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.
Email: birgit.skuballa@bayer.com
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
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.
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
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

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.
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

**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

<table>
<thead>
<tr>
<th>1</th>
<th>2</th>
<th>3</th>
</tr>
</thead>
<tbody>
<tr>
<td>Driving leadership practices at member companies</td>
<td>Enabling suppliers to continuously improve</td>
<td>Improving engagement across the industry &amp; with key stakeholders</td>
</tr>
</tbody>
</table>

## Priority Issues

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

## Governance

- Governing with Transparency and Managing with Accountability
Strategy Framework: **Priority Issues**

**Priority Issues**
What we will influence

**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

- Audit Collaboration
- Capability Building
- Communications
- Governance
Audit Collaboration

• 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 (AstraZeneca)
- 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

• 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

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)
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

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

Wolfgang Rauch
Chief Procurement Officer, Novartis
Novartis, PSCI & You

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

INNOVATIVE MEDICINES

Novartis Oncology

Sandoz

Novartis Pharmaceuticals

R&D

Corporate functions

Business services

Manufacturing

Alcon

Novartis Procurement

3 PSCI Training – Hyderabad, India 2017 - Business Use
The Novartis Global Service Centers are a key enabler of the NBS strategy ...

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

... in 5 locations chosen based on multiple criteria

- **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

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

Rationalizing supply base
Competitive bidding
Negotiation
Using spend

Year-over-year savings

Cost reduction
Cost management
Risk and working capital reduction
Revenue enablement

Supplier innovation
Process re-engineering
Risk management

Standardizing specs
Make vs buy
Setting policy
Encouraging cost discipline

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

Novartis Procurement
3 PSCI Training – Hyderabad, India 2017 - Business Use
Regulated and globally acting industries, like Pharmaceuticals face significant risks - Novartis has responded to this challenge

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

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)

Conducted a ‘Materiality Assessment’, involving Novartis expert functions, to identify best practices and potential gaps

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

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:

• What impact our supply chain has in the communities where we buy

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• How we can use our collective influence to improve labor, health & safety, and other rights of workers across the pharmaceutical supply chain

Information Source: PSCI, 2017
Using our collective influence to drive change

PSCI ethos

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

Information Source: PSCI, 2017
Thank You
Process Safety Management Session
Quantitative Risk Assessment (QRA)

Presented by
Sakila Bhadu
Senior Manager
Dekra Insight
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

WHY QRA

QRA Basics

Hazard Screening

Defining Source Terms

The Consequence Models (Fire, Explosion, toxic release)
Agenda

- Estimating the Event Frequency and the Risk
- Risk Acceptability and Criteria
- Interpreting and Using Risk Assessment Results
WHY QRA
Why Risk Assessment?

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

Define risks here.
## Simple Risk Assessment

<table>
<thead>
<tr>
<th>Hazard</th>
<th>Causes</th>
<th>Consequence</th>
<th>Safeguards</th>
<th>Actions</th>
</tr>
</thead>
<tbody>
<tr>
<td>Fall from height</td>
<td>Man slips</td>
<td>Possible death or serious injury</td>
<td>Platform</td>
<td>Man should wear harness Cage around platform</td>
</tr>
<tr>
<td>Fall from height</td>
<td>Platform fails</td>
<td>Possible death or serious injury</td>
<td>None</td>
<td>Platform safety checks</td>
</tr>
</tbody>
</table>
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
Simple Approach?

Complexity

Major hazard

Serious consequences
Reason for QRA

- 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
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
Seveso II

- 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

• 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

• New project
  – Major process hazards
  – Likely to be made early

• External
  – Regulatory
  – Insurance
  – Planning

• PSM policy
When on a project?

Decision made here

Typical start point for QRA
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

1. Hazard
2. Frequency
3. Consequence
4. Quantification
5. Acceptability
6. Reduction

Quantified risk
QRA Flowchart

HAZARD IDENTIFICATION

Can Hazard Be Eliminated Cost Effectively?

No

CONSEQUENCE ANALYSIS

Can consequences be eliminated or reduced

No

QUANTIFICATION OF EVENT PROBABILITY AND RISK

Does Risk Meet Agreed Criteria?

