PSCI PHARMACEUTICAL SUPPLY CHAIN INITIATIVE

Building responsible supply chains

Opening Remark

Harish K Jain

President of Karnataka Drugs & Pharmaceuticals Manufacturer's Association (KDPMA)

PSCI PHARMACEUTICAL SUPPLY CHAIN INITIATIVE

Building responsible supply chains

Welcome everyone!

A bit about KDPMA

Karnataka Drugs And Pharmaceuticals Manufacturer's Association

- Formed in the 1960s
- Focus on solving various problems of the pharmaceutical industry in the state of Karnataka.
- Engaged positively with **various government departments authorities**, such as, Drugs Control Department, Drugs Controller General of India, Central Excise, Commercial Taxes Department, State Excise Department, Karnataka State Pollution Control Board, etc.
- Regularly conduct knowledge sharing seminars for the benefit of our members
- Have MOU's with many universities and associations that bring value to members
- Lead delegations to many trade fairs and conferences in India and abroad

Our members

- A few of them are also PSCI members…


National College of Pharmacy


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Addressing the challenge

Our partnership with PSCI

- MoU in place
- Have established a healthy relationship
- Exchange of PSCI promotional, other material and invite to key events.
- Push SME's to use the partnership to improve their capabilities

PSCI PHARMACEUTICAL SUPPLY CHAIN INITIATIVE
Building responsible supply chains

Karnataka Drugs And Pharmaceuticals Manufacturer's Association

PSCI – Adding value

- The post covid marketplace is going to be very different. We are already seeing the changes post covid from shortages in essential drugs to chips to the containers to carry our goods. ‘ **Make at Home** “ is the mantra with most governments especially in essential commodities . In India, the Government has announced a series of Production linked incentives on Pharma, API’s and KSMs to push for local production. Most other companies are doing this.

  This will drive new alignment & disruption in existing supply Chain is also a big opportunity.

  Expectations of global companies will increase .

  PSCI plays a pivotal role to help companies adapt as they scale up or launch new facilities. This is best time to adopt sustainable business practices and line up with PSCI as we start.

- Cost as a factor will slowly reduce putting pressure on companies to step up on other factors like sustainable manufacturing, best management practices and quality as these factors become important.
- Companies should use the knowledge bank that PSCI has to absorb it at the design stage and upgrade.

PSCI – Adding value

- Environment and health & safety have come to the forefront and high on the agenda of governments like India . There is no waiting for tomorrow anymore .Companies should make use of existing best practices to be prepared.
- Would like to recommend that PSCI to play a pivotal role and open up the training resources to non members (at a cost) or have a limited access member possibility for MSME's . This will help expand the reach of PSCI and also be of great value to the industry

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PSCI

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About the Secretariat
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PSCI PHARMACEUTICAL SUPPLY CHAIN INITIATIVE

Building responsible supply chains

ISO 45001:2018: Occupational Health & Safety Management System

Unravelling the Basics

ERM

SPEAKER BIO

- Name: Anupam Bhattacharyya, Idip-OSH, RSP
- Job Title: Principal Consultant
- Organization: ERM India Private Limited
- Contact: anupam.bhattacharyya@erm.com; M (+91-9582359446)

Anupam is presently working at the capacity of **Principal Consultant** based out of ERM's Kolkata office, India. Anupam has about 11 Years of demonstrated experience in assisting clients with wide range of HSE consulting and advisory services across industrial sectors in wide geographic regions including **South Asia** (India, Bangladesh, Nepal, Bhutan, Brunei), **Middle East** (UAE, Oman, Jordan) and **Africa** (South Africa, Ethiopia and Sierra Leone), USA & Australia (remotely).

Anupam specializes in the development and implementation of HSE Management System (ISO 45001, ISO 14001, IFC PS), Audits (275+ audits), EHS-DD, Phase I ESA, PSM Audits, Training services (1000 hours+), HSE Compliance Management, Safety culture transformation, BBS *etc*.

He has been engaged in development of HSE Management System for **25+ MNC** client Sites (across sectors) and have conducted **60+ PSCI assessments** for major Pharmaceutical companies in India.

AGENDA

Context Setting

What is ISO 45001:2018 and advantages

Migration from OHSAS 18001 to ISO 45001

ISO 45001:2018 Requirements: Outline

PSCI Expectations and relevance of ISO 45001:2018

Context Setting – Why ISO 45001:2018

- **2.3 million** women and men around the world succumb to work-related accidents or diseases every year; this corresponds to over **6000 deaths every single day**;
- Worldwide, there are around **340 million** occupational accidents and **160 million** victims of work-related illnesses annually;
- The corresponding loss of workdays accounts for almost **4%** of the world's GDP, or some **US$3.2 trillion**;
- Diseases related to work cause the most deaths among workers. Hazardous substances alone are estimated to cause **651,279** deaths a year;
- There are **860,000** occupational accidents every day, with consequences in terms of injuries;
- Every **15 seconds** a worker dies from a work-related accident or disease, and **153 people** experience a work-related injury.

Reference: ILO, World Congress on Safety and Health at Work

Context Setting – Why ISO 45001:2018

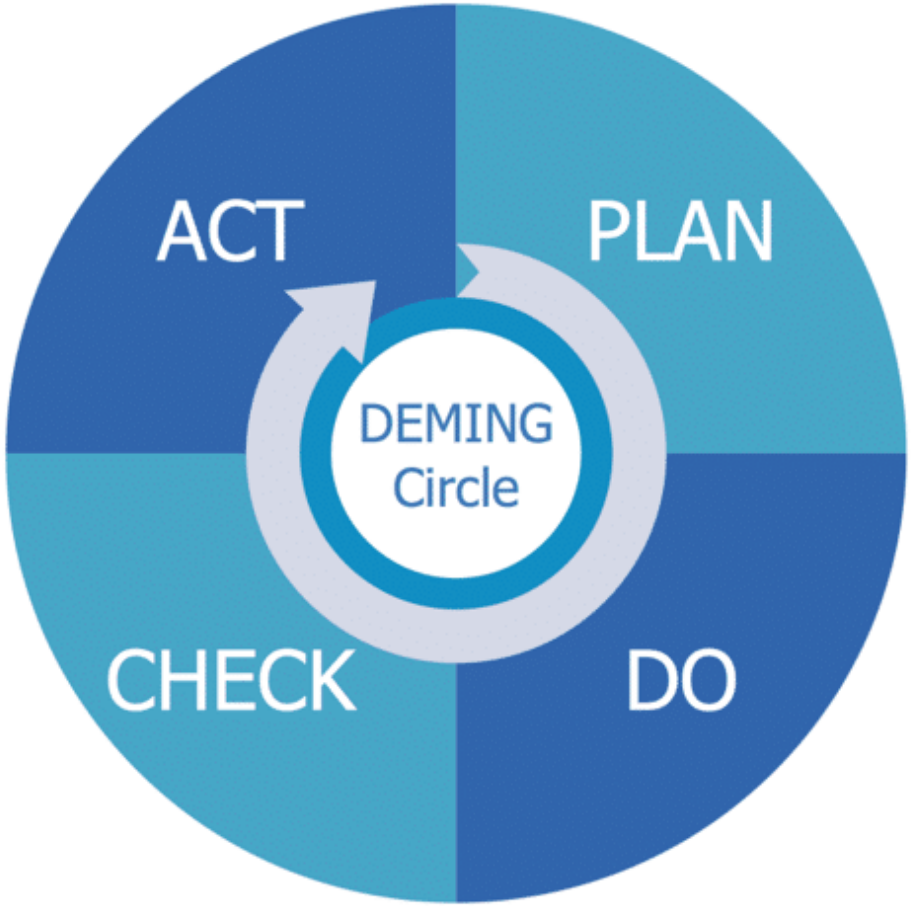
Key causes of workplace accidents:

- Failure to identify workplace safety hazards and risks/ Poor risk perception;
- Inadequacy of controls;
- Lack of management commitment and focus;
- Normalizing deviations;
- Cognitive biases: Optimism, Herding bias, Amnesia, Myopia *etc.;*
- Production over human safety;
- Lack of workers participation, motivation;
- Over reliance on contractors;
- Absence of monitoring and supervision;
- Failure to manage change;
- Cumbersome procedures: Safety only on paper;
- Absence of systematic approach to manage risk at workplace.

A step change with ISO 45001:2018:

- Provides a comprehensive Framework to manage H&S Risks at the workplace in a systematic manner;
- Usher in possibilities of reduced workplace incidents;
- Reduce downtime by minimizing disruption of the operations leading to increase in productivity;
- Enhanced Stakeholder's trust (Customer, Investor, Shareholders, employees)
- Lower insurance costs
- Foster management involvement & accountability;
- Establishing foundation of a strong Safety culture.

Context Setting – Why ISO 45001:2018

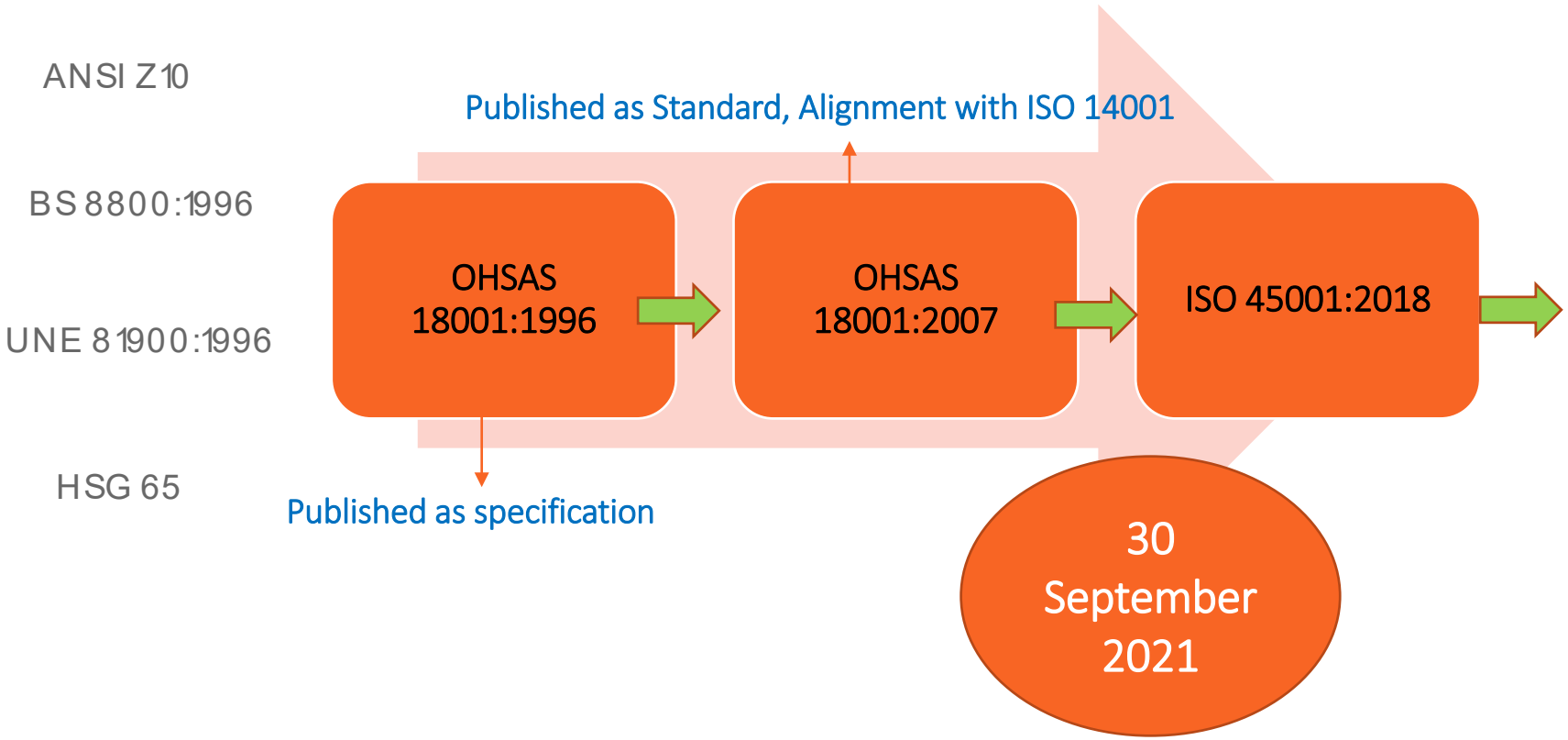


Occupational Health & Safety Management System

- Enable organizations to provide safe and healthy workplaces by preventing work-related injury and ill health,
- Continual improvement of OH&S performance;
- Fulfilment of legal requirements and other requirements;
- Achievement of OH&S objectives.

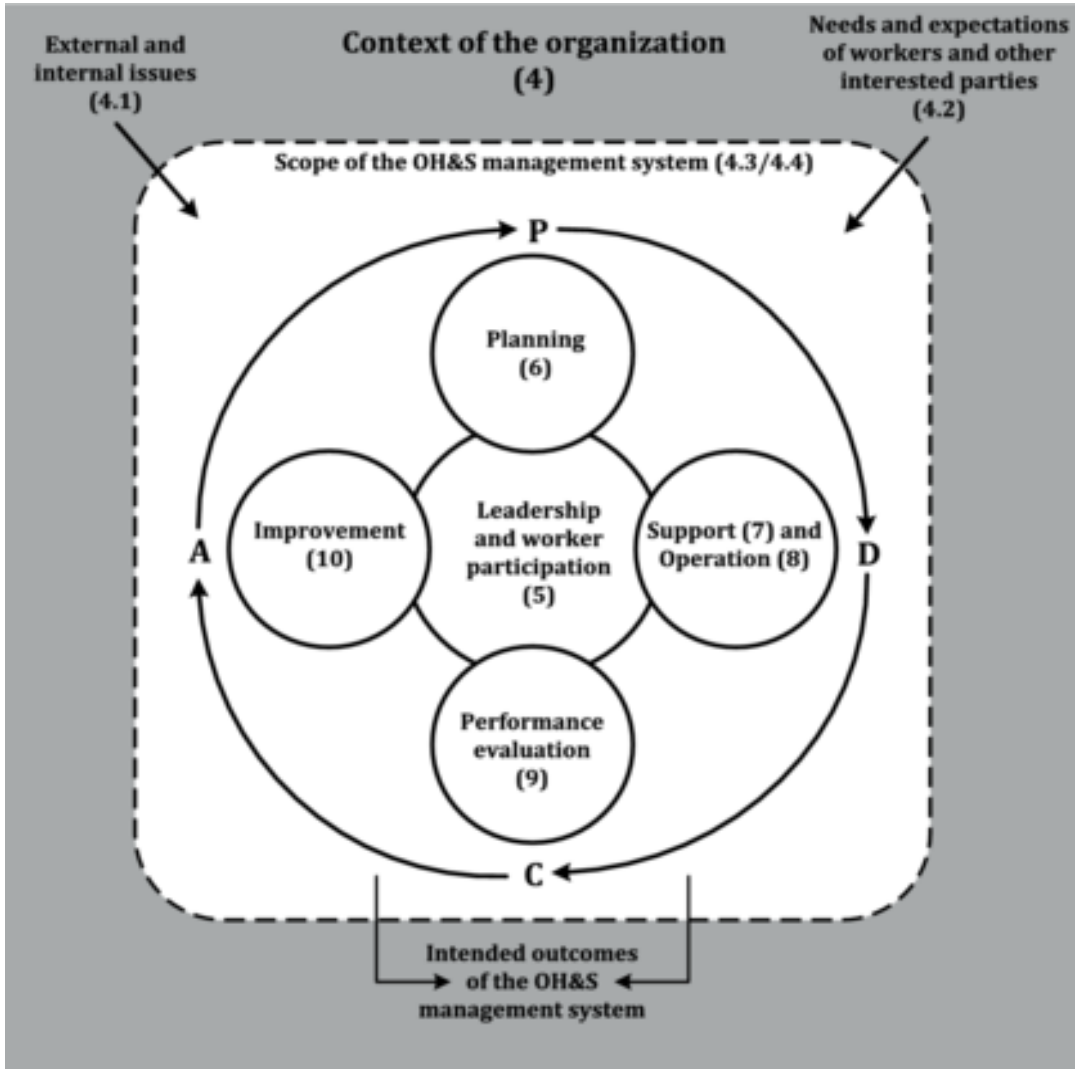
The journey from OHSAS 18001 to ISO 45001

ISO 45001 concentrates on the interaction between an organization and its working environment while OHSAS 18001 was focused on managing the occupational health and safety hazards and issues related to it.



