# AS9120:2016 (& ISO 9001:2015) Risk Management Requirements for Distributors

ASA RESTON, VA 2017 9-11 JULY parts • distribution • disassembly • recycling

This presentation and tools discussed are available for free at www.simpleque.com/ASA2017

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## Definitions - ISO 9000

### Risk - The effect of uncertainty

Notes:

- An effect is a deviation from the expected - positive or negative
- Uncertainty is the state, even partial, of deficiency of information related to, understanding or knowledge of, an event, its consequences, or likelihood.
- Risk is often characterized by reference to potential events, and consequences or a combination of these
- Risk is often expressed in terms of a combination of the consequences of an event and the associated likelihood of occurrence.

AS9120 A.4

- Within aviation, space, and defense, risk is expressed as a combination of severity and likelihood of having a potential negative impact to processes, products, services, customer, or end users.



## Definition

*The word "risk" is sometimes used when there is the possibility of only negative consequences.*

Opportunity - The effect of uncertainty, with exploitable circumstances, requiring commitment of resources and involving exposure to risk, to obtain a positive or favorable outcome, or to prevent negative effects.

# Risk in AS9120 & ISO 9001

Risks and opportunities have to be determined and addressed

- **No** requirement for formal risk management
- **No** requirement for documented risk management process
- **However, auditors aren't accepting the absence of documentation and want to see a formal criteria for assessing risks**



# Risk in AS9120 & ISO 9001

- Clauses 0.3.3 (Risk-based thinking)
- Clause 4.4 (QMS and its processes) the company is required to address the risks and opportunities for their QMS processes.
- Clause 5.1.1 (Leadership and commitment) top management must promote the use of the process approach and risk-based thinking.
- Clause 5.1.2 (Customer focus) top management must ensure that risks and opportunities that can affect product quality and services, and the ability to enhance customer satisfaction, are determined and addressed.
- Clause 6.1 (Actions to address risks and opportunities) planning the QMS shall determine the risks and opportunities that need to be addressed.
- Clause 9.1.3 (Analysis and evaluation) the results of analysis shall be used to evaluate the effectiveness of actions taken to address risks and opportunities.
- Clause 9.3.2 (Management review inputs) management review shall take into consideration the effectiveness of actions taken to address risks and opportunities.
- Clause 10.2 (Nonconformity and corrective action) when NC occurs the company must update risks and opportunities determined during planning.
- Annex A.4 (Risk-based thinking)

