Risk assessment Methodologies

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Outline

1) What is Risk Assessment?
2) Terminology
3) Why do we do a Risk Assessment
4) Expectations of a Risk Assessment
5) Planning your Risk Assessment
6) Five Steps in carrying out a Risk Assessment
7) Vulnerable Workers
8) Other Risk Methodologies

Risk Assessment?

- Risk Assessment is the procedure by which the risks posed by inherent hazards and associated risk involved in the processes or situations are estimated either quantitatively or qualitatively.
- Systematic process of managing risk proactively.
- Process of evaluating the risk(s) arising from a hazard(s),taking into account the adequacy of any existing controls, and deciding whether or not the risk(s) is acceptable (OHSAS 18001 2007)

Cornerstone of OHS management system


Goldilocks & the 3 Bears
?
I just can't beleive Goldilocks went into the woods without a risk assessment first

Terminology

Hazard

- “a source of or exposure to danger”, or more simply “something with the potential to cause harm”.

- OHSAS 18001 2007 Source, situation, or act with a potential for harm in terms of human injury or ill Health , or a combination of these

Terminology

RISK

- Is the likelihood or probability that harm from a particular hazard may occur.
- Combination of the likelihood of an occurrence of an hazardous event or exposure(s) and the severity of injury or ill health that can be caused by the event or exposure(s) (OHSAS 18001 2007)

WHY DO WE DO RISK ASSESSMENT?

- Legal
- Risk averse
- System Requirement (Policy based decisions)
- Financial.
- Moral

LEGAL REQUIREMENTS

Risk assessment forms the cornerstone of any SHE Management System. Why do you think this would be so?
You cannot manage what you cannot define or do not know.

This basic fact is recognised within our legislation in terms of Section 8(2) d of the OHSACT (85) of 1993, where an employer is required to establish, as far as is reasonable practicable:
"What hazard to the health or safety of persons are attached to any work which is performed, any article or substance with is produced, processed, used, handled, stored or transported and any plant or machinery which is used in his business" and it goes on to say that, "he shall, as far as is reasonably practicable, further establish what precautionary measures should be taken with respect to such work, article, substance, plant or machinery in order to protect the health and safety of persons, and he shall provide the necessary means to apply such precautionary measures."

OHSA Sec. 8

HIRA (Hazard Identification, Risk Assessment) - **d**

↓

Eliminate, mitigate before resorting to PPE – **b** **GSR 2**

↓

Safe: Systems, Plant, Machinery - **a**

↓

Information, instructions, training, supervision - e

SELF REGULATION

Articles and Substances - c

Sec. 13 Duty to inform

Prohibiting employee - f

Enforcement - (g - j)

FINANCIAL BENEFITS

Although there are costs associated with the implementation of controls, savings are also achieved.

These are in the form of:

- **Reduction** in incidents and associated incident investigation and reputational costs
- **Enhanced** productivity and staff morale
- Reduction in waste
- **Increase efficiency** and reduced down time
- Legal liability

MORAL REASONS

- Serving as the basis for a SHE Management System, doing risk assessments forms part of an employer's moral duties to provide a healthy and safe working environment for their employees and others. (Duty of Care)
- Furthermore, environmental resources are commodities shared with society, thus the employer has a duty to minimise the impact of the organisation on these commodities to the benefit of the community at large

When should we conduct Risk Assessments

The risk assessment procedure is intended for use:

- For existing operations where hazards appear to pose a significant threat and it is uncertain whether existing or planned controls are adequate in principle or in practice.
- When new plant or equipment is installed.
- Fire Risk Evaluation
- Occupational Hygiene Stressors
- Major Hazardous Installations installed or re-assessed by AIA
- Electrical zoning surveys

When should we conduct Risk Assessments (cont)

- Before new work is performed that is not governed by a safe working procedure.
- Before emergency work (out of routine activities/ non-routine) are to be performed.
- In pursuing continuous improvement in excess of the minimum legal requirements
- Risk Assessments must be reviewed after the occurrence of a significant OHSE incident.
- To determine those aspects that have or can have significant impact (s) on the environment (i.e. significant environmental aspects)

Acceptable risk standard

- Where it is clearly defined
- Self regulatory(Reasonably Practical)
  - Severity and scope of hazard /risk
  - Level of knowledge concerning hazard / risk and means of removing
  - Suitability and availability of ways of removing hazard
  - Cost vs. Benefit

Expectations of a Risk Assessment

The risk assessment process should be:

- Systematic
- Rigorous
- Structured
- Repeatable
- Consultative

Outcomes of the risk assessment process should be:

- Defensible
- Auditable

‘Suitable and Sufficient’

- Proportionate to level of risk
- Reviews all aspects of work activity
- Considers work organisation
- Identifies significant hazards and risks
- Evaluates the risks
- Identifies control measures
- Enables priorities to be set
- Considers non-routine operations
- Considers risks to the public
- Undertaken by competent person(s)
- Valid for a reasonable time

