

ISO 9001:2015 Risk Based Thinking

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Agenda

Risk Based Thinking in ISO 9001:2015

Define Risk

Define Risk Based Thinking

Risk in ISO 9001:2015

Risk vs Preventive Action

Risk-Based Approach to Quality Management

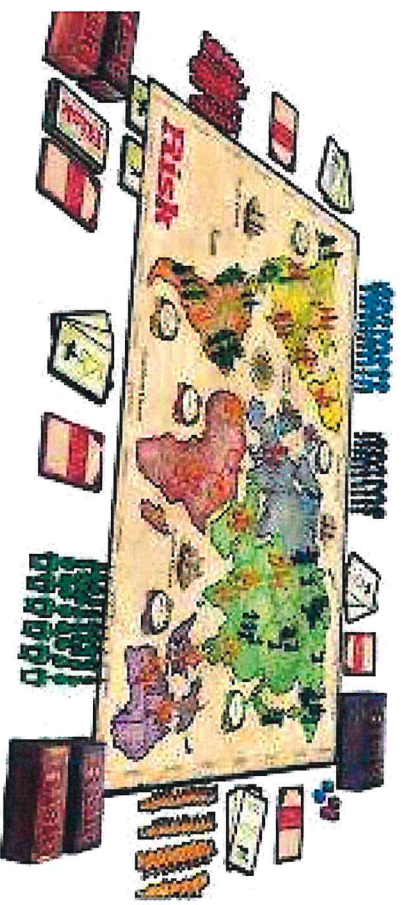
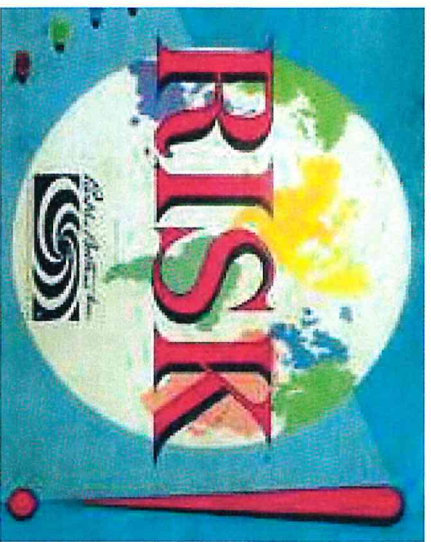
Risk Mitigation

Dealing with Risk

Tools and Techniques to Measure, Control and Mitigate Risk

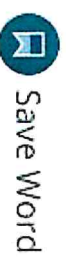
What Risk Isn't

- ▶ It is not the board game we loved to play as kids!



What Risk Is

risk noun



ˈrɪsk \

Definition of *risk* (Entry 1 of 2)

- 1 : possibility of loss or injury : PERIL
- 2 : someone or something that creates or suggests a hazard
- 3 **a** : the chance of loss or the perils to the subject matter of an insurance contract
also : the degree of probability of such loss
b : a person or thing that is a specified hazard to an insurer
c : an insurance hazard from a specified cause or source
// war risk
- 4 : the chance that an investment (such as a stock or commodity) will lose value

at risk

: in a state or condition marked by a high level of risk or susceptibility
// patients at risk of infection



What Risk Is

In ISO 9000:2015—“Quality management systems—Fundamentals and vocabulary,” risk is defined as the **“effect of uncertainty.”**

Notes in the definition further describe risk as a “deviation from the expected,” either positive or negative.

What Risk Based Thinking Is

Risk-based thinking requires companies to evaluate risk when establishing processes, controls and improvements in a Quality Management System.

It's important to note that risk isn't limited to negative possibilities.

Risk in ISO 9001:2015

Risk (and Opportunities) are mentioned 33 times in ISO 9001:2015

- ▶ Introduction – 0.1 General (c)
- ▶ 0.3 Process approach
 - ▶ 0.3.1 General
 - ▶ 0.3.2 Plan-Do-Check-Act cycle – under Plan
 - ▶ 0.3.3 Risk-based thinking (risk and opportunities - 6x)
- ▶ 4.4 Quality management system and its processes
 - ▶ 4.4.1 (f)
- ▶ 5.1 Leadership and commitment
 - ▶ 5.1.2 (b) Customer focus
- ▶ 6.1 Actions to address risks and opportunities
 - ▶ 6.1.1
 - ▶ 6.1.2 (a) & last sentence
 - ▶ Note 1 (6x)
- ▶ 9.1.3 (e) Analysis and evaluation
- ▶ 9.3.2 (e) Management review inputs
- ▶ 10.2 Nonconformity and corrective action
 - ▶ 10.2.1 (e)
- ▶ Annex A:
 - ▶ A.4 Risk-based thinking (8x)
 - ▶ A.5 Applicability

ISO 9001:2015 Risk & Opportunities

Introduction

0.1 General

The adoption of a quality management system is a strategic decision for an organization that can help to improve its overall performance and provide a sound basis for sustainable development initiatives.

