Risk-Based Thinking in Quality Management Systems:

How to Incorporate Risk into Your Processes

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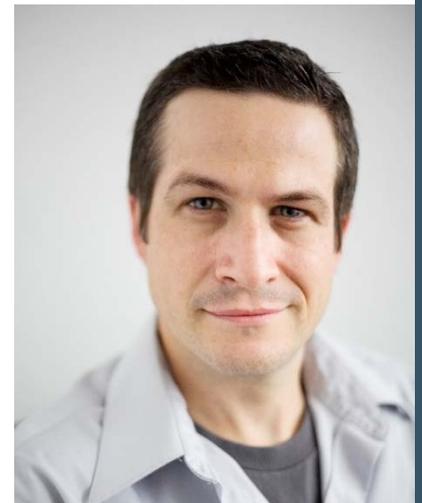
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Agenda

- Understanding Operational Risk Management
- How Risk Management processes drive new ways of looking at compliance in operations
- ISO 9000:2015 and Risk Management
- Common tools for leveraging risk in compliance

Increasing Rate of Change

There is an Increasing Rate of Change

- **We are more complex**
  - Global Scale of Production, Design, Sourcing
  - More Mergers, Acquisitions
  - Growing Supply-Chain

- **There is more competition**
  - Competition leads to shorter product lifecycles
  - Increases in product complexity
  - More variety of goods in more areas

- **Companies need to maintain compliance AND keep up with the pace of business!**

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Time to shift our mindset?

- **How compliance keeps up with change**
  - Automation of compliance processes
  - Integration with business systems
  - Harmonization of compliance processes

- **Cost of compliance is skyrocketing**
  - Cost of systems, people and time
  - Cost of holding back operations
  - Cost of holding back inventory

- **Quality and Compliance need to expand!**
  - We must think beyond Quality silo
  - From audit results to risk assessments
  - Risk is a more efficient measure of compliance

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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: Hazard

- *1.Insurance: Condition or situation that creates or increases chance of loss in an insured risk, separated into two kinds (1) Physical hazard: physical environment which could increase or decrease the probability or severity of a loss. It can be managed through risk-improvement, insurance policy terms, and premium rates. (2) Moral hazard: attitude and ethical conduct of the insured. It cannot be managed but can be avoided by declining to insure the risk.*

- *2.Workplace safety: Dangerous event or situation that may lead to an emergency or disaster. It could also be a biological, chemical, or physical agent in (or a property of) an environment that may have an adverse health effect, or may cause injury or loss. As such, a hazard is a potential and not an actual possibility.*

Read more:
http://www.businessdictionary.com/definition/hazard.html#ixzz3miUj2jq1

Risk Management: Risk

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

$$\text{Risk} = \text{Hazard} \times \overset{\text{Probability of}}{\text{Exposure}}$$

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

Risk Management: Hazard vs Risk

Consider the following example from David Okrent's 1980 article, "Comment on Societal 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

Consider the following example from David Okrent's 1980 article, "Comment on Societal 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

Consider the following example from David Okrent's 1980 article, "Comment on Societal 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

Risk Evaluation

Development and evaluation of risk assessment methods

Risk management decisions

Implemented solution

Identify all relevant risks (e.g., hazard analysis)

Quantify the risk (e.g., probability and severity)

Implement a process
Use objective and proven tools

Accept (worth it), reduce (mitigate), compensate (insure), transfer (partner), avoid (stop)