- High Level Structure (HLS)
- Leadership & Management Commitment
- Worker Consultation & Participation
- PROCESS Approach
- RISK based thinking
- Risk & Opportunity Management
- Life Cycle Approach
- Needs and expectation from Stakeholders
- Proactive approach

PDCA – ISO 45001:2018



1. Scope
2. Normative references
3. Terms and definitions
4. Context of the organization
5. Leadership and worker participation
6. Planning
7. Support
8. Operation
9. Performance evaluation
10. Improvement

Anatomy of ISO 45001:2018

PLAN			DO		CHECK	ACT
4. Context of the organization	5. Leadership and workers participation	6. Planning	7. Support	8. Operation	9. Performance and Evaluation	10. Improvement
4.1 Understanding the organization and its context	5.1 Leadership and commitment	6.1 Actions and address risks and opportunities	7.1 Resources	8.1 Operational and Planning Control	9.1 Monitoring, measurement, analysis and performance evaluation	10.1 General
4.2 Understanding the needs and expectations of workers and other parties	5.2 OH&S policy	6.2 OH&S objectives and planning to achieve them	7.2 Competence	8.2 Emergency Preparedness Response	9.2 Internal Audit	10.2 Incident, Nonconformity and corrective actions
4.3 Determining the scope of OH&S management system	5.3 Organizational roles, responsibilities and authorities		7.3 Awareness		9.3 Management review	10.3 Continual Improvement
4.4 OH&S management system	5.4 Consultation and Participation of workers		7.4 Communication			
			7.5 Documented Information			

PSCI Assessment and relevance of ISO 45001:2018

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

PSCI Assessment and relevance of ISO 45001:2018

Q 1: Does the facility have any current ethics, labor, environment, **health and safety management system** accreditations, certifications, or awards?

Q 3: Does the facility assess ongoing compliance with Health, Safety, and Environment, Business Ethics issues, and Labor regulations? (Clause 9.1.2 of ISO 45001:2018)

Q 4: Does the facility have processes in place to enforce responsible business practices, aligned with the PSCI Principles, with their suppliers, i.e. Labour, Ethics, Environment, Health & Safety? (Clause 5.2 of ISO 45001:2018)

Q 6: Does the facility or company have a process to manage all changes (e.g. raw materials, processes, personnel non-GMP, facilities, etc.) (Clause 8.1.3 of ISO 45001:2018)

Q: 11: Does the facility or company have formal processes and procedures to assess the effectiveness of its labour, ethics and HSE (**Health, Safety** & Environment) practices, to identify and implement corrective actions and/or recommendations, and to track corrective actions? (8.1 of ISO 45001:2018)

PSCI Assessment and relevance of ISO 45001:2018

Q:47 - Does the facility have a written Health & Safety policy, procedures, and practices? (Clause 5.2, 8.1 of ISO 45001:2018)

Q:48 - Does the facility have any documented Health & Safety objectives and targets or goals for performance improvement, including metrics? (Clause 6.2.1 of ISO 45001:2018)

Q 50: Does the facility provide HSE (Health, Safety & Environment) training to employees (full-time, temporary, or contractor)? (Clause 5.4, 7.2 of ISO 45001:2018)

Q 58: Does the facility use any of the following processes for managing risks related to contractor activity onsite? (Clause 8.4.1.2 of ISO 45001:2018)

Q 65: Does the facility perform risk assessments for chemicals handled? (Clause 6.1.2 of ISO 45001:2018)

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."

Question and Answer

QUIZ / POLL

- Please feel free to add quiz or live polling if you would like to interact with the audience.

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PSCI

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PSCI PHARMACEUTICAL SUPPLY CHAIN INITIATIVE

Building responsible supply chains

Contractor Safety Management

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AGENDA

Basic introduction – definition, regulations

Contractor Safety Management - Challenges in India

Key elements of Contractor Safety management

Contractor Management some best practices

PSCI Questions w.r.t. Contractor Management

Common observations during PSCI supplier audits

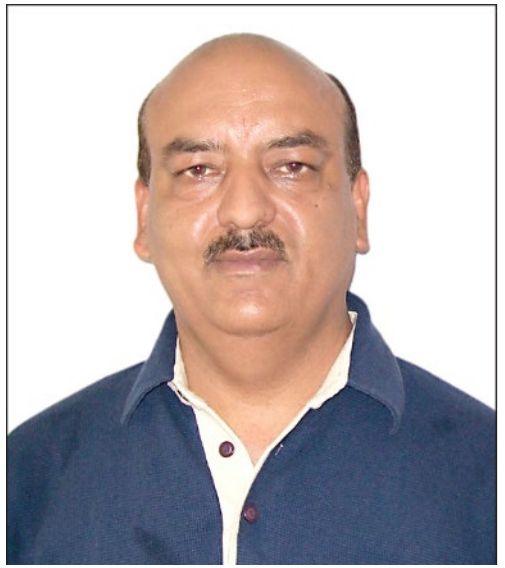
Bio

ROBERTA HASKI

Company Role	
2015 - present	HSE Adviser, Elanco Asia- Pacifc, Japan, ANZ
2012 – 2015	Legal work and practice
Prior to 2012	Variety of positions in HSE and HR senior management at global pharmaceutical company, university, hospital.
2011:	Variety of consulting work.
2011:	Admitted to practice law, graduated JD from UTS
2007	MLLR – Sydney Uni
Prior to 2007	MSc – UNSW
	BSc – Sydney Uni

Bio

RAJIV NARANG



Company Role	
Present	Associate Director Safety, Health & Environment – Corporate
	Centrient Pharmaceuticals (previously known as DSM Sinochem Pharmaceuticals)
	Rajiv.Narang@centrient.com
2015 / 2016	Special assignment as Corporate Safety, Health and Environment auditor with DSM Netherlands Corporate.
1996 – 2017	Various roles in Safety, Health and Environment
1986 – 1996	Various roles in Production
1986	Graduation from Punjab University, Chandigarh

Contractors

- Contractor; The term 'Contractor' refers to any individual or organisation who enters into an agreement (either written or orally) with a Company to carry out services.
- The scope for contractors can be wide enough to cover any type of work covering major projects to day to day activities e.g. housekeeping and cleaning, security services, electrical services, plumbing services, specific maintenance and repair of equipment, etc.
- Today we shall limit ourselves to Contractors related to projects , construction and maintenance activities.
- Contract labour hire is out of scope of this presentation – they should be treated as you treat your employees

Contractor Safety Management - Regulations

- Indian Factories Act 1948
- The Companies Act, 2013
- As per Indian regulations the Principal employers is responsible for compliance including of contractors.
- The Occupational Safety, Health and Working Conditions Code (OSH) is a bill, currently under consideration for enactment by the Indian Parliament. The proposed OSH Code repeals and replaces 13 labour laws relating to health, safety and working conditions.

Contractor Safety Management – Challenges in India

Let's get your voice

- In the Chat, please type some challenges you face OR you think w.r.t. Contractor Safety Management.

Contractor Safety Management – Challenges in India

- Many companies don't realise they are responsible for the H&S of contractors on site;
- Cost is still a major driving criteria at many companies, over the aspects of compliance, knowledge, experience, safety performance of the contractors;
- Contractor management is still largely an un-organized sector in India and many other countries;
- Reluctance by many contractors to adopt a safety culture; OT they consider Safety rather a **HURDLE**
- Contractors often take short-cuts to get the work done quickly and move on to the next job;
- Safety requirements listed in contracts are considered as a documentation formality, and generally not enforced by all.

Contractor Safety Management – Challenges in India

- Many companies rely on specialist contractors as they don't have the internal resources to conduct all the tasks necessary at the site;
- Resources lacking to adequately supervise contractors;
- Misconceptions;
  - that contractors know everything about the site – so no need to have any types of orientation/induction;
  - that contractors know what they are doing – so no need to check their procedures, permit requirements, no check or requirements for risk assessments, use of PPE;

Key elements of Contractor Safety Management

- Contractor Selection
- Agreement to contract conditions (including Safety, Health, Environment + Sustainability)
- Issuance of Contract.
- Orientation of each Contractor member.
- Day to day management / Regular monitoring / Celebrate the success
- Periodic evaluation and review
- Final evaluation

Contractor Selection

- Clearly list all requirements for Safety, Health, Environment and Sustainability etc.;
  (Best Practice – develop a Contractor Manual)
  - List of legal requirements.
  - SHE Policy, including leadership commitment.
  - SHE rules and practices.
  - SHE procedures applicable (including work permit)
  - Clear standards w.r.t. Tools, PPE's etc.
  - Clear policy on subcontractors.
  - Special conditions if any (e.g. competence, Supervision, etc.)
  - Special restrictions if any (w.r.t. materials, others).
- Issue above requirements to potential contractors along with expected work scope.
- Request information covering technical competence, Safety performance, safety management structure, company overview, qualification of staff etc. for evaluating pre-qualification of contractors.
- Perform pre-qualification visits to their ongoing contract sites. Collect feedback from their customers.

Contractor Selection contd.

- Perform pre evaluation basis work scope, technical competence, SHE management / performance etc. and shortlist few contractors (2-3)
- Have detailed pre discussions including technical work scope + expected safety culture / management structure. Get Quotes.
- Finalize suitable contractor(s).
- Be-aware of subcontractors involved (if any) – If yes, include them as part of your pre qualifications.

Issuance of Contract

- Have detailed discussions with selected contractor, reaffirm and agree technical work scope and expected safety culture / management structure, along with the cost. Beware if a contractor is showing low cost and showing high commitment to expected safety standards, he may disappoint you later during work.
- Make clear if contractor shall be allowed to use his established standards / processes OR those provided by company.
- Once agreed sign off the contract including all agreed conditions as part of the contract. Consider clause related to action in case of noncompliance to agreed conditions.

Remarks; Best results are achieved only through joint commitment and participation.

Contractor mobilization

Phase 1;

- Organize an orientation meeting (1 day) with Contractor management team allocated for your work scope / location. Include physical round of work area.
- Set clear expectation on safety management (in line with agreed contract conditions)
- Agree management structure for control of all elements of safety, health, environment management (including incident reporting, management of emergencies, introduction to persons involved on behalf of your company, along with clear roles and responsibilities).
- Clarify queries if any.
- List key high risk activities and agree to conduct / review / agree risk assessment and safe working conditions to be adopted during shopfloor working. (ongoing activity)
- Develop basic infrastructure in advance / beginning to start with a 1st time right standard.

Contractor mobilization contd.

Phase 2;

- Organize orientation of each and every contractor member (in collaboration with contractor representative) before start of the work, and agree to be abide by safety rules, introduce to emergency management procedures of your respective sites. Use video's pictures where feasible.
- Train workforce to specific risks to their job, along with safe working rules, basis risk assessments done. (involve them in risk assessment as well)
- Develop a training schedule and organize trainings on various important topics.

Day to Day Management

- Daily toolbox talks (in case of big projects, suggest to split in groups).
  - Motivate for good work safe execution of previous day(s)
  - Work scope for the day.
  - key risks and special instructions if any.
  - Specific observations / incidents / near misses / learnings from the previous day(s), and agreed mitigating actions if any.
  - Re affirm expected behaviour, and whom to contact if they have any challenges / questions during the work.
- High focus on housekeeping (contributes to 60% of safe conditions).
- Work permit for all high risk jobs.
- Supervision for high risk jobs.
- Periodic field audits (preferably in collaboration with contractor team).
- Set short term milestones on safety performance and celebrate the success, including rewarding individuals for demonstrating safe behaviour.

Periodic evaluation and review

- Basis day to day management, evaluate contractor / subcontractors for various elements including workmanship, safety, health and environment compliance / performance, discipline, involvement etc.
- Have periodic (recommended minimum once a month) review meeting with contractor management, discuss outcome of the evaluation, agree for actions to be taken (if any), with clear responsibility / targets.
- Review progress on previously agreed actions if any.
- Include pictures where possible.

Contractor management – some best practices

- Management visibility rounds.
- Lead by example.
- Contractor information contained in a booklet/on line/ that is provided to all contractors;
- Rewards and recognition programs.
- Risk assessment for jobs (must for high risk activities). Develop detailed construction management program in case of large projects.
- Daily toolbox talks (Pre start up meetings).
- Clearly defined / agreed rules and processes (including zero tolerance rules).
- Safety orientation / trainings for each one.
- Clear identification for specialized / skilled individuals Vs general labour.
- Strong supervision (with competent supervisors) (dedicated supervision preferred)
- Periodic audits (along with contractor team).
- Periodic reviews with contractor.

