Multi-division operating model

Shared Country Procurement pilots

Regulated and globally acting industries, like Pharmaceuticals face significant risks - Novartis has responded to this challenge

2003 — Novartis launched its first **corporate citizenship program (CC5)**, designed **to monitor adherence** to the Novartis Third Party Code of Conduct in a **retrospective approach**

2013 — **Responsible Procurement (RP)** introduced, a **pro-active risk-based** approach during the **on-boarding process (**Labor Rights, HSE, Animal Welfare, Anti-Bribery and Fair Competition and Data Privacy)

2015 — Conducted a **'Materiality Assessment'**, involving Novartis expert functions, **to identify best practices and potential gaps**

2016 — Cross functional steering committee established to oversee the expansion of the RP program into a **comprehensive third party risk management framework** across Novartis.

2017 — **Significant progress already made**, fully resourced program team now in place to deliver the comprehensive framework under a new operating model with an integrated end-to-end process.

Responsible Procurement

With the breadth and diversity of our supply chain, we *must* ensure our goods and services are ethically sourced

Responsible Procurement ensures that the commitment to corporate responsibility is reflected in…

How we select and work with our suppliers

- Promoting **ethical behavior** and **social responsibility**
- Identifying suppliers who have potential **ethical risk**
- Identifying **opportunities** to improve conditions at suppliers
- Fostering mutually beneficial **relationships**
- Managing **reputational risk**

Doing business responsibly

Striving for ethical and sustainable business practices

- Caring for our associates
- Protecting the environment
- Promoting ethics and strengthening governance

The collaborative approach of PSCI members is an important driver in doing business responsibly, because...

Sustainability is expected of PSCI Members

PSCI stakeholders' expectations are changing:




- The global marketplace has created more complex supply chains, with increased social, economic and environmental risks
- The extent to which we manage our supply chains responsibly is becoming a key measure of our Corporate Social Responsibility competence
- Global companies are subject to increased scrutiny by NGOs, and the media in relation to their supply footprint
- Consumers increasingly expect to buy from companies who "purchase responsibly", respecting the rights of citizens in local communities

Information Source: PSCI, 2017

Meeting the sustainability challenge

To increase the sustainability of our supply chains, we must understand:

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Information Source: PSCI, 2017

Using our collective influence to drive change

PSCI ethos

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Information Source: PSCI, 2017

Thank You

Process Safety Management Session

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Quantitative Risk Assessment (QRA)

Presented by

Sakila Bhadu

Senior Manager

Dekra Insight

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Bio

- Sakila Bhadu

- Senior Manager – Technical

- Graduate in Chemical Engineering, having 10 years of experience in Technical Safety and Risk Management. She has working knowledge of conducting safety studies like HAZOP, HAZID, Consequence Analysis and physical effects modelling, SIL, RAM, QRA, EERA, Safety Audit, ESSA, Dispersion and FERA etc. for oil & gas and petrochemical industries.

Sakila Bhadu
Dekra Insight
Senior Manager – Technical
Email: Sakila.bhadu@dekra.com

Agenda

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- WHY QRA
- QRA Basics
- Hazard Screening
- Defining Source Terms
- The Consequence Models (Fire, Explosion, toxic release)

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- Estimating the Event Frequency and the Risk
- Risk Acceptability and Criteria
- Interpreting and Using Risk Assessment Results

WHY QRA

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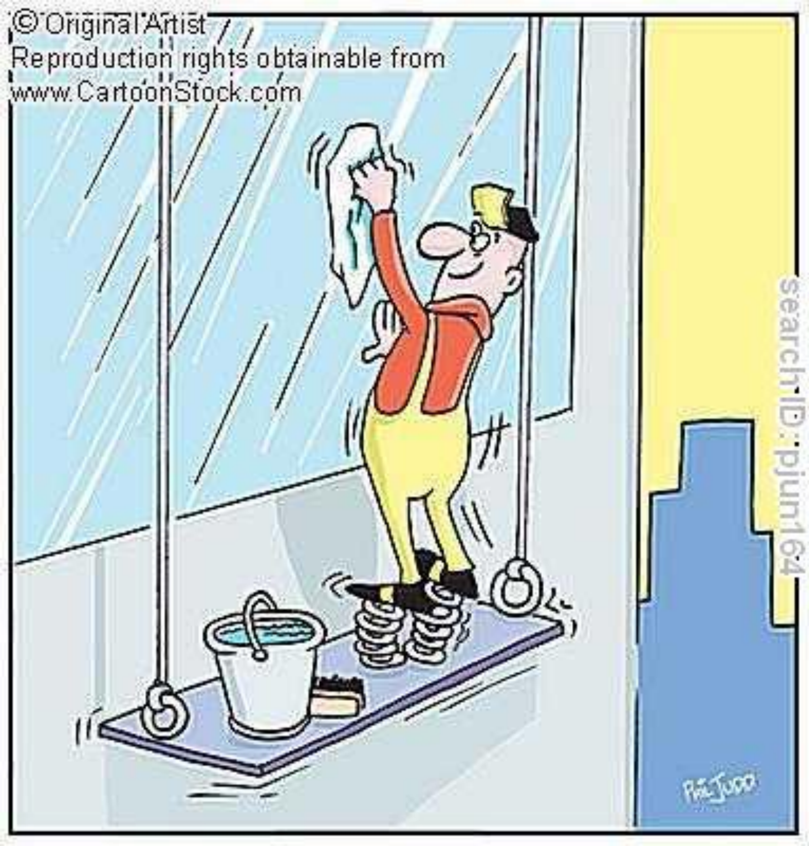
Why Risk Assessment?

- Maintain a safe working environment
- Manage risk effectively
- Make money
- Meet legislation

Traditional Approach

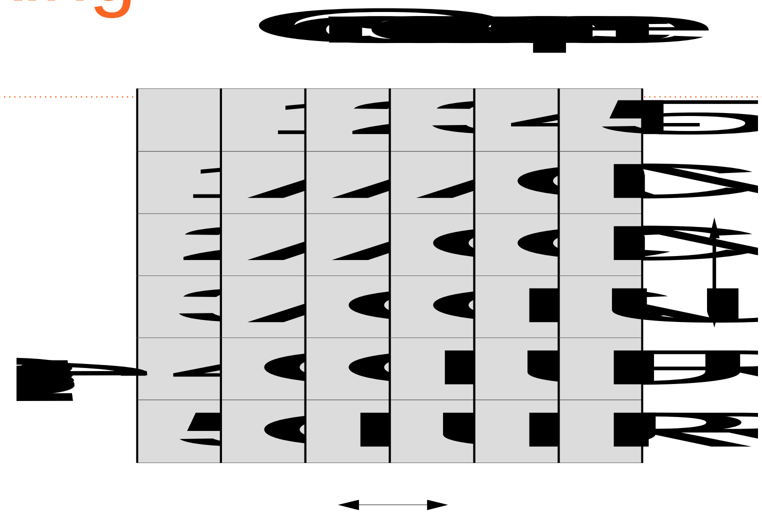


Define risks here.

Simple Risk Assessment

Hazard	**Causes**	**Consequence**	**Safeguards**	**Actions**
Fall from height	Man slips	Possible death or serious injury	Platform	Man should wear harness Cage around platform
Fall from height	Platform fails	Possible death or serious injury	None	Platform safety checks

Risk Ranking



Can be used to complement
Simple risk assessment

A : Acceptable as designed
C : Acceptable; risk control measures already specified
N : Not Desirable; risk control measures to be installed within specified period
U : Unacceptable; only acceptable if risk control measures installed before operation
R : Re-design required

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Simple Approach ?

Complexity

Major hazard

Serious consequences

Reason for QRA

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- Complex plant and processes
- Major process hazards (toxic release, fire, explosion)
- Serious consequences
  - Fatalities and multiple injuries (on and offsite)
  - Major plant damage
  - Harm to the environment

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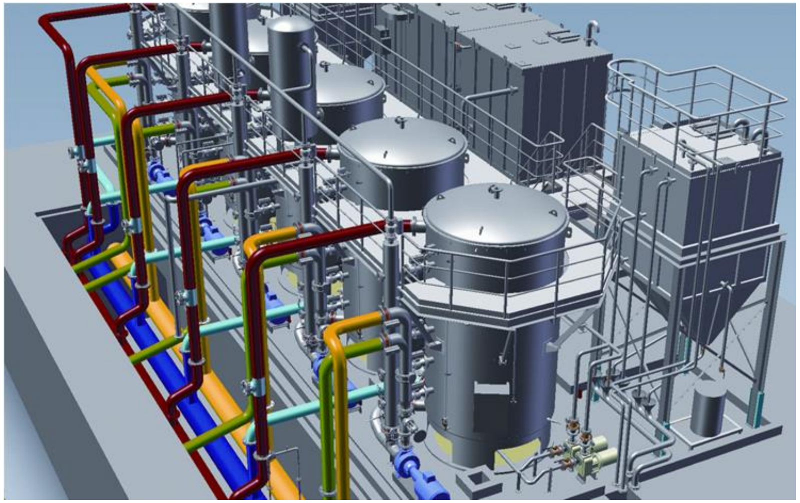
When is a QRA useful?



- **Plant** layout and location
- **Protective** system definition
- **Process** route definition
- **Prioritise** investment
- **Permit** regulatory compliance
- **Promote** responsible management

Regulatory compliance
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- Protect people and the environment from major hazards (fires, explosions, releases of hazardous material)

- Safety report for upper tier sites
  - Detailed description of possible major accidents, with probability or conditions under which they can occur
  - Assessment of extent and severity of consequences

- IN UK COMAH Regulations 1999 (as amended):
  - onsite AND offsite risk has to be covered.

COMAH Regulations: guidance L111

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- Risk assessment effort has to be “proportionate to hazard and risk”.
- “Quantified arguments “might be a convenient way of limiting the scope of the safety report”.
- Consequence assessment should include both direct and “domino” effects.
  - Hazard ranges on maps or drawings
  - Number of people affected by an accident.

Decision For QRA

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- New project
  - Major process hazards
  - Likely to be made early
- External
  - Regulatory
  - Insurance
  - Planning
- PSM policy

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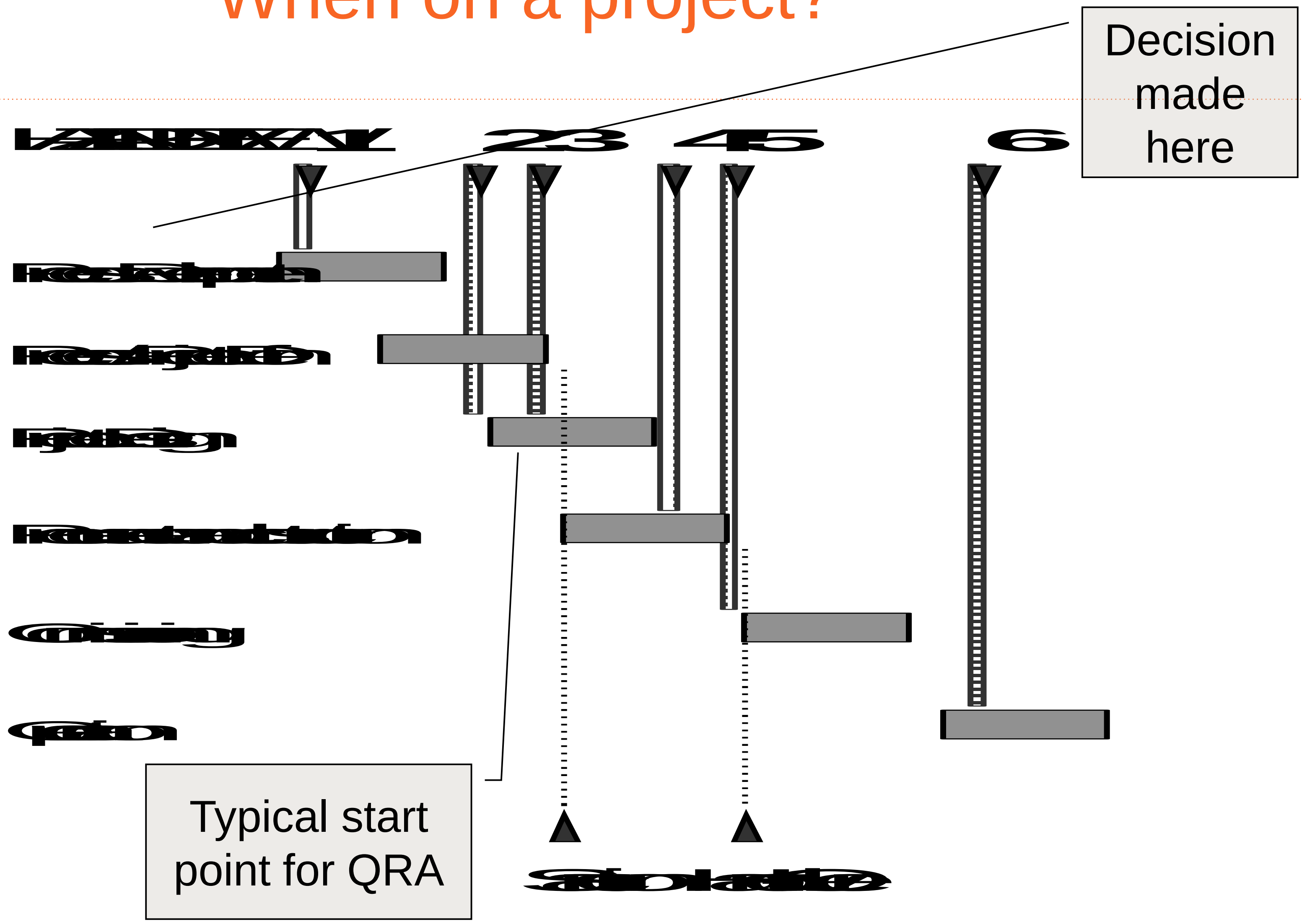
When on a project?



When on a project?

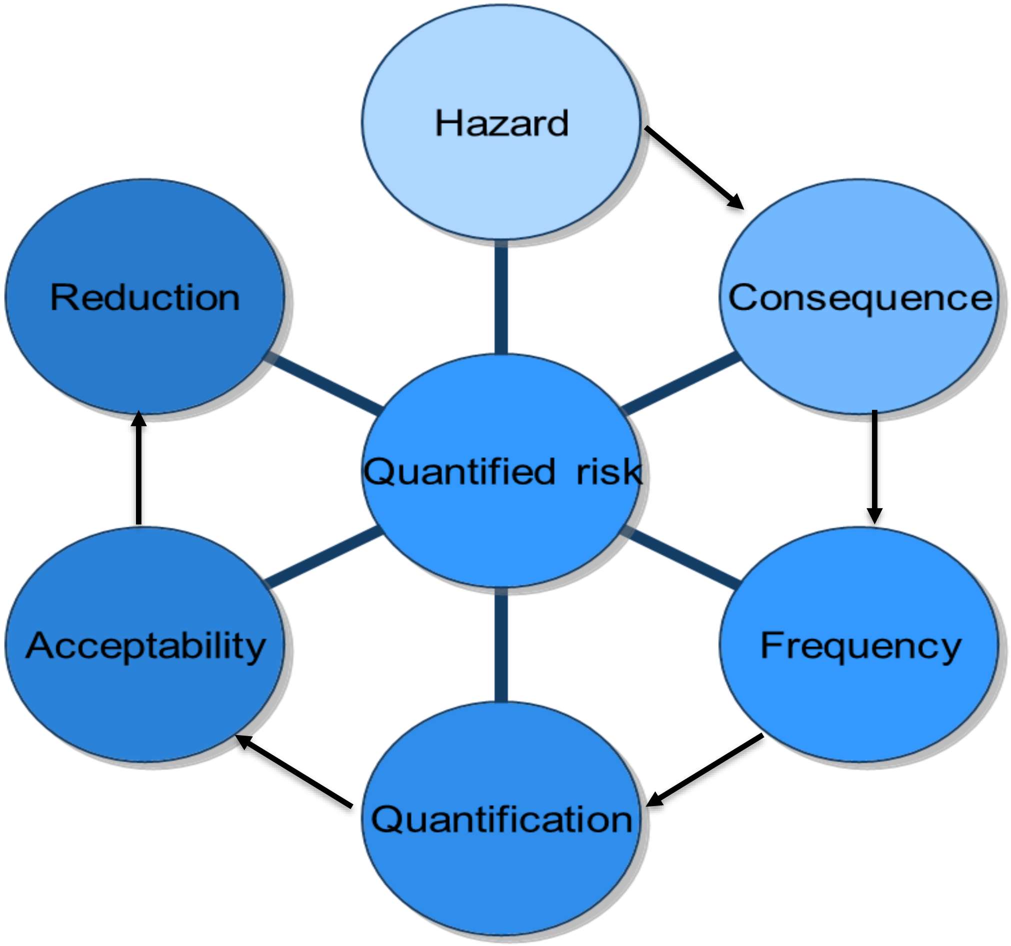
YES

- Materials and inventory identified
- Plant location(s) and layout defined
- Process route(s) defined
- Basic plant design
- Civil engineering design complete
  - Drainage and bunding arrangements

MAYBE (e.g. if fully quantifying frequency)

- Detailed design complete
- Operating procedures defined
- Computer control defined

Steps in QRA


Hazard
Consequence
Frequency
Quantification
Acceptability
Reduction
Quantified risk

QRA Flowchart

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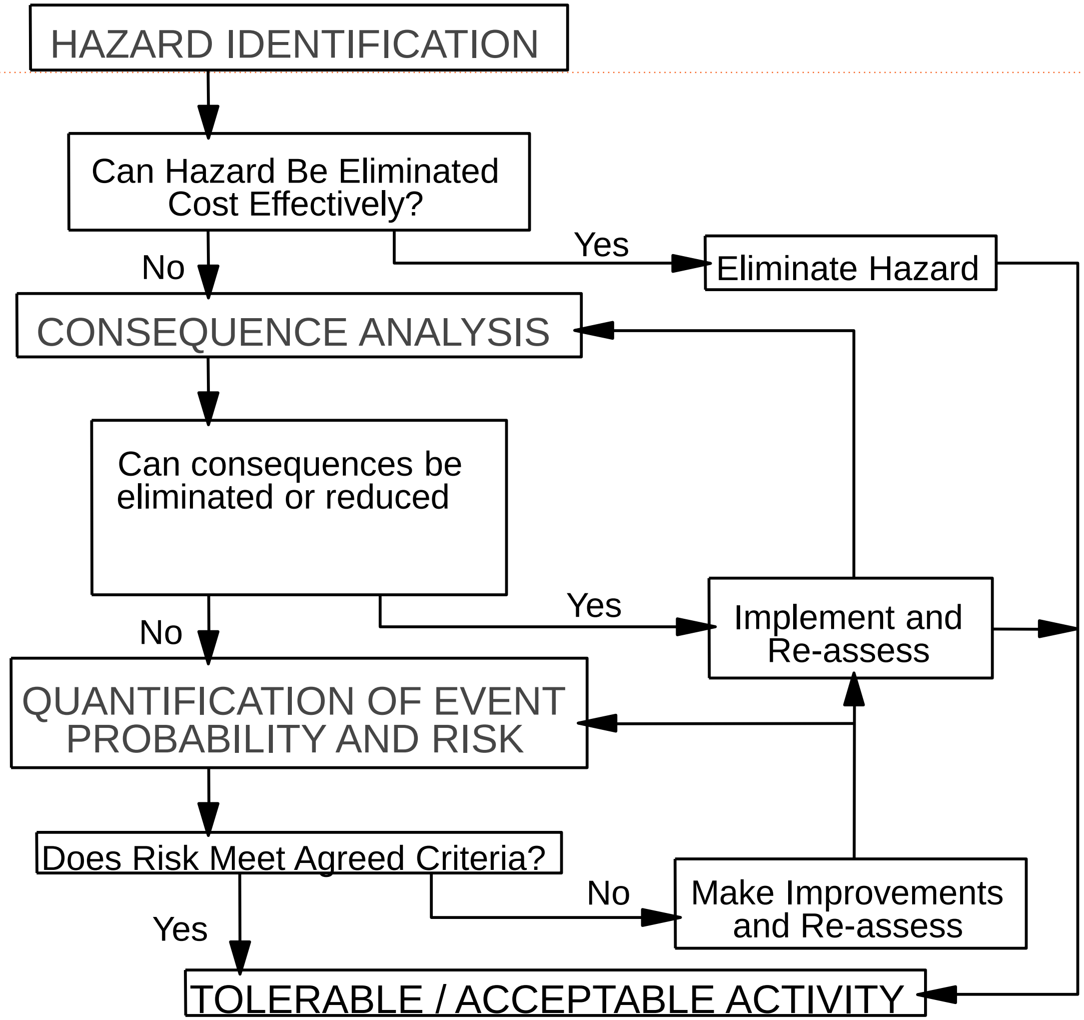
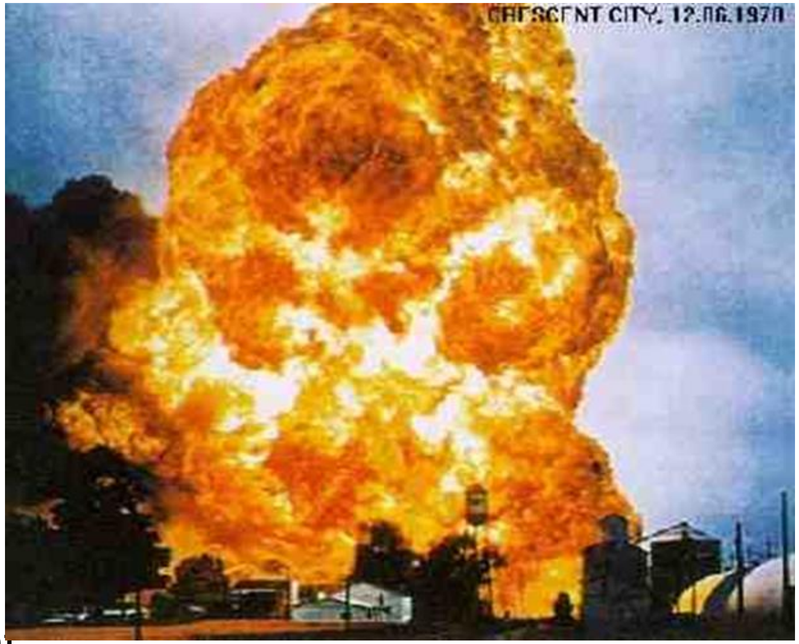


Conclusions

- Why QRA
  - 4Ms, for complex plant and major hazards
    - Maintain
    - Manage
    - Make
    - Meet
- Uses
  - **Plant** layout
  - **Protective** system
  - **Process** route definition
  - **Prioritise** investment
  - **Permit** regulatory compliance
  - **Promote** responsible management



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HAZARD SCREENING

Hazard Screening - Techniques for identifying major hazards

- HAZOP
- FMEA
- What-If
- Hazard Review

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Consequence

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The consequence models (fire, explosion, toxic release)

Toxic gas

Fire

Explosion

Fire and explosion types vapour/gas dispersion

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- Ignition of vapour above liquid pool

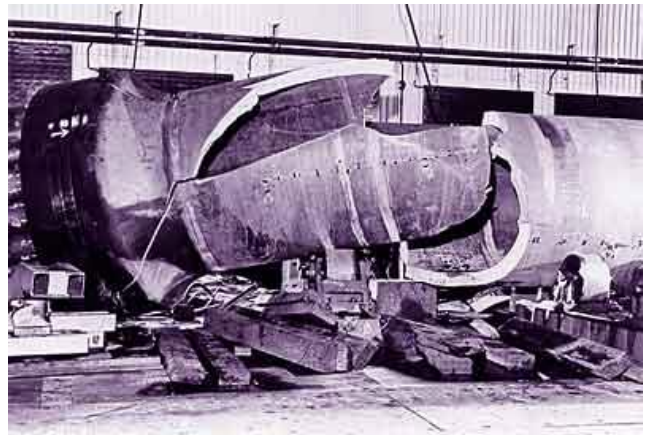
Pool fire

- Ignition of gas/aerosol jet e.g. from pipe or vessel

Jet fire

Fire and Explosion types
Vessel rupture

- Rupture of a pressure vessel
  - Overpressure
  - Defect
- Ignition of flammable vapours released from ruptured pressure vessel



Physical explosion

Boiling Liquid Expanding Vapour Explosion (BLEVE) plus fireball

Toxic gas clouds

- Release of gas or aerosol from:
  - Pipe or vessel
  - Liquid pool

Toxic gas (or aerosol) dispersion

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Estimating the Event Frequency and the Risk

Estimating the event frequency and the risk

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- In a QRA the frequency to be estimated is the one of the event for which we have calculated the consequences (Ex: 10 mm leak in the pipeline)
- Depending upon the source term or the QRA scope, different methodologies can be followed:
  - Databases for generic loss of containment events / failures (estimates from industrial experience)
  - Leak base frequencies + parts count
  - Fault Tree Analysis

Risk Definition

Risk is the unwanted consequences of an activity connected with the probability / frequency of occurrence

Generalities

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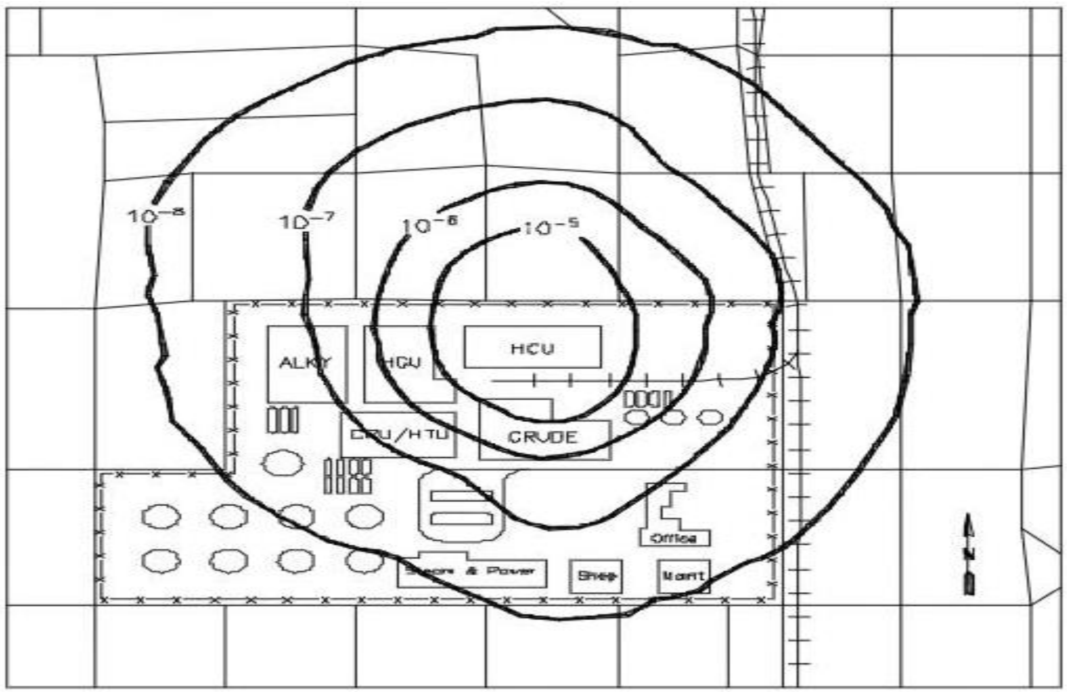
- Risk determination is conditioned by how are we willing to represent the risk.
- Two types of outputs can be obtained from a QRA:
  - <u>Individual Risk</u>
  - <u>Societal Risk</u>
- In any case, the use of a specific software is strongly advised!