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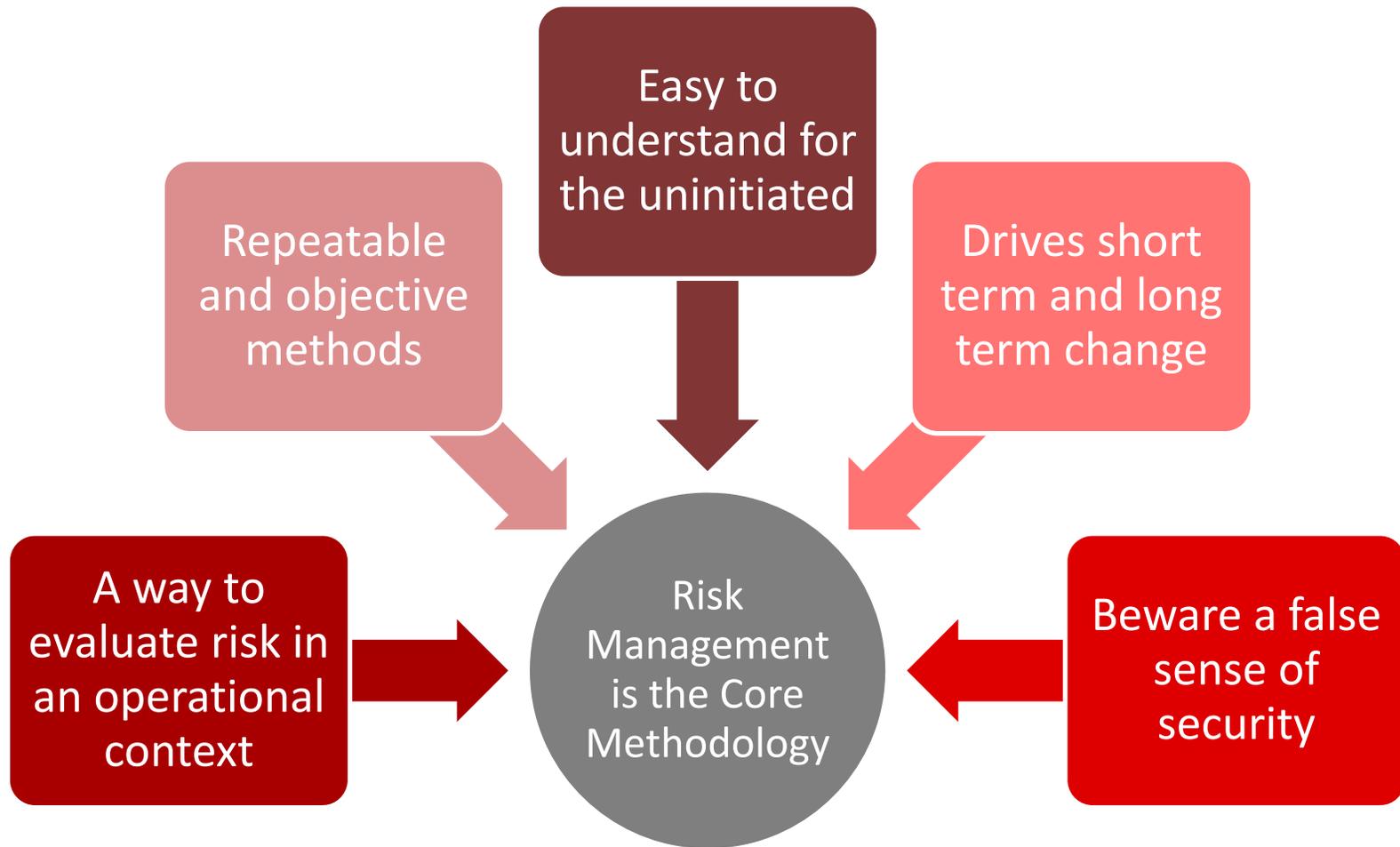
# ISO 9000:2015....it's not just requirements,

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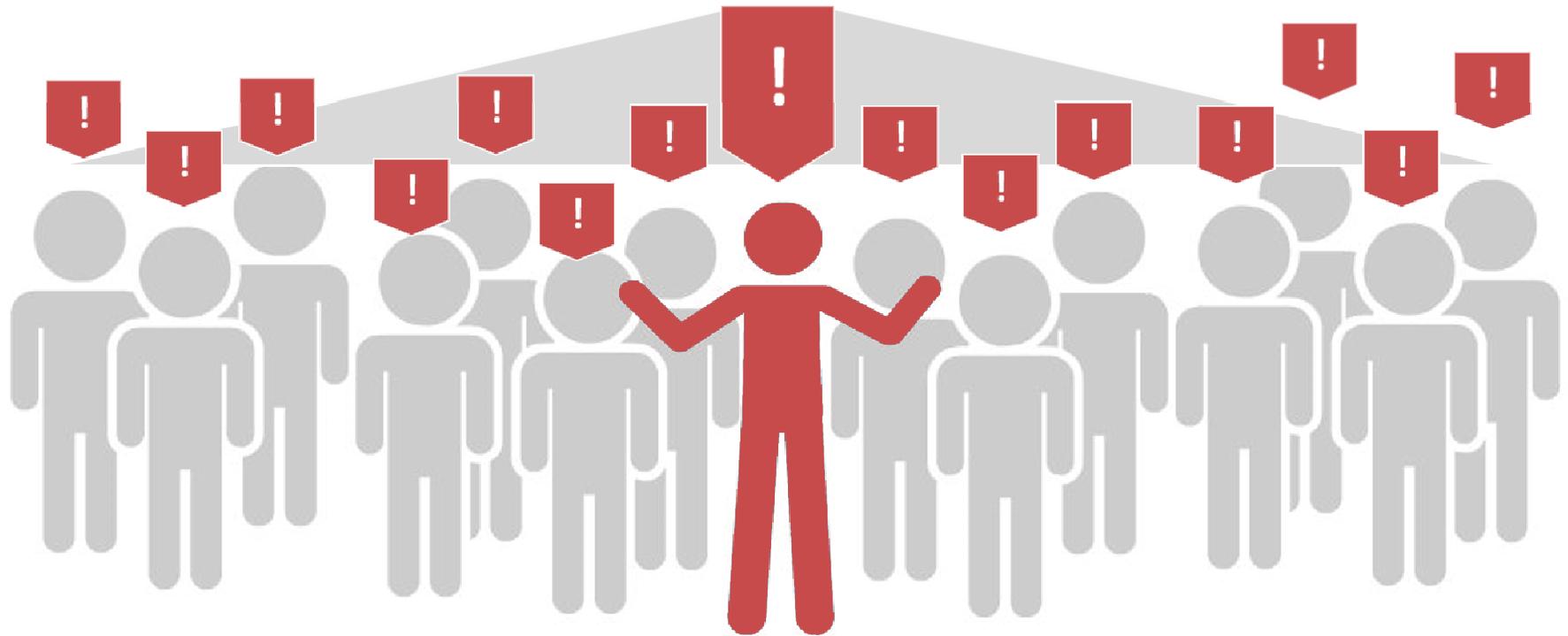
There should be a company-wide commitment/leadership around Quality