Yes

TOLERABLE / ACCEPTABLE ACTIVITY

No

Eliminate Hazard

Make Improvements and Re-assess

Implement and Re-assess
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
HAZARD SCREENING
Hazard Screening - Techniques for identifying major hazards

- HAZOP
- FMEA
- What-If
- Hazard Review
Consequence
The consequence models (fire, explosion, toxic release)

- Toxic gas
- Fire
- Explosion
Fire and explosion types
vapour/gas dispersion

- 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
Estimating the Event Frequency and the Risk
Estimating the event frequency and the risk

• 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

• Risk determination is conditioned by how are we willing to represent the risk.

• Two types of outputs can be obtained from a QRA:
  - Individual Risk
  - Societal Risk

• In any case, the use of a specific software is strongly advised!
Representation of IR

- **Location specific risk contours**: 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)

<table>
<thead>
<tr>
<th>Worker group</th>
<th>PLL</th>
<th>IR</th>
</tr>
</thead>
<tbody>
<tr>
<td>Administration</td>
<td>2.31E-05</td>
<td>1.86E-07</td>
</tr>
<tr>
<td>Maintenance</td>
<td>9.03E-03</td>
<td>8.92E-05</td>
</tr>
<tr>
<td>Operators</td>
<td>1.31E-02</td>
<td>2.85E-04</td>
</tr>
<tr>
<td>Laboratory</td>
<td>4.72E-06</td>
<td>4.62E-07</td>
</tr>
<tr>
<td>Security</td>
<td>4.90E-09</td>
<td>5.13E-10</td>
</tr>
<tr>
<td>Visits</td>
<td>4.31E-04</td>
<td>6.8E-06</td>
</tr>
</tbody>
</table>

• 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

<table>
<thead>
<tr>
<th>Region</th>
<th>Workers</th>
<th>General Public</th>
</tr>
</thead>
<tbody>
<tr>
<td>Intolerable</td>
<td>$1 \cdot 10^{-3}$</td>
<td>$1 \cdot 10^{-5}$</td>
</tr>
<tr>
<td>Broadly acceptable</td>
<td>$1 \cdot 10^{-4}$</td>
<td>$1 \cdot 10^{-6}$</td>
</tr>
</tbody>
</table>
Tolerability of Risk

- **Unacceptable Region**: Risk cannot be justified save in extraordinary circumstances.
- **Tolerable Region**: Control measures must be introduced in this region to drive residual risk to the broadly acceptable region.
- **Broadly acceptable Region**: Risk is tolerable only if effort required to reduce it further is grossly disproportionate to the reduction achieved.
- **Negligible risk**: 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.

Increasing Individual risks and societal concerns
Interpreting and Using Risk Assessment Results
Interpretation of Results

• 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

• 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

- 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
PSMI in Pharma and Enterprise Sustainable Development

Presented by

Jitendra Kumar

Director

CTPL- Dekra Insight
Bio

- Jitendra is Director at Chilworth leading the business in India and most parts of Asia.
- 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

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OSHA PSM Overview
Why OSHA PSM?

Valero Refinery, Feb 2007
Venezuela Oil Refinery, 2012
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

<table>
<thead>
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<td>Medium</td>
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</table>

- **Occupational Safety**
- **Process Safety**
Why PSM in Pharma?

High severity (consequence) incidents possible:

• Solvents
• Powders
• Toxics
• Chemical reactions
Why PSM in Pharma?

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

- **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 elements from the following narrative:

During a routine inspection of equipment, the maintenance worker discovers a valve that no longer meets the applicable code and must be changed. Since the type of valve is no longer made, a different type of valve must be selected and installed. The type of valve selected will mandate different steps for the operators, who will require training and verification in the new procedures. The rationale for selecting the type of valve must be made available for review by employees and their representatives.

When the new valve is installed by the supplier, it will involve shutting down part of the process as well as brazing some lines. The employer must review the response plan to ensure 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

- 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

• 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.)

• 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)

- 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
Importance of Process Hazards Analysis (PHA)

- 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

• 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

- 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

- 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

• 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, but had the potential to do so.
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.)

• 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
Importance of Audits

• Audits ensure that the process safety systems are in place and working as intended.
Requirements

• 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

<table>
<thead>
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<th>Quality Standard</th>
<th>Operating Procedure</th>
<th>12 2.3 Nonconformance Report</th>
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<td>Approval Date</td>
<td>Approved by</td>
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<tr>
<td>March 10, 2010</td>
<td>March 10, 2010</td>
<td>Quality Manager</td>
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### 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. 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.


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.
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

• 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.)

