A PROCESS CAPABILITY STUDY GUIDELINE FOR MEDTRONIC WORLDWIDE OPERATIONS

CORPORATE QUALITY AND STATISTICAL RESOURCES
April 1992

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CONTENTS

Introduction 3

What is a Process Capability Study?.....3

The Four Possible States of a Manufacturing Process.....4

The Role of Control Charts.....5

The Role of Design of Experiments.....7

Process Capability Indicies (Cp, Cpk).....9

Implementation Strategy.....12

Process Capability Study Flowchart.....14

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INTRODUCTION

A Process Capability Study (PCS) is an activity which helps us to understand a production process and to refine the process to the extent that it allows us to achieve our quality and cost objectives. To conduct the study and improve the capability of the process, we use some familiar analytical tools for quality improvement. The most successful Process Capability Study will utilize a wide variety of effective statistical principles. These include such fundamental concepts as process flow charts, cause-and-effect diagrams, Pareto analysis, control charts, and design of experiments.

Medtronic's emphasis on continuous quality improvement of its products and services and on achieving unsurpassed quality is well described in its Third Corporate Mission Statement. To continuously improve our products and services, we must continuously improve the processes which turn out these products and services. With Process Capability Studies, we intend to work towards the same mission.

Process Capability Studies also fit into our philosophy of Customer-Focused Quality. With PCS, we intend to increase the uniformity of process outputs which will result in more predictable processes. This will help sales people to promise deliveries only to the level we can manufacture while maintaining the highest quality.

This booklet provides guidance to conduct Process Capability Studies for Medtronic facilities. It describes some important concepts necessary to conduct good studies and also some pitfalls which should be avoided.

WHAT IS A PROCESS CAPABILITY STUDY?

A Process Capability Study is a sequential, analytical investigation aimed at determining the capability of a process, and identifying and reducing its major sources of variation. This investigation is pursued until the desired capability is achieved, or economic considerations dictate its end.

It should be noted that it is not merely determining the capability of a process but also effecting a change if necessary. A Process Capability Study improves a process by actively finding and eliminating the special causes that upset the process and/or identifying when action is required to reduce process variability.

HOW DOES IT DIFFER FROM PROCESS VALIDATION?

Often, process validation and process capability are thought to be the same activity. The objective of both activities is to ensure that a specific process will consistently produce a product that meets predetermined specification and quality attributes. They also share many of the analytical tools that are essential for process improvement. However, there are distinct differences in terms of the time at which these activities are performed and the degree of assurance one attains regarding the capability of the process. These differences are detailed in Table 1 on the opposite page.

Table 1
DIFFERENCES BETWEEN PROCESS VALIDATION AND PROCESS CAPABILITY STUDIES

	PROCESS VALIDATION	PROCESS CAPABILITY STUDIES
1.	It is a one time activity unless some change occurs in process, material, equipment, etc.	It is a continuous activity for improvement until it becomes economically unjustifiable.
2.	It stops when the process produces the required yields (outputs) with a prespecified degree of confidence.	It continues even after required yields are achieved.
3.	It gives the potential of the process as estimates are made based on a limited number of trial runs.	It gives the real capability of the process under normal operating or production conditions.
4.	The most challenging conditions of the process are deliberately generated for trial runs.	The most challenging conditions are not deliberately generated but occur sooner or later.
5.	Total validation includes equipment qualification, process performance qualification and product performance qualification.	It focuses only on process performance and in greater detail.

THE FOUR POSSIBLE STATES OF A MANUFACTURING PROCESS

A manufacturing process can be categorized into one of four possible states when both process performance and process stability are considered. The four possible states are described on the opposite page and are summarized below.

IS THE PROCESS IN A STATE OF STATISTICAL CONTROL?	IS THE PROCESS CAPABLE OF MEETING REQUIREMENTS 100% OF THE TIME? **Yes**	**No**
Yes	STATE 1 Control charts for monitoring	STATE 2 Requires changes to the system
No	STATE 3 Control charts to find and remove special causes	STATE 4 System changes and removal of special causes

THE FOUR POSSIBLE STATES OF A MANUFACTURING PROCESS

State 1:
A process running in this state is not only statistically stable over time, but is producing nothing but conforming product. This is an ideal state for any process.

State 2:
This process is statistically stable and predictable over time but produces some nonconforming product. Management or engineering action is needed to change the system to reduce variability and/or improve the process average.