PSCI questions related to Contractor Management

Quest 58 – Specifically deals with contractor management:

- Does the facility use any of the following processes for managing risks related to contractor activity onsite?
- On site pre-approval
- Training/orientation before entry
- Electronic access control
- Drug/alcohol testing
- On going and recurrent safety training
- Mandatory accident reporting
- Other…

PSCI questions related to Contractor Management

Contractor management implied in :

- Quest 10 – Training and competency – are workers (including Contractors) made aware of policies, procedures and trained accordingly;
- Quest 49 – list significant H&S incidents ay site over last 3 years – includes contractors - eg serious injuries, fatalities;
- Quest 50 – Is HSE training provided to employees, including contactors, this includes orientation/induction training;
- Quest 55 – deals with use of work permits – ensure contractors are using a permit system as required;
- Quest 72 – Use of PPE – ensure contractors are using the correct PPE;

Common observations during PSCI supplier audits

- Lack of due diligence regarding choice of contractors for specific work;
- Lack of clarity from site regarding the work required to be performed by contactor;
- Lack of orientation/induction, training about the site for contractors;
- Lack of risk assessments prior to commencing work;
- Contractors are not adequately supervised;
- Contractors do not use permit system when required;
- Contractors are not using required PPE;
- Emergency procedures and incident reporting are excluded from the induction/orientation training;
- Contractors may be pre-qualified, but there is no timeline for re-qualification;
- Lack of review at completion of work

Questions?

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PSCI PHARMACEUTICAL SUPPLY CHAIN INITIATIVE

Building responsible supply chains

Introduction to QRA and Consequence Modelling

ANTI-TRUST STATEMENT

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iv. codes of ethics administered in a way that could inhibit or restrict competition;
v. group boycotts;
vi. validity of patents;
vii. on-going litigation;
viii. specific R&D, sales or marketing activities or plans, or confidential product, product development, production or testing strategies or other proprietary knowledge or information."

AGENDA

Imparting basic knowledge about QRA

Hazard identification

Consequence assessment

Likelihood assessment

Risk summation

Risk presentation and reduction

SPEAKER BIO

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- Job Title: Technical Manager
- Organization: Sigma HSE India Private Limited
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Sunil Deshmukh is a graduate in Chemical Engineer from Mumbai University, currently working as Technical Manager with Sigma HSE India Private Limited, with total around 10 years of experience in process safety field. He has conducted safety studies like HAZID, HAZOP, QRA, HAC, FRA, EHS/ Safety Audits , Dust Explosion Risk Assessment, ATEX Assessment, Electrostatic Hazard Assessment, etc. for Oil & Gas, Chemicals, Petrochemical, FMCG and Pharmaceutical Industries.

AREAS OF EXPERTISE

- We bring together our Indian and UK experts to provide our clients with EHS services and appropriate engineering solutions.
- We undertake Laboratory testing in our UK laboratories to ISO, BSI ASTM and VDI individual test standards.

Consultancy

Testing

Training

CONSULTANCY SERVICES

Our Consultancy team provides a wide range of specialist technical knowledge covering the following sectors:

- Process Safety Management (PSM) Implementation
- Industrial Fire & Explosion Hazards
- Electrostatic Hazard Assessment
- Process Hazard Analysis (PHA)
- Functional Safety
- Chemical Reaction Hazards
- Training Workshops

LABORATORY TESTING

- Powder Fire & Explosion Properties
- Gas and Vapor Properties
- Electrostatic Properties
- Chemical Reaction Hazard Testing

RISK MANAGEMENT AND HAZARD IDENTIFICATION

BP, TEXAS CITY

- On March 23, 2005 at 1320 hrs.; an explosion and fire occurred at the BP Texas City Refinery Isomerization (ISOM) plant. In this incident, 15 people were killed and 180 were injured.

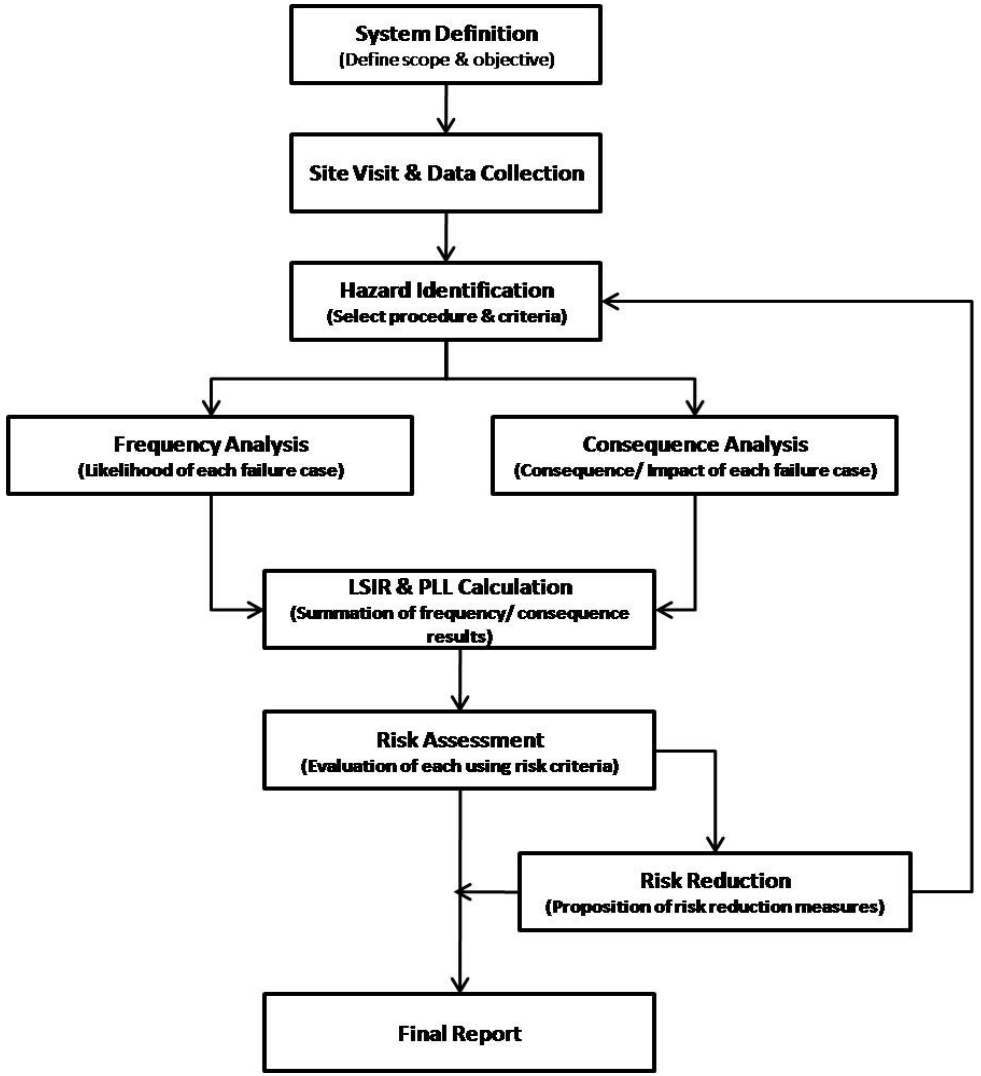
QRA TO BE USED FOR

- Risk Management
- Decision making
- To increase awareness of hazards
- Emergency Response Planning
- Communication of risk to public

RISK MANAGEMENT PROCESS - QRA

- What are we trying to achieve? (Design Intent)
- What could go wrong? (Hazard Identification)
- How likely and how big an impact? (Risk Analysis)
- How significant is this estimated risk and do we need to reduce this risk? (Risk Assessment)
- If so, what is the most cost-effective control/mitigation option? (Risk Management)

TYPICAL QRA METHODOLOGY & RISK MANAGEMENT



HAZARD IDENTIFICATION TECHNIQUES

Experience Based

- Checklists and What-If / Checklists
- Indices & Layers of Protection Analysis

Analytical

- Failure Mode and Effects Analysis (FMEA)
- Fault Tree Analysis & Event Tree Analysis

Creative

- Brainstorming
- HAZID
- HAZOP

SECTIONALISATION

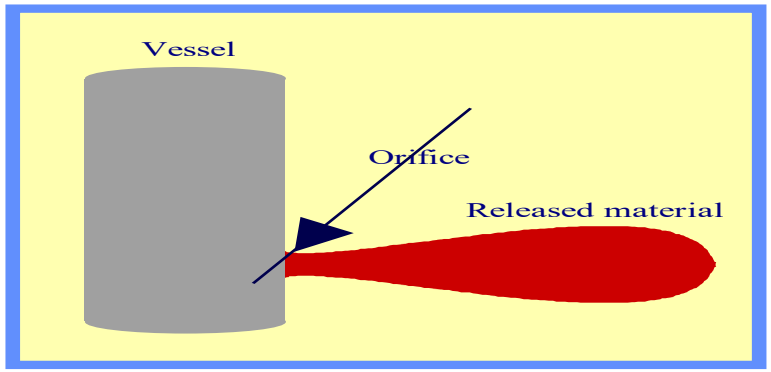
WHY SECTIONALISATION?

- Division of each process into various Isolatable Sections.
- Easier understanding of process
- Every single element is given importance.
- To determine the leak size distribution

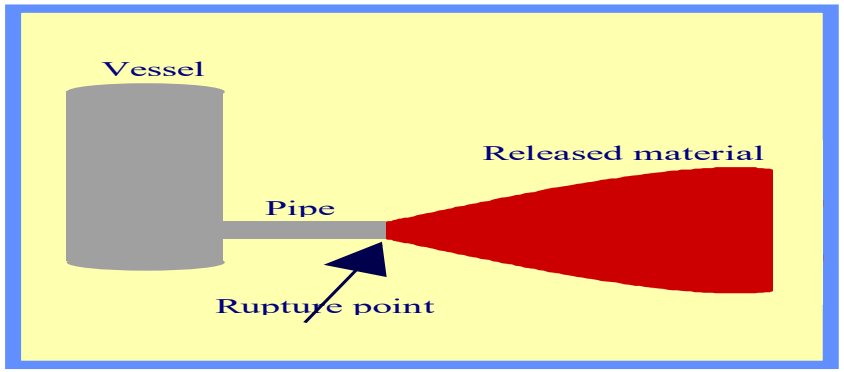
BASICS OF ISOLATABLE SECTIONS

- Each isolatable section extends from one ESD valve to another ESD valve.
- Pumps and Compressors are also considered as an isolation
- Control valves are valves used to control conditions such as flow, pressure, temperature, and liquid level by fully or partially opening or closing in response to signals received from controllers that compare a "set-point" to a "process variable“. Hence, not considered as isolation

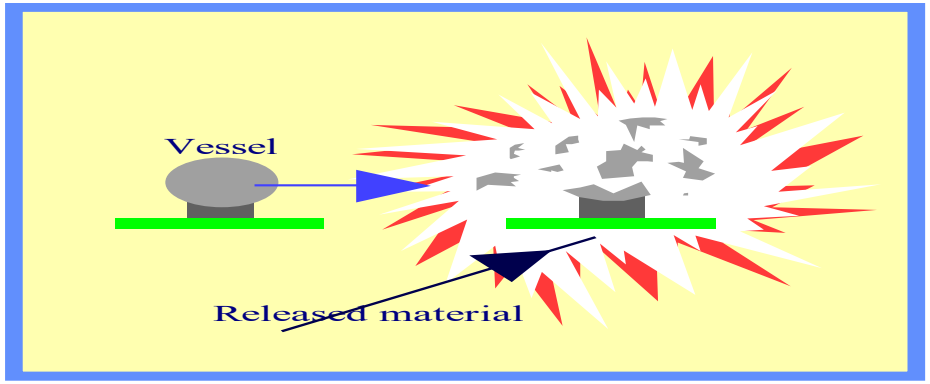
DISCHARGE



Leak



Line rupture



Instantaneous

CONSEQUENCE CALCULATIONS

WHAT IS CONSEQUENCE MODELLING

- Application of mathematical formulae to predict consequences from toxic & flammable releases

Techniques cover modelling of:

- discharge rates
- size and shape of flammable and toxic gas clouds
- flame and radiation of ignited releases
- explosion effects

CONSEQUENCE EFFECTS

Fire

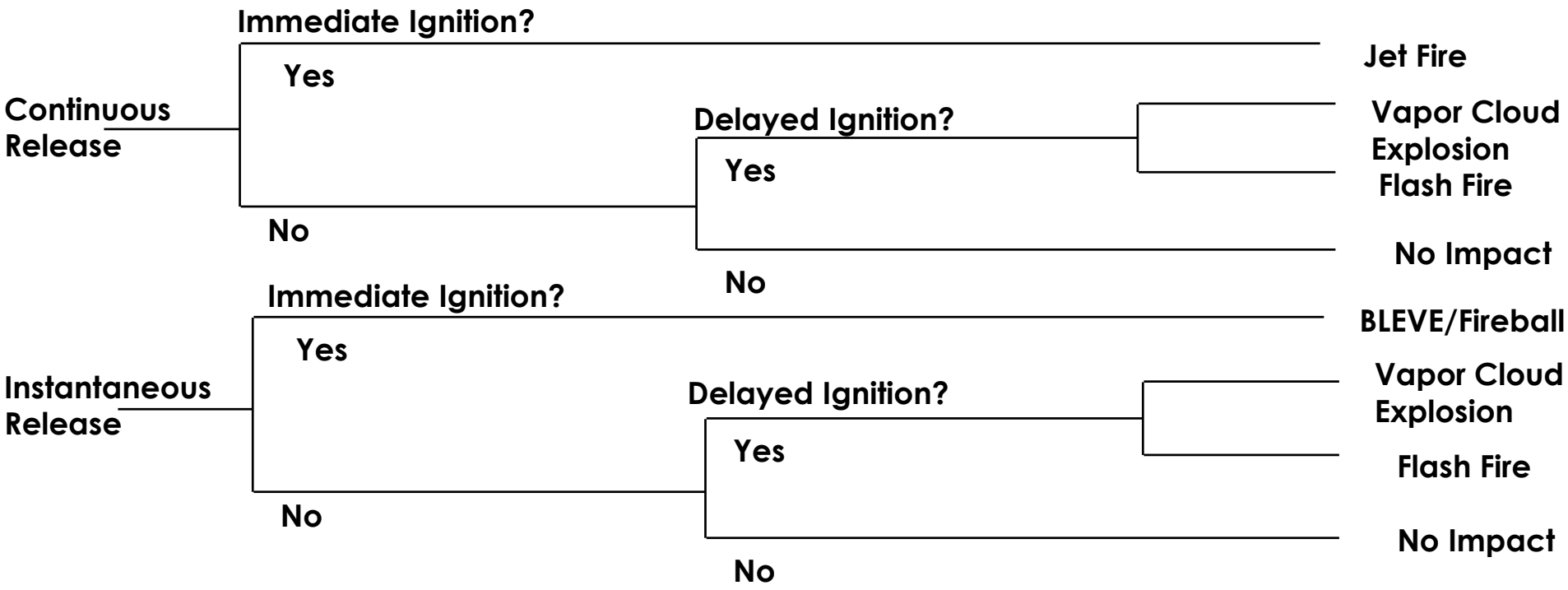
- Pool fire
- Flash fire
- Fire ball
- Jet fire

