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Control Plans

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Learning Objectives

Upon completion of this module, the student should be able to:

- Understand the concepts of Control Plans to process improvement projects
- Understand how FMEA and Cause and Effect Diagrams can help in completing
- Understand Reaction Plans

What's In It For Me?

- By the end of this module you should be able to
- Explain the importance of Control Plans to a DMAIC project
- Explain the importance of Control Plans to process management
- Given a process, develop a control plan for that process
- Explain the impact of SOPs on the process improvement
- Describe how to develop an SOP in a project
- Given a process, develop a usable SOP

Task 3: Control Plans
What Is a Control Plan?

- Control plans provide a written summary description of the systems used in minimizing process and service variation
- Control plans do not replace information contained in detailed instructions
- In a grand sense the control plan describes the actions that are required at each phase of the process including receiving, in-process, outgoing, and periodic requirements to assure that all process outputs will be in a state of control
- Ultimately, the control plan is a living document reflecting current methods of control and measurement systems used

Control Plan Minimum Requirements

- What is the process that is being controlled?
- What measures (numbers) are we monitoring?
- For each measure, what are the “trigger point” values where action should be taken?
- What action should be taken when a “trigger point” is reached? Who is responsible for taking action?

Elements of Outstanding Process Control Plans

1. Holds the performance gains made!
2. Assists in highlighting opportunities for further improvement activities
3. Is a living document
   - Adjusted as conditions change and further improvements made
   - Has formal provision for periodic review
4. Is interesting and easy to understand – use pictures and colors

Why Is a Process Control Plan Necessary?

- Processes have a tendency to degrade over time
- Also, at this stage, the process is generally moving beyond the hands of the Six Sigma team. Those who are responsible for continuing it need a clear understanding of how to implement it consistently and steps to take if it gets out of control. Therefore, as part of the Process Control System the Six Sigma team needs to create an implementation plan that includes a strategy for controlling each improved sub-process
- The improved process needs to be communicated to all involved parties through documentation and training
- A data collection plan is also necessary to test the improved process and confirm that the solutions are indeed having positive impact

Existing Control Documentation

- Many processes already have in place what are called "quality plans" to ensure each service characteristic or sub-process stays in conformance with their overall process
- You should take into consideration any existing quality plans as part of establishing a process control system for your project
  - The existing plan may include process procedures and tolerances, as well as items to be monitored for control and response plans in the event of a process breakdown. These can inform your own control plan
  - Your improved sub-process may have an impact on the quality plan, so you need to include changes to it as part of your documentation

Control Plan Defined

- Intended to control process and identify corrective actions
- Summary of all control activities for a process
- Used by Project Sponsor to sustain gains
- Living document

Control Plans

- Linked to the FMEA to minimize risks
- Assures well thought-out reaction plans are in place in case an out-of-control condition occurs
- Links to Cause-and-Effect, CTX's, and FMEA
- Empowers personnel to make corrective actions
- Provides protection against process drift
- Provides for timely process trouble-shooting and repair
- Aids in training and audit activities

Control Plan Information

- Identification of the control factors
- Specification and tolerances
- Measurement system
- Sample size
- Sample frequency
- Control method
- Decision rule / Reaction plan

Process Control Plan Template

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Quality Control Plan

Compentency (PM /		Master Black Belt:		Page:	1 of 1
Project / Event Name:		Deployment Champion:		Document #:	
Process Owner:		Dir CPI/LSS Office /		Revision Date:	
Process Sponsor:		MCSC LSS MBB:		Supercedes:	

Subprocess	Subprocess Step	Critical To Process (CTP)		Specification Characteristics	Specification Requirement			Measurement Method	Sample Size	Frequency	Who Measures	Where Recorded	Decision Rule/ Corrective Action	SOP Reference
		KPIV (Xs)	KPOV (Ys)		LSL	Target	USL							
	1													
	2													
	3													
	4													
	5													

Header

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Quality Control Plan

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	1													
	2													
	3													
	4													
	5													

- Populate with appropriate information for your event

Mid-Section Guidance

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Quality Control Plan

Compentency (PM /		Master Black Belt:		Page:	1 of 1
Project / Event Name:		Deployment Champion:		Document #:	
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	5													