Representation of IR

- <u>Location specific risk contours</u>: contour lines on a topographic map which connect all grid points with a given IR (usually 10^{-4}, 10^{-5}, 10^{-6}, 10^{-7}, 10^{-8} per year)



Representation of IR (continued)

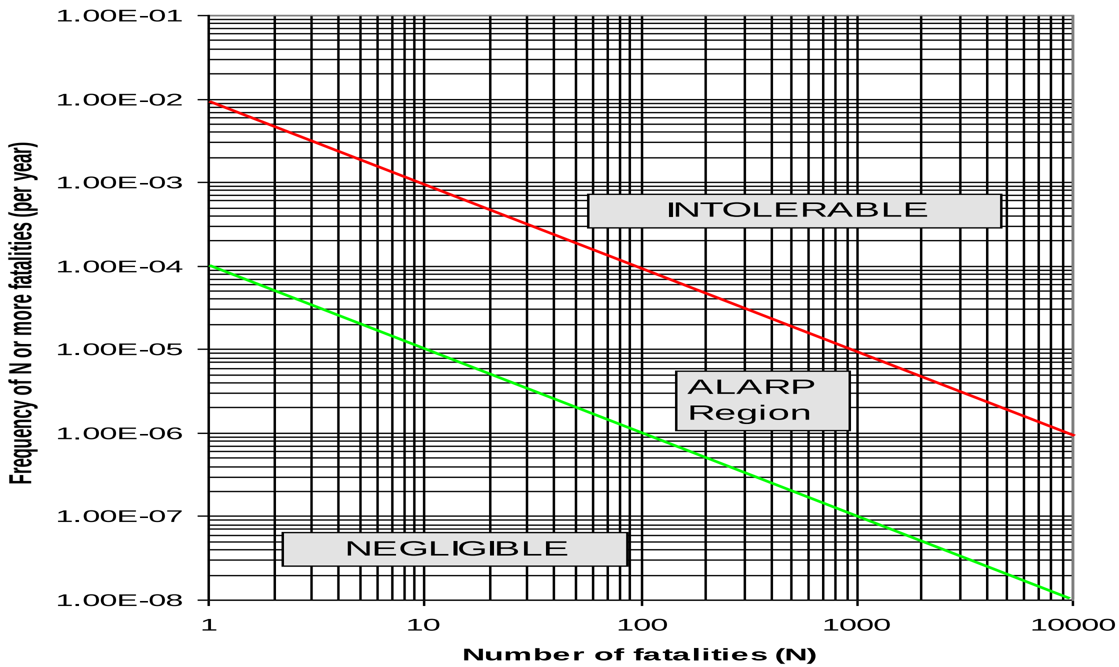
- Individual risk to worker groups
  - Considering their distribution on-site (buildings / routes)
    - Average of Individual risk (per year)
  - Accounting for the number of workers per group
    - Potential Loss of Life (fatalities per year)

Worker group	a. PLL	IR
Administration	2,31E-05	1,86E-07
Maintenance	9,03E-03	8,92E-05
Operators	1,31E-02	2,85E-04
Laboratory	4,72E-06	4,62E-07
Security	4,90E-09	5,13E-10
Visits	4,31E-04	6,8E-06

- Risk contribution by unit / event

Representation of SR

- FN curve: logarithmic plot where the x-axis represents the number of deaths (N) and the y-axis represents the cumulative frequency of the accidents, with the number of deaths equal to N or more (F)



Risk Acceptability Criteria

IR Tolerability Criteria

- Values shown on the table are derived from existing regulatory requirements

Region	Workers	General Public
Intolerable	$1 \cdot 10^{-3}$	$1 \cdot 10^{-5}$
Broadly acceptable	$1 \cdot 10^{-4}$	$1 \cdot 10^{-6}$

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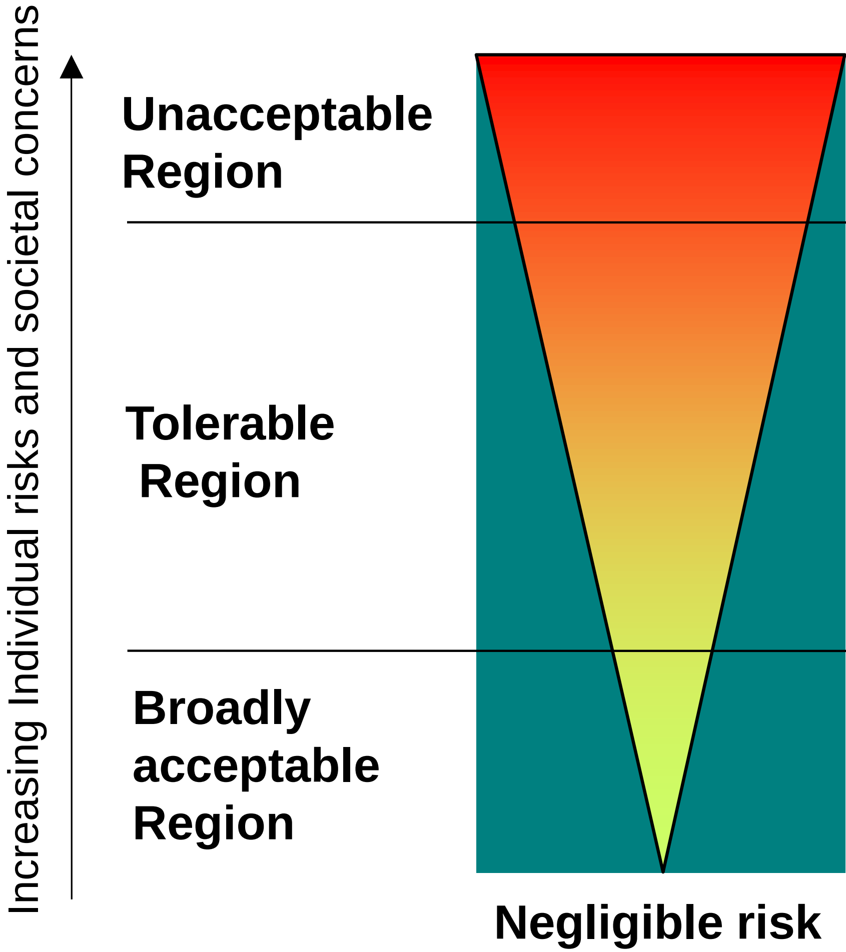
Tolerability of Risk



Risk cannot be justified save in extraordinary circumstances

Control measures must be introduced in this region to drive residual risk to the broadly acceptable region.

Risk is tolerable only if effort required to reduce it further is grossly disproportionate to the reduction achieved.

Level of risk regarded as insignificant and further effort to reduce risk not likely to be required as resources to reduce risk likely to be grossly disproportionate to the risk reduction achieved

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Interpreting and Using Risk Assessment Results

Interpretation of Results

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- Whenever the assessed risk is in the ALARP or the Intolerable region, risk reduction measures have to be analysed
- Not all the LOCs have the same contribution to the overall risk
- Not all the LOCs have the same contribution to the unaccepted value of risk (IR o SR)
- In order to define risk reduction measures the top risk contributors have to be listed.
- The use of adequate software is very important

Analysis of Top Risk Contributors

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- The listing of contributors can follow different criteria:
  - By LOCs (usually)
  - By type of equipment (reactors, pumps,...)
  - By physical division of the plant of effect (warehouse, cracker unit, utilities...)
  - By physical effect
  - By type of population (operators, outside population,...)
  - Other?

Risk Reduction Measures

- One of the key benefits of the QRA is that it gives enough information to help in defining the appropriate risk reduction measures
- The investment effort should be done starting with the top risk contributors
- Examples of risk reduction measures:
  - Implement a high pressure SIF on R-223
  - Define a risk based maintenance program for NG compressors
  - Reduce the amount of phosgene in T-2.3
  - Implement double containment in the 036-BD-201 ammonia piping with leak detection
  - Redefine the operators manning in the sulphur unit

Cost-benefit Analysis

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- A cost-benefit analysis consists in establishing for all identified risk reduction measures the cost versus the benefits in order to help in decision-making issues:
  - ALARP
  - Priorization of measures
  - Comparison between different measures
- The cost are usually expressed in Currency/year
- The benefits can be expressed in any of the risk representation parameters

Q&A

THANK YOU

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PSM in Pharma and Enterprise Sustainable Development

Presented by

Jitendra Kumar

Director

CTPL- Dekra Insight

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Bio

- Jitendra is Director at Chilworth leading the business in India and most parts of Asia.
- Having 25 years of Process Safety, Risk Management consulting experience.
- He is looking after the Indian, South East Asia, Australia and Middle East projects carried out by Chilworth.
- His work experience includes executing and managing Safety and Risk consulting assignments at over 700 sites Globally.

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Agenda

1. Why PSM
2. OSHA PSM Overview
3. OSHA PSM Elements
4. Employee Participation
5. Process Safety Information
6. PHA
7. Incident Investigation
8. Compliance Audits/ Exercise
9. Operating Procedures
10. Work Permits

Agenda

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OSHA PSM Overview

Why OSHA PSM?

Valero Refinery, Feb 2007

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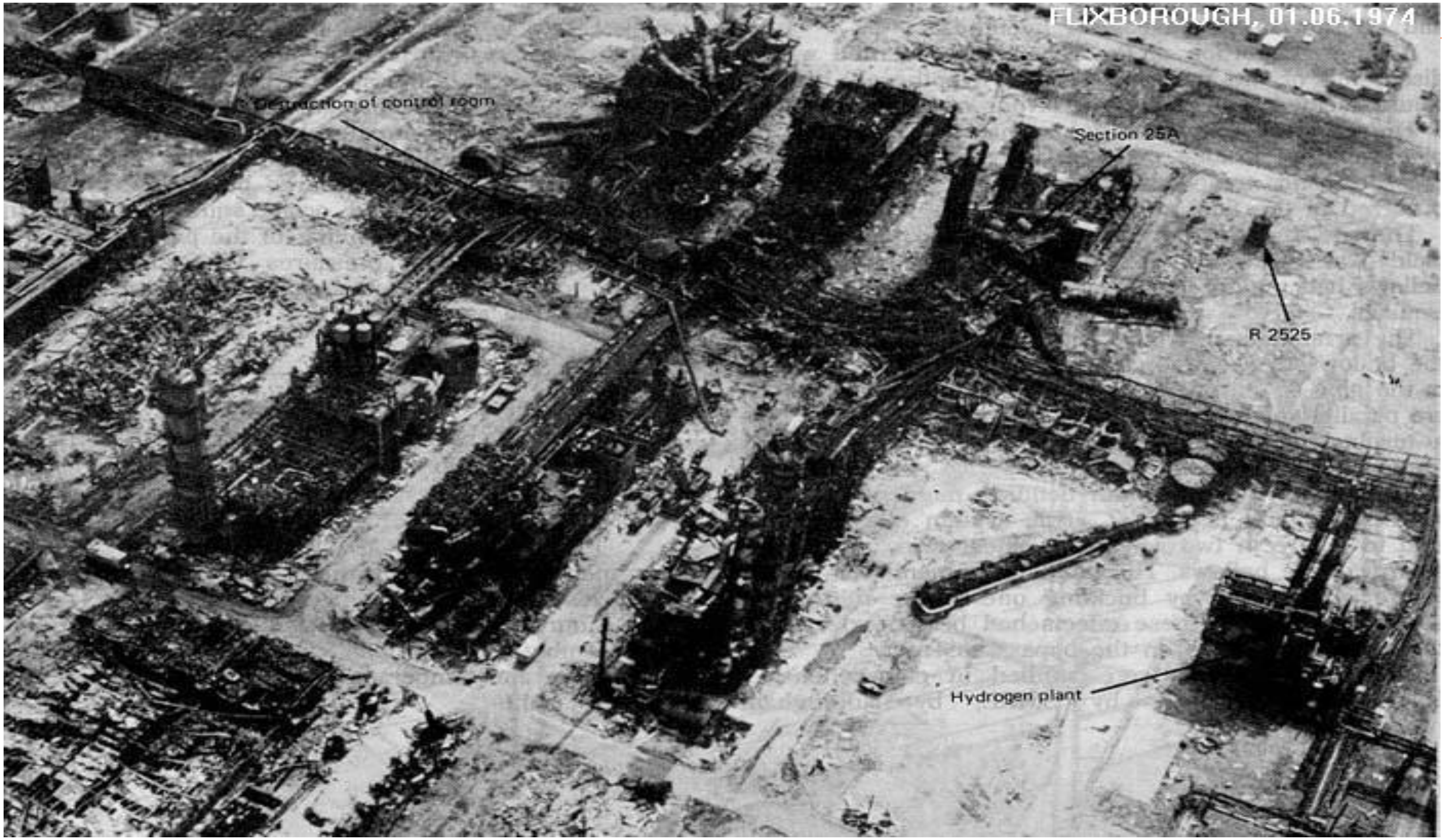
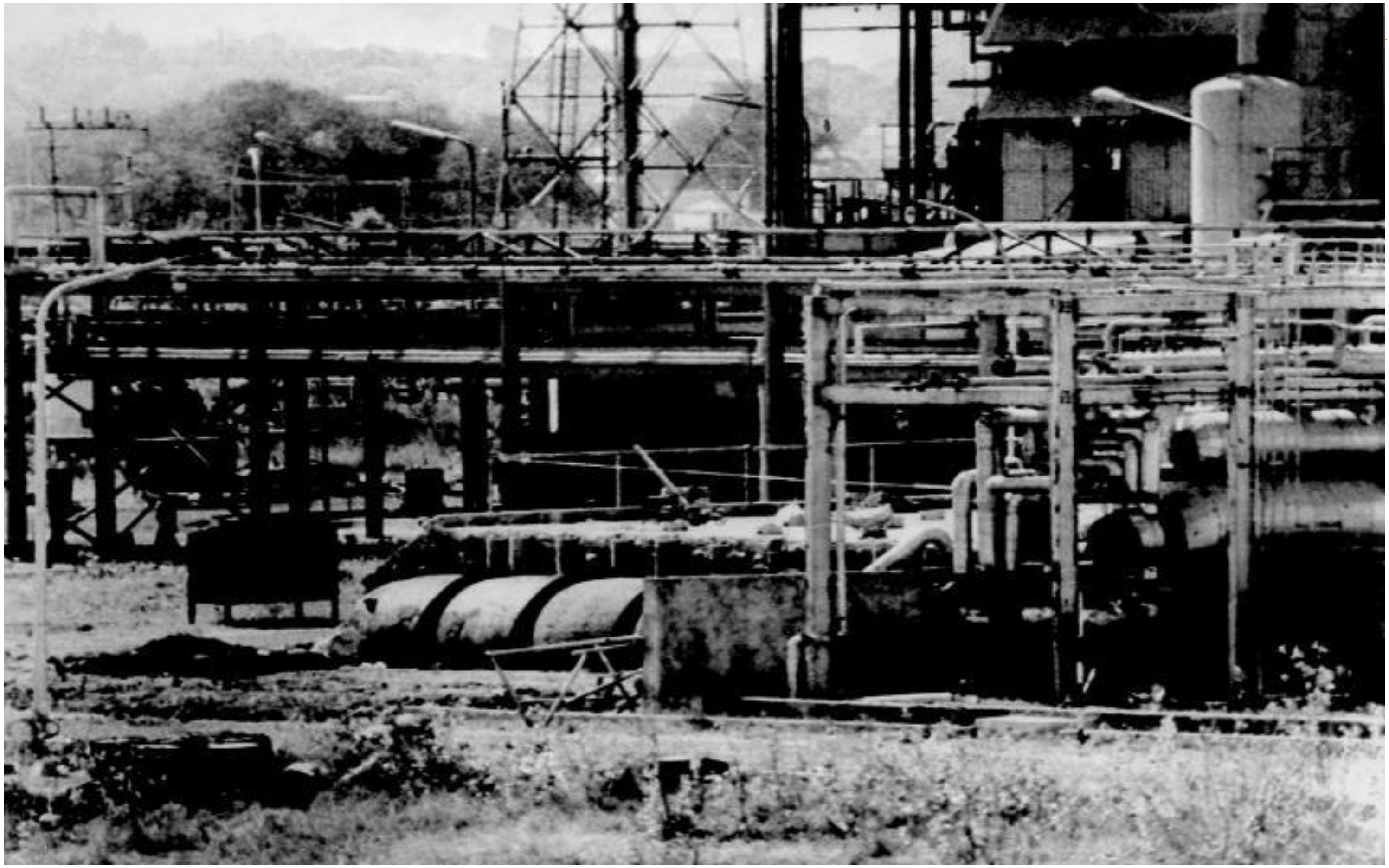


Flixborough, England (1974)

Venezuela Oil Refinery, 2012

Hayes Lemmerz, Oct 2003

BP Refinery Explosion, March 2005



Bhopal Gas Tragedy, December 1984

OSHA PSM Approach

- **Traditional OSHA**
  - **Industrial Hygiene (slips, trips and falls)**
  - **Relatively frequent, low consequence events**
  - **Regulations are prescriptive**

- **PSM Regulation**
  - **Industrial fires and toxic gas releases**
  - **Relatively rare, high consequence events**
  - **Regulation is performance oriented**

Personnel (Occupational) vs. Process Safety

Likelihood	Severity		
	Low	Medium	High
High			
Medium			
Low			

Occupational Safety   Process Safety

Why PSM in Pharma?

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High severity (consequence) incidents possible:

- **Solvents**
- **Powders**
- **Toxics**
- **Chemical reactions**

Why PSM in Pharma?

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Potential hazards

- **Fires**
- **Explosions**
- **Toxic exposure / Asphyxiation**
- **Bio - hazards**

Why PSM in Pharma?

Critical issues to be considered

- **Properties of chemicals**
- **Facility Siting**
- **Quantity handled**
- **Hazards related to Processing, handling and transporting**
- **Exposure to personnel.**

OSHA PSM Elements

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

Interdependence of Elements

Identify the PSM ele **Mechanical Integrity** he following narrative

During a routine inspection of equipment, the maintenance worker discovers a valv **MOC** nger meets the applicable code and must be change the type **Operating Procedures** s no longer made, a different type of valve must be sel stalled. The ty **Training** valve selected will mandate differ the operators will require training and verification in **Employee Participation** cedures. The rationale for selecting the type of valv ade available for review by employees and their represe **Contractor**

When the new valve is installed by the supplier, it wil **Hot Work** shutting down part of the process as well as brazing som **PSSR** lines. The employer must review the response plan to en procedures are adequate for the installation hazards.

Review of PSM Elements

Employee Participation

Importance of Employee Participation

- **Empowers each employee to be responsible for process safety, thereby strengthening the process safety culture.**
- **Taps into a wider range of knowledge and experience.**
- **Improves communication and trust between hourly workforce and management.**

Requirements- Employee Participation

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- **Employers shall develop a written plan of action regarding the implementation of the employee participation required by this section.**
- **Employers shall consult with employees and their representatives on the conduct and development of process hazards analyses and on the development of the other elements of process safety management.**
- **Employers shall provide access to PHA's and to all other PSM information.**

Development of Employee Participation

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- **Develop written policy**
- **Suggestions to increase employee participation:**
  - **Hold monthly safety meetings**
  - **Review all incidents and near misses.**
  - **Suggestion boxes**
  - **Employees to participate in Job Safety Observations**
  - **Implement a reward or prize system for employees who make safety suggestions.**
  - **Include production personnel on safety committee.**
  - **Include production personnel (or their rep) on PSM policy development committee.**

Development of Employee Participation (cont.)

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- **Include operating employees in the following:**
  - **Participation in PHA's as team members**
  - **Reviewing SOP's**
- **Use Intranet to store and share process safety information.**
  - **Train employees in how to access and understand the data.**
- **Inform operators of all changes and provide training in the change, if needed.**
- **Consult with employees regarding the frequency of refresher training.**
- **Encourage/reward employees for reporting incidents and near misses.**
- **Include all production personnel as members of the on-site Emergency Response Team**

Process Safety Information

Importance of Process Safety Information (PSI)

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- **Fundamental information required to support other PSM activities**
  - **Support PHA's**
  - **Training and operating procedures**
  - **Contractor safety**
  - **Pre-startup safety reviews**
  - **Emergency preparedness**

Requirements of PSI

- Information pertaining to the hazards of the chemicals
  - Toxicity
  - Permissible exposure limits
  - Physical data
  - Reactivity data
  - Corrosivity data
  - Thermal and chemical stability data
  - Hazardous effects of inadvertent mixing of different materials that could foreseeably occur.
- Chemical properties are normally contained in Material Data Safety Sheets (MSDS).

Development of PSI

- **Hazards of the materials**
  - **Updated MSDS for all highly hazardous materials**
  - **Table giving potential hazardous effects of inadvertent mixing of different materials.**
- **Process Technology**
  - **Process description, including process chemistry.**
  - **Process block flow diagram.**
  - **Process flow diagrams.**
  - **Table giving safe upper and lower operating parameter limits, including consequences of deviations from these safe limits.**

Development of PSI (Cont.)

- **Process Equipment**
  - **PID's, showing materials of construction**
  - **Electrical classification drawings, with basis**
  - **Relief system design with basis**
  - **Ventilation system design**
  - **Material and energy balances (if built after May 26, 1992)**
  - **Safety Systems**
  - **Design codes and standards used.**

Process Hazard Analysis

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Importance of Process Hazards Analysis (PHA)

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- **Cornerstone of PSM**
- **You cannot manage a risk if you are unaware of the hazard**
- **PHA's answer the following questions:**
  - **What can go wrong?**
  - **How bad could it be?**
  - **How often might it occur?**

Requirements of PHA

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- **PHA shall address:**
  - **Hazards of the process**
  - **Any previous incident which had a likely potential for a catastrophic consequence.**
  - **Engineering and administrative controls**
  - **Consequences of failure of engineering/admin. controls**
  - **Facility Siting**
  - **Human Factors**
  - **A qualitative evaluation of a range of possible safety and health effects of failure of controls.**

Requirements of PHA (Cont.)

- **Team approach**
  - **One member with expertise in the engineering and process operations**
  - **One member who has experience and knowledge specific to the process**
  - **One member knowledgeable in the specific PHA methodology being used.**
  - **Other team members, as needed.**
- **Respond to findings and take necessary corrective action in a timely fashion.**
- **Revalidate at least every 5 years**

Conducting a Process Hazard Analysis

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- **Decide upon an appropriate methodology(s)**
- **Define study purpose, scope and objectives**
- **Prepare for study**
- **Conduct study**
- **Document results**
- **Follow up on recommendations**

Selecting a PHA Methodology

- **Hazard and Operability Study (HAZOP)**
- **What-If**
- **Checklist**
- **What-if/checklist**
- **Failure Mode and Effects Analysis (FMEA)**
- **Fault Tree Analysis**
- **An appropriate equivalent methodology**

PHA Re-validation

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- **Options:**
  - **Keep PHA “evergreen”**
  - **Update PHA**
  - **Re-do PHA**
- **Ensure that all changes and previous incidents are included.**

Incident Investigation

Elements of Incident Investigation Definitions

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- **Incident: A process safety event that results in a consequence.**
- **Examples:**
  - **A lost time injury or hospital admission, or greater.**
  - **An officially declared community evacuation or community shelter-in-place.**
  - **A plant evacuation.**
  - **An event resulting in significant financial impact**
- **Near Miss: A Hazard that results in an adverse event that does not result in a consequence, <u>but had the potential to do so</u>.**

Example of a Near Miss

Requirements of Incident Investigation

- **Investigate each incident which resulted in, or could reasonably have resulted in, a catastrophic release of a highly hazardous chemical.**
- **Begin the investigation as promptly as possible, but no later than 48 hours following the incident.**
- **An incident team shall be established, including:**
  - **One person knowledgeable in the process**
  - **Other persons with appropriate knowledge and experience to investigate the incident.**

Requirements of Incident Investigation (Cont.)