The potential benefits to an organization of implementing a quality management system based on this International Standard are:

- c) Addressing **risks and opportunities** associated with its context and objectives.

ISO 9001:2015 Risks and Opportunities

Introduction

0.3 Process approach

0.3.2 Plan-Do-Check-Act cycle

The PDCA cycle can be briefly described as follows:

- Plan: establish the objectives of the system and its processes, and the resources needed to deliver results in accordance with customers' requirements and the organization's policies, and identify and address **risks and opportunities**

ISO 9001:2015 Risks and Opportunities

Introduction

0.3 Process approach

0.3.3 Risk-based thinking

To conform to the requirements of this International Standard, an organization needs to plan and implement actions to address **risks and opportunities**. Addressing both **risks and opportunities** establishes a basis for increasing the effectiveness of the QMS, achieving improved results and preventing negative effects.

Opportunities can arise as a result of a situation favorable to achieving an intended result, for example, a set of circumstances that allow the organization to attract customer, develop new products and services, reduce waste or improve productivity. Actions to address opportunities can also include consideration of associated **risks**. **Risk** is the effect of uncertainty, and any such uncertainty can have positive and negative effects. A positive deviation arising from a **risk** can provide an opportunity, but not all positive effects of **risk** result in opportunities

ISO 9001:2015 Risk & Opportunities

4.4 Quality management system and its processes

The organization shall establish, implement, maintain and continually improve a quality management system, including the processes needed and their interactions, in accordance with this International standard.

The organization shall determine the processes needed for the quality management system and their application throughout the organization and shall determine:

f) The **risks and opportunities** in accordance with the requirements of 6.1, and plan and implement the appropriate actions to address them;

ISO 9001:2015 Risk & Opportunities

6 Planning for the quality management system

6.1 Actions to address **risk and opportunities**

6.1.1 When planning for the quality management system, the organization shall consider the issues referred to in 4.1 and the requirements referred to in 4.2 and determine the **risks and opportunities** that need to be addressed to:

- a) give assurance that the quality management system can achieve its intended result(s)
- b) prevent, or reduce, undesired effects;
- c) achieve continual improvement

4.1 Addresses Context of the Organization

4.2 Addresses Interested Parties

ISO 9001:2015 Risk & Opportunities

6.1.2 The organization shall plan:

- a) Actions to address these **risks and opportunities**
- b) How to:
 - 1) Integrate and implement the actions into its quality management system processes (see 4.4);
 - 2) Evaluate the effectiveness of these actions.

Actions taken to address **risks and opportunities** shall be proportionate to the potential impact on the conformity of products and services.

ISO 9001:2015 Risk & Opportunities

9.1.3 Analysis and evaluation

The organization shall analyze and evaluate appropriate data and information arising from monitoring and measurement.

The results of analysis shall be used to evaluate:

- e) The effectiveness of actions taken to address **risks and opportunities**.

ISO 9001:2015 Risk & Opportunities

9.3 Management Review

9.3.2 Management review inputs

The management review shall be planned and carried out taking into consideration:

e) The effectiveness of actions taken to address **risks and opportunities**.

ISO 9001:2015 Risk & Opportunities

10.2 Nonconformity and corrective action

10.2.1 When nonconformity occurs, including any arising from complaints, the organization shall:

e) Update **risks and opportunities** determined during planning, if necessary.

Risk-Based Thinking in ISO 9001:2015

Risk based thinking is mentioned 12 times in ISO 9001:2015

- ▶ Introduction –
 - ▶ 0.3 Process approach
 - ▶ 0.3.3 Risk-based thinking (3x)
 - ▶ 0.4 Relationship with other management system standards
- ▶ 5.1 Leadership and commitment
 - ▶ 5.1.1 (d) General
- ▶ Annex A:
 - ▶ A.4 Risk-based thinking (4x)
 - ▶ A.8 Control of externally provided processes, products and services



ISO 9001:2015 Risk Based Thinking

Introduction

0.3 Process approach

0.3.1 General

The process approach involves the systematic definition and management of processes, and their interactions, so as to achieve the intended results in accordance with the quality policy and strategic direction of the organization. Management of the processes and the system as a whole can be achieved using the PDCA cycle with an overall focus on **risk-based thinking** aimed at taking advantage of opportunities and preventing undesirable results.