ISO 9000:2015 view on risk
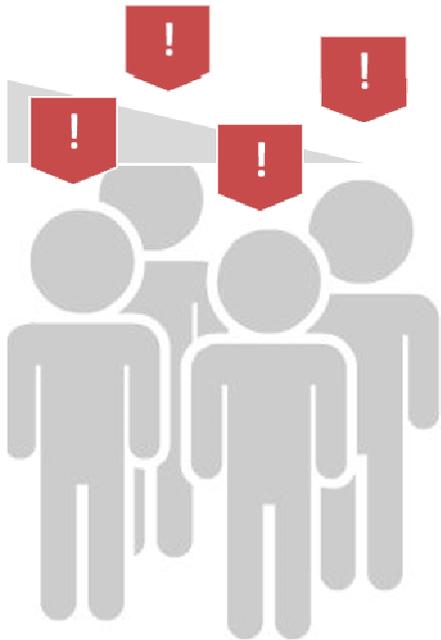
Section 5: Leadership

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 |
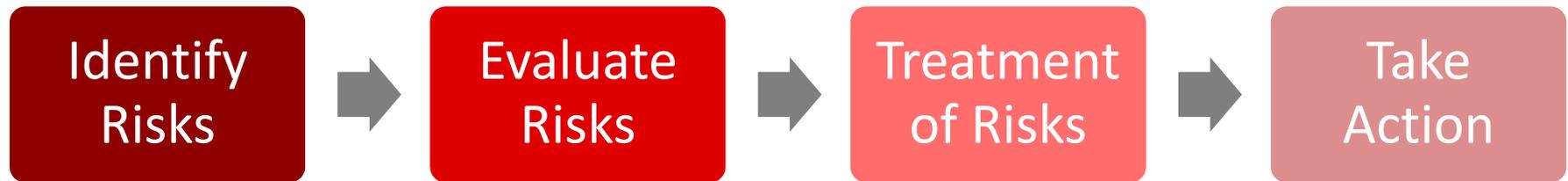
- Identify risks and opportunities to influence QMS performance
- Determine how you're going to measure those risks
- Build risk treatment options
- Define actions to address these risks

Planning your QMS with risk mind

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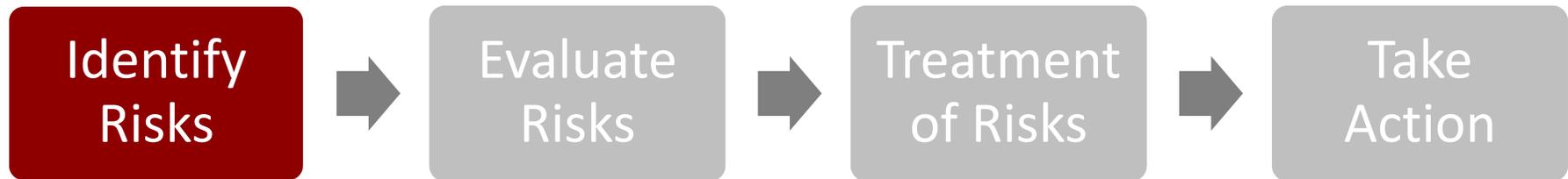
- **How to start Identifying risks?**
  - Survey your operations
  - Audit, Survey, collect, analyze