- 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
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
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

- 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.
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

• 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.
MOC Process

INITIATE CHANGE

APPROVAL

NOTIFICATION

IMPLEMENT

DOCUMENT
Requirements of MOC

• 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

• 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

Guidelines for Performing Effective Pre-Startup Safety Reviews

CD-ROM Included

CCPS - CHEMICAL PROTECTIVE SAFETY
AICHE Industry Technology Alliance

WILEY
Importance of PSSR

• 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
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

- 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
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)

Process Safety Related Fatalities
(per 1,000 employees)

United States BLS data
Beyond Compliance - Commitment to Safety

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

“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!
TYPICAL IGNITION SOURCE ANALYSIS IN PHARMACEUTICAL PLANTS

Presented by

Naveen D
Assistant manager
Chilworth Technologies Pvt. Ltd.
(a DEKRA Company)
Bio

- 8+ years of experience
- 100+ Process Risk & Safety consultancy projects
- EHS audits in pharmaceuticals
- Experience in Engineering and Design

Naveen Devara
Assistant manager – Safety & Risk
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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 $3 \times 10^{12}$ Hz

9. Visible electromagnetic radiation, $3 \times 10^{11}$ Hz to $3 \times 10^{15}$ Hz

10. Ionising electromagnetic radiation

11. Ultrasonic

12. Adiabatic compression and shock waves

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

Preventive or protective measures are needed
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**

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</table>
FLAMES AND HOT GASES (INCLUDING HOT PARTICLES)

- 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)

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

Example:

- Impact: hand tool, power tool, boot stud, loosening of caked material.

- Rubbing: belt, conveyor, roller, skidding of road tanker.
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 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.
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
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 $3 \times 10^{12}$ Hz

- 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.
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.
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

- 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

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

Example Format:

<table>
<thead>
<tr>
<th>No.</th>
<th>Ignition hazard analysis (Step 1)</th>
<th>Assessment of the frequency of occurrence without application of an additional measure (Step 2)</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Potential Ignition Source</td>
<td>Description of the basic cause</td>
</tr>
<tr>
<td>1.</td>
<td>Electrostatic discharge</td>
<td>Parts of non-metallic material with a surface resistance exceeding 1Gohms</td>
</tr>
</tbody>
</table>
In this step the individual ignition hazards are evaluated to determine, how often an individual ignition source may become effective.

Example Format:

<table>
<thead>
<tr>
<th>No.</th>
<th>Potential Ignition Source</th>
<th>Description of the basic cause</th>
<th>Assessment of the frequency of occurrence without application of an additional measure (Step 2)</th>
</tr>
</thead>
<tbody>
<tr>
<td>1.</td>
<td>Electrostatic discharge</td>
<td>Parts of non-metallic material with a surface resistance exceeding 1Gohms</td>
<td>During normal operation</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>X</td>
</tr>
</tbody>
</table>
DETERMINATION OF MEASURES AND EQUIPMENT CATEGORIZATION

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

<table>
<thead>
<tr>
<th>Measures applied to prevent the ignition source becoming effective (Step 3)</th>
<th>Frequency of occurrence incl. all measures (Step 4)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Description of the measure</td>
<td>Basis (citation of standards)</td>
</tr>
<tr>
<td></td>
<td></td>
</tr>
</tbody>
</table>
EXAMPLE OF AN IGNITION HAZARD ASSESSMENT

Fig: Vibratory Sifter:
## EXAMPLE OF AN IGNITION HAZARD ASSESSMENT

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

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

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

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
CONTROL OF IGNITION HAZARDS

RADIO FREQUENCY (RF) ELECTROMAGNETIC WAVES FROM $10^4$ Hz TO $3 \times 10^{12}$ 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.
CONTROL OF IGNITION HAZARDS

ELECTROMAGNETIC WAVES FROM $3 \times 10^{11}$ Hz TO $3 \times 10^{15}$ 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

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
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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Chilworth Technology P Ltd
Email: sunil.deshmukh@dekra.com
<table>
<thead>
<tr>
<th></th>
<th>Agenda</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>Understanding Flammable Atmospheres &amp; Explosion Hazards</td>
</tr>
<tr>
<td>2</td>
<td>Conditions For A Vapour Explosion</td>
</tr>
<tr>
<td>3</td>
<td>Conditions For A Dust Cloud Explosion</td>
</tr>
<tr>
<td>4</td>
<td>Different Electrostatic Discharges</td>
</tr>
<tr>
<td>5</td>
<td>Explosion Prevention Techniques</td>
</tr>
<tr>
<td>6</td>
<td>Explosion Protection Techniques</td>
</tr>
<tr>
<td>7</td>
<td>Questions and Wrap up</td>
</tr>
</tbody>
</table>
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

Oxidant

Mixing

Confinement

Fuel

Ignition source
Fire Or Explosion?

