# Statistical Procedures

Mo/Yr



| Revisions | | Rev: | |
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| Letter | E.O. Number - Description | Date | |
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| Used On | Contract#: | | **Your Company Name** |
|---|---|---|---|
| Prepared By: | | Date | |
| [redacted] | | [redacted] | **POLICIES AND PROCEDURES** |
| | | | Your Procedure # |
| | | [redacted] | Form Rev: Orig |



Your Company Logo

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## 1.0 Scope

Describe a process for systematically evaluating or reducing variation of key process and product characteristics. Begin by addressing obvious sources of variation and progressively move to more subtle sources. Continue variation analysis or reduction until a key characteristic is in statistical control and capable of meeting engineering requirements, or is determined to be 'state-of-art' with inherent variation that is not capable of statistical control.

## 2.0 Goals

Implement procedures that allow for the determination and measurement of key process and product characteristics, and ensure that action is taken when a key characteristic is not in-control, or a record of analysis is available that determined that a characteristic is not capable of control.

## 3.0 Referenced Documents

3.1 Figure 1, Statistical Process Implementation Matrix
3.2 Figure 2, Statistical Process Plan, (Your #)
3.3 ASQ Quality Engineering

## 4.0 Statistical Planning

### 4.1 Statistical Process Implementation Matrix

Figure 1 shows the step-by-step process and documentation requirements for implementation of statistical process control. Any equivalent process or documentation that achieves these requirements may be used.

### 4.2 Statistical Process Plan

Figure 2, the Statistical Process Plan, is the collector of all relevant information on a process or product. The information on this form, or equivalent form, serves as the basis for a database.

## 5.0 Requirements

### 5.1 Key Characteristics

A **key characteristic** is a product or process variable that can be directly manipulated to achieve an engineering requirement. Key characteristics are viewed as changeable over time, with some characteristics dropped from the 'key' category, while others are added. If a Customer has not identified key characteristics of a product or process, (Your Co) is responsible for [redacted]

### 5.2 Collect Data to Determine Key Characteristics

Collecting information pertinent to the process or product is the first step in identifying key characteristics. Data collected should be relevant to [redacted]

This data may include [redacted]

## 5.3 Establish Key Characteristics

There are no set rules for establishing key characteristics. Even if a feature is not identified as a key characteristic, that feature will still receive the same attention it has historically. Features designated 'key' receive special attention and do not diminish the importance of other characteristics. [redacted]

## 5.4 Document Key Characteristics and Engineering Requirements

The Statistical Process Plan shown at Figure 2 is the collector of all information needed to assure control of key characteristics. The key characteristic identified by (Your Co) or its Customer must be documented on the Process Plan. In the column designated Characteristic, the **key characteristic** is [redacted]

## 5.5 Determine Process Steps Where Key Characteristics are Measured

Before measurements can be taken on the key characteristic, it must be decided where in the manufacturing flow the measurements will be taken, and [redacted]

## 5.6 Select Appropriate Control Charts

Evidence of variation in the key characteristic must be shown using control charts with variable data if at all possible. Only if variable data cannot be established may attribute data be substituted. Use of attribute data will [redacted]

**Variable data** is quantifiable. It can be put on a numeric scale. Examples are: [redacted] The most common control chart is Shewhart's X-bar and R chart.

**Attribute data** is 'go/no-go' data. The key characteristic passes or fails; [redacted]

### 5.6.1 Acceptance Chart

When the question of 'in-control' is not relevant or has very little value, acceptance charts which are standardized in such a fashion that ongoing process monitoring can be done on a single chart is considered, similar to the [redacted]

## 5.7 Document Process Steps, Control Charts, Sample Size and Frequency

Once the appropriate control chart has been selected, the next step is to establish the sample size and sampling frequency. Sample size is the number of measurements per plot point on the control chart. To ascertain the control and capability of a key characteristic when no existing data is available, the [redacted]

## 5.8 Collect Measurements and Maintain Control Charts

Once in production, measurements on the key characteristics must be collected and control charts maintained. Samples must be taken in such a manner that [redacted]

[redacted]

## 5.9 Is the Key Characteristic in Statistical Control?

Statistical control is determined directly from the control chart being used to monitor the key characteristic. All control charts place statistical limits upon the natural (common cause) variation of a process. These limits are called control limits. [redacted]

## 5.10 Does the Key Characteristic Meet Minimum Capability?

Once a key characteristic is in statistical control, its capability can be established.
An index called Cpk is used to determine if the capability is sufficient to meet engineering specifications. A key characteristic will be considered capable if [redacted]

## Cpk Table

| Number of Measurements Taken | 90% Probability That True Cpk Equals or Exceeds | | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|
| | 1.00 | 1.10 | 1.20 | 1.30 | 1.40 | 1.50 | 1.60 | 1.70 | 1.80 | 1.90 | 2 |
| 250 | | | | | | | | | | | |
| 200 | | | | | | | | | | | |

The values in the above table are the calculated Cpk values required to be 90% confident that the actual Cpk is greater than or equal to the Cpk value at the top of the respective column. The values listed in the column titled 'Number of Measurements Taken' are the actual number of measurements, not the numbers of plot points. The table assumes [redacted].

Examples: If 30 parts are measured and the required Cpk is 1.0, the calculated Cpk from the 30 parts needs to be at least 1.23 - if 20 parts are measured and the calculated Cpk is 1.91, the actual Cpk is between 1.40 and 1.50.

