Applying Risk-based Thinking to Operations

Tim Lozier, EtQ

Agenda

- Understanding Operational Risk Management

- How Risk Management processes drive new ways of looking at compliance in operations

- ISO 9001:2015 and Risk Management

- Common tools for leveraging risk in compliance

Risk Management: Hazard vs Risk

- The terms "hazard" and "risk" are often used interchangeably. However, in terms of risk assessment, these are two very distinct terms.
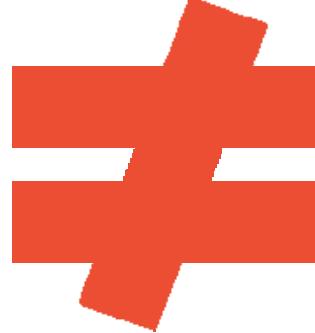
HAZARD ≠ RISK

Risk Management: Risk

- Risk is defined as the probability that exposure to a hazard will lead to a negative consequence, or more simply:

Probability of
Risk = Hazard x Exposure

- Thus, a hazard poses no risk if there is no exposure to that hazard.

Risk Management: Hazard vs Risk

3 in a boat

Three people crossing the Atlantic in a rowboat face a hazard of drowning…

300 in a ship

Three hundred people crossing the Atlantic in an ocean liner face the same hazard of drowning

Risk Management: Hazard vs Risk

The risk to each individual per crossing is given by the probability of the occurrence of an accident in which he or she drowns

RISK = probability of accident occurring x hazard

High Probability = equipment, # of people, environment

Low Probability = equipment, # of people, environment

Risk Management: Hazard vs Risk

The hazard [drowning] is the same for each individual, but the risk [probability of drowning] is greater for the individuals in the rowboat than in the ocean liner

Hazard = Hazard

Probability > Probability

MORE RISK
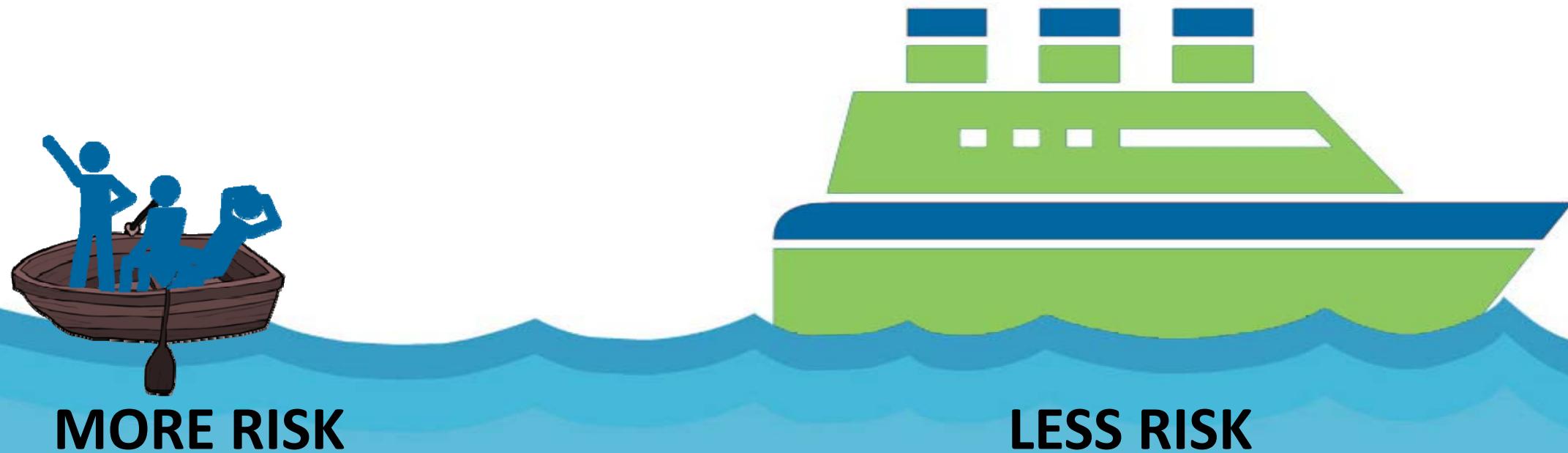
LESS RISK

Risk Management: the Process

- Risk Management is a broad standard (ISO 31000)

Risk Identification	Identify all relevant risks (e.g., hazard analysis)
Risk Evaluation	Quantify the risk (e.g., probability and severity)
Development and evaluation of risk assessment methods	Implement a process Use objective and proven tools
Risk management decisions	Accept (worth it), reduce (mitigate), compensate (insure), transfer (partner), avoid (stop)
Implemented solution	Change management to introduce or improve controls

