GSFC
Supplier Assessments

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Mitigating Risks through Corrective Action

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Data Trends in Assessments

Full Assessments

- From 2010 to 2011 the number of non-conformances per assessment **increased** 25%Y-T-D.
- From 2010 to 2011 the number of observations per assessment **decrease** from 2008 is 17% Y-T-D.

Follow-Up Assessments

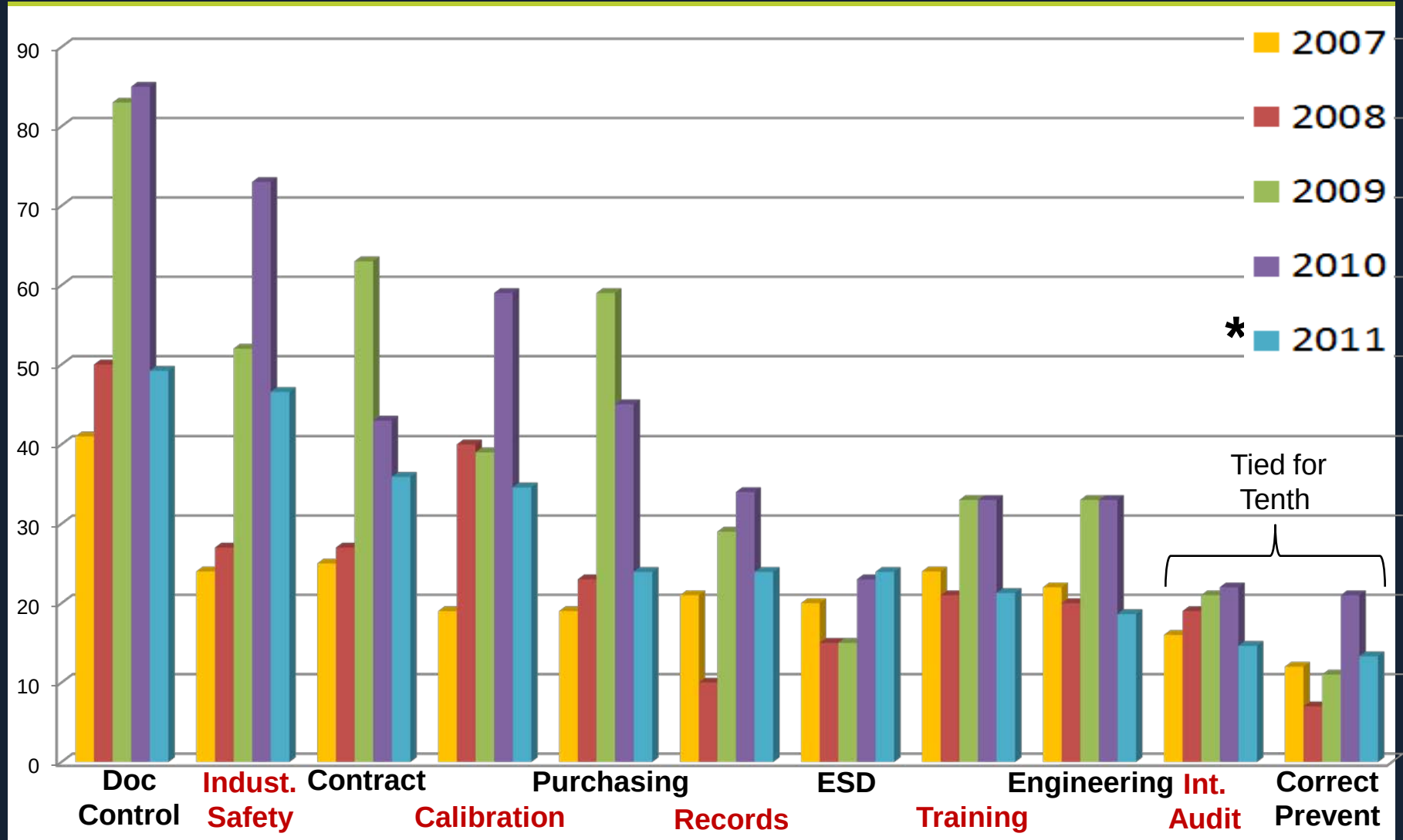
- From 2010 to 2011 the number of non-conformances per assessment **decreased** 54% Y-T-D.
- From 2010 to 2011 the number of observations per assessment **decreased** 70% and Y-T-D.