State 3:
This is the most deceptive state because a process is producing nothing but conforming product yet it is out of control (unpredictable over time). A process in this state is being influenced by special causes of variability that may eventually change the process to the point of producing some nonconforming product. A process in this state is a signal of a potential impending crisis.

State 4:
The crisis state. This process not only produces nonconforming product, but the quantity of nonconformance is inconsistent over time. Further, the effect of needed modifications on process performance may be misinterpreted due to the presence of special causes of variability. The only solution to the problem is to identify and remove the special causes.

THE ROLE OF CONTROL CHARTS

The purpose of control charts is to determine when a process can be considered to be in a state of statistical control, i.e., the process is exhibiting a consistent pattern of variability over time. Such variability is considered to be inherent to the system.

Processes that contain more than the usual, predictable amount of variability are said to be out of control or unstable over time. The extra variability seen in these processes can be attributed to the existence of special or assignable causes acting on the system.

Control charts should be used to monitor a process so that action can be taken to find and remove special causes of variability as they occur. If a process is in statistical control, but is not capable of meeting specification requirements 100% of the time, then a change to the system is required.

IMPORTANCE OF RATIONAL SUBGROUPS

The way in which data is collected has the biggest impact on the ability of a control chart to detect the presence of special causes of variability. Subgroups should be chosen so that the items within a subgroup are as homogeneous as possible.

Factors suspected of contributing to special cause variability can be used to form the basis of subgrouping. Examples include different lots of material, different operators, different machines, or different days of production.

If time is chosen as the subgroup factor, then groups of consecutively produced items should be chosen. For example, if it is desired to sample four items from a process every hour, it would be better to sample four consecutive items from the process at the beginning of each hour rather than one item every fifteen minutes.

INTERPRETING CONTROL LIMITS AND SPECIFICATION LIMITS

Figure 1 on the next page shows an Xbar, R chart for a particular characteristic of a process. The subgroup factor was day of production with four readings taken per day for twenty consecutive days. This yielded a total of 80 observations. The average and range of the four readings for each day were computed and plotted on the average and range charts. The overall averages and control limits for each chart were then computed and added as solid lines.

For the Xbar chart, the grand average is 34.8 with upper and lower control limits of 42.7 and 26.9, respectively. For the R chart, the grand average is 10.8 with upper and lower control limits of 24.6 and 0.0, respectively. Because all of the points on each chart are within the control limits and there appear to be no obvious signs of nonrandom patterns, the process can be considered to be operating in a state of statistical control.

The control limits from the Xbar chart of a stable process give the natural limits of variability for subgroup averages. In this case, the process can be relied on to deliver average values for subgroups of four items between 26.9 and 42.7.