Risk Management: Areas of Coverage

Risk Management: Rationale for Risk

Easy to understand for the uninitiated

Repeatable and objective methods

Drives short term and long term change

A way to evaluate risk in an operational context

Risk Management is the Core Methodology

Beware a false sense of security

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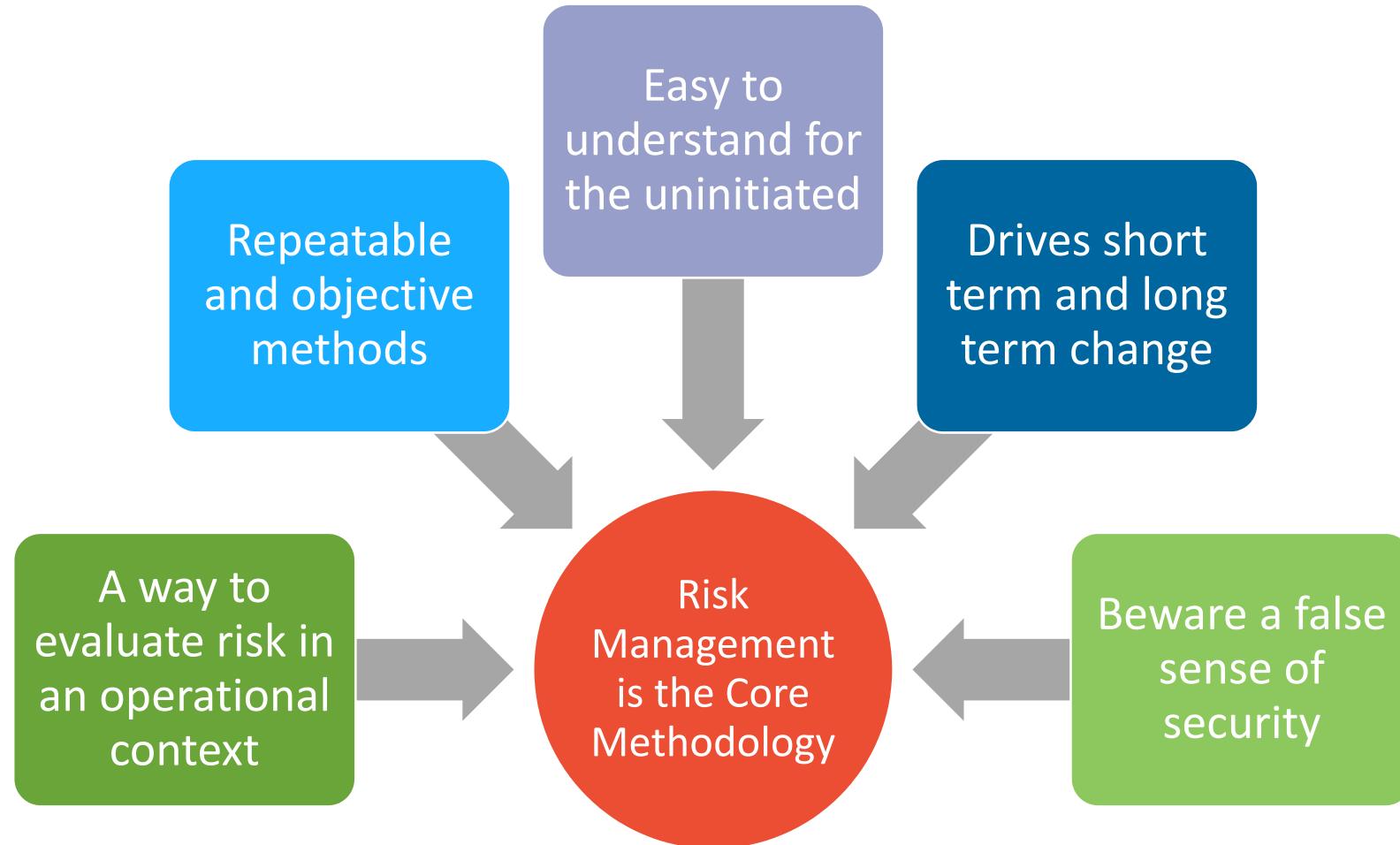
ISO 9000:2015....it's not just requirements,