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

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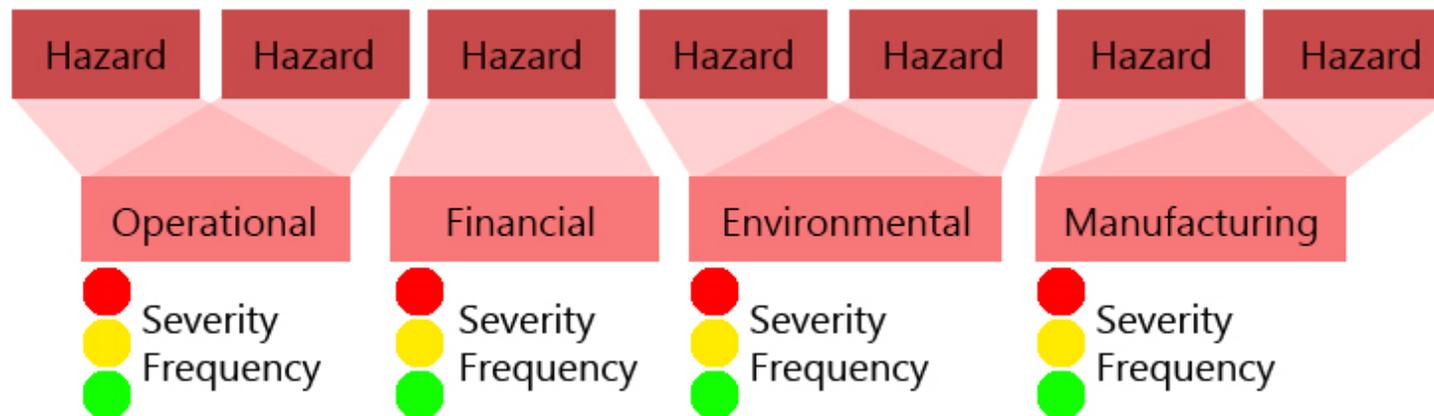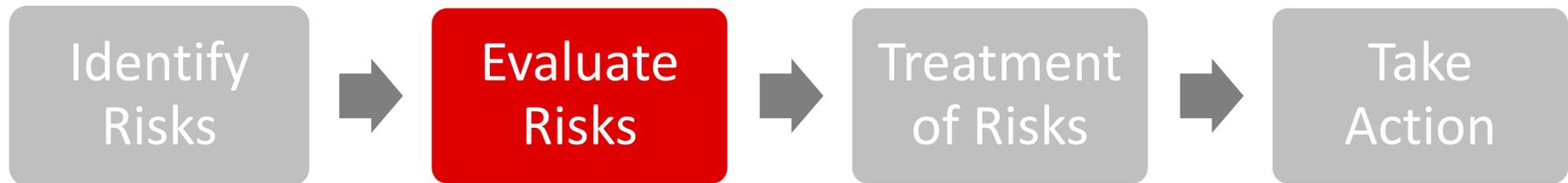
- **Evaluate How to handle the risk**
- **Risk Assessment**
  - Should be repeatable, objective
  - Should be backed by REAL-WORLD DATA
- **Quantitative means to build a risk assessment**