ISO 9001:2015 Risks-Base Thinking

Introduction

0.3 Process approach

0.3.3 Risk-based thinking

Risk-based thinking is essential for achieving an effective QMS. The concept of **risk-based thinking** has been implicit in previous editions of this International Standard including, for example, carrying out preventive action to eliminate potential nonconformities, analyzing any nonconformities that do occur, and taking action to prevent recurrence that is appropriate for the effects of the nonconformity.

ISO 9001:2015 Risk Based Thinking

Introduction

0.4 Relationship with other management system standards

This International Standard enables an organization to use the process approach, coupled with the PDCA cycle and **risk-based thinking**, to align or integrate its quality management system with the requirements of other management system standards.

ISO 9001:2015 Risk Based Thinking

5.1 Leadership and commitment

5.1.1 General

Top management shall demonstrate leadership and commitment with respect to quality management system by:

- d) Promoting the use of the process approach and **risk-based thinking**



Preventive action VS Risk based thinking



Preventive Action

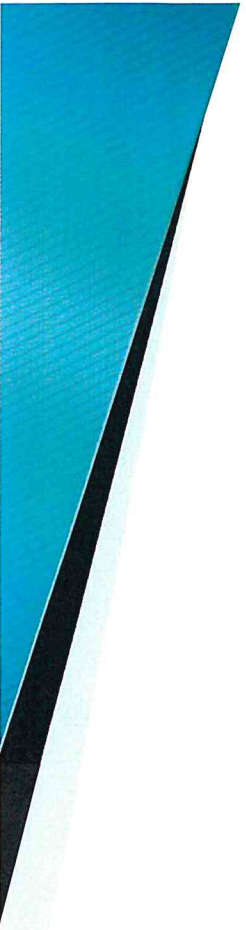
In most organizations preventive actions tended to be a “box-ticking exercise” borne out of the need to satisfy an ISO 9001 requirement, as opposed to a real driver for change and continual improvement.

Preventive actions were typically actioned at mid to lower levels in organizations, typically by quality teams.

They usually failed to capture the issues that really affected the organization to drive continual improvement.

Risk-Based Approach to Quality Management

- ▶ Involves taking a greater strategic view of risk
- ▶ Ties in with the changes in leadership requirements within ISO 9001:2015



Risk-Based Approach to Quality Management

- ▶ Top management team must be involved in the process of identifying, recording, removing, and mitigating risk
 - Use management review for identifying risk
 - Ensure all employees have a channel where they can feed their opinions upwards for consideration by top management
- ▶ When these two processes are in place, there is a “risk-based thinking” process that is presided over by the top management team, which holds all the key strategic knowledge about threats to the business and is supported by information from all levels.

What is Risk Mitigation?

- ▶ Lowers exposure to risk
- ▶ Moderates the adverse effects.
- ▶ A slightly more complete risk mitigation definition is:
 - Developing preventive action plans for reducing the likelihood of risk, or damage from risk.
- ▶ Risk mitigation can also be thought of as risk control.
 - For example, regular maintenance of a machine can help control the risk of breakdowns.
- ▶ Preventive efforts to mitigate or control risk costs money or resources. However, the cost of reacting to risk can end up being much higher.

What Are Risk Mitigation Strategies?

By understanding the likelihood and impact of threats in advance, risk mitigation helps the organization understand the total risk to assume. When mitigating risk, various techniques are commonly used in parallel.

- 1. Prioritize risk:** Evaluate the areas the business relies on. These are the first risks to control. Risk prioritization of certain categories or processes, however, is just the first step. Only a holistic approach will allow for true mitigation of risk in the organization.
- 2. Accept risk:** Murphy's law says: When something can go wrong, it will, and at the worst possible time. Risk mitigation involves a certain degree of risk acceptance, in which the probability of a threat is accepted, along with its consequences.

What Are Risk Mitigation Strategies?

- 3. Avoid risk:** Risk mitigation can include risk avoidance. This is when organizations steer clear of certain types of risk through proactive measures.
- 4. Reduce risk:** Similarly, risk reduction serves to lower or minimize specific risks and their impact.
- 5. Transfer risk:** This is when another party agrees to accept the consequences of risk. A common example of transferred risk is insurance. Here, too, mitigation involves the balance of cost and risk.