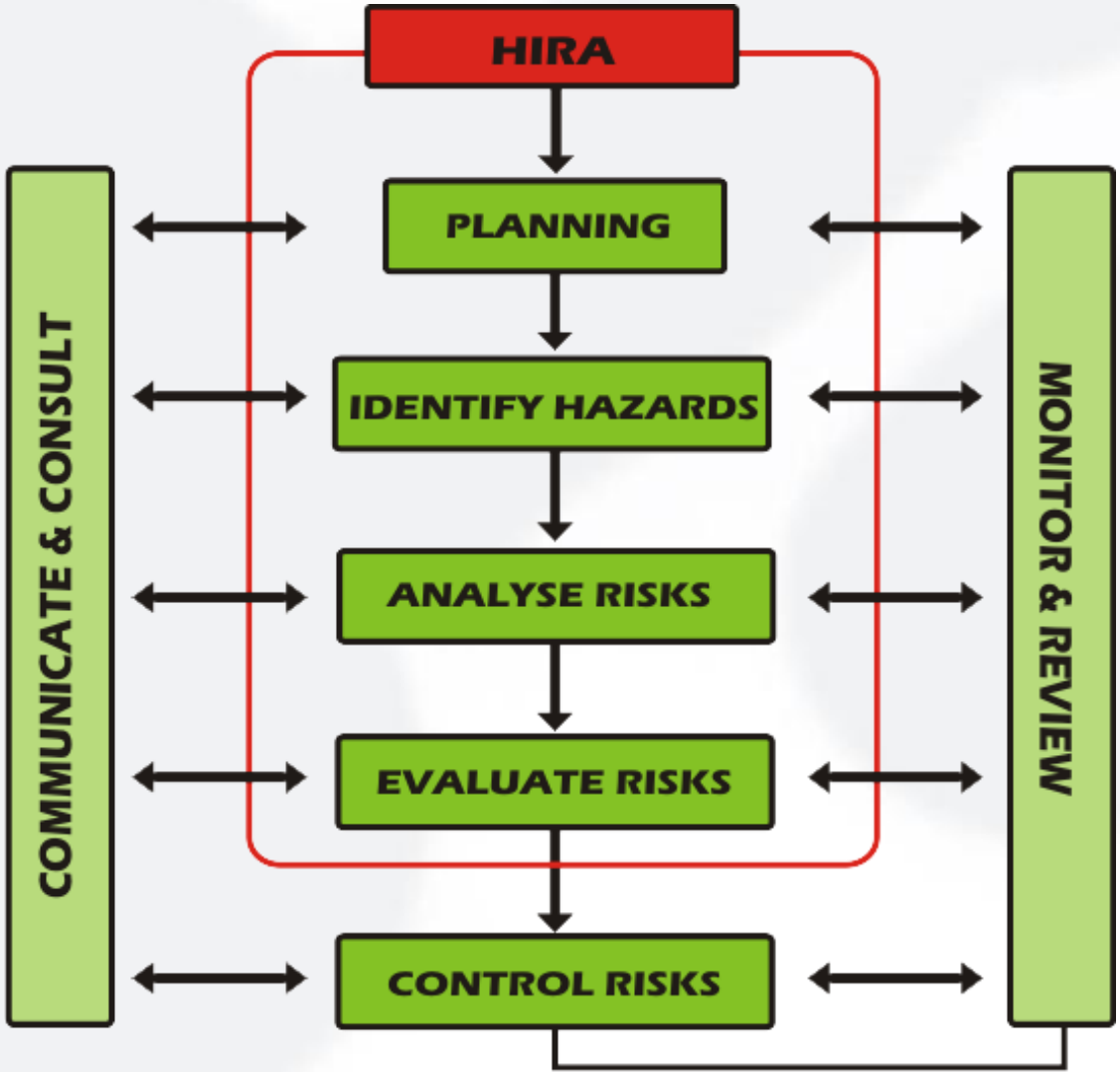
Competent Risk Assessors

- Experience and training in hazard identification and carrying out risk assessments
- Knowledge of the process or activity
- Technical knowledge of the plant or equipment
- Good communication and report writing skills
- Ability to interpret legislation and guidance
- Positive attitude

Consultative (Team Effort)

- Knowledge of risk assessment techniques
- Knowledge of the process to be assessed
- Ability to interpret standards
- Attention to detail
- Recording and communication skills
- Managerial influence to authorise and implement change

WHAT DOES A FORMAL RISK ASSESSMENT ENTAIL?

