



PDHonline Course P237 (3 PDH)

Risk Management Fundamentals

Instructor: Davis M. Woodruff, PE, CMC

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Overview

- ❑ Risk Management Concepts & Terms
- ❑ Risk Considerations & Factors
- ❑ Risk Management Process
- ❑ Quantifying & Evaluating Risk(s)
- ❑ Examples of Risk Management Tools
- ❑ Risk Choices
- ❑ What Next?

This is an overview of the fundamentals rather than detailed 'how to' for each of the techniques. With the knowledge gained from this course, one should be able to identify the tools to use and learn more in detail how to use the tools in other courses or from texts and articles.

- General Business
- Processes
- Programs
- Products
- Projects

**Anything that
can
compromise
the mission!**



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Risk: Anything that can compromise the mission—Minimizing Risk is the focus!

Risk Factors—a multitude of factors affect risks—project risk management vs. business process or product

Risk Analysis—processes, products, people, safety, quality

Risk Evaluation—potential severity, frequency and probability

Risk Control/Mitigation—action steps using your corrective action process

Residual Risks—acceptable risk levels for interested parties

Risk Management Reports—an output of the process

Risk Information and Communication—for all

Failure to identify and manage risks leads to failure—no matter what the project involves!

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EXAMPLE: Vacuum vessel—installing sampling device—kettle at <1mm Hg and ~510 deg. F. NO project risk management plan—led to significant issues during installation and then upon start-up—you guessed it.....big time trouble....ultimately had to remove, weld the sample port and start over....>\$100k lost immediately plus production schedules not met on time for customers. Technology and operational risks were not identified; no risk management plan up front for the project which was actually a major change to a process vessel.

http://www.amazon.com/Numbers-People-Making-Technical-Successful/dp/145637379X/ref=tmm_pap_swatch_0?encoding=UTF8&qid=&sr=

Once you finish studying the above course content, you need to take a quiz to obtain the pdh credits.

Reasons for Failure

- **Scope/Objectives**
- **Planning**
- **Resources**
- **No Risk Management Plan or Process**
- **Poor Execution/Ineffective Leadership**

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Typically related to projects—however, most major changes in a business are PROJECTS; E.G. New product development; new design; major process changes; new IT system; new ERP or MRP system; revised quality management system; a major construction process; moving a business to a new location;

Previous project example of the vessel and sample port—scope was not verified for technical capability to install and operate the sampling device. Failed to consider the operational environment.

Key Terms & Definitions

- **Risk**
- **Process**
- **Management**
- **Mitigation**
- **Contingency**
- **Risk Register**

Risk: anything that can compromise the mission or the effect of uncertainty

Process: any set of steps working together to produce or create and outcome

Management: planning ,organizing, staffing, directing and controlling the work—getting the work done

Mitigation: actions taken to minimize or eliminate the effects of a real or potential risk

Contingency: a plan or action step to take in the event another specific situation occurs

Risk Register: a LIVING document that contains the identified risks, mitigation or action plans, responsibilities and timelines or targets

Risk

ISO 9000: (3.7.9) effect of uncertainty

ISO 14971: (2.16) combination of the probability of occurrence of harm and the severity of that harm.

Working Definition: the effect of uncertainty on an expected result; a situation or circumstance that has both a likelihood of occurring and a potentially negative consequence; or, anything that can compromise the mission

Dictionary definition: a situation involving exposure to danger; the possibility that something unpleasant or unwelcome will happen

In the medical device world (ISO 14971, def. 2.16)—the combination of the probability of occurrence of harm and severity of that harm.

Risk Management

1. **Protects the organization**
2. **A systematic & structured process**
3. **Input for decision making**
4. **Involves knowledgeable people**
5. **Based on best information available at the time**
6. **Considers multiple factors**
7. **Leads to continual improvement**

Risk Management (ISO 14971, def. 2.2) Systematic application of management policies, procedures and practices to the tasks of analyzing, evaluating, controlling and monitoring risk



Maybe instead of buying giant gauges, we should have spent the money on relief valves.

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Manage risks by identifying and mitigating up front, not after the fact

Risk Management Standards

- **ISO 31000**
- **IEC 62198**
- **ISO 14971**
- **PMBOK**

ISO 31000 presents a process approach that standardizes risk management

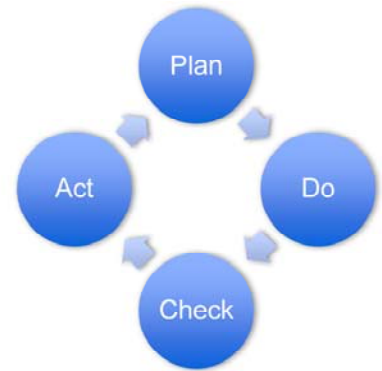
IEC 62198 lists 11 principles for effective management of project related risks adapted from ISO 31000

ISO 14971 is Risk Management for Medical Devices which presents tools and techniques in a readily adaptable format

