Statistical Procedures

Mo/Yr

Revisions		Rev:	
Letter	E.O. Number - Description	Date	

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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 [redacted] Continue [redacted] until [redacted] capable of meeting [redacted], or is determined to be [redacted]

2.0 Goals

Implement procedures that allow for [redacted], and ensure that [redacted] 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 [redacted]

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 [redacted]

5.0 Requirements

5.1 Key Characteristics

A **key characteristic** is a product or process variable that [redacted] has not identified key characteristics of a product or process, [redacted]

5.2 Collect Data to Determine Key Characteristics

Collecting information pertinent to the process or product is [redacted] relevant to Form, Fit, Performance, and Service Life.

This data may include [redacted] a likely candidate as a key characteristic. Knowledge of a part's intended use and [redacted]

5.3 Establish Key Characteristics

There are no [redacted] appropriate tools for [redacted] The fewer key characteristics [redacted] may be necessary for [redacted] such as an [redacted]

5.4 Document Key Characteristics and Engineering Requirements

The Statistical Process Plan shown at Figure 2 is the collector of all information [redacted] associated with the key characteristic, e.g., 210 Vickers Hardness, is [redacted]

5.5 Determine Process Steps Where Key Characteristics are Measured

Before measurements can be taken [redacted] it must be decided where [redacted] possible, the collection of [redacted] key characteristic. If an item is to be manufactured for the first time, a [redacted] should be developed. For items already in production, [redacted] should be taken. Process flowcharts are [redacted] into a library for future use.

5.6 Select Appropriate Control Charts

Evidence of variation in the key characteristic must be shown using control charts [redacted] Only if variable data cannot be [redacted] will penalize the user because [redacted]

Variable data is quantifiable. It can be put on a numeric scale. Examples are: [redacted]

Attribute data is 'go/no-go' data. The key characteristic passes or fails; has a defect or doesn't have a defect. Common control charts used are [redacted]

5.6.1 Acceptance Chart

When the question of 'in-control' is not relevant or has very little value, acceptance charts [redacted] can be done on a single chart is considered, similar to [redacted] These charts are applicable when the inherent process variation is [redacted]

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

Once the appropriate control chart has been selected, the next step is [redacted] Once statistical control has been achieved and the capability requirement met, then [redacted]

5.8 Collect Measurements and Maintain Control Charts

Once in production, measurements on the key characteristics must [redacted] Copies of control charts, each Process Plan, and supporting documentation must [redacted]

[redacted]

5.9 Is the Key Characteristic in Statistical Control?

Statistical control is determined directly from the control chart being used to [redacted] All control charts place statistical limits upon the natural (common cause) variation of a process. These limits are called control limits. At least [redacted] Once established, these limits should not be recalculated unless [redacted] For any given period of time, a **key characteristic** will be considered in statistical control if [redacted] When a **key characteristic** is not in control, special causes [redacted]

5.10 Does the Key Characteristic Meet Minimum Capability?

Once a key characteristic is in statistical control, its capability can be [redacted] used to determine [redacted] 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	[redacted]										
200											
150											
125											
100											
90											
80											
70											
60											
50											
46											
42											
38											
34											
30											
28											
26											
24											
22											
20											

The values in the above table are the calculated Cpk values required to be [redacted]

The values listed in the column titled 'Number of Measurements Taken' are the actual number of measurements, not the [redacted] 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 [redacted]

If attribute data is used, then capability is measured in terms of the proportion of defective units. To meet an equivalent Cpk of 1.0, the maximum acceptable proportion of defectives is [redacted] If the key

characteristic cannot demonstrate capability, then the next course of action is [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, [redacted] A control chart tells [redacted] If a reason can be assigned [redacted] then they can be [redacted] Conditions in the manufacturing system that are contributing toward assignable causes of variation must [redacted]

5.12 Remove Special Causes of Variation

Corrective action consists of [redacted] Commonly, the process operator readily [redacted] An operator log of changes [redacted] should be [redacted] This often sheds light on the special causes. A frequent special cause of variation is [redacted]

5.13 Collect New Measurements

Once a special cause of variation has been assigned [redacted] Out-of-control points must [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 [redacted]

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 [redacted] Therefore, a measurement system that provides [redacted] should be used.