This is a good trend, but let's not pat ourselves on the back yet.

- 12.3 non-conformances during a full assessment in 2010
- 4.43 non-conformances during a follow-up assessment in 2011

A 64% reduction is good; however…

Top Ten (10) Findings - 2011



KNOWLEDGE MANAGEMENT CONCEPTS

NASA SAFETY CENTER

* *2011 Numbers Projected for Full Year.*

Data Trends in Assessments

Not all non-conformances are equal

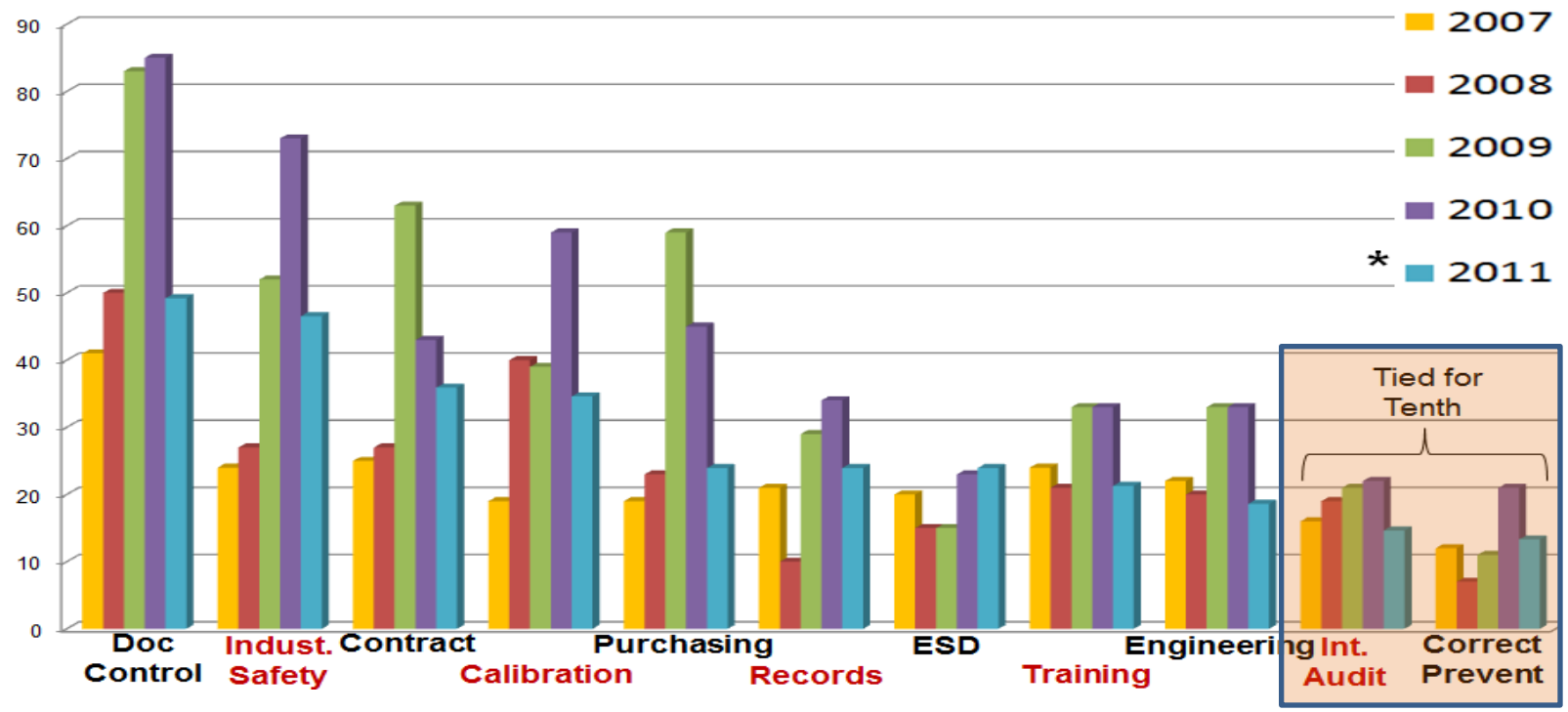
Look at the impact, not the number of non-conformances