It's a company mindshare of Quality.
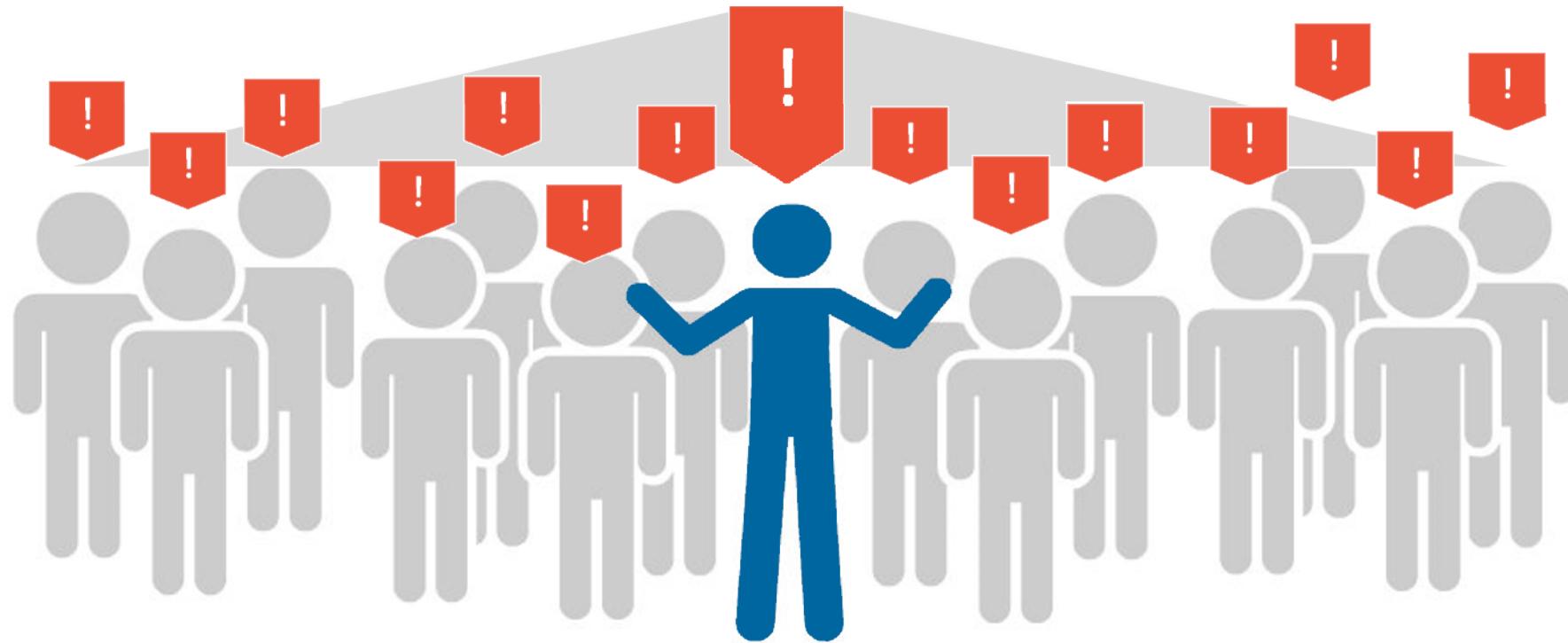
There should be a company-wide commitment/leadership around Quality

ISO 9001:2015 view on risk
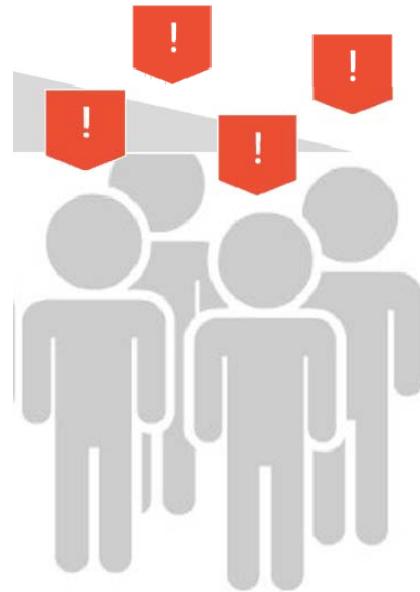
Section 5: Leadership
　　Provide leadership by encouraging a focus on quality

　　Promote the use of risk-based thinking.

Section 6: Planning
　　Consider risks and opportunities when you plan your QMS
　　Plan how you're going to manage risks and opportunities

DISCLAIMER: The ISO view on risk is SIMPLY STATED.   "Use Risk-based thinking" to manage and plan…. But what does that really mean? Broad, and simple – lots of interpretation!

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Planning your QMS with risk in mind

| Identify Risks	→	Evaluate Risks	→	Treatment of Risks	→	Take Action
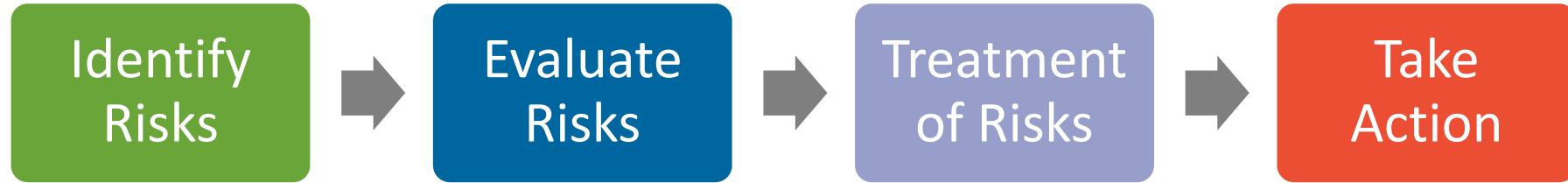
- Identify risks and opportunities to influence QMS performance