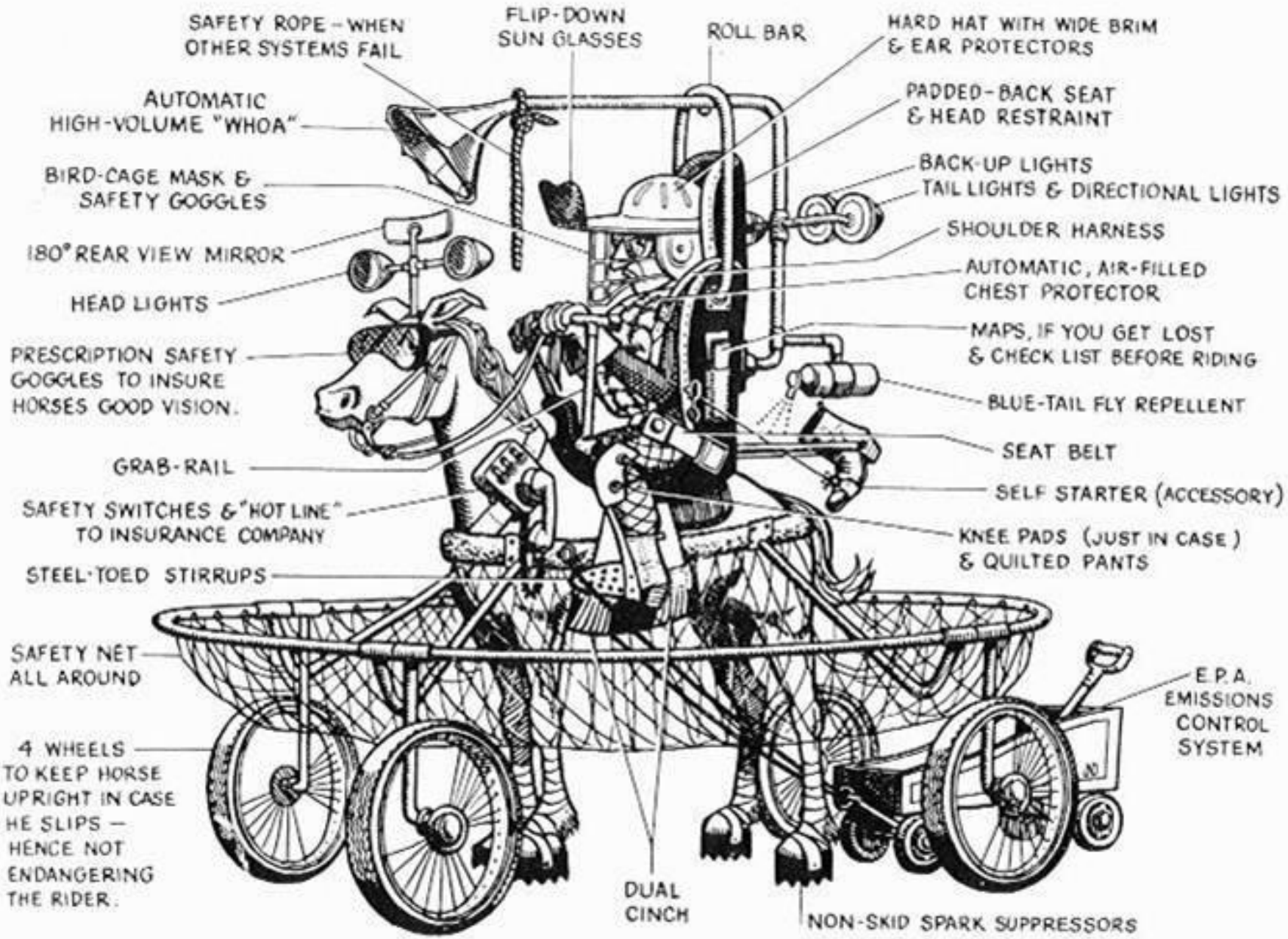


PLANNING

- Defining the scope and depth of risk ass.
- Clarify the methodology to be used.
- Resource requirements
- Identify and access input data Example Incident record hygiene survey ,MSDS etc.
- Determine documentation needs
- Compile an operational flow diagram
- Establish the duties and responsibilities of all the role players
- Determine training and team composition requirements
- Risk assessment cannot be done in isolation.
- Outline communication and consolation process.
- Risk assessment team: Cross Section
- Operations, Technical , Unions, SHE Rep, OHP

3 Levels of Risk Assessment

1) **Baseline Risk Assessment: Primary, Broad based:**
   - Geographical- Location of activities example welding on the ground has certain risk , the same task in a vessel or in elevated position identifies additional risk.
   - Functional - Types of activities
   - Pure hazards – inherently dangerous
2) **Issue-Based Risk Assessment:**
   - New process, Equipment. New legislation changes, Accident
3) **Continuous Risk Assessment:**
   - Day to Day Assessment, Pre start up checks, SHE Rep inspections , Operator checks.



Cowboy after O.S.H.A.

Five steps in carrying out a Risk Assessment

- Step One: Identify Hazards
- Step Two: Analysis
- Step Three: Evaluation
- Step Four: Record findings
- Step Five: Review and update

Step One: Identify Hazards

- Process mapping and creating a flow
- Review input data
  - Absenteeism records
  - MSDS's
  - Statistics
- In Situ Physical assessment in areas
- Interviews with operators, maintenance staff
- Benchmarking with other companies.

