Product Safety versus Personnel Safety

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Definitions

• **Product Safety** - The state in which a product is able to perform to its designed or intended purpose without causing unacceptable risk of harm to persons or damage to property. (AS9100D)

• **Personnel Safety** – Personnel safety is a cross-disciplinary area focused on protecting the safety, health and welfare of workers.
Examples of Personnel Safety

- Inform Supervisors of unsafe conditions
- Use equipment, machines, and tools properly
- Wear safety equipment (PPE)
- Prevent slips and trips
- Keep work areas and Emergency Exits clear
- Eliminate fire hazards
- Ensure all fire extinguishers are functional and maintained
- Avoid tracking hazardous materials into other areas
- Prevent objects from falling
- Use correct posture when lifting
- Take work breaks from time to time
- Well lit areas inside and outside the facility
Examples of Product Safety

- Ensure that the equipment contains all the safety features required to protect the equipment
- All pinch and shear points, sharp edges, and protruding objects must be eliminated wherever possible.
- Burrs and sharp edges shall be eliminated
- All elements of the “operator-machine interface” such as controls, signaling, or display elements, shall be designed to be easily understood so that clear unambiguous interaction between the operator and the machine is possible.
- Warnings on labels and in installation instructions
- Assessment of hazards and mitigation of associated risks:
  - Implement FMEA relating to product (DFMEA) and processes (PFMEA)
  - Perform safety analysis
  - Identify and mitigate risks relating to the organization and its personnel (human factors, management of responsibilities)
Examples of Product Safety

• Management of safety critical items:
  • Define and implement a monitoring control plan for critical items identified through FMEA and safety analysis

• Analysis and reporting of occurred events affecting safety:
  • Organize the collection of potential and occurred events, and analyze their impacts with specialists
  • Organize the internal escalation process and external reporting to interested parties
  • Analyze the adverse trends of products in service reliability and define appropriate actions

• Communication of these events and training of personnel:
  • Promote safety culture and lessons learned from occurred events (impacts of the parts delivered by the organization on the final product safety)
  • Prevent occurrence of safety issues by taking into account industry experience (including occurrences on other products with similar functions or based on same technologies or components).

• 6 Ms on following slides
6 Ms Related to Product Safety

Machines – Check the facilities’ stability, functionality, such as the precision, the cooling and lubrication state of all equipment. If the machinery/equipment is rusting or eroding, the production/maintenance/distribution efficiency may decrease. Proactively maintain and repair equipment.

- Understanding of machine operation
  - Appropriate selection for the operation / capacity analysis
  - Set-up / calibration
  - Maintenance – Scheduled Preventive Maintenance, reliability & maintainability
  - Operational documentation & associated continuous training update

- Tool condition
  - Controls
  - Scheduled Preventive Maintenance

- Safeguards
  - Numerical Control Programs
  - Program Controls
6 Ms Related to Product Safety (cont)

Methods – The methodology, methods or techniques that may affect or impact a process or set of processes in the manufacturing/maintenance/distribution operations. Other factors include, choice of technical parameters, technical guidance and the preciseness and execution of workflow.

- Workflow
- Choice of technical parameters
- Technical guidance
- Preciseness and execution of workflow
- Operational documentation & associated continuous training update
6 Ms Related to Product Safety (cont)

Materials – Think about the materials’ components, physical and chemical properties. Examine whether different parts match well. Are material suppliers and their processes stable or not?

• Conformity
  – Material Testing
  – Certifications / approved sources
  – Contamination / defects

• Suspected Unapproved Parts (ref IAQG SCMH 3.5)
  – Counterfeit and fraudulent parts
  – Parts substitution

• FOD (ref IAQG SCMH 3.4)

• Material handling
  – Damaged during processing
  – Shelf life/Life limited
  – Preservation
6 Ms Related to Product Safety (cont)

Mother Nature – The environment in production field, including temperature, humidity, noise disturbance, vibration, lightening, and indoor pollution will all influence the products or service.

• Environmental impacts
  – Temperature
  – Humidity
  – Dust
  – Particulate contaminants
  – Pollution

• Acts of nature
  – Weather conditions
  – Lightning

• Noise

• Vibration
6 Ms Related to Product Safety (cont)

Manpower/People Power – Do personnel meet expectations and/or standards relating to technology proficiency and experience? Has the employee been properly trained and motivated? Does the staff have quality consciousness, sense of responsibility and discipline?

• Education / Insufficient training
• Personal Certifications
• Out of station work / substitutes
• Employee motivation
• Human Factors
• Stress
• Health of the employee
• Proper mindset
• Attitude, Focus, Distraction
• Management
• Attention / commitment
• Instruction
6 Ms Related to Product Safety (cont)

Measurement – Factors to be considered for correct results: gauge method, calibration, accuracy, appropriate resolution, operator’s fatigue, and readability of the results.

