

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



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

by Jim Lee

simpleQue

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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.

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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.

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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

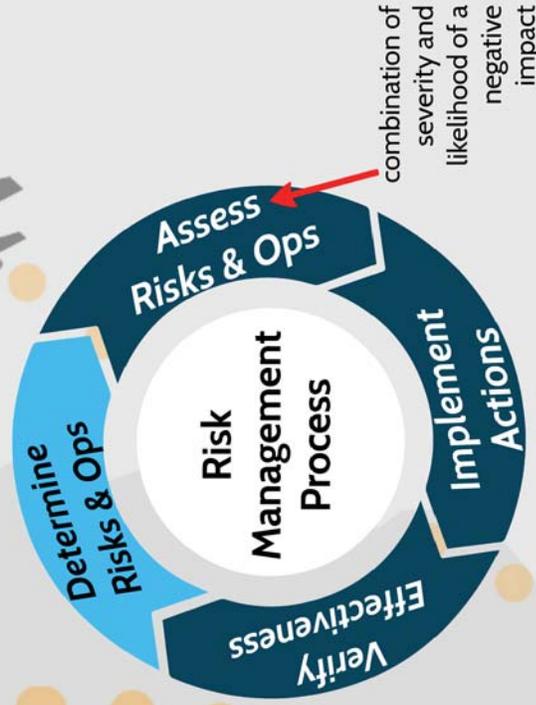
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Risk in AS9120 & ISO 9001

- Clause 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)

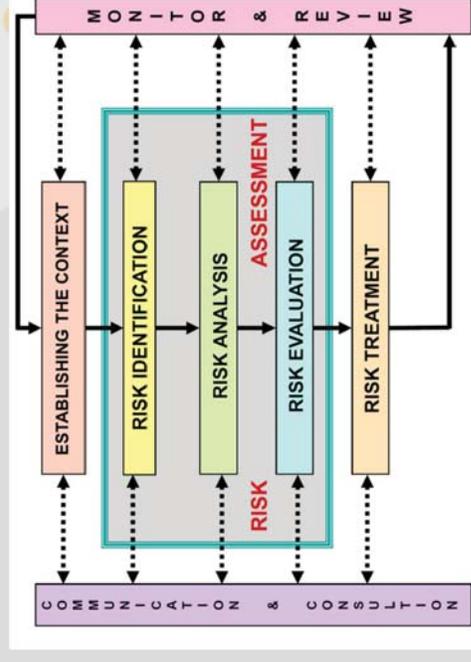
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Risk Management Process



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



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The screenshot shows the IAQG website with a navigation menu on the left. A red arrow points to the 'Supply Chain Management Handbook SCMH' link. The main content area includes sections for Leadership, Quality, and Communication, along with a detailed description of the IAQG's purpose, objectives, and mission.

IAQG
INTERNATIONAL AEROSPACE QUALITY GROUP

Home
Organization
Membership
IAQG Dictionary
IAQG Forms
Supply Chain Management Handbook SCMH
Publications
Deployment Support Materials
Events
Contact Us
News

Leadership
Quality
Communication

The IAQG is an international non-profit association under the Belgian law with office registered in Brussels (Belgium).
The IAQG is a cooperative organization within the aerospace & defense industry comprised of 3 sectors (Americas - AAQG, Asia/Pacific - APAQG and Europe - EAQG).

Purpose

- Establish and maintain a dynamic cooperation based on trust between aerospace & defense companies on initiatives to make significant improvements in quality performance and reductions in cost throughout the value stream.
- Initial focus is to continuously improve the processes used by the supply chain to consistently deliver high quality products, thereby reducing non-value added activities and costs.

Objectives

- Establish commonality of aviation, space and defense quality systems, "as documented" and "as applied"
- Establish and implement a process of continual improvement to bring initiatives to industry
- Establish methods to share best practices in the aviation, space and defense industry
- Coordinate initiatives and activities with regulatory/government agencies and other industry Stakeholders

Mission

The IAQG implements quality initiatives for improvements throughout the aerospace product and services value stream.
For that purpose, the IAQG:

- Promotes a Quality culture

IAQG Standards Questions

9100:2016 Support Materials

Quick Links

- QASIS Database
- IAQG Synchronized Aerospace Auditor
- Transition Training Support Material
- Americas Association Quality Group (AAQG)
- Asia-Pacific Association Quality Group (APAQG)
- European Association Quality Group (EAQG)
- Members Only

Contract Requirements Risks



The diagram shows a 3D box labeled 'Contract Requirements' with several red arrows pointing to it from text boxes describing various risks. The risks include: Inadequate Definition of Environments, Poor Interface Definition, Inadequate Requirements Traceability, Poor Control Over Requirements Changes, Unstable Requirements, Weak Change Control, and Poorly Developed BOE's. A final text box discusses 'Bad Assumptions, Inappropriate Margin' tied with sales.

