Risk assessment Methodologies

Presented by Mike Erasmus GradIOSHSA (SAIOSH); GradIOSH(IOSH UK)
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
I just can’t believe 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

Articles and Substances - c

Sec. 13 Duty to inform

SELF REGULATION

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
Identify the hazards in the following pictures.
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
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

- **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.

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 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
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
  \[ S \times (P + E) \] other examples are \( S \times P \times E \) etc...

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

<table>
<thead>
<tr>
<th>Circumstance</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>N</strong></td>
<td>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</td>
</tr>
<tr>
<td><strong>A</strong></td>
<td>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</td>
</tr>
<tr>
<td><strong>E</strong></td>
<td>Emergency circumstances: indicates a hazard which may lead to emergency conditions, i.e. catastrophic incidents or accidents which are unplanned events</td>
</tr>
</tbody>
</table>
# Simple risk-ranking Matrix

<table>
<thead>
<tr>
<th>LIKELIHOOD OF HARM</th>
<th>SEVERITY OF HARM</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Slight (1)</td>
</tr>
<tr>
<td>Low (1)</td>
<td>1</td>
</tr>
<tr>
<td>Medium (2)</td>
<td>2</td>
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<tr>
<td>High (3)</td>
<td>3</td>
</tr>
</tbody>
</table>
## Examples

### Hazard Identification & Risk Assessment

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

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

<table>
<thead>
<tr>
<th>Likelihood Class</th>
<th>Factor L</th>
</tr>
</thead>
<tbody>
<tr>
<td>Might well be expected</td>
<td>10</td>
</tr>
<tr>
<td>Quite possible</td>
<td>6</td>
</tr>
<tr>
<td>Unusual but possible</td>
<td>3</td>
</tr>
<tr>
<td>Only remotely possible</td>
<td>1</td>
</tr>
</tbody>
</table>
Exposure (E): How often is the person exposed to the operation?

<table>
<thead>
<tr>
<th>Exposure Index</th>
<th>Factor E</th>
</tr>
</thead>
<tbody>
<tr>
<td>Continuously or Inherently Hazardous</td>
<td>10</td>
</tr>
<tr>
<td>Daily (few times per day)</td>
<td>6</td>
</tr>
<tr>
<td>Weekly (few times per week)</td>
<td>3</td>
</tr>
<tr>
<td>Monthly (few times per month)</td>
<td>2</td>
</tr>
<tr>
<td>Annually or less often</td>
<td>1</td>
</tr>
</tbody>
</table>
Severity (S): What is the outcome of the event should it occur?

**Severity Index**

**Factor S**

<table>
<thead>
<tr>
<th>Effect</th>
<th>Index</th>
</tr>
</thead>
<tbody>
<tr>
<td>Irreversible effect</td>
<td>5</td>
</tr>
<tr>
<td>Severely harmful</td>
<td>4</td>
</tr>
<tr>
<td>Harmful</td>
<td>3</td>
</tr>
<tr>
<td>Slightly harmful</td>
<td>2</td>
</tr>
<tr>
<td>Minimal Effect</td>
<td>1</td>
</tr>
</tbody>
</table>
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

\[
\text{RAW Risk} = L \times E \times S \quad \text{assuming there are no controls in place (current or envisaged).}
\]

\[
\text{RESIDUAL RISK} = \frac{\text{RAW RISK}}{M} \quad \text{(Consider Mitigation measures already implemented and compliance to controls and procedures).}
\]
- RAW RISK = L (6) X E (10) X S (4) = 240
- RESIDUAL RISK = 240 / 2 = 120

<table>
<thead>
<tr>
<th>RISK CLASSIFICATION</th>
<th>RISK DESCRIPTION</th>
<th>RISK VALUES</th>
</tr>
</thead>
<tbody>
<tr>
<td>LOW</td>
<td>RISK DESCRIPTION</td>
<td>&lt; 50</td>
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<tr>
<td>MEDIUM</td>
<td>RISK DESCRIPTION</td>
<td>50 – 99</td>
</tr>
<tr>
<td>HIGH</td>
<td>RISK DESCRIPTION</td>
<td>100 – 299</td>
</tr>
<tr>
<td>INTOLERABLE</td>
<td>RISK DESCRIPTION</td>
<td>&gt; 300</td>
</tr>
</tbody>
</table>
## Risk Assessment Register

**Process Activity:**

**Date:**

**Compiled by:**

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</tbody>
</table>
## Example 3 Risk Severity-SH RA

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

<table>
<thead>
<tr>
<th>Safety</th>
<th>Health</th>
</tr>
</thead>
<tbody>
<tr>
<td>3 First aid</td>
<td>Physical discomfort</td>
</tr>
<tr>
<td></td>
<td>Irritation</td>
</tr>
<tr>
<td></td>
<td>Recurrent pain</td>
</tr>
<tr>
<td>6 Medical aid</td>
<td>Illness &amp; time off work</td>
</tr>
<tr>
<td>Temporary disablement</td>
<td></td>
</tr>
<tr>
<td>9 Medical aid</td>
<td>Permanent damage to health</td>
</tr>
<tr>
<td>Permanent disablement</td>
<td></td>
</tr>
<tr>
<td>12 Fatality</td>
<td>Terminal illness</td>
</tr>
<tr>
<td>15 Multiple fatalities</td>
<td>Multiple persons terminal illness</td>
</tr>
</tbody>
</table>
**Probability**

Probability (likelihood of the occurrence of a specific outcome, i.e. ‘Risk’)