Expired chemicals in cabinets	**Using unidentified material on customer products**
Delinquent calibrations	**Knowingly using an instrument with a 10 month delinquent calibration label to accept product**
Delinquent ESD training	**Pen resting on ESD sensitive product / Styrofoam on ESD pad**
MSDS sheet missing	**Fire alarm horn known to be defective for 3 months and not fixed until NASA asked why**

Risk Awareness in Quality Management Systems

- **Document Control – 2 year procedure reviews not enforced, procedures contradict each other, incorrect references**
- **Industrial Safety – Electrical panels blocked, MSDS Sheets not available, crane inspections not performed, Hazardous Material identification**
- **Contracts – CDRL's delinquent, Communication of requirements insufficient, Quality Assurance Plan not current**
- **Calibration – Requirement not on PO, Limited calibration not ID'ed, Facility calibration not aware of contractual requirements**
- **Purchasing – Requirements not flowed down, Supplier approval weak**
- **Records – Obliterations and strikethroughs w/out approval, Contract retention requirements not known**
- **ESD – ANSI/ESD S20.20 not followed, Smock violations, ESD bench in walkway**
- **Training – Records not maintained, Training not to contract requirements**
- **Engineering – Software QAP not followed, Coding standards not followed**

Risk Awareness in Quality Management Systems, cont'd.



The increased concerns with effective Internal Audits and Corrective/Preventive Actions presents a RISK to NASA programs.

- **Internal Audit – increased to 10th place from 14th in 2007**
- **Corrective/Preventive Action – increased to 10th place from 19th in 2007**

Mitigating Risks through Corrective Action

"I think, perhaps, we need to come up with a new approach to risk management."

AS9100 Rev C, Section 3.1 defines Risk as:

An undesirable situation or circumstance that

has both a likelihood of occurring

and

a potentially negative

consequence

AS 9100 Rev C and Risk

- There are nineteen (19) direct references or implied references to Risk, Risk Management, Risk Mitigation throughout the Standard.
- Compliance with AS9100 C requires a shift from traditional thinking in Risk Management / Management beyond Engineering Design and Control.
- Revision C implies consideration to Risk Management in **Purchasing, Corrective / Preventive Action** and **Internal Audits**.

Risk Management

- Up to the organization to determine how best to approach but it all starts with…

Identification of Risks

7.4.1 Purchasing Process

- The type and extent of control applied to the supplier and the purchased product **shall be dependent upon the effect of the purchased product on subsequent product realization or the final product**.
- The organization **shall evaluate and select suppliers based on their ability to supply product in accordance with the organization's requirements**. Criteria for selection, evaluation and re-evaluation shall be established.

8.2.2 Internal Audit

- An audit program **shall be planned taking into consideration the status and importance of the processes and the areas to be audited**, as well as the results of previous audits.