- Determine how you're going to measure those risks

- Build risk treatment options

- Define actions to address these risks

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Planning your QMS with risk mind

| Identify Risks | → | Evaluate Risks | → | Treatment of Risks | → | Take Action |
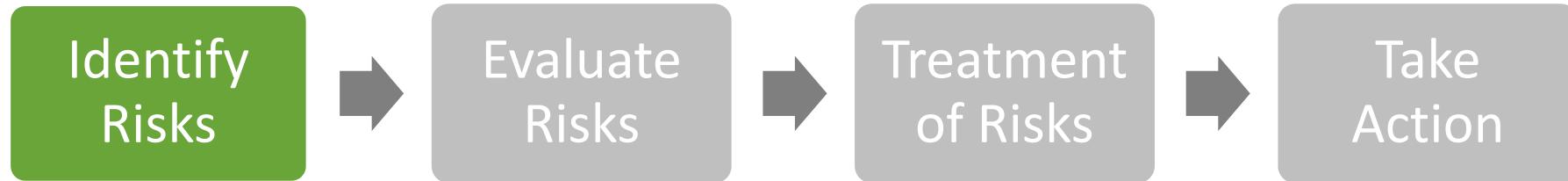
- How to start Identifying risks?
  - Survey your operations
  - Audit, Survey, collect, analyze

| Hazard | Hazard | Hazard | Hazard | Hazard | Hazard | Hazard |

| Operational | Financial | Environmental | Manufacturing |

🔴🟡🟢 Severity Frequency   🔴🟡🟢 Severity Frequency   🔴🟡🟢 Severity Frequency   🔴🟡🟢 Severity Frequency

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Planning your QMS with risk in mind

Identify Risks → **Evaluate Risks** → **Treatment of Risks** → **Take Action**
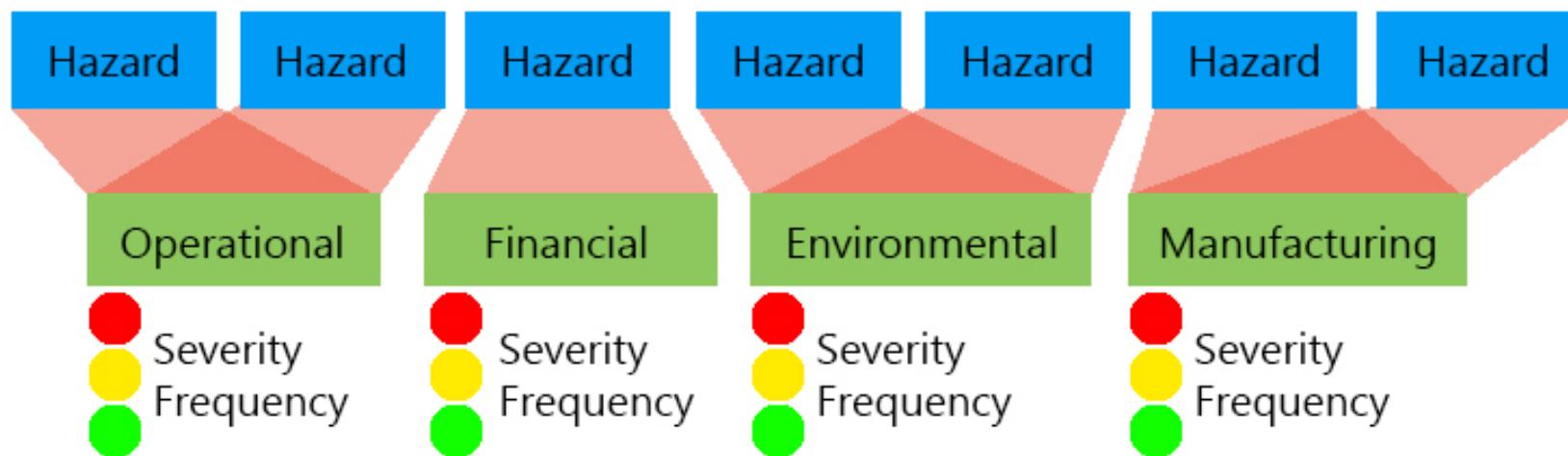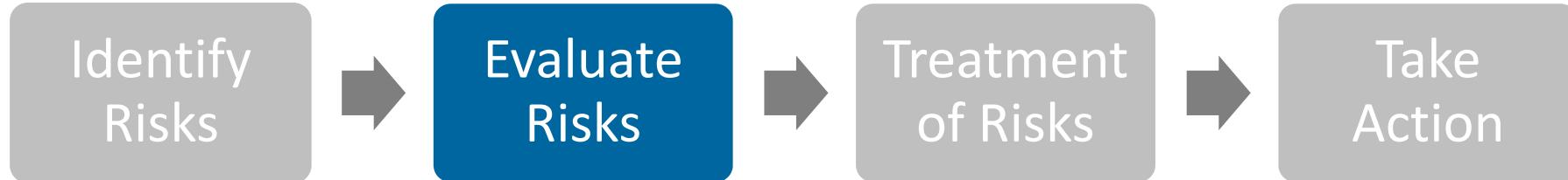
- Evaluate How to handle the risk

- Risk Assessment
  - Should be repeatable, objective
  - Should be backed by REAL-WORLD DATA

- Quantitative means to build a risk assessment

Planning your QMS with risk in mind

| Identify Risks	→	Evaluate Risks	→	Treatment of Risks	→	Take Action
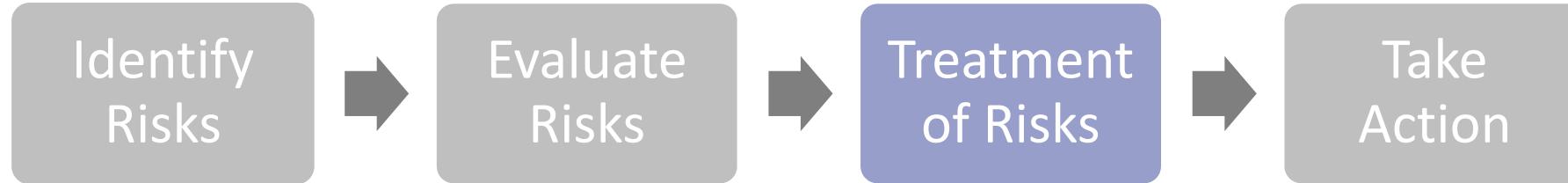
- We know the risk....how do we handle it?