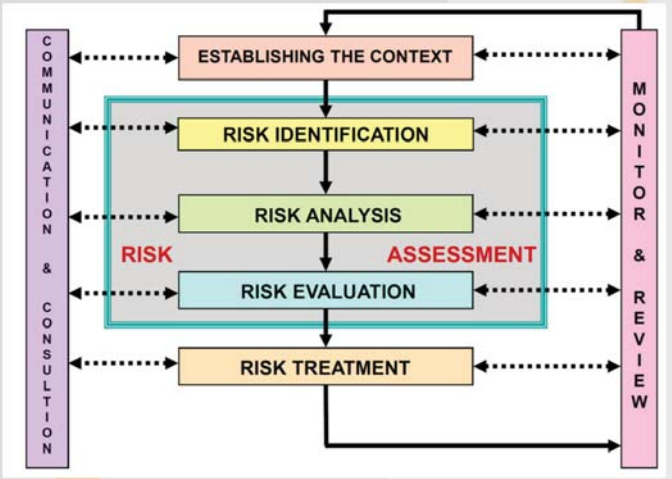


# Risk Management Process

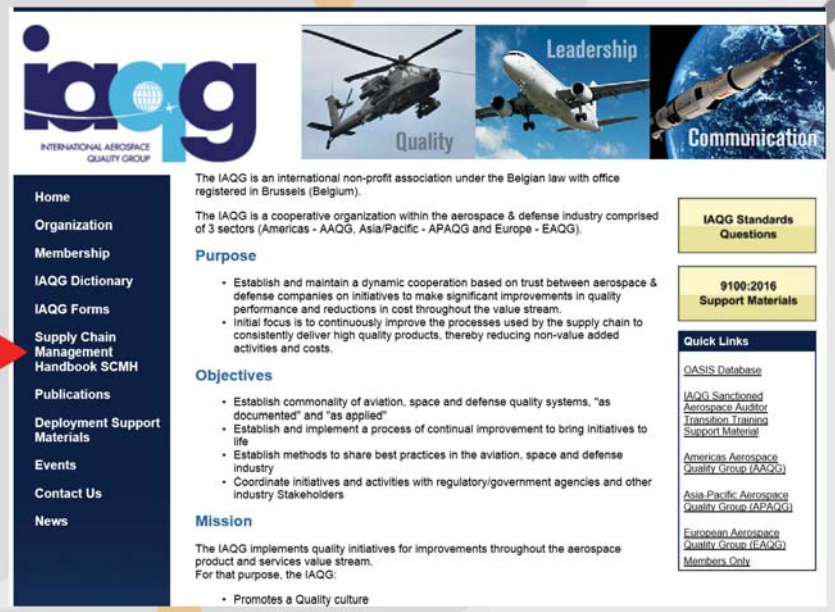

combination of severity and likelihood of a negative impact



ISO 31000 - Principles and Guidelines on Implementation
ISO 31010 - Risk Management - Risk Assessment Techniques
ISO Guide 73 - Risk Management - Vocabulary