8.5.3 Preventive Action

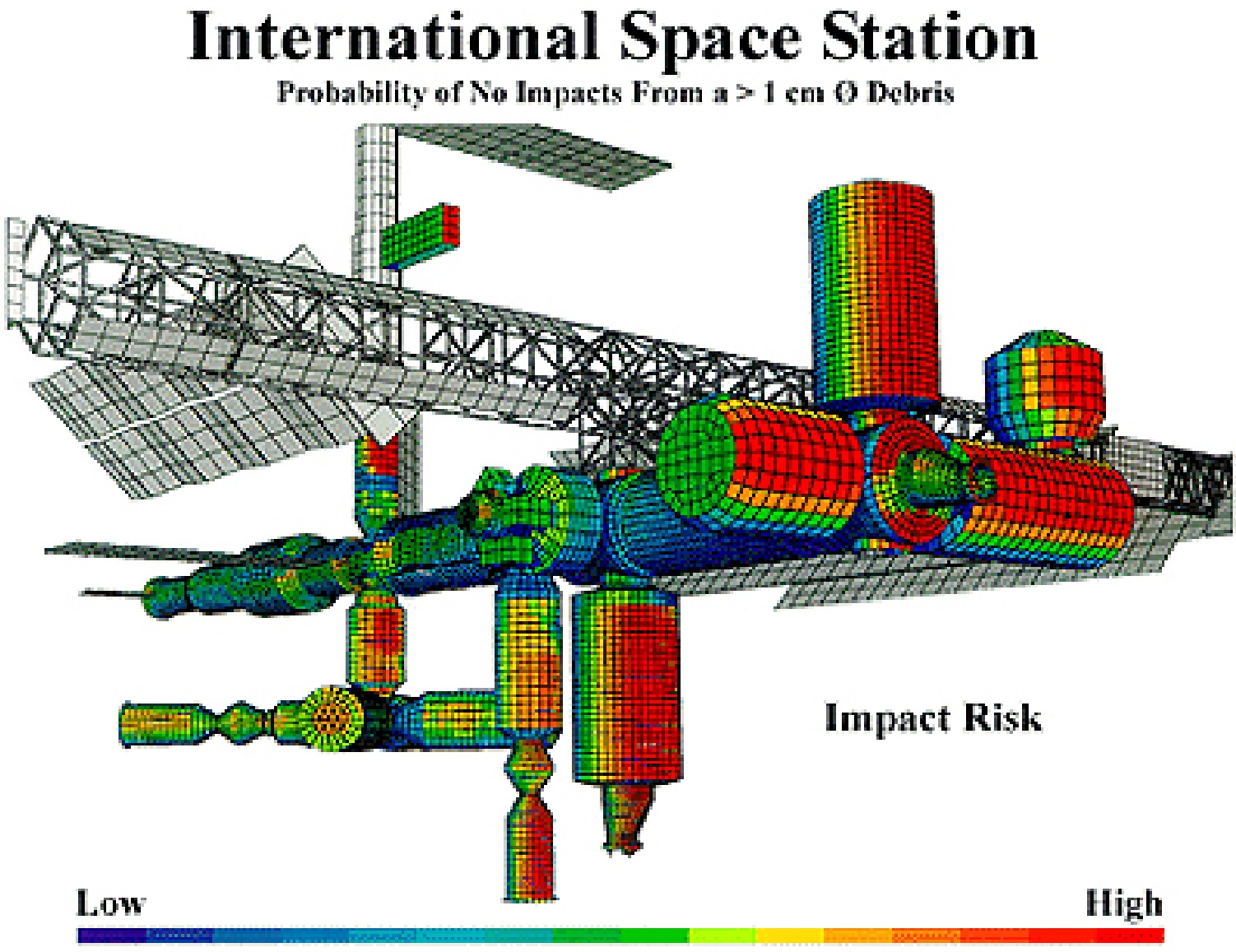
- ….Examples of preventive action opportunities include **risk management**, error proofing, failure mode and effects analysis (FMEA), and information on product problems reports by external sources.

Key Aspects of Risk

- **Likelihood** - the state of being probable; probability.
  - specific to an individual or company -- it is ***not the same*** for all.
- **Consequence** - Something that logically or naturally follows from an action or condition.

American Heritage Dictionary

NASA has been in the Risk Management Business For a Long Time



Risk Awareness in Quality Management Systems

- Most business decisions are choices that involve **“making a calculated risk"**
  - NASA defines this as “**Risk informed decision making**.”
- AS9100 Rev C moves organizations in the direction of understanding and making calculated business decisions based on risk assessment.

Prioritization Process

- The risks with the greatest loss and the greatest probability of occurring are typically handled first.
- Risks with lower probability of occurrence and lower loss are handled in descending order.
- Consequence and Likelihood drive the process.

What is the worst thing that can happen?