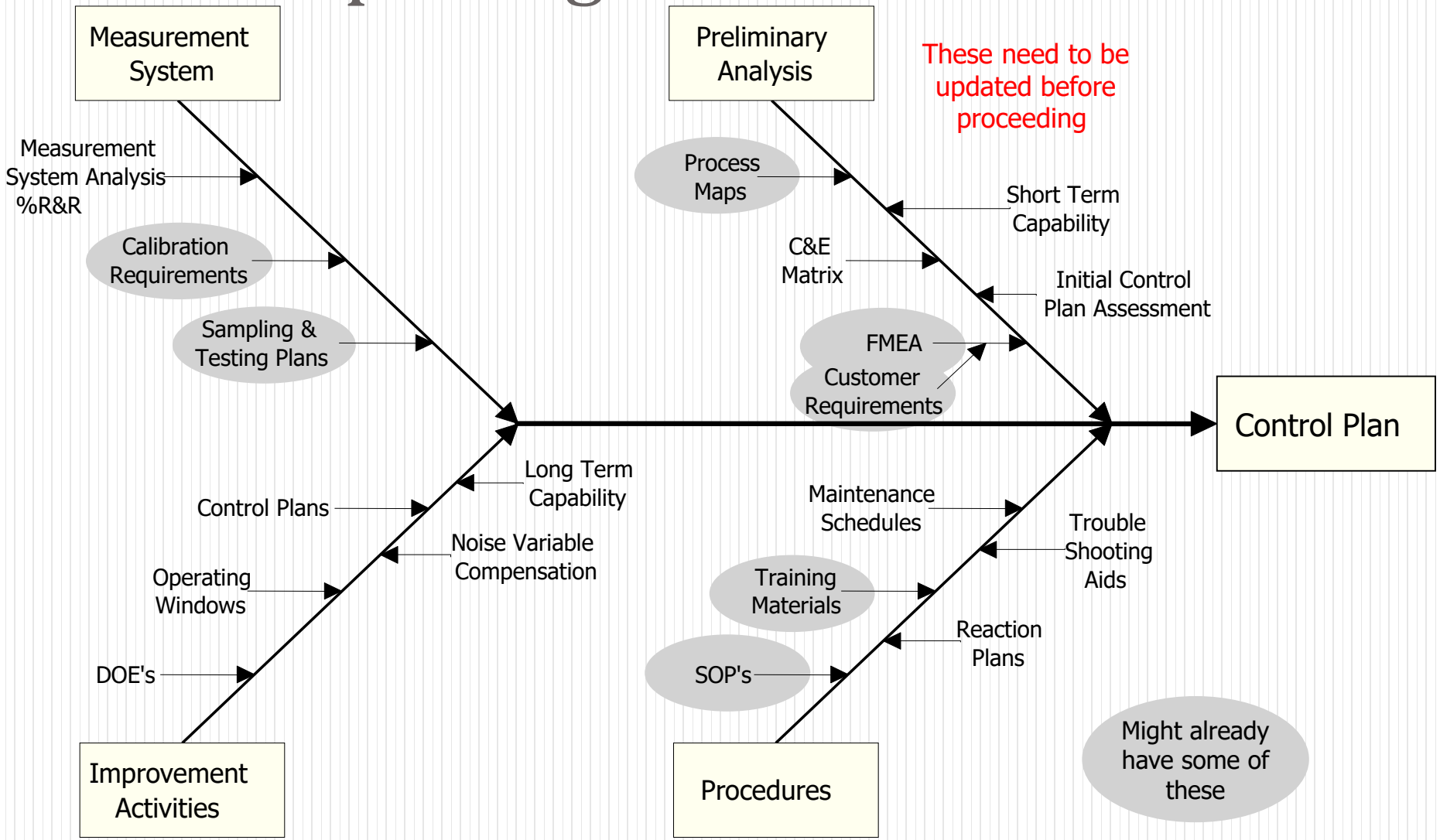
- Identify Sub-process
- Identify Critical to Process (CTP)
  - List Key Process Input Variables (KPIV)
  - List Key Process Output Variables (KPOV)
- List Customer Specifications
- Record Measurements
- Identify and List SOP References

Control Plan Strategy

- The intent of an effective control plan strategy is to:
  - Operate our processes consistently on target with minimum variation
  - Minimize process tampering (over-adjustment)
  - Assure that the process improvements that have been identified and implemented become institutionalized. ISO 9000 can assist here.
  - Provide for adequate training in all procedures
  - Include required maintenance schedules

Revise Quarterly

Factors Impacting a Good Control Plan



Documenting the Control Plan

- For Key Process Input and Key Process Output Variables, the measurement system and measurement system capability should be identified
- Targets and specification limits for Key Process Input Variables and Key Process Output Variables are recorded
- For continuous inputs and outputs, the C_p/C_{pk} indexes should be calculated. Record short and long term data where available
- The specifics of the sampling plan with associated reaction plan for out-of-spec conditions should be listed
- This document is an extension of the Current Controls column of the FMEA

FMEA In Control Planning

- The FMEA should be a primary source for the identification of key variables to control and for an initial evaluation of current control plan