Dealing with Risk – Risk Mitigation Plan

- ▶ A risk mitigation plan outlines the risks, anticipate the consequences, and plans options to moderate the effects.
- ▶ The risk mitigation plan should include:
 - **Collecting** key evaluation criteria in one place
 - **Rating** the processes being evaluated on indicators within different categories of risk
 - **Assigning** weights to the categories
 - **Seeing at a glance** where the greatest threats exist

Tools and Techniques to Measure, Control and Mitigate Risk

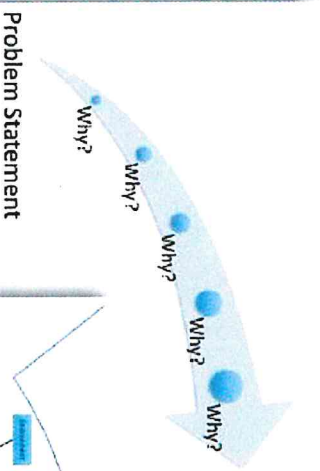
There are many tools and techniques that can be applied. Find the tool that works best for your organization. We will look at 3 commonly applied tools:

- ▶ Root Cause Analysis
- ▶ Risk Register – 3 types
- ▶ FMEA (Failure Modes Effect Analysis)

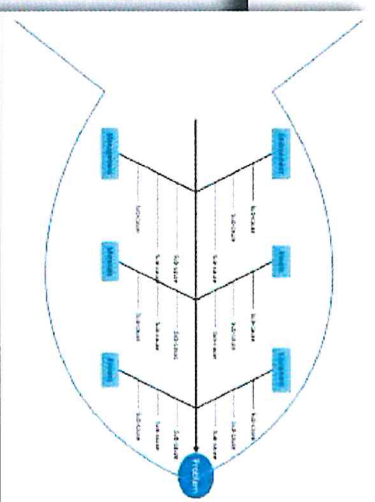
Root Cause Analysis

RCA Tools

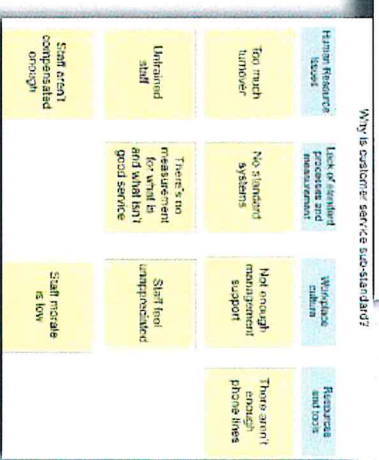
- 5 Why's Analysis



- Fishbone Diagram



- Affinity Diagram



Root Cause Analysis

- **5 Why's Analysis**

When looking at **one major cause** and needs drill-down to arrive at **one root cause**

- **Affinity Diagram**

When looking at several **inter-related** and **detailed causes** which have some things in common and can be grouped together to see the **Major Causes**

- **Fishbone Diagram**

When looking at **numerous major causes** and needs drill-down probing to arrive at **numerous root causes(s)** based on their **Cause and Effect Relationships**

Risk Register – Non-Scoring

RISK ASSESSMENT

PRODUCT NAME:
DESCRIPTION:

DATE:

ITEM	COMPONENT / RISK OPPORTUNITY	DESCRIPTION POSSIBLE RISK	RISK LEVEL	ACTIONS TO MITIGATE RISK
1				
2				
3				
4				
5				
6				
7				
8				
9				
10				
11				
12				
13				
14				
15				