Inadequate Definition of Environments
Where will the item/system operate (Hot or Cold regions)?
Accessibility to the environment (i.e. AEGIS region)

Poor Interface Definition, Interfaces not Understood
Does my system interface directly with other systems?

Inadequate Requirements Traceability
Which specifications affect my product, are there other specifications within the primary specification?

Poor Control Over Requirements Changes
Are changes tracked and disseminated once reviewed, is the system reviewed to impact of change, Feasibility analyzed? Are the incorporation of changes monitored?

Unstable Requirements, Weak Change Control
Has the change been verified against the system/interface requirements document?

Poorly Developed BOE's
Have best design practices been applied? Are the design practices been standardized and put into instructions/guidelines and readily available?

Bad Assumptions, Inappropriate Margin
Are standard safety margins been defined based on past performance and industry standards? Was cost the driving factor in the decision process?

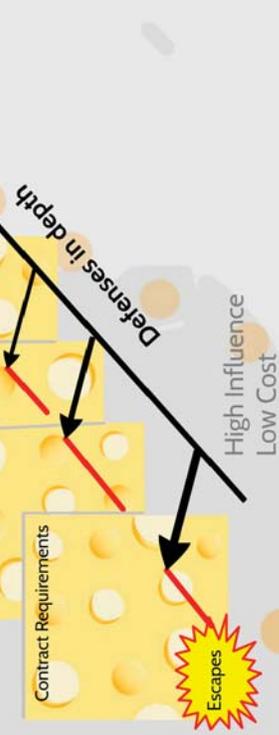
Adapted from: James Reason, Managing the Risks of Organizational Accidents, 1987, p. 12

Contract Requirements

tied with sales

Risks and Their Effects

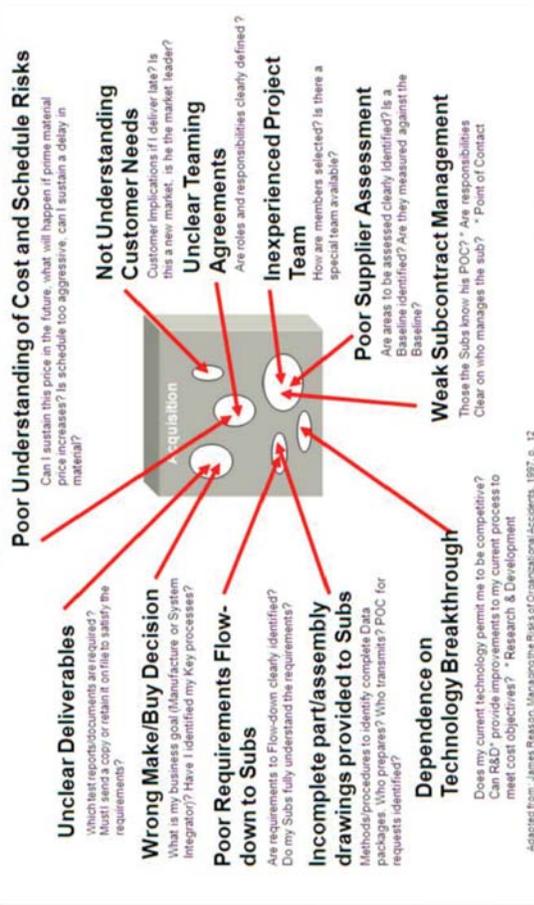
When screens fail consequences can be devastating



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

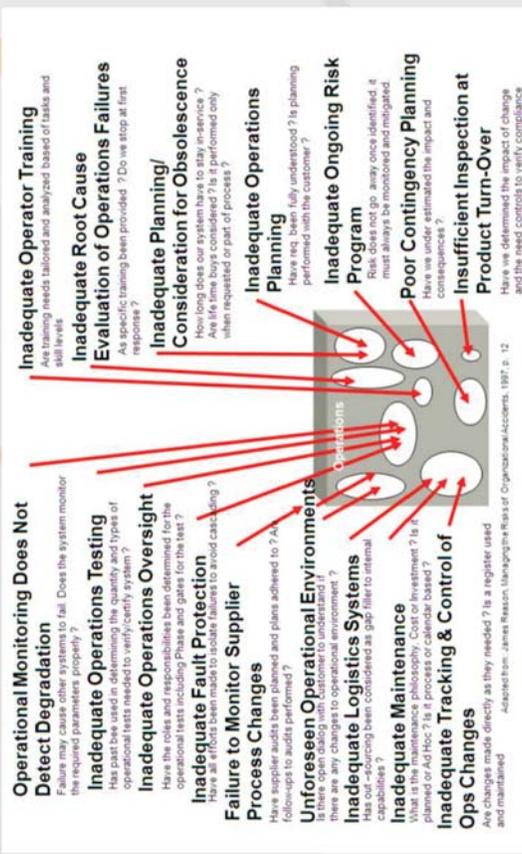
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Distributor's Purchasing Risks Examples

- 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

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Operations Risk Examples



Source: IAQG website, Supply Chain Management Handbook

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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

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General Process Risks

Poor Critical Process Control, Processes not Documented

Have I clearly documented the process after it has been proved? What happens if my key personnel are no longer available? Can process be executed by other personnel?