Process Step	Key Process Input	Potential Failure Mode	Potential Failure Effects	S E V	Potential Causes	O C C	Current Controls

Process	Process Step	Input	Output	Process Specification (LSL, USL, Target)	Cpk /Date (Sample Size)	Measurement System	%R&R %P/T	Current Control Method	Sample Size	Sample Frequency	Reaction Plan

Control Methods Finale

- Changes in the process require changes to the control method
- Control methods identify person responsible for control of each critical variable and details about how to react to out-of-control conditions (see next slide)
- Control methods include a training plan and process auditing system, e.g., ISO-9000
- Complicated methods can be referenced by document number and location

Reaction Plans

- Holding the Gain
- Monitor and respond to problems
- Manage the process day-to-day
- Practice continuous improvement

When You Improve a Process and Hold the Gain, It Ensures Your Efforts Have Not Been In Vain

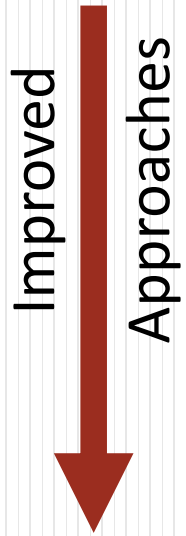
Reaction Plan and Procedures

- Actions should be the responsibility of people closest to the process
- The reaction plan can simply refer to an SOP and identify the person responsible for the reaction procedure
- In all cases, suspect or nonconforming service must be clearly identified and quarantined
- Can be built from the FMEA

Building a Reaction Plan

1. Examine Each Key Step in the Process
   - Entire SIPOC
2. Apply Preventive Planning
   - What could go wrong?
   - How would we respond – contingency?
   - Who would be responsible?
3. Set “Trigger” Measures
   - What would warrant response?
4. Document the Plan
   - Key ingredient for Process Management

Reaction Action Types



- **Compensate**
  - This type of control involves making a process adjustment to bring the variable back into control without identifying or correcting the factor which caused the situation
- **Correct**
  - In this type of control action, the cause of the variation is identified and corrected temporarily. The problem may reappear soon.
- **Prevent**
  - In this type of action, the cause of the variation is identified and permanently corrected. The cause will not happen again or at least will not occur as often.

Questions for Control Plan Evaluation

- Key Process Input Variables (KPIVs):
  - How are they monitored?
  - How often are they verified?
  - Are optimum target values and specifications known?
  - How much variation is there around the target value?
  - What causes the variation in the KPIV?
  - How often is the KPIV out of control?
  - Which KPIVs should have control charts?
- Uncontrollable (Noise) Inputs
  - What are they?
  - Are they impossible or impractical to control?
  - Do we know how to compensate for changes in them?
  - How robust is the system to Noise?

Questions for Control Plan Evaluation

- Standard Operating Procedures
  - Do they exist?
  - Are they simple and understood?
  - Are they being followed?
  - Are they current?
  - Is personnel training performed and documented?
  - Is there a process audit schedule?
- Maintenance Procedures
  - Have critical components been identified?
  - Does the schedule specify who, what and when?
  - Where are the manufacturer's instructions?
  - Do we have a trouble shooting guide?
  - What are the training requirements for maintenance?

Questions for Control Plan Evaluation

- What special equipment is needed for measurement? What is the measurement capability?
- Who does the measurement? How often is a measurement taken? How are routine data recorded?
- Who plots the control chart (if one is used) and interprets the information?
- What key procedures are required to maintain control?
- What is done with a service or product that is off spec?
- How is the process routinely audited?
- Who makes the audit? How often? How is it recorded?

Control Plan Check List

- Process maps detail process steps, information flow and important variables
- Key service variables identified with importance to customer, desired target value and specification range defined
- Long and short term capability trend charts track variation reduction progress
- Key and critical input variables identified with targets, statistically determined control limits and control strategies defined
- Reaction plan in place for out-of-spec processes
- Measurement systems are capable with calibration requirements specified
- Sampling, inspection and testing plans include how often, where and to who results reported
- Operating procedures identify actions, responsibilities, maintenance schedules and service segregation requirements
- Training materials describe all aspects of process operation and responsibilities
- ISO 9000 documentation standards met if required
- Process improvement efforts fully documented and available for reference
- Control plan is reviewed and updated quarterly and resides in the operating area

Standard Operating Procedures

- Standard Operating Procedure (SOP) regarded as a most important document for achieving a perfect process
- SOP documents each action required to complete a specified task
- SOP combines 3 elements – people, resources and technology

Summary

In this module you learned about:

- The concepts of Control Plans to process improvement projects
- How FMEA and Cause and Effect Diagrams can help in completing
- Reaction Plans