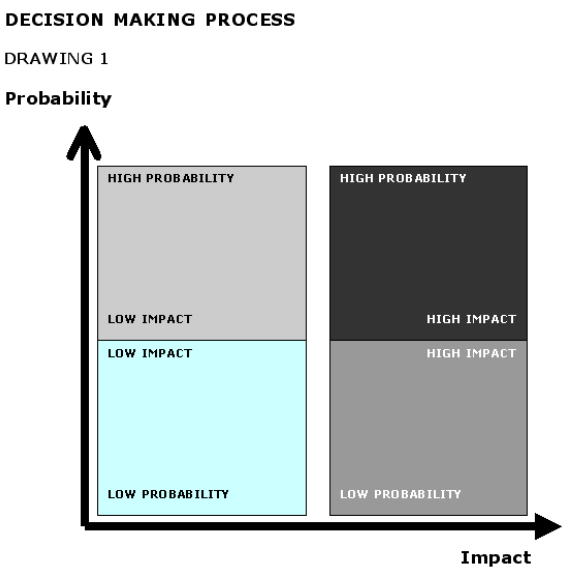
Risk Management and Corrective Action Process

- Perform Root Cause Analysis
- Complete Risk Assessment
  - Impact to Product
    - In-Process, In Stores, Delivered
    - Impact on other products
  - Impact to Processes
  - Impact to QMS stability
  - Personnel

Risk Management and Corrective Action Process

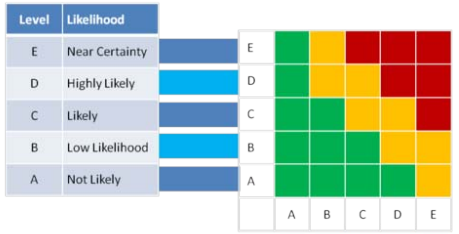
- Assessment of overall Risk
  - Cost/Benefit Analysis
  - Determination of Timing
- Containment Actions
  - Short Term
  - Long Term
- Corrective Action / Preventive Actions
  - Based on Priority/Impact/Risk

Risk Management Tools



Impact	Risk Management Actions		
Significant	Considerable management required	Must manage and monitor risks	Extensive management essential
Moderate	Risks may be worth accepting with monitoring	Management effort worthwhile	Management effort required
Minor	Accept risks	Accept, but monitor risks	Manage and monitor risks
	Low	Medium	High
	Likelihood		

Likelihood	Consequences				
	Insignificant *(Minor problem easily handled by normal day to day processes)*	Minor *(Some disruption possible, e.g. damage equal to $500k)*	Moderate *(Significant time/resources required, e.g. damage equal to $1million)*	Major *(Operations severely damaged, e.g. damage equal to $10 million)*	Catastrophic *(Business survival is at risk damage equal to $25 Million)*
Almost certain *(e.g. >90% chance)*	High	High	Extreme	Extreme	Extreme
Likely *(e.g. between 50% and 90% chance)*	Moderate	High	High	Extreme	Extreme
Moderate *(e.g. between 10% and 50% chance)*	Low	Moderate	High	Extreme	Extreme
Unlikely *(e.g. between 3% and 10% chance)*	Low	Low	Moderate	High	Extreme
Rare *(e.g. <3% chance)*	Low	Low	Moderate	High	High



Level	Technical Performance	Schedule	Cost
A	Minimal or no consequence to technical performance	Minimal or no impact	Minimal or no impact
B	Minor reduction in technical performance or supportability	Able to meet key dates	Budget increase or unit production cost increases. < **(1% of Budget)
C	Moderate reduction in technical performance or supportability with limited impact on program objectives	Minor schedule slip. Able to meet key milestones with no schedule float.	Budget increase or unit production cost increase < **(5% of Budget)
D	Significant degradation in technical performance or major shortfall in supportability	Program critical path affected	Budget increase or unit production cost increase < **(10% of Budget)
E	Severe degradation in technical performance	Cannot meet key program milestones. Slip > X months	Exceeds budget increase or unit production cost threshold