Risk Register – Non-scoring Example

PRODUCT ASSESSMENT

PRODUCT NAME: E-CARGO BIKE		DESCRIPTION: BIKE DESIGNED TO CARRY CARGO		DATE: 3/31/2021	
Item	Component	Description	Criticality	Actions	
1	BATTERY	BATTERY COULD OVERHEAT OR FREEZE	LOW	PUT BIKE IN THERMAL CHAMBER TO VERIFY THERMAL PROTECTION SHUTS BIKE OFF IF BATTERY OVERHEATS OR DURING EXTREME COLD CONDITIONS	
2	DASHBOARD	BOSCH'S ERROR CODES - LIST AVAILABLE ONLINE	LOW	POWER ON BIKE & RIDE: DETERMINE IF ANY ERROR CODES APPEAR ON THE SCREEN & HOW TO TROUBLE SHOOT THEM. IE 503- SPEED SENSOR (SENSOR NOT ALLIGNED CORRECTLY)	
3	RIMS	NEED TO DETERMINE STRUCTURAL INTEGRITY THAT RIMS CAN HANDLE HEAVY WEIGHT	LOW	LOAD BIKE WITH HEAVY WEIGHT & RIDE BIKE FOR DETERMINED AMOUNT OF TIME	
4	SUSPENSION	UPPER & LOWER COULD BEND WITH TOO MUCH WEIGHT		LOAD BIKE WITH HEAVY WEIGHT & RIDE BIKE FOR DETERMINED AMOUNT OF TIME	
5	STEERING	WEAK POINT: - 'RACK & PINION' HAS WEAK POINTS AT WELDS AT END OF SHAFT CONNECTED TO GEAR - MAIN STEERING BLOCK ATTACHED TO HANDLEBARS HAS WEAK POINTS AT WELDS- BOTH GEARS COULD SNAP AT WELD POINTS IF TOO MUCH LOAD IS PUT ON, OR HIT SOMETHING WITH HARD IMPACT.	MEDIUM	STRESS TEST TO DETERMINE IMPACT & LOAD THAT WILL BREAK GEARS AT WELD POINTS ON MAIN STEERING BLOCK & SHAFT/PINION	
6	OUTER STEERING ARMS (ALUMINUM, WHILE SUSPENSION COMPONENTS ARE STAINLESS)	STAINLESS IS HEAVIER & STURDIER THAN ALUMINUM & WITH HARD IMPACT ALUMINUM ARMS COULD BEND & CAN ALSO STRIP THE THREADS (WHERE HEIM JOINTS ARE ATTACHED)	MEDIUM	STRESS TEST TO DETERMINE IMPACT & LOAD THAT WILL BEND ARMS OR STRIP THREADS	
7	CARGO WEIGHT LIMIT	UNDETERMINED	MEDIUM	STRESS TEST TO DETERMINE LOAD CAPACITY	
8	BRAKES	BRAKES ARE PURCHASED	LOW	DETERMINE THE AMOUNT OF PRESSURE THE BRAKES CAN WITHSTAND	
9	LIGHTS: HEADLIGHTS, BREAKLIGHTS & TURNING SIGNAL	DETERMINE LIFESPAN & FUNCTIONALITY	LOW	BURN IN TEST FOR ALL LIGHTS	
10	MOTOR	DETERMINE IF MOTOR WILL BURN OUT OR OVERHEAT	LOW	BURN IN TEST FOR DETERMINED AMOUNT OF TIME WITH A HEAVY LOAD	

Risk Register - Scoring

RISK ASSESSMENT

PROJECT NAME:

PROJECT DESCRIPTION:

DATE:

SCORING FOR:

	SEVERITY	LIKELIHOOD
1 =	NO POTENTIAL FOR HARM	VERY UNLIKELY
2 =	DISTRACTION/LIMITED EFFECT	POSSIBLE BUT NOT LIKELY
3 =	NEGATIVE EFFECT ON BUSINESS	QUITE POSSIBLE
4 =	LOSS OF BUSINESS/SALES	LIKELY
5 =	MAY CAUSE HARM OR DEATH	VERY LIKELY

ITEM	PROCESS STEP	RISK / OPORTUNITY DESCRIPTION	IMPACT OF POSSIBLE RISK	SEVERITY	LIKELIHOOD	RISK PRIORITY NUMBER (RPN)	CONTROLS TO MITIGATE RISK
1							
2							
3							
4							
5							
6							
7							
8							
9							
10							
11							
12							
13							
14							
15							

Risk Register - Scoring

Example – 1 Product

RISK ASSESSMENT

PROJECT NAME: **BT-OAN-3724A**

PROJECT DESCRIPTION: **On-Board Access Node - 8x Ports w/ 24VDC, 9A, 1 Gigabyte ethernet**

DATE: **3/9/2020**

SCORING FOR:

	SEVERITY	LIKELIHOOD
1 =	NO POTENTIAL FOR HARM	VERY UNLIKELY
2 =	DISTRACTION/LIMITED EFFECT	POSSIBLE BUT NOT LIKELY
3 =	NEGATIVE EFFECT ON BUSINESS	QUITE POSSIBLE
4 =	LOSS OF BUSINESS/SALES	LIKELY
5 =	MAY CAUSE HARM OR DEATH	VERY LIKELY