IDENTIFY THE HAZARDS

PHYSICAL HAZARDS: Ionizing radiation (x-rays), Noise, Lighting, Vibration, extreme temperatures, Poor ventilation.

CHEMICAL HAZARDS: Acids, Pesticides, Herbicides, Fumes, Dusts, Gasses, Flammable substances, Solvents, Effluent, Solid waste, Pharmaceutical (Levothyroxine) 600 micrograms humans versus rats

- Chemical Physical
- Pharmacological
  - Side Effects
  - Therapeutic Effects

BIOLOGICAL HAZARDS: Vermin (rats & mice), Pathogens, Viruses, HIV/AIDS, Medical waste

MECHANICAL Lifts, Cutting machines, Electrical hand tools, Portable electrical equipment, Lifting equipment, Forklifts, Ladders scaffold, slip trip and falls.

ERGONOMIC HAZARDS: Manual handling, Repetitive movement, Poor design, Restricted space; Outdated design & technology, work stations. Prolonged standing

PSYCHO-SOCIAL HAZARDS: Shift work, Peer pressure, Alcohol / Drug misuse, Stress

ENVIRONMENTAL ASPECTS: Contaminated air and water, hazardous waste, Resource use

Identify the hazards in the following pictures

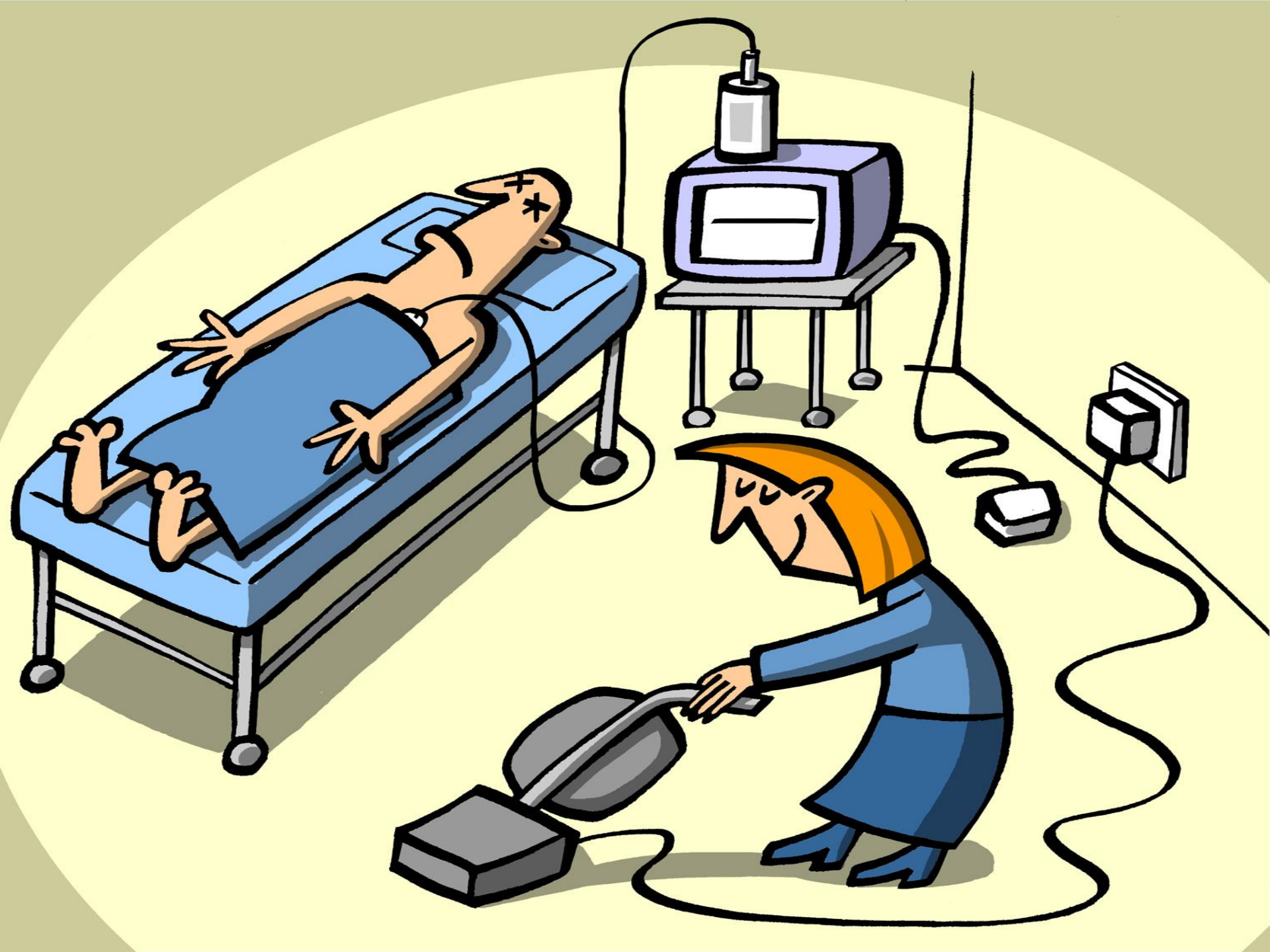

dreamstime.com


WASTE

IDENTIFICATION OF HAZARDS

- Brainstorming & process mapping
- Review input data – incident history, hygiene surveys, MSDSs
- Physical assessment
- Interviews
- Benchmarking – codes or practice/standards
- Don’t be scared to state the obvious


VITAMIN C
VITAMIN B12
VITAMIN C
VITAMIN B12




EXIT
EXIT

Step Two: Analysis Decide who might be harmed & how?