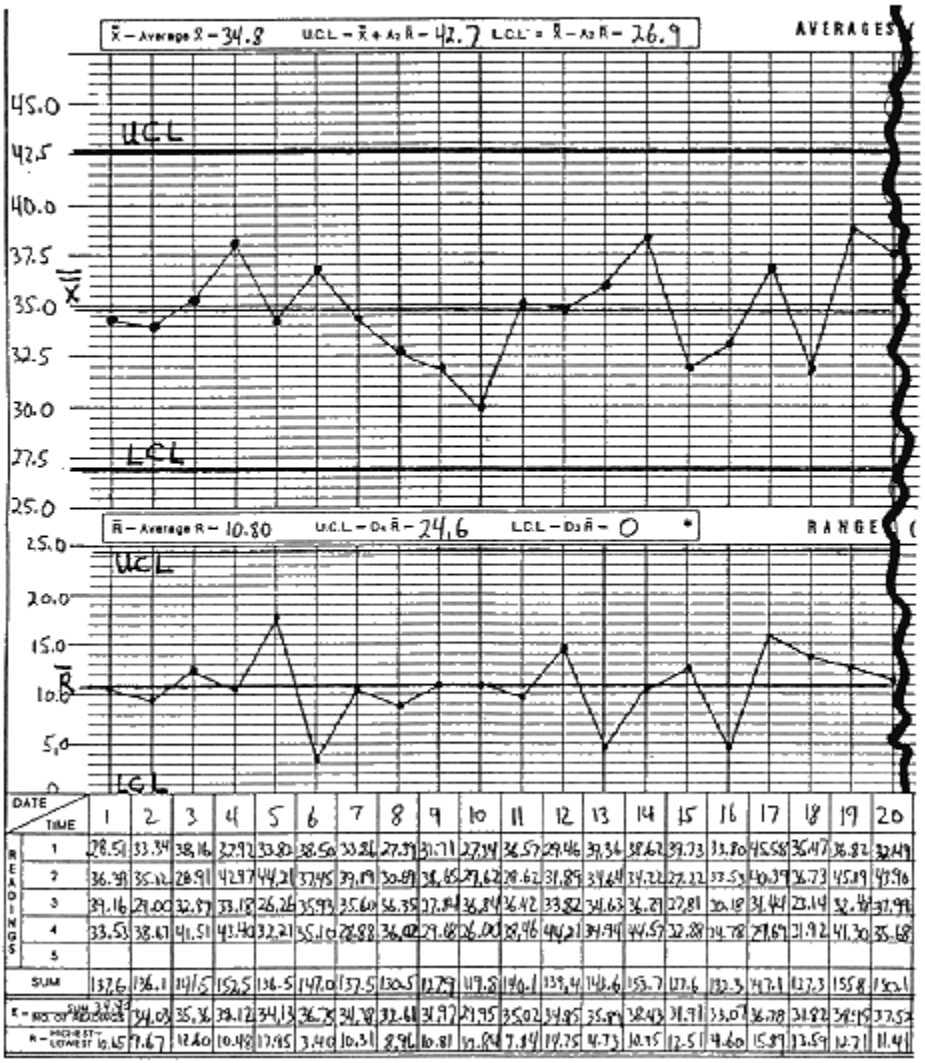
Note that the values of individual items will vary beyond the control limits. This is due to the fact that there is always less variability between sample averages than between individual observations. For this reason, specification limits should not be compared to control limits or placed on an Xbar chart.

Specification limits define the **desired** range of variability in **individual** items while control limits define the **expected** range of variability in subgroup **averages** based on actual process data. The calculation of control limits and the assessment of statistical stability are made without regard to specifications.

The best way to measure the natural variability in individual items is to compute the standard deviation of all observations. This measure is then used to determine the capability of the process to produce individual items that meet the specification requirements.

Figure 1

CONTROL CHART EXAMPLE



THE ROLE OF DESIGN OF EXPERIMENTS

The goal of planned experimentation is to increase our knowledge of a process by studying the effects of factors on process performance. Increasing the understanding of how various factors contribute to the total amount of variability in a process will ultimately lead to a more consistent and predictable process.

If a control chart indicates that a process is out of control, it is imperative to discover the factors that are causing the additional variability. Many times, people working in the process will suspect or know the cause of specific out of control points (a broken machine, uncalibrated instrument, or defective material). Other times, there may be no obvious reason for the out of control condition. In these cases, investigative work is needed to uncover the cause.

Use of brainstorming and a cause-and-effect diagram with a team of people familiar with the process is a good start. The variability of the output of a process is the "effect" of interest and is caused by the variability in the inputs to the process. Five main categories of inputs are method, manpower, material,

equipment, and environment. In addition, the measurement system used should be checked to ensure that valid data is being collected and analyzed.

Some factors from the cause-and-effect diagram will be easy to control, e.g., the settings of a machine, while others are more difficult, e.g., "noise" factors such as the temperature and humidity in the production area. Design of experiments techniques can be used to quantify the impact of both control and noise factors. Ideally, settings for the control factors should be found that minimize the effects of the noise factors. This is the central theme of Taguchi's parameter design philosophy.

DETERMINING THE COMPONENTS OF VARIATION

If a process is determined to be operating in a state of statistical control, then improvements to the process will occur when the amount of common cause variability is reduced. This is typically difficult to accomplish because the variability in the process output is not due to just one or several large factors, but probably due to many small factors associated with the process.

The total amount of variability observed in a stable process, represented by σ_{total}, can be considered to be made up of many components. The relationship is as follows:

$$\sigma_{total} = \text{SQRT} [\sigma^2_{CauseA} + \sigma^2_{CauseB} + \sigma^2_{CauseC} + \ldots]$$

One of the components of variability may be due to the measurement system itself. If measurement error is found to be a large percentage of the total variation, then this component must be reduced before proceeding with an effort to reduce the variability due to other sources.