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- **Prepare a report:**
  - **Date of incident**
  - **Date investigation began**
  - **A description of the incident**
  - **The factors that contributed to the incident**
  - **Any recommendations resulting from the investigation**
- **Employer shall establish a system to promptly address and resolve the findings.**
- **Report to be reviewed by all affected personnel.**
- **Retain reports for at least 5 years.**

Compliance Audits

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Importance of Audits

- **Audits ensure that the process safety systems are in place and working as intended.**

Requirements

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- **Audits must be conducted at least every three years.**
- **At least one team member must be knowledgeable in the process.**
- **An audit report is required.**
- **Employer to respond to audit findings and document deficiencies.**
- **Must retain the two most recent compliance audit reports.**

Operating Procedures

Caldeira Construction
Nonconformance Report
Version March 10, 2010

...ect Name
...nature / Disposition Date
...ative? Yes ❑ No ❑
...s ❑ No ❑

Caldeira Construction	Quality Standard Operating Procedure 12.2.3 Nonconformance Report		
	Version	Approval Date:	Approved by:
	March 10, 2010	March 10, 2010	Quality Manager

Purpose:
To clearly document a nonconformance found by test or task completion inspection, monitor the disposition status, and to record its disposition.

Scope:
All projects tests and task completion inspections

Definitions:
None:

Responsible Person(s):
Superintendent reports nonconformance on a Nonconformance Report Form
Quality Manager assigns disposition of the nonconformance
Superintendent stores the completed forms

References:
Quality Manual Section 12.2.3 Nonconformance Report
Quality Manual Section 15.4.2 Project Records Control

Procedure:
1. Use the Nonconformance Report Form and Nonconformance Report Control Log contained in this procedure unless the customer contract or Contract Quality Plan specifies the use of a modified or customer supplied form. In that case, the specified form replaces the standard form for that contract.
2. The Responsible Person records nonconformances as required by the Quality Manual on the Nonconformance Report Form and records the nonconformance report on the Nonconformance Report Log.
3. The Responsible Person records disposition of nonconformances as required by the Quality Manual on the Nonconformance Report Form.
4. The Responsible Person records the disposition on the Nonconformance Report Log.
5. When the corrective actions and/or preventive actions have been completed, the Responsible Person records the action on the Nonconformance Report Form, updates the status on the Nonconformance Report Log.
6. The Responsible Person stores the completed form in the construction project office as required by Quality Manual Section 15.4.2 Project Records Control

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Importance of Operating Procedures

- **Documents collective experience**
- **Establishes “best way” to conduct operation**
- **Provides consistency between shifts**
- **Removes guesswork**
- **Supports employee knowledge and experience**

Requirements of Operating Procedures

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- **Steps for each operating phase**
- **Operating Limits**
  - **Consequences of deviation**
  - **Steps required to correct or avoid deviation**
- **Safety and health considerations**
  - **Properties and hazards of the chemicals**
  - **Precautions necessary to prevent exposure**
  - **Control measure to be taken if exposed**
  - **Quality control for raw materials, and control of hazardous chemical inventory levels**
  - **Any special or unique hazards.**

Requirements of Operating Procedures (Cont.)

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- **Safety systems and their functions**
- **Operating procedures must be readily available to employees who work in or maintain a process.**
- **Operating procedures shall be reviewed as often as necessary to ensure they are current. They are to be certified annually that they are current and accurate.**

Summary

- **Make sure your SOPs are:**
  - **Clear and unambiguous**
  - **Direct**
  - **Concise**
  - **Easy to read**
  - **Provide sufficient detail**

Non-Routine Work Authorization

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Non-Routine Work Authorization Permits

- **Non-routine work authorization permit need to reference and coordinate, as applicable:**
  - **Lockout/ Tag-out**
  - **Line breaking**
  - **Confined space entry**
  - **Hot Work**
  - **Elevated work**
  - **Temporary bypassing safety devices**
  - **Others**
- **Work Authorization Permit must have a procedure that describes the steps the personnel involved in job, needs to follow in order to proceed with the work.**
  - **Example: Hot Work Authorization Permit**

Requirements of Hot Work Permits

- **Employer shall issue hot work permit for hot work operations conducted on or near a covered process.**
- **Permit to include:**
  - **Fire prevention and protection requirements have been implemented.**
  - **Date of authorized work.**
  - **Equipment where hot work is to be performed.**
- **Permit kept on file until completion of work.**

Note: a hot work permit is not required in a welding shop.

Mechanical Integrity

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Importance of Mechanical Integrity

- **Prevent catastrophic release of a highly hazardous chemical**
- **Ensure highly reliable safety systems and critical utilities that prevent or mitigate these releases**

Required Elements of Mechanical Integrity

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- **Identification and categorization of equipment and instrumentation**
- **Inspections and tests requirements and frequencies**
- **Established criteria for acceptable tests**
- **Documentation of inspections and tests**
- **Maintenance procedures**
- **Quality Assurance**

ITPM Activities

- **Establish ITPM activities, acceptance criteria and frequencies based on:**
  - **Manufacturer's equipment mean-time failure or recommendations**
  - **Codes and standards**
  - **Good engineering practices (RAGAGEP)**
  - **Operating history**
  - **Operating environment**
  - **Governing laws and regulations**
  - **Potential consequence of equipment failure**

Contractors

Importance of Contractor Management

- **Contractors are frequently used for very specialized jobs – often during turnaround and other busy times.**
- **Contractors are at risk if they are not familiar with the hazards and safety procedures at the plant.**
- **Contractors could inadvertently disable safety systems.**

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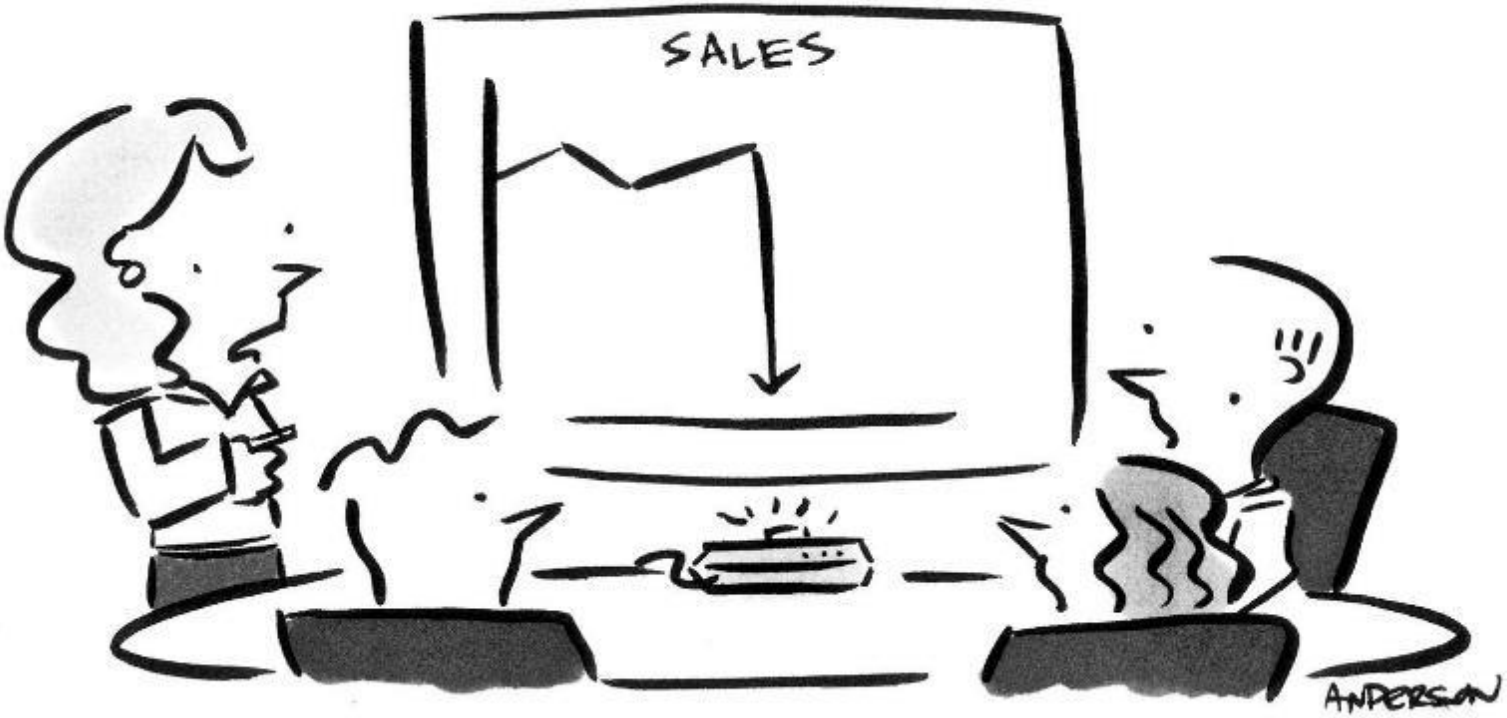
Requirement- Contract Management

- **Facility responsibilities:**
  - **Obtain and evaluate the contractor's safety performance and program.**
  - **Inform contractor of known potential fire, explosion or toxic release hazards related to their work and work area.**
  - **Explain the applicable sections of the emergency action plan.**
  - **Control the entrance, presence and exit of contractors.**
  - **Periodically evaluate the performance of contractors.**
  - **Maintain a contractor illness and injury log.**

Requirement- Contract Management (Cont.)

- **Contract Employer responsibilities:**
  - **Ensure that each contract employee is trained in the work practices for his job.**
  - **Ensure that each contract employee is aware of the known fire, explosion and toxic hazards related to their job.**
  - **Document that each contract employee has received and understood the training.**
  - **Supervise the contract employees, ensuring that they are following the safety rules.**
  - **Inform the facility of any unique hazards presented by the contractor’s work.**

Training



"This is what we in the training department call a teachable moment."

Importance of Training

- **Training maintains a high level of performance.**
- **Insufficient training is a common root cause for many process safety incidents/near misses.**

Requirements

- **Initial Training : Overview training for all employees in the process, specific safety and health hazards, emergency operations and safe work practices associated to their job.**
- **Refresher Training: At least every three years.**
  - **Employer to consult with employees in establishing refresher training schedule.**
- **Documentation : Provide documentation that each employee involved in a process has received and understood the training required.**

Management of Change

What is Management of Change

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- **Change can inadvertently add new hazards or increase the risks from existing hazards.**
- **Process to help ensure that a change to a process does not result in an unacceptable risk is Management of Change.**

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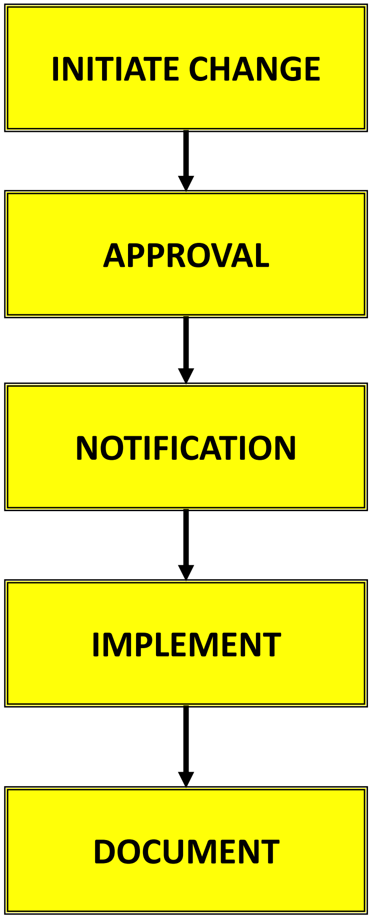
MOC Process



Requirements of MOC

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- **Develop written procedure for managing changes.**
- **Procedures to consider:**
  - **Technical basis for the change**
  - **Impact of the change on safety and health**
  - **Modifications to the operating procedures**
  - **Necessary time period for the change**
  - **Authorization requirements**
- **Employees affected by the change must be informed of and, if necessary, trained in the change.**
- **Process safety information and operating procedures must be updated, if changed.**

Implementation of MOC

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- **MOC is required for all changes except for “replacement in kind.”**

  Example:

  - **Mechanical modification, addition or deletion of piping, instruments, gaskets or other equipment.**
  - **Change in material of construction.**
  - **Bypassing of interlocks or other safety instrumentation, except where done as part of an approved operating or maintenance procedure.**
  - **Changes to allowable operating conditions or ranges: operating temperatures, pressures, etc. (i.e., safe operating window).**

Implementation of MOC

- **Modification of plant operating procedures, e.g. batch sheets, standard operating procedures (SOP's), etc.**
- **Modifications to control documents that impact plant operations.**
- **Change of raw material or product packaging (i.e. drums, totes, etc.)**

Actions under MOC

- **Conduct Pre-Startup Safety Review (PSSR) for change.**
- **If the change requires a change to the operating procedures, then the procedures must be updated before the change is implemented.**
- **Process Safety Information (PID's, control set-points, etc.) can be updated post change, but need to be done in a timely manner.**

Pre-Startup Safety Review

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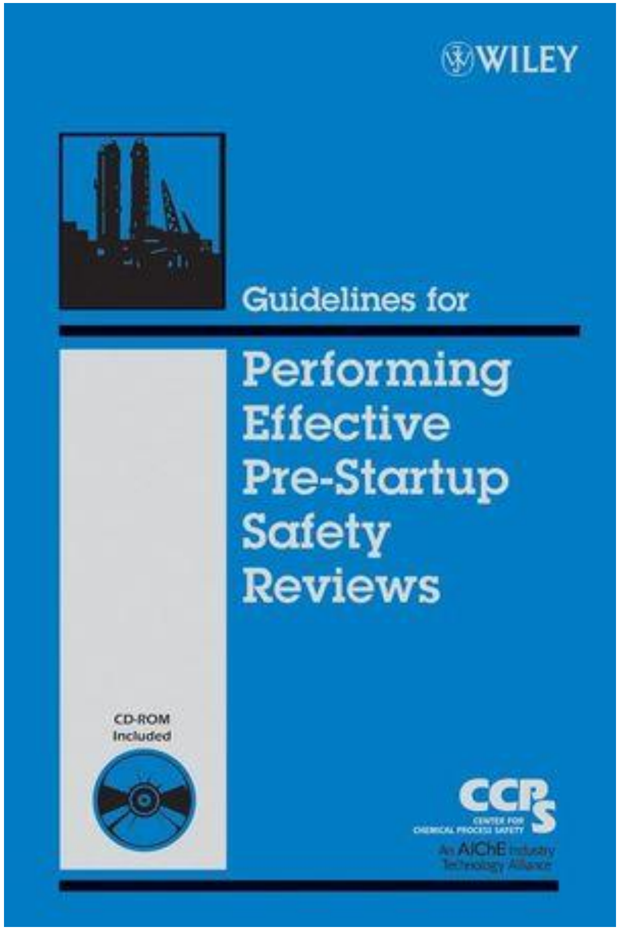

Importance of PSSR

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- **PSSR checks to make sure that the plant is ready for startup.**
- **Startup can be hazardous**
  - **Rarely performed, therefore, lack of operator experience**
  - **Non-standard operating conditions**
    - **Valves in wrong setting**
    - **Blinds not removed**
    - **Tanks empty**
    - **New or modified equipment**
  - **Increased number of manual operations**
  - **Time pressures**
  - **Overworked operators**

Requirements of PSSR

- **Perform a PSSR for new facilities and for modified facilities when the modification is enough to require a change in the process safety information.**
- **PSSR to confirm:**
  - **Construction and equipment is in accordance with design specifications**
  - **Safety, operating, maintenance and emergency procedures are in place and are adequate**
  - **For new facilities, a PHA has been performed and recommendations resolved prior to startup.**
  - **Modified facilities have undergone MOC**
  - **Training has been completed.**

Emergency Procedures

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Importance of Emergency Procedures

- **Emergency preparedness is the third layer of protection, following prevention and control of accidental releases.**
- **By preplanning emergencies, the facility can quickly jump into action to protect employees and surrounding neighbors.**

Requirements of an Emergency Plan

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- **Emergency plan to be activated by an alarm system;**
- **Include procedures for post-evacuation employee accounting;**
- **Establish duties and procedures for employees that remain behind to operate critical equipment and to provide rescue and medical support;**
- **Provide name of persons to contact for plan information;**
- **Review plan with employees;**
- **Ensure support for physically impaired employees.**

Elements of an Emergency Plan

- **An emergency preparedness plan should include the following:**
  - **Determine what scenarios constitute an emergency release**
  - **Determine what actions should be taken to respond to various release scenarios**
  - **Establish an evacuation plan for non-responders**
  - **Establish communications with outside community agencies**

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Trade Secrets

Requirements of Trade Secrets

- **Employers shall make all information necessary to comply with the section available to those persons responsible for:**
  - **Compiling process safety information**
  - **Developing operating procedures**
  - **Involved in incident investigations**
  - **Involved in emergency planning and response**
  - **Involved in compliance audits.**
- **Employees and their designated representative shall have access to trade secret information contained with PHA's and other PSM documents.**
- **Information can be protected under confidentiality agreements.**

Beyond Compliance

Process Safety Fatalities Trends
(Chemical Manufacturing Industry)

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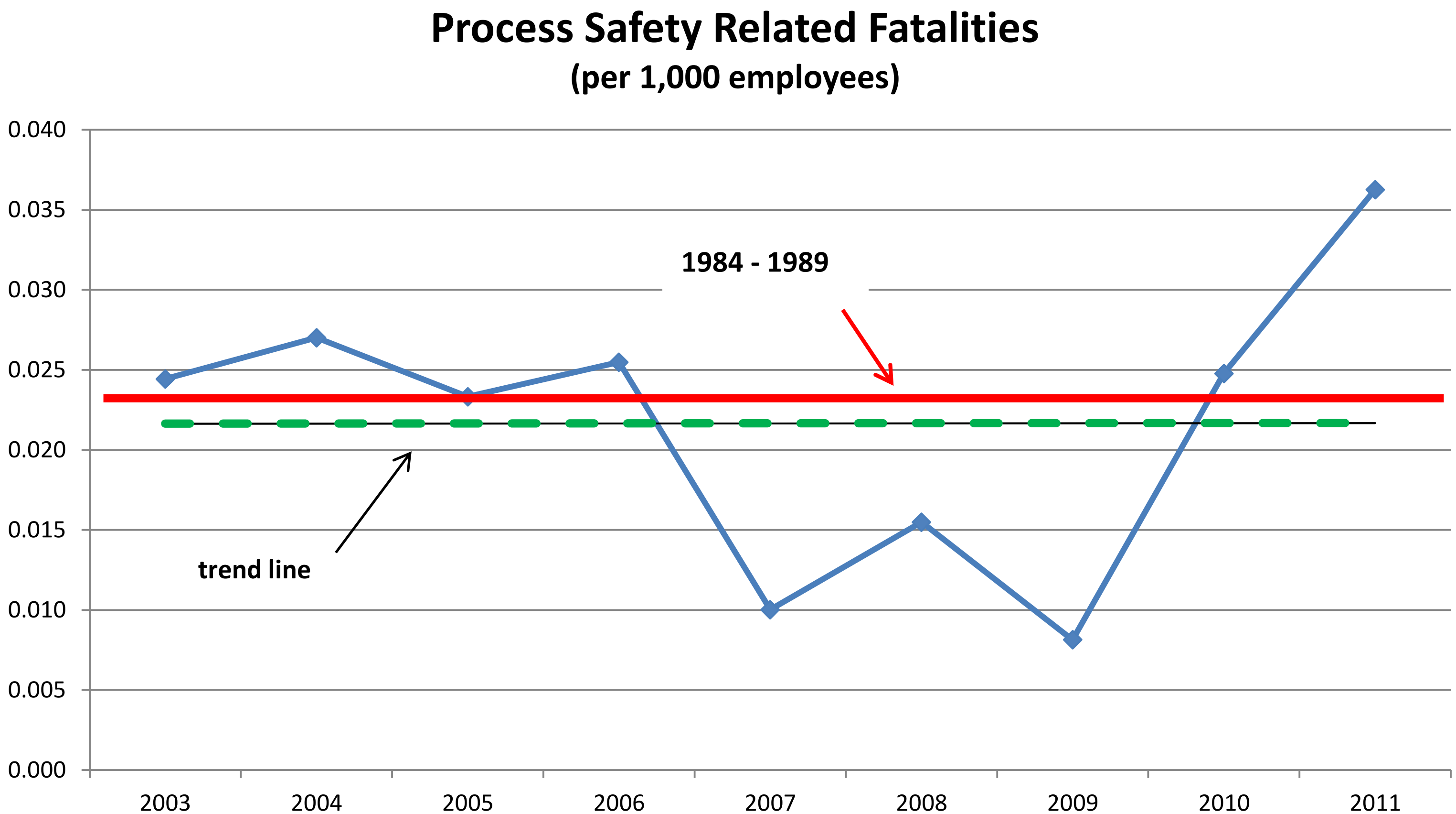

United States BLS data

Beyond Compliance- Commitment to Safety

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- **Manage All Process Hazards**
- **Process Safety Culture**
- **Process Safety Metrics**
- **Inherent Safety**

Process Safety Metrices

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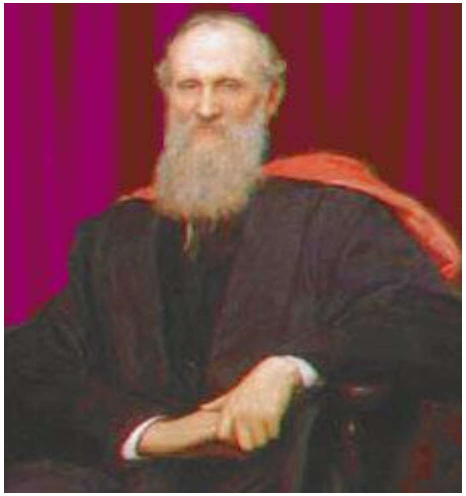
“When you can measure what you are speaking about and express it in numbers, you know something about it." - Lord Kelvin



“Measure what is measurable, and make measurable what is not.” - *Galileo*

Finally

- **This is only the start, not the end, of the journey!**
- **Good luck!**

Thank you

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TYPICAL IGNITION SOURCE ANALYSIS IN PHARMACEUTICAL PLANTS

Presented by

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Bio

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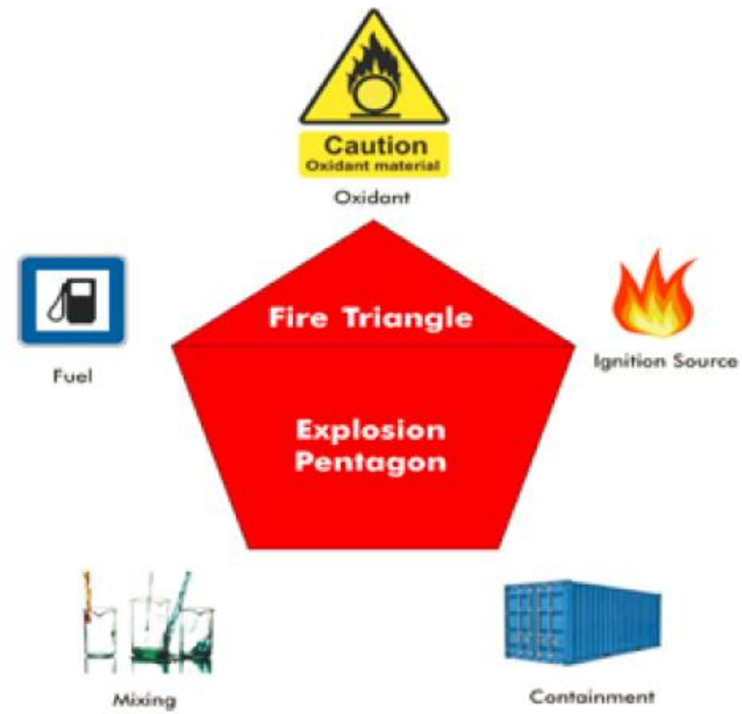
Agenda

1. How flammable atmosphere can be ignited
2. To understand the possible ignition sources
3. To understand the methodology for their assessment and control

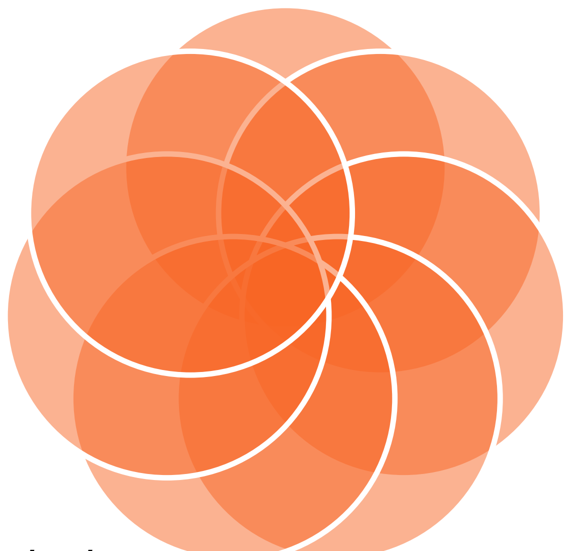
CONDITIONS FOR AN EXPLOSION

The Fire Triangle:
There are three things needed for combustion;
1 - Fuel
2 - Oxidant, typically the oxygen in air
3 - Sufficiently energetic Ignition Source.

