

Benchmarking Risk and Compliance with your Peers: How Do You Measure Up?

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What we're covering today

- **Compliance – what are we talking about?**
- **Shift in the mindset of compliance along with operational excellence**
- **Compliance Grader – questions and results from peers**
- **Measuring Risks – what is being tracked in Risk management today?**
- **How to build a risk management program for your organization**

Compliance Management

- **Compliance is:**

Quality
Operations
Safety
Governance
Risk
Regulatory
Financial
Sustainability



It's **BROAD.**

[It's also only a component of a larger theme]

Relationship of Compliance and Operational Excellence

- **Compliance**

- Adherence to Guidelines
- Specifications created by a standards body
- Required in order to do business in certain industries
- Abiding by both industry regulations and government legislation

- **Operation Excellence**

- Adherence to company strategy
- Specifications created to the sustainable improvement of key performance metrics.
- Abiding by process to foster long-term change in organizational culture, not just remain in “compliance”

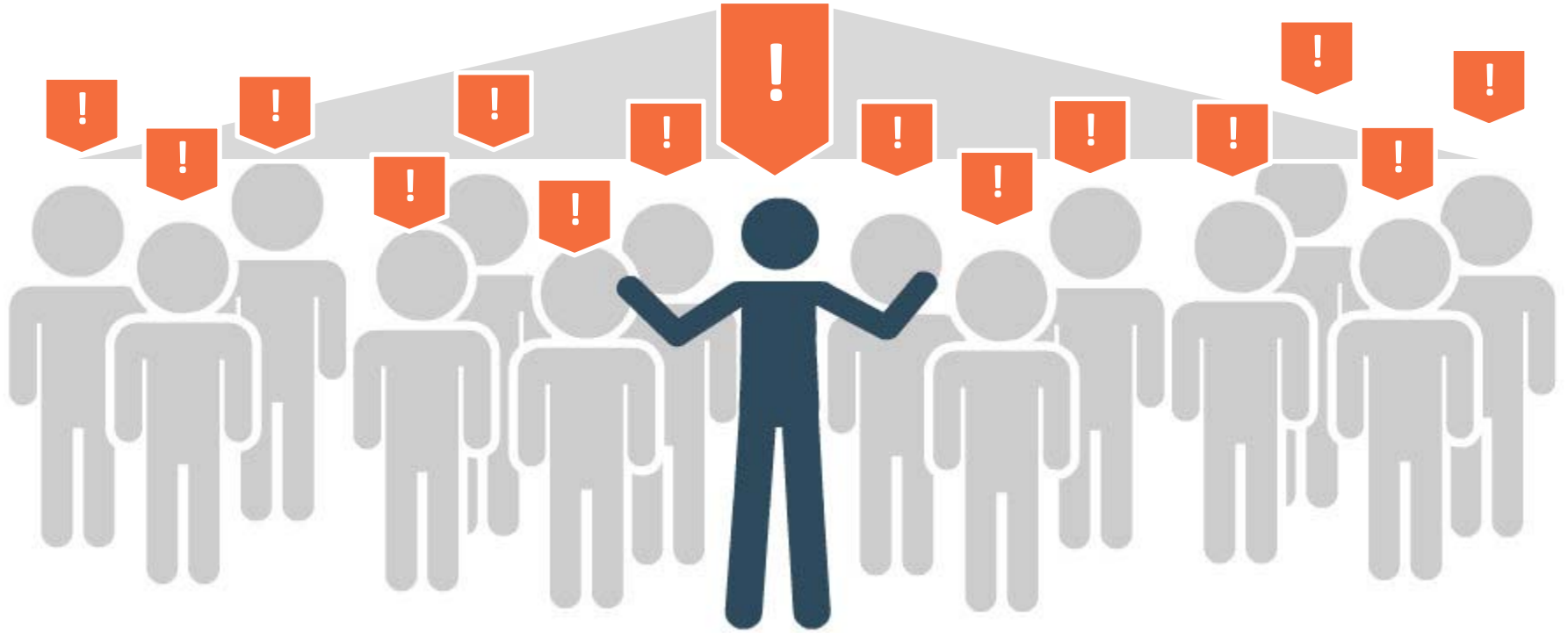
What's Required

What's Desired

Mindset Shift.

Not just about the processes....

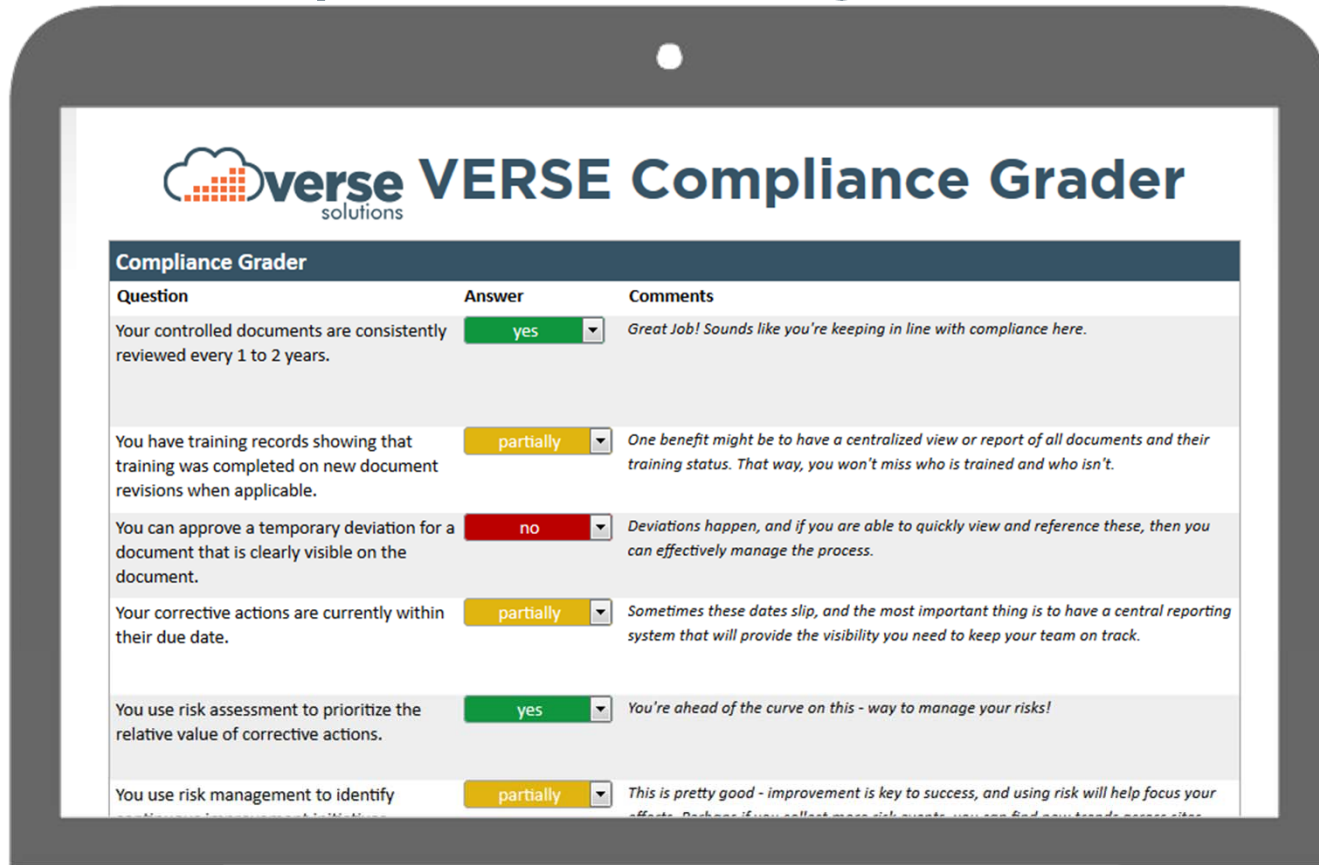
It's the mindset.