Planning your QMS with risk in mind

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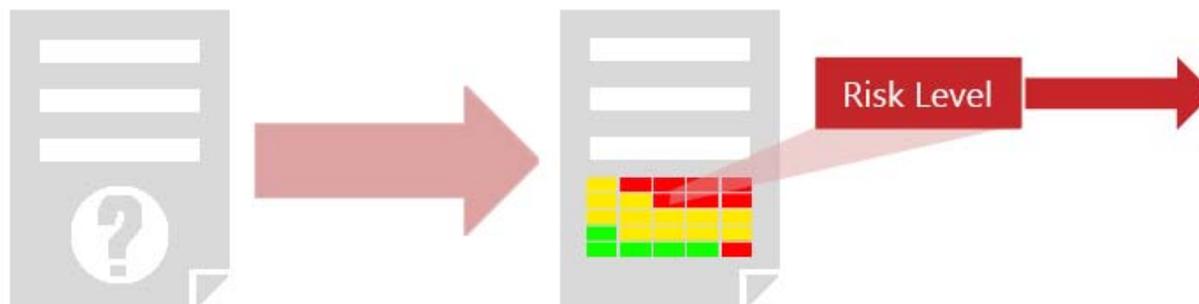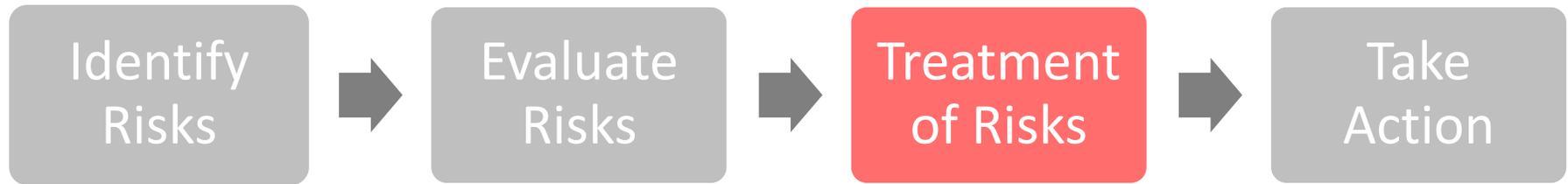
- **We know the risk….how do we handle it?**

Risk Level →

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

Planning your QMS with risk in mind

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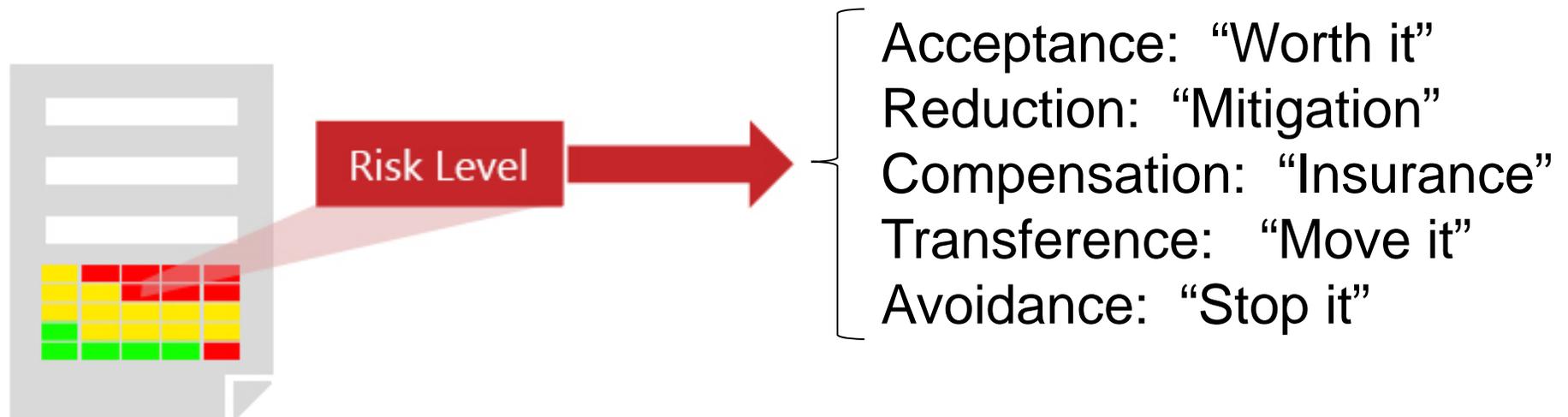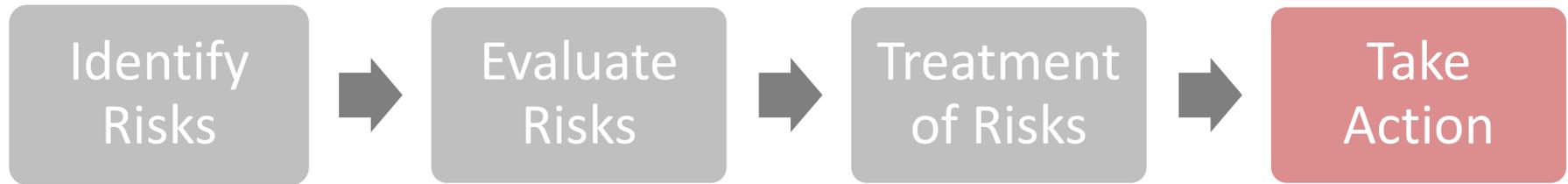
- **Take Action: Create Visibility and Control the Risk**