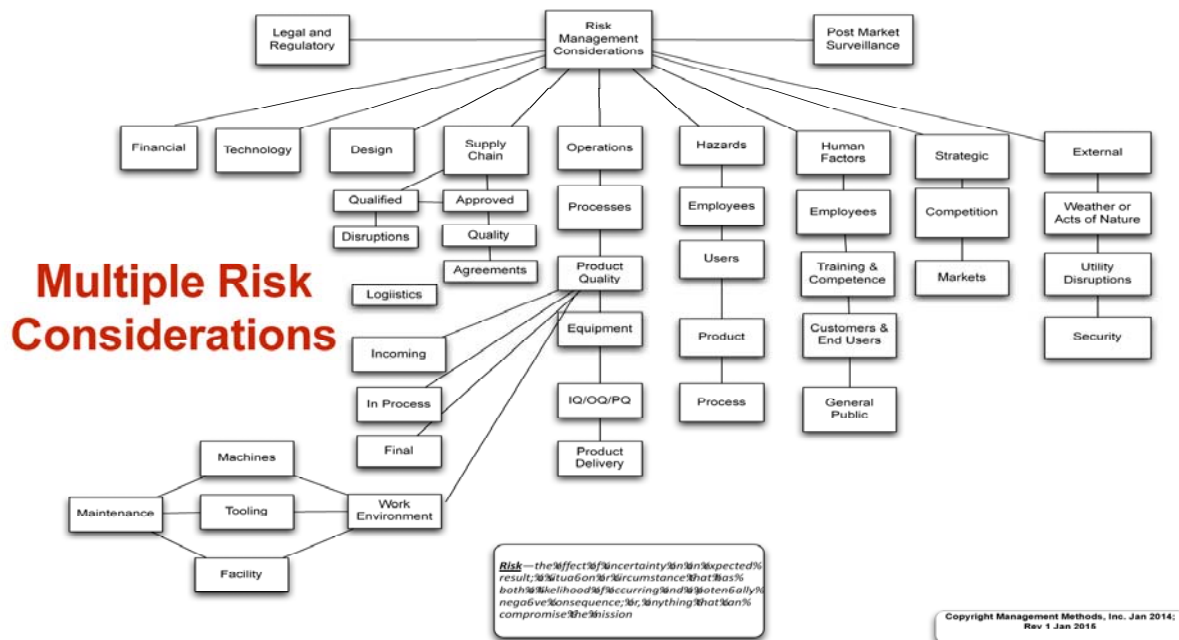
Project Management Body of Knowledge from PMI, Process Management Institute is the core knowledge for project management including risk management

General Approach

- **Plan**
- **Identify & Analyze**
- **Qualify & Quantify**
- **Action Steps or Mitigation**
- **Establish & Implement Controls**



Risk management begins with proper planning which means resources must be allocated to identify and analyze risks, define the action steps and actually implement the actions to mitigate identified risks. This is a management responsibility.



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Examples: Dermatome—a surgical device—look at all factors!—; TS 16949 quality system implementation focus on supply chain for sure; API Quality System considers all factors; New Design of Sampling Device for vacuum vessel overlooked technology and several other factors including no risk management plan at all; New product line for aerospace applications should consider all of these and maybe more—regulatory would be a bigger deal here, too with FAA; seats for an automotive assembly plant—delivery—JIT so weather should be consideration and contingencies in the case of ice/snow or other event; safety considerations in process/product such as bolt torque.

For a complete business continuity/contingency plan—consider all possibilities—ie. Weather, spills, rail car incidents, active shooter....you get the idea....API Q1 and TS 16949 require contingency plans. ISO 9001:2015 requires risk based thinking throughout. A risk management plan is not a contingency plan, but a contingency plan is a risk management plan.

'Top 3' Considerations

- **Scope**
- **Schedule**
- **Resources**

- General Business**
- Processes**
- Programs**
- Products**
- Projects**

Don't forget Quality and Safety! Sometimes in major projects such as equipment modifications or bridge building safety is one of the key considerations—but it generally shows up when these 3 are considered.

Inputs



Outputs

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**A Process can be defined as inputs being converted to outputs or any set of steps that take inputs and produce outputs. Risk Management is a process. ISO Standards for Risk Management include:
ISO 14971 Risk Management for Medical devices—
“the gold standard”—principles, tools and techniques
ISO 31000:2009 gives the framework, principles and practices for risk management
ISO 9001:2015 now considers risk based thinking—it does not require a full blown risk management plan or process.**

Inputs



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Strategic: business model; locations; financial; competitive

Organizational: leadership; structure; relationships; centralized services

Operational: supply chain; tpm; environmental performance

Processes: design; performance; capabilities; maintenance; equipment; IQ/OQ/PQ

Products: Suppliers; Supply chain; materials; material handling; product quality

People: training; competence; employees; end users; public

Regulatory: Legal and other requirements; changes; monitoring compliance

Inputs

Remember: SCOPE, SCHEDULE, RESOURCES in each category as we discuss them!

Strategic

- **Business Model**
- **Locations**
- **Market**
- **Financial**
- **Competitive**

Have you seen risks associated with a business model that has been 'left behind' by technology? Most likely, yes. It's a good idea to look at your business model and identify risks associated with the overall 'landscape' of the business and especially how it may be impacted technology and perhaps by regulations—more on regulatory later.

Organizational

- **Leadership**
- **Structure**
- **Relationships**
- **Transition Plans**
- **Centralized Services**

Transition planning is a significant risk for many businesses today with the retirement years approaching for most of the baby boomers. In one case a foundry has hired another metallurgist over six months in advance of the announced retirement of the current metallurgist. This is risk management in action. Take a good look at your organization.

Operational

- **Supply Chain**
- **Transportation & Logistics**
- **Maintenance, TPM, PM,**
- **Safety**
- **Environmental performance**

supply chain; tpm; environmental performance—Suppliers---
performance, location, lead times—contingencies—etc.—all can
affect operations.

Processes

- **Design**
- **Performance**
- **Capabilities**
- **Controls**
- **IQ/OQ/PQ**
- **MOC**
- **Operating Conditions:**
 - ◆ **Start-up; shut-down; abnormal; normal**

Product and Process design; performance; capabilities; maintenance; equipment; IQ/OQ/PQ

Process Design—a requirement for TS 16949 and will be a consideration in ISO 9001:2015.

Don't overlook operating conditions—most risks in processes occur during start-up; shut-down and abnormal or upset conditions. These may be safety, product or equipment related to name some possibilities.

Products

- **Suppliers & Materials**
- **Supply Chain**
- **Material Handling & Storage**
- **Specifications & Requirements**
- **Measurement Systems**
- **Product Quality**

Suppliers; Supply chain; materials; material handling; protecting product from debris and trash, foreign objects or debris in product (FOD) product quality and measurement variability are all potential risk factors. Sampling is in this category as well.

