Product Safety as it applies to AS9100D/AS9110C/AS9120B

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(This presentation was created using the information available in the IAQG SCMH.)

Objective

The objective of this workshop is to raise the awareness and need for promoting a culture of product safety for organizations that might be a manufacturer, MRO facility, stockist distributor supplying the aviation, space and defense industries.

By increasing the awareness of potential safety impacts brought about by errors resulting from manufacturing, MRO or distribution processes a level of understanding should be the resultant for all involved to make product safety a priority within their organizations management system.

The challenge any organization may encounter is how to gain and hold the attention of the employee so it is fully understood that the potential safety impacts of their actions may affect the product being manufactured, maintained or distributed to the end customer.

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Scope

The Scope of this workshop is to;

Provide policies/guidance on what perspective an organization may want to consider when planning and implementing awareness initiatives and training relating to product safety.

Identify how and where product safety awareness may impact the product life cycle. This may be found in design to end of life for parts procured, manufactured/assembled, maintained/serviced and distributed.

Capture lessons learned, best practices, training guidance, and principles that are uniform and comply with international standards/practices.

Focus on Product Safety AQMS 2016

Why the addition of Product Safety in AS9100/AS9110/AS9120:2016?

- **Industry acknowledgement of the importance of increasing safety.**
- **Recognition of the AS9000 series certifications by authorities is part of the IAQG strategy.**

Implementation considerations

- **Address product safety considerations throughout the product lifecycle.**
- **A full Safety Management System (SMS) as defined by ICAO (International Civil Aviation Organization) is not required by 9100, but the introduction of this new clause contributes to the SMS approach.**

Definitions

Product Safety IAQG 9100 and 9110 definition;

- **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.**

Product Safety IAQG 9120 definition;

- **Maintaining the state of product so that it is able to perform to its designed or intended purpose without causing unacceptable risk of harm to persons or damage to property.**

IAQG 9100 requirements

The standard touches upon product safety several places.

The first is found in section 7 ”Awareness” relating to personnel.

- **Personnel must be aware of their contribution to product safety.**

The next reference can be found in section 8 “Operational Planning and Control”.

- **While this is a note, the organization is being asked to consider determining the requirements for the products and services for personal and product safety.**

Section 8.1.3 “Product Safety” is the main area of the standard that addresses this new requirement.

- **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.**

IAQG 9100 requirements continued

In the standard examples of these processes are included but not limited to:

- **Assessment of hazards and management of associated risks with a reference to 8.1.1 which is operational risks.**

- **Management of safety critical items. Critical items are those having significant effect on the provision and use of the products and services, including safety, performance, form, fit, function, producibility, service life.**

- **Analysis and reporting of occurred events affecting safety. And,**

- **Communication of these events and training of personnel.**

IAQG 9110 requirements

The standard touches upon product safety several places.

The first is found in section 7.3 ”Awareness” relating to Personnel.

- **Ensure awareness in their contribution to product safety.**
- **Ensure awareness of the safety policy and safety objectives related to the product.**

The next reference can be found in section 7 “Communication”.

- **While this is a note, the organization is being asked to communicate and promote product safety information.**

Secton 7.5 “Documented Information”.

- **The QMS shall include documented information determined by the organization as being necessary for the effectiveness of product safety management.**

IAQG 9110 requirements continued

The next reference can be found in section 8 “Operational Planning and Control”.

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- **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.**

IAQG 9110 requirements continued

In the standard examples of these processes are included but not limited to:

- **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)**
- **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**

IAQG 9110 requirements continued

- 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 standard requires under section 8.4. “Control of Externally Provided Processes, Products, and Services” the following.

- The flow down of relevant product safety principles are flowed down to applicable external providers (see 8.4.1.1f)
- Ensuring persons are aware of their contribution to product safety (see 8.4.3i second bullet)

Management review inputs now ask the organization to consider safety performance monitoring (product safety, see 9.3.2g)

IAQG 9120 requirements

The standard touches upon product safety several places.

The first is found in section 7.3 ”Awareness” relating to personnel.