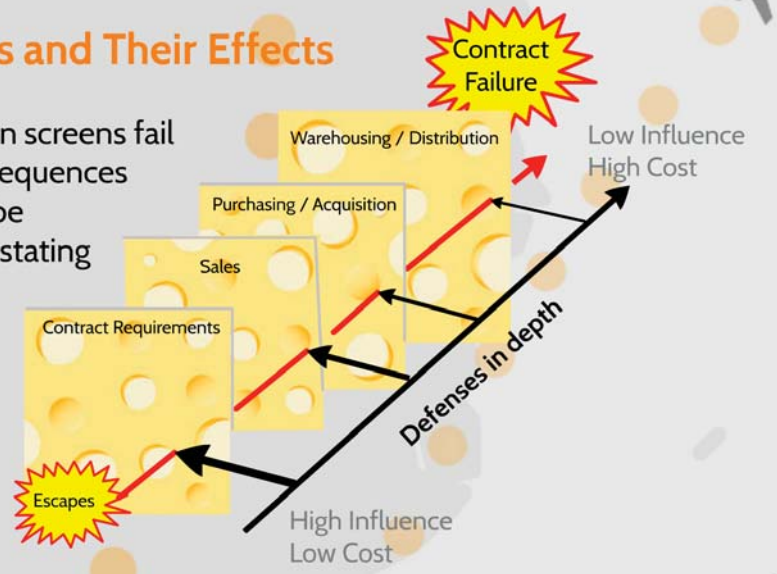
# www.sae.org/iaqg





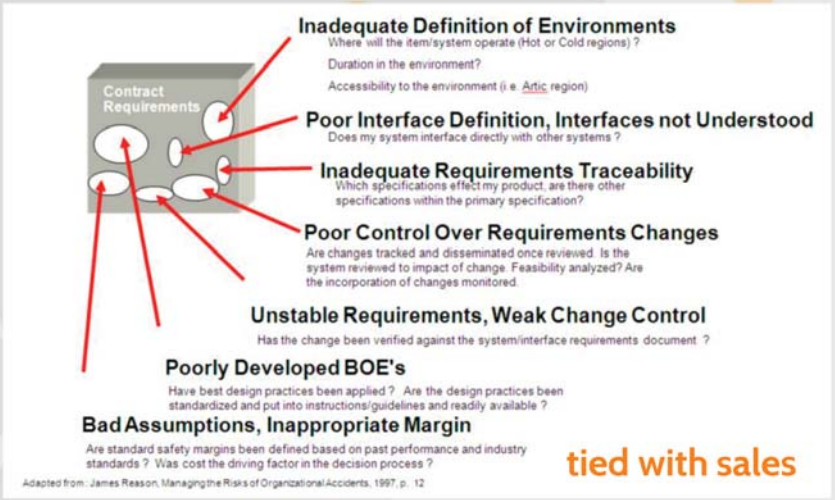

# Risks and Their Effects

When screens fail consequences can be devastating






# Contract Requirements Risks



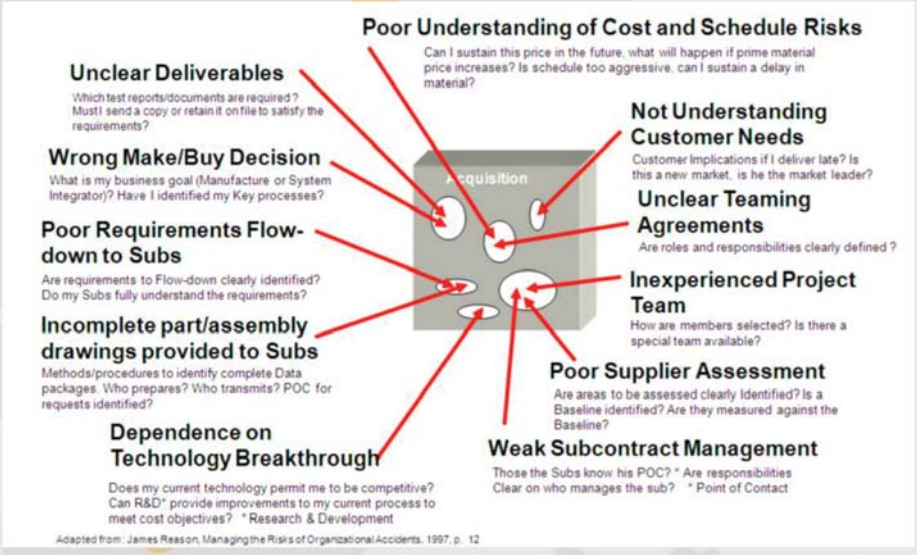

Source: IAQG website, Supply Chain Management Handbook



# Distributor's Sales Risk Examples

- Financial risks (customer credit, ability to pay, payment terms, late payments, collections)
- Over promise, under perform
- Awareness, communication, and flow down of customer and special requirements
- Approving vendors after sales commitment
- Proper sales team training to prevent issues
- Meeting sales goals or targets
- Accuracy of quotes - making margins, errors
- Review RMA requests - Why the return?
- Clearly understood and specified requirements at time of quote

# Acquisition / Purchasing Risk Examples




Source: IAQG website, Supply Chain Management Handbook



# Distributor's Purchasing Risks Examples

- Supplier approval process (certifications, audit, lead time, supplier performance, scope of approval, warranty, RMA process, design authority)
- Financial (D&B, terms, stability)
- Supplier is purchased, merged, bankrupt
- Contracts (broken, long term agreements, partnerships)
- Location (time change, shipping costs, insurance)
- Customer service (responsiveness)
- Cyber security (ITAR, documents, exports)
- Traceability records (airworthiness certs)
- Outsourcing by supplier
- Drop shipments direct to customer (no inspection, customer bypasses in the future, still responsible for problems). Positively: access to more inventory and not carrying inventory exposures
- Hazmat
- Corrective action process
- Sole source, purchasing strategy, customer dictated



# Operations Risk Examples

## tied with warehousing and distribution


Source: IAQG website, Supply Chain Management Handbook



# Warehousing / Distribution Risk Examples

- Hazardous materials (awareness, identification, transport, waste, safety, packaging)
- International shipping (paperwork, customs)
- Custom shipping requirements, different from the norm
- Drop shipments, direct shipments from suppliers
- Similar parts by appearance or by part number getting mixed up
- Identification and traceability to airworthiness documents
- Counterfeit parts, suspect counterfeit partsPackaging compliant with ATA 300
- Employee errors - human factors
- Right paperwork with shipments, complete paperwork with shipments
- Foreign object damage or debris
- Safety risks (employees, product)
- Employee knowledge and competency - adequate training

## General Process Risks


Source: IAQG website, Supply Chain Management Handbook



## How do we address risks and opportunities today in our business?

- Where documented?
- What records?
- Evidence of completed actions items?



## Some Risk Identification Techniques:

- Brainstorming
- SWOT analysis
- Strategic planning, business planning
- Risk questionnaires and surveys
- Audits (internal, customer, external)
- Lessons learned
- What else?