People

- **Staffing & Continuity**
- **Training & Competence**
- **Employees, end users, public**
- **Safety & Health**

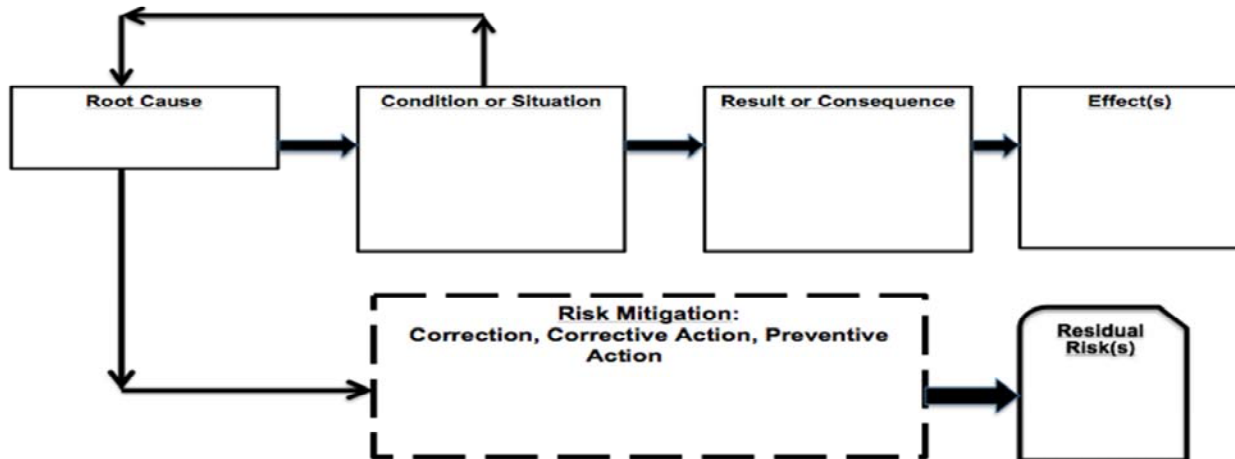
Specialized skills, training; competence; employees; end users; public

Regulatory

- **Legal & Other**
- **EH & S**
- **Products & Materials**
- **Relevance**
- **Changes**
- **Compliance**

Legal and other requirements; changes; monitoring compliance. Rapidly changing regulations are affecting many businesses today, even those who provide temporary employees. Establish a process to insure these are monitored and are looked at before an issue arises.

Risk Analysis Approach



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Use your Corrective and Preventive Action (CAPA) system as a part of the Risk Management Process. Analyze risks, considerations, events—feed forward within the organization and to other interested parties.

Risk Analysis and Evaluation—potential severity, frequency and probability

Quantifying Risk

- **Severity & Frequency—potential impact**
- **Likelihood of Occurrence—probability**
- **Risk = potential impact x probability**

Two key factors for risk: probability of occurrence of harm and the consequences of that harm—severity
Harm—physical injury or damage to the health of people, damage to property or the environment

Typical Approaches

- **Potential Impact**
 - ❖ **Low, Medium, High**
- **Probability**
 - ❖ **<10% chance**
 - ❖ **10-50% chance**
 - ❖ **>50% chance**

For example—in some organizations if it is regulatory it is automatically considered high impact and high risk regardless of probability This is a subjective approach and not an exact science. In fact, Risk Management always deals in probabilities of some kind. That's why knowledgeable people are a must when identifying and documenting risks and action plans.

Another Approach

↖

Risk Interpretation			
Likelihood of occurrence	Severity if it occurs	Combined Risk	Action Required
Low	Low	Low	No
Low	Med	Med	Maybe
Low	High	Med	Yes
Med	Med	Med	Yes
Med	Low	Low	No
Med	High	High	Yes
High	Med	Med	Yes
High	Low	Med	Maybe
High	High	High	Yes

↗

↖

	Occurrence		Severity
Low	Almost never		No significant impact
Med	Possible but not likely		Slight Impact on customer
High	Frequently occurs		Miss dates or lose money

↗

Note: if effective processes and procedures are in place, then H and Yes could be no action required.

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Create a matrix that represents your situation and makes sense for you to use in interpreting and mitigating risks.



Corrective Actions—use your system; get to root causes—corrections/corrective actions/feed forward

Risk Evaluation—potential severity, frequency and probability

Risk Control/Mitigation—action steps using your corrective action process

Residual Risks—acceptable risk levels for interested parties

Risk Management Reports—an output of the process

Risk Information and Communication—for all interested parties—this is the ‘forgotten link’ in the process!

Outputs

Risk Register & Corrective Actions

- **Use YOUR CAPA system**
- **Risk Evaluation & Risk Register**
- **Fix Root Causes to Mitigate Risk**
- **Corrections/Corrective Actions/Action Plan & Results**
- **Feed Forward**

Corrective Actions—use your system; get to root causes—corrections/corrective actions/feed forward

Risk Evaluation—potential severity, frequency and probability

Risk Register—a compilation of risks, probabilities, impacts, responsibilities and mitigation steps

Risk Control/Mitigation—action steps using your corrective action process

Residual Risks—acceptable risk levels for interested parties

Risk Management Reports—an output of the process

Risk Information and Communication—for all interested parties

Mitigated Risks

- **Risk Register**
- **Action Plans/Steps**
- **Responsibilities**
- **Monitoring & Measurement**
- **Corrective Actions—use your process**

Action steps using your corrective action process; don't create another process. If you don't have a corrective action process in place get it in place or use the risk register as your basis

Residual Risk Evaluation

- **Systematic Approach**
- **Tools & Techniques**
- **Potential Severity--Impact**
- **Frequency**
- **Probability**
- **Ranking**

Potential severity, frequency and probability are the best estimates based on knowledge, experience, industry standards or other research.

Residual Risk

- **Risk Register**
- **Acceptable Risks**
- **Interested Parties**

Identify risks, assign a unique identifier, evaluate the risk, document the evaluation, develop your action steps for mitigation and follow up.

Residual Risk: risk remaining after risk control measures have been taken (ISO 14971, def. 2.15)

Decide what is acceptable risk, record the decision and the basis for the decision.

Risk Management Report(s) and/or Plans

- **Processes & Products**
- **Potential Impacts**
- **Interested Parties**

Risk reports are required for medical devices as a part of the risk management file. Clause 8 of ISO 14971 required a risk management report that is reviewed and approved by top management—this is a ‘best practice’ model for any project.

Risk Communication

- **“Missing Link”**
- **Approvals to Release**
- **Interested Parties**

Who are your interested parties? They probably include employees, suppliers, community, customers, shareholders, regulatory bodies or agencies.