**There should be a company-wide commitment/leadership around Quality
Safety and Compliance**

The Compliance Grader

- We wanted to see where companies stood in their compliance, and how it factored to their operational excellence goals:

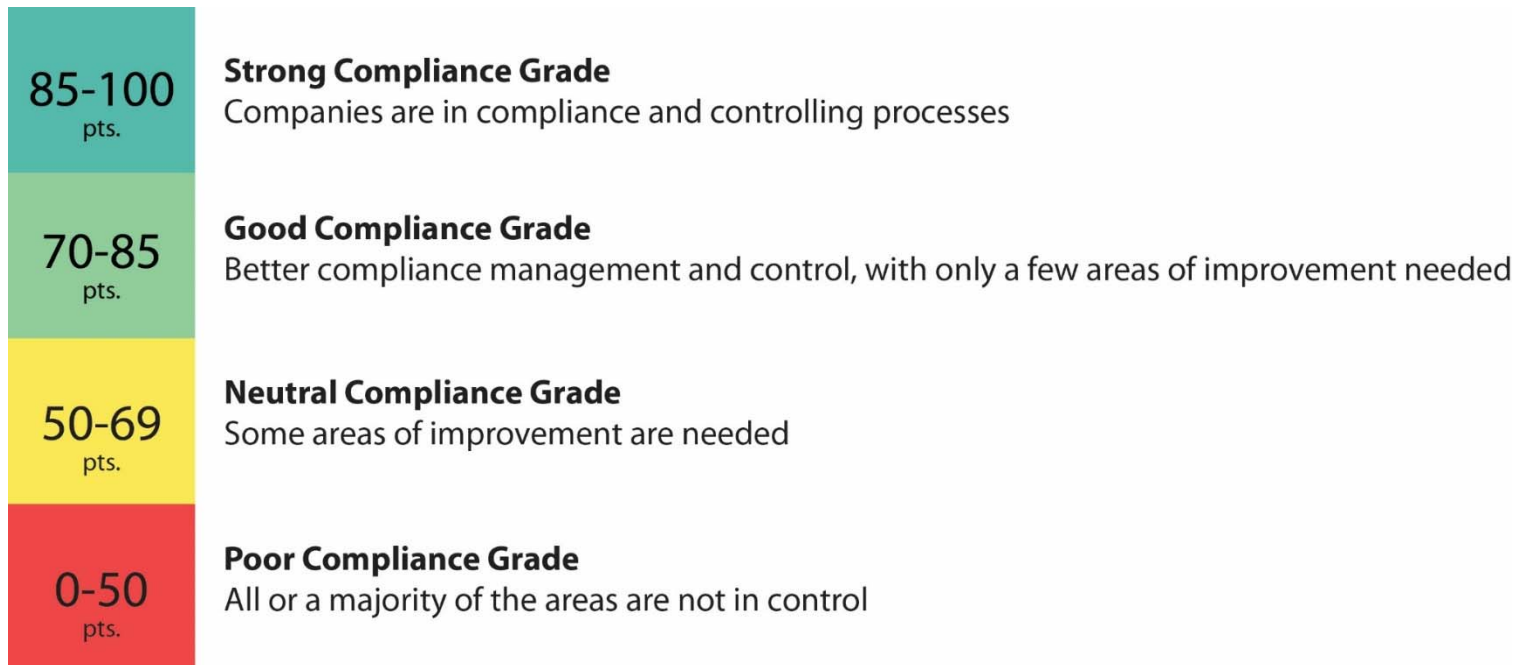


<http://grader.versetools.com/>

Compliance Grader – Questions

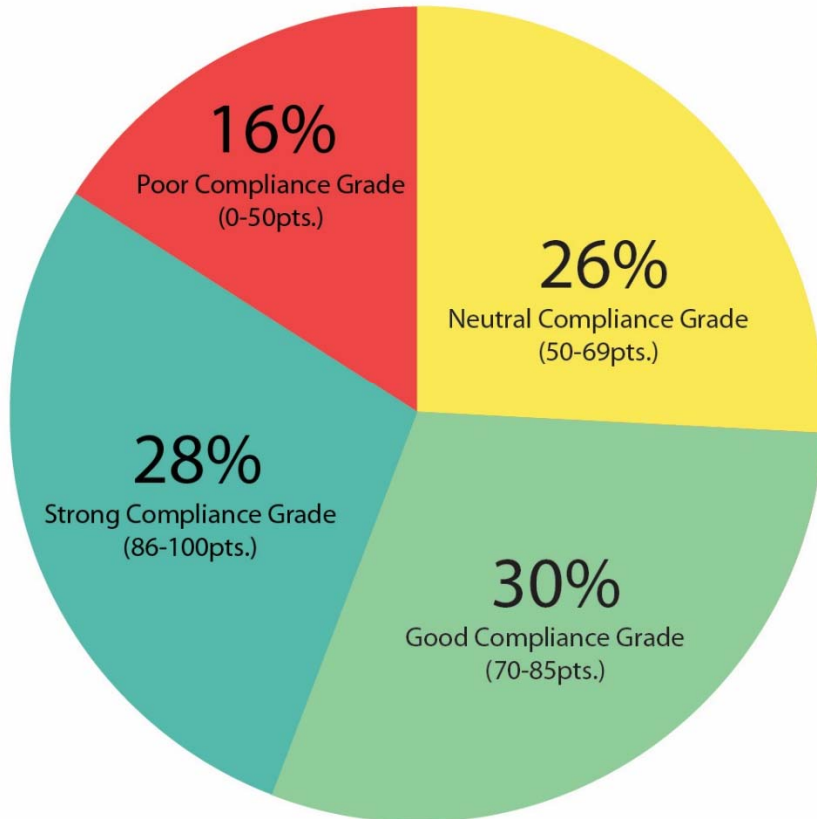


- **Document Control, Training and Deviations**
- **Corrective Action Timeliness**
- **Audit Management Controls**
- **Reporting and Key Compliance Metrics**
- **Customer Feedback and Action planning**
- **Change Management Processes**
- **Risk Management Processes**



Making the Grade – Compliance Stats

Overall Compliance Grade



Overall Result:

58% are scoring well in their compliance

26% are just getting by

16% are in poor compliance

This is aggregate – to truly see where compliance is needed, we need to drill down!

Making the Grade – Documentation and Training



Document Control: Documents are reviewed consistently every 1 to 2 years



Training: Training records are tracked and maintained



Deviations: You can approve a temporary deviation for a specification/element that is clearly visible on the document

The Takeway:

Documentation and Training are key aspects of compliance...

Companies are tracking well – it's a requirement and part of the core to compliance.

Making the Grade – Corrective Action

Yes Partially No

 = 10%



Corrective Action: Corrective actions are currently within their due date

The Takeway:

Overdue Corrective Actions are a major source of non-compliance!

