ISO 9001:2015 and AS91XX:2016 Risk Management Requirements for Distributors and Their Suppliers

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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.

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 ISO 9001 and AS9120

Risks and opportunities have to be determined and addressed

- **No** requirement for formal risk management
- **No** requirement for documented risk management process

Risk in ISO 9001 and AS9120

- Clauses 0.3.3 & A.4 (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 managment 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.

Risk Management Process

one size does not fit all

Workshop Exercise

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

- In **sales**, quoting, contracts, orders, customer requirements, regulatory requirements?
- In **purchasing**, sourcing, outsourcing, supply chain, sub-suppliers?
- In **direct shipments** to customers, verification by suppliers, regulatory requirements?
- In **warehousing**, shipping and receiving?
- As **owners and leadership** of the business to achieve the strategic direction?

Workshop Exercise

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

- As **owners and leadership** of the business to achieve the strategic direction?

Let's brainstorm together...

Workshop Exercise

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

1. In **sales**, quoting, contracts, orders, customer requirements, regulatory requirements?
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3. In **direct shipments** to customers, verification by suppliers, regulatory requirements?
4. In **warehousing**, product verification, shipping and receiving?

Risk in ISO 9001 and AS9120

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Brainstorm Results from Workshop Exercise

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

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

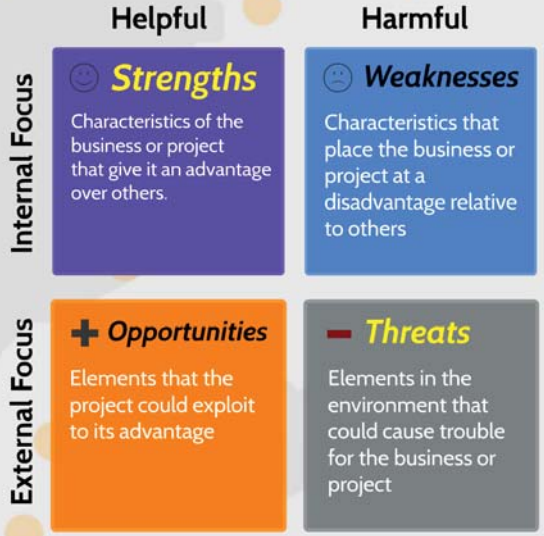
Did the workshop will help you identify many areas where risks are managed or help you identify where risks need to be managed?

Some Risk Identification Techniques:

- Brainstorming
- SWOT analysis
- Strategic planning, business planning
- Risk questionnaires and surveys
- Audits (internal, customer, external)
- Lessons learned
- What else?
- What came out of our Workshop Exercise?

Some Risk Identification Techniques:

SWOT Analysis



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

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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

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

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) 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.	3	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, 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.		

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

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 #
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FMEA Severity Scoring
x
FMEA Occurrence Scoring
x
FMEA Detection Scoring
=
Risk Priority Number (RPN)

SEV	CLASS	Potential Cause(s)/ Mechanism(s) of Failure(s)	Current Process Controls Prevention	OCCUR	Current Process Controls Detection	DETECT	RPN #	Recommended Action(s) and Action Results	Responsibility & Target Completion Date	Action Results				
										Actions Taken	SEV	OCC	DET	RPN
10		1. Supplier lost paperwork 2. Paperwork doesn't exist 3. Paperwork not shipped with part	Receiving process checks paperwork	7	Shipping process checks paperwork. Warehouse Management System retains electronic files	3	210							

Risk Management Requirements for Distributors and Their Suppliers

- Did the workshop will help you identify many areas where risks are managed or help you identify where risks need to be managed?
- Did this workshop will 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 & AS91XX:2016 require?
- Do we have to do anything differently?
- Are there any tools covered that we will use?

Questions?

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POTENTIAL FAILURE MODE AND EFFECTS ANALYSIS (PROCESS PFMEA)

P/N or Item: _____ Eng. Revision: _____ FMEA Number: _____

Part Name: _____ Process Responsibility _____ Prepared by: _____

Model Year(s)/Vehicle(s) _____ Key Date _____ Date (Orig.) _____

Core Team: _____ Date (Rev.) _____

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 #	Recommended Action(s) and Action Results	Responsibility & Target Completion Date	Action Results				
													Actions Taken	SEV	OCC	DET	RPN

SUGGESTED PROCESS FMEA SEVERITY RANKINGS

Severity Effect	Criteria: Severity of Effect Customer Effect	Ranking	Severity Effect	Criteria: Severity of Effect Mfg/Assy Effect
Failure to Meet Safety and/or Regulatory Requirements	Potential failure mode affects safe vehicle operation and/or involves noncompliance with government regulation without warning	10	Failure to Meet Safety and/or Regulatory Requirements	May endanger operator (machine or assembly) without warning
	Potential failure mode affects safe vehicle operation and/or involves noncompliance with government regulation with warning	9		May endanger operator (machine or assembly) with warning
Loss or Degradation of Primary Function	Loss of primary function (vehicle inoperable, does not affect safe vehicle operation)	8	Major Disruption	100% of product may have to be scrapped. Line shutdown or stop ship
	Degradation of primary function (aircraft operable, but at reduced level of performance)	7	Significant Disruption	A portion of the production may have to be scrapped. Deviation from primary process including decreased line speed or added manpower.
Loss or Degradation of Secondary Function	Loss of secondary function (vehicle operable, but comfort/convenience functions inoperable).	6	Moderate Disruption	100% of production run may have to be reworked off line and accepted.
	Degradation of secondary function (vehicle operable, but comfort/convenience functions at reduced level of performance).	5		A portion of the production run may have to be reworked off line and accepted.
Annoyance	Appearance or Audible Noise, vehicle operable, item does not conform and noticed by most customers (>75%).	4	Moderate Disruption	100% of production run may have to be reworked in station before it is processed.
	Appearance or Audible Noise, vehicle operable, item does not conform and noticed by many customers (50%)	3		A portion of the production run may have to be reworked in-station before it is processed.
	Appearance or Audible Noise, vehicle operable, item does not conform and noticed by discriminating customers (<25%).	2	Minor Disruption	Slight inconvenience to process, operation, or operator.
No effect	No discernible effect.	1	No Effect	No discernible effect.

