

w4.1- Understanding the Control Phase (4:15)

# Milestones

- Effectiveness
- Comparison
- Robustness
- Documentation
- Sustain the gains
- Yardstick

The milestones of the control phase are outlined here.



KENNESAW STATE  
UNIVERSITY

# Measurement System Re-analysis

- < 10% error      Acceptable
- 10% to 30% error      Marginal
- > 30% error      Needs improvement

Process improvements often result in reduced variation.



KENNESAW STATE  
UNIVERSITY

## Definition of Control

- Consistently meet *standards*
- Observing actual performance
- Three purposes
  - Promote analysis of variation
  - Work toward achieving “self-control”
  - Maintain the gains from an improvement project

We control things to  
consistently meet standards.



w4.1- Understanding the Control Phase (4:15).mp4

## P-D-C-A Process

- Facilitate continually improvement of the process
- Focus on:
  - What are our goals?
  - How can we confirm that change is an improvement?
  - What changes can we make to improve?
- Standardize
- Maximize the gain



6

00:03:17 / 00:04:15

85

In this Six Sigma Black Belt module, the focus shifts to the **Control Phase**, specifically how organizations maintain the **process improvements** they have implemented. Sustaining these gains is often cited as a greater challenge than the initial rollout.

## 1. The Challenge of Maintaining Control

A major risk to process stability occurs when the "Superior Black Belts" who designed the improvement are promoted or moved to different projects. To combat this, a robust control system must be built to be self-sustaining.

- **Checks and Balances:** The system should be designed so that every signal triggers a corresponding action.
- **Urgency in Gaps:** If a performance signal is missing, it should create immediate awareness and urgency among operators and management to correct the process.

## 2. Milestones of the Control Phase

To successfully close out an improvement project, Black Belts must hit several key milestones:

1. **Characterization:** Use data to prove the effectiveness of the solution.
2. **Comparative Analysis:** Compare actual results against the original planned results.
3. **Scalability:** Evaluate if the solution is robust enough to be rolled out to other departments.
4. **Sustainment Plan:** Create a strategy that acknowledges process improvement is not "set it and forget it."
5. **Reflection:** Document lessons learned—what went well and what failed—to build best practices for the business.

### 3. Measurement System Re-evaluation

As a process improves and variation is reduced, the instruments used to measure that process **must be re-evaluated**. If your process becomes highly precise, your old measurement tools might no longer be sensitive enough to detect errors.

#### Acceptable Error Thresholds (Gage R&R)

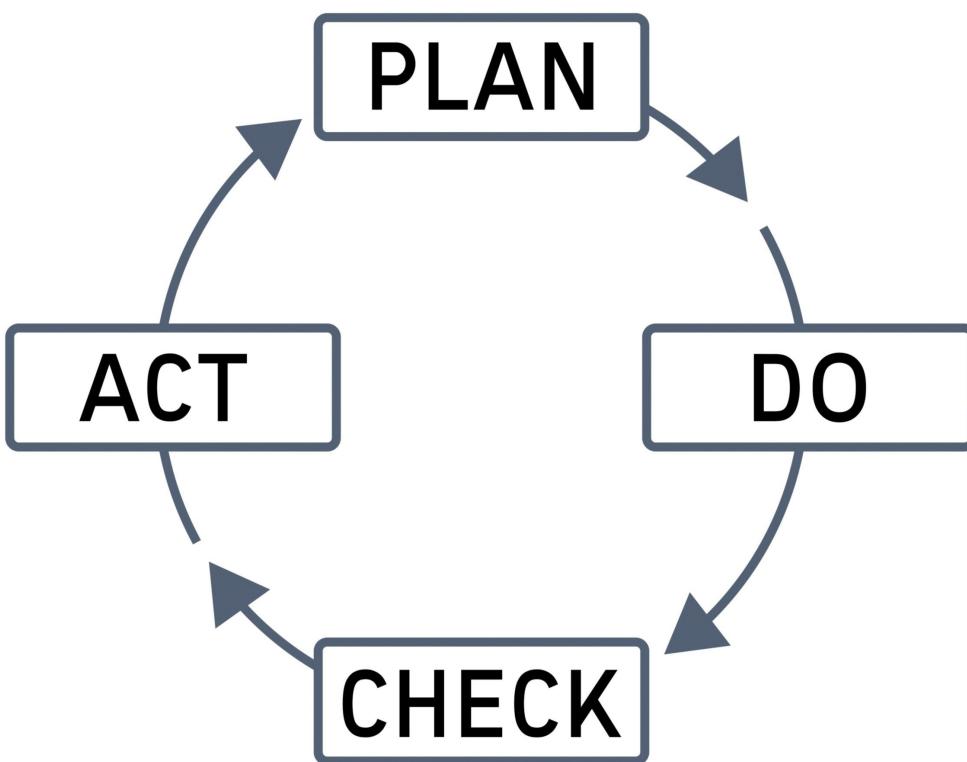
When assessing the error within a measurement system:

Error Percentage	Classification	Action Required
< 10%	Acceptable	No immediate action needed.
10% – 30%	Marginal	Corrective measures may be warranted based on cost/risk.
> 30%	Unacceptable	Instrument must be taken out of service immediately.