Inputs



Outputs

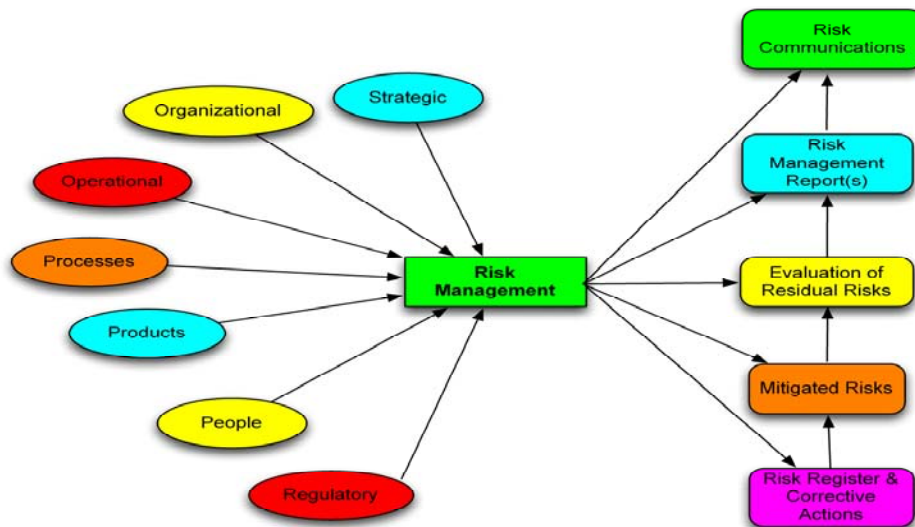
So it's a process—let's quickly review the process again so you can begin to 'get it' to put it to use!

ISO Standards for Risk Management

ISO 14971 Risk Management for Medical devices—“the gold standard”—principles, tools and techniques

ISO 31000:2009 gives the framework, principles and practices for risk management

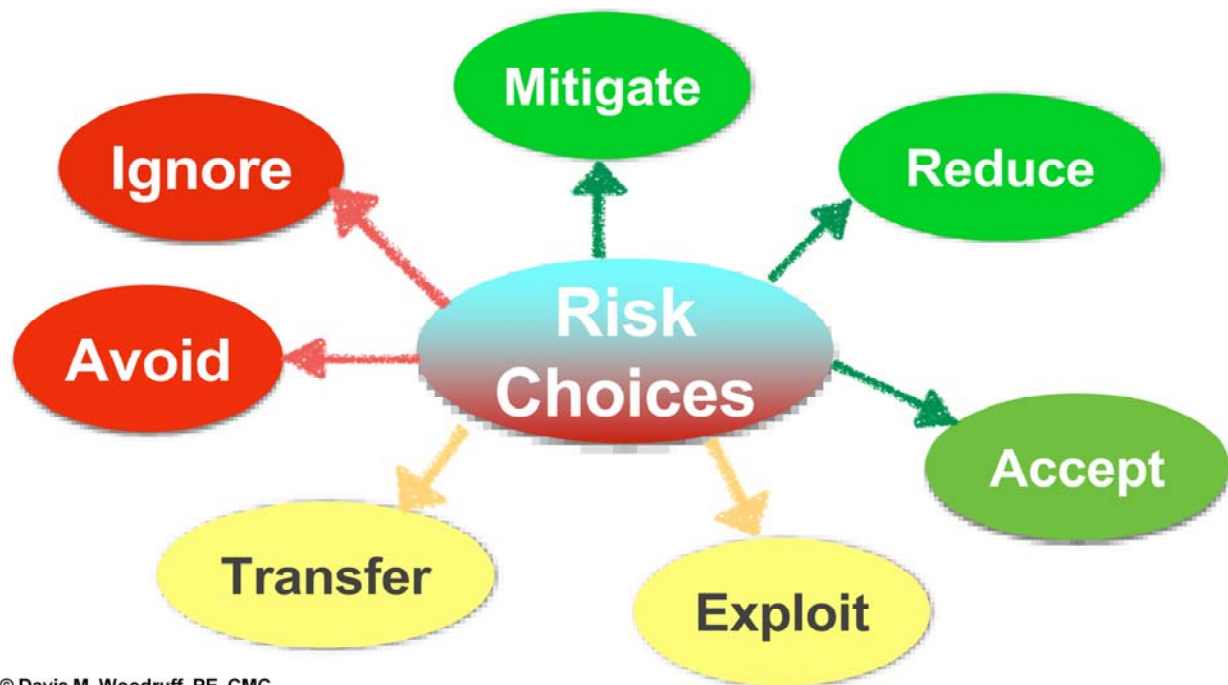
Review The Process



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A comprehensive process. Consider using a checklist. An example is included in the course materials. Contingency Plans and Business Continuity Plans!! TS and API require a contingency plan—do it right, don't just make a pass at it.



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What we can do with Risks——Be careful of what you choose to avoid or ignore!

Risk Management Tools

- **Fault Tree Analysis/Decision Trees**
- **Failure Mode & Effects Analysis (FMEA)**
- **Process, Product or Project Integrity Matrix**
- **Risk Register/Probability Simulations**

This is not a course on using these tools. it is intended as an overview. They are covered in detail and 'how to' in other Risk Management courses on pdh and other sites. We will mention these tools as we look at the outputs of RM process and then briefly look at examples to see how these work. We will overview each of these tools with an example in the following slides. The examples are very simple by design.

Process & Product Matrix

- **Simple tool to identify process or product risks**
- **Knowledgeable people identify risks & mitigation**
- **Utilizes a process flow chart**
- **Does not include a numerical value for quantifying risk or prioritize risks**

This is one of the simplest tools of risk management and is used in what are generally considered 'low' risk situations.