Making The Grade – Audit Management

Yes Partially No

 = 10%



Audits: Audit checklists include a reference to the most at risk controls in the quality and safety system

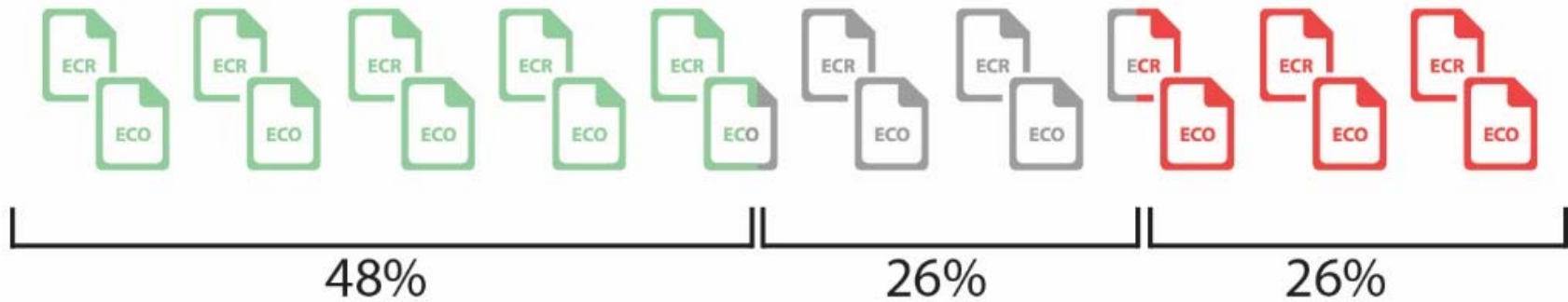
The Takeway:

Are we doing audits properly? Are we looking at it from a risk-based view?

Making the Grade – Managing Change

Yes Partially No

ECR
ECO = 10%



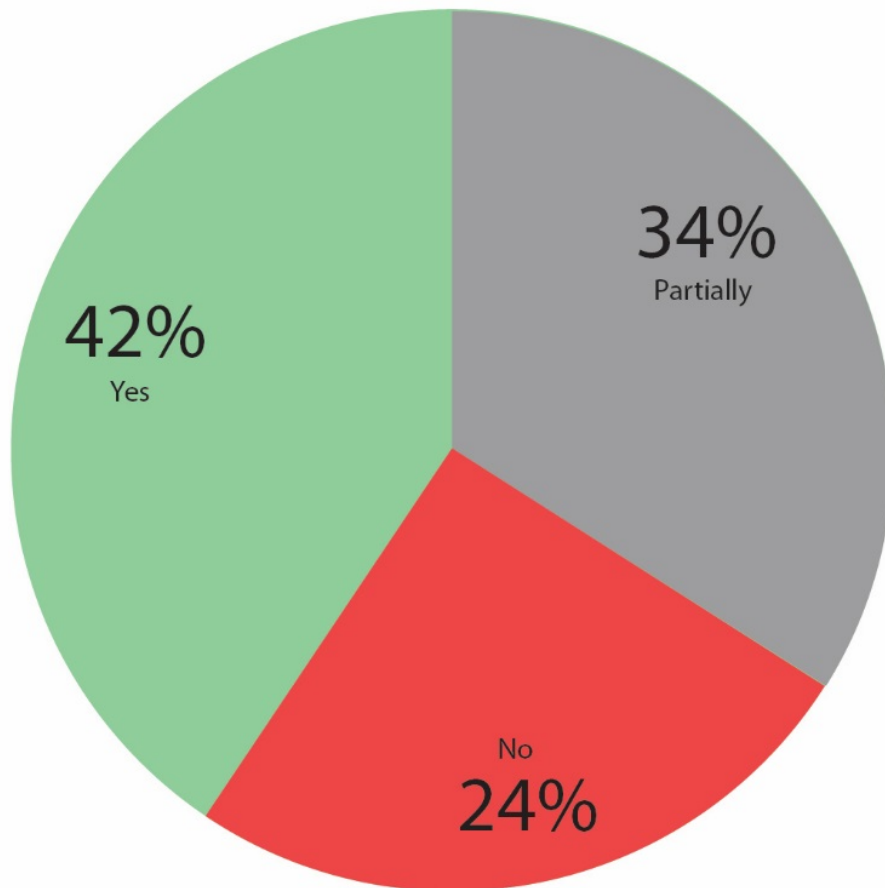
Change Management: There is an established Change Management Process

The Takeway:

We are managing change well – processes are in place and seem to work.

Making the Grade - Reporting

Reporting: Have the ability to produce metrics on problem areas and their causes



The Takeaway:

We're doing what's "required"
Are we doing what's "desired"?

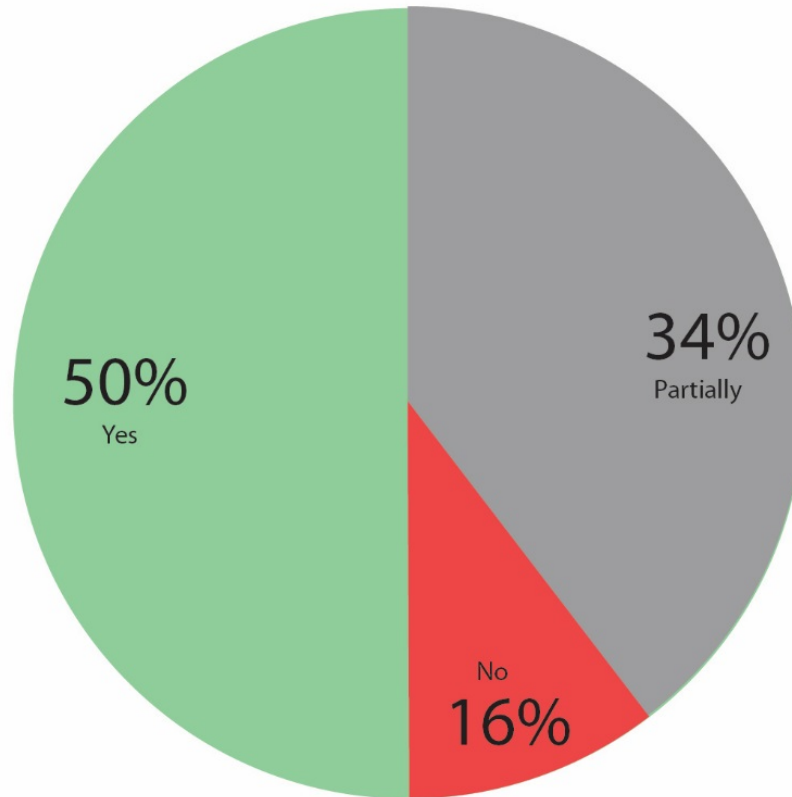
Operational Excellence drives for deeper look into Key Performance indicators to achieving improvement.

24% are not doing this, and **34%** are partially doing this.

Majority is not getting the desired effect!

