Notes:

Control

Key Learning Points

1. Define and validate the monitoring of controls to hold the gains.
2. Develop a transfer plan for your organization.
3. Close out the project.

The DMAIC Methodology

DMAIC Steps	Tools Used
Control Step: Control future process performance.	
Define and validate the monitoring of controls to hold the gains Develop a transfer plan for culture Handoff to process owner Verify benefits Close project Finalize documentation Communicate to the business Celebrate **For high risk and larger projects:** Implement statistical process control if necessary	Process Sigma Calculation Control Plan Control Charts (Variable and Attribute) Cost Savings Calculation **For high risk and larger projects:** Statistical Process Control

Purpose of the Step

Control refers to the step by which the means to keep the process at the new performing level are identified. Without controls, the process will revert to its old level of performance.

As part of the DMAIC methodology, control provisions must be made prior to the implementation of a new process.

The Plan, Do, Check, Act (PDCA) cycle best describes how to carry out process controls.

PDCA

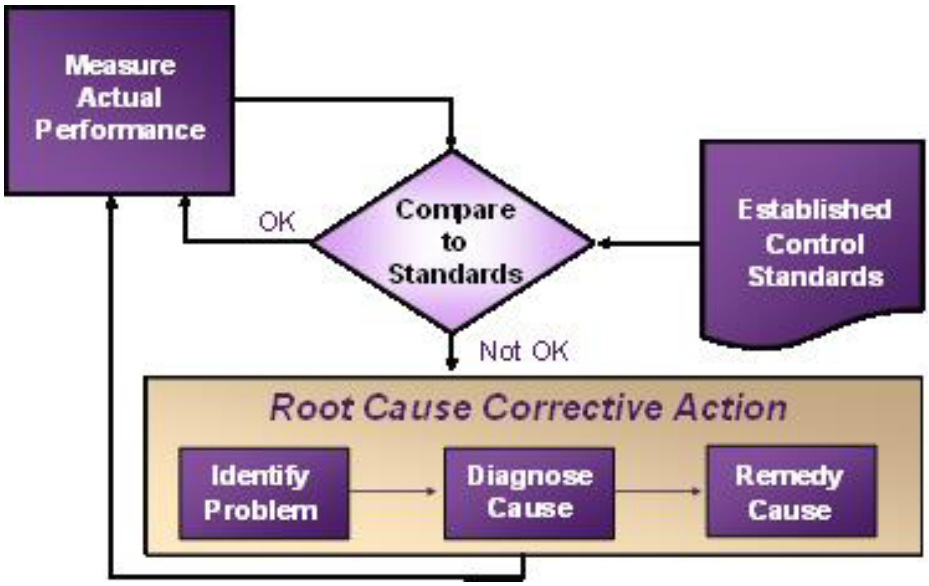
All processes have critical tasks that must be measured and controlled to assure the process outcomes are effective. Process controls need to be in place and acted upon well before the output is produced for better quality performance.

Processes are influenced by many variables, but often few variables are more important than others. The team must identify what elements of the process must be monitored, and by whom, before it concludes the project. This is Plan of "Plan, Do, Check, Act."

Once the variables are selected, to control the team must create a process control plan which includes "Do, Check, Act."

Notes:

Create a Feedback Loop



The flow of information and action within a feedback loop is as follows.

1. The actual performance of the operating process is measured.
2. The results or outputs of the process are compared against established control standards or control targets. The tool used to measure the process is usually called the sensor.
3. A decision is made as to whether there is adequate conformance of the process to the established goal, typically by someone or something performing as judge or umpire. If the performance meets or exceeds the established standard, the process continues to run.
4. Whenever the performance does not conform to the goal, troubleshooting begins to identify the problem, diagnose the causes, and initiate a series of activities that adjust the process and restore conformance, thereby bringing the performance in line with the goal. The operation of the feedback loop continues as long as the process stays on line.

Control Plan

Each control subject requires a feedback loop made up of multiple process control features. To keep track of all this detail, use a process control plan matrix. A very important aspect to the process control plan matrix is to tell the assigned employee when a process is out of control, or how to determine out of control, and what to do to get it back into control.

Process control plans are critical for:

- Designing for Control: They document the critical aspects of the control plan.
- Implementing: They communicate the control plan to those who will

Notes:

operate the improved process.

- Holding the Gains: They are a vital reference for continuing in-control operations.