Inadequate Definition of Critical Processes

Have I clearly identified my Key process and those processes which if not performing properly give me immediate conforming products or services. Primarily those process which can not be easily seen or detected (i.e. Heat treatment, welding, soldering, etc.)

Inadequate Inspection & Auditing Processes

Have Key Inspection points been identified to prevent defects from being covered up by subsequent manufacturing processes? Have process KPI been identified and audits scheduled as a function of the KPI? Have all efforts been made to eliminate or reduce over-inspections?

Poor Corrective & Preventative Action System

Has the root cause of the problem been adequately identified? Have we only identified the results and not causes? (i.e. illegible markings, do to stamp being worn out, not that the operator incorrectly marked the part)

Inadequate use of Best Practices & Lessons Learned

What are the best practices that we have learned from our past problems. Do we have a database or register of what worked and what didn't?

Weak Risk Management Process

Have we analyzed all the possible consequences? Do we have a method of recording our decision making process to avoid repeating mistakes or going down the same old road to failure.

Inadequate System Safety Evaluations & Controls

Do we fully understand the consequences of what occurs through the system? Can we detect (e.g. Have I put in warning indicators before complete system failure or do I wait till it stops working (i.e. engine overheat warning light turns on at 20° C or normal failure occurs at 50° C over normal (normal temp 50° C)

Design Practices not Standardized and Controlled

Are design practices standardized to avoid that each Design Engineer personalises the Data package making it difficult to transfer the package without provide a specific dictionary to interpret the data package

Adapted from: James Reason, *Managing the Risks of Organizational Accidents*, 1997, p. 12

Source: IAQG website, Supply Chain Management Handbook

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

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

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Some Risk Identification Techniques:

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

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Some Risk Identification Techniques:

SWOT Analysis



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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

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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

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Some Risk Identification Techniques:

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

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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

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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

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Some Risk Management Tools: AS9134 Detailed Risk Register

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

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Some Risk Management Tools: Risk Matrix

Issue	Description & Action Taken	Closure Due Date	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 (Mar 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 process to escalate and question hazard when uncertain. 4. Create a field in the warehouse management system (WMS) to identify hazardous materials when received. Items to ensure they are coded properly in WMS.	03/2016	8/17/2016	M	H	H	18
Process and/or requirements are called out on RPNs but not followed and/or not completed 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

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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	Class of Failure	Potential Cause(s)/ Mechanism(s) of Failure(s)	Current Process Controls Prevention	Current Process Controls Detection	RPN
							DETECT
	How can it fail to meet or deliver the intended function? 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.	SS	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 Pokes/Yokes, mistake proofing, fail safe? These process controls justify the OCCURRENCE score and have no effect 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.	

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FMEA Example

Process Function Require	Potential Failure Mode	Potential Effect(s) of Failure	AS	SC	Potential Cause(s)/ Mechanism(s) of Failure(s)	Current Process Controls Prevention	Occur	Current Process Controls Detection	RPN
30 Ship	Missing paperwork	Customer can't use part due to loss of traceability and evidence of airworthiness	9	3	1. Supplier lost paperwork (7) 2. Paperwork doesn't exist (1) 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	189
	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, Subcontractors, Assembly plants, Vehicle owners, Vehicle drivers, Gov't regulations.			List all the underlying potential root causes of the failure to the left of the cell. Give each potential cause their own cell or box	Current Process Controls Prevention? Any Poke-Yokes, mistake proofing, fail safe? 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 Severity Scoring

X

FMEA Occurrence Scoring

X

FMEA Detection Scoring

=

Risk Priority Number (RPN)

High RPN's require action

Some Risk Management Tools: PHA

PROBLEM DESCRIPTION OR QUESTION:	PRELIMINARY HAZARD ASSESSMENT This document is subject to the attorney-client and attorney work product privileges.						Hazard Analysis #: DATE: _	
	F	E	D	C	B	A		
Introduction: An individual conclusion of the Risk/Hazard Assessment process by marking the initials of each individual in the square for which he or she independently voted.	Impossible (Physically impossible to occur)	Improbable (Probability of occurrence cannot be distinguished from zero)	Remote (Not likely to occur in system life cycle, but possible)	Occasional (likely to occur sometime in product life cycle)	Probable (likely to occur several times in product life cycle)	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)							
RISK MATRIX ACTIONS	CATEGORY 1						CATEGORY 2	Category 1: Operating risks are contained within acceptable levels. No corrective action is required. 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?

simple**QUE**



740-305-0868



jlee@simpleque.com or info@simpleque.com



simpleque.com

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