The Explosion Pentagon:
4 - Containment
5 - Mixing or Dispersion (Suspension for dust explosions)



IGNITION SOURCES – EN 1127-1



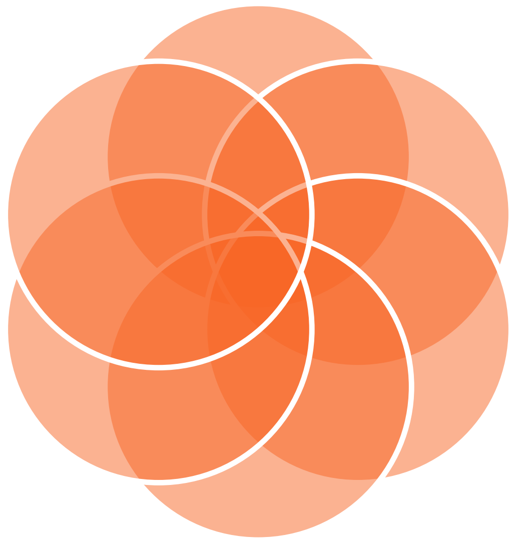
1. *Hot surfaces – including frictional heating*
2. *Flames and hot gases (including hot particles)*
3. *Mechanically generated sparks*
4. *Electrical apparatus*
5. *Stray electrical currents, cathodic corrosion protection*
6. *Electrostatic discharges*
7. *Lightning*

IGNITION SOURCES

8. Radio frequency electromagnetic radiation, 10^4 Hz to 3×10^{12} Hz

13. Self-heating (including self-ignition of dusts) and other exothermic reactions

9. Visible electromagnetic radiation, 3×10^{11} Hz to 3×10^{15} Hz



12. Adiabatic compression and shock waves

10. Ionising electromagnetic radiation

11. Ultrasonic

RELATION BETWEEN IGNITION SOURCE

Possible Ignition source
(any Ignition source listed in EN 1127-1)

Equipment related Ignition source
(any possible ignition source, which is caused by the equipment under consideration regardless of its ignition capability)

Potential Ignition source
(equipment related ignition source which has the capability to ignite an explosive atmosphere (i.e. to become effective))

Effective Ignition Source
(Potential ignition source which is able to ignite an explosion atmosphere when consideration is taken of when it occurs (i.e. in normal operation, expected malfunction or rare malfunction) which determines the intended category)

Equipment has these ignition sources → Potential Ignition source

Preventive or protective measures are needed → Effective Ignition Source

HOT SURFACES

- Surfaces that exceed the minimum auto-ignition temperature of the material that is being handled have the potential to ignite flammable atmosphere.

- *A dust layer or a combustible solid in contact with a hot surface and ignited by the hot surface can also act as an ignition source for an explosive atmosphere.*

Examples:

- General: vessel and pipelines;

- Machinery: engines; turbines; exhausts.

- Laboratory equipment: hot plate; oven.

HOT SURFACES

- *Classification of Maximum surface temperature for equipment*

Temperature class	Max. Surface Temp. ^{0}C
T1	450
T2	300
T3	200
T4	135
T5	100
T6	85

FLAMES AND HOT GASES (INCLUDING HOT PARTICLES)

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- Flames are associated with combustion reactions at temperatures of more than 1000 °C.
- Hot gases are produced as reaction products and, in the case of dusty and/or sooty flames, glowing solid particles are also produced.
- Flames, their hot reaction products or otherwise highly heated gases can ignite an explosive atmosphere. Flames, even very small ones, are among the most effective sources of ignition

FLAMES AND HOT GASES (INCLUDING HOT PARTICLES)

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Example:

- Fluid bed dryer
- Fired heater.
- Boiler.
- Laboratory heater: Bunsen burner; furnace.
- Burning operations: burning rubbish; burning during demolition.
- Accidental fire.
- Hot material: hot particles.

MECHANICALLY GENERATED SPARKS

- As a result of friction, impact or abrasion processes such as grinding, particles can become separated from solid materials and become hot owing to the energy used in the separation process.
- If these particles consist of oxidizable substances, for example iron or steel, they can undergo an oxidation process, thus reaching even higher temperatures.
- These particles (sparks) can ignite combustible gases and vapours and dust/air-mixtures.

MECHANICALLY GENERATED SPARKS

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Example:

- Impact: hand tool, power tool, boot stud, loosening of caked material.
- Rubbing: belt, conveyor, roller, skidding of road tanker.

ELECTRICAL APPARATUS

- In the case of electrical apparatus, electric sparks and hot surfaces can occur as sources of ignition. Electric sparks can be generated

Example:

a) when electric circuits are opened and closed;

b) by loose connections;

c) by stray currents

STRAY ELECTRICAL CURRENTS, CATHODIC CORROSION PROTECTION

- Stray current refers to the electricity flow via buildings, ground or equipment due to electrical supply system imbalances or wiring flaws. It refers to an existence of electrical potential that can be found between objects that should not be subjected to voltage
- It can be fatal when it is present in dangerously high levels. Apart from electrocution, stray current is also capable of causing damage by causing metals within the ground to corrode.

STRAY ELECTRICAL CURRENTS, CATHODIC CORROSION PROTECTION

- Stray currents can flow in electrically conductive systems or parts of systems as:

a) return currents in power generating systems - especially in the vicinity of large welding systems;

b) a result of a short-circuit or of a short-circuit to earth owing to faults in the electrical installations;

c) a result of magnetic induction (e.g. near electrical installations with high currents or radio frequencies; and

d) a result of lightning

STATIC ELECTRICITY

- Incendive discharges of static electricity can occur under certain conditions.
- The discharge of charged, insulated conductive parts can easily lead to incendive sparks.
- With charged parts made of non-conductive materials, and these include most plastics as well as some other materials

STATIC ELECTRICITY

- Non-Polar materials like hydrocarbons accumulate static charges readily as they have high insulating values:

22 mJ of ignition energy from walking across a rug, many hydrocarbons require only 0.25 mJ

- Splashing of liquid
- Stirring and Mixing
- Solid handling-Sieving, pouring, grinding, pneumatic conveying

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LIGHTNING

- If lightning strikes in an explosive atmosphere, ignition will always occur.
- Large currents flow from where the lightning strikes and these currents can produce sparks in the vicinity of the point of impact.
- Even in the absence of lightning strikes, thunderstorms can cause high induced voltages in equipment, protective systems and components

RF ELECTROMAGNETIC WAVES FROM 10^4 Hz TO 3 X 10^{12} Hz

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- Electromagnetic waves are emitted by all systems that generate and use radio-frequency electrical energy (radio-frequency systems), e.g. industrial RF generators for heating, drying, welding, cutting.
- All conductive parts located in the radiation field function as receiving aerials. If the field is powerful enough and if the receiving aerial is sufficiently large, these conductive parts can cause ignition in explosive atmospheres

ELECTROMAGNETIC WAVES FROM 3×10^{11} Hz TO 3×10^{15} Hz

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- Radiation in this spectral range can (especially when focused) become a source of ignition through absorption by explosive atmospheres or solid surfaces.

- Sunlight, for example, can trigger an ignition if objects cause convergence of the radiation (e.g. bottles acting as lenses, concentrating reflectors).

- Under certain conditions, the radiation of intense light sources is so intensively absorbed by dust particles that these particles become sources of ignition for explosive atmospheres.

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IONIZING RADIATION

- X-ray tubes and radioactive substances can ignite explosive atmospheres (especially explosive atmospheres with dust particles) as a result of energy absorption.
- Moreover, the radioactive source itself can heat up owing to internal absorption of radiation energy to such an extent that the minimum ignition temperature of the surrounding explosive atmosphere is exceeded

ULTRASONICS

- In the use of ultrasonic sound waves, a large proportion of the energy emitted by the electro-acoustic transducer is absorbed by solid or liquid substances.
- As a result, the substance exposed to ultrasonics warms up so that, in extreme cases, ignition may be induced.

ADIABATIC COMPRESSION AND SHOCK WAVES

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- In the case of adiabatic or nearly adiabatic compression and in shock waves, such high temperatures can occur that explosive atmospheres (and deposited dust) can be ignited.

- The temperature increase depends mainly on the pressure ratio, not on the pressure difference.

E.g. During the sudden relief of high-pressure gases into pipelines. The shock waves are propagated into regions of lower pressure faster than the speed of sound. When they are diffracted or reflected by pipe bends, constrictions, connection flanges, closed valves etc., very high temperatures can occur.

EXOTHERMIC REACTIONS, INCLUDING SELF-IGNITION OF DUSTS

- Exothermic reactions can act as an ignition source when the rate of heat generation exceeds the rate of heat loss to the surroundings.
- Many chemical reactions are exothermic. Whether a reaction can reach a high temperature is dependent, among other parameters, on the volume/surface ratio of the reacting system, the ambient temperature and the residence time.

IGNITION HAZARD ASSESSMENT AND CONTROL

STEPS INVOLVED IN IGNITION HAZARD ASSESSMENT AND CONTROL

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- Identification of ignition hazards (analysis of ignition hazard and their causes).
- Preliminary ignition hazard estimation and evaluation.
- Determination of measures.
- Determination of the equipment category

IDENTIFICATION OF IGNITION HAZARDS

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The step will result in a complete list of all ignition hazards applicable.

Example Format:

No.	Ignition hazard analysis (Step 1)		Assessment of the frequency of occurrence without application of an additional measure (Step 2)			
	Potential Ignition Source	**Description of the basic cause**	During normal operatio n	During foreseeable malfunction	During rare malfunction	Not relevant
1.	**Electrostat ic discharge**	**Parts of non-metallic material with a surface resistance exceeding 1Gohms**		x		

PRELIMINARY IGNITION HAZARD ESTIMATION AND EVALUATION

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- In this step the individual ignition hazards are evaluated to determine, how often an individual ignition source may become effective.

Example Format:

No.	Ignition hazard analysis (Step 1)		**Assessment of the frequency of occurrence without application of an additional measure (Step 2)**			
	Potential Ignition Source	Description of the basic cause	**During normal operatio n**	**During foreseeable malfunction**	**During rare malfunctio n**	**Not relevan t**
1.	Electrostati c discharge	Parts of non-metallic material with a surface resistance exceeding 1Gohms		**x**		

DETERMINATION OF MEASURES AND EQUIPMENT CATEGORIZATION

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- Format for determination of preventive or protective measures (step 3) and Categorization (Step 4)

Measures applied to prevent the ignition source becoming effective (Step 3)			**Frequency of occurrence incl. all measures (Step 4)**					
Description of the measure	Basis (citation of standards	Technical documentation	during normal operation	During foreseeable malfunction	During rare malfunction	Not relevant	Equipment categorization	

EXAMPLE OF AN IGNITION HAZARD ASSESSMENT

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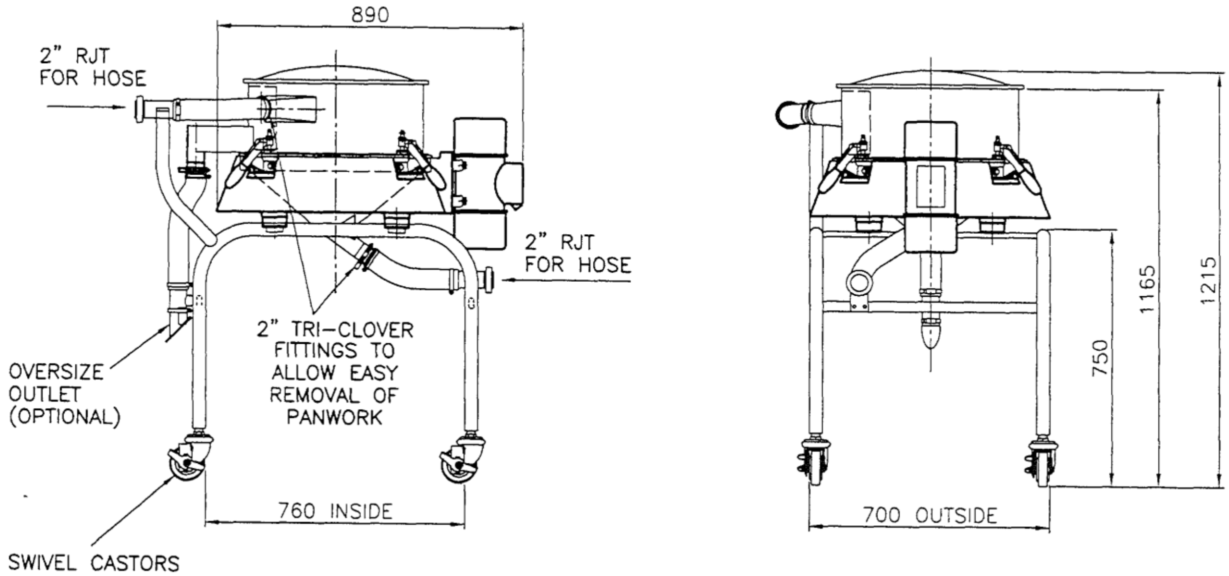
Fig: Vibratory Sifter:



EXAMPLE OF AN IGNITION HAZARD ASSESSMENT

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Potential Ignition source	Normal Operation	Expected malfunction	Rare malfunction	Measures applied	Categorization
Hot surfaces	Vibratory surface temperature				
Mechanical sparks				There are no moving components within the sieve	
Electrostatic discharge		Spark discharge from isolated sieve screen		Earthing of component	
		Spark discharge from isolated metal reinforcement spiral in flexible hose			
		Spark discharge from isolated metal clamping ring			

CONTROL OF IGNITION HAZARDS

HOT SURFACES:

The temperatures of all equipment, protective systems and components surfaces which can come into contact with explosive atmospheres

Category 1:

- shall not – even in the case of rare malfunctions – exceed 80 % of the minimum ignition temperature of the combustible gas or liquid in °C.

Category 2:

- shall not exceed the minimum ignition temperature of the combustible gas or liquid in °C during normal operation and in the case of malfunctions. However, where it cannot be excluded that the gas or vapour can be heated to the temperature of the surface, this surface temperature shall not exceed 80 % of the minimum ignition temperature of the gas measured in °C.

Category 3:

- shall in normal operation, not exceed the minimum ignition temperature of the gas or liquid

CONTROL OF IGNITION HAZARDS

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FLAMES AND HOT GASES:

All categories: Naked flames are not permitted except as described below

Category 1:

- In addition to the elimination of naked flames, gases from flame or other heated gases are not permissible unless special preventive measures are taken, e.g. restricting the temperature or eliminating incendive particles.

Category 2 and 3:

- Devices with flames are only permissible if the flames are safely enclosed and the temperatures specified in Hot surfaces are not exceeded on the outer surfaces of the installation parts. Furthermore, for equipment, protective systems and components with enclosed flames (e.g. special heating systems), assurance shall be given that the enclosure is adequately resistant to the effect of the flames and that flame propagation into the hazardous area cannot occur.

CONTROL OF IGNITION HAZARDS

MECHANICALLY GENERATED SPARKS:

All Categories:

- Equipment intended for use in explosive gas/air, vapour/air and mist/air atmospheres which can produce mechanically generated sparks shall be excluded if the possible explosive atmosphere can contain one or more of the gases acetylene, carbon disulphide, hydrogen, hydrogen sulphide, ethylene

CONTROL OF IGNITION HAZARDS

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ELECTRICAL APPARATUS:

All Categories:

- Electrical apparatus shall be designed, constructed, installed and maintained in accordance with the relevant European Standards

CONTROL OF IGNITION HAZARDS

STRAY ELECTRIC CURRENTS AND CATHODIC CORROSION PROTECTION:

Category 1 and category 2

- *For use in explosive dust/air mixtures:* Compensation of the potential shall be carried out for all conductive parts of the installation.
- If conductive parts of the system are incorporated in zones 0, 20 and 21, e.g. ventilation and suction pipes in tanks, first they shall be included in a potential compensation system.

Category 3:

- It is generally acceptable to dispense with the requirements for categories 1 and 2, i.e. the compensation of the potential, unless arcs or sparks due to stray currents occur frequently.

CONTROL OF IGNITION HAZARDS

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STATIC ELECTRICITY:

All categories:

- The most important protective measure is bonding all the conductive parts that could become hazardously charged and earth them.
- This protective measure, however, is not sufficient when non-conductive materials are present. In this case hazardous levels of charging of the non conductive parts and materials, including solids, liquids and dusts shall be avoided

CONTROL OF IGNITION HAZARDS

LIGHTNING:

All categories:

- Installations shall be protected by the appropriate lightning protection measures.
- The effects of lightning occurring outside zones 0 and 20 from damaging zones 0 and 20 shall be prevented, e.g. overvoltage protection systems could be installed at appropriate areas.
- For earth-covered tank installations or electrically conductive system components which are electrically insulated from the tank, bonding shall be carried out and an earth ring electrode system provided

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RADIO FREQUENCY (RF) ELECTROMAGNETIC WAVES FROM 10^4 Hz TO 3 X 10^{12} Hz:

All categories:

- As a general safety measure against the ignition effect of electromagnetic waves, a safety distance shall be maintained in all directions between the nearest radiating parts and the receiving aerial in the area which could contain explosive atmosphere.

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ELECTROMAGNETIC WAVES FROM 3 X 10^{11} Hz TO 3 X 10^{15} Hz:

All categories:

- Devices which can cause ignition by resonance absorption (see 5.3.10) shall not be permitted.

CONTROL OF IGNITION HAZARDS

IONIZING RADIATION:

All categories:

- The directions in Electrical apparatus shall be followed for the electrical systems needed for operation of the sources of radiation..

CONTROL OF IGNITION HAZARDS

ULTRASONICS:

All categories:

- Ultrasonic waves with a frequency of more than 10 MHz shall not be permitted, unless the absence of an ignition risk is proved for the case in point by demonstrating that there is no absorption due to molecular resonance.

For ultrasonic waves with a frequency up to 10 MHz the following is required:

- Ultrasonic waves shall permit only if the safety of the work procedure is ensured. The power density of the generated acoustic field shall not exceed 1 mW/mm2, unless it is proved for the case in point that ignition is not possible

CONTROL OF IGNITION HAZARDS

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ADIABATIC COMPRESSION AND SHOCK WAVES:

Category 1:

- Processes that can cause compressions or shock waves which could produce ignition shall be avoided. This shall be ensured even in the case of rare malfunctions. As a rule, hazardous compressions and shock waves can be eliminated if, for example, the slides and valves between sections of the system where high pressure ratios are present can only be opened slowly.

Category 2:

- Processes which can cause adiabatic compressions or shock waves can be tolerated only in the case of rare malfunctions.

Category 3:

- Only those shock waves or compressions occurring during

CONTROL OF IGNITION HAZARDS

EXOTHERMIC REACTIONS, INCLUDING SELF-IGNITION OF DUSTS:

All categories:

- Substances with a tendency to self-ignition shall be avoided whenever possible.

When such substances have to be handled, the necessary protective measures shall be adapted in each individual case. The following protective measures can be suitable:

a. inerting;
b. stabilization;
c. improvement of heat dissipation, e.g. by dividing the substances into smaller portions;
d. limiting temperature and pressure;
e. storage at lowered temperatures
f. limiting residence times

Thank You

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PHARMACEUTICAL SUPPLY CHAIN INITIATIVE

Fire & Explosion Hazards in Pharmaceutical Industry

Presented by

Sunil R. Deshmukh

Senior Consulting Engineer

CTPL- Dekra Insight

Bio

- Sunil Deshmukh is working as Sr. Consulting Engineer at Chilworth, Mumbai Office.
- Having 5 years of Process Safety, Risk Management consulting experience. His work experience includes executing and managing Safety and Risk consulting assignments at 100+ sites Globally.
- In his career, He has conducted safety studies like HAZOP, QRA, Dust explosion Hazard (DEH) Assessment, Electrostatic Hazard Assessment (EHA), Safety audits, Hazardous Area Classification (HAC), Fire and life safety Audits, Incident Investigation etc. for Metal, Petrochemical and Pharmaceutical Industries.

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Agenda

1 Understanding Flammable Atmospheres & Explosion Hazards

2 Conditions For A Vapour Explosion

3 Conditions For A Dust Cloud Explosion

4 Different Electrostatic Discharges

5 Explosion Prevention Techniques

6 Explosion Protection Techniques

7 Questions and Wrap up

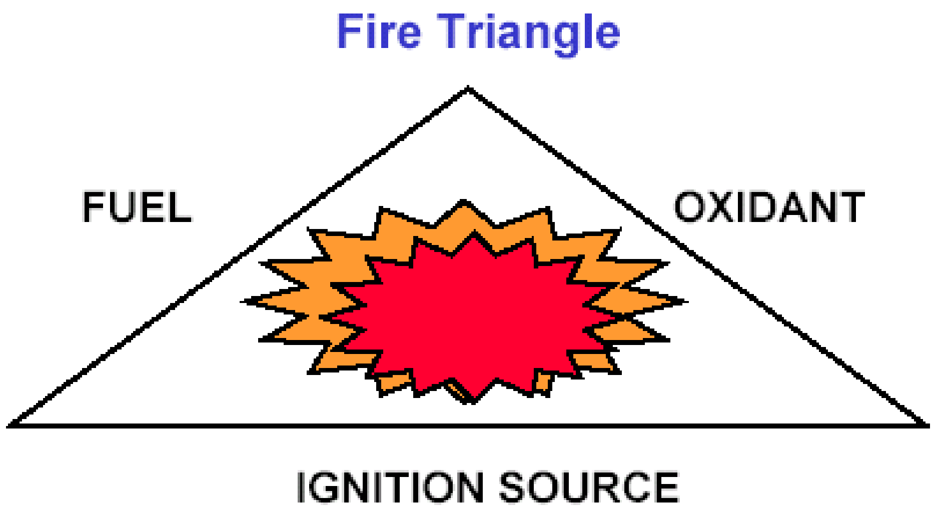
UNDERSTANDING FLAMMABLE ATMOSPHERES & EXPLOSION HAZARDS

Definition of an Explosion

- A loud bang?
- A burst followed by a report?
- A rapid increase of pressure in a confined space, generally caused by the occurrence of exothermic chemical reactions in which gases are produced in relatively large amounts

- **A sudden release of stored energy, resulting in the generation of pressure effects, blast waves and missiles**

Definition of an Explosion

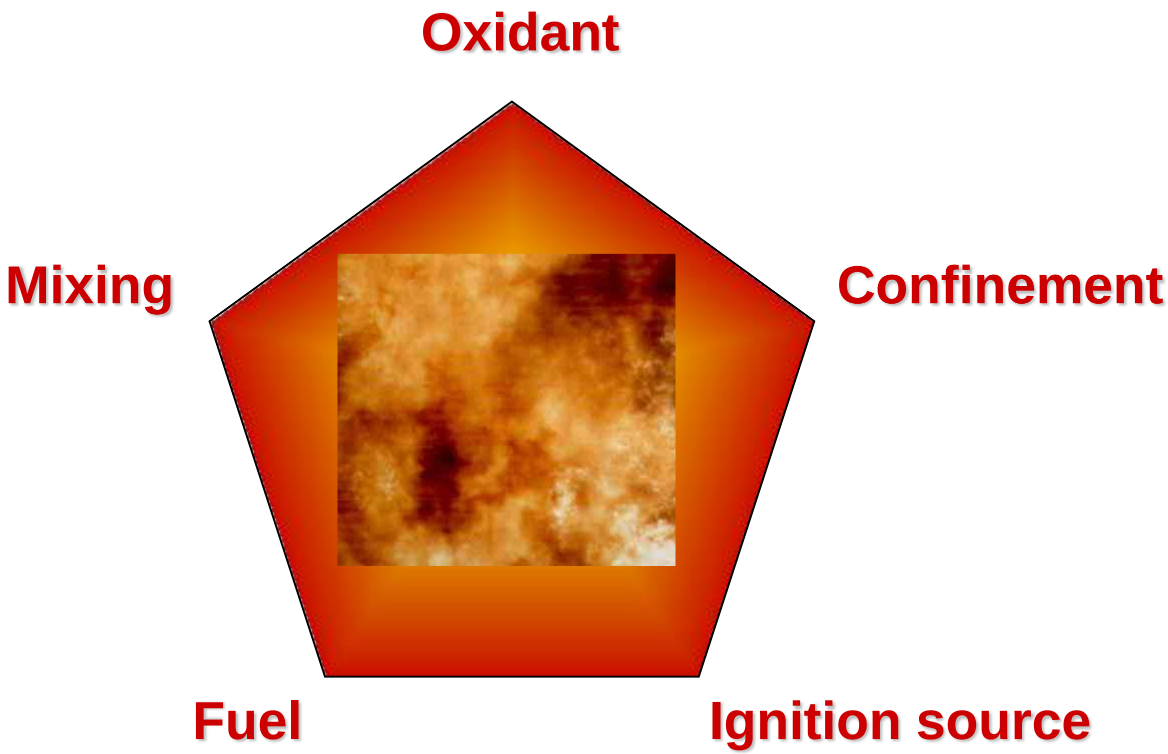


FUEL – Liquid (vapour or mist), gas, or solid capable of being oxidized.

OXIDANT – A substance which supports combustion – Usually oxygen in air

IGNITION SOURCE – An energy source capable of initiating a combustion reaction.

Conditions For Explosion



Fire Or Explosion ?