ITEM	PROCESS STEP	RISK / OPPORTUNITY DESCRIPTION	IMPACT OF POSSIBLE RISK	SEVERITY	LIKELIHOOD	RISK PRIORITY NUMBER (RPN)	CONTROLS TO MITIGATE RISK
1	Fiberglass attachment	Screws loosen over time	Loose screws inside chassis	4	3	12	Use locite screws
2	PCB Handling	DCM and CTRL PCB connector is weak	Breaking connector	3	4	12	Ensure assembly person takes caution
3	Long lead time items	Locite screws + Heat pipes + Thermal epoxy	Delays	4	3	12	Pay Attention!!!!
4	DC In cables	Torque value	Power cables dislodge	5	2	10	Solder screws in place
5	DC In cables	Fraying	Power cables conductor becomes	5	2	10	Use wire mesh
6	Solder Screws	DC power wires loosen	DC power in shorts to chassis	5	2	10	Add soldering station on assembly floor
7	Epoxy Application	PPE	Harm to operator	3	3	9	Check assemblers for PPE regularly
8	Fiberglass screws	Torque value	Loose screws inside chassis	3	3	9	Use locite screws
9	LED Cover	Forgotten about	Contaminants entering chassis	4	2	8	Check each cover before ship
10	PCB	Functionality testing prior to conform	Irreversibly coat non functional PCB	3	2	6	Add indicator to pcb at every functionality test
11	Conformal Coating	Uncured conform	Liquid conform on PCB	3	2	6	Implement better conform process
12	Epoxy Application	Chassis needs to be kept level	Epoxy may run causing improper bond	2	2	4	Use level racks and inform assemblers
13	Assembly	Order of operations	Epoxy cures before assembly is	2	2	4	Good work instructions
14	PCB	Burn in testing	Ensure PCBs are working properly	2	1	2	Burn-in unit at high load

Risk Register – Scoring

Example 2 – QMS Processes

Risk Assessment							Revision Date	Rev:		
Item	Process	R = Risk O = Opportun	Risk & Opportunity Description	Impact of Possible Risk	Total	Controls and Mitigation Plan	C/PAR Assignee	Action Taken	Dated Action Complete	
2018-56			Change requests take too long to implement; Hard to manage; Change requests not followed up on	Manufacturing and shipping old Rev, Adding excess inventory of old Rev, time confusion resource allocation cost	887	Controls and Mitigation Plan monthly meeting to review open CRs Allocated resource to review and move CRs forward; assignment methodology add improved metrics for completion of CR and for completion to build this product add marked up drawing with CR to next rev on GSS as opportunities arise, document them add link to form into C/PAR folder All Top Managers should seek out opportunities regularly (at least once per month)	0053	Monthly meetings implemented in Jan 2018 and continue monthly; Meeting and monitoring resulted in closure of 17 old CRs in Jan 2018; Actual days to closure reduced from 78 on average in Jan 2018 to 12 in Feb 2018	3/21/2018	
2018-60	Document Management (Maintained, Retained and Change Management)	R	Not recording all opportunities; Ineffective root cause analysis; Insufficient root cause analysis	Misused opportunities for improvement Non-compliance with ISO 9001 Loss of historical evidence of design	857		NA		1/18/2018	
2018-67	Corrective / Preventive Action	R	lack of documentation; product delivery delays and cost overruns; Insufficient records of design progress; Incomplete hand-off to production; delayed hand-off to production	No clear line between end of design and start of production Excessive rework due to changes after Building wrong revision Using older components Delivering wrong revision / wrong product	829	Juan developing a policy for R&D use a traveler that is useful as a tool need meaningful evidence by end of May 2018 (OW/From)				
2018-01 2018-02 2018-03 2018-07	Design and Development	R	not updated BOM's incorrect work order, missing parts from inventory Design for Manufacturing, Testing, Documentation Engineering working closer to production		805	Joint effort between Production and Engineering on BOM preparation			1/18/2018	
2018-48	Assembly	R			252					
2018-07	Design and Development	R			123					
2018-08	Design and Development	O	orders not placed in time, and ordering incorrect parts; late deliver, wrong materials, cost overruns; long lead times, Purchase too much or too little, JIT, Product Obsolescence ; Purchasing too late, wrong part	Late delivery/missing promise date	781	No longer happening Automated purchasing, good signals Non-GSS PO requests? Need required dates, job - this happens with development projects typically; R&D needs to start with actual stock items before spec'ing out new part numbers Reduce use of McMaster Carr and credit card purchases build an inventory catalogue for use by engineering; shop our inventory	NA		Not considered an issue at present	1/18/2018

Note: This Risk Assessment was developed before the aforementioned form was developed

FMEA Process Flow Chart

Compliments of QualityWBT.com Training Center

- 1** Establish the need - Why
Required business risk improvement
- 2** Define the scope and Team - What & Who
Part, container, product, material, activity, process, service, transaction
- 3** Determine object requirements and brainstorm potential failure cause and effect - What
Size, temperature, pressure, weight, color, speed, performance, clear, correct, protect, wrong, late, etc
- 4** Assess failure risk given the current controls - Risk
Low to high risk of field failure (RPN 0-1K).
Inspect, SPC, sample, check
- 5** Define preventative action plans and measure effectiveness - How
Change, method, measure, control, material, market, specification, equipment, competency

* High risk and important step

FMEA WORKSHEET

Process/Product:	Employee Competency		FMEA Number:	210322-01
FMEA Team:	David B Levy	Date Opened:	22 Mar 2021	
Team Leader:	David B Levy	Date Closed:		

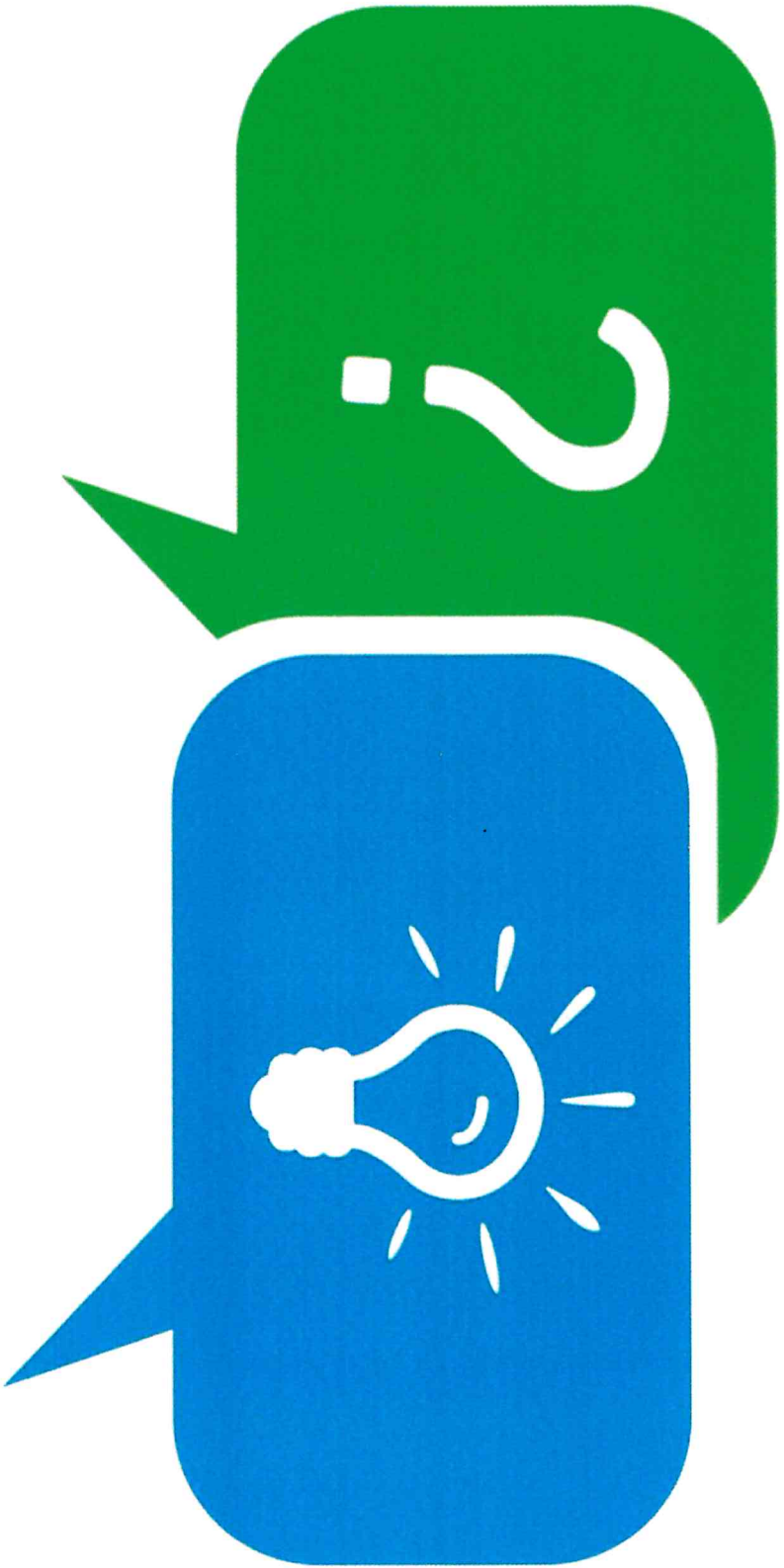
1	2	3	4	5	6a	7	8	9	10	11	12	Final		
Item/ requirement function characteristic	Potential Failure (fail to meet design/ process intent)	Potential Effects	Severity	Potential Cause	Current Controls Prevention	Current Controls Detection	Detection RPN	Recommended Action	Party in charge / date due	Action Taken	6	2	2	
Measure of competency – new employees	No evidence available at hire	Inability to perform designate d tasks	6	Employee has no prior experience	Provide necessary training	Interview	5	1 2 0	Provide OJT before assigning tasks Document training in a work instruction; generate and retain training records as evidence of training Ref: Training procedure Doc # 2.7.01 Rev 7 and Individual Training Record form # 4.6.03 Rev 3 Create job- specific training work instructions for each task requiring OJT	Supervisor/ DAY 1	Train operator on sample materials prior to performing new task; use adult training process: 1. Teach 2. Guided Training 3. Trainer Observes student 4. Student Demonstrates Competency Document OJT provided on form 4.6.03 Rev 3 Document OJT in step by step training using Dozuki tool. Note: this is a software package we use for Work Instructions Use SurveyMonkey for testing.	6	2	2