- In an explosion fuel and oxidant are mixed
What Is An Explosion?

- **Explosion** - Confinement Required
- **Flash Fire** - Unconfined
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 sustained 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


<table>
<thead>
<tr>
<th>LIQUIDS</th>
<th>LFL (%V/V)</th>
<th>UFL (%V/V)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Acetone</td>
<td>2.5</td>
<td>12.8</td>
</tr>
<tr>
<td>1-Butanol</td>
<td>1.4</td>
<td>11.2</td>
</tr>
<tr>
<td>Toluene</td>
<td>1.1</td>
<td>7.1</td>
</tr>
<tr>
<td>Carbon-disulfide</td>
<td>1.3</td>
<td>50</td>
</tr>
<tr>
<td>Methyl Alcohol</td>
<td>6</td>
<td>36</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>GASES</th>
<th></th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>Hydrogen</td>
<td>4</td>
<td>75</td>
</tr>
<tr>
<td>Butane</td>
<td>1.9</td>
<td>8.5</td>
</tr>
<tr>
<td>Methane</td>
<td>5</td>
<td>15</td>
</tr>
<tr>
<td>Ethylene</td>
<td>2.7</td>
<td>36</td>
</tr>
</tbody>
</table>
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)
CONDITIONS FOR A DUST CLOUD EXPLOSION
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).

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 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)

- **a** PRIMARY EXPLOSION
- **b** BLAST WAVE
- **c** EXTENSIVE SECONDARY EXPLOSION

**DUST LAYER**

**DUST CLOUD FORMED**

**RESULTS**
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

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, \(< 0.1 \text{ mJ}\)

- **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
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 clouds
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
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
• 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 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
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.
Sparks produced during normal working of switches, contact breakers, motors, fuses, etc can ignite gas, vapor, and dust cloud atmospheres
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
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
Explosion Suppression Examples

fluid bed dryer
dust collector
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
Thank you
Hazardous Area Classification

Presented by

Pierre Reuse
Head HSE & BC Third Party Inspection and Compliance
Novartis
Bio

- Chemical Engineer, PhD in Heterogeneous Catalysis
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Agenda

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

Solvent vapour

Concentration gradient

Air
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)

- No Explosion
  - “too poor”
  - Not enough fuel

- Explosion

- No Explosion
  - “too fat”
  - Not enough air

Fuel concentration in air
Ignition sources

- Electrical ignition sources
- Hot Surface
  - Glowing Nests
- Electrostatic Discharges
- Flames
  - Mechanical Sparks
Agenda

1. Review of explosion basics
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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

<table>
<thead>
<tr>
<th>Zone</th>
<th>Operational area</th>
</tr>
</thead>
</table>
| 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 |
Examples

Outside drum storage

Outside tank storage

Inerted vessel (controlled inertisation)
Zone Definition for «dust» Atmosphere

**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

<table>
<thead>
<tr>
<th>Zone</th>
<th>Operational area</th>
</tr>
</thead>
</table>
| 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

Distance between 1 to 3 m depending on situation

Addition in vessel with controlled inertisation

Zone 20  Zone 21  Zone 22
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)

- 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

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 under 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.
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

Non Hazardous Area

Zone 1

Zone 2

Zone 0

Hazardous Area
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

<table>
<thead>
<tr>
<th>Zone</th>
<th>Class / Division</th>
<th>Zone</th>
<th>Class / Division</th>
</tr>
</thead>
<tbody>
<tr>
<td>0</td>
<td>I / 1</td>
<td>20</td>
<td>II / 1</td>
</tr>
<tr>
<td>1</td>
<td>I / 1</td>
<td>21</td>
<td>II / 1</td>
</tr>
<tr>
<td>2</td>
<td>I / 2</td>
<td>22</td>
<td>II / 2</td>
</tr>
</tbody>
</table>

#### Class I, Flammable Gases, Vapours Or Liquids

<table>
<thead>
<tr>
<th>Division 1:</th>
<th>Zone 0:</th>
</tr>
</thead>
<tbody>
<tr>
<td>Where ignitable concentrations of flammable gases, vapours or liquids can exist all or some of the time under normal operating conditions.</td>
<td>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.</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Division 2:</th>
</tr>
</thead>
<tbody>
<tr>
<td>Where ignitable concentrations of flammable gases, vapours or liquids are not likely to exist under normal operating conditions.</td>
</tr>
</tbody>
</table>