Process & Product Matrix

Risk Management Process, Ref. Procedure Number if Applicable								
Process and Product Integrity Risk Management Matrix								
Scope: NOTE THE PROCESSES THAT ARE INCLUDED								
Process	QMS Reference	Steps	Potential Failures Potential Issues	Prevention of Failures or Issues	ID-Recall	Product Control Testing/Verification	Action taken if Failure	
Quoting	SOP 7.11	Review quote for feasibility	Quoting something we can't make on time	Insure info available or no quote	No Quote	Quote review process	Management reviews to determine if approach with customer	
		Available capacity	Not having adequate information about equipment	Up to date equipment availability and backlog	N/A			
		Technical capability	Part geometry or materials not considered	Engineering and production reviews	N/A			
			Insure quote review process is followed	Use a checklist with sign-off	N/A			
Purchasing	SOP 7.41	Need identified	Not addressing the need properly	Inventory control	Identification based on Purchase Order	Complete verification against purchase order	Contact vendor if problem is due to their error. Otherwise, terminate warehouse personnel	
		Approved vendors	Mis-representation by vendor of goods	Pictures of goods / Safe pricing				
		Issue PO	Issue incorrect PO	Double check PO				
		Receive goods	Getting the goods here in good condition and quickly	Good communication with vendor and shipper				
		Verify goods received	Receipt of incorrect or faulty goods	Good knowledge of products and means of shipping				
Calibrations	SOP 7.61	Identify items that need calibration	Not calibrating a device that should be calibrated	Good knowledge of equipment	Identification based on specific item identification number	Through daily use of items, accuracy can be verified.	Contact calibration company if error found. Take equipment out of service.	
		Get calibrations done	Not getting calibrations done					Diligent record maintenance
		Maintain calibration status	Letting records lapse					Diligent record maintenance
			Not reviewing calibration certs upon receipt					

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Simply have a team of knowledgeable people go through each of your processes—begin with a good flow chart of the process then work through the various processes following the flow charts and identify potential risks. No value is assigned for the risk using this tool. This tool may not be unique to my consulting practice, but others say they have not seen it quite like this and several of my clients prefer this simplistic approach to other approaches when the overall risks are low in their business.

Business Process Example

Risk Management Process--Manufacturing Processes; WI-04; WI-07
 Process and Product Integrity Risk Management Matrix; initial date 7/21/15 TEAM: LIST TEAM MEMBERS
 Manufacturing Process--QMS Reference--Work Instructions

Process Steps (flow chart)	QMS Reference	Steps	Identified Risks of Potential Failures or Potential Issues	Risk Likelihood of Occurrence	Risk Severity	Risk Mitigation: Prevention of Failures or Issues	Risk	Accepted Risk	Action to be taken	Responsibility	Due Date	
Production Schedule	SOP 7.1	Capacity Review & Management	Rework on a specific machine	L	M	Pre-production Planning Meeting	M	Y	None			
			Not having a machine available	M	H	More visibility of machine schedules	H	No	Work on scheduling process	JL & DW	10/1/15	
			Outsourced machine constraints	M	M	Revise scheduling process; identify sources	H	Y	Revise scheduling process	CK	10/1/15	
				Incorrect planning: hours not correct; sequence not correct	M	M	Making appropriate people aware of new orders	M	No	None		
		Human Resources	Vacation planning	L	L	Pre-production Planning Meeting	L	Y	None			
	Sickness		L	L		L	Y	None				
	Turnover		L	L		L	Y	None				
		SOP 6.22		Training, Competency & Qualifications	L	L	Welding and : training plan and process			Identify backups; implement revised training process	DJ and TL	8/1/15
		SOP 5.1	Establishing Realistic Dates	Improper planning	M	M	Pre-production Planning Meeting	M	No	Review production planning meeting process	GL	8/1/15
	Incorrect information			L	L	QE verification/contract reviews	L	Y	None			
	Data not available in E-2			M	M	QE reviews	M	Y	None			
Outsourced processing	L			H	Approved suppliers/otd tracking	H	Y	None due to present controls				
		Information Timeliness	Expediting requirements	L	M	Pre-production Planning Meeting	M	Y	None			
			Missing information	L	M	Defined information flow	M	Y	Current reviews o.k.			
			Procrastination	L	L	Defined responsibilities and schedules	L	L	None			
									Production scheduling process review	GL and CK	10/1/15	
© Davis M. Woodruff, PE, CMC			Constraints/Issues not identified	43	H	Pre-production meetings/plans	H	No				

Expanding the matrix a bit, one can then begin to ‘quantify’ risk in the process. This is a simple analysis of a production scheduling process. This goes a bit deeper than the previous approach. You can see we are building the system for managing risks. This is an approach that I prefer in many cases. Again, process flow chart and knowledgeable people are required.

Risk Evaluation Criteria

↘ Risk Interpretation

Likelihood of occurrence	Severity if it occurs	Combined Risk	Action Required
Low	Low	Low	No
Low	Med	Med	Maybe
Low	High	Med	Yes
Med	Med	Med	Yes
Med	Low	Low	No
Med	High	High	Yes
High	Med	Med	Yes
High	Low	Med	Maybe
High	High	High	Yes

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	Occurrence		Severity
Low	Almost never		No significant impact
Med	Possible but not likely		Slight impact on customer
High	Frequently occurs		Miss dates or lose money

Note: if effective processes and procedures are in place, then H and Yes could be no action required.

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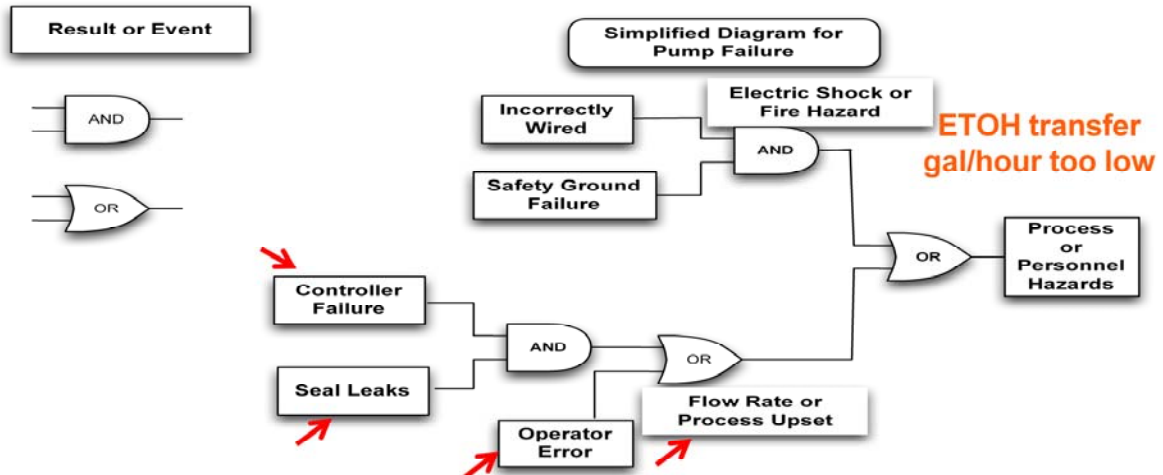
This is one method that is very simple, yet works—when knowledgeable people are involved. It is not to be done by the engineer alone or manager alone, etc.!