Making the Grade – Post-Market Feedback

Post-Market: Are tracking customer feedback and the resulting actions



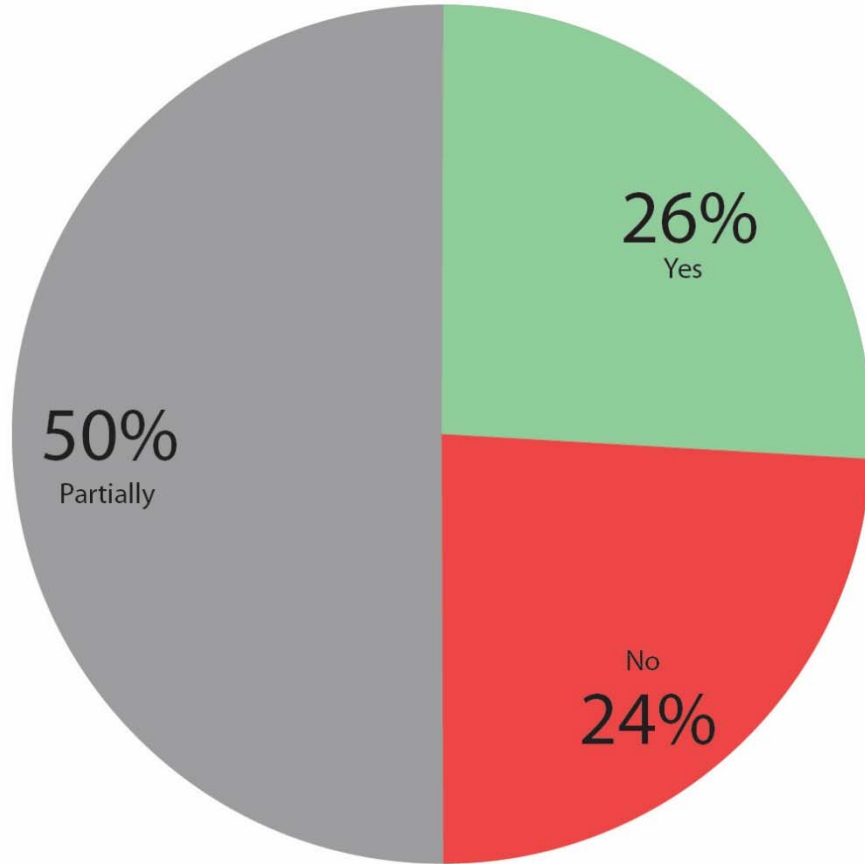
The Takeaway:

50/50 – Customer feedback is critical towards what is desired.

Customer-focused continuous improvement is needed!

Making the Grade – Risk Management

Risk: User of risk assessment to prioritize the relative value of corrective actions

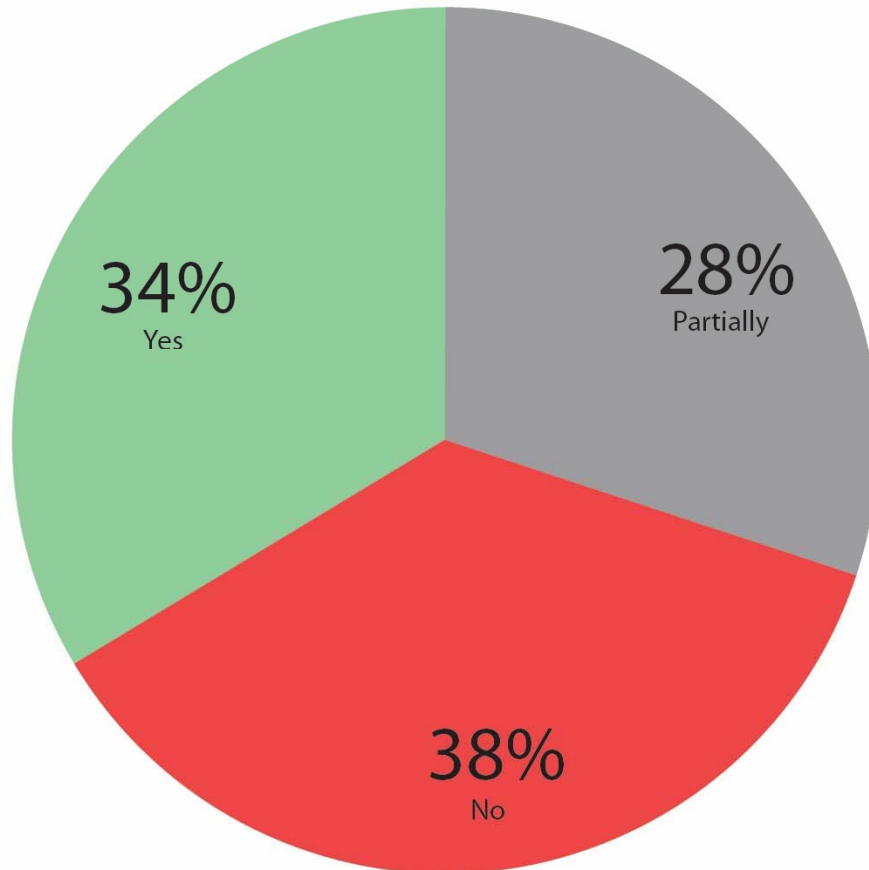


The Takeaway:

Risk is still a concept that is not fully utilized by organizations.

Making the Grade – Risk Management

Risk: Use of risk management to identify continuous improvement initiatives



The Takeaway:

Leveraging Risk is the link from taking **compliance** related activities and driving towards **operational excellence** and improvement.

How does risk take what's **required** and drive towards what's **desired**?

More on Risk Management

Risk is a major area for improvement



But...what does the data say?

Risk Tracking – the tool

- We provided a simple Risk Assessment tool

The screenshot shows the VERSE Risk Tracker web application. The interface includes a navigation bar with links for 'What is Verse?', 'The Solution', 'Pricing', 'About Us', 'Blog', and 'Free Trial'. The main content area is titled 'VERSE Risk Tracker' and is divided into two main sections: 'Event Details' and 'Risk Assessment'.

Event Details:

- Author:
- Email:
- Department:
- Subject:
- Problem Description: *Describe the nature of the adverse event you are facing.*
- Potential Risk/Effect: *What is the potential impact or effect that this adverse event will have on your business?*

Risk Assessment:

- Risk Category: *What category are you assessing? (Operational, Safety, Financial, etc.)*
- Probability: *Please select how frequently you expect this hazard to occur*
- Severity: *Please enter a value for how severe this hazard is*
- Result:

Risk Matrix:

Frequency	4	3	2	1
Probable	4	3	2	1
Occasional	3	2	1	0
Infrequent	2	1	0	0
Probable	4	3	2	1
Occasional	3	2	1	0
Infrequent	2	1	0	0

Severity (S): Insignificant, Marginal, Critical, Catastrophic

Risk Levels:

- Intolerable (Red)
- Unacceptable (Yellow)
- Tolerable (Green)
- Acceptable (Light Green)