Toxic release

Explosion

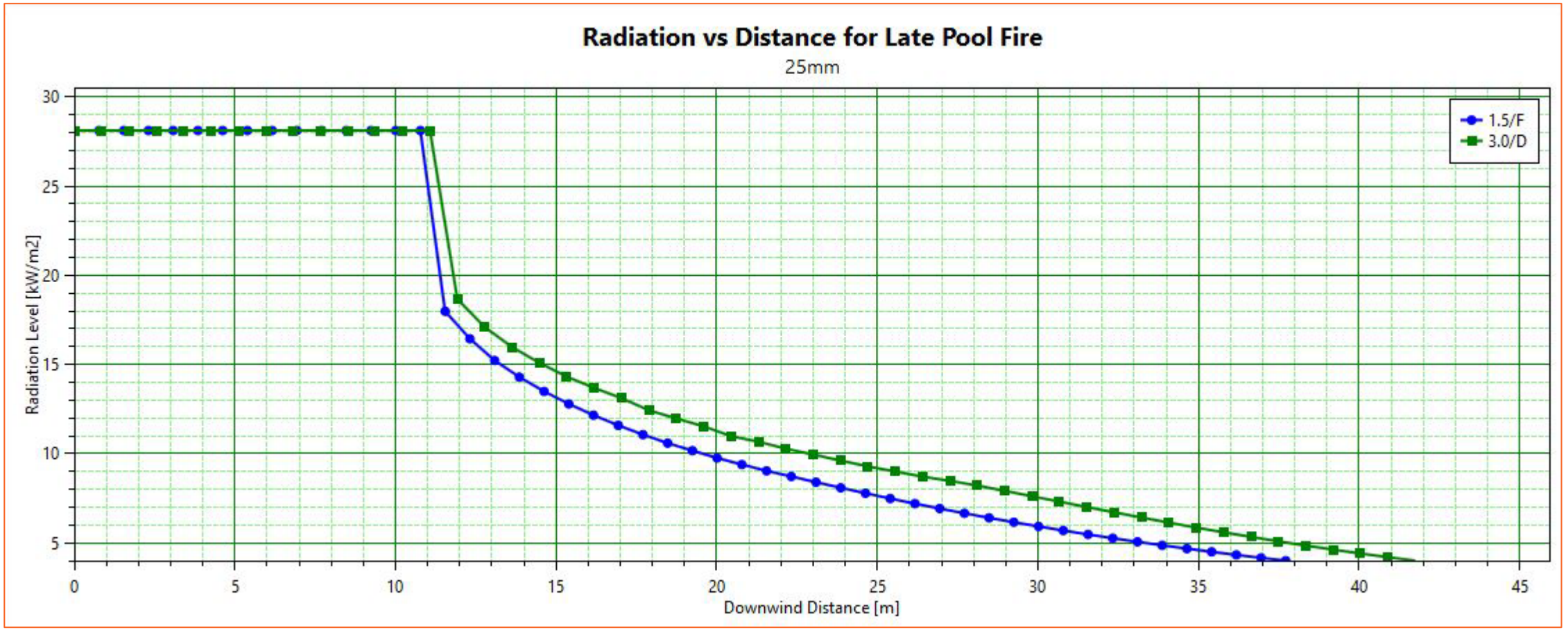
- BLEVE
- Vapor cloud explosion

EVENT TREE – FLAMMABLE CHEMICAL

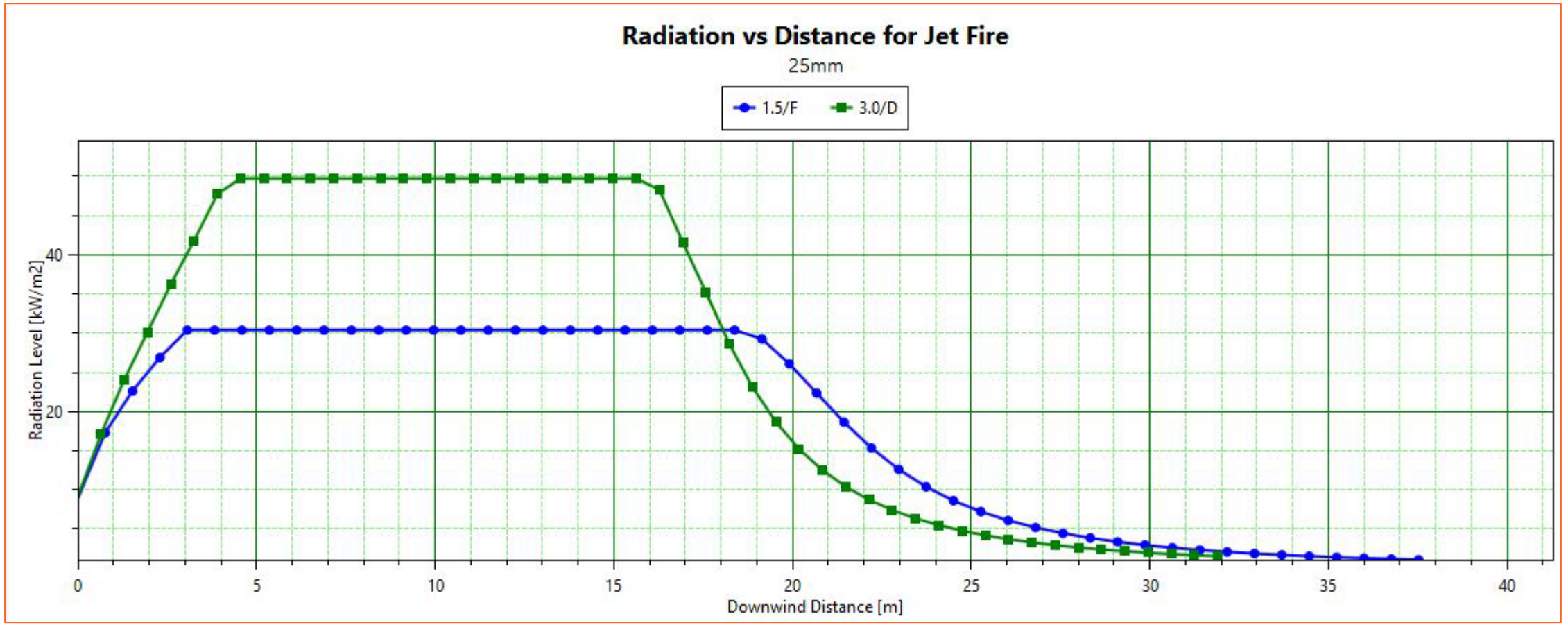


Note: Above events will also ignite pools of flammable liquids (Pool Fire)

POOL FIRE


Radiation vs Distance for Late Pool Fire
25mm
Radiation Level [kW/m2]
Downwind Distance [m]
1.5/F
3.0/D
30
25
20
15
10
5
0
5
10
15
20
25
30
35
40
45

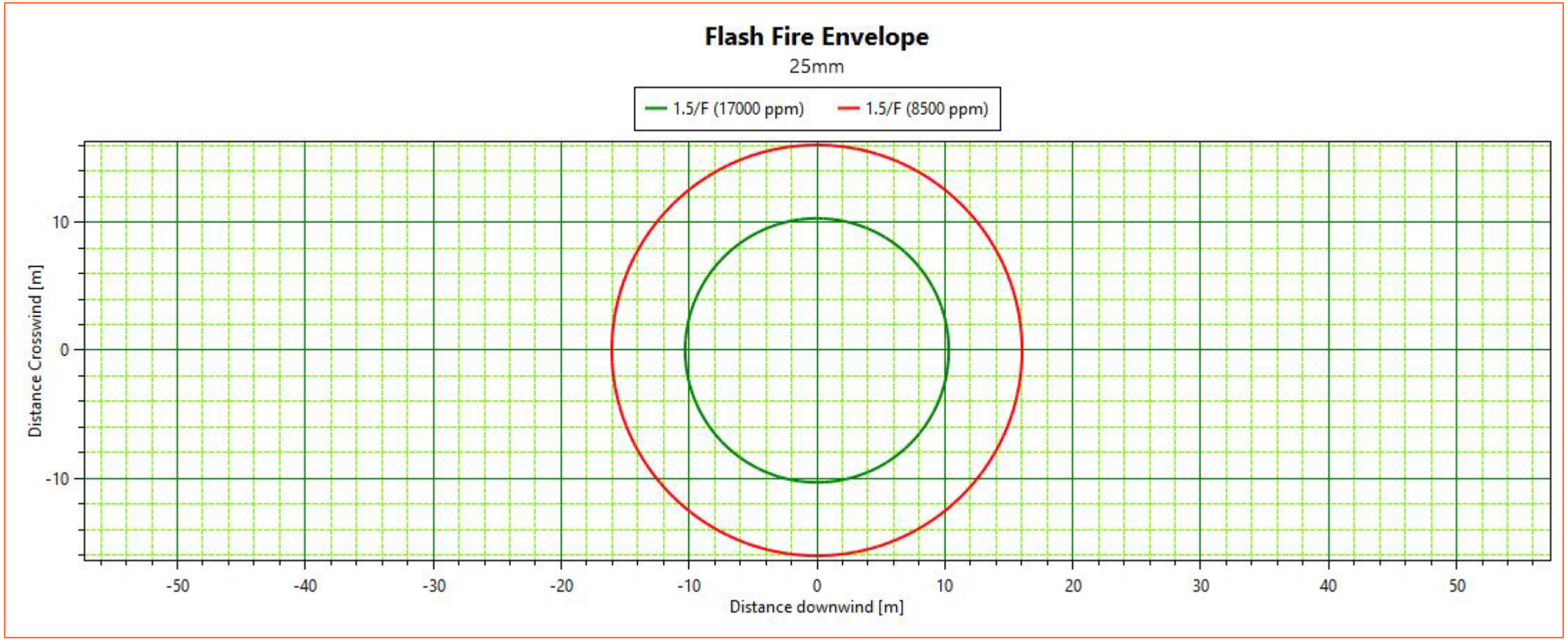
JET FIRE


Radiation vs Distance for Jet Fire
25mm
1.5/F
3.0/D
Radiation Level [kW/m2]
40
20
0
5
10
15
20
25
30
35
40
Downwind Distance [m]

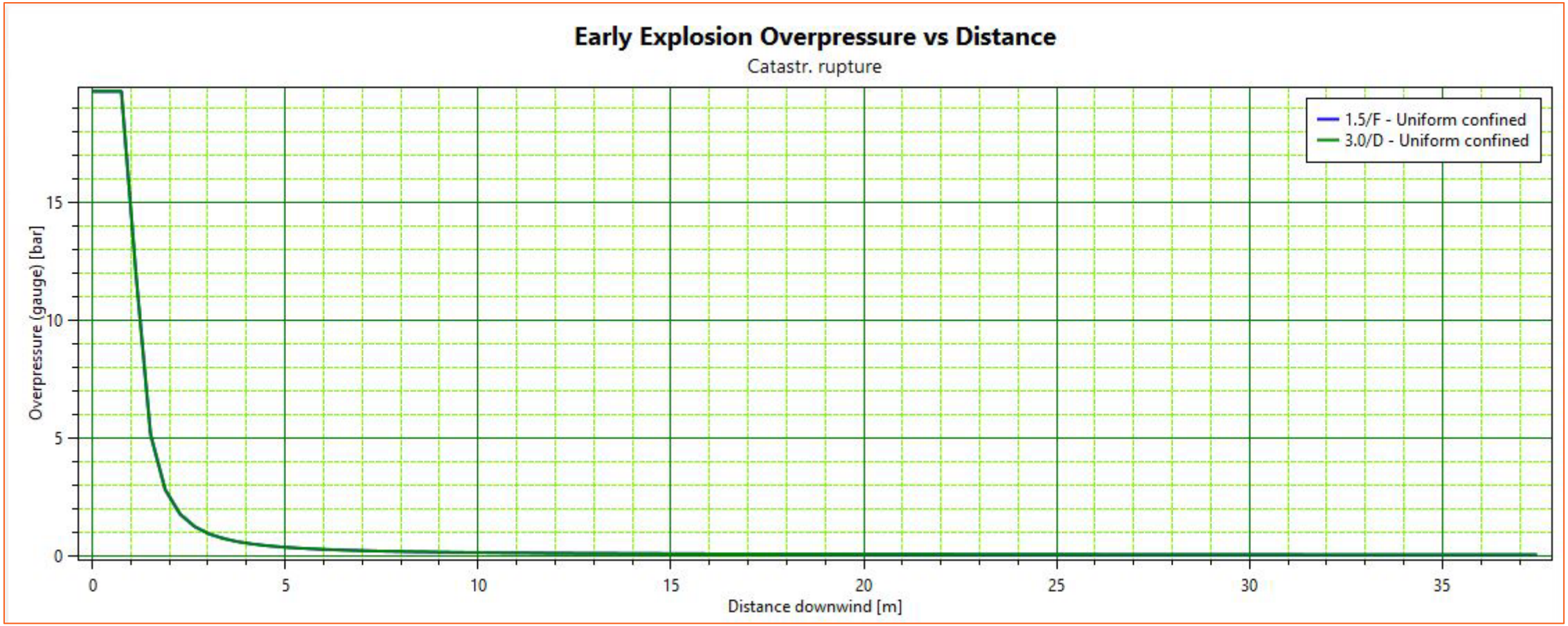
FIRE DAMAGE

Radiation Intensity (kW/m^2)	Casualty Threshold
4.7	Sufficient to cause pain within 20 sec. Blistering of skin (first degree burns are likely)
12.5	Minimum energy required for piloted ignition of wood, melting plastic tubing etc. 10% lethality
37.5	100% lethality

FLASH FIRE


Flash Fire Envelope
25mm
1.5/F (17000 ppm)
1.5/F (8500 ppm)
Distance Crosswind [m]
10
0
-10
-50
-40
-30
-20
-10
0
10
20
30
40
50
Distance downwind [m]

VAPOUR CLOUD EXPLOSION



EXPLOSION DAMAGE

OVERPRESSURE		EFFECT ON HUMAN	EFFECT ON STRUCTURES
bar g	Psi g		
0.03	0.435	Light injuries from fragment may occur	Large & small windows usually shattered, Occasional damage to window frames
0.1	1.45	People damaged by flying glass, debris	Partial collapse of walls/ roofs of houses
0.3	4.35	30% Fatality for impacted area	Near complete destruction of impacted buildings

TOXIC IMPACT

Toxic Impact is a factor of:

- Toxicity of material
- Exposure Duration

Guideline	Target Group	Definition	Exposure Duration
ERPG	Public	Three-tier guideline for emergency response	1 hour
IDLH	Worker	Highest concentration from which escape possible without permanent damage	Used to be 30 minutes. The revised IDLH (1994) mentions no exposure duration.
TLV, PEL, REL	Worker	Occupational exposure for 8-hour workday	8 hours per day, 20 to 30 years
STEL	Worker	Occupational short-term exposure limit	15 minutes

ATMOSPHERIC STABILITY

Thermal Turbulence

- Generated by atmospheric temperatures

Mechanical Turbulence

- Generated by wind speed

WEATHER STABILITY

Wind Speed	DAY Incoming Solar Radiation			NIGHT Cloud Cover	
m/s	Strong	Moderate	Slight	Overcast	Clear
<2	A	A-B	B	E	F
2-3	A-B	B	C	E	F
3-5	B	B-C	D	D	E
5-6	C	C-D	D	D	D
>6	D	D	D	D	D

- "D" stability is usually the most common stability category,
- EPA RMP specifies that "F / 1.5" m/s wind is the "worst case" meteorological condition

LIKELIHOOD ESTIMATION

WHAT IS LIKELIHOOD?