Fault Tree Analysis

- **A simple ‘top down’ approach to failure mode analysis**
- **Knowledgeable people list the known hazards (risks)**
- **Identify the events (failures) or combination of events that will lead to the identified hazard(s)**
- **Diagram the Fault Tree**
- **Use the tool to intervene in the process or design out the unacceptable consequence**

To find more information you might want to consider NASA papers on the topic. They have some excellent materials on the web.

Fault Tree Example



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In this case the risk is a process upset of Ethanol transfer rate being too low. There are several opportunities for this to occur without it being a hazard to employees. Here it could be controller failure and seal leaks or operator error that led to flow rate or process upsets. You get the idea. Keep it simple, but yet a very visual technique. By the way, this can also be an effective tool for root cause analysis.

Failure Mode & Effects Analysis

- **Team Process**
- **Analytical Process Approach**
- **Begins with a Flow Chart**
- **Living Document(s)**
- **Risk Management Tool**
- **Potential Failure Modes & Resulting Effects**
- **Root Causes of Failures**
- **Measures to contain or eliminate root causes of failure**

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One of the Automotive Core Tools required by TS 16949 for risk management: DFMEA for Design and PFMEA for processes and SFMEA for services. It may be the 'granddaddy of risk management tools' for manufacturing.

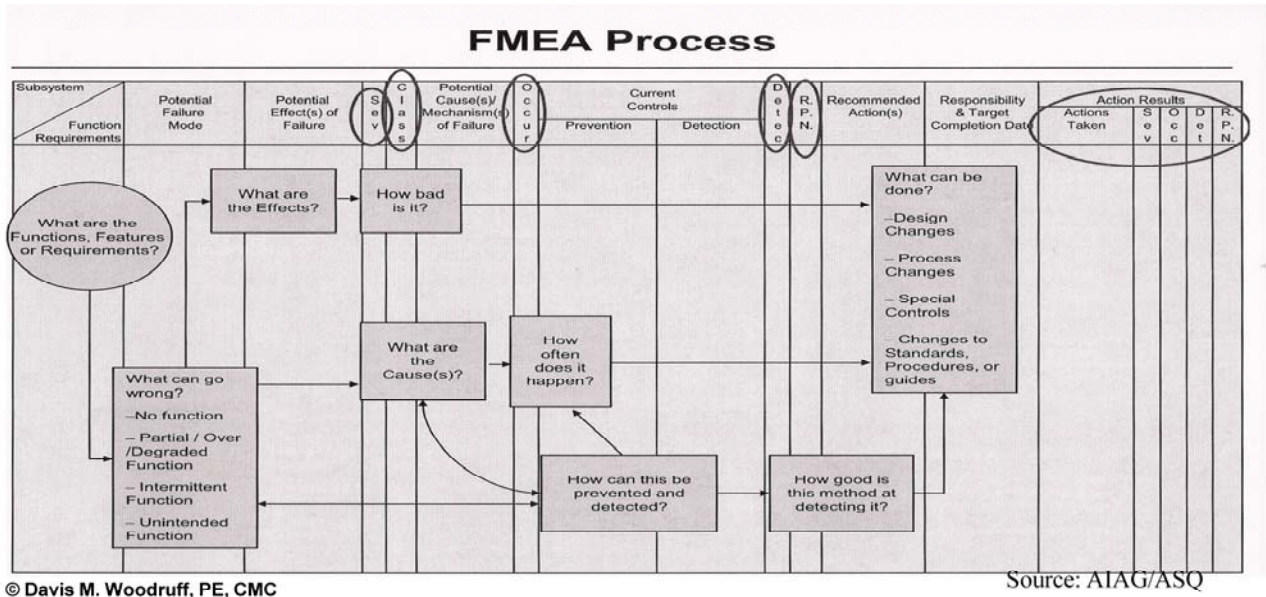
FMEA's Include

- **Functions for the product or process**
- **Failure modes when requirements are not met**
- **Effects & Consequences of the Failure Modes**
- **Potential Causes of the Failure Modes**
- **Actions & Controls to address the causes**
- **Actions to prevent recurrence of the failure**
- **Uses 'RPN' approach to quantify failure risks**

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FMEA's are comprehensive and can be time consuming. Yet, they are effective tools for identifying, mitigating and managing risks. They are required for companies that are TS 16949 certified for automotive.

FMEA



This slide is from the AIAG FMEA manual just so you can see how they are formatted and the information required. In one case we had an f a group of Engineers and PhD scientists in an FMEA training session and used petroleum storage tanks as the example in a petroleum terminal setting—don't design the tank—use the tank—it's already there identify the function of the tank—for example, to safely store up to 50,000 bbl of gasoline without leaks. So, how does it do that and what are the risks? Leaks, inaccurate volume gauges, overfill protection failure, pump failure, you get the idea. Now, on to the effects of each. Severity is the real issue in most cases.