Risk Level →

Acceptance: "Worth it"
Reduction: "Mitigation"
Compensation: "Insurance"
Transference: "Move it"
Avoidance: "Stop it"

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Planning your QMS with risk in mind

Identify Risks	→	Evaluate Risks	→	Treatment of Risks	→	Take Action
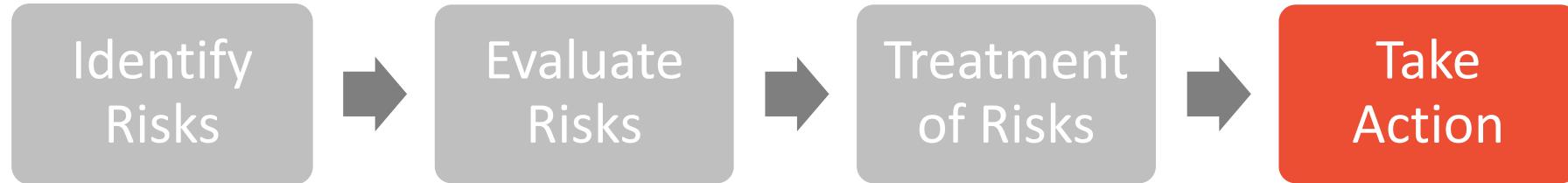
- Take Action: Create Visibility and Control the Risk

Risk Level

Corrective/Preventive Action

Controls/Action Plans

Reporting/Trending

Planning your QMS with risk in mind

Identify Risks		Evaluate Risks		Treatment of Risks		Take Action
	→		→		→	

DOCUMENT YOUR ACTIVITIES

How? Audit Findings Survey Results Report on Findings	Document your Evaluation: Control your methods, tools, processes	Document the treatment, the overall decision factors	Link Assessments to Actions taken, improvements made

- Document the process in order to have traceability.

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Planning your QMS with risk in mind

Identify Risks	→	Evaluate Risks	→	Treatment of Risks	→	Take Action

Proactive Continuous Improvement

Potential but not realized Hazards: Survey improvement areas	How can we determine the impact of potential events?	Where can we measure impact and determine improvement?	Change Management, Process Improvements, Etc.
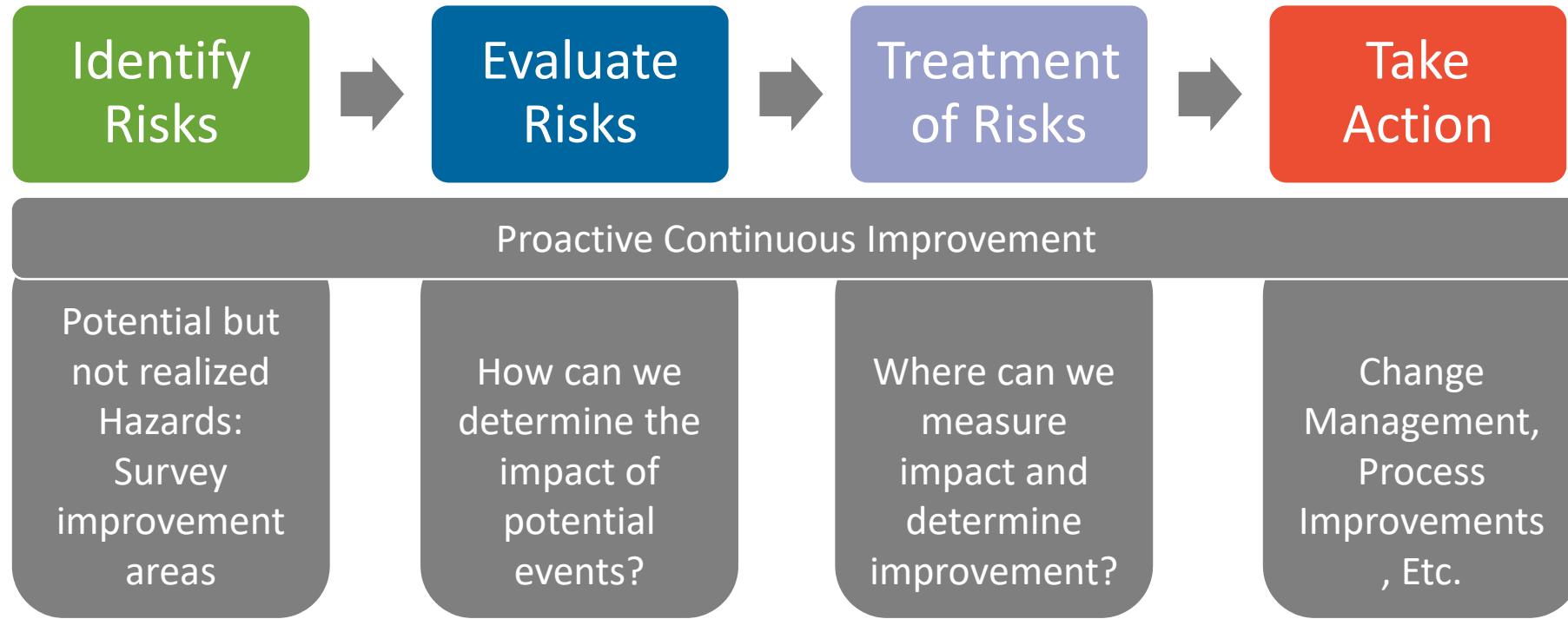
- It's not all for just the Risks! Identify Opportunities too!