- Likelihood is Probability / Frequency of an event!
- 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)

PARTS COUNT

- For each isolatable section, no. of components (Valves, Flanges, Fixed Equipment) are counted and filled in calibrated sheet.
- Parts count sheet for each section is linked to base frequency sheet (based on UK HSE/ OGP/ E&P Forum etc.)
- Parts count output includes release frequency for each section divided for individual leak sizes; sectional hold up inventory based on volume calculations.

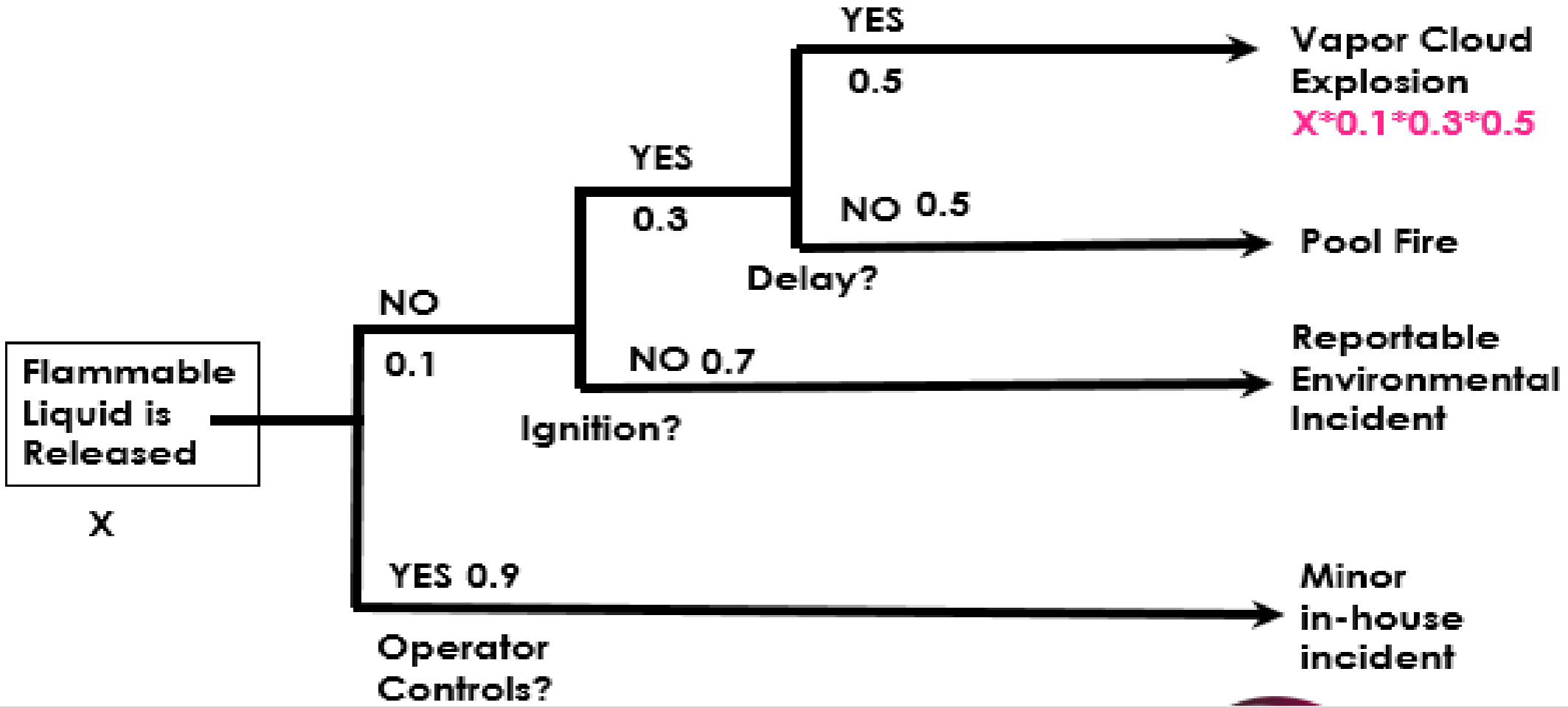
Equipment Name	Unit / year	Frequency		Hole Nominal Diameter (mm)			Total
				10	50	100	
COMPRESSORS / CENTRIFUGAL	per Item	9.61E-03	Prob. Dist.	0.87	0.09	0.04	1.00
			Frequency	8.38E-03	8.70E-04	3.63E-04	9.61E-03
COMPRESSORS / RECIPROCATING	per Item	7.08E-02	Prob. Dist.	0.85	0.10	0.04	1.00
			Frequency	6.04E-02	7.30E-03	3.08E-03	7.08E-02
FILTERS	per Item	3.34E-03	Prob. Dist.	0.79	0.13	0.08	1.00
			Frequency	2.65E-03	4.20E-04	2.69E-04	3.34E-03
FIN FAN COOLERS	per Item	1.84E-03	Prob. Dist.	0.81	0.13	0.06	1.00
			Frequency	1.49E-03	2.40E-04	1.09E-04	1.84E-03
FLANGES / D < = 2"	per Flange Face	6.91E-05	Prob. Dist.	0.82	0.18	0.00	1.00
			Frequency	5.65E-05	1.26E-05	0.00E+00	6.91E-05
FLANGES / 2" < D < = 12"	per Flange Face	1.23E-04	Prob. Dist.	0.84	0.09	0.07	1.00
			Frequency	1.03E-04	1.14E-05	8.21E-06	1.23E-04
FLANGES / D > 12"	per Flange Face	2.59E-04	Prob. Dist.	0.87	0.09	0.05	1.00
			Frequency	2.25E-04	2.25E-05	1.20E-05	2.59E-04
HEAT EXCHANGERS / HC IN SHELL	per Item	4.61E-03	Prob. Dist.	0.77	0.14	0.09	1.00
			Frequency	3.54E-03	6.30E-04	4.36E-04	4.61E-03
HEAT EXCHANGERS / HC IN TUBE	per Item	3.12E-03	Prob. Dist.	0.78	0.14	0.09	1.00
			Frequency	2.42E-03	4.30E-04	2.70E-04	3.12E-03
INSTRUMENTS / SMALL BORE CONNECTIONS	per Item	6.92E-04	Prob. Dist.	0.89	0.11	0.00	1.00
			Frequency	4.82E-04	6.10E-05	0.00E+00	5.43E-04
PIG LAUNCHERS	per Item	5.78E-03	Prob. Dist.	0.75	0.12	0.13	1.00
			Frequency	4.32E-03	7.00E-04	7.57E-04	5.78E-03

IN-LINE EQUIPMENT						
Equipment Diameter		Valves		Flanges	Instruments / Small Bore Connections	Piping Length
		Actuated	Manual			
(mm)	(inches)	No.	No.	No.	No.	(m)
900	36					
850	34					
800	32					
750	30					
700	28					
650	26					
600	24					
550	22					
500	20					
450	18					
400	16					
350	14					
300	12					
250	10					
200	8					
150	6					
100	4					
80	3		11	24		7.00
60	2 1/2					
50	2	4	9	18		4.00
40	1 1/2					
25	1					
20	3/4				17	2.000
< = 15	< = 0.5				4	1.000

LIKELIHOOD DATABASE

- CCPS
- TNO : BEVI v3.2 guidance
- DNV Database
- UK HSE database
- Lees
- Cox et al
- OGP

LIKELIHOOD ANALYSIS – EVENT TREE



LIKELIHOOD ESTIMATION

Factors to be considered:

- Leak frequency
- Number / inventory of equipment / fittings
- Isolation auto (ESD / FSD / interlocks) or manual (operator)
- Ignition probability
- Weather class
- Wind Direction
- Day / Night
- Presence (number and probability) of personnel / public
- Probability of fatality (consequences) from the event

RISK SUMMATION AND ANALYSIS

INDIVIDUAL RISK

- The risk experienced by a hypothetical individual at a particular location in a given time period - usually risk of death per year.

Measures:

- Location-specific individual risk (LSIR)
- Individual-specific individual risk (ISIR)

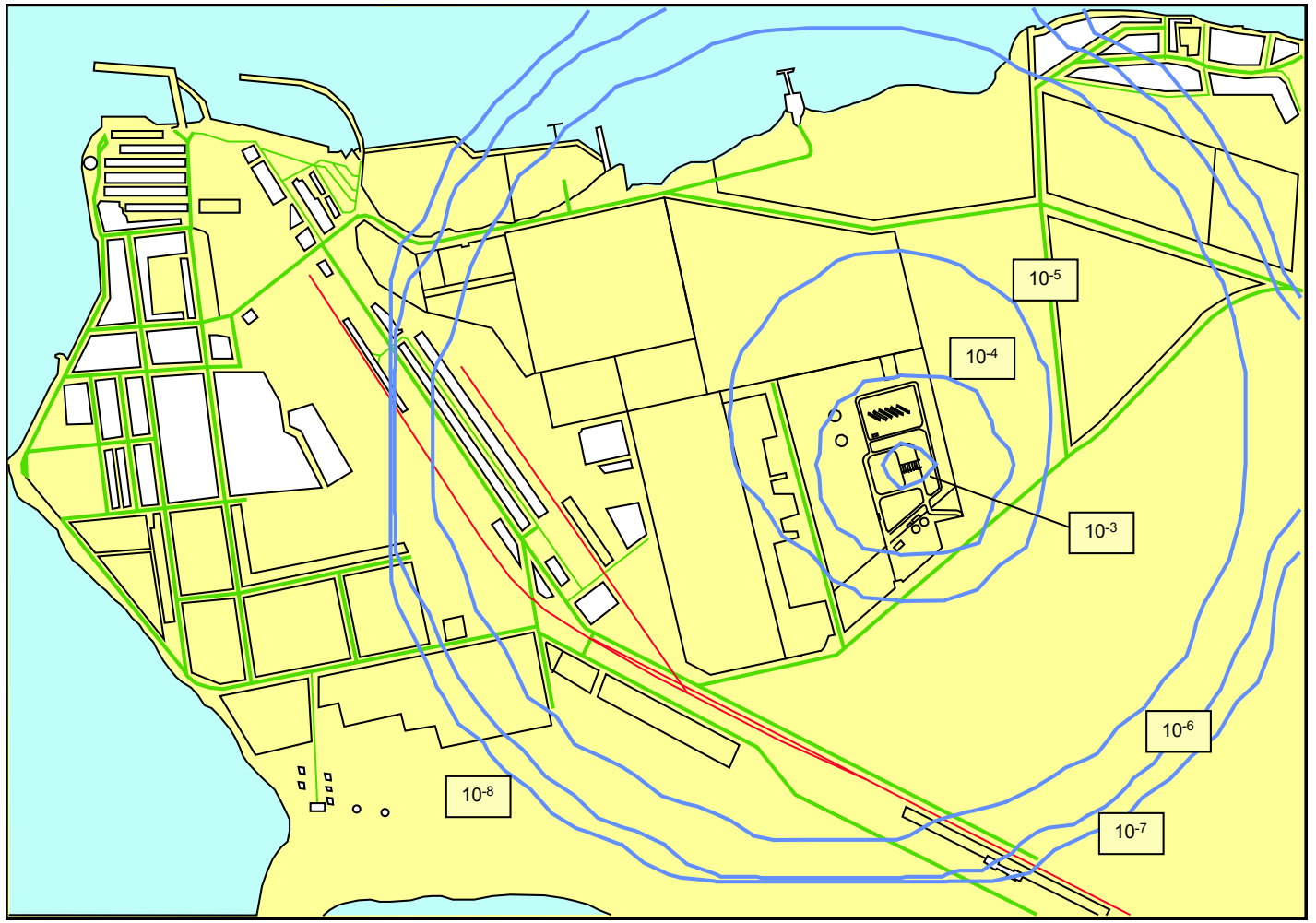
Expressed as:

- Individual risk per year

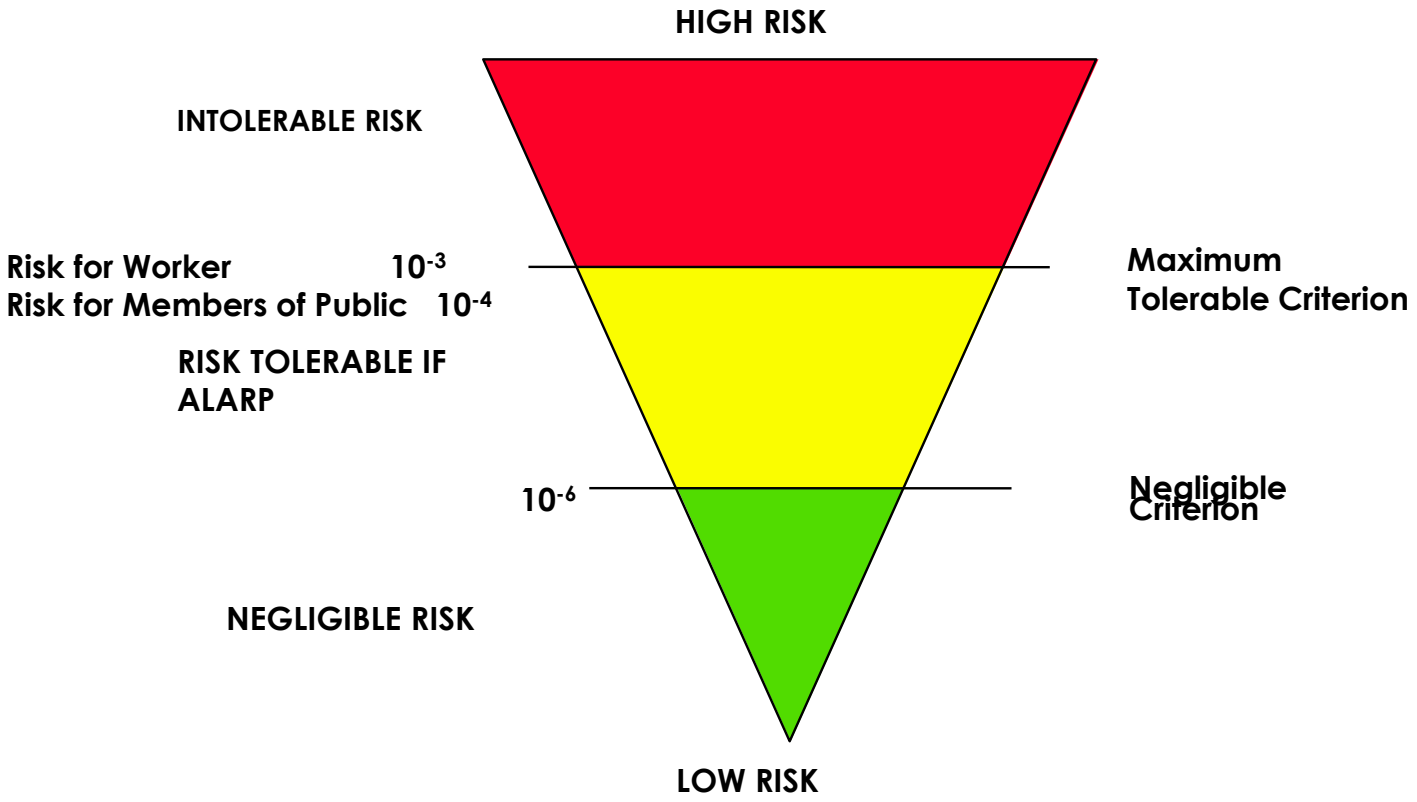
INDIVIDUAL RISK CONTOURS

- A commonly used presentation form for risk to the public is the so-called risk contour.
- The number at this contour represents frequency at which a person, assumed to be permanently present at location of the contour, sustains a given level of harm.
- The risk contours must be interpreted as characterising points in space & not the risk to individual people; people move from place to place during their normal living activity.