## 4. The PDCA Method

The **Plan-Do-Check-Act (PDCA)** cycle is the fundamental engine for driving and maintaining change.

- **Plan:** Understand the goal and define the measurement criteria.
- **Do:** Implement the change on a small scale or focus on the single most important root cause first.
- **Check:** Measure the results to see if the improvement was actually achieved.
- **Act:** If successful, standardize the activities. If not, develop a new plan based on the results.



## **Standardizing Gains**

Standardization allows a business to exploit "economies of process." By addressing root causes in descending order of importance, the organization achieves the most substantial gains first before moving to secondary issues.

w4.2- The Control Plan (6:15)

# Control Plan

- Assess policies
- Modify procedures
- Modify the quality plan
- Update pricing models and forecast
- Information systems
- Process map
- Training
- Mistake proofing



As we deploy control plans,

8

# Elements of the Control Plan

- Standardization
- Documentation
- Monitoring
- Detection
- Diagnosis
- Response

Let's discuss the elements  
of a sound control plan.



KENNESAW STATE  
UNIVERSITY

# Levels of the Control Plan

- Prototype
- Pre-launch
- Production

There are three phases  
of control plans.



# Dynamic Control Planning

- Combines many facets to:
  - Plan
  - Monitor
  - Control
  - Study
  - Maintain
- Living document



## Key Characteristics of Dynamic Control Planning

Unlike static plans that use fixed boundaries, a DCP is designed for flexibility and continuous improvement:

- **Adjustable Control Limits:** Instead of rigid  $\pm 3\sigma$  boundaries, limits are updated based on the actual, observed variability of the process over time.
- **Agility:** It allows managers to respond quickly to market shifts, new opportunities, or unforeseen process changes without having to rebuild the entire planning framework.
- **Integration with FMEA:** A truly dynamic plan is often linked directly to **Failure Mode and Effects Analysis (FMEA)**. As new risks are identified or existing risks change their RPN (Risk Priority Number), the control plan automatically shifts its monitoring focus.
- **Real-Time Data Usage:** Modern DCPs often leverage **AI and IoT** (Internet of Things) to process data at the "edge," allowing for near-instantaneous adjustments to manufacturing parameters.

# Gage Control Planning

- Facilitates proper control **of gages used in the process**
- Seeks to establish roadmap to minimize measurement variation
- Covers
  - Maintenance
  - Calibration
  - Proper handling



Gage control plan focuses

In Six Sigma, **Gage Control Planning** is the bridge between your Measurement System Analysis (MSA) and your daily operations. Its purpose is to ensure that the "ruler" you are using to measure your process remains accurate and precise over time.

If your gages aren't controlled, you might "adjust" a process that is actually fine, or "ignore" a process that is failing—simply because the measurement equipment drifted.

## Core Components of a Gage Control Plan

A robust plan for a Black Belt level includes several layers of verification:

- **Gage R&R (Repeatability & Reproducibility):** This is the baseline study performed to determine if the variation comes from the measurement device or the person using it.
- **Calibration Schedule:** Gages must be periodically compared against a known standard (NIST traceable) to correct for bias.
- **Stability Monitoring:** Using a control chart to measure a "standard" part every day to ensure the gage hasn't drifted due to wear, temperature, or humidity.
- **Preventive Maintenance:** Scheduled cleaning and part replacement for the measurement equipment itself.

# Standard Operating Procedures

- Step-by-step instructions for performing a single activity
- Describe how to perform as set of instructions
- Ensure
  - Consistency
  - Accuracy
  - Quality

Procedures define how  
we do it and help to



13

In Six Sigma, **Standard Operating Procedures (SOPs)** are the backbone of the "Control" phase in DMAIC. While the Control Plan tells you *what* to monitor, the SOP tells the operator exactly *how* to perform the task to ensure the process stays within those  $\pm 3\sigma$  boundaries.

Without a documented SOP, your process will naturally drift, leading to "special cause" variation that ruins your Six Sigma capability.

# Summation



As mentioned earlier, control plans are living documents.



In this final module of the Six Sigma Control phase, the focus is on the **Control Plan**—a living document that serves as a roadmap to bridge the gap between high-level organizational goals and the daily work performed by operators.

## 1. The Anatomy of a Control Plan

A control plan describes the **Critical to Quality (CTQ)** characteristics of a process. It ensures that monitoring metrics align with customer requirements and that process variation remains in check.