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Common Tools for Risk Management Treatment

(a sample)

RISK
- Decision Tree
- Risk Matrix
- FMEA
- Bowtie
- Risk Register

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Decision Tree Analysis

Easy to integrate with everyday processes
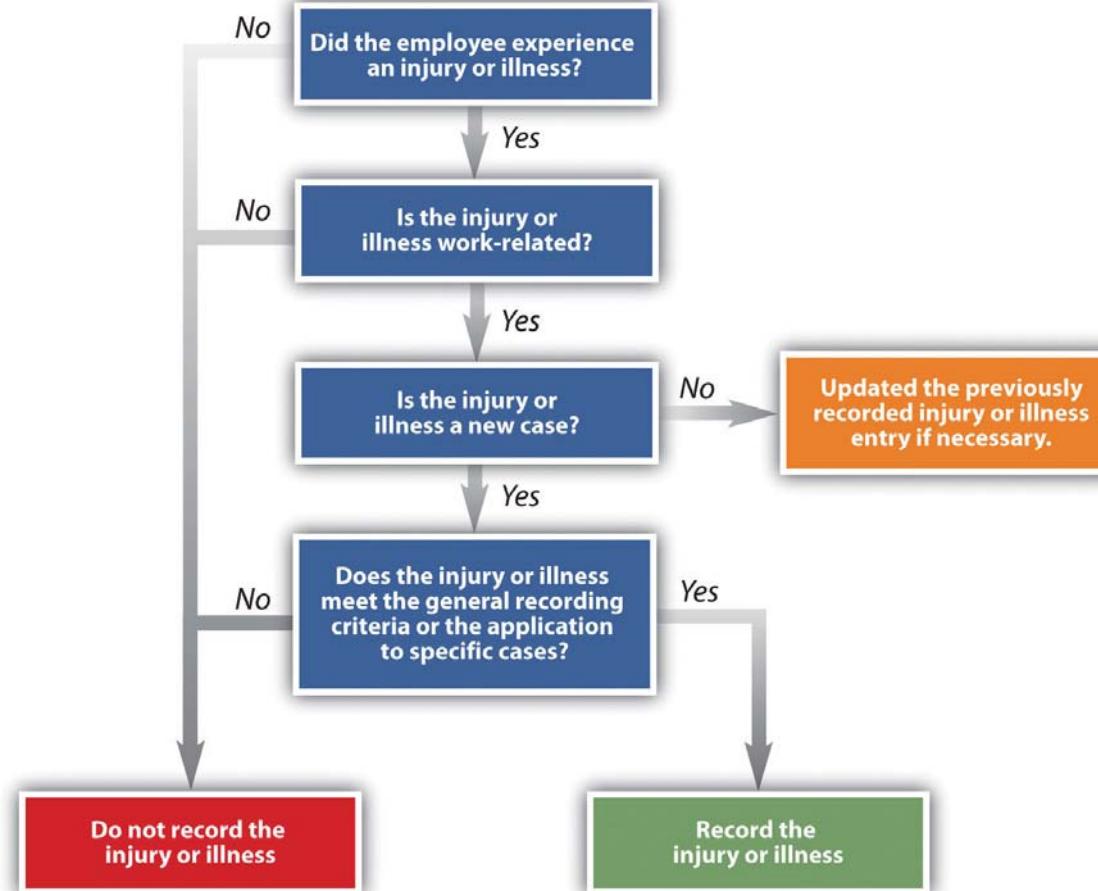
Risk Matrix