LSIR CONTOURS



RISK ACCEPTANCE CRITERIA – UK HSE

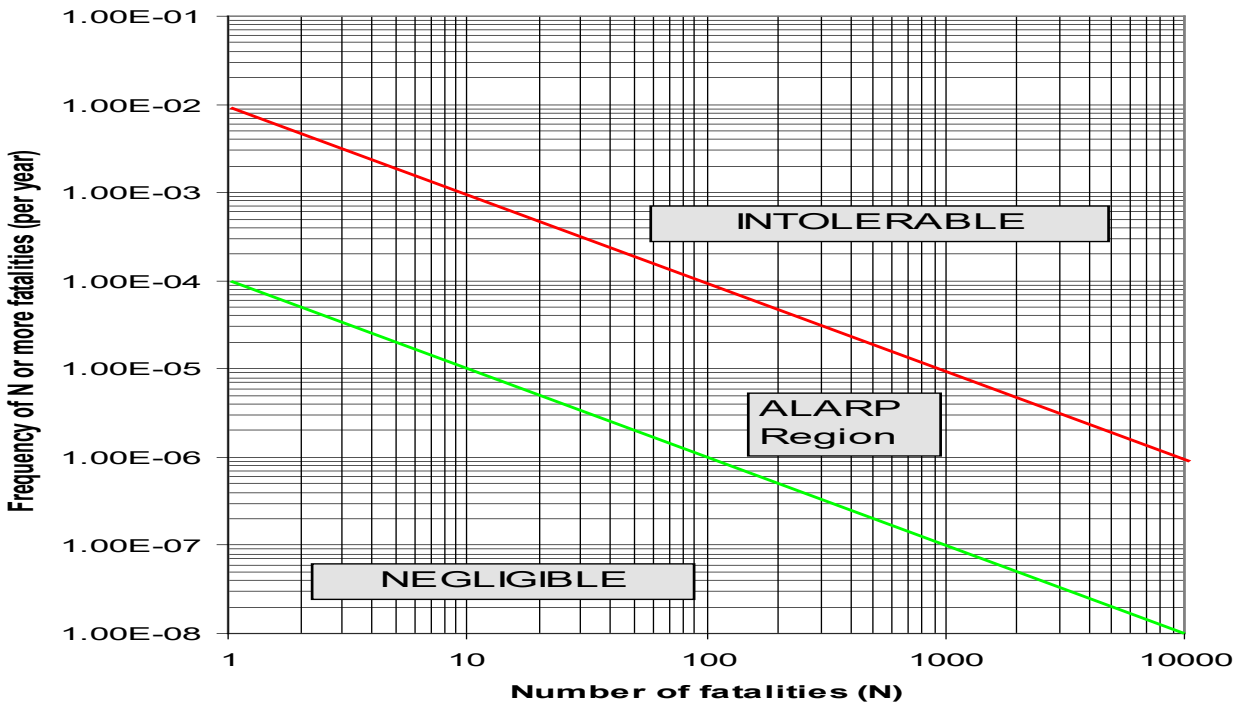


GROUP RISK / SOCIETAL RISK

- The risk experienced in a given time period by the whole group of personnel exposed.

Expressed as:

- FN curves



ALARP

- For operations with risk between intolerable and negligible, it is necessary to ensure that risk levels have been reduced to ALARP (as low as reasonably practicable) using techniques like Cost Benefit Analysis (CBA).
- For cases which are not so straight forward, QRA will be required to assist in demonstration of ALARP.

RECOMMENDATIONS FROM QRA

- Hazard elimination (by substitution)
- Cost effective Safety measure
- Selection of alternatives
- Risk mitigation (barriers)

THANK YOU!

For Queries, contact our Process Safety Expert on

+91 (0)11 43565446 or

write to us on safety-india@sigma-hse.com

PSCI PHARMACEUTICAL SUPPLY CHAIN INITIATIVE

Building responsible supply chains

CMR Substances Safety

PSCI Virtual Conference Sept 2021

SPEAKER BIO

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- M.Sc. (Chemistry), M. Tech. (Environmental Management), Diploma in Ind. Safety, BOHS OHTA modules.
- >15 years of multidisciplinary experience in EH&S in various industries (Pharmaceutical, Consumer & Medical devices)
- Support EH&S for J&J External Suppliers in India & Southeast Asia - EH&S Onsite Assessments, Technical / Capability Building
- Core team member of J&J PSM Team
- PSCI Role: Co-Lead PSM sub team

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vi. validity of patents;
vii. on-going litigation;
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AGENDA

1. CMR Definitions
2. Importance of focus on CMR at the Workplace
3. Hazard Communication & Classifications
4. Risk Assessment
5. Controls of Hazards
6. Training
7. Solvent Selection
8. CMR Exposure Control – Takeaways

CMR Definitions

- **Carcinogens (C)**: substances and preparations which, if they are inhaled or ingested or if they penetrate the skin, may induce cancer or increase its incidence.

- **Mutagens (M)**: substances and preparations which, if they are inhaled or ingested or if they penetrate the skin, may induce heritable genetic defects or increase their incidence.

- **Reprotoxins (R)**: substances and preparations which, if they are inhaled or ingested or if they penetrate the skin, may produce or increase the incidence of non-heritable adverse effects in the progeny and/or an impairment of male or female reproductive functions or capacity.

Report ILO: Facts & Figures

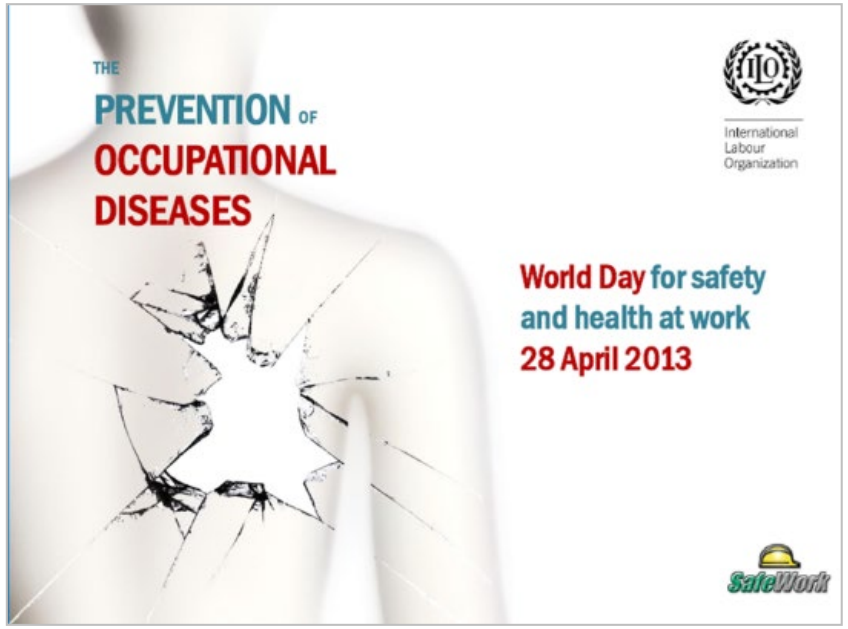
Workday for Safety & Health 28.4.2013

2.02MM people die each year from work-related diseases

321,000 people die each year from occupational accidents

160MM non-fatal work-related diseases per year

317MM non-fatal occupational accidents per year



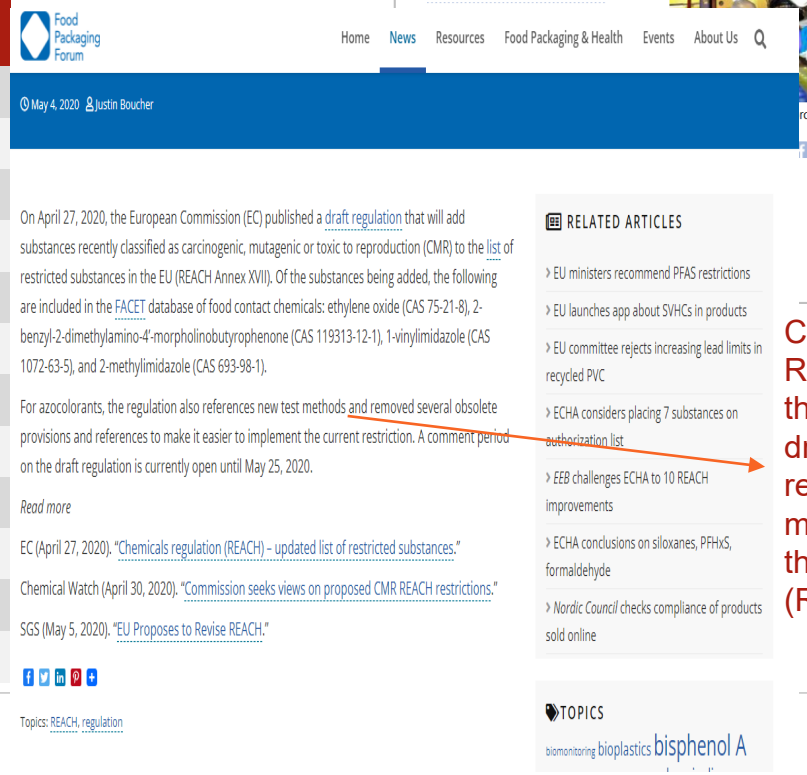
This means that:

- Every 15 seconds, a worker dies from a work-related accident or disease.
- Every 15 seconds, 151 workers have a work-related accident.
- Carcinogens, pneumoconiosis & Asbestos Related Diseases

EU Roadmap on CMR

The European Commission has outlined exposure limits for 13 cancer-causing chemicals in a move designed to reduce the estimated **102,000 occupational cancer deaths** across **Europe** each year.

Chemical agents	Proposed OELs mg/m³
1,2- Epoxypropane	2.4
1,3-Butadiene	2.2
2-Nitropropane	18
Acrylamide	0.1
Bromoethylene	4.4
Chromium (VI) compounds	0.025
Ethylene Oxide	1.8
Hardwood dusts	3
Hydrazine	0.013
o-Toluidine	0.5
Respirable Crystalline Silica (RCS)	0.1
Refractory Ceramic Fibres (RCF)	0.3 f/ml



CMR classified substances being added to REACH restriction list. On **April 27, 2020**, the European Commission (EC) published a draft regulation that will add substances recently classified as carcinogenic, mutagenic or toxic to reproduction (CMR) to the list of restricted substances in the EU (REACH Annex XVII)

CDC US - ICMR

INDIA AGAINST CANCER | icmr NICPR

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Occupational Carcinogens

More than 40 agents, mixtures and exposure circumstances in the working environment are carcinogenic to humans and are classified as occupational carcinogens. Occupational cancers are concentrated among specific groups of the working population, for whom the risk of developing a particular form of cancer may be much higher than for the general population. It is well documented that occupational carcinogens are causally related to lung cancer, mesothelioma, and bladder cancer. For example, mesothelioma (cancer of the outer lining of the lung or chest cavity) is to a large extent caused by work-related exposure to asbestos.

- Common Cancers
- Breast Cancer
- Oral Cancer
- Cervical Cancer
- Gastric Cancer
- Lung Cancer
- Colorectal Cancer
- Esophageal Cancer
- Prostate Cancer
- Gall Bladder Cancer

www.cdc.gov/niosh/topics/cancer/

CDC Centers for Disease Control and Prevention
CDC 24/7: Saving Lives, Protecting People™

Search NIOSH SEARCH

CDC A-Z INDEX

The National Institute for Occupational Safety and Health (NIOSH)

Providing National and World Leadership to Prevent Workplace Illnesses and Injuries NIOSH

Workplace Safety & Health Topics

- Cancer (Occupational)
  - Carcinogen List
  - Cancer Clusters
  - Cancer Policy at NIOSH
  - Diesel Exhaust in Miners Study (DEMS)

Related Topics

NIOSH > Workplace Safety & Health Topics

OCCUPATIONAL CANCER

Around the world, 12.7 million people are diagnosed with cancer every year, and the number is expected to increase due to the growth and aging of the population, as well as reductions in childhood mortality and deaths from infectious diseases in developing countries(1). Cancer is the leading cause of death in

On this Page

- Cancer Clusters

Millions of U.S. workers are exposed to substances that have been tested as carcinogens in animal studies or found to be possibly carcinogenic in human studies. However, less than 2% of chemical or physical agents manufactured or processed in the U.S. have been evaluated by the International Agency for Research on Cancer for carcinogenicity(2). Based on well-documented associations between occupational exposures and cancer, it has been estimated that 3-6% of all cancers worldwide are caused by exposures to carcinogens in the workplace (3,4). Using cancer incidence numbers in the U.S. (5), this means that in 2012 (the most recent year available), there were between 45,872 and 91,745 new cancer cases that were caused by past exposure in the workplace. This is probably an underestimate, partly because we continue to discover new information about agents in the workplace that may cause cancer. Also, these estimates may change over time as the number of cancers increase or decrease in the U.S. Cancers that occur as a result of exposures in the workplace are preventable, if exposures to known or suspected carcinogens can be reduced(6-8).