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.**

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. |
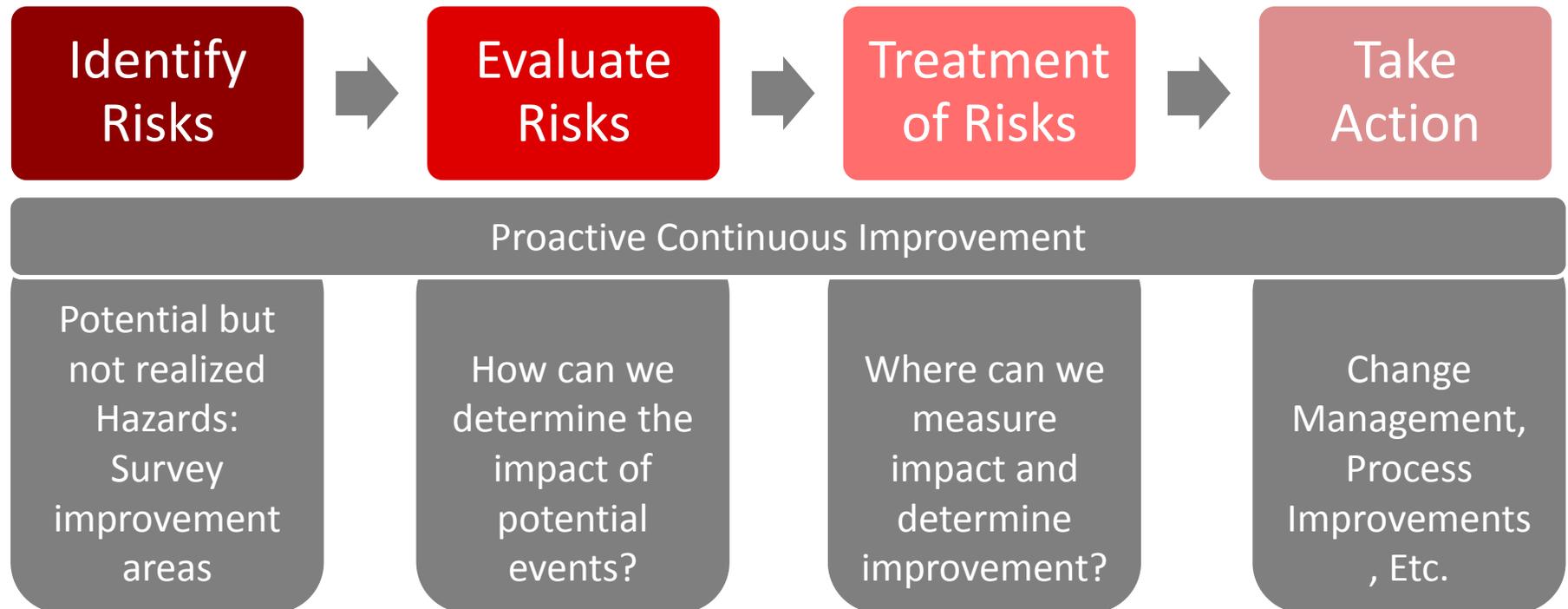
- **It's not all for just the Risks! Identify Opportunities too!**

Common Tools for Risk Management Treatment

(a sample)