The variation in observations from an instrument used to measure a series of production items is due to two sources: (1) the variation due to the measuring method, and (2) the variation in the product itself. This relationship is as follows:

$$\sigma_{total} = \text{SQRT} [\sigma^2_P + \sigma^2_E]$$

where σ_P = standard deviation of the product
σ_E = standard deviation of the measuring method

To obtain an estimate of σ_E, we can repeatedly measure the same item and compute the standard deviation of all observations. Then, since σ_{total} can be estimated from the control chart data, we can use the equation above to solve for σ_P the true amount of variation in the product.

PROCESS CAPABILITY INDICES

For processes that are in control, the grand average of all observations is used to estimate the process mean. Similarly, the standard deviation of all observations (σ) is used to estimate the natural process spread or variability.

A process can be in statistical control and still not be capable of meeting either the upper specification limit (USL) or the lower specification limit (LSL). This occurs when the process spread is too large or the process mean is off target (see Figure 2). To summarize the capability of a stable process, two measures are commonly used: Cp and Cpk.

$$\mathbf{Cp = (USL - LSL) / 6\sigma}$$

$$\mathbf{Cpk = (USL - Process\ Mean) / 3\sigma}$$
or
$$\mathbf{(Process\ Mean - LSL) / 3\sigma}$$
whichever value is smaller

Cp is a measure of the potential capability of a process. Cp is not concerned with the location or aim of a process, just the total amount of variability as measured by 6 σ. A Cp value greater than 1.0 indicates that the total amount of process variability is less than the width of the specification limits.

Cpk directly accounts for the location or aim of a process. Cpk is a prediction of the proportion of nonconforming units produced by a process. Table 2 gives the process fallout in parts per million (PPM) for various Cpk values. The Cpk goal for a critical process should be 1.33, or greater, which equates to a defective rate of 64 PPM or less.

Both Cp and Cpk indices explicitly assume that the process under study follows a normal distribution and is operating in a state of statistical control.

Figure 2

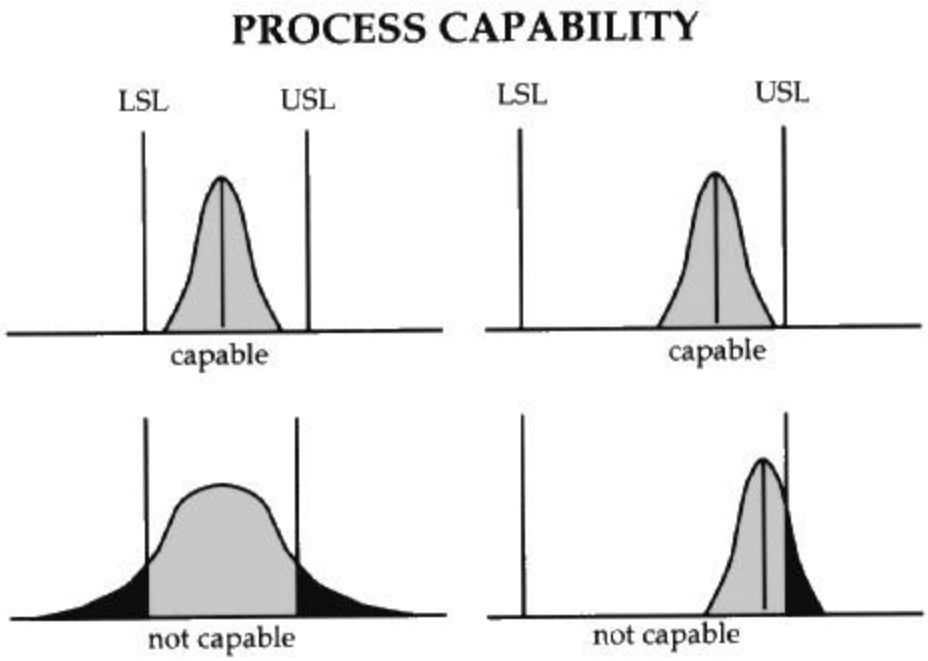


Table 2

THE RELATIONSHIP BETWEEN Cpk AND PPM

Cpk	Maximum Process Fallout (in defective PPM)
.50	133614
.60	71861
.70	35729
.80	16395
.90	6934
1.00	2700
1.10	967
1.20	318
1.30	96
1.40	27
1.50	7
1.60	1.6
1.70	0.3

COMMON PITFALLS

1. Inadequate Sample Size

Sampling variability should be considered when interpreting a Cpk value. For instance, a Cpk value of 1.0 computed using 100 data points is more reliable that a Cpk value of 1.0 computed from only 30 data points.