Hazard Communication

- GHS pictogram for CMRs categories 1 (A or B) and 2;

GHS pictogram to illustrate CMR hazards

- Signal word '**Danger**' for category 1 (A or B) and '**Warning**' for category 2;
- CMR classified substances are classified with the following **hazard statements**:

  H350: May cause cancer (Cat 1 (A or B))

  H340: May cause genetic defects (Cat 1 (A or B))

  H360: May damage fertility or the unborn child (Cat 1 (A or B))

CMR Classification (EU CLP/GHS)

Effects / Hazard Class	Categories	Category definitions
Carcinogens	Category 1A	Substances known to have carcinogenic potential for humans.
	Category 1B	Substances presumed to have carcinogenic potential for humans.
	Category 2	Substances suspected of having carcinogenic potential for humans.
Mutagens	Category 1A	Substances known to induce hereditary mutations in the germ cells of humans.
	Category 1B	Substances presumed to induce hereditary mutations in the germ cells of humans.
	Category 2	Substances of concern because they could induce hereditary mutations in the germ cells of humans.
Reprotoxins	Category 1A	Substances known to be toxic for human reproduction.
	Category 1B	Substances presumed to be toxic for human reproduction.
	Category 2	Substances suspected of being toxic for human reproduction.

CMR Classification (EU CLP/GHS)

- A substance can have one or more of the CMR hazards. When it has more it is classified according to the evidence for each type of hazard, for example:
- CM: benzene is carc. 1A, muta. 1B;
- CR: lead (II) chromate is carc. 1B, repr. 1A;
- MR: dibutyltin dichloride is muta. 2, repr. 1B;
- CMR: benzo(a)pyrene is carc. 1B, muta. 1B, repr. 1B;
- C or M or R: nickel dioxide is carc. 1A, trifluoroiodomethane is muta. 2, carbon monoxide is repr. 1A.

Carcinogen Classification Comparison

Risk

High

Low

IARC	ACGIH	China	GHS
Group 1 Known Human Carcinogen	A1 Confirmed Human Carcinogen	G1 Known Human Carcinogen	1A Known Carcinogen
Group 2A Probable Human Carcinogen	A2 Suspected Human Carcinogen	G2A Probable Human Carcinogen	1B Presumed Carcinogen
Group 2B Possible Human Carcinogen	A3 Confirmed Animal Carcinogen With Unknow Relevance to Humans	G2B Possible Human Carcinogen	2 Suspected Carcinogen
Group 3 Not Classifiable for Human	A4 Not Classifiable as a Human Carcinogen	G3 Not Classifiable for Human	
Group 4 Probably not Human Carcinogen	A5 Not Suspected as a Human Carcinogen	G4 Probably not Human Carcinogen	

**IARC(International Agency for Research on Cancer)*

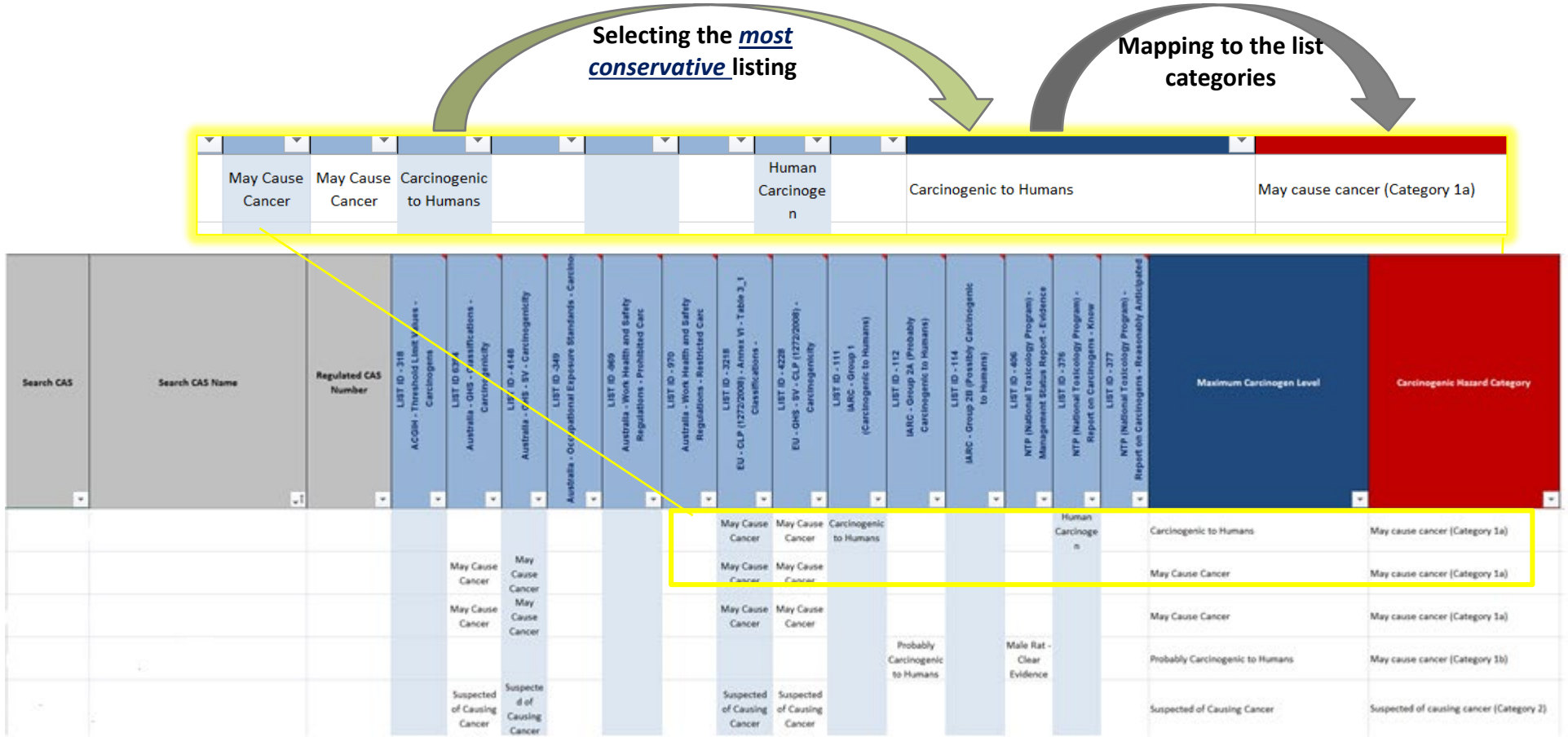
**ACGIH(American Conference of Governmental Industrial Hygienists)*

** Refer to IARC*

《GBZ 2.1-2019》

Carcinogen look up tool (same applicable for M&R)

Carcinogen reference matrix: map most conservative classification



CMR substances exposure control program Risk Assessment

- The CMR Exposure Control procedure is a written document describing the site risk management of GHS defined category 1A and/or 1B carcinogens, mutagens, reprotoxins

  - The document should include:

- **Location** on site where CMR substances are stored and used;
- **Communication** means to inform personnel of hazards and risks;
- **Risk assessments** conducted to evaluate personnel exposure potential;
- **Exposure assessment** linked to Medical Surveillance;
- **Controls** in place strictly following the hierarchy of controls process to manage risk for both personnel and the environment and
- **A process to avoid introduction of new CMR substances**

Chemical Identification

- The facility should review all chemicals handled on site
- Including those in laboratories, research, development, and operations,
- Determine if any GHS defined 1A & 1B CMR substances are present.
- In addition, all chemicals on site should have an up-to-date Safety Data Sheet and must be available to employees.

Safe handling of substances classified as CMR

Chemical identification: example chemical inventory

Pls pay attention to “H350, H340, H360 ”

Define substances.						Hazard data						Substances of Very High Concern				
Material Code SAP	Material/Substance Name	CAS Number	EC Number: EINECS / ELINCS	SDS / REACH compliant	SDS issue date	Hazard Classification	CLP hazard classification	PBOEL MAC	OEL	STEL	CMR C=Carcinogen M= Mutagen, R= Toxic for reproduction	SVHC Substance of very high concern Substance on Candidate List OR Substance on Authorisation List (Annex XIV) Y/N?	Acute Toxicant oral LD_{50} <200mg/kg	LD_{50} Oral rat mg/kg Default. LD_{50} Oral rat mg/kg ; LC_{50} inhalation rat; LD_{50} Dermal mg/kg	Other	Explosion Hazard
				Yes/No	4/20/2017	Danger	Reproductive Toxicity-Cat 1B, Eye Irritation Cat 2, STOT - Single Exposure - Cat 3, Skin Irritation Cat 2.	n/a	10ppm Sk	20ppm Sk	R= Cat 1B	CL=Yes	n/a	LD50 Oral rat = 4150mg/kg ; LC50 Inhalation rat>5.1mg/l 4hr; LD50 Dermal rat = 5000mg/kg	May cause respiratory irritation. May damage the unborn child. Irritating of the skin	LEL 9.5% UEL 1.9%
				Yes/No	5/19/2016	Danger	Skin Irritation Category 2 Serious Eye Damage Category 1 Acute Toxicity Oral Category 3 Acute Toxicity Dermal Category 2 Acute Toxicity Inhalation Dust / Mist Category 3 Specific Target Organ Systemic Toxicity Single Exposure Category 1 Environmental Chronic Category 2	3B	0.5ug/m³ Sk	n/a	n/a	No	Yes	LD50 Oral rat 140mg/kg ; LD50 Dermal (rabbit) = 90 mg/kg LD50 Dermal LC50 (guinea pig) = 100 - 200 mg/kg	Dermal - readily absorbed via Skin. Aqueous solution may increase dermal toxicity.	n/d
				Yes/No	10/28/2014	Danger	Flammable Liquid Cat 3, Acute Toxicity-Inhalation Cat 2, STOT Single Exposure 3, Skin Irritation Cat 2 Eye Damage Cat 1 Respiratory Sensitiser Cat 1. Skin Sensitiser Cat 1	n/a	n/d	n/a	n/a	no	Yes	LD50 Oral Rat 38mg/kg LD50 Dermal Rat.. >2000 mg/kg LC50 Inhalation Rat 0.105mg/l 4hr	Causes severe eye irritation. May cause allergy or asthma symptoms or breathing difficulties if inhaled. May cause an allergic skin reaction.	n/d
				Yes/No	3/15/2013		Danger Skin Corrosion Category 1	n/a	10ppm	15ppm	n/a	no	n/a	LD50 Oral rat = 3530mg/kg ; LC50 Inhalation rat >16000ppm 4hr ; LD50 Dermal rat = N/D mg/kg	Corrosive to skin, eyes and respiratory system. Causes serious eye damage, severe burns to skin, and burns to mouth, throat and stomach.	4.0 – 19.9
				Yes/No	11/22/2013		Flammable Liquid. 3 Skin Corrosion. Cat 1A	n/a	10ppm	15ppm	n/a	no	n/a	n/d	May cause burns in mucous membranes, throat, oesophagus and stomach. Causes severe burn if in contact with skin. Causes serious eye damage	LEL 4 % UEL 16%
				Yes/No	9/29/2016	Danger	Flammable Liquids Cat 2, Eye Irritation Cat 2A,	n/a	TLV 250ppm, stel = 500ppm	ACGIH - 500ppm	n/a	No	n/a	LD_{50} Oral rat= 5800 mg/kg, LD_{50} Inhalation mouse = 3300mg/kg	Vapours may irritate throat and respiratory system and cause headache, dizziness and dullness. May cause internal injury. Ingestion may cause nausea and irritation to the mouth, throat and digestive system. May cause skin dryness and irritation. Prolonged contact may cause defatting of the skin. Causes eye irritation. Irritant of eyes and mucous membranes	n/a

New Chemical Approvals

- New chemical requester should include a review by EHS staff to determine if the substance is a GHS (Globally Harmonized System) defined 1A & 1B CMR substance
- If the new chemical is defined as a 1A or 1B CMR substance, the chemical requester should justify the need for the compound and measures should be taken to substitute with a less toxic alternative.
- If a substitute cannot be found for a CMR substance, the CMR exposure control procedure should be followed to manage potential risk of handling the substance.
- A new CMR substances can only be introduced after approval from the Site Chemical Approval process including a completed risk assessment of its intended use.
- Internal Occupational Health Department should be informed of any GHS defined 1A & 1B CMR compounds brought onto the site.

Designated Use Area

- Areas where GHS defined 1A & 1B CMR substances are used or stored should be identified with signs and labels.
- Areas where quantitative risk assessments identify exposure risk above the OEL should have restricted access for “**authorized personnel only”.**

Process or Experiment Description

- Details should be specific enough to provide information needed for risk assessments. Details of the process/experiment should include:
  - ✓Procedure/Use
  - ✓Scale
  - ✓Engineering Controls/Equipment
  - ✓PPE
  - ✓Procedure Steps & Precautions

Process or Experiment Description

- Determining if situations might cause harm to people and decide whether reasonable steps have been taken to prevent that harm.

- **Qualitative Risk Assessment** is used to document potential risk for each Process/Experiment where 1A & 1B CMR substances are used.