Process Control Plan

A process control plan must be developed by the team which provides the PDCA cycle for employees to be able to maintain effective processes. Minimally the example below lists the most important aspects of a control plan.

Example of A Process Control Plan

Ref.	Control Subject	Subject Goal (Standard)	Unit of Measure	Sensor	Frequency of Measurement	Sample Size	Measured By	Criteria for Taking Action	What Actions to Take	Who Decides	Who Acts
1											
2											
3											

Identifying Control Subjects

Many processes only measure then attempt action on the output. Controls need to be placed within the process and acted upon well before the output is produced for better quality performance.

The number of control subjects are few. Operating processes are influenced by many variables, but often one variable is more important than all the rest combined. Such a variable is said to be the "dominant variable."

Dominant Variables

Dominant Variable	Example	Process Description	Strategy
Setup	Sheet metal stamping	Stable, reproducible over many cycles	Precision set up, validation
Time	Metal cutting, visual inspection	Change progressively	Periodic evaluation or prediction of change, convenient adjustment
Employee	Pharmacist dispensing medication, staff	Dynamic, changing according to the situation and skill of the employee	Employee training, mistake proofing, periodic evaluation
Component	Electrical appliance assembly, dispensing meals at a fast food restaurant	Input components retain identity	Control components within supplier organization

Notes:

Dominant Variable	Example	Process Description	Strategy
Information	Order entry, Airline scheduling	Dynamic information/decision stream	System design for accurate, timely information

Notes:

Where to Control

A review of numerous control stations shows that they are usually designed to provide evaluations and/or early warnings during the following times:

- At changes of authority, where responsibility is transferred from one organization to another
- Before embarking on some significant, irreversible activity
- After creation of a critical quality feature
- At the site of dominant process variables
- At areas ("windows") that allow economical evaluation to be made

A flow diagram of the process is very helpful in identifying the clusters of control subjects within appropriate control stations.

You will always require measures related to the end results or outcomes of the process. As you learned in the Measure step, when a project team analyzes problem symptoms, it uses measures of the results of the process. Some of these measures may be used later to control the process. Be certain your measures include those factors that have the greatest impact on the stakeholder.

When to Control

Control can take place at several stages in the progression of operations.

Setup (Startup Control)

- A countdown or checklist listing the preparatory steps needed to get the process ready to produce
- Evaluation of a process and/or product features to determine whether, if started, the process will meet the goals
- Criteria to be met by the evaluation
- Verification that the criteria have been met
- Assignment of responsibility

During Process: Running Control

- The purpose is to make the "run or stop" decision.
- Running control consists of closing the feedback loop, over and over again.

- If there is non-conformance or if there has been a significant change, then corrective action is in order.
- Is the indicated change a real change OR a false alarm because of common cause variation?

Supporting Operations: Facilities Control

Preventative maintenance helps keep equipment operating at optimal or peak performance to help ensure that the outcome meets quality goals.
Most processes include various physical facilities: equipment, instruments, and tools. The trend has increasingly been the use of automated processes, computers, robots, etc. This same trend makes product quality more and more dependent on maintenance of the facilities.

The elements of design for facilities control include the following:

- Establishing a schedule for conducting facilities maintenance.
- Establishing a checklist—a list of tasks to be performed during a maintenance action.
- Training the maintenance forces to perform the tasks.
- Assigning clear responsibility for adherence to the maintenance schedule.
- Auditing compliance.

Examples of Timing

Stage	Type	Decision	Elements
Start	Start	Start Process?	Countdown, product conformance measurement, acceptance criteria
During Process	Running Control	Continue/Adjust/Stop?	Feedback loop, standard, measurement, umpire, troubleshoot
	Product Features	Accept/do not accept?	Standard, measurement, acceptance criteria
Supporting Operations	Facilities control	When?	Schedule maintenance, checklist, train, assign responsibility

Who Acts?