Quantifies the risk level using tested assumptions

SEVERITY

PROBABILITY	Minor (1)	Negligible (2)	Marginal (3)	Critical (4)	Catastrophic (5)
Frequent (5)	Yellow	Red	Red	Red	Red
Probable (4)	Yellow	Yellow	Yellow	Red	Red
Occasional (3)	Yellow	Yellow	Yellow	Yellow	Yellow
Remote (2)	Green	Yellow	Yellow	Yellow	Yellow
Improbable (1)	Green	Green	Green	Green	Green
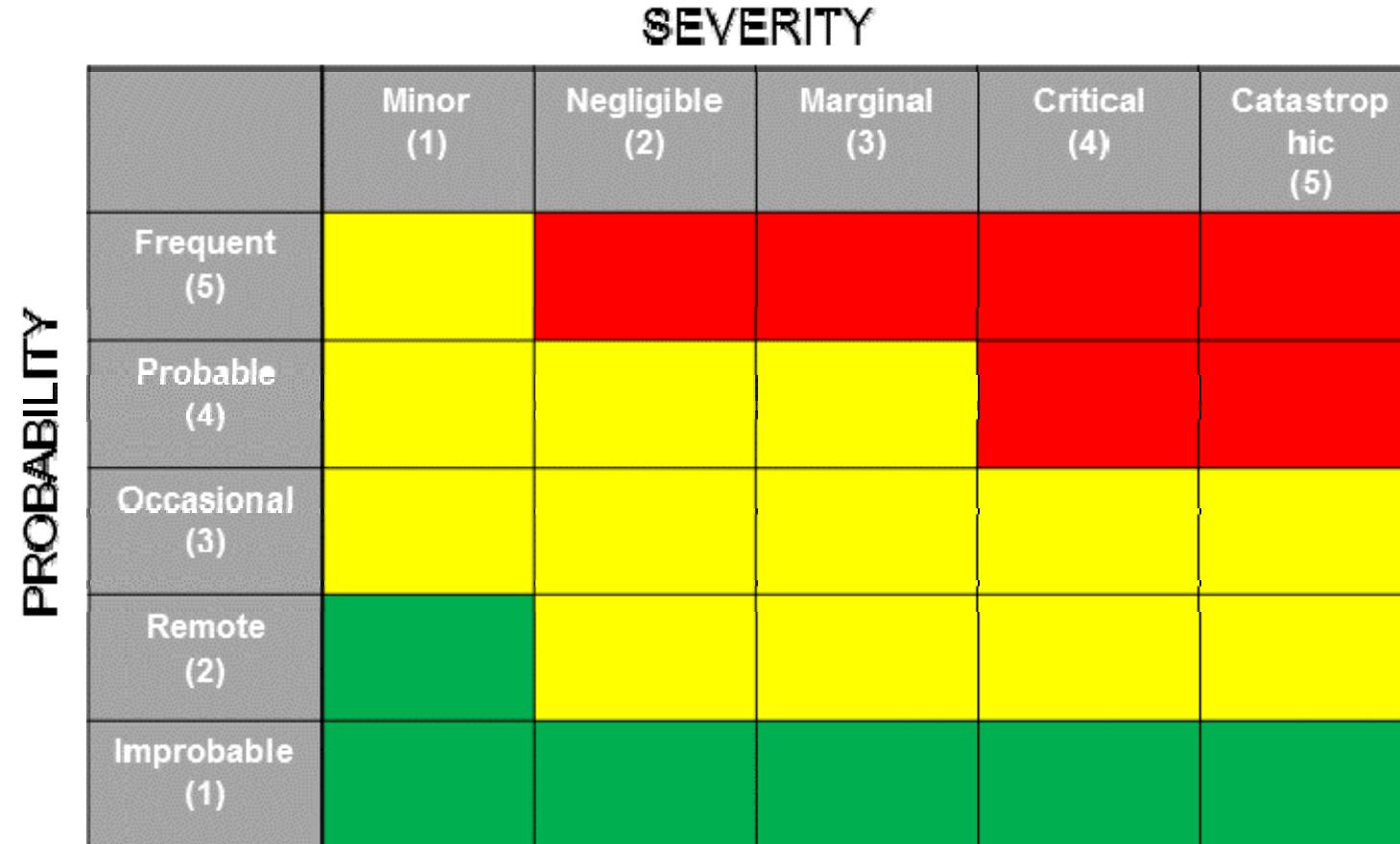
Failure Modes and Effect Analysis

For design of products and processes

System	Customer		Customer Part No.			Org. Date	Page
Subsystem	Chrysler Motors Corporation		DC-77323-XYZ			2/11/98	1 of 2
✓ Component	Supplier Any Company, Inc.	Code ACI-001	Supplier Part No. A-9514		Dwg. Rev. 8	Key Date 2/11/98	FMEA No. DFMEA-001

Part Name Filter	Design Responsibility Brad Anderson	Application/Model Year Sedan / 1998

Core Team Brad Anderson,Jerry Benware,Lisa Brown,Ken Caracci,Bill Cox,Fred Jordan,Ken Kratz	Prepared By Brad A. Anderson	Date 2/11/98