- Operator type (Final assembly)
- Maintenance staff
- Support staff
- Cleaning staff
- Contractors
- Visitors
- Vulnerable employees

Consequences

SAFETY CONSEQUENCES

- Consequences that are the result of direct energy transfer fall under this category. They usually result from contact between the person and the plant or machinery.

These could include but are not limited to the following:

- Amputations
- Contusions
- Lacerations
- Unconsciousness
- Fractures
- Electric Shock
- Burns

HEALTH CONSEQUENCES

Consequences that are the result from existing conditions within the working environment fall under this category. They usually result from exposures to fumes, dust, chemicals, radiation, noise, poor lighting and ergonomics.

These could include but are not limited to the following:

- Dermatitis
- Cancer
- Asbestosis
- NIHL
- Silicosis

Acute and Chronic

Step 3: Evaluation (to prioritise risks for action)

- Quantitative risk assessments
  - Numerical value assigned giving hazards measurable qualities to prioritize.
- Qualitative risk assessments
  - Rely on experience and opinion of risk assessors and team
  - You can not argue one risk assessments better than the next.
- *One must keep in mind that the success of any evaluation methodology employed is measured on the outcomes it has achieved.*
- *Must pass the test of reasonably practicability.*

- **There may be several risk related to one hazard.**

Evaluate The Risk

- **Risk Estimation**
  - Consider 3 parameters (**Severity**, **Probability** and **Exposure**)
    - **Probability**– extent of possible exposure
      - **Two approaches:**
        - » Ignore existing controls and consider **Probability** = raw assessment
        - » Consider controls and establish **Probability** once off
    - **Severity**
      - Consider the worst consequence of the possible exposure
    - **Exposure**
      - refers to the number of persons, expressed as a percentage of the facility, which could be exposed to a specific health and safety risk

Hierarchy of Control/ Prevention

Safe Place

- **ELIMINATION/SUBSTITUTION**

Eliminating the hazard or the task or by substitution e.g. using less hazardous chemicals

- **CHANGING WORK METHODS**
- Automation of high risk tasks, job rotation etc.
- **ISOLATION/SEGREGATION**
- Isolating the hazard e.g. flammable store, machine guarding or by segregating
- e.g. radiographers are segregated from X-Ray equipment.
- **ENGINEERING CONTROL**
- Local exhaust ventilation to remove contaminants can be utilised to minimise risks.
- **ADMINISTRATIVE CONTROL**
- **PERSONAL PROTECTIVE EQUIPMENT**
- PPE should only be considered as a last resort or in combination with other more effective control measures.

Safe Person

4 T's of risk control

General Principles of Prevention

ILO-OSH 2001(Guideline on OHS Management Systems) order of priority

a) Eliminate the hazard/risk
b) Control the hazard/risk at source, through the use of engineering controls or organisational measures
c) Minimise the hazard/risk by the design of safe work systems, which include administrative control measures
d) Where residual hazards/risks cannot be controlled by collective measure, the employer should provide for
e) appropriate personal protective equipment, including clothing, at no cost, and should implement measures
f) to ensure its use and maintenance

WHAT CONTROLS WOULD YOU IMPLEMENT?

EFFECTIVENESS OF CONTROLS

- Look at standards and requirements and if they are in place. i.e. Lock out procedure.
- Engineering controls i.e. Guarding, barriers
- Administrative control i.e. Job rotation SOP, medical surveillance, monitoring and measurement and training programs.
- PPE , Goggles, safety shoes us used as a last resort.
- NO CONTROLS.

Hazard prevention and control procedures or arrangements should:

a) Be adapted to the hazards and risks encountered by the organisation
b) Be reviewed and modified if necessary on a regular basis
c) Comply with national laws and regulations, and reflect good practice
d) Consider the current state of knowledge, including information or reports from organisations, such as labour inspectorates, occupational safety and health services, and other services as appropriate

Action Plan

Once you have identified the necessary control, you may put an action plan together for your program.

Such a plan should include:

- Short-term controls that are cost-effective and can reduce the risk with little fuss
- Long-term solutions for significant risks (preferably engineering or elimination controls) which would further reduce the risk
- Actions for training or conveying the information regarding the risks
- A means to follow up implementation of the plans
- Assignment of responsibilities and roles for accountability
- A time frame for implementation

Step 4: Record your findings

Significant findings and action plans recorded as proof of implementation and control.