RISK

- **Decision Tree**
- **Risk Matrix**
- **Risk Register**

Decision Tree Analysis

Easy to integrate with everyday processes
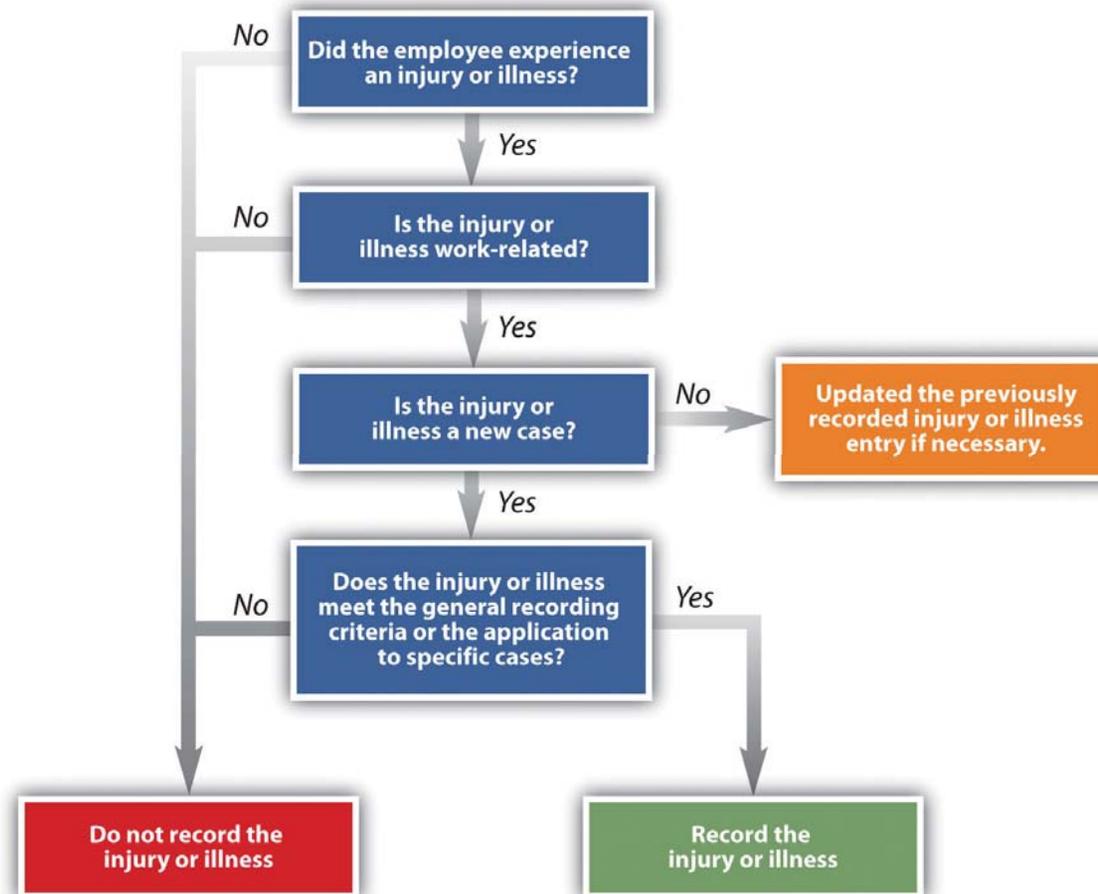
Decision Tree Example
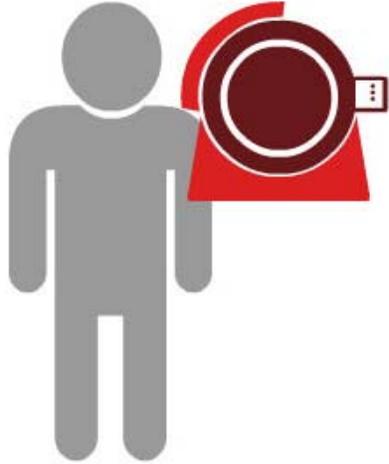
- **When to report to the FDA**
  - Medical device manufacturer
  - Reporting decision embedded in complaint handling process
  - Filled out by analysts for every potential adverse event
  - Drives decision to report (Yes/No) and acceptable delay (when?)
- **Prioritize internal notification**
  - Global Utilities company
  - Automated determination of who needs to be notified of incidents based on risk level
  - Immediate initial risk assessment determines risk level
  - Risk level determines email distribution list, including SMS (text) alerts for highest level
  - Follow up risk assessment performed after investigation is completed (for long term trend analysis)
  - Take immediate action on critical issues, and implement long term improvements on unacceptable trends

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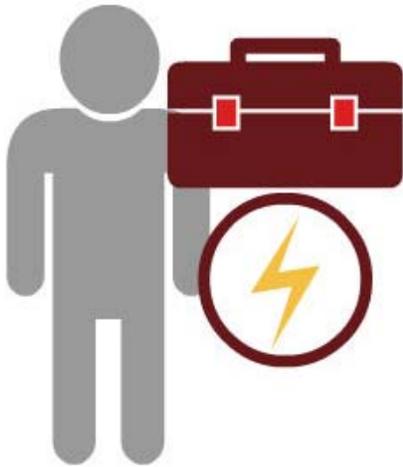
Risk Matrix

Quick, easy, colorful

Quantifies the risk level using tested assumptions

SEVERITY

	Minor (1)	Negligible (2)	Marginal (3)	Critical (4)	Catastrophic (5)
Frequent (5)	🟨	🟥	🟥	🟥	🟥
Probable (4)	🟨	🟨	🟨	🟥	🟥
Occasional (3)	🟨	🟨	🟨	🟨	🟨
Remote (2)	🟩	🟨	🟨	🟨	🟨
Improbable (1)	🟩	🟩	🟩	🟩	🟩