## Some Risk Identification Techniques:

### SWOT Analysis

| | Helpful | Harmful |
|---|---|---|
| Internal Focus | ☺ ***Strengths*** Characteristics of the business or project that give it an advantage over others. | ☹ ***Weaknesses*** Characteristics that place the business or project at a disadvantage relative to others |
| External Focus | ✚ ***Opportunities*** Elements that the project could exploit to its advantage | ▬ ***Threats*** Elements in the environment that could cause trouble for the business or project |

## Some Risk Identification Techniques: SWOT Analysis

- Solicit input from customers, suppliers, employees, management (360 view)
- Group key themes and come up with the top 3
  - Top 3 strengths
  - Top 3 weaknesses
  - Top 3 opportunities
  - Top 3 threats
- These top issues should provide input to the strategic direction and priorities for the business
- Records should exist and be maintained



## SWOT Analysis

- Does this tool help us determine the risks and opportunities that need to be addressed? Clause 6.1.1
- Does this tool take into account the company's context and interested parties? Clause 6.1.1
- Are these risks expressed as a combination of severity (weaknesses) and likelihood (top 3) of having a potential negative impact (weaknesses and threats)? Annex A.4



## Some Risk Identification Techniques:

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- What else?



## Some Risk Management Tools

If necessary

- Risk ranking, risk matrix
- Potential Failure Modes & Effects Analysis (FMEA)
- Preventive actions
- Preliminary hazard assessment
- Fraudulent/Counterfeit Electronic Parts; Tool for Risk Assessment of Distributors - SAE Recommended Practice 6178
- AS6081 - Counterfeit Electronic Parts; Avoidance Protocol, Distributors
- AS6301 Compliance Standard or Guide for AS6081 (includes Audit Checklist)
- AS9107 Direct Delivery Authorization - Guidance
- AS9114 Direct Shipment - Guidance
- AS9134 Supply Chain Risk Management Guidelines
- AS9117 Delegated Product Release Verification (DPRV)
- AS9146 FOD
- AS9147 Management of Unsalvageable Items
- ISO 31000 and 31010 Risk Assessment Techniques

# Some Risk Management Tools: Risk Ranking - Simple

| Issue | Risk of Negative Consequence (L,M,H) | Likelihood To Occur (L,M,H) | Comment |
|---|---|---|---|
| Hazmat material received and not identified. Employees don't recognize hazardous material and don't treat, identify, handle and communicate appropriately. | H | H | Action required |
| Parts shipped without proper paperwork | H | L | No action required |



# Some Risk Management Tools: Risk Matrix

| Issue | Description & Action Taken | Closure Due Date | Date Action Completed | Verification & Close Date | Likelihood of Occurrence (L,M,H) | Severity of Potential Problem (L,M,H) | Chance of Non-Detection (L,M,H) | Risk Level (3x3 - Max 27) |
|---|---|---|---|---|---|---|---|---|
| Hazmat material received and not identified. Employees don't recognize hazardous material and don't treat, identify, handle and communicate appropriately. | 1. Educate employees on types of hazardous materials; 2. Create a bullet list of types of hazardout materials handled; 3. Create a process to escalate and question hazmat when uncertain; 4. Create a field in the warehouse management system (WMS) to identify hazardous materials when received; 5. Evaluate the WMS descriptions to identify known hazmat items to ensure they are coded properly in WMS. | Q3 2016 | 7/5/2016 | 8/1/2016 | M | H | H | 18 |
| Unique customer requirements are called out on PO's but are not evaluated, understood and complied with for all departments that are affected. | Action required..... | | | | H | M | H | 18 |
| Parts shipped without proper paperwork | No action required | | | | L | H | L | 3 |

H = 3
M = 2
L = 1



# Some Risk Management Tools: AS9134 Detailed Risk Register

**RISK REGISTER**

| A | | | | B | | C | | | D | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|
| Supplier _____ Site _____ | | | | Recovery Indicator _____ | | Product/Service-Supplier Criticality RAG | | | Supply Manager _____ | | | |
| E | F | G | | H | I | J | K | L | M | N | O | P |
| Risk Item No. | Risk Title | Risk Description | | Risk Impact | Risk Prob'ty | Risk Criticality | Risk RAG | Date Raised | Risk Owner | Action Plan | Plan Status | Status RAG |
| | | Cause | Impact | | | | | | | | | |
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EXAMPLE