The reliability of larger sample sizes can be quantified. The 95% lower confidence bound for a Cpk value of 1.0 computed from 30 data points is 0.72. For a sample of size 100, the lower bound is 0.85. Because sampling variability can be large for small samples, a sample size of at least 100 is recommended before Cpk is used as a measure of process performance.

2. Computation of Standard Deviation (σ)

There are two methods to estimate σ (and thus Cp and Cpk):

1) $\sigma \approx S = R/d_2$ based on control chart data (least accurate)
2) σ calculated from all data merged together (more accurate)

These two procedures will produce different estimates for σ. The difference arises because the first method only accounts for the variability within subgroup samples while the second method includes additional variability observed between subgroup samples over time. Unless the process is in a perfect state of control, the second method will produce a larger estimate of σ, and thus smaller values of Cp and Cpk.

The actual variation in the overall process output (the variation that customers must live with) is the sum of the within subgroup and the between subgroup variation. Thus, the second method above should be used when calculating Cp and Cpk.

3. Failure to Check Assumptions

Estimates of the process mean and spread are required to compute Cpk. It is easy to collect a sample of data in one "snapshot" of time and compute the sample mean and standard deviation to determine the Cpk. Values of Cpk obtained in this manner may be misleading for several reasons.

a) If the process does not follow a normal distribution, then the predicted process fallout could be significantly higher than that shown in Table 2. While there is no need to be rigorously concerned about normality, we should at least check for a gross violation of this assumption.

b) If the sample is collected in a very short period of time under uniform processing conditions, then the sample standard deviation is likely to underestimate the actual process spread, σ. This would cause Cpk to be artificially inflated.

c) Cpk represents a prediction of how much acceptable product a process will consistently provide over time. By definition, a process that is out of statistical control is unpredictable. Therefore, a Cpk value computed for a process that is not stable over time is meaningless.

IMPLEMENTATION STRATEGY

STAGE 1: PROCESS CHARACTERIZATION

The first stage in a Process Capability Study is the process characterization. The purpose of this stage is to thoroughly describe the process to be studied. This requires the following steps:

a) Map out the process flow.
b) Identify input and output variables.
c) Rank all potential key process variables.
d) Determine appropriate measures and customer specifications.
e) Determine measurement method and its reliability.

STAGE II: CAPABILITY DETERMINATION

The objective of this stage is to determine and quantify the ability of the process to produce product within the specification limits (tolerance). This is done by determining capability indices (Cpk) and the process potential (Cp) for each response (output) variable being studied. At this stage, a knowledge of statistics is essential to understand the shape of the sample distribution, and interpret the control charts for detecting nonrandom patterns. The following are the major steps in this stage:

a) Set process to a known optimum condition.
b) Collect data on response variables.
c) Determine the state of control using control charts.
d) Determine capability indices (Cp, Cpk) and compare to the predetermined goals.

During this stage, we may observe the process to be out-of-control or to have unsatisfactory Cp or Cpk values. If this occurs, we need to proceed to the next stage of optimization.

STAGE III: OPTIMIZATION AND EXPERIMENTATION

Optimization is the most important stage because it focuses on reducing the amount of variation encountered in the previous stage. Statistically designed experimentation is the primary tool to identify the input variables that have a significant effect on reducing variability and to determine the optimum levels that produce the most desirable outputs. Major steps for this stage are:

a) Evaluate the characteristics of variation and develop theories which may explain the cause of variability.
b) Conduct planned experiments to evaluate the theory.
c) Interpret the results and make changes in the process.
d) Validate the decision to gain a high degree of confidence.

STAGE IV: PROCESS CONTROL

After the process is determined to be stable (Stage II) and optimized (Stage III), it is necessary to put preventive controls into the process. By this stage, we have obtained considerable knowledge about the process and the information can be transferred to production and to the operators. The critical response variables are monitored and controlled through control charts. The following steps are suggested:

a) Identify critical variables to monitor.
b) Set up control charts for preventive control.
c) Complete the documentation of the Process Capability Study.