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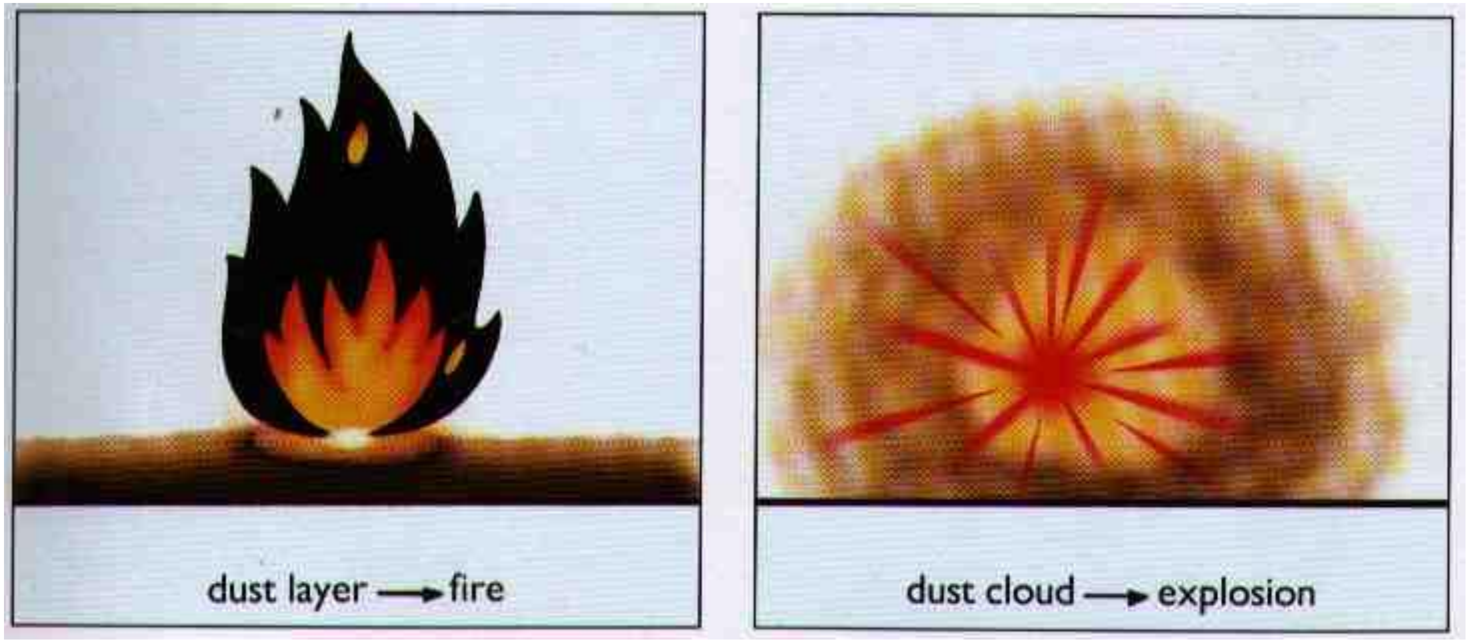

– In an explosion fuel and oxidant are mixed

What Is An Explosion?

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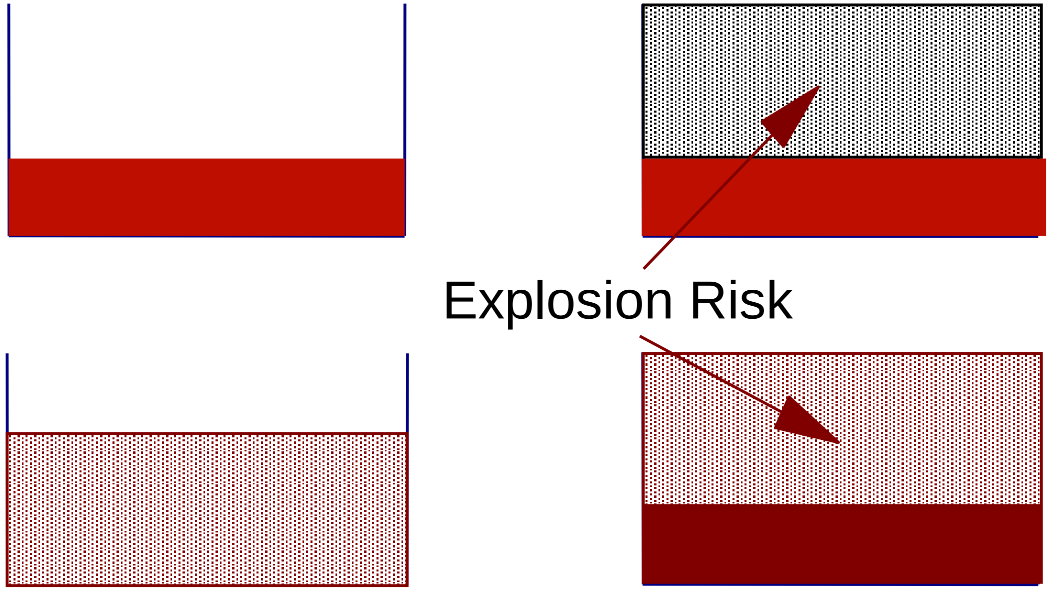
- **Explosion - Confinement Required**

- **Flash Fire - Unconfined**



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CONDITIONS FOR A VAPOUR EXPLOSION

Conditions for a Vapour Explosion

- Liquid must be above its Flash Point temperature
- Concentration must be within flammable range
- Atmosphere must support combustion
- Ignition source must be of sufficient energy

Flash Point Temperature (FP)

Minimum temperature at which the liquid gives off sufficient vapour to form an ignitable mixture with air near the surface of the liquid

- Flash Point temperature can be determined in open or closed test vessels depending on what the data is to be used for (I.e. an open spillage or a sealed reactor vessel)
- Open cup flash point is generally higher than the closed cup flash point

The minimum temperature at which combustion can be <u>sustained</u> is referred to as Fire Point (higher than Flash Point)

Limits of Flammability

Lower Flammable Limit (LFL)
Minimum concentration of vapour or gas in air (or oxygen) below which propagation of flame does not occur on contact with an ignition source

Upper Flammable Limit (UFL)
Maximum concentration of vapour or gas in air (or oxygen) above which propagation of flame does not occur on contact with an ignition source

Normally expressed as % v/v in air at atmospheric pressure

Typical Flammability Limits

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Ref: Fire Protection Guide to Hazardous Materials, NFPA, 11th Edition

LIQUIDS	LFL (%V/V)	UFL (%V/V)
Acetone	2.5	12.8
1-Butanol	1.4	11.2
Toluene	1.1	7.1
Carbon-disulfide	1.3	50
Methyl Alcohol	6	36
GASES		
Hydrogen	4	75
Butane	1.9	8.5
Methane	5	15
Ethylene	2.7	36

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Atmosphere Must Support Combustion

To produce combustion, sufficient amount of oxidant must be available.

Typical oxidants include fluorine, oxygen, chlorine, bromine

- Explosion prevention can be accomplished by depletion of oxidant
- In general, combustible organic compounds are unlikely to propagate flame if oxygen content is below 8 % v/v using nitrogen or carbon dioxide as inert gas
- The concentration of oxidant below which a deflagration cannot occur in a specified mixture is referred to as the **Limiting Oxidant Concentration (LOC)**

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CONDITIONS FOR A DUST CLOUD EXPLOSION

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Conditions for a Dust Explosion

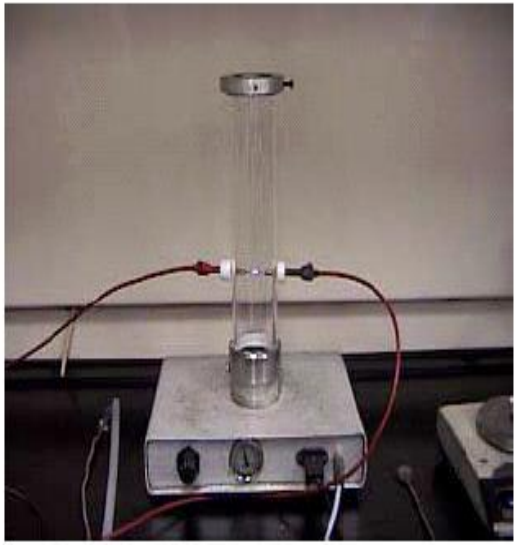
- Dust must be explosible (flammable, combustible)
- Dust must be airborne
- Concentration must be within explosible range
- Particle size distribution capable of propagating flame
- The atmosphere must support combustion
- An ignition source must be present

Is Dust Cloud Explosible?

Use a Hartmann Bomb, 20L sphere or 1m3 sphere test vessel to determine whether the dust cloud is explosible at the dust handling/ processing conditions

Dusts which ignite and propagate away from the source of ignition are considered "explosible" (Group A)

Dusts which do not propagate flame away from the ignition source are considered "non-explosible" (Group B)



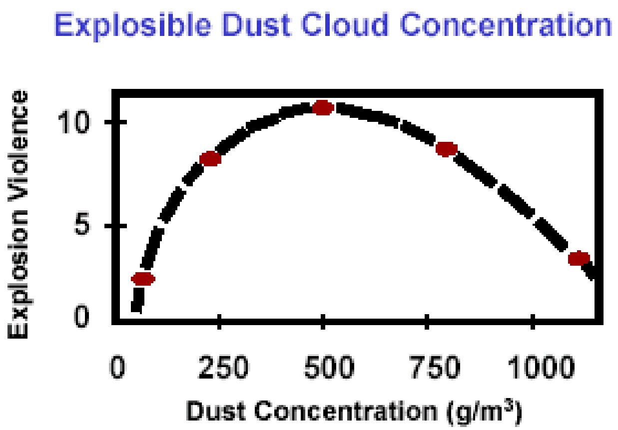
Modified Hartmann Apparatus

Group B powders are known to present a fire hazard and may be explosible at elevated temperatures (e.g. in dryers)

Is Dust Cloud Concentration within the Explosible Range?

When the concentration of dispersed dust is below a certain value, (Minimum Explosible Concentration), an explosion cannot be propagated. The explosion violence of the cloud increases as the dust concentration increases until an optimum concentration is reaching giving the highest explosion violence.

At higher concentrations the explosion violence decreases or stays roughly constant. The Maximum Explosible concentration – the concentration above which an explosion cannot be propagated - is not always clearly defined.



Ref. (Geoff Lunn)

Range of Explosible Dust Cloud Concentration

Range of explosible dust concentration in air at normal temperature and atmospheric pressure for a typical natural organic dust (maize starch), compared with typical range of maximum permissible dust concentrations in the context of industrial hygiene, and a typical density of natural organic dusts

(Ref. R. K. Eckhoff, 1997)

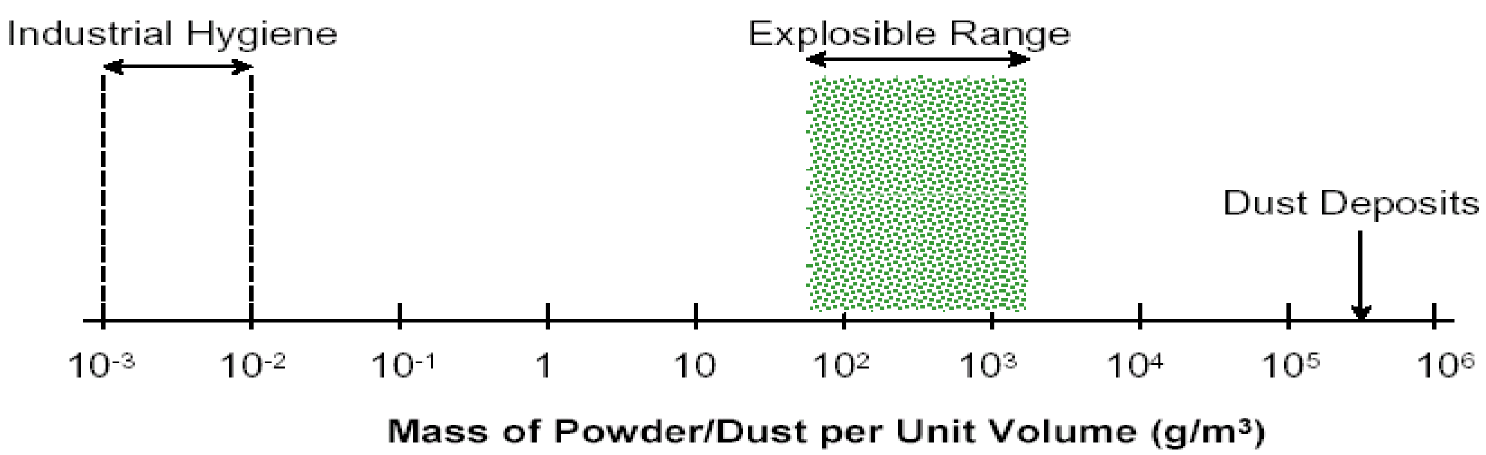
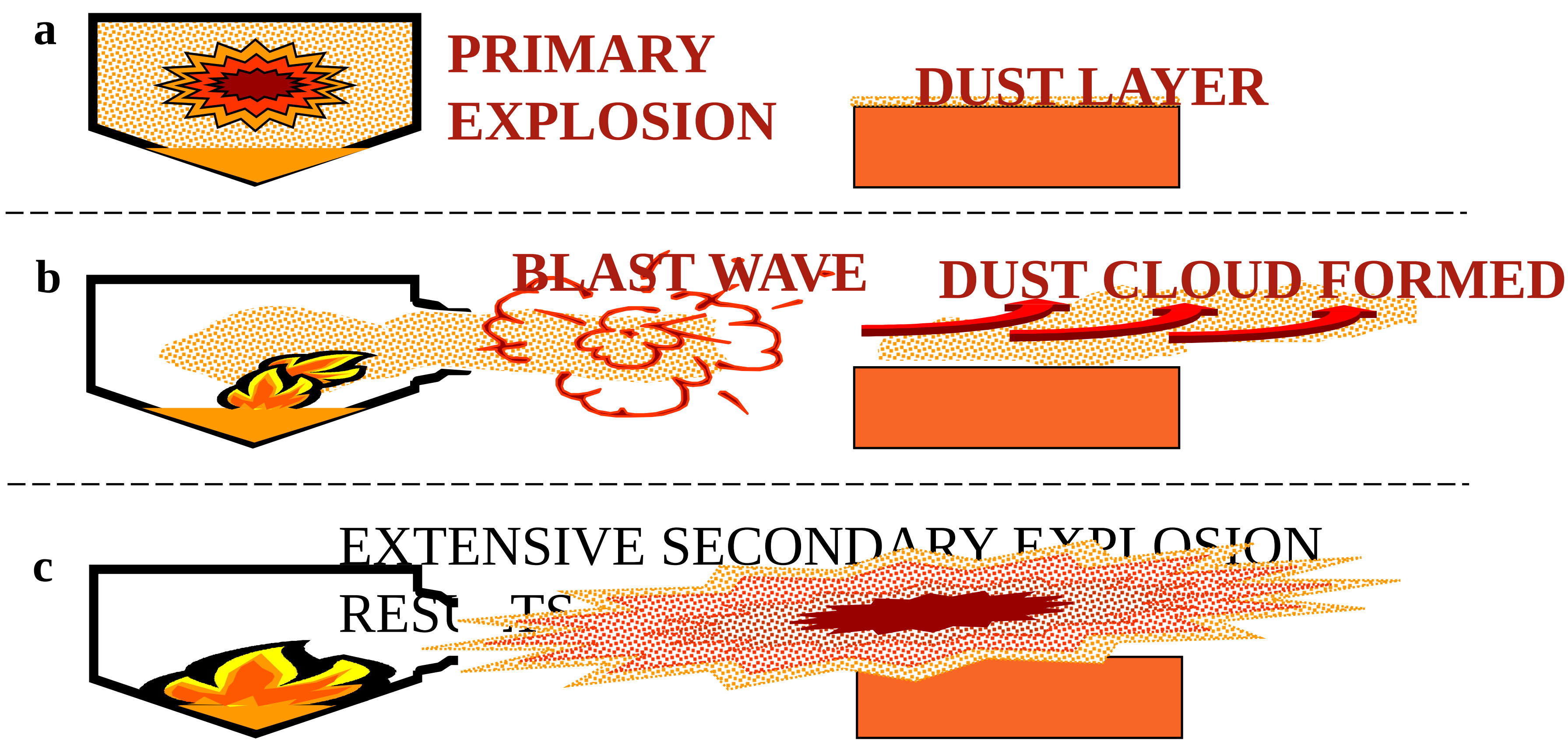


Illustration of how the blast wave from a primary explosion entrains and disperses a dust layer, which is subsequently ignited by the primary dust flame (R. K. Eckhoff, 1997)



Is Particle Size Distribution Capable of Propagating Flame?

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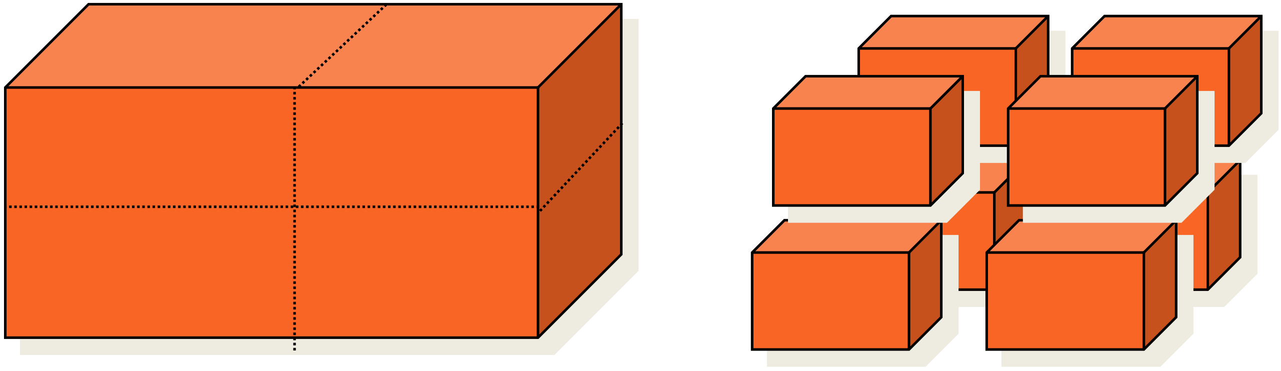
Powder include pellets, granules, and dust particles. Pellets have diameters greater than 2mm, granules have diameters between 0.42 mm and 2 mm, and dusts have diameters of 0.42 mm (420 μm) or less.

The finer the particles the greater the surface area and thus the more explosible a given dust is likely to be. When the dust is made up of a series of particle sizes ranging from fine to coarse, the fines may play a more prominent part in the ignition and the explosion propagation.



Atmosphere Must Support Combustion

To produce combustion, sufficient amount of oxidant must be available.

Typical oxidants include fluorine, oxygen, chlorine, bromine

- Explosion prevention can be accomplished by depletion of oxidant
- In general, combustible organic compounds are unlikely to propagate flame if oxygen content is below 8 % v/v using nitrogen or carbon dioxide as inert gas
- The concentration of oxidant below which a deflagration cannot occur in a specified mixture is referred to as the Limiting Oxidant Concentration (LOC)

Hybrid Mixtures

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When combustible dust and flammable vapors co-exist

Hybrid mixture is hazardous for the following reasons:

- When combustible dusts and flammable gas/vapor mixtures are present below their respective flammable limits, they may form an explosible (hybrid) atmosphere when mixed together

- Dust mixtures in the presence of flammable vapors/gases may be more easily ignitable in air, even if the concentration of the vapor/gas is below its LFL

- Materials that are too coarse to be explosible may become explosible when in the presence of a flammable vapor/gas even if the vapor/gas is below its LFL

Potential Ignition Sources

- Open light
- Smoking
- Open flames
- Welding
- Cutting
- Grinding
- Hot surfaces
- Frictional heating
- Mechanical impacts
- Electric sparks
- **Electrostatic discharges**

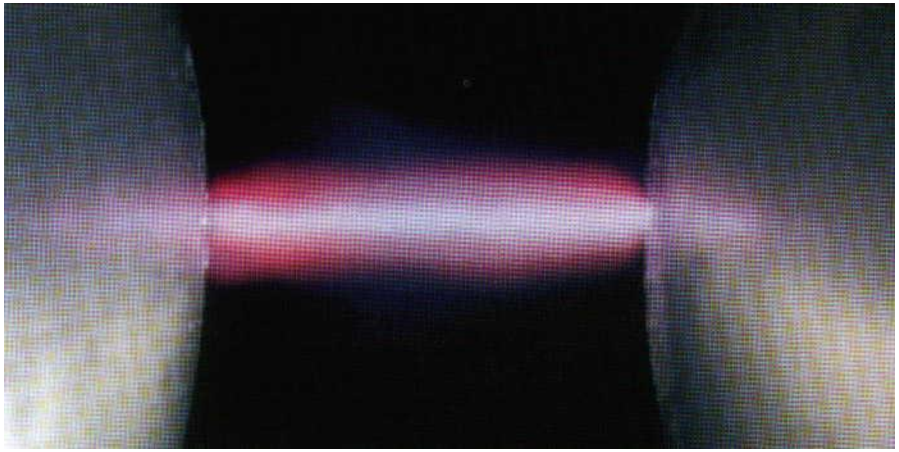
Different Electrostatic Discharges

- Types of discharges
  - spark
  - brush
  - propagating brush
  - corona
  - Cone (Bulking)

- Effective / available energy depends on the source of the discharge

Spark Discharge

- Origin
  - charged isolated conductor



- Energy
  - $E = 0.5 \times C \times V^2$
  - in practice
    up to a few 100 mJ
- Incendivity
  - gases, vapours, dusts and mists
  - as long as E > MIE

Brush Discharge

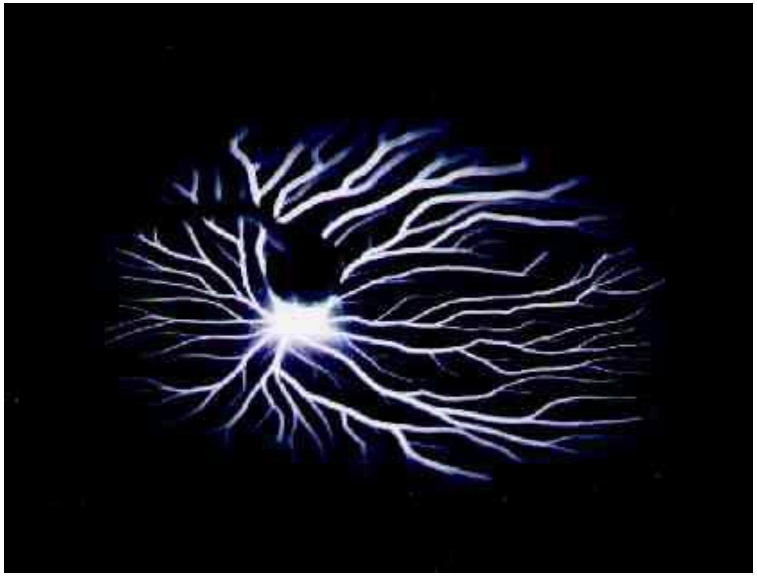
- Origin
  - insulator
- Energy
  - up to 4 mJ
- Incendivity
  - gases
  - vapours
  - some sensitive dusts?

Propagating Brush Discharge

Origin
- high charging situations on high resistivity materials
- insulator with metal close by

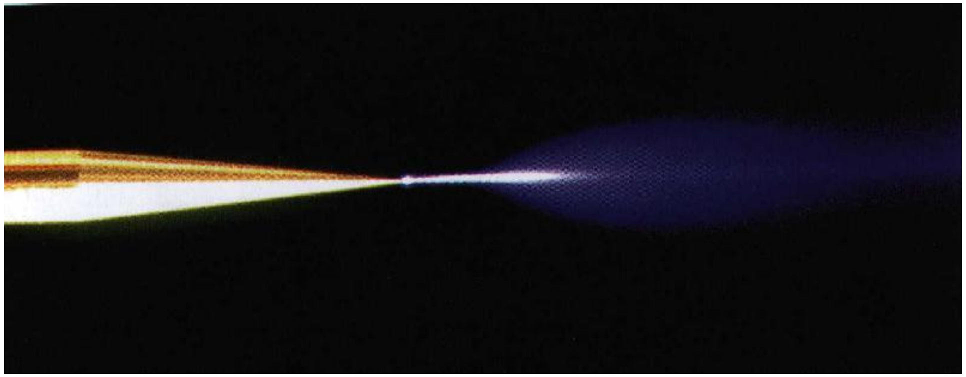
Energy
- not established
- > 1 Joule (1000 mJ)

Incendivity
- vapour
- gases
- dusts
- mists?