- **Strategy vs. Execution:** While the Control Plan is the high-level strategy, **Work Instructions** provide the specific "how-to" for operators.
- **Documentation:** Prevents "tribal knowledge" (informal, unwritten ways of working) by standardizing and entrenching improved processes across the organization.
- **Standardization:** Focuses on the four W's: **What** is measured, **When**, **Who** does it, and **How** it is measured.

## 2. Elements of Success: Detection to Response

A sound control plan requires a structured approach to identifying and fixing issues without overreacting.

- **Monitoring:** Detects changes early to ensure continued delivery of expected results.
- **Diagnosis:** Careful analysis **is required to avoid "knee-jerk" reactions** Overreacting to minor fluctuations can often make process variation worse.
- **Response Plan:** A documented set of next steps to be taken once an issue is detected, **specifying the actions**, the timeframe, and the responsible party.

### 3. The Three Phases of Control Plans

Control plans evolve through the lifecycle of a project or product:

Phase	Usage Context	Focus Areas
<b>Prototype</b>	Early development	Materials, basic measurements, and performance testing.
<b>Pre-launch</b>	Pilot/Trial phase	Frequent inspections, statistical analysis, and audits.
<b>Production</b>	Full-scale operation	Comprehensive process controls and finalized reaction plans.

## 4. Specialized Control Frameworks

Black Belts utilize several specialized tools to maintain long-term stability:

- **Dynamic Control Planning (DCP):** A holistic collection of "living" documents including SOPs, Control Plans, and FMEAs. It relies on operators to flag needed changes so training can stay current.
- **Gage Control Plan:** Targets the specific instruments used for monitoring. It serves as a guide for performance, upkeep, and contingency planning, though it is not a substitute for actual calibration.
- **Poka-Yoke:** The plan should seek ways to "mistake-proof" the system so that errors are either prevented or immediately obvious.

## 5. Sources of Control Information

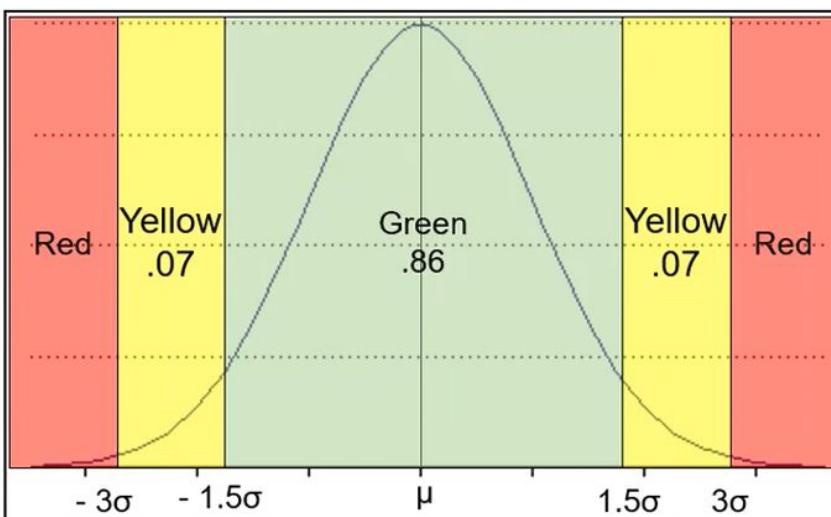
Control plans are synthesized from data and insights gathered throughout the Six Sigma journey, including:

- **Process Flow Diagrams** and **Fishbone Diagrams.**
- **FMEAs** (Failure Mode and Effects Analysis) and **QFDs** (Quality Function Deployment).
- **Design Reviews** and **Statistical Analysis.**

w4.3- Pre-Control (3:24)

Muss cover 3 sigma= + or -

## Pre-Control



The green zone captures 86% of all the data under the curve at plus or minus 1.5 sigma.



KENNESAW STATE  
UNIVERSITY

## 1. The Control Plan (Monitoring)

For a standard control plan using control charts (like an X-bar chart), we use **3 standard deviations** ( $\pm 3\sigma$ ) from the mean. 

- These are called **Control Limits**.
- Statistically, 99.73% of all data points will fall within these limits if the process is stable. If a point falls outside these  $3\sigma$  boundaries, it's a signal that your process is "out of control" and requires action. 

## 2. The Six Sigma Goal (Capability)

The "Six Sigma" name itself comes from the requirement that the **Customer Specification Limits** should be 6 **standard deviations** ( $\pm 6\sigma$ ) away from the mean. 

- This allows the process mean to shift by up to  $1.5\sigma$  over time (the "1.5 Sigma Shift") while still producing only 3.4 defects per million opportunities (DPMO). 

**In short:** You use  $3\sigma$  to define the boundaries of your daily control plan, but your process must be capable enough that the customer's limits are  $6\sigma$  away.