#### Class II, Combustible Dusts

<table>
<thead>
<tr>
<th>Division 1:</th>
</tr>
</thead>
<tbody>
<tr>
<td>Where ignitable concentrations of combustible dusts can exist all or some of the time under normal operating conditions.</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Division 2:</th>
</tr>
</thead>
<tbody>
<tr>
<td>Where ignitable concentrations of combustible dusts are not likely to exist under normal operating conditions.</td>
</tr>
</tbody>
</table>
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1. Review of explosion basics
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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.
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)

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

<table>
<thead>
<tr>
<th>Label of the notified body, and graphic Ex-Label</th>
<th>Equipment Group (II for the process industry)</th>
<th>D for dust</th>
<th>Equipment category, see above</th>
<th>Protection type, see EN 50015-21, 50028 and 50039</th>
<th>Dust Group (options: IIIA, IIIB or IIIIC)</th>
<th>Maximum surface temperature: (the value is directly indicated for equipment to be used in dust zones)</th>
</tr>
</thead>
</table>
Agenda

1. Review of explosion basics
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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.

<table>
<thead>
<tr>
<th>Zone</th>
<th>Explosive atmosphere</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>does not occur</td>
</tr>
<tr>
<td></td>
<td>is not likely during normal operations or only for short period</td>
</tr>
<tr>
<td></td>
<td>is likely to occur in normal operation</td>
</tr>
<tr>
<td></td>
<td>occurs continuously or for long periods or frequently</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Ignition source</th>
<th>None</th>
<th>2/22</th>
<th>1/21</th>
<th>0/20</th>
</tr>
</thead>
<tbody>
<tr>
<td>A. occurs during normal operation</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>B. does not occur during normal operation but only as a result of rare malfunctions</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>C. does not occur during normal operation but only as a result of very rare malfunctions</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>D. does not occur</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

- 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).

<table>
<thead>
<tr>
<th>MIE (mJ)</th>
<th>&lt;3</th>
<th>3-10</th>
<th>10-30</th>
<th>30-100</th>
<th>100-300</th>
<th>300-1000</th>
<th>&gt;1000</th>
</tr>
</thead>
<tbody>
<tr>
<td>MIT (°C)</td>
<td>any</td>
<td>&lt;500</td>
<td>&lt;465</td>
<td>&lt;430</td>
<td>&lt;395</td>
<td>&lt;360</td>
<td>&lt;325</td>
</tr>
</tbody>
</table>
Other ignition sources

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.
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.
Process Safety Accidents in Pharmaceutical Industry & Lessons Learned

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

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<td>Details of the Accidents</td>
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<tr>
<td>3</td>
<td>Impact of Accident</td>
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<td>Blueprint for Safety Transformation Model</td>
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<td>7</td>
<td>People create and sustain a strong process safety culture</td>
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<tr>
<td>8</td>
<td>Questions and Wrap up</td>
</tr>
</tbody>
</table>
Process Safety Accidents in Pharmaceutical Industry & Lessons Learned

Sunil Deshmukh, Sr. Consulting Engineer
Chilworth Technology Pvt. Ltd.
Accidents Happed in Past

- 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.
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

- 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 happened during the solvent charging operation. After investigation, it was concluded that root cause for the accidents are unavailability of the N2 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.
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

Elevation

Plan view of reactor floor

Control Room
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

- 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

- 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

- **Leadership**
  - Organisational Culture
  - Facilities & Equipment
  - Working Interface

- **Organisational Sustaining Systems**
  - Selection and Development
  - Structure
  - Performance Management
  - Rewards and Recognition

- **Safety Enabling Systems**
  - Hazard Recognition and Mitigation
  - Skills, Knowledge, and Training
  - Policies and Standards
  - Exposure Reduction Mechanisms

- **Worker**
- **Processes**
Traditional focus of process / catastrophic event safety has been enabling systems

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

- **Anticipation**: Organisation seeks and uses “weak signals”
- **Inquiry**: Effective analysis that counteracts cognitive biases
- **Execution**: Consistent and reliable use of enabling systems
- **Resilience**: Knowledge and culture that minimise impacts

Organisational performance
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
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
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
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
Thank you