Before investigating common cause variation, [redacted] must be determined. This is done by performing a [redacted]

5.16 Was Corrective Action Taken on the Measurement System?

The decision to take corrective action on the measurement system is [redacted] It is suggested that the measurement system consume no more than [redacted] Corrective action may consist of [redacted] Types of corrective action for measurement systems include: [redacted] If corrective action was taken, the Process Plan must be updated to show changes. New measurements must [redacted]

5.17 Identify Potential Sources of Process Variation

Sources of common cause variation can be found by [redacted] Variation within these relevant processes is influenced by [redacted] Tools such as [redacted] should be used to systematically identify and [redacted] This record should be available for audit. A cause and effect diagram graphically portrays the relationship between [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 [redacted] When feasible, control charts should be [redacted] Elimination of out-of-control conditions in processes may [redacted]

[redacted] One option is to make [redacted] Such changes can [redacted] The preferred option is to use statistically designed experiments (DOE). They are a much more powerful tool and may, in the long run, cost less than the option discussed above. Experimental design is a tool suited to [redacted] Designed experiments should be conducted until [redacted] Perceived process improvements gained through experimentation should be confirmed by [redacted] If all sources of variation have been accounted for, process settings 'optimized' through statistically designed experiments, and the key characteristic is still out-of-control or not capable, then the process or product is identified as [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] Though control charts, in and of themselves do not 'control' processes, they are [redacted] By controlling these process parameters, operators can [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 [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]

It is expected that operators will use this database in pre-production planning activities to [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]

Some discretion must be used when a sampling plan is derived using these formulas. The results may be [redacted] If a periodic measurement needs to be made and no rationale exists to estimate the sampling frequency, then [redacted]

5.23 Evaluating Outlying Data Points

Reject outlier(s) from a set of data if $Q_{exp} > Q_{crit}$; where Q_{exp} = [redacted] [x_q is the questionable data point; x_n is the next highest data point in the set; w is the spread or range of the entire set (from W.J. Dixon, Ann. Math. Stat. 1951 - 22, 68)]

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]

The pooled sigma is obtained by [redacted]

$$\sqrt{\frac{\text{[redacted]}(\text{[redacted]})_i^2}{n-i}}$$

# of Samples	Value Obtained	Mean	$\sum(\times-\overline{\times})_i^2$
[redacted]	[redacted]	[redacted]	[redacted]
[redacted]	[redacted]	[redacted]	[redacted]
[redacted]	[redacted]	[redacted]	[redacted]
[redacted]	[redacted]	[redacted]	[redacted]
[redacted]	[redacted]	[redacted]	[redacted]
[redacted]	[redacted]	[redacted]	[redacted]
[redacted]	([redacted]) [redacted]	([redacted])^2 [redacted]	[redacted]^2 [redacted]
[redacted]	[redacted]	[redacted]	[redacted]
[redacted]	[redacted]	[redacted]	[redacted]
[redacted]	[redacted]	[redacted]	[redacted]
[redacted]	[redacted]	[redacted]	[redacted]
[redacted]	[redacted]	[redacted]	[redacted]
[redacted]	[redacted]	[redacted]	[redacted]
[redacted]	[redacted]	[redacted]	$\sqrt{\frac{.83+.83+.83+1.33+74+.83}{27}}$ [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]

[redacted]

6.3 Quality Targets

Establish individual workstation targets in [redacted]

Compare actual results against targets.