<http://risktracker.versetools.com/>

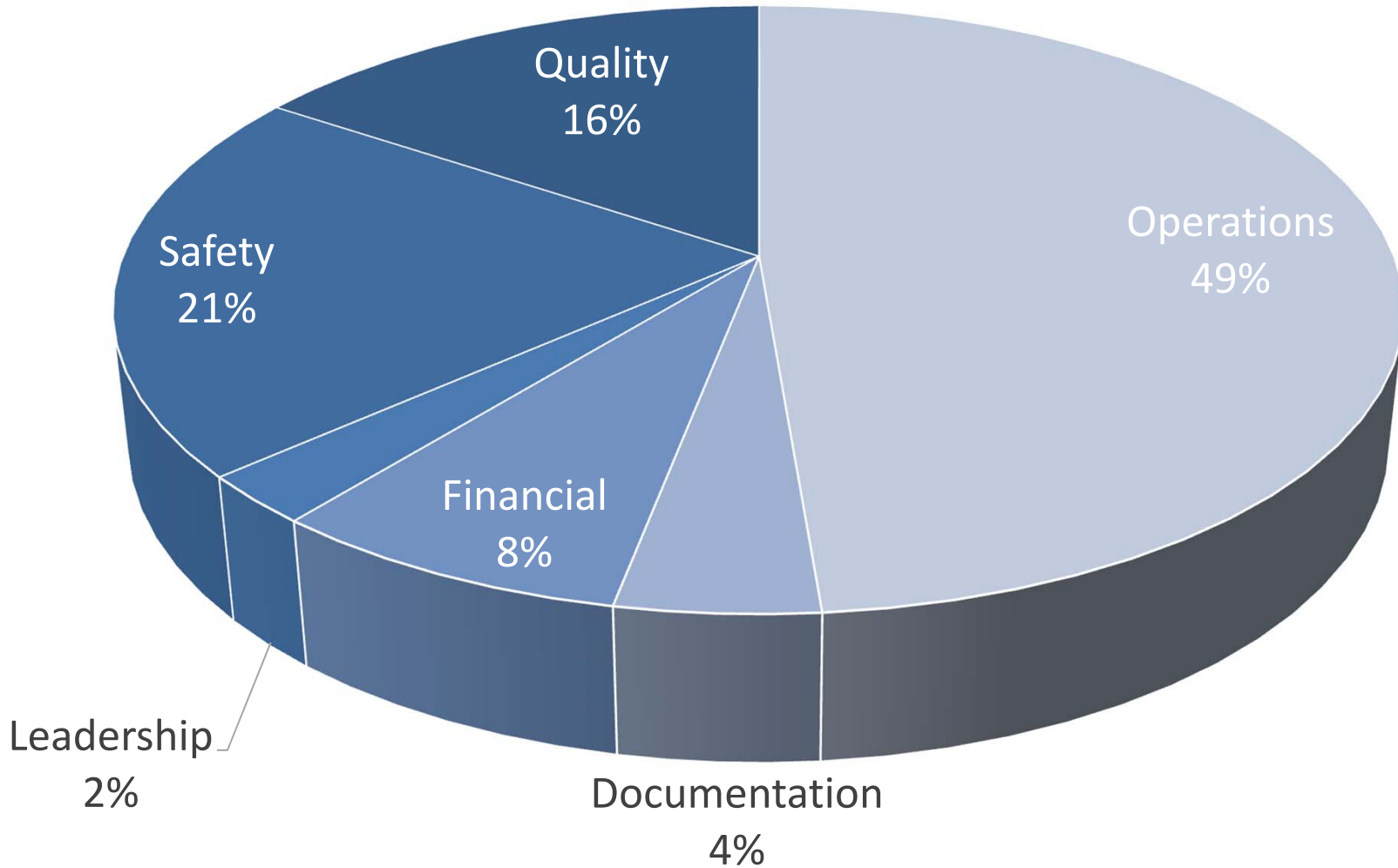
Risk Categories

Probability (P)	Frequent	4				
	Probable	3				
	Occasional	2				
	Improbable	1				
				1	2	3
			Negligible	Marginal	Critical	Catastrophic
			Severity (S)			

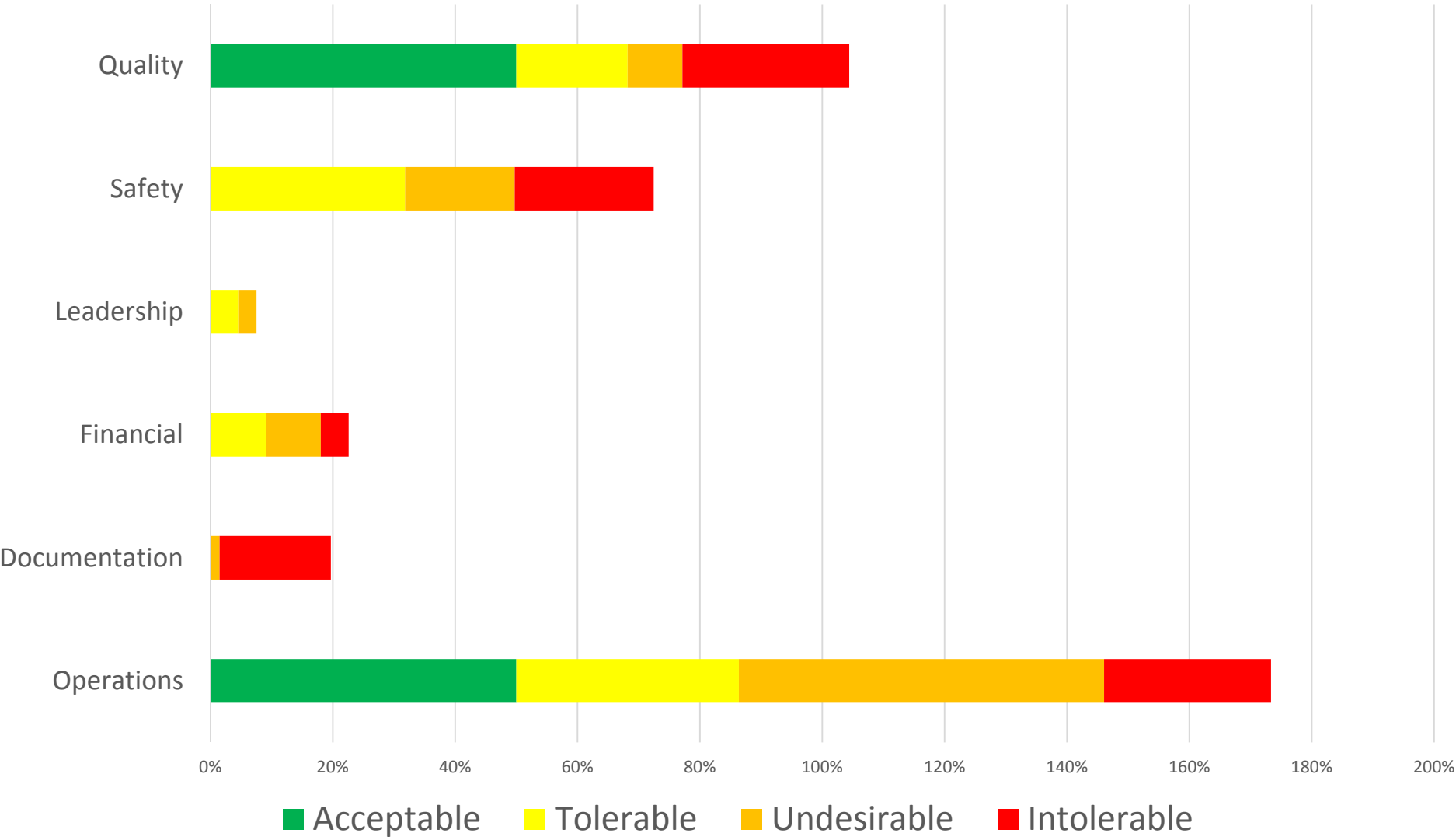
	Intolerable
	Undesirable
	Tolerable
	Acceptable

- Acceptable Risk:** No recall, regulatory reporting or Corrective Action is required. However, you may want to consider for improvements to the product or processes.
- Tolerable Risk:** You may want to issue a recall only for events resulting in a physical injury or cost impact. While a Corrective Action is not required, you may want to consider voluntary action.
- Undesirable Risk:** This risk is As Low as Possible, but undesirable for the business. A recall or investigation is likely unless there is clear mitigation. Corrective Action is usually required unless there is a documented reason.
- Intolerable Risk:** Requires a product recall, investigation, and immediate action on the product or process. A Corrective Action must be initiated and a regulatory report may be required.