- Hazards, risks and ratings
- Affected persons, groups and departments
- Existing controls
- Planned controls
- Persons responsible for implementing controls
- Reference to standards, legislation, codes of practice

Raw Risk Score

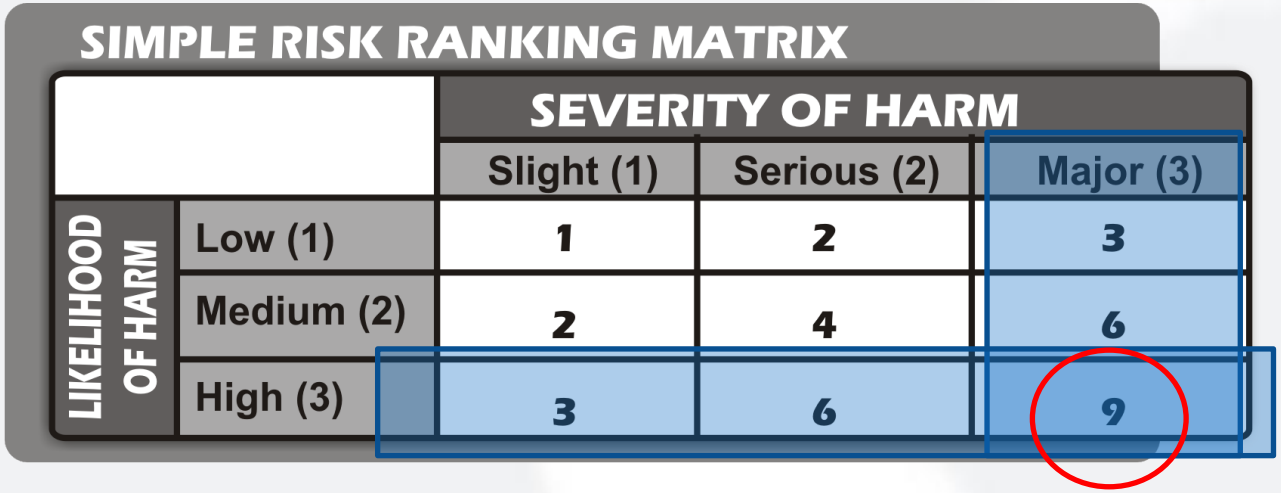
- **Raw Risk = Risk without controls in place**

S x (P + E) other examples are S xPxE ect…

- **Residual Risk =**‘Residual Risk’ refers to the level of risk that remains after controls have been implemented.

N	Normal circumstances: indicates a hazard which occurs under normal operating conditions, i.e. the way a process or activity is presently carried out during everyday routine work
A	Abnormal circumstances: indicates hazard which occurs during planned or unplanned non-daily routines that may occur around a process or activity, i.e. maintenance, plant up-grades, start-up/shut down
E	Emergency circumstances: indicates a hazard which may lead to emergency conditions, i.e. catastrophic incidents or accidents which are unplanned events

Simple risk-ranking Matrix



Examples

Hazard Identification & Risk Assessment

Item	Task	Hazard	Risk	S SAFETY	H HEALTH	E ENVIRONMENT	Legislation	Exposure (E)	Probability (P)	Severity Index (S)	Risk score	Rating	Current Controls (Mitigation)	Residual Risk Score E	P	S	Risk score
Cleaning Mixers (Plant 1 and Plant 2)																	
1	Cleaning Mixers	Electrical - Emergency stop button	Shock	x				6	6	15	540	VERY HIGH RISK	SWP & PM Schedule	6	1	15	90
2		Electrical - Switch box	Shock	x				6	6	15	540	VERY HIGH RISK	SWP & PM Schedule	6	1	15	90
3		Manual handling - removing mud with poker	Back injuries	x				6	6	3	108	SUBSTANTIAL RISK	Train employees	6	3	3	54
4		Entanglement - with screws if they have not stopped	Loss of limbs	x				6	1	15	90	SUBSTANTIAL RISK	SWP & Train Employees in procedures	1	1	15	15
5		Chemical - Carbon black (large quantities - if cover is removed)	Respiratory damage		x			6	10	7	420	VERY HIGH RISK	PPE	6	1	7	42
6		Chemical - Carbon black (large quantities - if cover is removed)	Ground and water pollution			x		6	10	3	180	SUBSTANTIAL RISK	Concrete Floors, Seperate drainage system, effluent plant, recycle water	6	3	3	54
7		Tripping hazards - hoses	Injury to employees	x				10	6	3	180	SUBSTANTIAL RISK	Housekeeping	6	1	3	18
8		Slipping hazard - washing screws or area around mixer	Injury to employees	x				6	6	3	108	SUBSTANTIAL RISK	PPE	6	3	3	54

Example 2

- *Likelihood or frequency (L): How often can the event be expected to happen?*

Likelihood Class	**Factor L**
Might well be expected	10
Quite possible	6
Unusual but possible	3
Only remotely possible	1

Exposure (E): How often is the person exposed to the operation?