*bing.com/images/search?q=**Risk Assessment Matrix***

Risk Management Tools

Impact of Loss	Risk Point Value				
	Will Occur over 90%	Extreme 90%<=>75%	High 75%<=>25%	Moderate 25%<=>10%	Low Under 10%
Catastrophic	8	7	6	5	4
Very High	7	6	5	4	3
Noticeable to ENTERPRISE	6	5	4	3	2
Minor	5	4	3	2	1
None	0	0	0	0	0

Interpretation of scores	
6 to 8	These risks are extreme. Countermeasure actions to mitigate these risks should be implemented immediately.
5	These risks are very high. Countermeasure actions to mitigate these risks should be implemented as soon as possible.
3 to 4	These risks are moderate. Countermeasure actions to mitigate these risks should be implemented in the near term.
1 to 2	These risks are low. Countermeasure actions to mitigate these risks should be implemented as convenient as they will enhance security overall.
0	These currently pose no risk but should continue to be monitored.

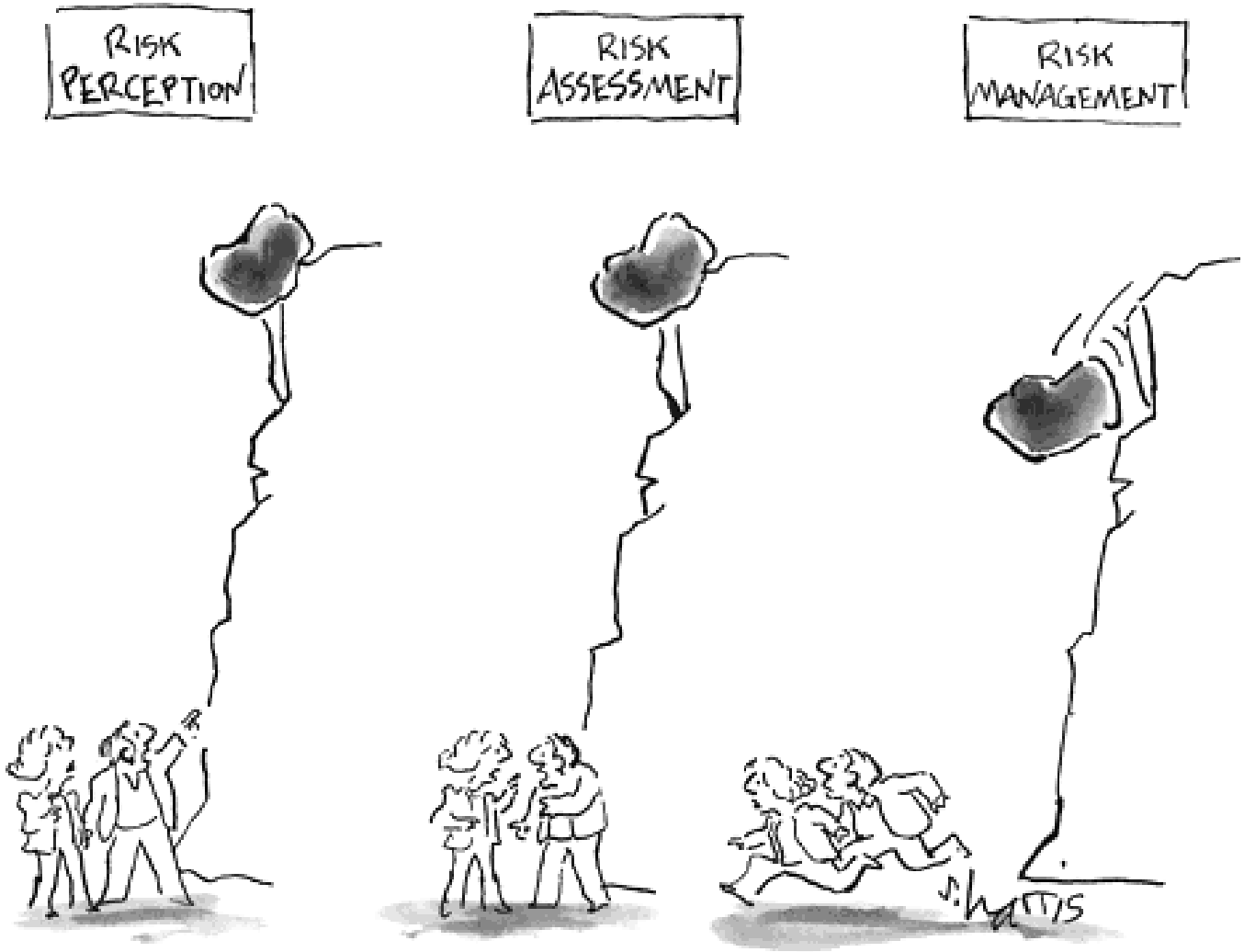
Risk Management Should

- Create value.
- Be an integral part of organizational processes.
- Be systematic and structured.
- Explicitly address uncertainty and assumptions.
- Be based on the best available information.
- Be dynamic, iterative and responsive to change.
- Be capable of continual improvement and enhancement.