FMEA Example

Process Responsibility: JK		Product/Part Name/Number/Rev Level/PSAD "3" product line										Prepared By: DW/GR/LB								
Process Description:		Project: N/A																		
Program: Quality Improvement		Core Team: DW/GR/LB										Latest Rev Date: 2/6/16								
Process Step or Function	Process Description, Requirements, Instructions	Potential Failure Modes	Potential Effects of Failure	Process and Failure Modes										Action(s)			Action Results			
				Severity	Classification	Potential Cause(s) of Failure	Frequency	Current Controls	Control Controls (Detection)	Detection	RPN	Recommended Action(s)	Responsible	Target Date	Action Taken & Eff. Date	SEV	FR	DET	RPN	
Purchasing	To obtain materials for plant operations on time that meet requirements including cost	Raw Materials not available	Customers out of product	2	NR	Failed to order on time, delivery schedules not met by suppliers	2	Supplier approval process and inventory control	ASL inventory monitored, Full system used	2	6	NR	NR	NR	NR	NR	NR	NR	NR	
			Lose customers	4	Critical	Previous similar issues	2	Monitor shipping volumes	production plans & schedules	2	16	NR	NR	NR	NR	NR	NR	NR	NR	
			Competitor takes our business	4	Critical	Being out of materials for +2 days	1	Inventory planning	Maintain 1 week inventory of PO	2	10									
			RM's not acceptable	Bad product	3	Critical	Out of spec RM's	1	Approved suppliers, history with them	COA's required and/or samples tested	2	10	Review all EM specs and history with supplier performance	Quality Mgr.	7/1/15	Reviewed and changes made to tighten sugar purity	3	1	2	6
				Higher production costs		NR	Poor yields and rates	3	Recipe sheets and production controls	Rates and yields monitored	1	6	NR	NR	NR	NR	NR	NR	NR	NR
				More testing required		NR	Unsure about product quality	2	Validated sample schedule	Testing schedules	3		NR	NR	NR	NR	NR	NR	NR	NR
				Maintenance parts	Equipment not in operation	3	NR	Too long to make repairs, unscheduled downtime	4	Training, equipment methods	Critical equipment monitored	3	36	Review past year results, update training plan	Maint. Supv.	12/31/15	Added training on Aghator repairs and controls	3	2	3

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You will note this follows the information in the AIAG requirements. The steps in the process should align with your process flow chart. It all begins with an understanding of the process flow. This was created in Excel, so it is rather simple for you to construct your own spreadsheets for FMEA's. A key factor is to identify the RPN (severity x frequency x detection) value that will trigger an action to be done and then taking action and re-calculating the RPN. Focus on both severity and RPN when interpreting the information.

PFMEA Severity

Rank	Classification	Descriptive Information/Criteria
1	Minor	Not likely to occur at all; unreasonable to expect this failure would cause any real effect on the product or service
2	Low	Low due to this type failure causing only a slight customer annoyance. Probably will be noticed, could be a slight rework issue or inconvenience
3	Moderate	This failure could cause some customer dissatisfaction. May cause unscheduled repairs and/or damage to equipment in the plant.
4	High	High degree of customer dis-satisfaction; product is not as intended; significant inconvenience to the customer; does not involve safety or regulatory issues.
5	Very High	This failure involves safety and noncompliance with government regulations, or a fatality or serious injury to an employee or others.

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This is a simple 5 point rating scale that we use many times. AIAG and automotive use a 10 point rating scale as defined in the AIAG FMEA manual.

PFMEA Probability (Occurrence)

Rank	Likelihood	Description
1	Improbable	Although theoretically possible, very unlikely to occur
2	Remote	Likely to occur no more than 5% of uses/production
3	Occasional	Likely to occur no more than 15% of uses/production
4	Probable	Likely to occur no more than 25% of uses/production
5	Frequent	Likely to occur more than 50% of the time when the product is used/produced

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You could choose to modify this to other estimates of probability or in some cases actual product ppm defective levels using other measures.

PFMEA Detection

Rank	Likelihood	Description
1	Very High	Controls almost certain to detect existence of this defect or situation; remote likelihood the product or service will be delivered. Defect is functionally obvious and readily detected.
2	High	Controls have a good chance of detecting the existence of this failure. Low likelihood of product or service being delivered. Defect is obvious.
3	Moderate	Controls may detect the existence of the defect. Moderate likelihood product or service could be delivered with the defect. Easily identifiable defect or situation.
4	Low	Controls will not likely detect the existence of this defect or situation. Highly likely that the product or service will be delivered with the defect. Defect is subtle and not easily observed.
5	Very Low	Controls will not detect the existence of this defect or situation. Product will be delivered with this defect or situation. Often the defect is latent and occurs only after use. Probability of detection is < 90%.

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If an issue can be detected then it is a low rating value for the PFMEA and if it cannot be detected easily then the rating value is higher as the risk is higher.

Risk Register

- **“Repository” for current information about identified risks**
- **Documents the Controls & Mitigation Plans**
- **A ‘Living’ Document that includes:**
 - **Key element of the project or process or product**
 - **Identified Risk(s)**
 - **Existing controls**
 - **Level of risk**
 - **Actions to mitigate with responsibilities & timelines**
 - **Generally can be a spreadsheet or use specialized software**

The Risk register is the core document for Risk Management—it can be the record of identifying and managing risks for the life of project or product or service.

Risk Register Example

Project Risk Register for the new PSAD Distillation Column											
Risk Analysis Team: DW/GM/LW/KG			Original Date: 2/2/16			Rev: Initial Register			Project Completion Target: 7/18/16		
Project I.D.: PSAD-DC20216			Risk I.D.: Sequential Numbers, DC-1; DC-2, etc								
Risk Identification			Risk Analysis			Risk Evaluation		Risk Treatment			
Risk I.D.	Category	Description	Project Impact	Likelihood	Impact	Rank/Grade	Risk Trigger	Prevention	Contingency	Risk Owner	Residual Risk
DC-1	Schedule	Late approval of final drawings	Delayed installation	Low	High	Med	Drawings not ready by 3/1/16	Monitor weekly with Engineering	After 3/1 review for additional engineers	KG	Low
DC-2	Schedule	Process equipment list not ready in time	Delayed installation	Low	High	Med	Final list due by 4/1/16	Monitor weekly with Engineering and Process Eng.	After 3/1 review for potential impact in order dates and added freight	GM	Low
DC-3	Scope	Upon installation we find the pumps or piping for the Cooling Kettle is undersized	Delayed start-up and cost increases	Low	High	Med	Review drawings upon completion of P&ID set to determine additional sizing required.	Discuss with engineering before the due dates and verify with column supplier	Have alternate sizing calculations completed and ready to submit the review indicates the need	LB	Med
DC-4	Resources	Inadequate funding to complete the project	Delays after beginning the project or not being able to complete the project at all.	Low	High	Low	Initial bids are too high.	Verify costing after drawings are completed and also include 5% contingency in the budget	Re-bid the job if all bidders are too high. Expand the bid list. Review all requirements again.	DW	Med
DC-5	Resources	Contractor not available for installation	Not being able to complete the project.	Med	High	High	Contractor should be selected by 4/1/16	Begin reviewing available contractors by 3/12/16	Expand contractor selection base to surrounding states to have others on stand-by	DW	Med
DC-6	Safety	Lifting plans not completed for heavy equipment lifts	Injuries to people or equipment, delays.	Med	Med	High	Select if contractors by require lifting plans to be submitted by 6/1/16	Plans not submitted by 6/5/16	Have back-up contractor for lifts in place by 6/20 with plans due by 6/25	KG	Med