Item / Function	Potential Failure Mode	Potential Effect(s) of Failure	Sev	Class	Potential Cause(s) / Mechanisms of Failure	Occur	Current Design Controls	Detec	R.P.N.	Recommended Action(s)	Responsibility & Target Completion Date	Actions Taken	Sev	Occ	Det	R.P.N.
Filter for assembly with B44 to firewall	Insufficient wax coverage over specified surface	Deteriorated life of door leading to: Unsatisfactory appearance due to rust through paint over time, Impaired function of interior door hardware	4	◇	Insufficient wax thickness specified	4	Supplier certification	1	16	None	N/A 2/11/98					
					Inappropriate wax specified	5	set up set up	4	80							
							Five piece setup, in-process, end of run study	2	40	None	N/A 2/11/98					
	Corroded interior lower door panels	Improper oxide coating	6		Entrapped air prevents wax from entering corner/edge access	6	Test spray pattern at startup and after idle periods, and ...	5	180	Add team evaluation using production spray equipment and specified wax	Engineering and Assembly Operations 2/18/98	Based on test reults (Test #9989) spray head modified to ...	6	2	5	60
					Spray heads clogged: Viscosity too high, Temperature too low, Pressure too low	4	Incomming audit per 200-16 certification, SPC Lot/Qtr	2	48							
							Laboratory test using "worst case" wax and application hole size	3	72	Add laboratory accelerated corrosion testing	ABC Labs 2/27/98	Test results show specified ...	6	3	3	54
										Conduct DOE on wax thickness	Engineering Associates 2/18/98	DOE shows 25% variation in specified thickness is acceptable	6	2	2	24
					Feeder not properly or	3										

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FMEA Process

Sample FMEA Form

Design FMEA

Revision 6.0 2/11/98

System ☐	Customer			Customer Part No.		Org. Date	Page
Subsystem ☐	Chrysler Motors Corporation			DC-77323-XYZ		2/11/98	1 of 2
Component ☑	Supplier		Code	Supplier Part No.	Dwg. Rev.	Key Date	FMEA No.
	Any Company, Inc.		ACI-001	A-9514	8	2/11/98	DFMEA-001

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Bowtie Model

For low-occurrence events that are catastrophic

Threat — Preventive Controls — Undesired Event (Hazard) — Recovery Controls — Consequence

Frequency → Likelihood → ← Likelihood ← Severity

Bowtie Example

For low-occurrence events that are catastrophic

Bad Weather	Windshield Wipers		Seatbelts	Vechicle Damage
Tired Driver	Coffee	Car Accident	Airbags	Driver Injury
Poor Visibility	Headlights		Crash Barrels Guard Rails	Driver Death

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Risk Register

- Monitors risk levels over time
    - Library of hazards (typically known for each industry)
    - Collects risk assessment data from many processes
    - Provides visibility into critical events and data for trend reporting

Risk Register

PDCA Cycle
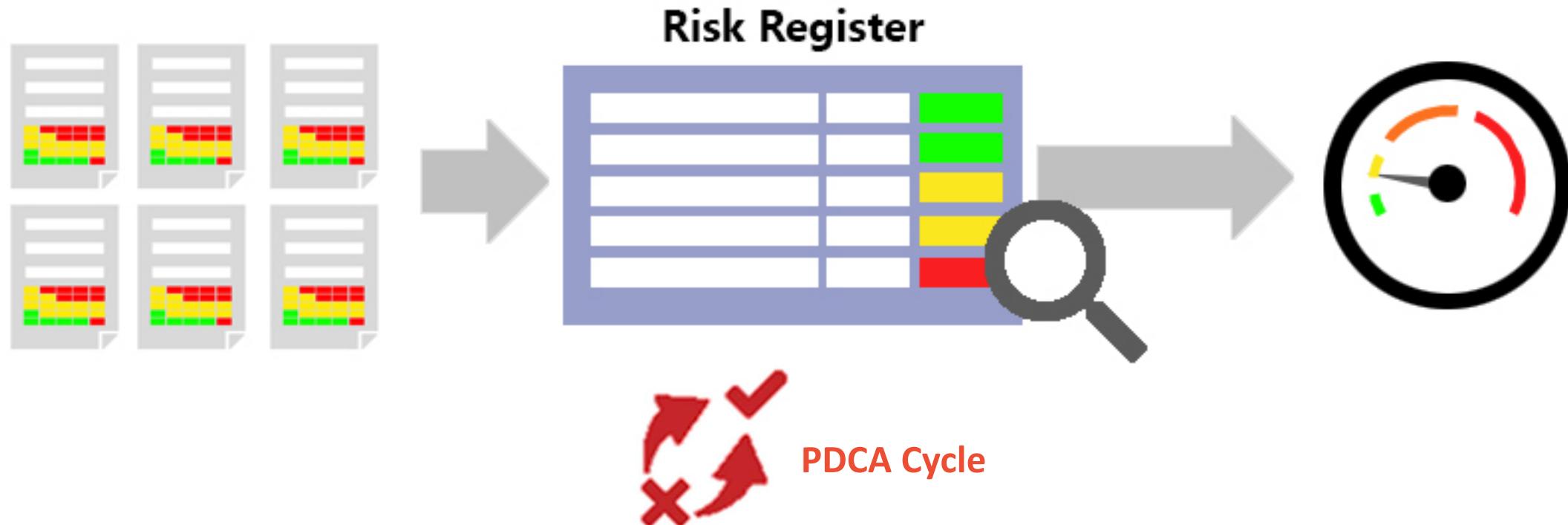
Summary

- Risk is a universal compliance constant
- ISO 9001:2015 is about enrolling everyone in Quality
- Risk in ISO 9001:2015 is simply stated, but maps well to the risk methodology
- Figure out your path to risk, and leverage tools to expand to a risk-based QMS
- There are tools to help ease this transition!

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