- **Personnel must be aware of their contribution to product safety.**

The next reference can be found in section 8 “Operational Planning and Control”.

- **While this is a note, the organization is being asked to consider determining the requirements for the products and services for personal and product safety.**

Section 8.4.3 “Information for External Providers”

- **Under sub-section 8.4.3k, Ensure persons are aware of their contribution to product safety.**

Methodology

The 6M's are a mnemonic tool used primarily during the creation of a cause & effect diagram.

The 6 M's are:
- **Machines**
- **Methods**
- **Materials**
- **Mother Nature**
- **Manpower/People Power**
- **Measurements.**

Machines: Tools and equipment used to complete production task. Facility systems also are included in this category.

Methodology

Methods: Product and support processes.

Materials: Raw materials, components, and supplies used for production. General materials used for business operations (i.e. cleaning supplies, 5S supplies, etc.) fall into this category.

Mother Nature: Weather and other natural, uncontrollable events fall into this category. Environmental systems (i.e. AC, heating) would fall into machines.

Manpower/People Power: People issues fall into this area. Note that many people issues are really methods, machine, or material issues.

Measurements: Measurements include physical measurement, automatic sensor readings, and inspections. Note there may be overlap with machines regarding the measuring devices.

Methodology

What to potentially look for in each category.

- **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.**

- **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 workflow, choice of technical parameters, technical guidance and the preciseness and execution of workflow.**

- **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?**

Methodology

What to potentially look for in each category.

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

- **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?**

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

Methodology

Please note these categories are used to help with brainstorming portion of the development of a Cause and Effect Diagram. This methodology encourages people to look at the problems in multiple ways.

Keep in mind that it is very likely that a single cause may fall into numerous categories. Don't get 'caught in the weeds" when this happens. Take a quick vote on where to put the cause and move on.

Contributions to cause and effect on Product Safety

Machine

- **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

Contributions to cause and effect on Product Safety

Materials

- **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
  - Perservation

Contributions to cause and effect on Product Safety

Mother-nature

- **Environmental impacts**
  - Temperature
  - Humidity
  - Dust
  - Particulate contaminants
  - Pollution
- **Acts of nature**
  - Weather conditions
  - Lightning
- **Noise**
- **Vibration**