<table>
<thead>
<tr>
<th>Value</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>4</td>
<td>Rare = almost impossible</td>
</tr>
<tr>
<td>8</td>
<td>Unlikely = has happened before in industry</td>
</tr>
<tr>
<td>12</td>
<td>Possible = happens regularly in industry</td>
</tr>
<tr>
<td>16</td>
<td>Likely = has happened before in this employer</td>
</tr>
<tr>
<td>29</td>
<td>Certain = happens regularly in this employer</td>
</tr>
</tbody>
</table>
## 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)

<table>
<thead>
<tr>
<th>Rating</th>
<th>Number of persons exposed</th>
<th>Environmental exposure</th>
</tr>
</thead>
<tbody>
<tr>
<td>2</td>
<td>0-20%</td>
<td>Site specific</td>
</tr>
<tr>
<td>4</td>
<td>20-40%</td>
<td>Immediate surroundings</td>
</tr>
<tr>
<td>6</td>
<td>40-60%</td>
<td>Local community</td>
</tr>
<tr>
<td>8</td>
<td>60-80%</td>
<td>Regional</td>
</tr>
<tr>
<td>10</td>
<td>80-100%</td>
<td>National</td>
</tr>
</tbody>
</table>
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
## SHE Risk Register Example

**FACILITY NAME**

**SHE RISK REGISTER**

**DEPT / AREA:**

**Conducted by (Name & designation):**

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

**Last Review:**

| Ref No. | Step in Operation / Activity | Hazard | Risk | S/H/E | N/A/E | Raw Risk Sx(O+E) | Raw Risk Rank | Elimination / Substitution | Engineering | WARNINGS | Administrative |
|---------|------------------------------|--------|------|-------|-------|-----------------|--------------|--------------------------|-------------|----------|-----------------
|         |                              |        |      |       |       |                 |              | ELIMINATION / SUBSTITUTION | ENGINEERING | WARNING S | ADMINISTRATIVE |
|         |                              |        |      |       |       |                 |              | Elimination / Substitution | Engineering | Signage & Demarcation |                           |
|         |                              |        |      |       |       |                 |              | Operational Instructions / Checklists |                           | Training | Medico Surveillance | PPE |
|         |                              |        |      |       |       |                 |              | Planned Inspections / Prev Maint / Task Observations |                           |          |                    | PPE |
|         |                              |        |      |       |       |                 |              | Hygiene Surveys / Enviro Sampling |                           |          |                    | PPE |
|         |                              |        |      |       |       |                 |              | Medical Surveillance |                           |          |                    | PPE |

**Res Risk Rank:**

<table>
<thead>
<tr>
<th>Ref No.</th>
<th>Risk Severity (O)</th>
<th>Occurrence Probability (E)</th>
<th>Exposure Probability (E)</th>
</tr>
</thead>
<tbody>
<tr>
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</table>

<table>
<thead>
<tr>
<th>Ref No.</th>
<th>Risk Severity (O)</th>
<th>Occurrence Probability (E)</th>
<th>Exposure Probability (E)</th>
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</thead>
<tbody>
<tr>
<td>0</td>
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</table>
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.
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)
<table>
<thead>
<tr>
<th>Risk Severity- FMECA</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Effect</strong></td>
</tr>
<tr>
<td>---</td>
</tr>
<tr>
<td><strong>3</strong></td>
</tr>
<tr>
<td>Hazardous / potential hazardous effect without warning. Safety related. Regulatory non-compliant / in jeopardy. <strong>Irreversible or severe disabling illness</strong> <strong>Irreversible environmental damage</strong></td>
</tr>
<tr>
<td><strong>2</strong></td>
</tr>
<tr>
<td>Performance moderately affected. Fault on non-vital part requires repair. Customer experiences some dissatisfaction. <strong>Reversible illness without lasting effect</strong> <strong>Reversible environmental damage</strong></td>
</tr>
<tr>
<td><strong>1</strong></td>
</tr>
<tr>
<td>Very slight effect on performance. Non-vital fault may be noticed. Customer is not annoyed. <strong>Toxic effect without illness</strong> <strong>Environmental impact without damage</strong></td>
</tr>
<tr>
<td>Safety</td>
</tr>
<tr>
<td>--------</td>
</tr>
<tr>
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<td>15</td>
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</tr>
<tr>
<td>Ranking</td>
</tr>
<tr>
<td>---------</td>
</tr>
<tr>
<td>3</td>
</tr>
<tr>
<td>2</td>
</tr>
<tr>
<td>1</td>
</tr>
</tbody>
</table>
## Detection System / Criticality Ranking

<table>
<thead>
<tr>
<th>Ranking</th>
<th>Detection</th>
<th>Likelihood of Detection by Design Control</th>
</tr>
</thead>
<tbody>
<tr>
<td>3</td>
<td>Remote</td>
<td>Remote chance that design control will detect potential cause; Undetectable; Absence of system of detection but detection is still possible by chance</td>
</tr>
<tr>
<td>2</td>
<td>Moderate</td>
<td>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</td>
</tr>
<tr>
<td>1</td>
<td>Almost Certain</td>
<td>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</td>
</tr>
<tr>
<td>No.</td>
<td>System</td>
<td>Risk Scenario</td>
</tr>
<tr>
<td>-----</td>
<td>---------</td>
<td>---------------</td>
</tr>
<tr>
<td>Facility</td>
<td>Process</td>
<td>Potential Failure Mode</td>
</tr>
</tbody>
</table>
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