# Some Risk Management Tools: Potential Failure Modes and Effects Analysis (FMEA)

see www.aiag.org

| Process Function Requirements | Potential Failure Mode | Potential Effect(s) of Failure | SEV | CLASS | Potential Cause(s)/ Mechanism(s) of Failure(s) | Current Process Controls Prevention | OCCUR | Current Process Controls Detection | DETECT | RPN # |
|---|---|---|---|---|---|---|---|---|---|---|
| | | | | | | | | | | |
| | How can it fail to meet or deliver the intended function? Typical failure modes: Too much, large Too little, small missing, omitted no function excessive variation wrong, incorrect damaged, broken | What are the effects to the customers if the failure occurs? All levels of customers should be considered. Next operation, Downstream ops, Outsources, Subcontractors, Assembly plants, Vehicle owners, Vehicle drivers, Gov't regulations. | | | List all the underlying potential root causes of the failure to the left. May often be more than one. Give each potential cause their own cell or box | Current Process Controls Prevention? Any Poke-Yokes, mistake proofing, fail-safes? These process controls justify the OCCURRENCE score and have no affect on Detection scores. | | What is being done to detect the potential failure? What checks, inspections, tests, etc? List all process controls that help detect the potential failure, including subsequent, downstream controls. All the combined controls justify the detection score. | | |

## FMEA Example

| Process Function Requirements | Potential Failure Mode | Potential Effect(s) of Failure | SEV | CLASS | Potential Cause(s)/ Mechanism(s) of Failure(s) | Current Process Controls Prevention | OCCUR | Current Process Controls Detection | DETECT | RPN # |
|---|---|---|---|---|---|---|---|---|---|---|
| 30 Ship | Missing paperwork | Customer can't use part due to loss of traceability and evidence of airworthiness | 9 | | 1. Supplier lost paperwork (7)<br>2. Paperwork doesn't exist (1)<br>3. Paperwork not shipped with part (7) | Receiving process checks paperwork | 7 | Shipping process checks paperwork. Warehouse Management System retains electronic files of required paperwork and links orders to parts to paperwork. | 3 | 189 |
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## FMEA Severity Scoring
## x
## FMEA Occurrence Scoring
## x
## FMEA Detection Scoring
## =
## Risk Priority Number (RPN)

**High RPN's require action**



## Some Risk Management Tools: PHA

| | PRELIMINARY HAZARD ASSESSMENT<br>This document is subject to the attorney-client and attorney work product privileges. | HARARD ANALYSIS #:<br>DATE: _ |
|---|---|---|

**PROBLEM DESCRIPTION OR QUESTION:**

| Instructions: Record final conclusion of the Risk/ Hazard Assessment process by marking the initials of each individual in the square for which he or she independently voted. | SEVERITY OF CONSEQUENCE | PROBABILITY OF MISHAP | | | | | |
|---|---|---|---|---|---|---|---|
| | | F Impossible (Physically impossible to occur) | E Improbable (Probability of occurrence cannot be distinguished from zero) | D Remote (Not likely to occur in system life cycle, but possible) | C Occasional (Likely to occur sometime in product life cycle) | B Probable (Likely to occur several times in product life cycle) | A Frequent (Likely to occur repeatedly in product life cycle) |
| | I CATASTROPHIC (Death or permanent disabling injury) | | | | | | |
| | II CRITICAL (Severe injury or illness) | | | | | | |
| | III MARGINAL (Minor injury or illness) | | | | | | |
| | IV NEGLIGIBLE (No injury or illness) | | | | | | |
| RISK MATRIX ACTIONS | | CATEGORY 1 | Category 1: Operating risks are contained within acceptable levels. No corrective action is required. | | CATEGORY 2 | Category 2: Operating risks are not within acceptable levels. Corrective action plan must be recommended. | |



## Risk Management Requirements for Distributors

- Did the workshop help you identify areas where risks are managed, or help you identify where risks need to be managed?
- Did this workshop help give you confidence where you already comply and give you tips on what you might do if you are weak in an area.
- What does ISO 9001:2015 & AS910:2016 require?
- Do we have to do anything differently?
- Are there any tools covered that we will use?

# Questions?

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