1	2	3	4	5	6a	7	6b	8	9	10	11	12	Final		
Item/ requirement characteristic	Potential Failure (fail to meet design/ process intent)	Potential Effects	Severity	Potential Cause	Current Controls Prevention	Current Controls Detection	Detection	Recommended Action	Party in charge / date due	Action Taken	Score	Score	Score	Score	
	No method to verify competency	Background check fails to provide evidence	7	Former employer will not provide evidence	Provide necessary training	Interview	5	2 1 0 Pre-hire testing / evaluation Ref: Training procedure Doc # 2.7.01 Rev 7 and Individual Training Record form # 4.6.03 Rev 3	Supervisor / AT INTERVIEW	Pre-hire testing to identify competency prior to joining the company and performing any tasks: Ex: Drafter must complete drafting software demo; Welders must provide evidence of cert plus perform a sample weld for qualification testing	7	2	1	1	
	Employee falsified documents	Background check provides different feedback	1	Former employer provides negative or differing feedback	Provide necessary training	Interview	4	8 0 DO NOT HIRE	HR / AFTER INTERVIEW	Do not hire; weeds out potential problems before they occur	1	1	1	1	

1	2	3	4	5	6a	7	6b	8	9	10	11	12	Final			
Item/ requirement function characteristic	Potential Failure (fail to meet design/ process intent)	Potential Effects	Severity	Potential Cause	Current Controls Prevention	Occurrence	Current Controls Detection	Detection Rate	Recommended Action		Party in charge / date due	Action Taken	Score	Score	Score	Score
Measure of competency – current employees	No experience with task	Inability to perform assigned task	7	Not properly trained; not competent / trained to perform task	Work Instructions /SOPs	4	In process inspection	8 2 4	2 2 4	Improve OJT; Document training in a work instruction; generate and retain training records as evidence of training	Supervisor / UPON ASSIGNMENT	Train individual employees on specific task; verify performance prior to doing the task; use adult training process: 1. Teach 2. Guided Training 3. Trainer Observes student 4. Student Demonstrates Competency	7	2	2	2
	Performs tasks incorrectly	Excessive Non- conformin g Material	7	Not properly trained; competency / ability is lacking	Work Instructions /SOPs	4	In process inspection	8 2 4	2 2 4	Improve OJT; Document training in a work instruction; generate and retain training records as evidence of training	Supervisor / UPON IDENTIFICATION OF ISSUE	Train individual employees on specific task; verify performance prior to doing the task; use adult training process: 1. Teach 2. Guided Training 3. Trainer Observes student 4. Student Demonstrates Competency	7	2	2	2

Food For Thought

- ▶ ISO 9001:2015 mentions Risk and Opportunities and Risk Based Thinking a total of 45 times
 - The majority of discussion associated with Risk / Risk Based Thinking is related to Risk to the Quality Management System.
 - There is no requirement for any tools, processes or procedures associated with Risk.
 - Methods for addressing Risk associated with ISO 9001:2015 and the QMS is at your organization's discretion.
 - Regardless of the approach, your organization must consider risk associated with all critical processes within your QMS.
 - The process of Risk Based Thinking should never end.



References

- ▶ ISO 9001:2015
- ▶ Risk Methods - <https://www.riskmethods.net/resilient-enterprise/risk-mitigation>
- ▶ <https://www.merriam-webster.com/dictionary/risk>
- ▶ ISO/TC 176/SC2/N1284 www.iso.org/tc176/sc02/public
- ▶ RCA Root Cause Analysis by Jeremy Jay Lim
- ▶ Desk Reference FMEA v2020RR; www.qualityWBT.com – JP Russell and Associates