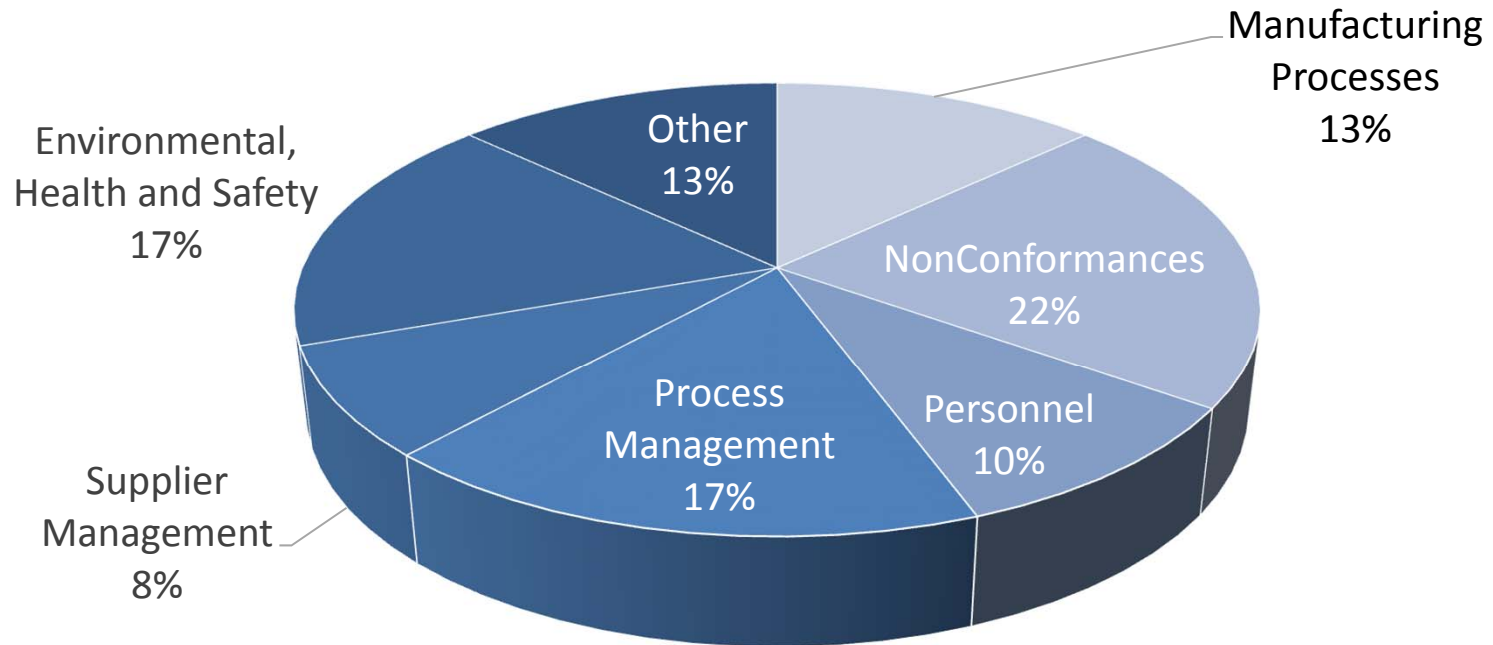
Most Common Risk Areas



Risk Levels by Risk Area



Reasons for Assessing Risk



Manufacturing Processes: inconsistencies in the manufacturing process poses risk

NonConformances: Defects in products leading to risk

Personnel: Improper Training and Resource planning poses a risk

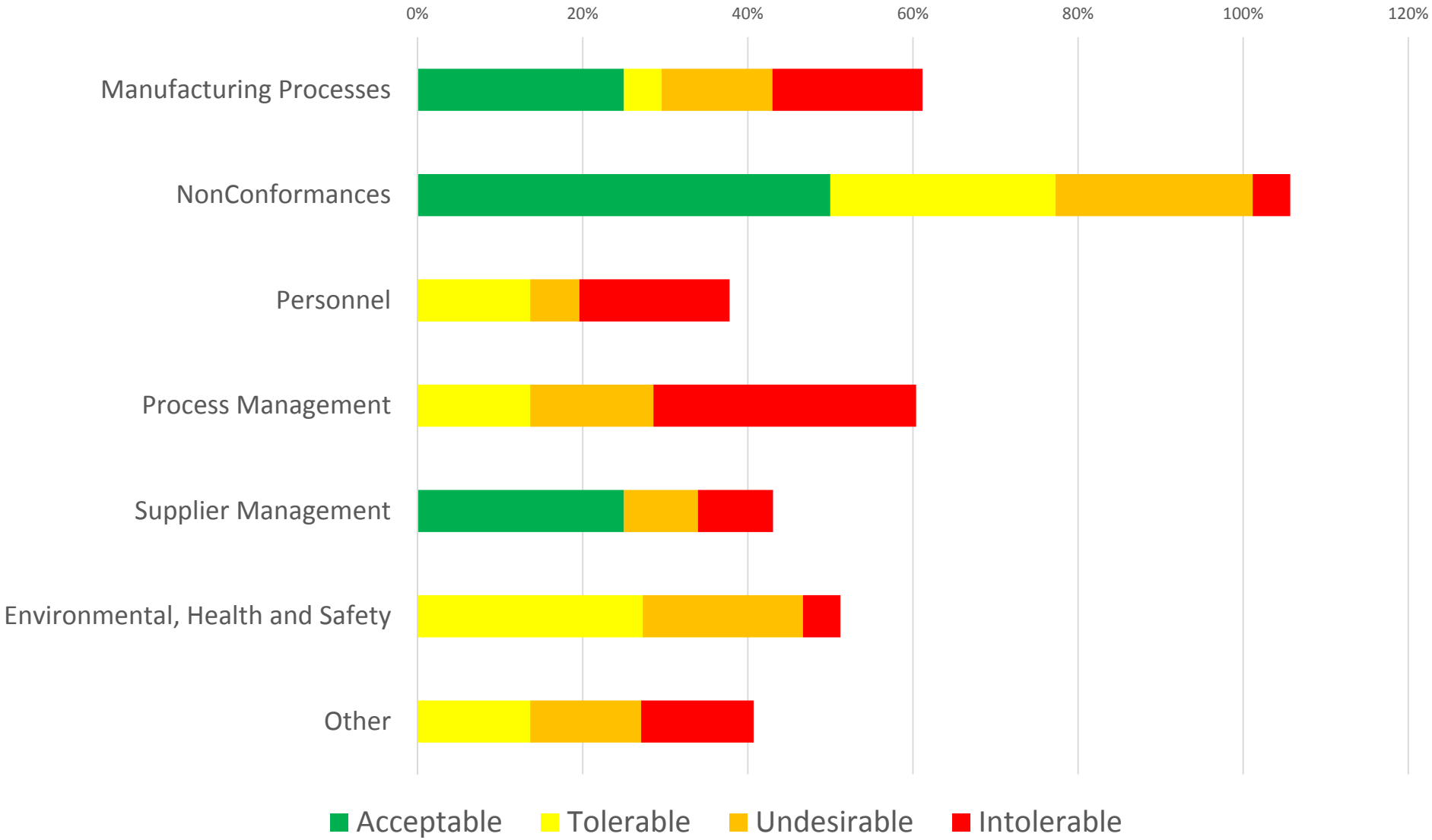
Process Management: Processes are not well-defined and could lead to high risk events

Supplier Management: Risks associated with Supplier non-compliance

Environmental, Health and Safety: Risks to the environment, health and safety within the organization

Other: Risks associated with other items

Risk Rankings by Reason

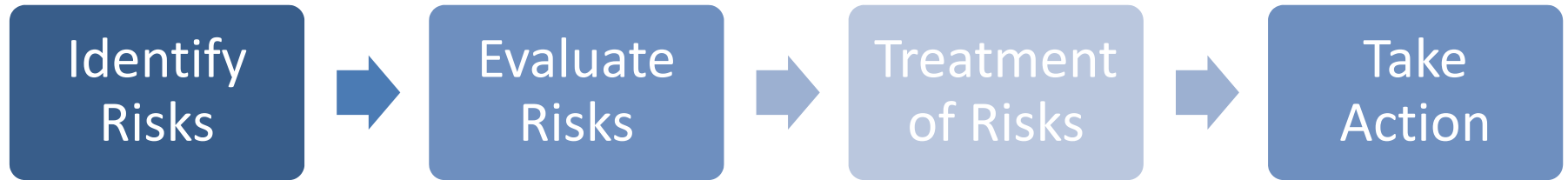


Yeah but...