• Selection of appropriate measurement tools & equipment
• Calibration & accuracy of inspection tools & equipment
• Measurement System Analysis
• Statistical Product Acceptance (reference 9138, SCMH 3.7)
• Statistical Process Control (reference 9103, SCMH 3.1)
• Critical items & key Characteristics (reference 9103, SCMH 3.1)
• Control of records & records retention
# Causes of Unsafe Product

<table>
<thead>
<tr>
<th>Category</th>
<th>Details</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>3. Material</strong></td>
<td>- Material, Parts</td>
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<tr>
<td></td>
<td>- The parts which must not be used are used.</td>
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<td></td>
<td>- Use of unreliable parts</td>
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<td>- Foreign material mixes in a product.</td>
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<td><strong>2. Machine</strong></td>
<td>- Facility, Tool, etc.</td>
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<td></td>
<td>- Maintenance performed without using the suitable tool.</td>
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<td>- The facility is not complete.</td>
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<tr>
<td><strong>1. Man</strong></td>
<td>- Personality, skill level, education, condition, etc.</td>
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<td></td>
<td>- The act which is not in the procedure which comes from practice</td>
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<tr>
<td></td>
<td>- The incorrect judgment and the work error which come from poor health</td>
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<td></td>
<td>- There is no eagerness to commit.</td>
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<tr>
<td><strong>4. Method</strong></td>
<td>- Working method, Work procedure, inspection, etc.</td>
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**Accident case No.3**
- Non-suitable functional/working environment.

**Accident case No.2**
- Calibration of Measuring instrument or Testing device is not controlled.
- "Variation" occurs in measurement data.

**Accident case No.1**
- The complicated procedure which induces a mistake
- Omission in an Inspection of Important work

**Resulting Effect**
- Accidents and mistakes occur due to the factors listed above.
Effects of Poor Product Safety Accident

Case #1 - Man

Commercial Airline Accident

Underlying Issue – Man choosing to install via his experience versus following documented planning and verbal guidance with no inspection oversight.

Problem – Cockpit windscreen blew out during flight

Impact – Pilot was ejected through the opening

Why – Incorrect type of fasteners were installed in the cockpit windscreen frame assembly.

Lessons Learned –

- Maintenance manager did not confirm use of the fasteners selected for the application.
- Employee should have selected proper hardware for the specific installation and application rather than using personal judgment.
- Failure to following planning:
  - Although the installer was advised to use the A211-8D screw he did not listen and used the A211-8C.
  - The installer recognized there was something different about the screw fit but chose to ignore the misfit.

Source: Japanese Ministry of Land, Infrastructure, Transport & Tourism
Effects of Poor Product Safety Accident
Case #2 - Machine

Space Industry, Apollo 1, AS-204 Command Module Fire
Underlying Issue – Unsafe conditions unrecognized – complacency probably a key factor, unfueled module was considered low-risk and non-hazardous test
Problem – On-pad fire in Command Module during “Plugs Out” test on Jan 27, 1967
Impact – Three astronauts perished, Virgil Grissom, Edward White II, and Roger Chaffee
Why – Contributors included a cabin sealed with a hatch cover that could not be quickly removed at high pressure, a pure oxygen atmosphere at higher than atmospheric pressure, and an ignition source “vulnerable wiring carrying spacecraft power”
Lessons Learned – Complacency can creep into what are otherwise extremely vigilant & disciplined programs
  • Mature, successful programs can be especially vulnerable
  • That, “it” has been trouble-free is no guarantee that “it” is flawless
  • Need to foster an alertness for what can go wrong
    – Insufficient attention to the routine and obvious can be catastrophic
    – Have fresh eyes look at the “it” and question what can go wrong
    – (verbal hazard analysis)
  • Increased Hazard analysis and awareness
  • Increased safety procedures

Source: NASA, Report of the Apollo 204 Review Board
Effects of Poor Product Safety Accident
Case #3 - Material

Commercial Airline Accident
Underlying Issue – Material Defect
Problem – Engine gear failure due to raw material contamination
Impact – Engine failure, but because dual engine aircraft no loss of life or injury
Why – Contamination of raw stock not detected before gear manufacturing

Lessons Learned –
• Ensure there is a robust inspection process to eliminate contamination of the raw material.
• The importance of a heightened awareness and oversight of inspection processes required of raw material suppliers.
• It is impossible to find material defects in post-process (e.g. assy. line). Quality assurance of material is important (critical). Therefore, it is mandated to manage supplier quality.
• Ensure that the raw stock supplier understands the importance of their material as it relates to the criticality of the product usage.