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This is a risk register example for a project to install a distillation column in a processing plant. It is a team effort, should be done up front and is a critical document for a successful project. The rating scale is similar to the one used earlier for the process matrix. Selecting your rating scale is not an exact science but should reflect your business needs and understanding. Please note the category column and see schedule, scope, resources and safety are included. A simple spreadsheet works quite well in most cases, however for major construction projects specialized software is typically used and simulations run using statistical techniques and contingencies developed.

Management of Change (MOC Procedure)

- **Considers at a minimum:**

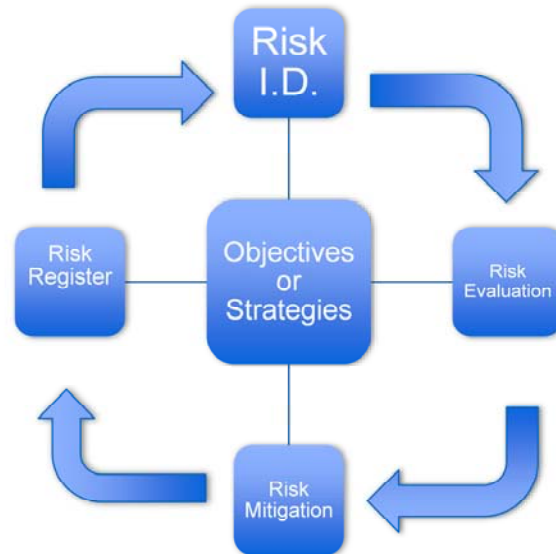
- **Organizational**
- **Critical Suppliers/supply chain**
- **Essential Personnel**
- **Management System**
- **Machines or Processes**
- **Safety & Health**

- ✓ **Reason for the Change**
- ✓ **Affected areas, processes, people, products or customers**
- ✓ **Risks associated with the change and mitigation steps**
- ✓ **Approvals required**
- ✓ **Notifications required including customer notifications**
- ✓ **Document changes required**

Purpose: Minimize risks associated with changes

A management of change procedure is in itself a risk management tool. Create a procedure for your organization for MOC and actually use it to get the most benefit from your risk management efforts. Many times the greatest risks occur when changes are being made—to products, processes or the organizational structure.

Risk Management Cycle



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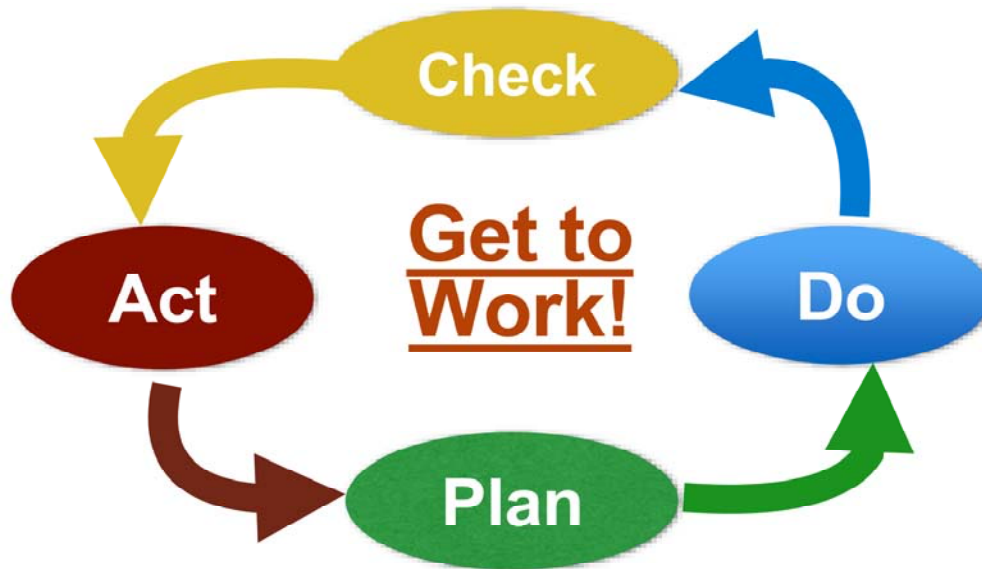
Risk management can be tied to specific objectives or strategies in an organization. Again, this looks like the plan-do-check-act approach. This is just reminder of the overall process. All phases are equally important, but nothing happens here until you identify the risks!

Review

- ✓ **Risk Concepts & Terms**
- ✓ **Risk Considerations & Factors**
- ✓ **Risk Management Process**
- ✓ **Quantifying Risk(s)**
- ✓ **Examples of Risk Management Tools**
- ✓ **Risk Choices**
- ✓ **What Next?**

This has been a quick tour of the risk management process and some of the tools for risk management. You should be able to develop a risk management process, or improve your current process, using the information in this course. You may want to consider additional courses in the specific tools and applications for risk management.

What Next?



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Get to work! PLAN: Define, Document & Deploy YOUR Risk Management Process; Consider appropriate inputs/outputs DO: Make it practical, reasonable & useable ; carefully document your risk register and follow up on action plans! CHECK: Record and Analyze ACT: On what you learn DO IT AGAIN and Remember to Communicate

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