Exposure Index	**Factor E**
Continuously or Inherently Hazardous	10
Daily (few times per day)	6
Weekly (few times per week)	3
Monthly (few times per month)	2
Annually or less often	1

Severity (S): What is the outcome of the event should it occur?

Severity Index

Factor S	
Irreversible effect	5
Severely harmful	4
Harmful	3
Slightly harmful	2
Minimal Effect	1

Mitigation Measures

No Effective Mitigation	1
Written Procedure and PPE	2
Training Complete	3
Monitoring & Measurement Conducted	4
Preventative Maintenance Conducted	5
Engineering Method Effective e.g. guarding	6
Project Completed to remove or reduce risk substantially	10

RAW Risk = L (Likelihood) X E (Exposure) X S (Severity) assuming there are no controls in place (current or envisaged).

RESIDUAL RISK = RAW RISK ÷ M (Mitigation) (Consider Mitigation measures already implemented and compliance to controls and procedures).

- RAW RISK= L (6) X E (10) X S (4) = 240
- RESIDUAL RISK=240/2 = 120

	RISK CLASSIFICATION	
RISK DESCRIPTION		RISK VALUES
LOW		< 50
MEDIUM		50 – 99
HIGH		100 – 299
INTOLERABLE		> 300

Risk Assessment Register

Process Activity:

Date:

Compiled by:

Machine / Process	Ref.	Macro Hazard / Aspect	Environmental	Aspect/Hazard Source	Impact/Risk/Consequence	Likelihood	Exposure / Quantity	Severity	Raw Risk Rating	Mitigation Rating	Residual Risk (H & S)	Residual Risk (E)	Controls	Compliance	Comments	Additional Controls Implemented	Likelihood	Exposure / Quantity	Severity	Raw Risk Rating	Mitigation Rating	Residual Risk (H & S)	Residual Risk (E)

Example 3 Risk Severity-SH RA

Severity (degree of harm ito injury or ill health or extent of damage to the environment)

	Safety	Health
3	First aid	Physical discomfort Irritation Recurrent pain
6	Medical aid Temporary disablement	Illness & time off work
9	Medical aid Permanent disablement	Permanent damage to health
12	Fatality	Terminal illness
15	Multiple fatalities	Multiple persons terminal illness

Probability

Probability (likelihood of the occurrence of a specific outcome, i.e. 'Risk')	
4	Rare = almost impossible
8	Unlikely = has happened before in industry
12	Possible = happens regularly in industry
16	Likely = has happened before in this employer
29	Certain = happens regularly in this employer

Exposure

Exposure (the number of persons, expressed as a % of the facility, that could be exposed to a specific H&S risk; the geographical extent to which the environment could be exposed to a specific impact)

Rating	Number of persons exposed	Environmental exposure
2	0-20%	Site specific
4	20-40%	Immediate surroundings
6	40-60%	Local community
8	60-80%	Regional
10	80-100%	National

Raw Risk = Risk without controls in place

S x (P + E) other examples are SxPxE ect…

Residual Risk =‘Residual Risk’ refers to the level of risk that remains after controls have been implemented.

Hazardous Event

Identify the hazardous events within each step of the operation.

Identify the hazards associated with each hazardous event and the corresponding risk/s

Indicate if the Hazardous Event is a normal, abnormal or an emergency situation

Example

FACILITY NAME

SHE RISK REGISTER

LEGEND:
A- adequate / effective current controls
B - inadequate / non-compliance to current
X - required controls

DEPT / AREA:

Conducted by (Name & designation):

Last Review:

Ref No.	Step in Operation / Activity	Hazardous Event	Hazard	Risk	S/H/E	N/A/E	Raw Risk Sx(O+E)	Raw Risk Rank	ELIMINATION / SUBSTITUTION	ENGINEERING	WARNINGS	ADMINISTRATIVE					PPE	Risk Severity (S)	Occurrence Probability (O)	Exposure Probability (E)	Res Risk Rank
									Elimination / Substitution	Engineering	Signage & Demarcation	Operational Instructions / Checklists	Planned: Inspections / Prev Maint / Task Observations	Hygiene Surveys/ Enviro Sampling	Training	Medical Surveillance	PPE				
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Step 5: Review and Update

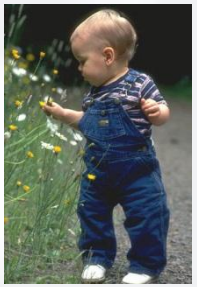
Review if significant changes:

- New machinery/equipment
- Relocation of plant or machinery
- New substances
- Legislative changes/directives
- Personnel changes
- Accident, Incidents or near misses
- New standards
- Audit or monitoring findings

- Periodic review (usually annual)

Vulnerable workers

- Young persons



- Expectant and nursing mothers

Young persons

- Young Persons, under age of 18
- Physically not fully developed and prone to physical stress injuries
- Susceptible to carcinogenic, mutagenic and toxic agents
- Susceptible to workplace hazards e.g. Noise and heat
- Lack of experience and ability to assess risks
- Prone to peer pressure, risk taking and impulsive behaviour

New and expectant mothers

Risks to mother, nursing or unborn child

Risk factors

- Physical and ergonomic risks
- Chemical agents e.g. Carcinogen, mutagens
- Biological agents
- Workplace stressors - noise and heat

METHODS OF ANALYSIS?