If attribute data is used, then capability is measured in terms of [redacted]

[redacted]

## 5.11 Can Special Causes of Variation be Assigned?

If an out-of-control condition arises, the question 'What has changed?' should be asked; not, 'What has gone wrong?'. A control chart tells where and when the change took place. If a reason can be assigned to these special causes of variation, then they can be [redacted]

## 5.12 Remove Special Causes of Variation

Corrective action consists of [redacted]

## 5.13 Collect New Measurements

Once a special cause of variation has been assigned and removed, new measurements must be collected. [redacted]

## 5.14 Has Gage Variation Study been Performed and Documented?

If the measurement system has been analyzed by conducting a gage variation study, and results have been documented on the Process Plan, then other potential sources of variation should be addressed. If not, a gage variation study must be performed and documented on the Process Plan. Because the measurement system is frequently found to be a major source of variation, a gage variation study should be performed before any measurements are collected.

## 5.15 Perform Gage Variation Study and Document Results on the Process Plan

Poor measurement systems reduce the ability to demonstrate control or capability and make investigation into the sources of variation difficult. Therefore, a measurement system that provides accuracy, repeatability, reproducibility, and stability should be used.

Before investigating common cause variation, [redacted]

## 5.16 Was Corrective Action Taken on the Measurement System?

The decision to take corrective action on the measurement system is not mandatory. It is suggested that the measurement system consume no more than [redacted]

## 5.17 Identify Potential Sources of Process Variation

Sources of common cause variation can be found by investigating all of the processes that are relevant to the manufacture of a **key characteristic**. Variation within these relevant processes is [redacted]

## 5.18 Correlate Sources of Process Variation With the Key Characteristic

Based on experience, rejection history, or other historical information, relevant processes should be prioritized according to [redacted]

the remaining common cause variation. One option is to [redacted]

## 5.19 Establish Controls for Key Process Parameters

It is necessary to establish controls that will ensure that the **key process parameters** and their settings do not change. Controls may be in the form of [redacted]

## 5.20 Document Operation, Key Process Parameters, Settings and Control Method

Each **key process parameter** must be documented on the Process Plan. The name and operation number of the pertinent manufacturing process should be recorded in the column titled Process Name and Op #. Key process parameters, their settings, and the control method used to monitor them must also be documented in the appropriate columns. [redacted]

## 5.21 Update Process Database or Historical Records

The results of the correlation study and data contained on the Process Plan must be placed in a permanent record system for future use. The preferred database is an automated system that is conducive to digital processing and analysis. The following data should be stored:

[redacted]

## 5.22 Statistically Estimating Required Samples

When the sigma of a population is known, a means to estimate the number of samples to measure that will provide 95% confidence in the sample measurement is given by:

[redacted]

The results may be too high to be of economic value. This sampling calculation can be used to determine a [redacted]

## 5.23 Evaluating Outlying Data Points

Reject outlier(s) from a set of data if [redacted]

## 5.24 Pooled Standard Deviation

When a large population of samples cannot be easily obtained, an estimate of sigma can be calculated that is superior to the value from any individual subset. To obtain a pooled estimate of sigma, deviations from the mean for each subset of samples are [redacted]

$$\sqrt{[\text{redacted}]^2}$$

| # of Samples | Value Obtained | Mean | $\Sigma(x-\bar{x})_i^2$ |
|---|---|---|---|
| [redacted] | [redacted] | [redacted] | [redacted] |

## 5.25 Bias Problems in Process Monitoring

Avoid unpleasant surprises in production by (a) [redacted] and (b) [redacted] Employ the following suggestions:

1) [redacted]

2) [redacted]

3) [redacted]

## 5.26 Chemical Batch Process Capability

Establish written procedures for every task to ensure that all employees conduct the task in the same manner. Maintain checklists for batch and equipment preparation. Determine each solution's key parameter analysis capability using [redacted]

## 6.0 Example Implementation Routine

## 6.1 Training Plan

Training includes:

[redacted]

[redacted]

## 6.2 Systematic Process

**Step 1: Identification**

Define the process using Figure 1 and Figure 2, Statistical Process Planning Records

**Step 2: Performance Measurements**

Measure performance in quality, productivity and schedule.

Measure success level relative to time that reflects the criteria sighted in the project using a simple graph.

**Step 3:** [redacted].

**Step 4:** [redacted]

**Step 5:** [redacted]

**Step 6:** [redacted]

**Step 7:** [redacted]

[redacted]

**Step 8:** [redacted]

**Step 9:** [redacted]

**Step 10:** [redacted]

## 6.3 Quality Targets

Establish individual workstation targets in percent defect, number of defects/100 or PPM defects.
Compare actual results against targets.
Take action when actual results exceed targets in an unfavorable direction. Revise target when achieved to further improve process.

Figure 1: SPC Implementation Matrix

| | Management | Steering Committee | SPC System | SPC Training | SPC Analysis | Improvement | Prevention | Suppliers | Pro-gress |
|---|---|---|---|---|---|---|---|---|---|
| 10 | SPC in all business operations? | Customers receive reports? | Are teams defined? | Training ongoing? | Reviews ongoing? | Processes charted? | Equipment capable? | SPC a contractual req'mt? | Row 10 done? |
| 9 | Suppliers involved? | Teams provide reports? | SPC Plan current? | 75% of personnel trained? | All processes subject to analysis? | 90% Ops Cpk >1<br>80% f >2 | Maintenance schedules exist? | SPC impacts purchases? | Row 9 done? |
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Figure 2: Sample Statistical Process Plan