Corona Discharge

- Origin
  - highly charged conductor or insulator
  - sharp point or edge
- Energy
  - not established
  - very low, << 0.1 mJ
- Incendivity
  - very sensitive gases
  - gas - oxygen mixtures

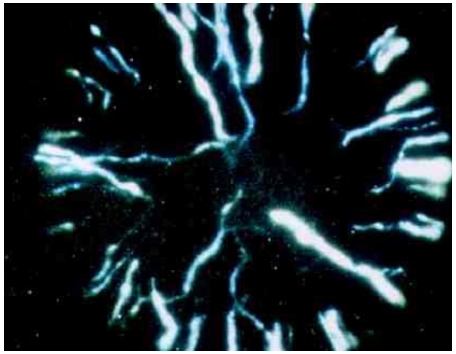


Cone (Bulking) Discharge

Origin
- highly charged powder in bulk

Energy
- up to ~25 mJ for fine powders
- higher energies for granular materials

Incendivity
- vapours
- gases
- sensitive dusts



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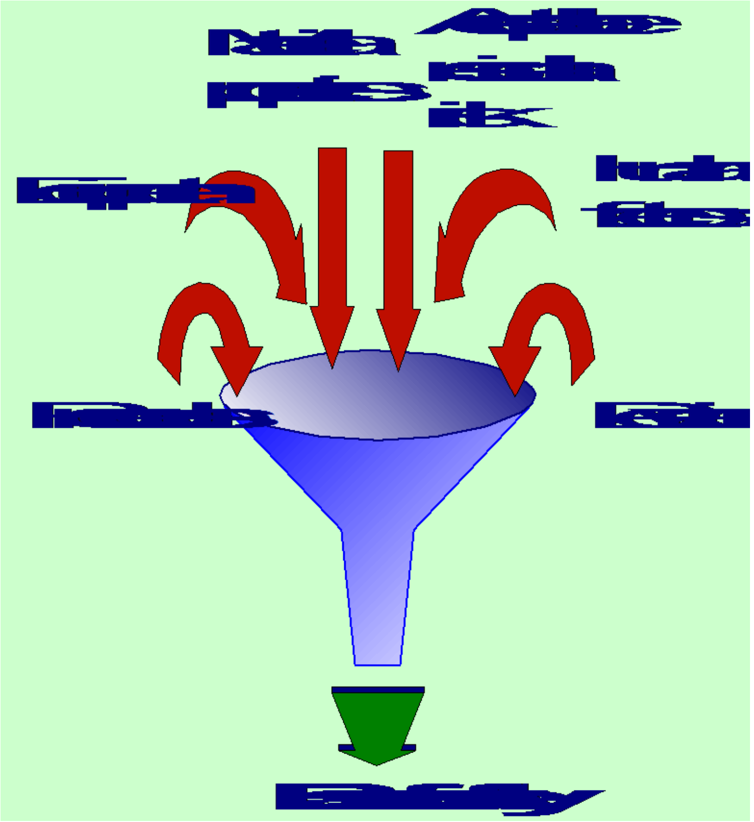
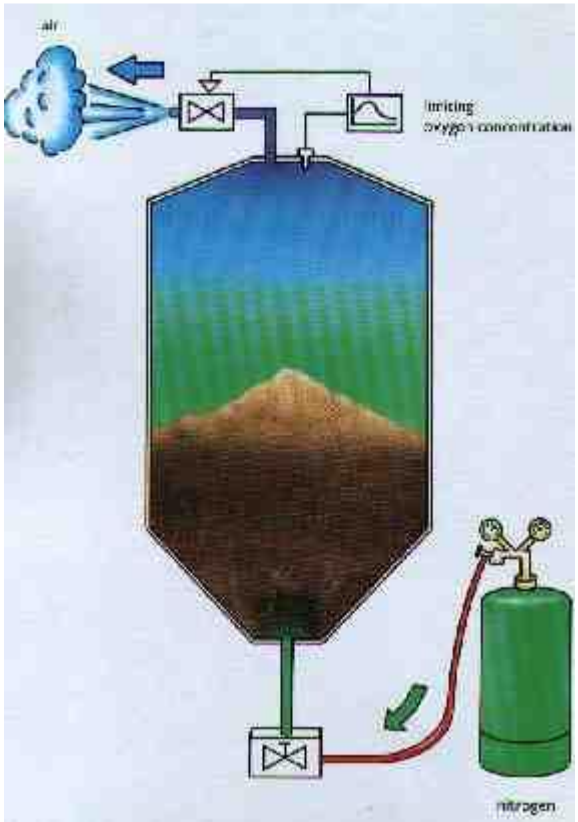
EXPLOSION PREVENTION TECHNIQUES

Basis Of Safety

- Inherent safety
- Explosion prevention
- Explosion protection



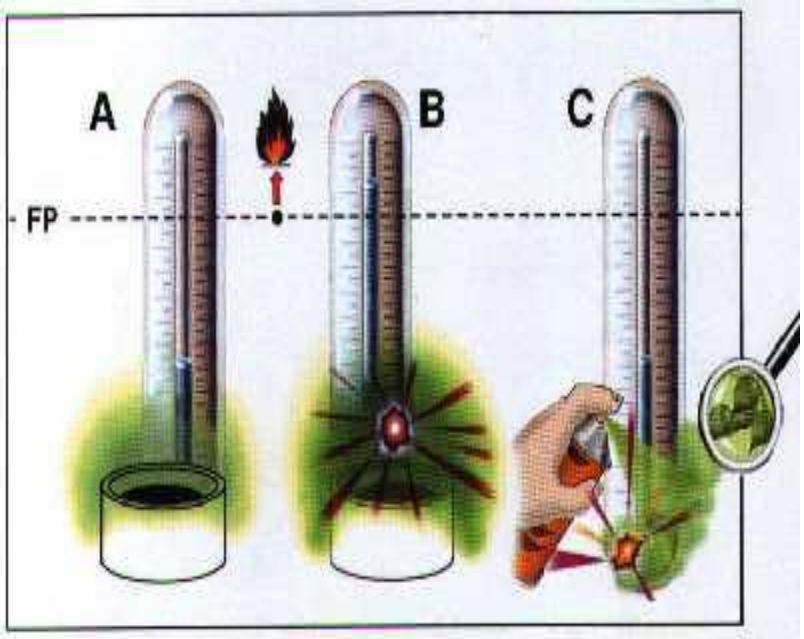
Explosion Prevention



- Avoid the fuel
  - is it the product?
  - attrition can be problem with dust
- Work outside flammable range
  - difficult with dusts (settling)
- Eliminate all ignition sources
  - ignition sensitivity data needed
- Remove oxygen
  - inerting
    - requires LOC data
  - work under vacuum

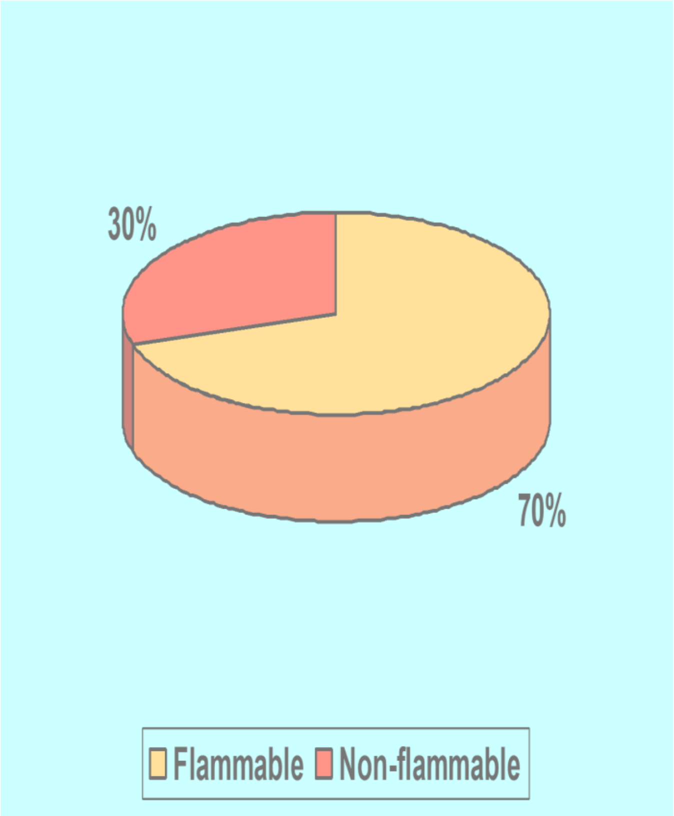
Remove The Fuel

- Use non-flammable materials
- Work below the flash point
  - at least 5 °C safety margin
  - remember effect of pressure on flash point



Flammable Dusts

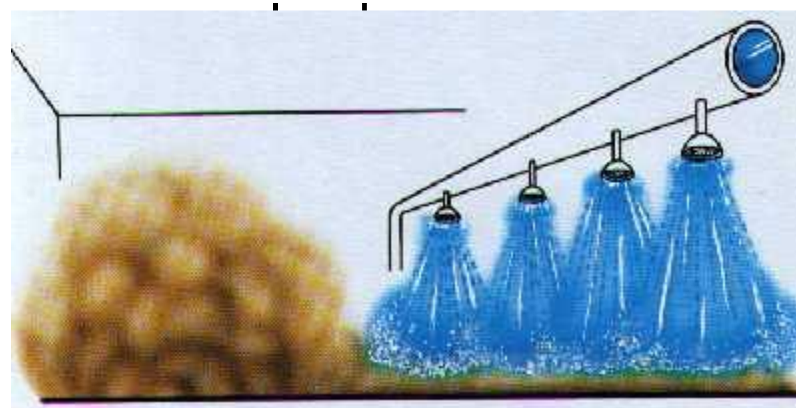
- Agricultural
  – corn, milk powder, sugar
- Carbonaceous
  – coal, peat, activated charcoal
- Chemical
  – adipic acid, sulphur, anthraquinone
- Pharmaceutical
  – aspirin, paracetamol, ibuprofen
- Metal
  – aluminium, iron, zinc



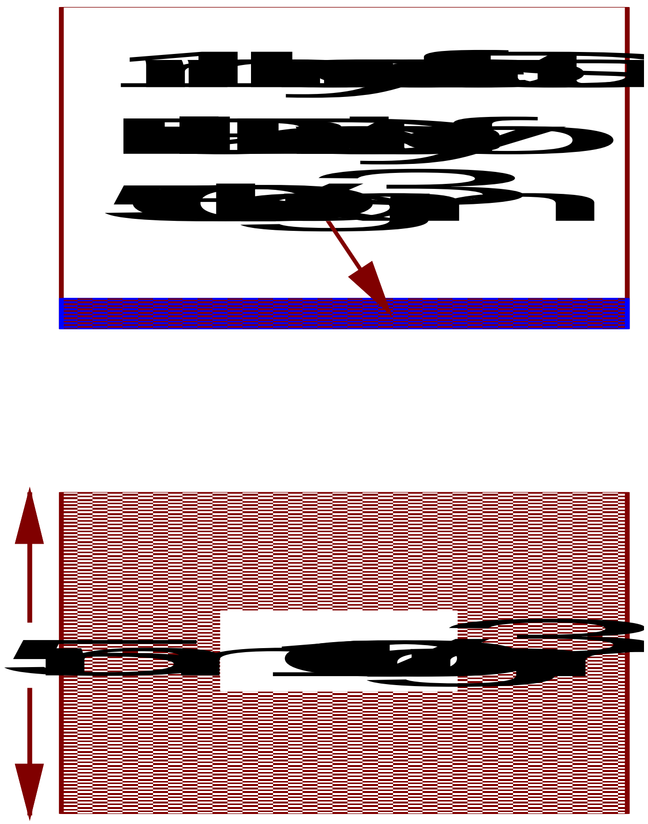
Remove The Fuel

FOR DUSTS ONLY:

- Use large particle size
  - >0.5 mm diameter
  - will not form dust clouds
  - watch out for fines
- Add an inert material
  - prevents ignition
  - large amount are needed
  - limited use
- Keep material damp
  - water or high flash point liquid
  - will not form dust



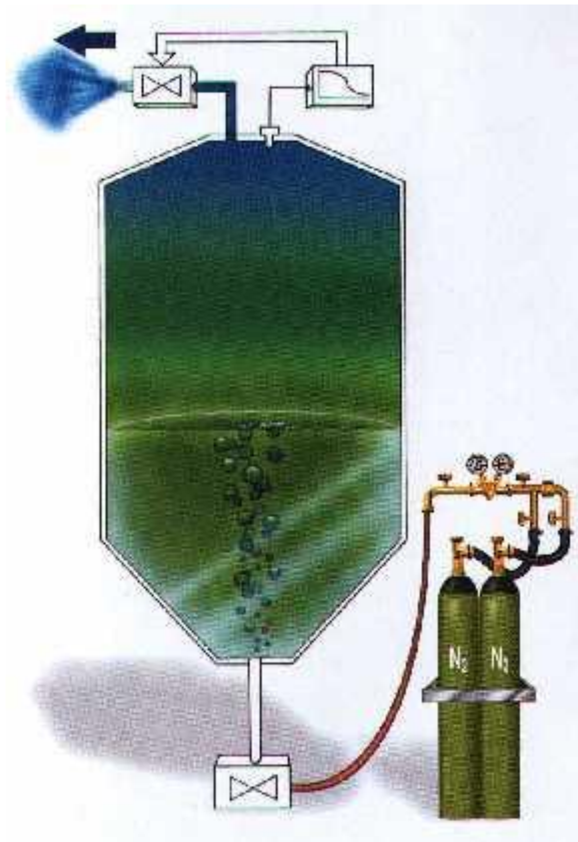
Secondary Dust Explosions



One of the main hazards associated with handling dusts is the potential for devastating secondary dust explosions

Remove The Oxidant

- Air is 21 % oxygen
- Reduce the oxygen concentration to below the LOC
- Safety factors must be applied
- Two main procedures
  - pressure swing inerting
  - flow through inerting



Explosion Prevention Techniques - Control of Heat Sources

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Examples of heat sources:

- External surfaces of hot process equipment such as heaters, dryers, steam pipes, electrical equipment
- Mechanical failure of equipment such as bearings, blowers, mechanical conveyers, mills, mixers, unprotected light bulbs
- Hot work

A hot surface may ignite:

- A dust layer that may be settled on it
- A flammable atmosphere (gas, vapor, or dust cloud) directly
- A dust layer that subsequently ignites flammable cloud

Explosion Prevention Techniques - Control of Heat Sources

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- If the material is subjected to heat as part of the normal process (e.g. during drying), the temperature should be maintained below the self heating temperature (for solids) or below the the AIT (for liquids)
- Regular inspection and maintenance of plant to prevent overheating due to misalignment, loose objects, belt-slip/rubbing etc.
- Preventing the overloading of processing plant (grinders, conveyors, etc.). Internal buildup will BOTH reduce heat loss from material AND increase operating temperature above “normal”. Consider the installation of overload protection devices on drive motors
- Preventing ingress of “foreign objects” by use of electromagnets or pneumatic separator
- Isolation or shielding of hot surfaces
- Prevention/removal of dust accumulations on hot surfaces
- Use of approved electrical equipment (correct temperature rating)

Explosion Prevention Techniques

Welding, Cutting, and Similar Hot Work Operations

Welding, cutting, brazing, soldering and similar operations are known explosion and fire risks.

- In any such work where flames are used, or sparks are produced, make sure that a flammable/explosible atmosphere does not exist or develop
- A gas/vapor detector may be used to ensure flammable vapors/gases are not present
- Formation of dust clouds should be prevented, and dust deposits should be removed

Explosion Prevention Techniques – Friction/Impact Sparks

- Friction/Impact Sparks
  In any work where sparks may be produced, flammable (gas, vapor, dust clouds) atmospheres should not be present

- "Non-sparking" tools
  "Non-sparking", "Spark-resistant", or "Spark-proof" tools are made from metals such as brass, bronze, titanium, alloys of copper-nickel, copper-aluminum, and Copper-beryllium

  All metals can produce sparks. While "non-sparking" tools may lower the risk of a spark, they do not eliminate the possibility of sparks

Explosion Prevention Techniques – Electrical Equipment

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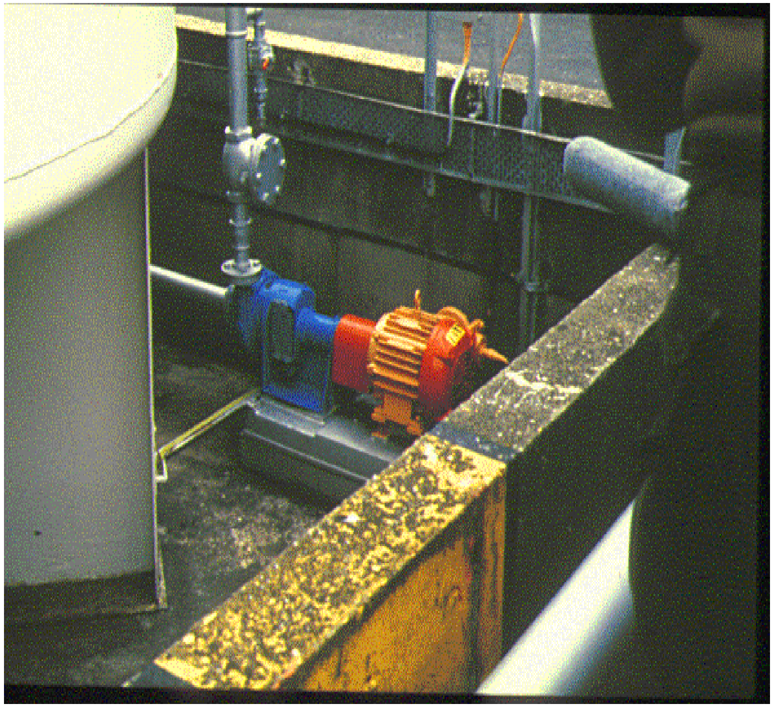
- Sparks produced during normal working of switches, contact breakers, motors, fuses, etc can ignite gas, vapor, and dust cloud atmospheres



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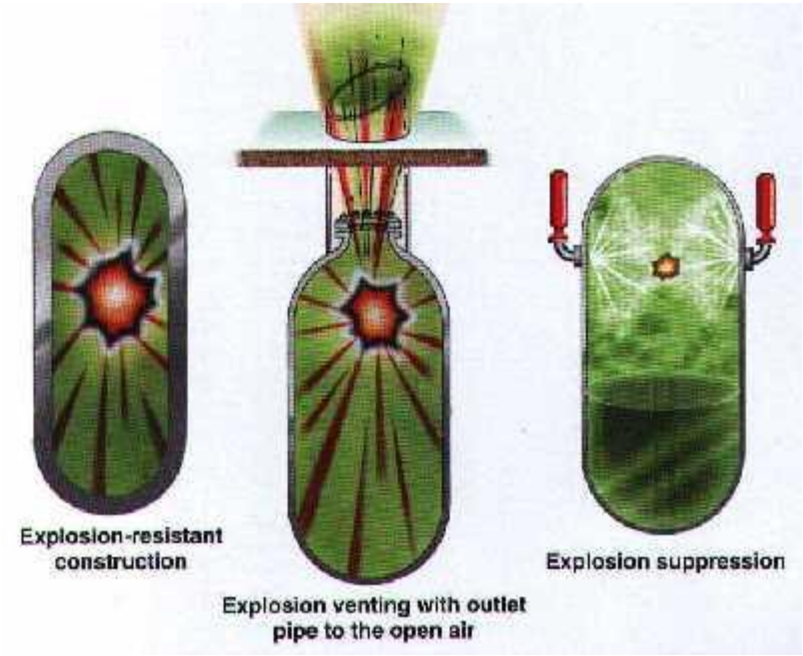
EXPLOSION PROTECTION TECHNIQUES

Explosion Protection

- Explosion containment
- Explosion relief venting
- Explosion suppression
- Needs to be combined with measures to prevent propagation (isolation measures)

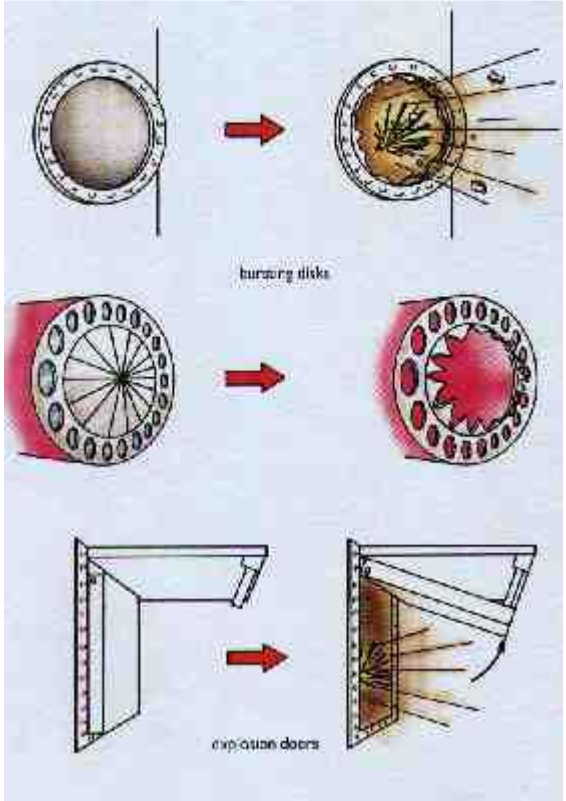


Containment

- All parts of the plant made strong
  – includes pipes, ducts, flanges, covers, etc.
- Must withstand the maximum pressure that is expected
- Maintain strength over lifetime
- Strong plant is expensive to build and can be difficult to operate

Explosion Relief Venting

- Protects plant and personnel from the effects of an explosion
- Uses weak panels or doors that open quickly at low pressure
- Panel has to be large enough
- Vent design has many pitfalls for the inexperienced



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Explosion Suppression

- Injects a suppressing agent into the vessel as soon as the explosion is detected
- The explosion is extinguished in the early stages
- Pressure is still low at that time
- No external effects of explosion

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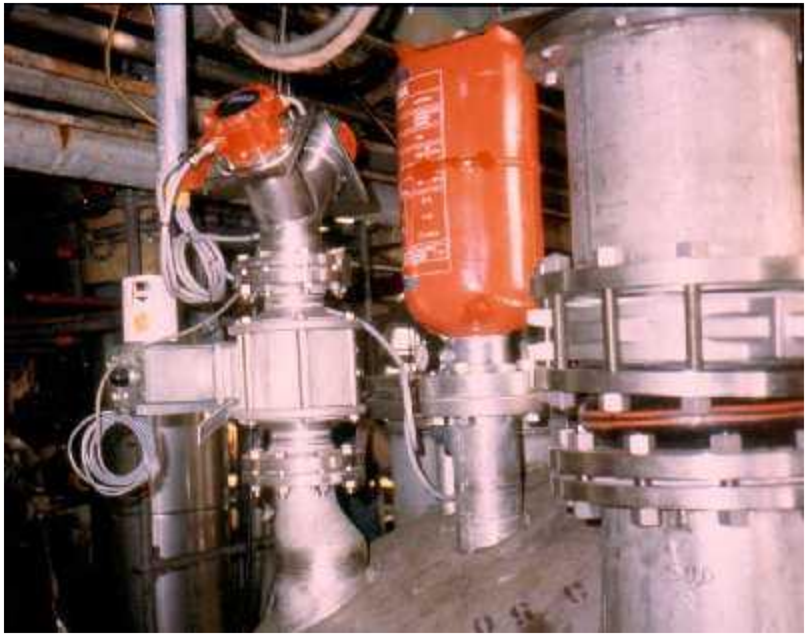
Explosion Suppression Examples



fluid bed dryer

dust collector

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Explosion Isolation

- Necessary to prevent pressure piling and flame jet ignition

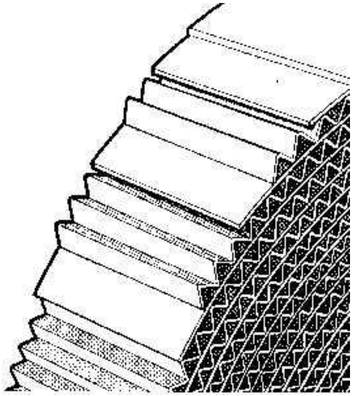
- When isolation fails, the explosion in secondary vessels can be more severe than the “design” explosion
  - explosion protection on secondary vessel may be insufficient

Isolation Devices

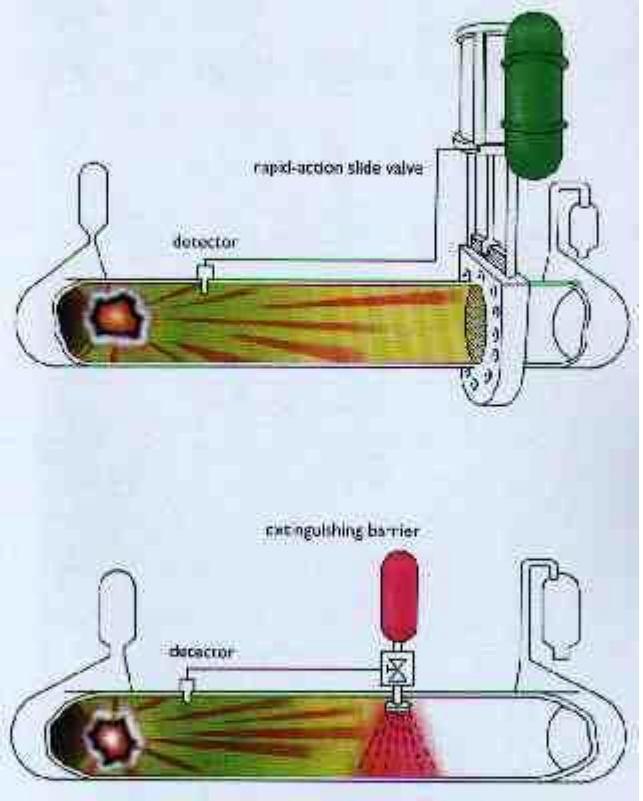
- For gases
  - deflagration (flame) arresters
  - detonation arresters
  - flashback preventers
  - extinguishing barriers
- For dusts
  - extinguishing barriers
  - rapid-action valves
  - rotary valves
  - explosion diverters
  - chokes (material as barrier)