PROBABILITY

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Risk Matrix Example

Identify potential adverse events
- Medical device manufacturer(a different one)
- Customer complaints routed for investigation
- Subject matter experts perform risk assessment (meeting)
- Risk levels drive decisions for recalls, notifications, CAPA
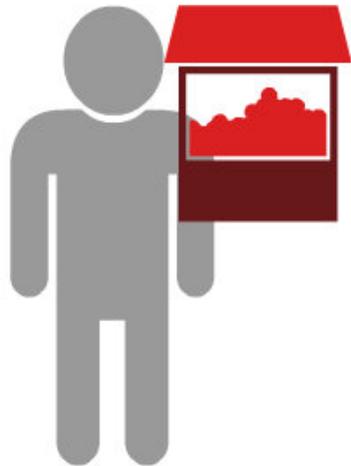
Survey of known and unknown threats
- Services organization
- Periodic survey to all business functions
- Managers re-calculate risk levels for known threats and suggest new threats
- Prioritization of compiled risk levels drives strategic risk mitigation initiatives (managed through CAPA process)

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
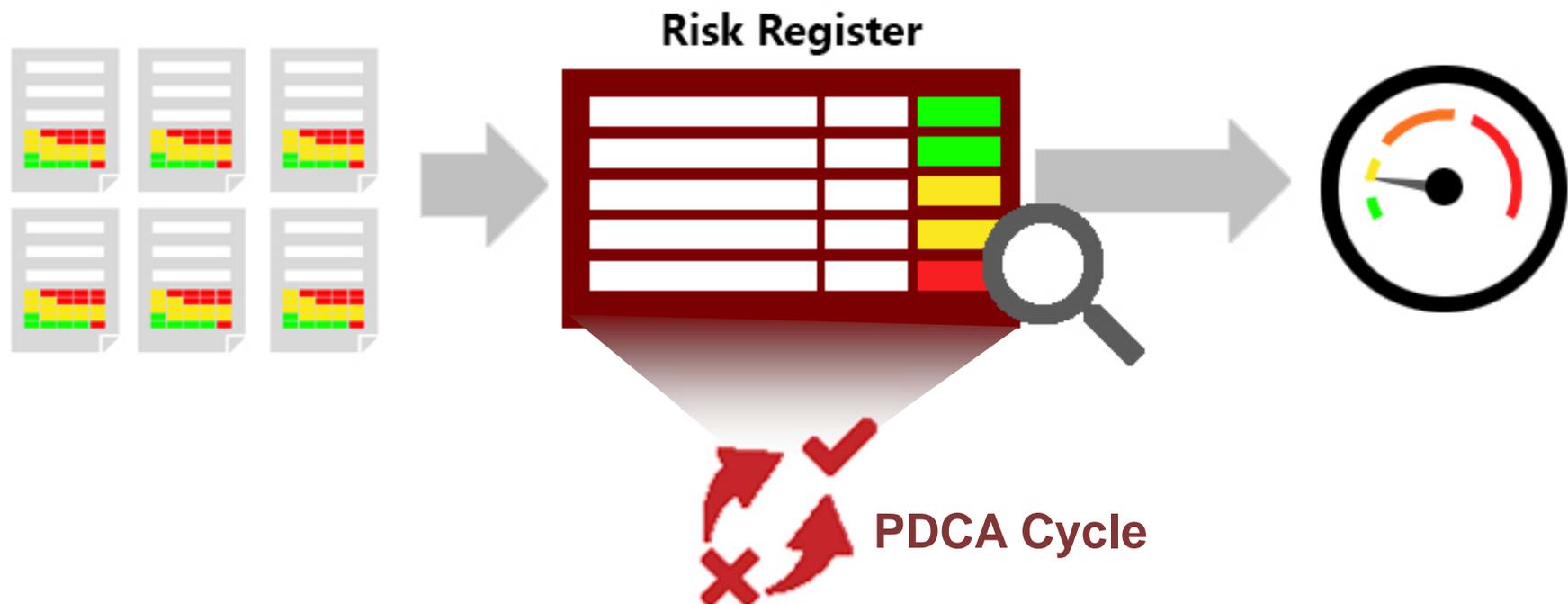
Summary

- Complexity and scale breeds the need for change
- Risk is a universal compliance constant
- ISO 9000:2015 is about enrolling everyone in Quality
- Risk in ISO 9000:2015 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!

Thank you!   Questions?

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traqpath

Designed for small workgroups in Quality, EHS and Compliance looking to track events, issue action items and launch corrective actions.

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