Risk Assessment – What IF

RISK ANALYSIS RELATED TO THE LOGISTIC FLOW OF A CARCINOGEN

Carcinogen: Process: Date:

'What-If' Question	Consequences	Detection/Protection Measures	Action No.	Fre-quency *	Conse-quence *	Risk Class *
General						
1. Warehouse reception: unloading trucks						
Damaged drums (bulging/dented/poorly sealing drum cap/etc.).	Release of carcinogen ➔ - intoxication by inhalation of product - sensitization reaction (contact) - eye injury	Check before unloading truck ➔ notify Fire Brigade if appropriate.		3 2 2	2 2 2	3 4 4
	Carcinogen spill.	Check before unloading truck ➔ notify Fire Brigade if appropriate.		3 2 2	2 2 2	3 4 4
Damage while unloading: - caused by forklift truck.	Release of carcinogen ➔ - intoxication by inhalation of product - sensitization reaction (contact) - eye injury	External training/annual refresher course for forklift truck drivers. Maintenance/inspection of forklift trucks. Emergency plan procedure.		3 3 3	2 2 2	3 3 3
	Carcinogen spill.	Containment with impermeable foundation. Spill control. Emergency plan procedure.		3 3 3	3 2 2	2 3 3
Damage while unloading: - caused by dropping product.	Release of carcinogen ➔ - intoxication by inhalation of product - sensitization reaction (contact) - eye injury	External training/annual refresher course for forklift truck drivers. Maintenance/inspection of forklift trucks. Emergency plan procedure.		3 3 3	2 2 2	3 3 3
	Carcinogen spill.	UN-approved drums. Containment with impermeable foundation. Spill control. Emergency plan procedure.		3 3 3	3 2 2	2 3 3
2. Transport to cold storage room						

Qualitative Risk Assessment - Inhalation factors

a.) Hazards group

OEL/MAK µg/m³	OEL/MAK ppm	H-Phrase if no OEL / MAK is available	Rating
10.000 – 1.000	500 – 50	no H-Phrase H304, H319, H335, H336	1
1.000 – 100	50 – 5	H302, H318, H332, H371	2
100 – 10	5 – 0,5	H301, H314, H331, H334, H341, H351, H361, H370, H373,	4
10 – 1	0,5 – 0,05	H300, H330, H372,	6
< 1	< 0,05	H340, H350, H350, H360,	10

b.) Amount/Volume

< 1g or < 1 ml	0.5
1 g - 100 g or 1 ml - 100 ml	1
100 g – 1 kg or 100 ml – 1 l	2
1 kg – 10 kg or 1 l – 10 l	4
10 kg -100 kg or 10 l -100 l	6
> 100 kg or > 100 l	10

c.) Frequency

less than monthly	1
monthly	2
several times a month	4
several times a week	6
daily	10

d.)Duration

< 0.5 h /day	1
0.5 – 1 hour /day	2
1 – 2 hours / day	4
2 - 4 hours / day	6
> 4 hours / day	10

e.) Dustiness/Vapour Pressure

Solids	
Film-coated tablets, capsules	1
Pellets, tablet cores	2
Coarse-grained dust (e.g. sugar, salt)	4
Fine powdery dust (e.g. flour, toner)/ micronized powder	6

Liquids Boiling point or vapor pressure (at room temp.)	
> 150 °C or < 0.5 kPa	1
100 to 150 °C or 0.5 to 5 kPa	2
50 to 100 °C or 5 to 25 kPa	4
< 50 °C or > 25 kPa	6

f.) Technical Controlls

Isolator with RTP Closed Containment	0.05
Containment to < 0.1ug/m³	0.075
High containment powder charging systems powder transfer valves split butterfly valve etc. containment <1ug/m³	0.1
Containment charging systems - <100ug/m³ Ventilated Enclosure	0.25
Laminar Flow Down Flow Booth	0.5
Local Exhaust Ventilation	0.75
Open; Room Ventilation	1

g.) # Employees (performing the task)

1-2 Employees	1
2-4 Employees	2
4-10 Employees	4
10-20 Employees	6
> 20 Employees	10

Risk Classifications & Required Control Measures

Categorie	Value	Wording	Conclusion
III	>=50	High Risk	High risk, above the OEL, immediate measures needed in combination with follow-up (quantitative risk assessment)
II	>=15 to <50	Medium Risk	Medium risk, close to OEL, follow up needed
I	<15	Low Risk	low risk, no PPE needed, no further actions needed

Calculation of Severity:
all values are multiplied:
hazard group x amount x dustiness x techn.

Calculation of Priority:
values get summarized:
duration + frequency + # employees

No categorize needed, but insteed a hoover over box or an info box showing the following info:
If the Prio value is <= 10 the prio is low,
if the value is > 10 but <= 20 the prio is medium,
if the value is >20 the prio is high.

Note: Risk assessment tool also available for Dermal hazards

	Substance parameters							Process paaremters					Qualitive Risk Assessemnt Calculation							Risk rating			
2	Material	CAS-#	OEL / TLV		Vapour Pressure	Dustiness	Form	Product	Amount	Concentration	Temperature	Duration	Frequency	Hazards Group	Amount/Volume	Duration	Frequency	Dustiness/ Vapour Pressure	# Employees	Techn. Measures	Hazard/Severity		Prio	
3			[µg/m3	[ppm]	[kPa]		S/L		[kg]	[%]	[°C]	[h]									Ex. Ris	Categorie	Value	Categorie
4				500	0.14		L		0.34	100	20	0.5	less than monthly	1.0	2.0	2.0	1.0	1.0	2.0	1.0	2	I	5.00	I
5				500	0.14		L		0.04	100	20	0.5	less than monthly	1.0	2.0	2.0	1.0	1.0	6.0	1.0	2	I	9.00	I
6			H 318				L		0.9	100	20	2	several times a mo	1.0	2.0	6.0	4.0	1.0	2.0	1.0	2	I	12.00	II
7				500	0.14		L		0.05	100	20	0.5	less than monthly	1.0	2.0	2.0	1.0	1.0	10.0	1.0	2	I	13.00	II

Sampling Results/ Quantitative Risk Assessment

- **Quantitative Risk Assessment** is used to measure airborne exposures to determine the risk posed by handling 1A & 1B CMR substances . The airborne levels measured are compared to the allowable exposure limit (e. g. OEL, TLV, PEL) to confirm the exposure risk is managed to levels below the limit.

- **Data Analysis:** An industry best practice includes a minimum of three air samples collected for the task duration of the work activity. Industrial hygiene data analyzed using IH statistics software or descriptive statistical tool; targeting the 95th percentile of the data.

Air Sampling Results - Personal

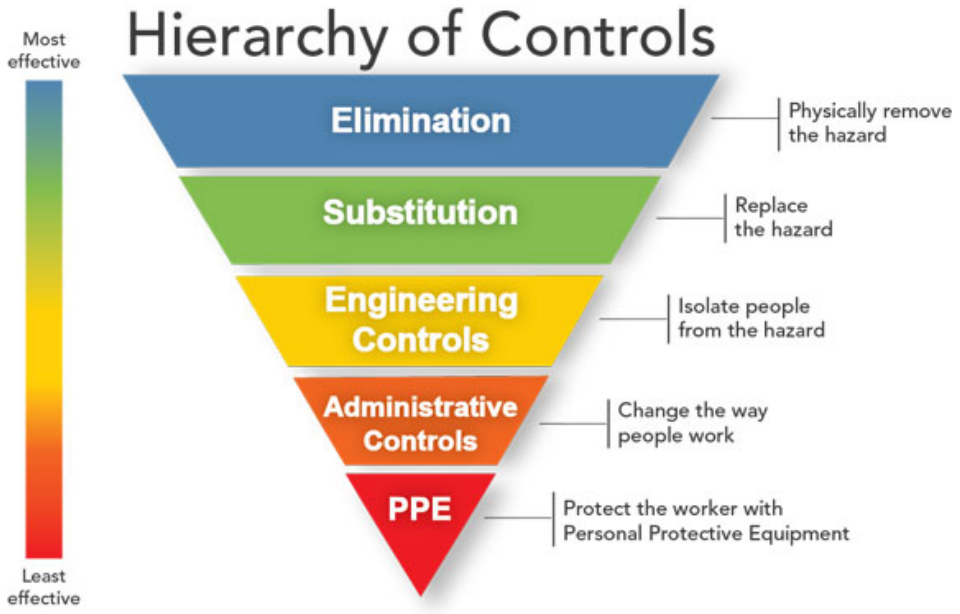
Chemical	Product / process	Sampling Date	Sampling Time (min)	Results (ppm)	8 Hour TWA (ppm)	Comments

Summary of Data

Task Duration Vs 8 Hour TWA	Number of samples	Mean (ppm)	Range (ppm)	Average Sampling Time (min)	Air Sampling Time Range (min)	UTL 95, 95 (statistical analysis)	APF	Conclusions
Task Duration								
8 Hour TWA								

Control of Hazards

- Always start evaluating if you can eliminate or substitute CMR substance
- Utilizing statistical analysis (e. g. Descriptive Statistics) of industrial hygiene personal exposure data, the operating company should establish, implement, and maintain a plan to reduce and/or control employee exposures to CMR substances below the allowable exposure limit.



Medical Surveillance

- To determine fitness for duty
- To identify the potential health effects due to possible occupational exposure to harmful substances or agents
- Based on site risk assessment (indicated the exposures from IH monitoring or qualitative assessment are above OEL)
- Check local legislation to determine medical surveillance requirements

Training

- Personnel working with CMR should receive initial training prior to working with chemicals and periodically thereafter.
- Records of conducted training must be kept on file and should include an outline of the topics covered. Training should include at a minimum:
  - ✓ The hazards/ toxicological effects associated with the CMR being used.
  - ✓ Proper methods and techniques for the safe use of the CMR substances.
  - ✓ Site medical surveillance process, including appropriate baseline, periodic, exit and post exposure evaluations
  - ✓ Decontamination practices and procedures (for both emergency and routine use)
  - ✓ Emergency practices and procedures.
  - ✓ A review of the SOPs and safety data sheets.
  - ✓ Containers, packages and installations containing carcinogens, mutagens or reprotoxins are clearly and legibly labelled, and that warning signs are clearly displayed.

Solvent Selection Guide (Example)

Family	Solvent	BP (°C)	FP (°C)	Worst H3xx[a]	H4xx	Safety score	Health score	Env. score	Ranking by default	Ranking after discussion[b]
Water	Water	100	na	None	None	1	1	1	Recommended	Recommended
Alcohols	MeOH	65	11	H301	None	4	7	5	Problematic	Recommended
	EtOH	78	13	H319	None	4	3	3	Recommended	Recommended
	i-PrOH	82	12	H319	None	4	3	3	Recommended	Recommended
	n-BuOH	118	29	H318	None	3	4	3	Recommended	Recommended
	t-BuOH[c]	82	11	H319	None	4	3	3	Recommended	Recommended
	Benzyl alcohol	206	101	H302	None	1	2	7	Problematic	Problematic
	Ethylene glycol	198	116	H302	None	1	2	5	Recommended	Recommended
Ketones	Acetone	56	−18	H319	None	5	3	5	Problematic	Recommended
	MEK	80	−6	H319	None	5	3	3	Recommended	Recommended
	MIBK	117	13	H319	None	4	2	3	Recommended	Recommended
	Cyclohexanone	156	43	H332	None	3	2	5	Recommended	Problematic
Esters	Methyl acetate	57	−10	H302	None	5	3	5	Problematic	Problematic
	Ethyl acetate	77	−4	H319	None	5	3	3	Recommended	Recommended
	i-PrOAc	89	2	H319	None	4	2	3	Recommended	Recommended
	n-BuOAc	126	22	H336	None	4	2	3	Recommended	Recommended
Ethers	Diethyl ether	34	−45	H302	None	10	3	7	Hazardous	HH
	Diisopropyl ether	69	−28	H336	None	9	3	5	Hazardous	Hazardous
	MTBE	55	−28	H315	None	8	3	5	Hazardous	Hazardous
	THF	66	−14	H351	None	6	7	5	Problematic	Problematic
	Me-THF	80	−11	H318	None	6	5	3	Problematic	Problematic
	1,4-Dioxane	101	12	H351	None	7	6	3	Problematic	Hazardous
	Anisole	154	52	None	None	4	1	5	Problematic	Recommended
	DME	85	−6	H360	None	7	10	3	Hazardous	Hazardous
Hydrocarbons	Pentane	36	−40	H304	H411	8	3	7	Hazardous	Hazardous
	Hexane	69	−22	H361	H411	8	7	7	Hazardous	Hazardous
	Heptane	98	−4	H304	H410	6	2	7	Problematic	Problematic
	Cyclohexane	81	−17	H304	H410	6	3	7	Problematic	Problematic
	Me-cyclohexane	101	−4	H304	H411	6	2	7	Problematic	Problematic
	Benzene	80	−11	H350	None	6	10	3	Hazardous	HH
	Toluene	111	4	H351	None	5	6	3	Problematic	Problematic
	Xylenes	140	27	H312	None	4	2	5	Problematic	Problematic
Halogenated	DCM	40	na	H351	None	1	7	7	Hazardous	Hazardous
	Chloroform	61	na	H351	None	2	7	5	Problematic	HH
	CCl_4	77	na	H351	H420	2	7	10	Hazardous	HH
	DCE	84	13	H350	None	4	10	3	Hazardous	HH
	Chlorobenzene	132	29	H332	H411	3	2	7	Problematic	Problematic
Aprotic polar	Acetonitrile	82	2	H319	None	4	3	3	Recommended	Problematic
	DMF	153	58	H360	None	3	9	5	Hazardous	Hazardous
	DMAc	166	70	H360	None	1	9	5	Hazardous	Hazardous
	NMP	202	96	H360	None	1	9	7	Hazardous	Hazardous
	DMPU	246	121	H361	None	1	6	7	Problematic	Problematic
	DMSO[c]	189	95	None	None	1	1	5	Recommended	Problematic
	Sulfolane[c]	287	177	H360	None	1	9	7	Hazardous	Hazardous
	HMPA	>200	144	H350	None	1	9	7	Hazardous	HH
	Nitromethane	101	35	H302	None	10	2	3	Hazardous	HH
Miscellaneous	Methoxy-ethanol	125	42	H360	None	3	9	3	Hazardous	Hazardous
	Carbon disulfide	46	−30	H361	H412	9	7	7	Hazardous	HH
Acids	Formic acid	101	49	H314	None	3	7	3	Problematic	Problematic
	Acetic acid	118	39	H314	None	3	7	3	Problematic	Problematic
	Ac_2O	139	49	H314	None	3	7	3	Problematic	Problematic
Amines	Pyridine	115	23	H302	None	4	2	3	Recommended	Hazardous
	TEA	89	−6	H314	None	6	7	3	Problematic	Hazardous

CMR Exposure Control Summary

CMR Exposure Control

1. Written CMR exposure control procedure -Describing the site risk management of GHS defined category 1A and/or 1B carcinogens, mutagens, reprotoxins
2. Chemical Identification
3. Chemical Approvals
4. Designated Use area – Areas where quantitative risk assessments identify exposure risk above the OEL values should have restricted access for 'Authorized personnel only'
5. Process or experiment description
6. Risk Assessment – Qualitative, Quantitative, Data Analysis
7. Control Hazards – General, Engineering controls, Administrative control & PPE, Special Handling & Storage, Spill Control & Reporting, Waste Disposal, Maintenance procedures, Decontamination
8. Medical Surveillance
9. Training

CMR Exposure Control – Takeaways

- Removal of the CMR substances at the source - appropriate local and general ventilation as needed
- **Good design** of work processes and **engineering controls** to avoid or minimize the release of CMR substances (work **as closed as possible** - avoid open handling)
- Collective protection measures and/or, where exposure cannot be avoided by other means, individual protection measures
- **Good hygiene practices!**
  (in particular regular cleaning of floors, walls and other surfaces)
- Clearly **trace / indicate zone** where CMR substances are handled
- Make up **emergency plan** how to deal with emergencies likely to result in abnormally high exposure of CMR substances
- Means for safe storage (e.g. keep CMR substances separated from flammables), handling and transportation, using sealed and clearly and visibly labeled containers
- Means for safe collection, storage and disposal of **waste**, including use of sealed, clearly and visibly labeled containers
- People who work with CMR substances need to receive appropriate **medical checks** (goal: early detection)
- All people need to be well **informed** and **trained** specifically to work with CMR substances

Thanks!

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

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