Quantitative vs. Qualitative (see next slide)

Plethora of methodologies

Different Analysing techniques

- FTA
- FEMA (FMECA)
- What if
- HAZOP
- Why's Process (5 Why's)

Choice of methodology should be guided by desired outputs of Risk Assessment

Level of complexity match situation and level of risk (HAZOP explosion environment SASOL).

"Reasonable practicable"

Methodology needs to indicate levels of control required

Take into consideration effectiveness of controls currently in place

Address actual practice

FMEA

Failure Mode Effects Analysis (FMEA);

- FMEA provides for an evaluation of potential failure modes for processes and their likely effect on outcomes and/or product performance.
- Once failure modes are established, risk reduction can be used to eliminate, contain, reduce or control the potential failures. FMEA relies on product and process understanding.
- FMEA methodically breaks down the analysis of complex processes into manageable steps.
- It is a powerful tool for summarizing the important modes of failure, factors causing these failures and the likely effects of these failures.

FMECA

Failure Mode, Effects and Criticality Analysis (FMECA)

- FMEA might be extended to incorporate an investigation of the degree of severity of the consequences, their respective probabilities of occurrence, and their **detectability**,
- FMECA can identify places where additional preventive actions might be appropriate to minimize risks.
- FMECA application in the pharmaceutical industry should mostly be utilized for failures and risks associated with manufacturing processes; however, it is not limited to this application. The output of an FMECA is a relative risk “score” for each failure mode, which is used to rank the modes on a relative risk basis.

FMECA

Failure mode = specific manner or way by which failure occurs; includes the end-failure state (e.g. leaking lay flat)

Failure effect = loss under the stated conditions (e.g. acute operator exposure)

Failure cause = defects in requirements, design, process, quality control, handling or part application, which are the underlying cause or sequence of causes that initiate a process (mechanism) that leads to a failure mode over a certain time. (e.g. improper application of tie-backs)

Failure mechanism: (e.g. slipping off the end of the lay flat at outlet)

Risk Severity- FMECA

	Effect	Criteria
3	High	Hazardous /potential hazardous effect without warning. Safety related. Regulatory non-compliant / in jeopardy. Irreversible or severe disabling illness Irreversible environmental damage
2	Medium	Performance moderately affected. Fault on non-vital part requires repair. Customer experiences some dissatisfaction. Reversible illness without lasting effect Reversible environmental damage
1	Low	Very slight effect on performance. Non-vital fault may be noticed. Customer is not annoyed. Toxic effect without illness Environmental impact without damage

Example Risk Severity-

	Safety	Health
3	First aid	Physical discomfort –Irritation -Recurrent pain Contact exposure-
6	Medical aid Temporary disablement	Illness & time off work – acute or chronic low dose exposure
9	Medical aid Permanent disablement	Permanent damage to health- acute or chronic high dose exposure
12	Fatality	Terminal illness- acute intoxication
15	Multiple fatalities	Multiple persons terminal illness

Occurrence

Attachment 2 - Occurrence Ranking System		
Ranking	Possible Failure Rates	Probability of Failure
3	1 in 100	High probability of failure; Event noted each time or almost Regularly happens at Aspen (i.e. > once a month)
2	1 in 1 000	Medium probability of failure; Frequent but non-systematic event Happens infrequently at Aspen (i.e. > once per year)
1	1 in 10 000	Remote probability of failure; Accidental event, occurrence exceptional Seldom happens at Aspen (i.e. < once per year)

Detection System / Criticality Ranking

Attachment 3 -		
Ranking	Detection	Likelihood of Detection by Design Control
3	Remote	Remote chance that design control will detect potential cause;
		Undetectable;
		Absence of system of detection but detection is still possible by chance
2	Moderate	Moderate chance that design control will detect potential cause;
		Presence of a single system of detection which is not
		100 % reliable
		Detection system dependent on operator vigilance
		Non-specific detection system in place
		Specific detection system in place but with NO feed-back reactivity
1	Almost Certain	High likelihood of detection;
		System of multiple and independent detection tools or a single system of detection which is 100 % reliable
		Specific detection system in place with feed-back reactivity

Template FMCEA

No.	System		Risk Scenario				GMP Bus. SHE Risk	Severity	Likelihood Occurrence
	Facility	Process	Potential Failure Mode	Failure Effects	Failure Causes	Failure detection			

Special population groups to consider in HPAPI manufacturing

- Drug restriction as indicated in the monograph.
- Pregnancy and lactation
- All current users of HPAPI.
- Specific population group in monograph

Thank you for your time