Flame Arresters

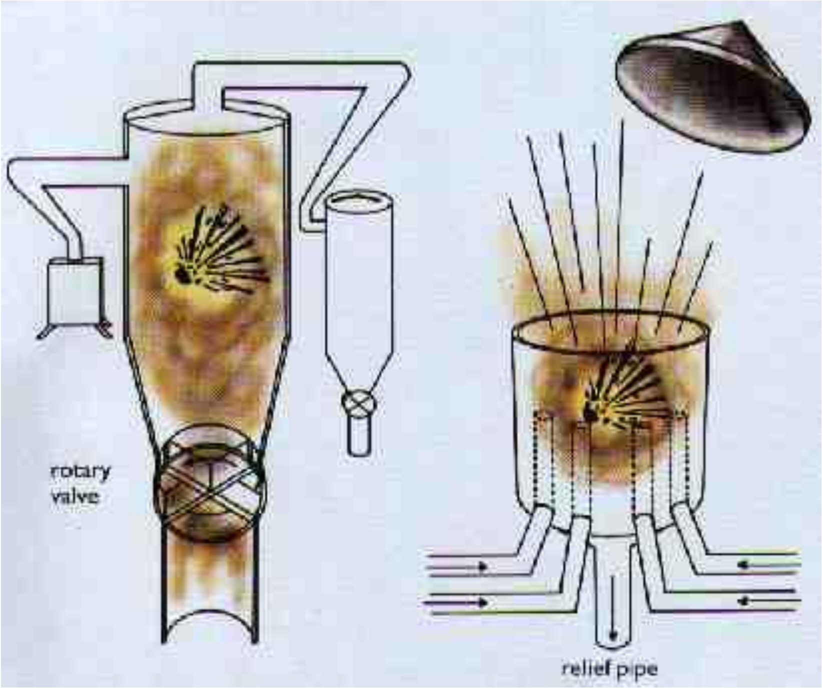
- Deflagration arresters
  - in-line (A)
  - end-of-line (B1)
- Flame arrester for endurance burning (B2)
- Detonation arrester (C)



Isolation Devices



rapid action valve
and extinguishing barrier



rotary valve and explosion diverter

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Thank you

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Hazardous Area Classification

Presented by

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Bio

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- Team Leader at Swissi Process Safety (Safety Lab)

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Agenda

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1 Review of explosion basics

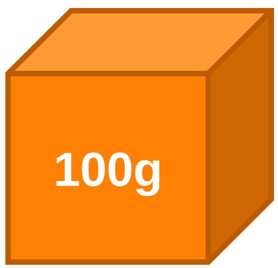
2 Classification criteria

3 Certified equipment

4 Risk assessment (all ignition sources)

Combustible Dust

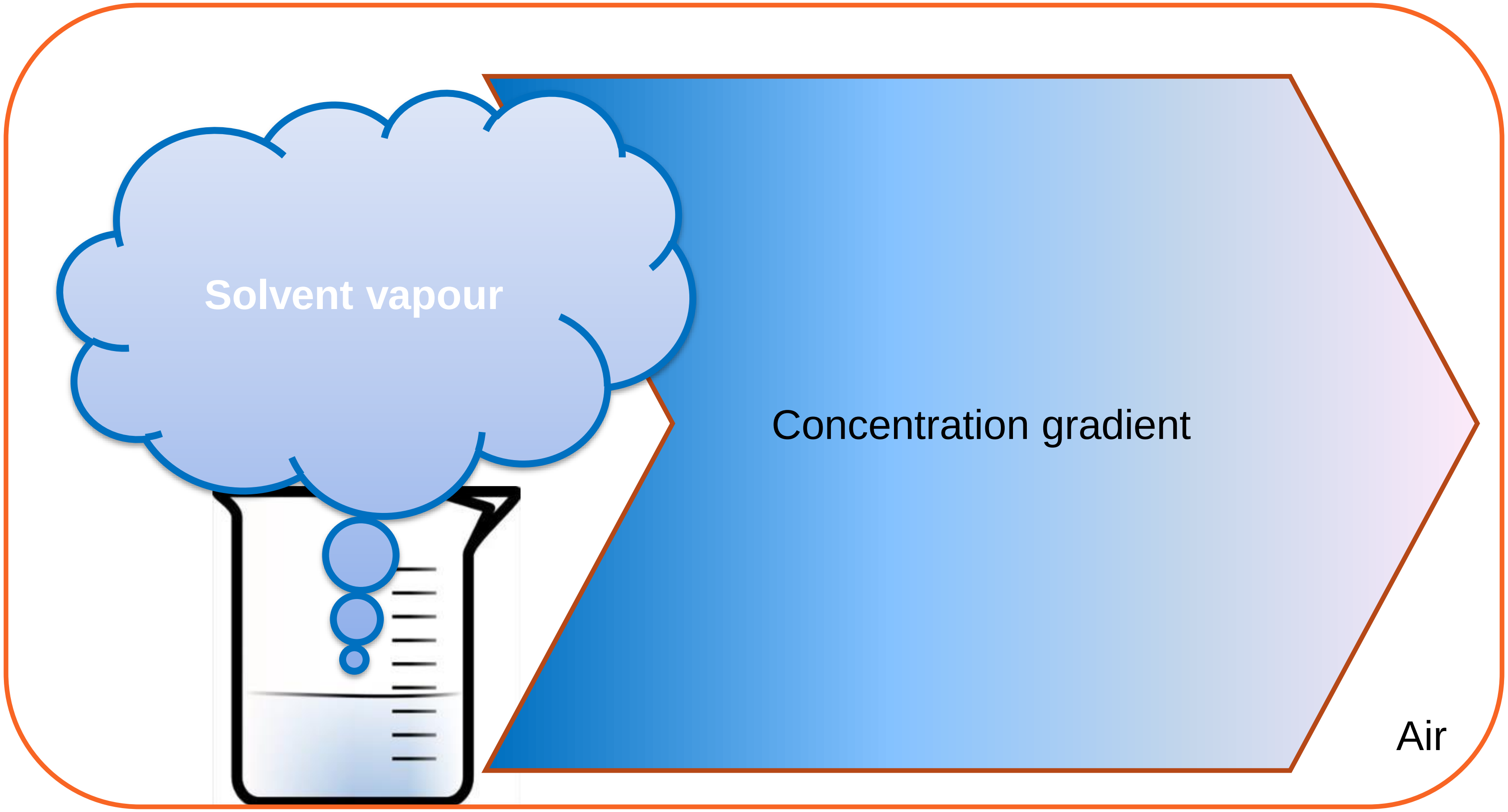
- Combustion is a heterogeneous reaction between a solid (combustible material) and oxygen (air)
- The reaction rate is a function of the concentration of oxygen in air...
- ... and the surface of the combustible material



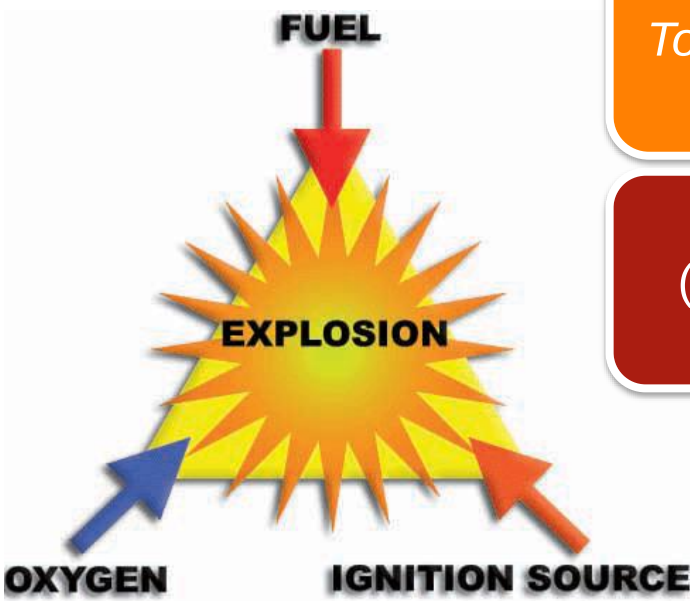
Particle size = 4 cm
Surface = 96 cm²

Particle size = 0.1 mm
Surface = 38’400 cm²

Flammable Vapours

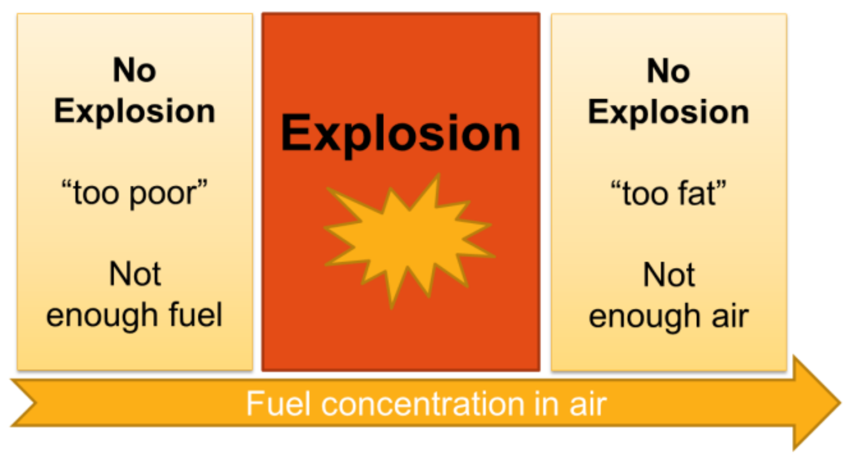


Explosion



Fuel = combustible dust / vapour
To have a rapid combustion (explosion) the dust must be finely dispersed → airborne

Ignition sources are numerous (electrical, electrostatic, hot surfaces, flames, mechanical sparks and glowing nests)



Ignition sources

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Electrical ignition sources

Hot Surface
Glowing Nests

Electrostatic Discharges

Flames
Mechanical Sparks

Agenda

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1 Review of explosion basics

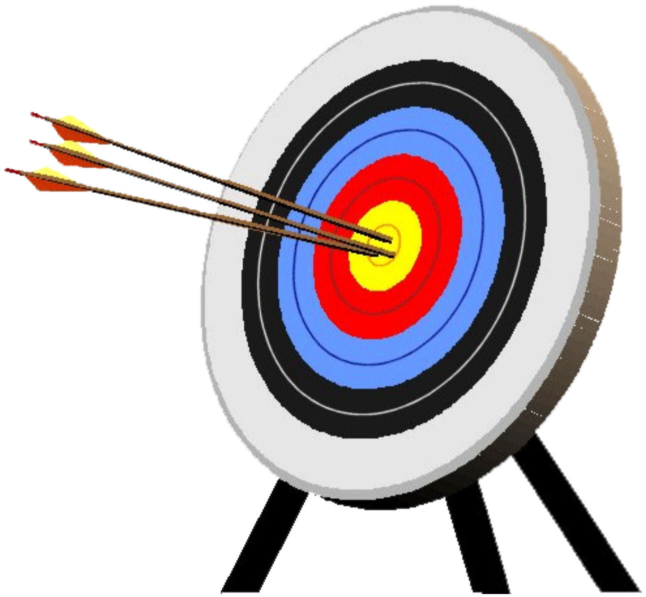
2 **Classification criteria**

3 Certified equipment

4 Risk assessment (all ignition sources)

Objective of Area Classification

- The objective of area classification is to minimize the probability of accidental ignition of explosive atmospheres.
- The area classification forms the traditional basis for design of electrical apparatus.
- Main idea is that more strict requirements have to be enforced to the design of electrical apparatus to be used in area where the probability of occurrence of explosible atmosphere is high, than to equipment to be used in area where this probability is low.
- Minimizes the probability of ignition not (necessarily) the risk of explosion



Management of Area Classification

- Area classification should be carried out before the design and layout of equipment is finalized.

  → opportunity to improve at little cost
- Area classification should be assigned to one responsible and competent person
- Area classification to be done by a multi-disciplinary team (knowledge of process systems and equipment, electrical engineering, HSE)
- Outcome should be documented and considered during changes

« For every dollar it costs to fix a problem in the early stage of design, it will cost $10 at flowsheet stage, $100 at the detail design stage, $1000 after the plant is build and $10,000 to clean-up the mess after an accident. »
Trevor Kletz

Zone Definition for «vapour/gas» Atmosphere

Ex-Zone 0 - An area in which a hazardous explosive atmosphere formed by vapor or gas in air is present continuously or for long periods or frequently

Ex-Zone 1 - An area in which a hazardous explosive atmosphere formed by vapor or gas in air is likely to occur in normal operation

Ex-Zone 2 - An area in which a hazardous explosive atmosphere formed by vapor or gas in air is not likely to occur in normal operation, and if it does occur, it will exist for a short period only

Zone Definition for «vapour/gas» Atmosphere

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Zone	Operational area
0	• inside containers, reactors and pipes containing flammable vapors (i.e. liquids above their flashpoint) • where open handling of flammable liquids occurs permanently or for long periods (degreasing stations) • in vent lines of containers, reactors and pipes containing flammable vapors
1	• inside pipes normally filled with liquids above their flashpoint • adjacent to zone 0 where there is no separation (wall, siphon) • at manholes of reactors containing flammable vapors • at outlet points of venting or breathing lines of containers and reactors containing flammable vapors • at filling stations open handling of flammable liquids occurs • in trenches and sumps below Zone 0 areas
2	• adjacent to zone 1 where there is no separation (wall, siphon) • at outlet points of pressure relief systems of containers and reactors containing flammable vapors and gases • where spillages of flammable liquids or gases could occur • around flanges and blind flanges of pipes containing flammable liquids or gases • around couplings of hoses, pipes and vapor return lines where flammable liquids are transferred • spraying/mist formation of combustible liquids in emergency cases • in and around locations where flammable liquids or gases are stored

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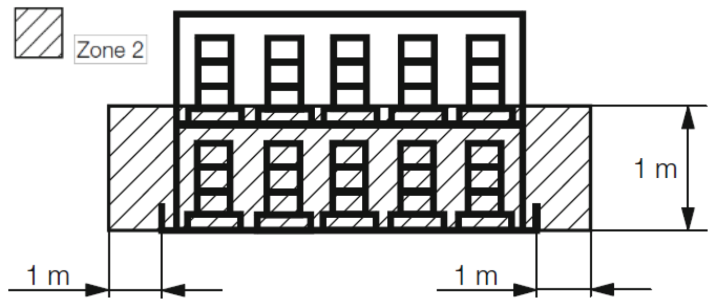
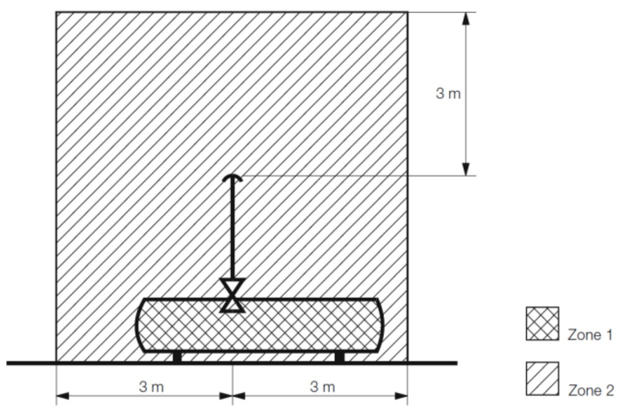
Examples

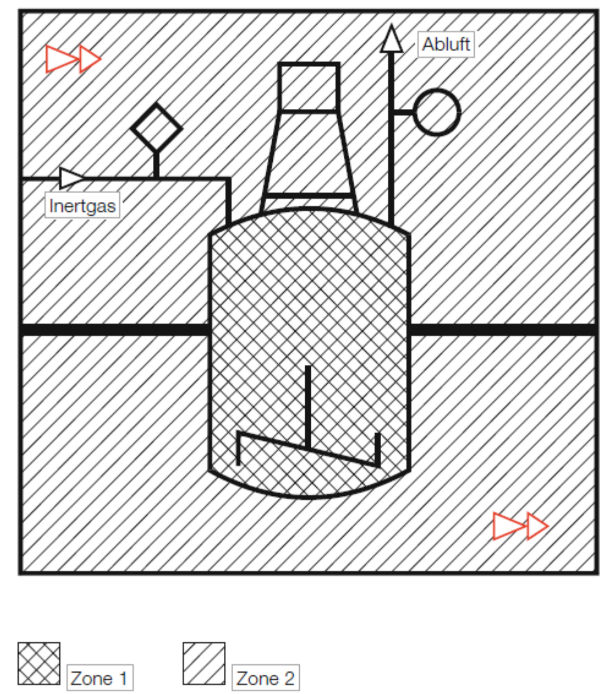
Outside drum storage



Outside tank storage



Inerted vessel (controled inertisation)



Zone Definition for «dust» Atmosphere

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Ex-Zone 20 - An area in which a hazardous explosive atmosphere formed by a dust cloud in air is present continuously or for long periods or frequently. Dust layers of unknown or excessive thickness may be formed. Dust layers on their own do not constitute a zone 20

Ex-Zone 21 - An area in which a hazardous explosive atmosphere formed by a dust cloud in air is likely to occur in normal operation. Layers of combustible dust will in general be present

Ex-Zone 22 - An area in which either:

- hazardous explosive atmosphere formed by a dust cloud in air is not likely to occur in normal operation, and if it does occur, it will exist for a short period only.
- accumulation or layers of combustible dust are present.

Zone Definition for «dust» Atmosphere

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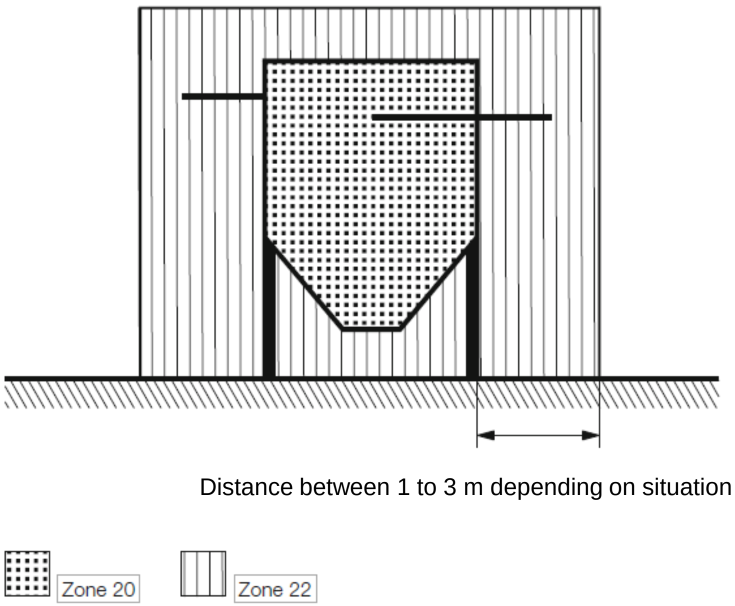
Zone	Operational area
20	• inside silos, containers, reactors, dryers, mixers and ducts where combustible powder is handled in explosive concentrations • where open handling of combustible powder occurs permanently or for long periods • in vent lines of containers, reactors and pipes containing combustible powder up to the filter
21	• adjacent to zone 20 where there is no separation • at openings for filling combustible powder into containers or reactors • at unloading chutes of containers for combustible powder • at outlet points of venting or breathing lines of containers and reactors containing combustible powder • inside silos, containers, reactors, dryers, mixers and ducts where combustible powder is normally handled below or above explosive concentrations, i.e. where explosive concentrations prevail only for short time
22	• adjacent to zone 21 where there is no separation • where layers of combustible powder could be raised to form an explosive atmosphere • where spillages of combustible powder could produce dust clouds • in vent lines of containers, reactors and pipes containing combustible powder on the clean air side of the filter

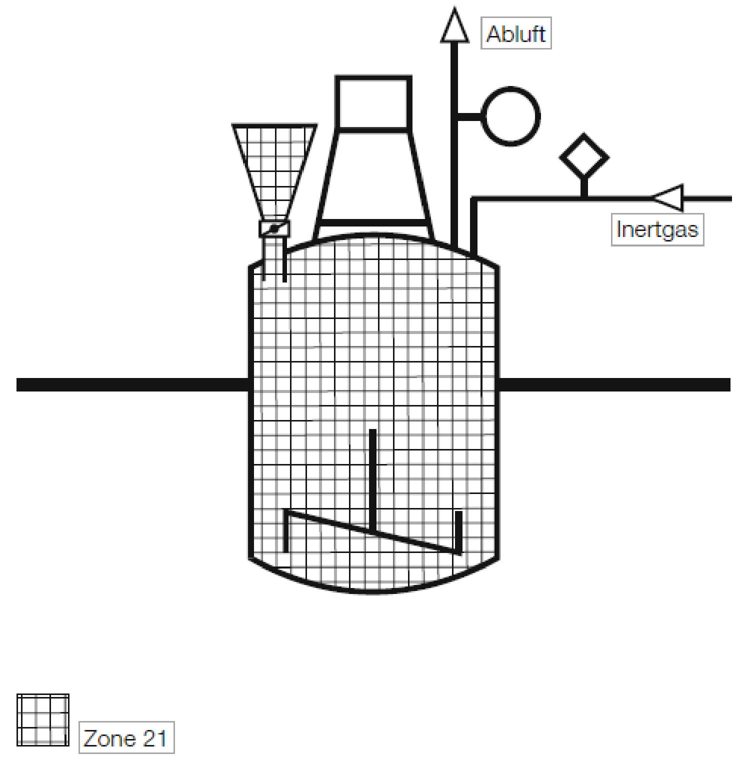
Inert gas blanketing or natural or active ventilation that ensures a sufficient dilution of the combustible component could justify classification in a less hazardous zone.

Examples

Installation not 100% leak proof



Addition in vessel with controled inertisation



Inerting

By operating under inert gas (e.g. nitrogen), the formation of explosive mixtures can be avoided but **not** thermal decomposition or smoldering of powder deposits.

Inerting inside closed containments must be ensured in all locations and during all process phases where explosive mixtures could be formed and relevant ignition sources can not be safely excluded.

Inert gas blanketing or natural or active ventilation that ensures a sufficient dilution of the combustible component could justify classification in a less hazardous zone.

Special precautions should be adopted when charging solids into inerted vessels in order to prevent accidents due to asphyxiation

Alternative Zone Définition (Duration)

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- If a hazardous explosive atmosphere is present more than 1’000 hours per year, a zone 0 or 20 must be defined.
- If a hazardous explosive atmosphere is present between 10 and 1’000 hours per year, a zone 1 or 21 can be defined. Very often it is safer to define inside equipment a zone 0 or 20 even if the 1’000 hours limit is not reached.
- If a hazardous explosive atmosphere is present between 1 and 10 hours per year, a zone 2 or 22 can be defined.

Factor influencing the extent of ex-zones outside of equipment

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The source of flammable substances --- Quantity, concentration and release rate: With increasing quantity, concentration and release rate of the flammable substance the extent of a potential explosive atmosphere will increase. The release of a flammable substance (vapor, gas) depends on:

- the size of the leak/opening
- the pressure und which the flammable substance is processed
- the viscosity of the substance.

(Secondary) Containment --- The dispersion of explosive atmospheres is effectively limited by continuous walls, whereas doors, windows etc. are to be considered as sources for the adjacent area.

Ventilation By effective ventilation the formation of explosive atmospheres can be prevented or their extent and persistence can be significantly reduced.

Con’t

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Physical properties of the flammable substance

- Density: Powders and high density vapors as most common solvents and gases with density higher than air will preferably be dispersed along the floor, whereas light gases such as hydrogen will accumulate below the ceiling.
- Temperature: With increasing temperature the vapor pressure of the hazardous substance will increase and the density and viscosity will decrease.
- Viscosity: Highly viscous media will have a lower release rate and thus produce a smaller explosive volume compare to low viscous media having otherwise the same properties.
- Explosion range: Substance with having a low Lower Explosive Limit (LEL) will in general lead to larger explosive volumes.