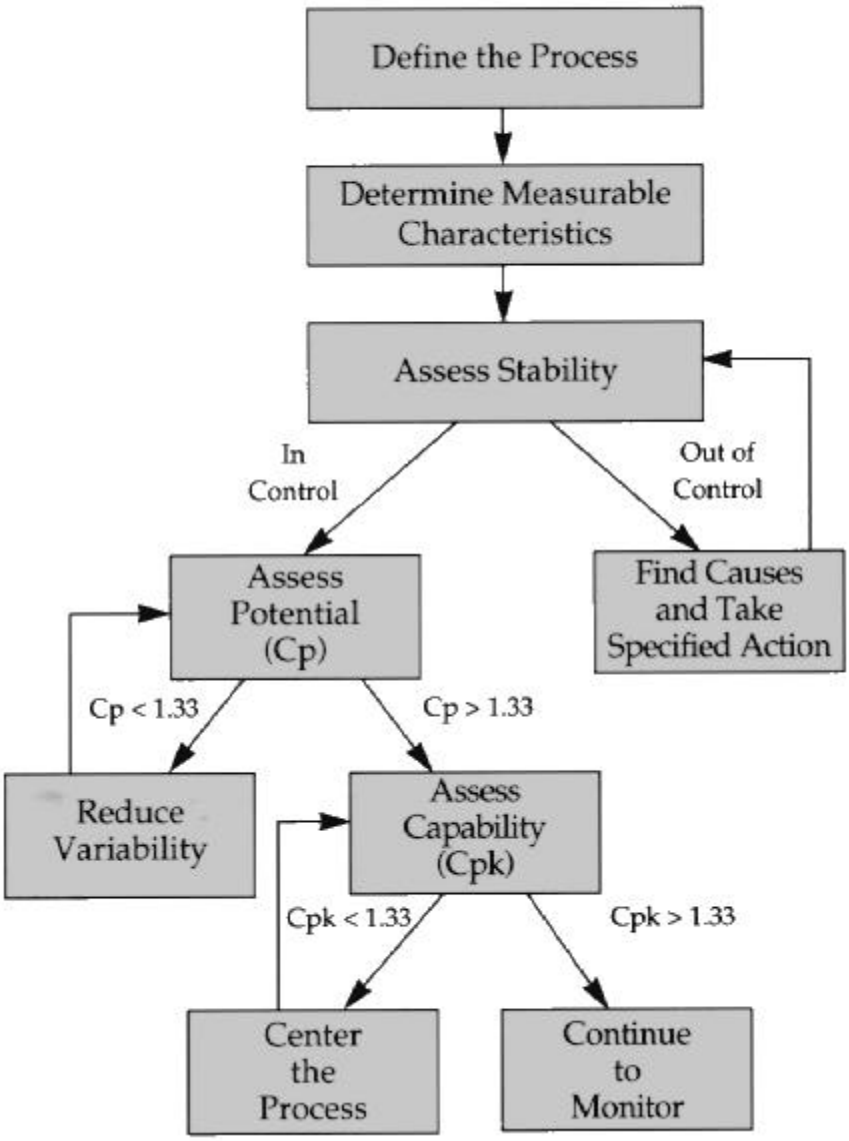
The life cycle of a Process Capability Study is summarized in Table 3.

Table 3

LIFE CYCLE OF A
PROCESS CAPABILITY STUDY

Stage	Step	Method
Preparatory	• Identify the process of interest • Assemble a team	• Relate to quality system • Team-building
Process Characterization	• Map out process flow • Detail all process variables, response variables • Rank critical process variables • Determine appropriate measure and measurement accuracy	• Brainstorm • Process flow diagram • Cause-and-effect diagram • Pareto chart • Engineering / customer specs
Capability Determination	• Set process to known optimum conditions • Determine state of control • Determine process capability	• Historical knowledge • Control charts • Capability Indices
Optimization	• Evaluate the characteristic of variation • Conduct planned experiments to quantify source of variation • Make changes to improve • Validate	• Look for patterns • DOE • Taguchi design • Increase statistical confidence
Control	• Identify variables to monitor • Implement control charts	• Monitor control charts • Log actions taken
Documentation	• Document study result	

PROCESS CAPABILITY STUDY FLOW CHART



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UC9201442EN

Converted to Electronic Format
June 6, 1996 by G. Bristol