How do I start my risk management journey?

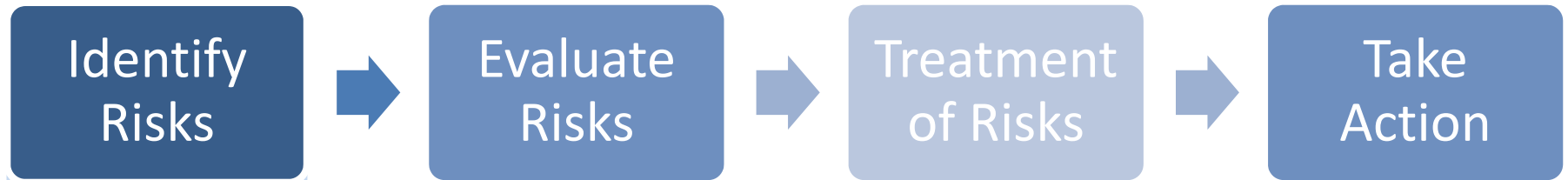


Planning your QMS with risk in mind...



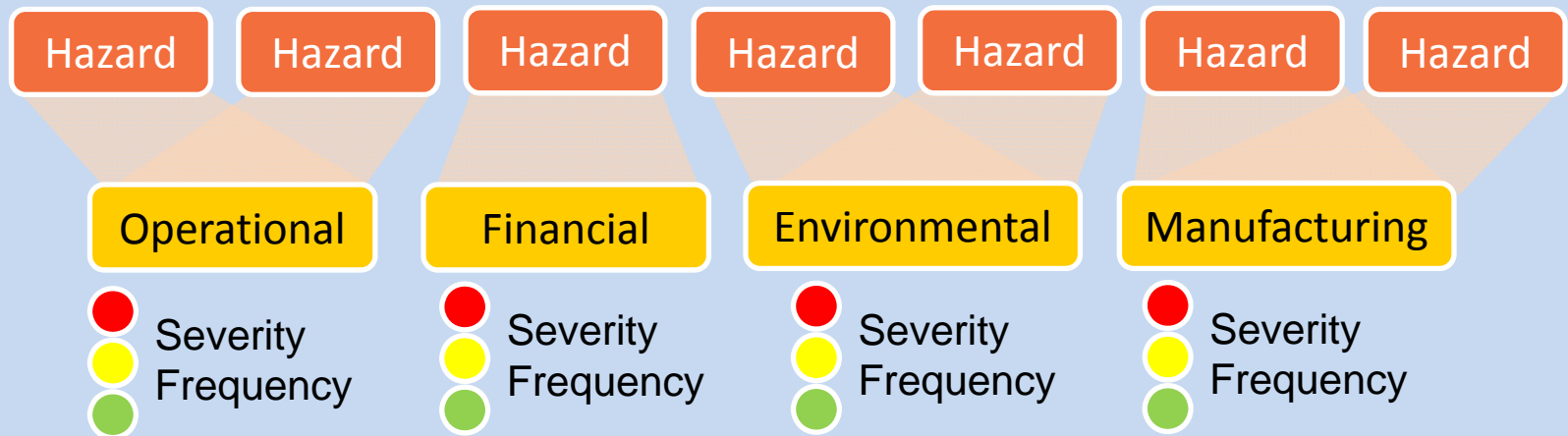
- **Identify risks and opportunities to influence QMS performance**
- **Determine how you're going to handle those risks**
- **Build risk treatment options**
- **Define actions to address these risks**

Planning your QMS with risk mind...

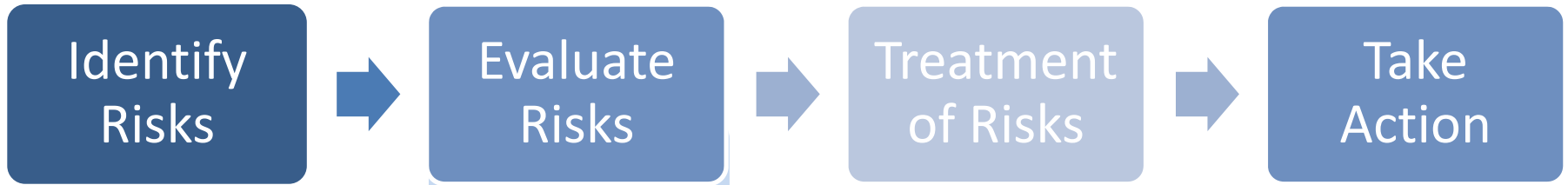


- **How to start Identifying risks?**

- Survey your operations
- Audit, Survey, collect, analyze



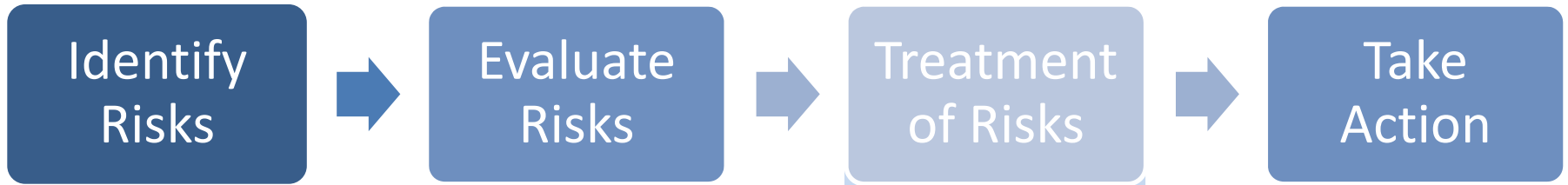
Planning your QMS with risk in mind...



- **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...



- We know the risk....how do we handle it?

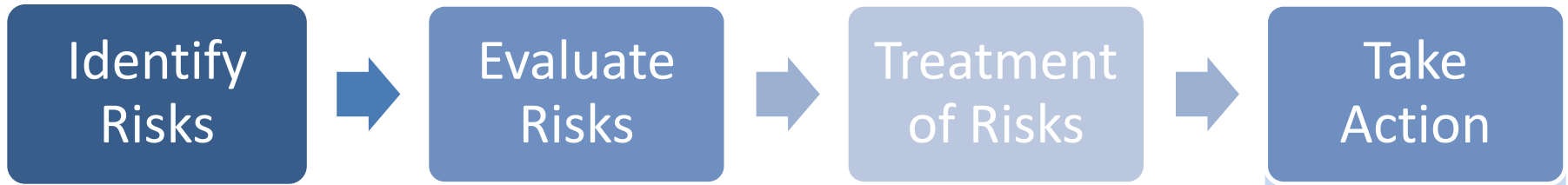


RISK LEVEL



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

Planning your QMS with risk in mind...