# Rules

- Rule 1: First part green, take no action, continue to run.
- Rule 2: First part yellow, check second part
  - If second part green, continue to run.
  - If second part yellow on same side , make adjustment
  - If second part yellow on opposite side, **STOP**
- Rule 3: Any part red, **STOP**. Go to rule 1.



Pre-control works under three rules.

In the context of your study materials, the diagram represents a **Pre-Control Chart**, which is a visual tool used to determine if a process should continue running or be stopped based on where samples fall relative to the standard deviation ( $\sigma$ ). 

## The Distribution Breakdown

The chart maps the normal distribution into three distinct regions to simplify quality control decisions:

- **Green Zone (The "Go" Zone):** This covers the center of the distribution from  $-1.5\sigma$  to  $+1.5\sigma$ . It captures **86%** of all data points under the curve. As long as your samples stay here, the process is considered stable and requires no adjustment.
- **Yellow Zones (The "Caution" Zones):** These are the "Pre-Control" areas located between  $1.5\sigma$  and  $3\sigma$  on both the high and low sides. Each yellow area represents about **7%** of the data (totaling 14%). Falling into this zone is a warning that the process mean might be shifting.
- **Red Zones (The "Stop" Zones):** These represent the tails of the distribution beyond  $3\sigma$ . If a data point lands here, it is a statistical signal that the process is out of control and must be stopped immediately.

w4.3- Pre-Control (3:24).mp4

# Pre-Control Statistics

Required Action	Yellow (.07)	Green (.86)	Yellow (.07)	Joint Prob.
None		A,B		0.7396
None	B	A		0.0602
None		A	B	0.0602
None	A	B		0.0602
None		A	B	0.0602
Adjust	A,B			0.0049
Adjust			A,B	0.0049
Stop	A		B	0.0049
Stop	B		A	0.0049



- cases which require action



KENNESAW STATE  
UNIVERSITY

### 3. Understanding the "Joint Probability"

The statistics slide shows why this method is effective—it minimizes "false alarms" while catching real issues:

- **Running smoothly:** There is a **73.96%** chance that both parts (A and B) will be Green, requiring no action.
- **Adjusting correctly:** The probability of getting two yellows on the same side (which triggers an adjustment) is only **0.0049**.
- **Stopping for variation:** The probability of getting two yellows on opposite sides (triggering a stop) is also **0.0049**.

By using these rules, you only intervene when there is a statistically significant reason to do so.

## Summation

- In pre-control, a process is considered “qualified” when 5 parts in a row are green.
- For a qualified process, the probability of decision error in pre-control is 2% (.0049+.0049+.0049+.0049).

Pre-control has trade offs with regard  
to precision compared to ease, but



This transcript introduces **Pre-control**, a highly visual and intuitive method for monitoring process quality directly on the factory floor. While it is rooted in statistical principles, it simplifies complex data into a "traffic light" system that operators can use to make immediate decisions.

## 1. The Pre-control "Traffic Light" Zones

Pre-control divides a normal distribution curve into three distinct colored zones based on standard deviations ( $\sigma$ ) from the mean.

- **Green Zone ( $\pm 1.5\sigma$ ):** Captures approximately **86%** of the data. This represents a process running smoothly.
- **Yellow Zone ( $1.5\sigma$  to  $3.0\sigma$ ):** Represents a warning area where the process may be starting to drift.
- **Red Zone (Beyond  $\pm 3.0\sigma$ ):** Indicates a high probability of defects. While the area under the curve here is very small, it is mathematically significant.

## 2. The Three Rules of Pre-control

Operators follow specific logic to determine whether to keep running, adjust, or stop the process based on part measurements.

Scenario	Resulting Action
Part is in the Green Zone	<b>Continue to run.</b> No action needed.
Part is in the Yellow Zone	<b>Check a second part immediately.</b>
Second part is Green	<b>Continue to run.</b> The first was likely a random outlier.
Second part is Yellow (Same side)	<b>Make an adjustment.</b> The process is drifting in one direction.
Second part is Yellow (Opposite side)	<b>Stop the process.</b> Variation is too high.
Any part is in the Red Zone	<b>Stop the process immediately.</b>

### 3. Statistical Validity

Pre-control is designed so that the probability of stopping the process unnecessarily is very low. Action is generally only required when the probability of the observed outcome falls below **0.005 (0.5%)**.

A process is considered "qualified" (ready for production) once **five consecutive parts** measure within the Green Zone.

## 4. Advantages and Trade-offs

Pre-control balances statistical precision with ease of use.

- **Pros:** Easy to deploy on the floor, empowers operators, and provides a clear visual signal for response.
- **Cons:** Slightly less precise than a full Statistical Process Control (SPC) chart; carries a decision error of about 2%.