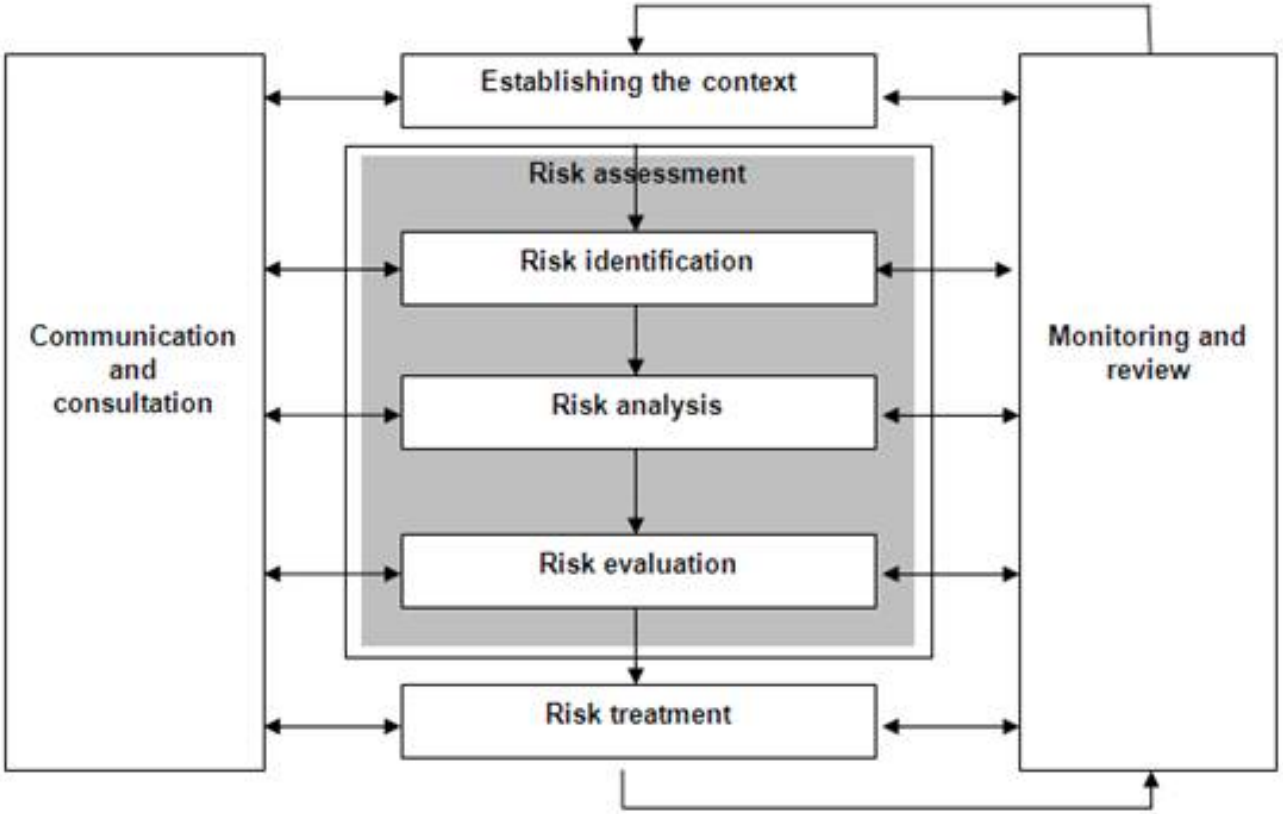
Summary

- Risk analysis allows you to examine the risks that your organization faces in a repeatable and sustainable manner.
- Based on a structured approach, followed by an evaluation of the probability and cost of real time or potential events.
- Risk analysis forms the basis for Risk Management and Crisis Prevention.
- The emphasis is on cost effectiveness and reduction of Risk to both the Supplier and the Customer.

THANK YOU FOR YOUR TIME AND ATTENTION



Reference Materials



*bing.com/images/search?q=**Risk Assessment Matrix***

AS9100 C References to Risk - Direct

- 0.1 General
  - The design and implementation of an organization's quality management system is influenced by a) its organizational environment, changes in that environment, and the risks associated with that environment
- 3.1 Risk
  - An undesirable situation or circumstances that has both a likelihood of occurring and a potentially negative consequence.
- 3.2 Special Requirements (New Term in Rev C)
  - Those requirements identified by the customer, or determined by the organization, which have high risks to being achieved, thus requiring their inclusion in the risk management process….
- 7.1.1 Project Management
  - ……the organization shall plan and manage product realization in a structured and controlled manner to meet requirements at acceptable risk……

AS9100 C References to Risk - Direct

- 7.1.2 Risk Management
  - The organization shall establish, implement and maintain a process for managing risk to the achievement of applicable requirements , that includes as appropriate to the organization and the product
    a) assignment of responsibilities for risk management
    b) definition of risk criteria (e.g., likelihood, consequences, risk acceptance),
    c) identification, assessment and communication of risks throughout product realization,
    d) identification, implementation and management of actions to mitigate risks that exceed the defined risk acceptance criteria, and
    e) acceptance of risks remaining after implementation of mitigating actions.
- 7.2.2 Review of Requirements Related to the Product
  - …..and shall ensure that e) risks (e.g. new technology, short delivery time frame) have been identified (see 7.1.2)