Contributions to cause and effect on Product Safety

Man

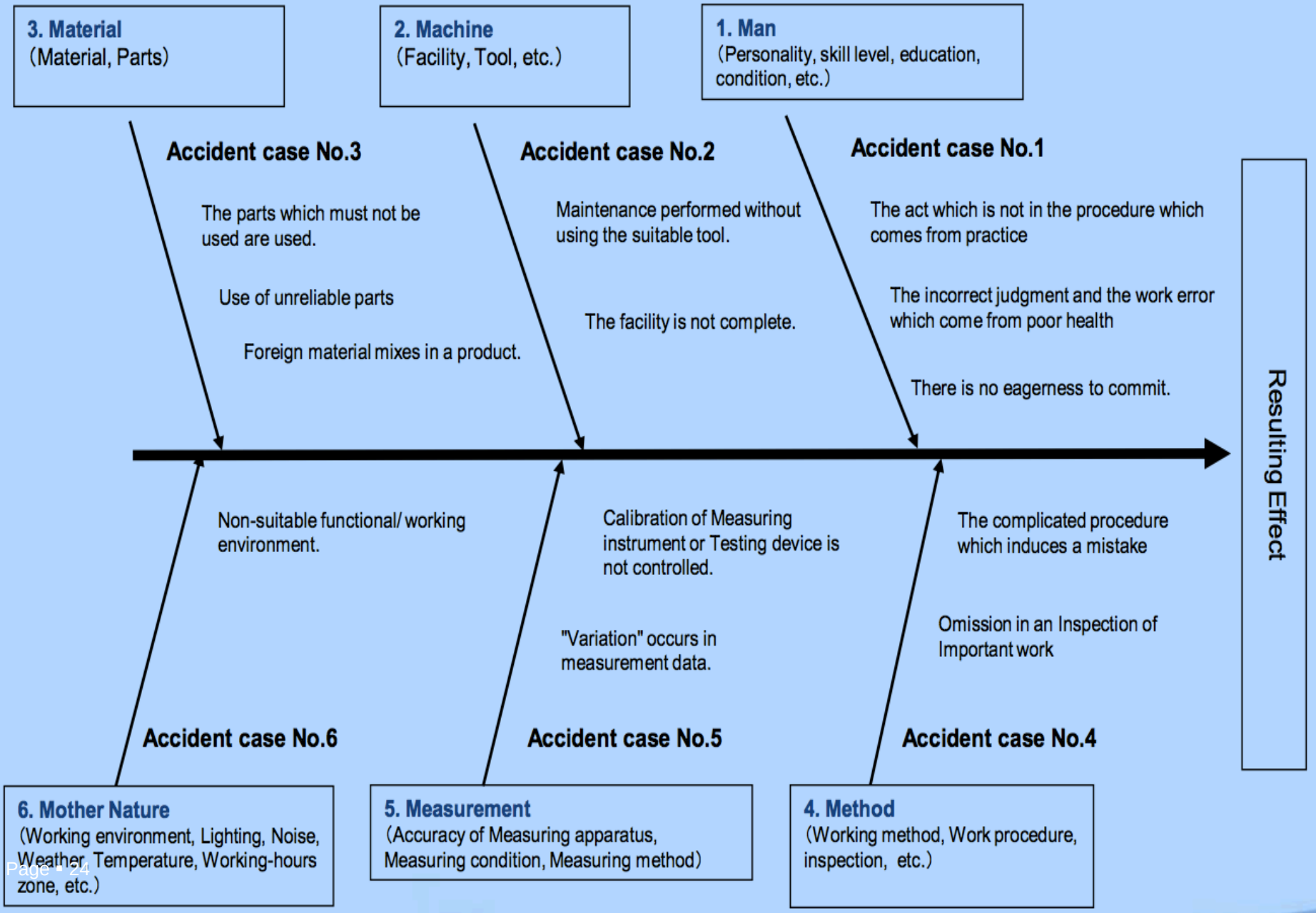
- **Education / Insufficient training**
- **Personal Certifications**
- **Out of station work / substitutes**
- **Employee motivation**
- **Human Factors**
  - Stress
- **Health of the employee**
  - Proper mindset
  - Attitude, Focus, Distraction
- **Management**
  - Attention / commitment
  - Instruction

Contributions to cause and effect on Product Safety

Measurement

- **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**

Cause and Effect Diagram



Accident Case No. 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 judgement.
- 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**.**

Accident Case No. 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

Accident Case No. 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**

Accident Case No. 4 - Methods

Commercial Airline

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

Accident Case No. 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

Accident Case No. 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, improved engine bird-ingestion certification testing, enhanced abnormal checklist design, improved aircraft ditching procedures, increased passenger safety controls, life-vest stowage and donning, and 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**

Training Plan and Considerations

Each organization should create training programs to increase the sensitivity of product safety throughout the life cycle of its product. The areas of the life cycle are but not limited to:

- **Design**
- **Development & Testing**
- **Manufacturing**
- **Assembly**
- **Inspection and measurement**
- **Shipping, storage, and preservation**
- **Transportation, docking, undocking**
- **Installation into next higher assembly**
- **End-use and Maintenance/Service**

Train each employee on the application and use of the product, process, or service they are responsible for.

Training Guidance

- **The IAQG has created best practices or examples on several topics. The Supply Chain Management Handbook offers compliance education recommendations and provides an easily adaptable training template that can be adapted to include product safety topics.**
  - 7.8 Compliance Education
    - 7.8.1 Compliance Education Introduction
    - 7.8.2 Compliance Education Guidance
    - 7.8.3 Compliance Education Training Template
  - Effective delivery methods include classroom, e-learning, self-education, and videos.

Training Goals Summary

1. Understand the importance of product safety
2. Understand the functions of your own products and services, and the way they are used by the end users
3. Understand the impact that our own work has on product safety
4. Understand that often, some small things may have critical consequences
5. Create appropriate training material to meet your specific company culture and products.

Thank You!

Questions?

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