Source: Japanese Ministry of Land, Infrastructure, Transport & Tourism
Effects of Poor Product Safety Accident
Case #4 - Methods

Commercial Airline Accident
Underlying Issues – Failsafe design, failure to follow a service bulletin, and assembly error.
Problem – Immediately upon completion of taxi to the apron the ground engineers observed fuel gushing from an area near the number 2 engine. The pilot shut off the fuel supply to the engines after he was alerted by the ground engineer about the leak. Fuel from the leak flowed beneath the aircraft towards the no. 1 engine.
Impact – The fuel ignited and the fire ultimately engulfed the airplane. Passengers and crew escaped but the aircraft was a complete loss.
Why – Inadequate design (machine) and lack of discipline to follow service instructions and assembly.

Lessons Learned –
• The designer should perform risk/safety analysis, DFMEA and failsafe design features. Additionally, design for manufacturing and maintenance should be incorporated.
• Compliance education should be reinforced to ensure service bulletins are followed.
• Employee should follow planning and engineering design drawings to ensure proper part assembly.
• Ensure there is adequate dialogue between the operator and manager to ensure compliance and issues are raised.

Source: Japanese Ministry of Land, Infrastructure, Transport, & Tourism
Effects of Poor Product Safety Accident Case #5 - Measurement

Commercial Airline

Underlying Issue – Improper maintenance procedures led to failure of the pylon structure.

Problem – Engine separation leading to loss of the aircraft May 25, 1979

Impact – All aboard plus two on the ground perished (273 total)

Why – The occurrence of repeated flange to clevis impacts induced during maintenance because improper tolerances.

Lessons Learned –

• Accurate, timely, and proactive flow of information within organizations, and across organizational interfaces is essential to maintain safety
• Failure of ground handling procedures can be fatal
• It is vital to have formal acceptance by manufacturers of critical maintenance procedures performed by operators
• When things go wrong during critical operations, it is vital to have a incident report and thorough assessment of potential damage.

Source: NTSB TSB-AAR-79-17, A/C Accident Report DC-10 Dec 21, 1979
Effects of Poor Product Safety Accident
Case #6 - Mother Nature

Commercial Airline Accident US Airways Flight 1549, 15 Jan 2009

Underlying Issue – A flock of migratory birds crossed the flight path of the airliner upon climb out from airport.

Problem – Aircraft unavoidably flew through a flock of large birds causing aircraft damage.

Impact – Loss of aircraft, potential loss of life, 155 passengers and crew safe but could have lost their life

Why – Loss of thrust due to engine Foreign Object Damage (FOD)

Lessons Learned –

• Improved - In-flight engine alerting, engine bird-ingestion certification testing, enhanced abnormal checklist design, improved aircraft ditching procedures, passenger safety controls, life-vest stowage and donning, passenger education.

• Value of experienced crew resource management during an accident.

• Highlighted the need for bird-strike procedure training.

Source: Report: NTSB/AAR-10/03 PB2010-910403
Good Example of Product Safety

A small motor has been designed, and a safety risk has been assessed:

- The integral battery could pose a risk.

The following processes are put in place to address the hazards throughout the lifetime of the product:

- Batteries are procured in safety sealed packaging so that contacts will not be inadvertently touched during assembly
- Safety training has been put in place for operators who will install the batteries
- Process documentation includes warning information at the process step of installing the battery.
- The design has ensured that, once installed, the battery is not a risk during subsequent assembly
- Labels on the motor include risk warnings in case the assembly is opened and the battery exposed
- Notification about the battery is included in delivery to the customer, which outlines the risks if the assembly is not handled correctly
Expectations of Section 8.1.3 Product Safety

An organization is required to plan, implement and control the processes needed to assure product safety the entire life cycle, as appropriate to the organization and product.

- Hazard identification, including reactive and proactive methods.
- Analysis, assessment, and control of safety risks associated with identified hazards (see 8.1.1 Operational Risk Management)
- Identification and management of changes that may impact product safety (see 8.5.6 Control of Changes)
- Assessment of the effectiveness of safety management processes (see 9.1.3 Analysis and Evaluation and 10.1 Improvement)
- Provision of training on product safety responsibilities to relevant personnel (see 7.2 Competence and 7.3 Awareness)
- Ensuring persons are aware of their contribution to product safety (see 8.4.3i second bullet)
- Communication of product safety information, including safety-critical information, safety events, and changes to safety procedures, as applicable (see 7.3 Awareness and 7.4 Communication)
Expectations of Section 8.1.3 Product Safety (cont.)

- Reporting of safety events to customer, authorities, and type certificate holder in accordance with customer and regulatory requirements (see 8.7 Control of Nonconforming Outputs)
- The flow down of relevant product safety principles are flowed down to applicable external providers (see 8.4.1.1f)

- During Witness Audits it has been observed that the following answer to the question “How do you affect/contribute to product safety?” is accepted.
  - *I make sure that I always wear/use the proper safety equipment (safety glasses, ear protection, ventilation mask, hard hat, safety shoes, safety shields, etc).*
  - This answer is related to personnel safety, not product safety.
  - If this answer is an isolated case, then this should be documented as an Opportunity For Improvement. If this answer is common, then this should be written as a nonconformance.
Acknowledgements

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Questions?