Hazardous Area Classification

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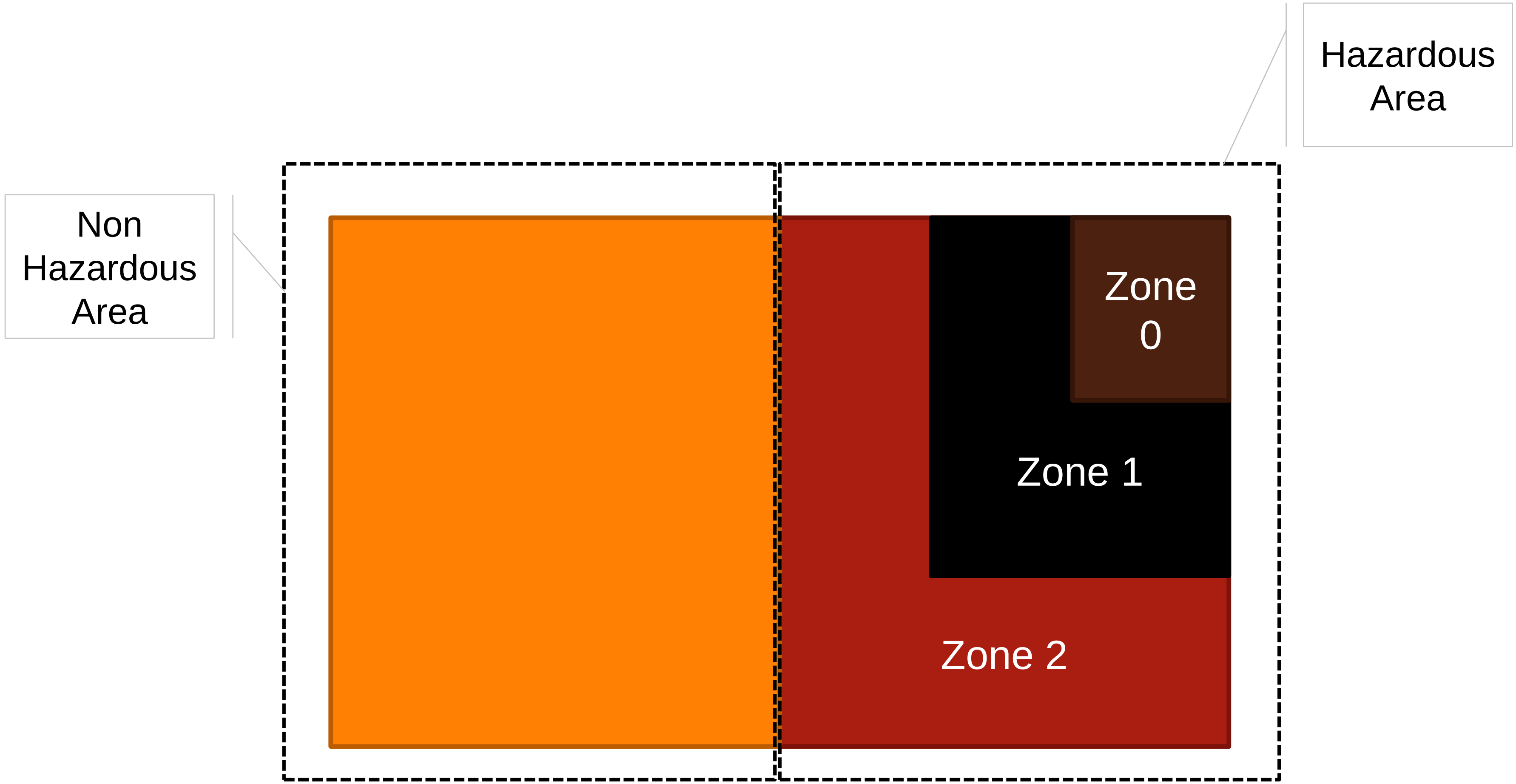

Signage

- It's good practice to indicate the presence of hazardous areas in a room with a sign on the door

- Aim is to avoid that someone bringing a not compatible electrical appliance in the room

- Hazardous Zones in a room should also be indicated graphically on a sketch (plan) of the room, visible to all

Correspondance EU <> USA

Zone	Class / Division	Zone	Class / Division
0	I / 1	20	II / 1
1	I / 1	21	II / 1
2	I / 2	22	II / 2

Class I, Flammable Gases, Vapours Or Liquids	Class I, Flammable Gases, Vapours Or Liquids
Division 1: Where ignitable concentrations of flammable gases, vapours or liquids can exist all or some of the time under normal operating conditions.	**Zone 0:** Where ignitable concentrations of flammable gases, vapours or liquids can exist all of the time or for long periods at a time under normal operating conditions. **Zone 1:** Where ignitable concentrations of flammable gases, vapours or liquids can exist some of the time under normal operating conditions.
Division 2: Where ignitable concentrations of flammable gases, vapours or liquids are not likely to exist under normal operating conditions.	**Zone 2:** Where ignitable concentrations of flammable gases, vapours or liquids are not likely to exist under normal operating conditions.

Class II, Combustible Dusts
Division 1: Where ignitable concentrations of combustible dusts can exist all or some of the time under normal operating conditions.
Division 2: Where ignitable concentrations of combustible dusts are not likely to exist under normal operating conditions.

Agenda

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1 Review of explosion basics

2 Classification criteria

3 **Certified equipment**

4 Risk assessment (all ignition sources)

Certified Equipment

According to EU directive 94/9/EG, equipment is classified into the following categories:

- Category G 1: for Zones 0, 1 and 2 for mixtures of gas, vapor or mist with air
- Category D 1: for Zones 20, 21 and 22 for mixtures of dust with air
- Category G 2: for Zones 1 and 2 for mixtures of gas, vapor or mist with air
- Category D 2: for Zones 21 and 22 if designed for mixtures of dust with air
- Category G 3: for Zone 2 for mixtures of gas, vapor or mist with air
- Category D 3: for Zone 22 if designed for mixtures of dust with air.

In new installations, electrical equipment should therefore be used in hazardous places only if it complies with the relevant standards.

According to NFPA 70 National Electrical Code Equipment Groups A; B C; D or IIA, IIB, IIC are used for Class I hazardous locations, and Equipment Groups E, F, G are used for Class II hazardous locations.

Special Rules

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For equipment to be used in Ex Zones in EU countries installed before June 30th 2003 or in jurisdictions were ATEX or NFPA Codes and Standards doesn't apply, the minimum requirements are:

- Electrical equipment in conformity with local regulations, IEC or NFPA 70 Codes and Standards
- An analysis of non-electrical ignition sources should be performed, especially:
  - Hot surfaces
  - Mechanical sparks
  - Static discharges.
- Proper installation and maintenance should be ensured.

Ex-Label on equipment

Example of an Ex-Label for a gas/vapours explosive atmosphere (some parts of this general structure do not apply in all Zones)

CE 0158 Ex	II	G	2	EEx ib	IIC	T3
Label of the notified body, and graphic Ex-Label	Equipment Group (II for the process industry)	G for gas/vapor	Equipment category, see above	Protection type, see EN 50015-21, 50028 and 50039	Gas Group (options: IIA, IIB or IIC)	Temperature Class, indicates maximum surface temperature: T1=450°C; T2=300°C; T3=200°C; T4=135°C; T5=100°C; T6=85°C

Ex-Label on equipment

Example of an Ex-Label for a dust explosive atmosphere
(some parts of this general structure do not apply in all Zones)

CE 0158 Ex	II	D	2	EEx ib	IIIB	160°C
Label of the notified body, and graphic Ex-Label	Equipment Group (II for the process industry)	D for dust	Equipment category, see above	Protection type, see EN 50015-21, 50028 and 50039	Dust Group (options: IIIA, IIIB or IIIC)	Maximum surface temperature: (the value is directly indicated for equipment to be used in dust zones)

Agenda

1. Review of explosion basics
2. Classification criteria
3. Certified equipment
4. Risk assessment (all ignition sources)

Risk Assessment

- Ignition sources have to be systematically identified and then eliminated to the extent as defined in the table below:
- The assessment of ignitions sources includes:
  - Likelihood, frequency and duration of occurrence
  - Energy in relation to the minimum ignition energy of the explosive mixture to be expected.

Explosive atmosphere	does not occur	is not likely during normal operation; if it occurs it will exist only for a short period	is likely to occur in normal operation	occurs continuously or for long periods or frequently
Zone	none	2/22	1/21	0/20
Ignition source	⇩	⇩	⇩	⇩
A. occurs during normal operation	□	■	■	■
B. does not occur during normal operation but only as a result of rare malfunctions	□	□	■	■
C. does not occur during normal operation but only as a result of very rare malfunctions	□	□	□	■
D. does not occur	□	□	□	□

□ acceptable
■ not acceptable

Other ignition sources

Mechanical sparks

Mechanical sparks are caused by friction or impact. Maintenance work (cutting, drilling) in ex-zones is therefore only permitted if the formation of explosive mixtures during the work is excluded by appropriate organizational measures, to be specified in the respective work permit system.

Equipment with moving mechanical parts (e.g. fans, conveyors) in ex-zones must be specially classified. While relative velocities between moving below 1m/s produced no dangerous mechanical sparks, there is always an ignition risk above 10m/s. Between 1 and 10m/s there is an ignition risk if the minimum ignition temperature MIT is lower than the following values depending on the minimum ignition energy MIE (determined with inductance).

MIE (mJ)	<3	3-10	10-30	30-100	100-300	300-1000	>1000
MIT (°C)	any	<500	<465	<430	<395	<360	<325

Other ignition sources

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Hot Surfaces

The maximum temperature of surfaces in ex-zones must not exceed either of the following values, depending on the type of explosive atmosphere that is involved:

- Gases : the auto-ignition temperature of the gas in °C. An additional safety gap of 20% must be taken into account in a zone 0.
- Vapors : the auto-ignition temperature of the respective liquid in °C. An additional safety gap of 20% must be taken into account in a zone 0.
- Dusts
  - the *self-ignition temperature* of a dust layer with a thickness representative for the process (the maximum being the self ignition temperature of a 5mm layer – 75°C) **AND**
  - 2/3 of the minimum ignition temperature of the dust cloud in °C (measured in a Godbert-Grenwald-Test).

In processes involving moving mechanical parts, the formation of hot spots by friction must be avoided e.g. by regular maintenance, lubrication, active cooling or temperature control for bearings.

Summary

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- The purpose of area classification is to avoid ignition of releases, intentional as well as accidental, that may occur in the operation of facilities handling flammable gases, liquids and vapors.
- The approach is to reduce to an acceptable minimum level the probability of coincidence of a flammable atmosphere and a source of ignition

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Process Safety Accidents in Pharmaceutical Industry & Lessons Learned

Presented by

Sunil R. Deshmukh

Senior Consulting Engineer

CTPL- Dekra Insight

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Bio

- Sunil Deshmukh is working as Sr. Consulting Engineer at Chilworth, Mumbai Office.
- Having 5 years of Process Safety, Risk Management consulting experience. His work experience includes executing and managing Safety and Risk consulting assignments at 100+ sites Globally.
- In his career, he has conducted safety studies like HAZOP, QRA, Dust explosion Hazard (DEH) Assessment, Electrostatic Hazard Assessment (EHA), Safety audits, Hazardous Area Classification (HAC), Fire and life safety Audits, Incident Investigation etc. for Metal, Petrochemical and Pharmaceutical Industries.

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Agenda

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Process Safety Accidents in Pharmaceutical Industry & Lessons Learned

Sunil Deshmukh, Sr. Consulting Engineer
Chilworth Technology Pvt. Ltd.

Accidents Happed in Past

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- **6 killed, one injured in explosion at pharma unit in India, 2008**
- **2 workers killed in pharma unit blast, India, 2015**
- **Fires and explosions at pharma manufacturing facilities, Croatia, Europe, 2012**
- **Two killed, two injured in fire at Pharma unit, 2016, India**
- **Fire in Pharma, one killed, 2016, India**
- **Runaway Chemical Reaction at Pharma Unit, Ireland, 2008**

There are many similar incidents happened in pharma companies.

6 killed, one injured in explosion at pharma unit in India, 2008

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- The incident occurred at around 6.05 AM at the pharma unit, resulting in on-the-spot death of six persons.
- As per investigation, the reactor exploded due to imbalance in maintenance of temperature in it, and resulted into chemical Runaway reaction.

2 workers killed in pharma unit blast, India, 2015

- The accident occurred at approximately 12 noon when there was a huge blast in the reactor, according to the workers factory was engulfed in smoke. The two workers died on the spot and five were wounded. There was not much of a fire but there was thick cloud of smoke.
- Root Cause for this accident was Chemical Runaway reaction.

Fires and explosions at pharma manufacturing facilities, Croatia, Europe, 2012

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- An explosion in 2012 at a Pharmaceutical plant in Croatia killed four workers and injured 17 others.
- Reaction between two chemicals in a solvent carrier.
- Accident happed during the solvent charging operation. After investigation, it was concluded that root cause for the accidents are unavailability of the N_2 purging, faster addition of the solvent to the reactor might caused static charge generation and resulted as ignition source for the flammable atmosphere inside reactor.

Two killed, two injured in fire at Pharma unit, 2016, India

- Two persons were killed and two others injured in a blast at a pharma unit
- Company confirmed the incident, saying a fire broke out during an excavation work at the facility.
- The Root cause for this incident is Non-compliance to the Permit system and not following safety practices for excavation work.

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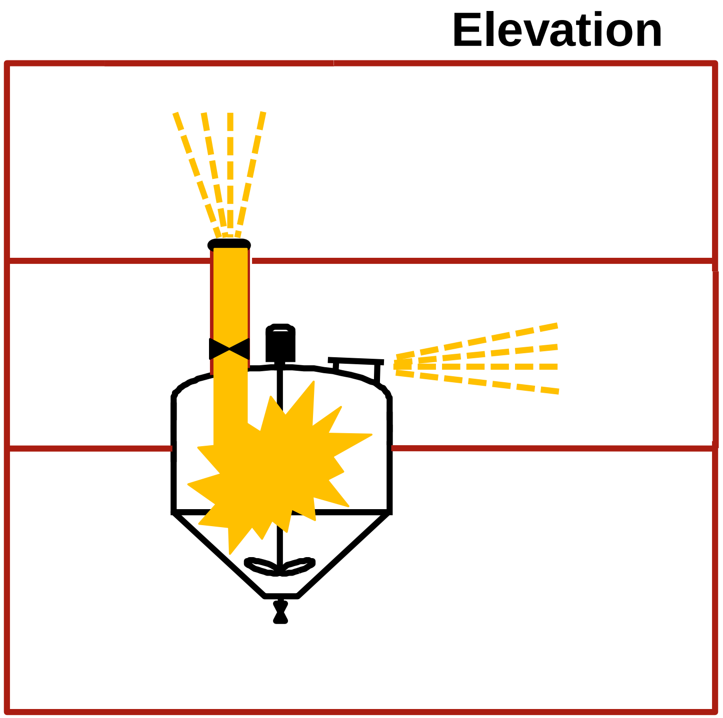
Fire in Pharma, one killed, 2016, India

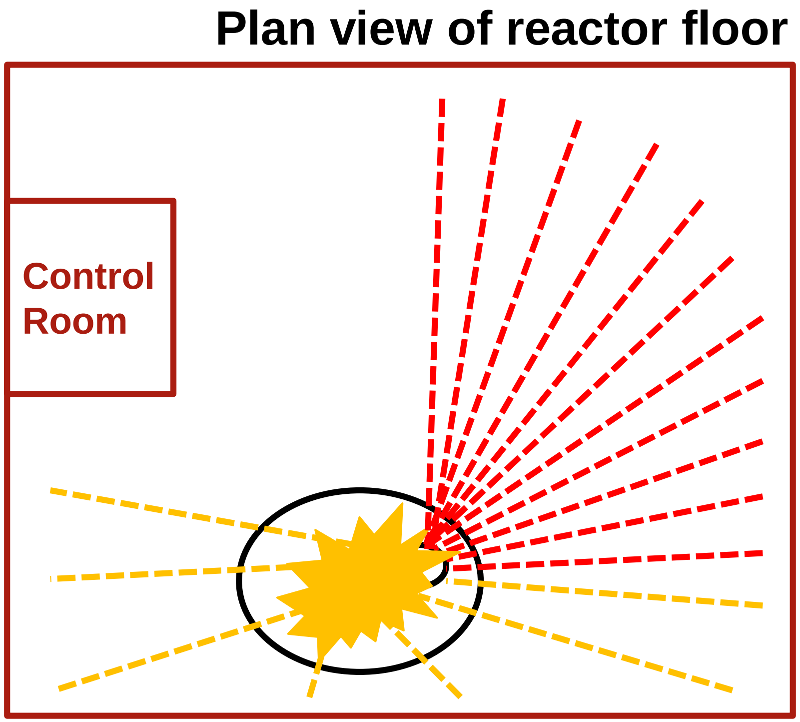
- Contract worker, was killed in fire accident.
- Fire was resulted During Manual Charging of the powder to the reactor having solvent.
- Investigation concluded that “during manual charging operation due to the characteristic of the powder material, static charge got generated and acted as ignition source for the flammable vapour atmosphere inside the reactor and resulted into flash fire”. There are no major impact on the facility but contract worker who was charging material was killed.

Runaway Chemical Reaction at Pharma Unit, Ireland, 2008

- 28th April 2008 at 1:25 am
- Reaction between two chemicals in a solvent carrier
- Large energy release
- Severe Consequences
  - Extensive building damage
  - One operator killed and one seriously injured
  - Prohibition notice
  - Site closure

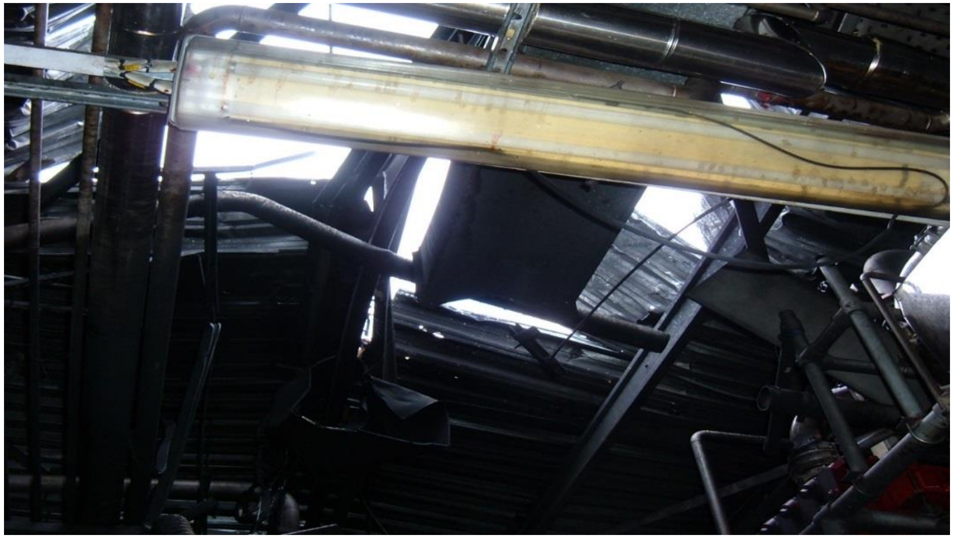
Energy and Material Release Pattern





Impact of Incident Outside

Impact of Incident Inside



Key Findings

- Conclusive evidence that the solvent charge was omitted. This resulted in the right conditions for a runaway reaction / decomposition.
- Despite operating, the emergency relief systems did not cope with this runaway reaction scenario.
- A key root cause of the incident was the failure to fully identify and address solvent omission as a safety critical step in the HAZOP.
- The severity of the incident in terms of human loss was influenced considerably by the lack of a suitable procedure for dealing with loss of control of the reaction.

Lessons Learned

Lessons

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- Runaway chemical reactions can lead to very serious consequences. R&D personnel need to be educated to consider process safety in synthetic route development
- The simple presence of a relief device is not a valid layer of protection, unless that device is adequately sized for the specific worst credible scenario.
- It is important to ensure that thorough reaction hazard assessments are carried out using suitable experimental data to make decisions about the basis of safety.
- Successful HAZOP / risk assessment for potentially hazardous processes requires a competent leader and knowledgeable team.

Lessons

- Knowing the potential severity of an unplanned event is paramount in determining the suitable integrity of incident prevention measures.
- Safety critical steps should be clearly identified in operating procedures and that operators carrying out these steps are trained and have demonstrated their competence.
- The consequences of incidents such as runaway reactions are not limited to the immediate aftermath. The socio-economic devastation can be far reaching affecting families and livelihoods.
- Before relying on operating procedures to prevent incidents, it is important to assess behavioural process safety elements.
- SOP to be followed strictly
- Correct Sequence of charging of the material to be ensured based on the material characteristics.

Lessons

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- Adequate precautions to be taken and included in the permit system in form of checklist. And it to be followed strictly.
- Contractor employees should be trained to follow Adequate safety measures & PPEs.
- Ensure adequate inertization of the reactors having solvent material.
- Ensure the runaway characteristics of the Reaction by carrying out adiabatic calorimetry tests to ensure maximum possible exotherm.
- Use proper earthing & bonding system during manual charging to reactors.

Blueprint for Safety Transformation™ Model

Traditional focus of process / catastrophic event safety has been enabling systems

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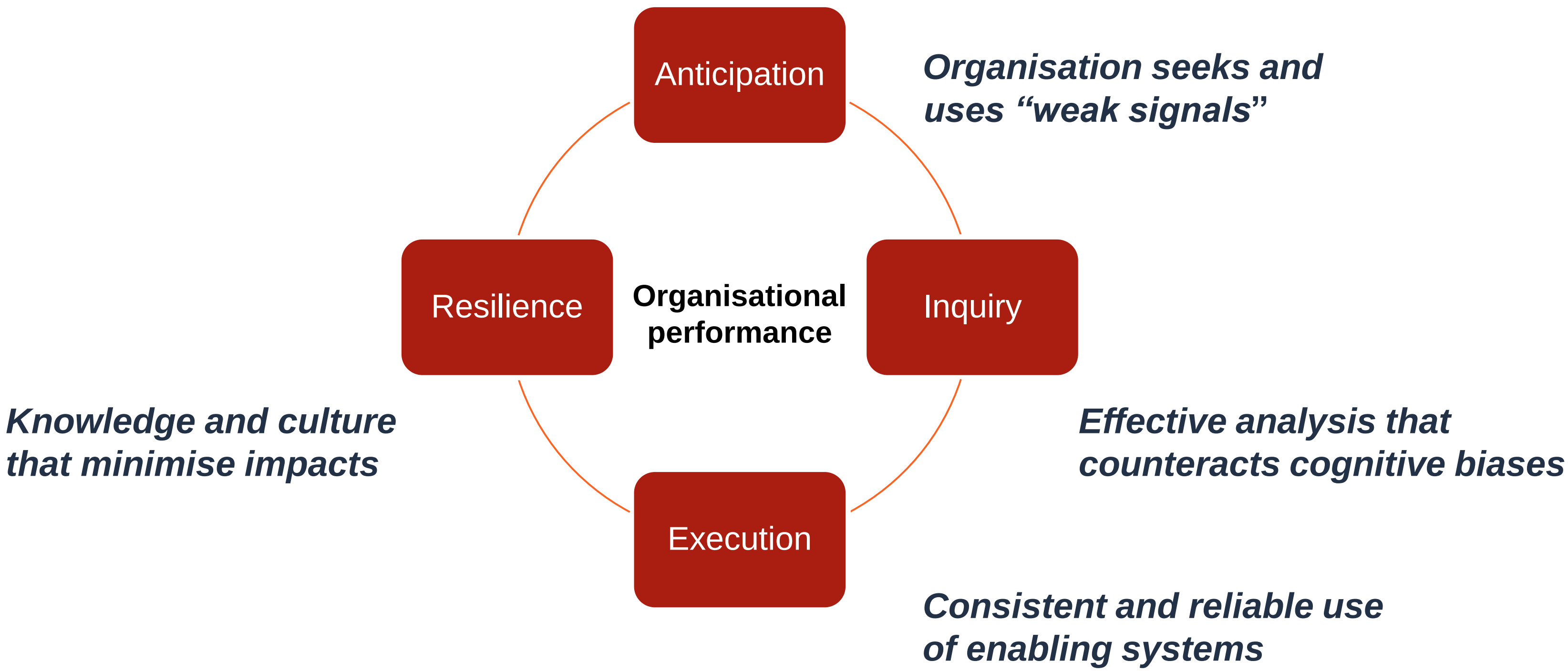
Process Safety Elements

- Process Safety Information
- Process Hazard Assessment (PHA)
- Operating Procedures –
- Training
- Contractor Management
- Mechanical Integrity
- Non Routine Work Authorisations
- Management of Change (MOC)
- Incident Investigation
- Emergency Planning and Response
- Self-Audits

People create and sustain a strong process safety culture



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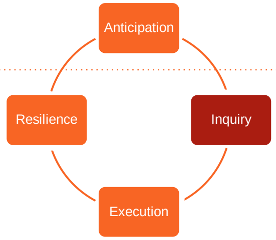
Anticipation

WHAT HAPPENED ….

- Previous incidents and near misses with another reaction process in a different building
- Process known to have high hazard potential
- This reaction had been carried out many times without incident
- Instances of incorrect solvent addition
- Strict time pressure from clients to make product was commonplace (changing the risk profile)

- Awareness of process and personal safety
- Reporting encouraged
- Curiosity encouraged
- Rewards & recognition reinforce desired culture
- All data is acted upon
- Open communication upward and downward

Inquiry



WHAT HAPPENED ….

- Inherently unsafe process with strong reliance on judgement and adding solvent
- When asked if the product could be made under contract, the ability to produce with minimal exposure should have been considered (commercial drivers?)

- Leadership & culture actively work
  to avoid influence of cognitive bias on analyses
- Risk acceptance decisions made by appropriate people
- Value for quality of content (not just "checking the box")
- Open communication upward and downward

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Execution

WHAT HAPPENED ….

- Use of double sign-off for critical steps was widespread
- Often on night shift, a second independent check was not available
- Procedural sign-off assumes competence
- A number of processes were reliant on people making correct decisions and additions
- Lack of periodic reviews of adherence to procedures.

- Leadership & culture support, behavioral reliability & accountability
- All employees feel safe and encouraged to raise issues
- Employees feel ownership for the safety systems
- Issues addressed promptly and with appropriate feedback

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Resilience

WHAT HAPPENED ….

- Operators knew their error and could see the consequence (exothermic event)
- Operator “instinct” was to compensate for this, and to protect the plant
- Operators went to reactor. This was one of the worse things to have done
- Having anticipated this would have saved a life
- Operators did not know what was expected of them in this circumstance
- Well trained operators, who understand the manufacturing process, the safety challenges and where the exposures are increases resilience

- Leadership & culture support employee intervention to minimise impact
- Exceptional conditions, metrics, alarms, etc., consistently produce response
- Exceptional conditions fed back to analysis
- Tolerance of false negatives
- Rewards & recognition reinforce desired culture

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Thank you