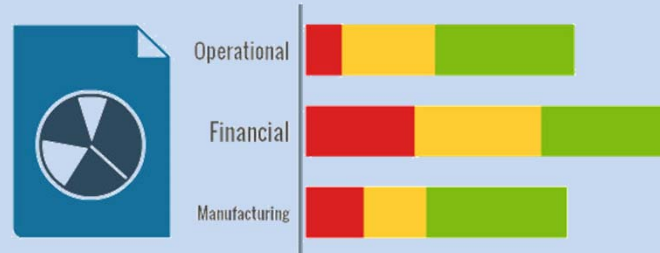
- **Take Action: Create Visibility and Control the Risk**



Corrective / Preventive Action

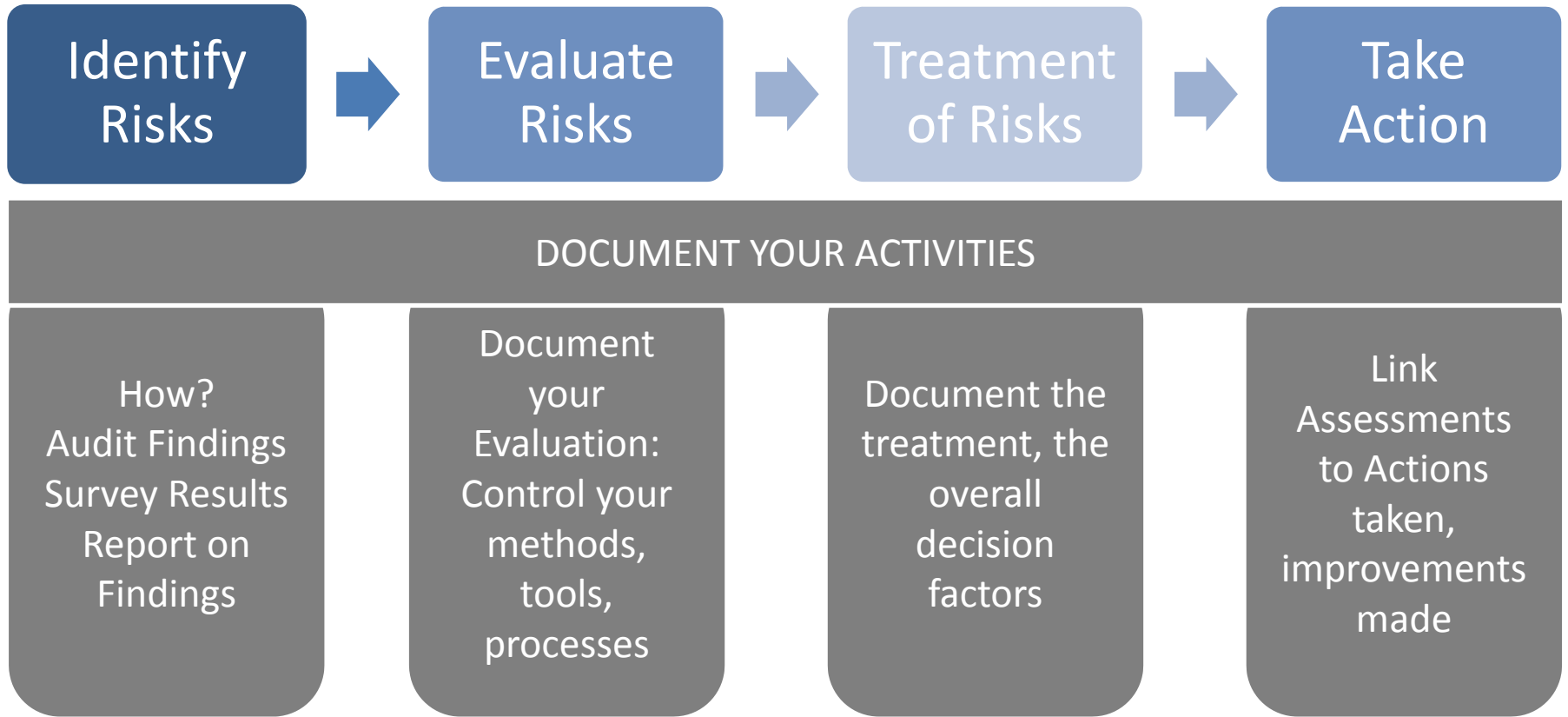


Controls / Action Plans



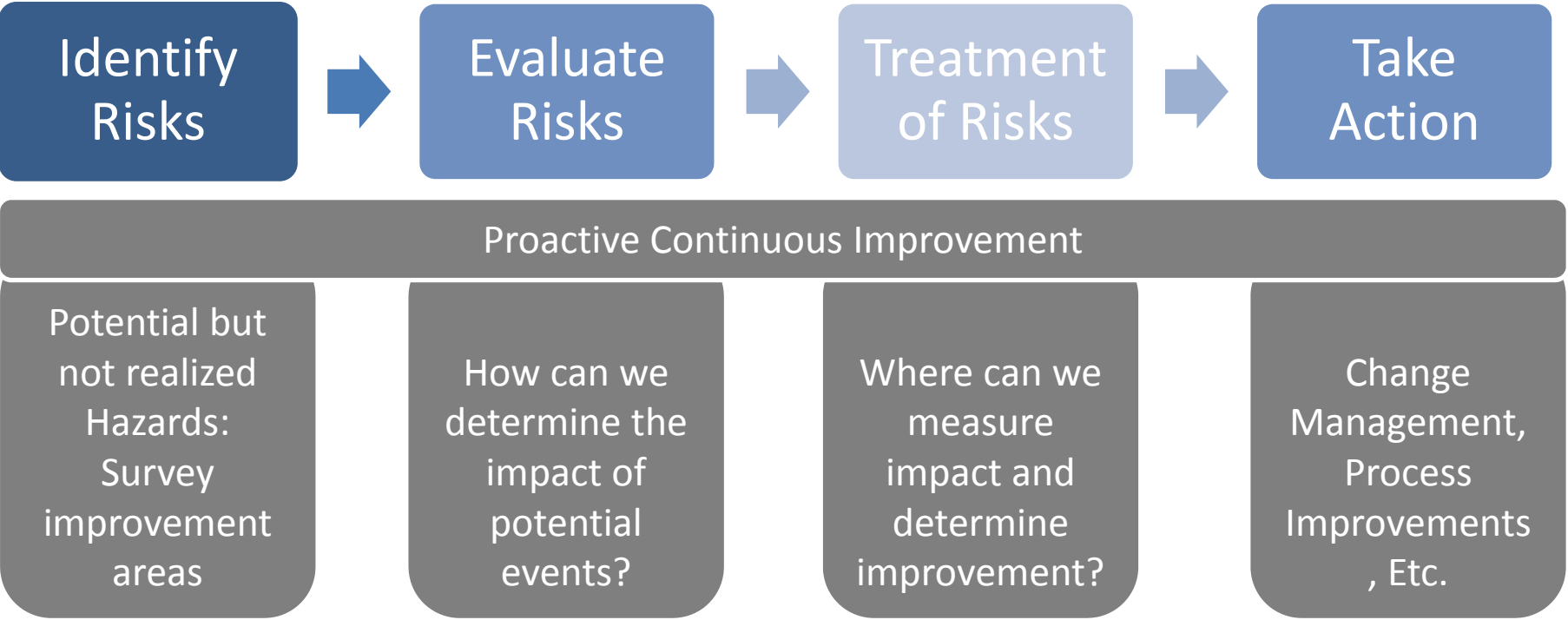
Reporting / Trending

Planning your QMS with risk in mind



Document the process in order to have traceability.

Planning your QMS with risk in mind



It's not all for just the Risks! Identify Opportunities too!

Summary

- **Understand the shift in combining your compliance management with Operational Excellence**
- **Companies are doing well at many things required, but still have work on what's desired**
- **Build a program that incorporates risk into your Quality program**
- **Risk is becoming a new standard of thinking – “risk-based thinking”**
- **Plan your QMS with risk in mind**

Thank you! Questions?

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risk **tracker**

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