Take action when [redacted]

Figure 1: SPC Implementation Matrix

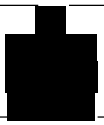
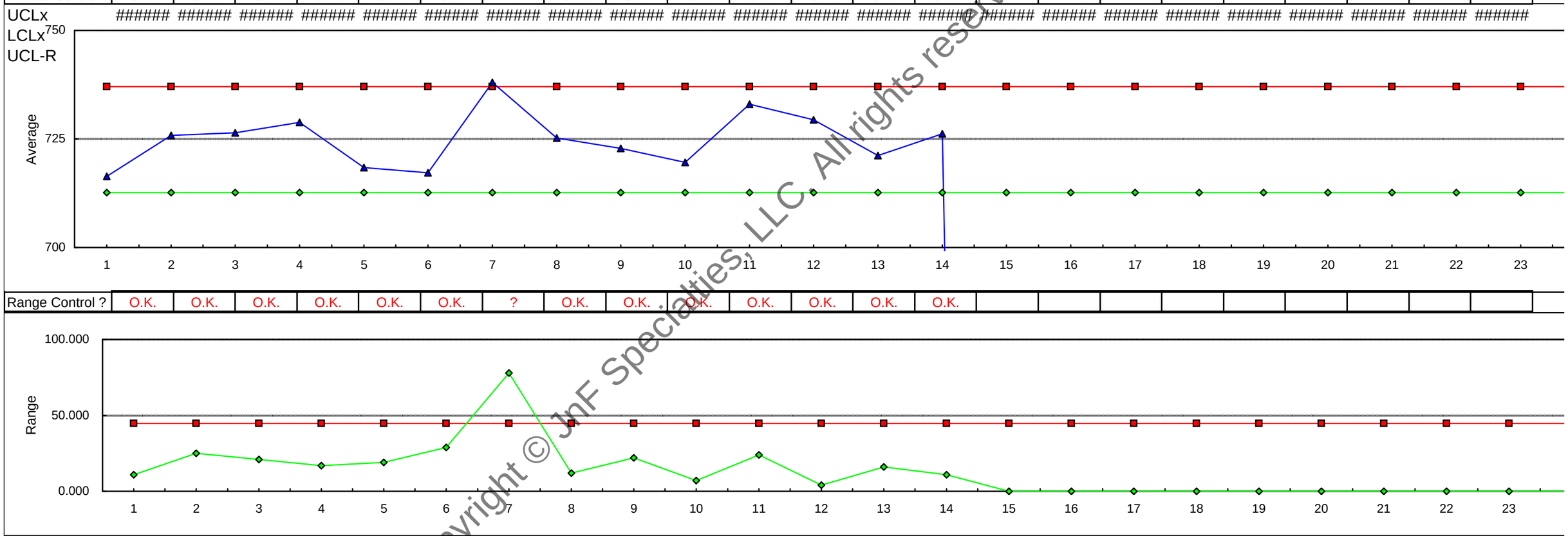
10									
9									
8									
7									
6									
5									
4									
3									
2									
1	Mgmt support?	Members selected?	System being developed?	Training package chosen?	Pareto's performed?	Some data analyzed?	Routing tickets used?	Supplier's providing data?	Row 1 done?
0	No knowledge	No Committee	No system	No SPC training.	No Pareto's	No techniques	No prevention	No effort	No pro-gress.

Figure 2: Sample Statistical Process Plan

Part/Process:				Operator:	
Part/Process #:		Rev:		Date:	Your # (mo/yr)

Week #	1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17	19	18	19	20	21	22
Comments:	**Daily Calibration**						**Serviced Equip**																
End of Week:																							
Operator:																							
Sample 1	723	713	723	732	716	703	793	728	734	718	725	731	726	728									
Sample 2	712	729	726	731	712	717	722	724	726	718	723	730	720	731									
Sample 3	719	738	719	732	709	716	724	729	715	723	747	731	712	726									
Sample 4	712	724	724	733	728	732	715	717	727	723	736	727	720	726									
Sample 5	716	725	740	716	727	718	736	728	712	716	734	728	728	720									
Sum:	3582	3629	3632	3644	3592	3586	3690	3626	3614	3598	3665	3647	3606	3631									
Average: (x)	716	726	726	729	718	717	738	725	723	720	733	729	721	726									
Range - R	11	25	21	17	19	29	78	12	22	7	24	4	16	11									
Xbar Control ?	O.K.	O.K.	O.K.	O.K.	O.K.	O.K.	?	O.K.	O.K.	O.K.	O.K.	O.K.	O.K.	O.K.									



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