SUGGESTED PROCESS FMEA OCCURRENCE RANKINGS

Probability of Failure	Likely Failure Rates	Likely Failure Rates	Ppk	Ranking
Very High: Persistent Failures	≥ 100 per thousand pieces ≥1 in 10 pieces ≥100,000 ppm or 10%	More than one occurrence per day	<0.55	10
	50 per thousand pieces 1 in 20 pieces 50,000 ppm or 5%	One occurrence every 3 to 4 days	≥0.55	9
High: Frequent Failures	20 per thousand pieces 1 in 50 pieces 20,000 ppm or 2%	One occurrence per week	≥0.78	8
	10 per thousand pieces 1 in 100 pieces 10,000 ppm or 1%	One occurrence every month	≥0.86	7
Moderate: Occasional Failures	2 per thousand pieces 1 in 500 pieces 2,000 ppm or 0.2%	One occurrence every three months	≥0.94	6
	.5 per thousand 1 in 2,000 pieces 500 ppm or 0.05%	One occurrence every six months	≥1.00	5
	.1 per thousand 1 in 10,000 pieces 100 ppm or 0.01%	One occurrence per year	≥1.10	4
Low: Relatively Few Failures	.01 per thousand 1 in 100,000 pieces 10 ppm or 0.001%	One occurrence every 1 to 3 years	≥1.20	3
	≤.001 per thousand ≤1 in 1,000,000 pieces ≤1 ppm or 0.0001%	One occurrence every 3 to 5 years	≥1.30	2
Remote: Failure is Unlike	Failure is eliminated through preventive control	One occurrence greater than 5 years	≥1.67	1

Note: Likely failure rates are based on internal occurences only, not frequency of defect escapes to the customer

SUGGESTED PROCESS FMEA DETECTION RANKINGS

Opportunity for Detection	Criteria Likelihood of Detection by Process Control	Rank	Likelihood of Detection
Almost Impossible	No current process control; Cannot detect or is not analyzed.	10	Almost Impossible
Very Remote	Failure Mode and/or Error (Cause) is not easily detected (e.g. **random audits**).	9	Very Remote
Remote	Failure Mode detection **post-processing by operator** through visual/tactile/audible means.	8	Remote
Very Low	Failure Mode detection **in-station by operator** through visual/tactile/audible means or post-processing through use of **attribute gauging** (go/no-go, manual torque check/clicker wrench, etc.).	7	Very Low
Low	Failure Mode detection **post-processing by operator** through use of **variable gauging** or in-station by operator through use of **attribute gauging** (go/no-go, manual torque check/clicker wrench, etc.)	6	Low
Moderate	Failure Mode or Error (Causes) detection **in-station by operator** through use of **variable gauging** or by automated controls in-station that will detect discrepant part and notify operator (light, buzzer, etc.). **Gauging performed on setup and first-piece check** (for set-up causes only)	5	Moderate
Moderately High	Failure Mode detection **post-processing by automated controls** that will detect discrepant part and lock part to prevent further processing.	4	Moderately High
High	Failure Mode detection **in-station by automated controls** that will detect discrepant part and automatically lock part in station to prevent further processing.	3	High
Very High	Error (Cause) detection **in-station by automated controls** that will detect error and prevent discrepant part from being made.	2	Very High
Certain	Error (Cause) prevention as a result of fixture design, machine design or part design. Discrepant parts cannot be made because item has been **error-proofed** by process/product design.	1	Certain

	PRELIMINARY HAZARD ASSESSMENT **This document is subject to the attorney-client and attorney work product privileges.**	**HARARD ANALYSIS #:** _____ **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 independ-ently 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/Hazard Assessment By:	Initials	Risk/Hazard Assessment By:	Initials

The independent conclusions reached by those performing the Risk/Hazard Assessments were recorded by:

Name:_____ Title:_____ Date:_____

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	PRELIMINARY HAZARD ASSESSMENT **This document is subject to the attorney-client and attorney work product privileges.**	**HARARD ANALYSIS #: _____** **DATE: _**

LOGIC/JUSTIFICATION FOR RISK ASSESSMENT:

POSSIBLE CORRECTIVE ACTIONS (IF CATEGORY 2 RISK):

DESIGN HAZARD OUT:

GUARD AGAINST HAZARD:

WARN AGAINST HAZARD:

CORRECTIVE ACTION(S) TAKEN TO BRING RISK OF HAZARD DOWN TO ACCEPTABLE LEVELS:

DATE CORRECTIVE ACTION(S) TAKEN:

DATE HAZARD ANALYSIS CLOSED: _____

APPROVED BY:_____ TITLE: _____