- 8.5.3 Preventive Action
  - ….Examples of preventive action opportunities include risk management, error proofing, failure mode and effects analysis (FMEA), and information on product problems reports by external sources.

AS9100 C References to Risk – Implied

- 7.4.1 Purchasing Process
  - The type and extent of control applied to the supplier and the purchased product shall be dependent upon the effect of the purchased product on subsequent product realization or the final product.
  - The organization shall evaluate and select suppliers based on their ability to supply product in accordance with the organization's requirements. Criteria for selection, evaluation and re-evaluation shall be established.
- 8.2.2 Internal Audit
  - An audit program shall be planned taking into consideration the status and importance of the processes and the areas to be audited, as well as the results of previous audits.
- 8.2.4 Monitoring and Measurement of Product
  - When the organization uses sampling inspection as a means of product acceptance, the sampling plan shall be justified on the basis of recognized statistical principles and appropriate for use (i.e. matching the sampling plan to the criticality of the product and to the process capability).
  - Where product is released for production use pending completion of all required measurement and monitoring activities, it shall be identified and recorded to allow recall and replacement if it is subsequently found that product does not meet requirements . (Risk Mitigation)

For Your Reading Pleasure

- ISO 3100 - "Risk management -- Principles and guidelines on implementation"
- ISO 14971 - "Medical Devices – Applications of Risk Management and Medical Devices"
- ISO/IEC Guide 73:2009 (2009). *Risk management — Vocabulary*. International Organization for Standardization.
- Hopkin, Paul "Fundamentals of Risk Management" Kogan-Page (2010) ISBN 978 0 7494 5942 0
- Alexander, Carol and Sheedy, Elizabeth (2005). *The Professional Risk Managers' Handbook: A Comprehensive Guide to Current Theory and Best Practices*. PRMIA Publications. ISBN 0-9766097-0-3.
- http://www.scu.edu.au/risk_management/index.php/2/