Since all this involves making a factual decision, it can, in theory, be delegated to anyone, including the front line or production workers. In practice, this decision is not delegated to those whose assigned priorities might bias their judgment. In

Notes:

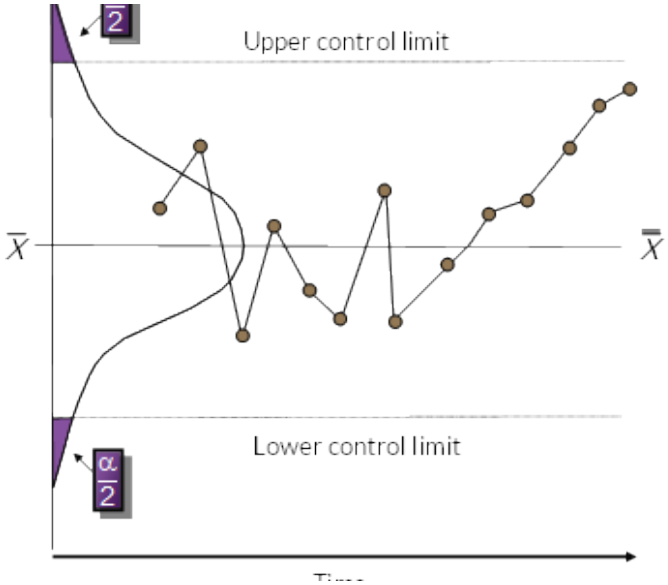
such cases, the decision is usually delegated to those whose responsibilities are free from such biases, e.g., independent inspectors or even automated instruments.

Control Charts

Process control charts are graphical depictions of data that show how a process is running over time. The goal is to monitor and control process inputs, and over time eliminate the need for process control charts when the process is running smoothly, and is under control.

Process control charts should be used:

- When a mistake proofing device is not feasible
- On processes with high Risk Priority Numbers
- When "gaps" in the control plan are determined
- Only where necessary based on project scope
- When it is value-added
- To initially monitor process outputs



Defects vs. Errors

A defect is a non-conformity with requirements, the result of an error.

An error causes a defect.

Errors are caused by people, machines, bad information, and measuring devices. Understanding how to prevent different types of errors will lead to process control.

Notes:

Common Defect Categories

- Missing information
- Late delivery
- Incorrect information
- Foreign matter present
- Mismatched parts, information, components
- Impossible to execute as described
- Inconsistent test results, test failure
- Bad incoming supplies, medicines, information
- Wrong supplies or medicines

Common Errors

- Processing omissions (skipped a task)
- Processing errors (task done incorrectly)
- Error in setting up the workplace (wrong or missing items)
- Missing information
- Incorrect information
- Recording errors
- Measurement errors
- Adjustment errors
- Error in supplies, instruments, equipment

Types of Errors

If one has all of the elements and all of the sub-elements of self-control, then one has the means necessary to be successful at a job.

Persons in self-control nevertheless, sometimes make errors. Dr. Juran called these "employee-controllable" errors.

- Source: One's own actions or the action of one's direct supervisor, and human physiology and psychology

Errors made by persons not in self-control (any sub-element missing) are what Dr. Juran called "management controllable" errors.

- Source: The systems (managerial, quality, workplace design, information etc.) and the processes—all of which are created by management

Notes:

Mistake Proofing

Mistake Proofing is the proactive approach to reducing defects by eliminating the opportunity to create them. It is the act of using wisdom and ingenuity to create devices that allow you to do your job 100% defect free 100% of the time.

You should use mistake proofing techniques when there are:

- Process steps where human intervention is required
- Decision points in the process
- Repetitive tasks where physical manipulation of objects is required
- Steps where errors are known to occur
- Opportunities for predictable errors to occur

Audit the Controls

Effective audits answer two questions:

- Are the intended results being achieved?
- Are the quality controls being followed?

These questions are related but different. The first looks at results, and the second at how the results are achieved. Satisfactory results without adequate controls may be a disaster waiting to happen. Using controls that do not produce the intended results is already a disaster.

To ensure that its work continues to be effective, a team needs to include the following in it's solution:

- Routine reporting of results
- Clear documentation of controls

Report Results

Be certain that the ongoing results of the improved process are routinely reported to a level of management prepared to monitor progress and respond if gains are not held.

These results can be shared with others in monthly presentations or simply passed along to those managing the progress of the organization through the use of tools such as scorecards or dashboards.

Close Out Project

To close out a project you need to complete the following:

- Finalize documentation
- Communicate to the business

Notes:

- Celebrate

The team must prepare a final presentation or story board to be approved by your champion. Included in this presentation is how the team will document all the critical elements of the project so they can be effectively audited.

Additionally, the team must provide a plan to communicate process changes to the stakeholders and process owners.

Once approved celebrate success.

Notes: