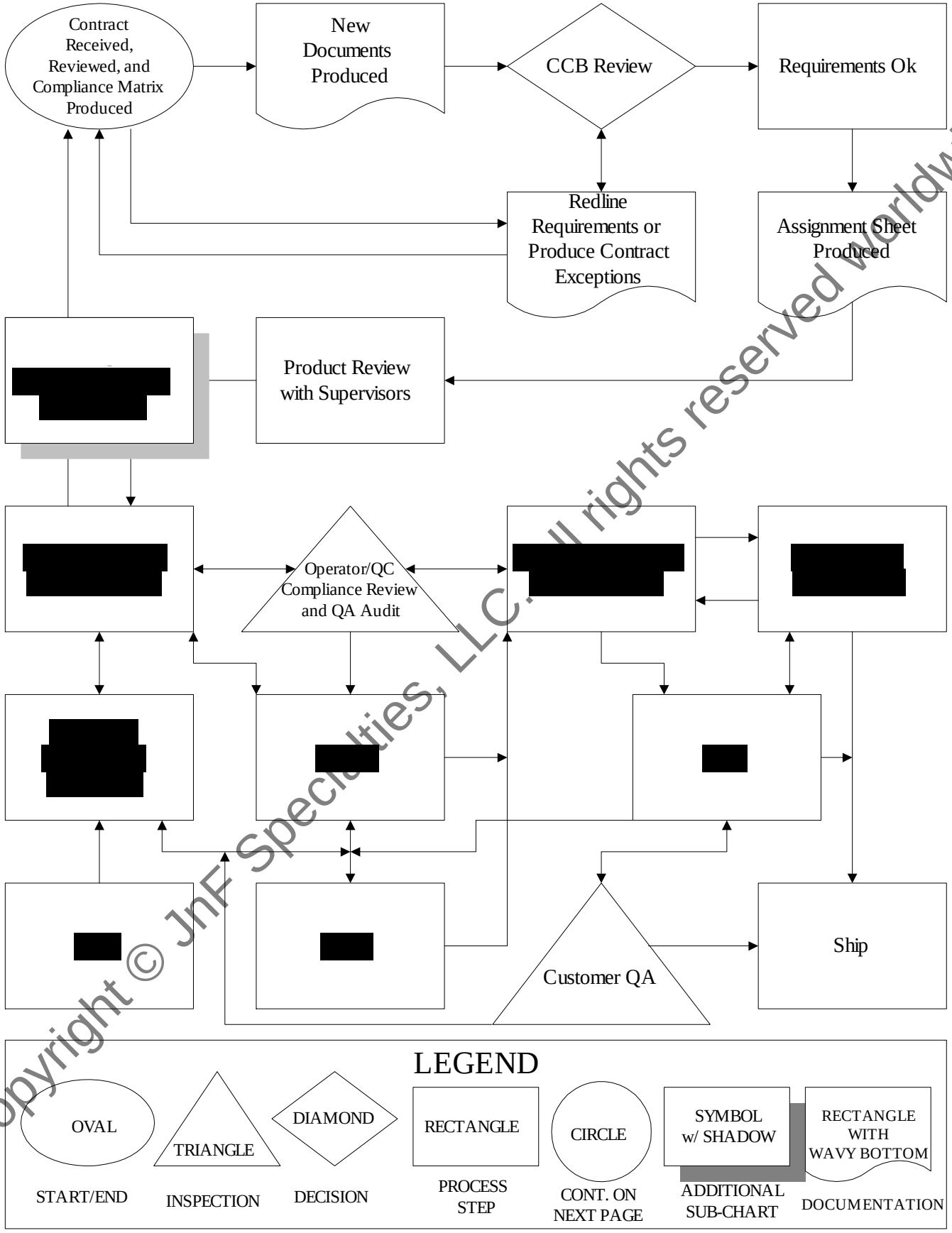
Continuous Improvement Workflow



Tips:
Double click grey area at top and bottom of page to edit header/footer
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Cost of Quality

Mo/Yr

Revisions		Rev:	
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Prepared By:			
[redacted]			**YOUR PROCEDURE NAME**
			Your Procedure Number
			[redacted]

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1.0 Costs Related to Quality

1.1 Responsibility

The Quality Group has the lead responsibility for collecting quality cost data; organizing, evaluating, and maintaining records of this information, and generating quality cost reports. The quality cost information is organized and summarized in four categories:

1-Prevention, 2-Appraisal, 3-Internal Failure, and 4-External Failure.

Quality cost data do not require 'to-the-penny-accuracy'. Hourly and salary Quality Group personnel record their time charges by the four categories.

1.2 Prevention Costs

The quality costs relative to the prevention category are those associated with the efforts devoted to keeping defects from occurring, such as corrective action, quality planning, test procedure preparation, quality training and indoctrination, data collection and reporting, process planning, and design review.

1.3 Appraisal Costs

[redacted]

1.4 Internal Failure Costs

[redacted]

1.5 External Failure Costs

[redacted]

1.6 Reports

Quality costs may be reported by category or by [redacted]

1.7 Cost of Quality Evaluation

The Quality Group has lead responsibility for evaluating the quality cost reports, which may be [redacted]

CAB=Corrective Action Board

Cost of Quality Data

Frank	01/04/03	8	3			5	2.5	1	1		
Michelle	01/04/03	5.5		4.5	4.5				13.5		
Wanda	01/04/03			1	6.25				24.75		
Mary	01/04/03				3.75						
Hannelore	01/04/03				1	4			27.5		
Suzy	01/04/03			3.5		21.5			7		
Melinda	01/04/03								32		
Debra	01/04/03								33		
Chantal	01/04/03				12				19		
Susan	01/04/03			32							
Laura	01/04/03							32			
Judith	01/04/03										38
Tiffany	01/04/03			32.25							
Test-Lab	01/04/03									24	
Frank	01/11/03	16					16		4		
Michelle	01/11/03			4	1.5	2			33		
Wanda	01/11/03			2.5	20.25				16.75		
Mary	01/11/03								4.5		
Hannelore	01/11/03				10	1.5			28.5		
Suzy	01/11/03					26.5			2		
Melinda	01/11/03								40		
Debra	01/11/03								43.5		
Chantal	01/11/03					6			34		
Susan	01/11/03			36.75							
Laura	01/11/03							40.5			
Judith	01/11/03										47
Tiffany	01/11/03			41							
Test-Lab	01/11/03									30	
Frank	01/11/03	3.5		3.5		12.5	2.5	2			
Michelle	01/11/03			6.25					28.25		
Wanda	01/11/03			4.75	28.25	2.5			4.5		
Mary	01/11/03	15		4		19.5			0.5		
Hannelore	01/11/03			2.75	8.25	2.25			26.75		
Suzy	01/11/03			2.5					29.5		

Cost of Quality Dollars

	p1	p2	p3	p4	p5	p6	p7	a1	a2	a3	a4
Calc Sum Row	24.75	696	552.25	1599.3	2632	556.25	139.5	1873.8	9999.5	1387.5	2199
Hours	24.75	696	552.25	1599.3	2632	556.25	139.5	1873.8	9999.5	1387.5	2199
	p1	p2	p3	p4	p5	p6	p7	a1	a2	a3	a4
Percentages	0.09	2.54	2.01	5.83	9.59	2.03	0.51	6.83	36.44	5.06	8.01

*Green = cells with formulas

Total Possible = (People in dept plus Test Lab * 40 hours in a week * Weeks with that number of people in dept

**Test lab=24 (for holiday) or 30 (regular days) total possible hours. For ease in calculation, it was assu

Actual vs. Available

85%

$189,837.84 Actual

$222,264.00 Available

Prevention Cost
- P1 Corrective Action
- P2 Quality Planning, PO's
- P3 Test Procedure Prep
- P4 [redacted]
- P5 [redacted]
- P6 [redacted]
- P7 [redacted]

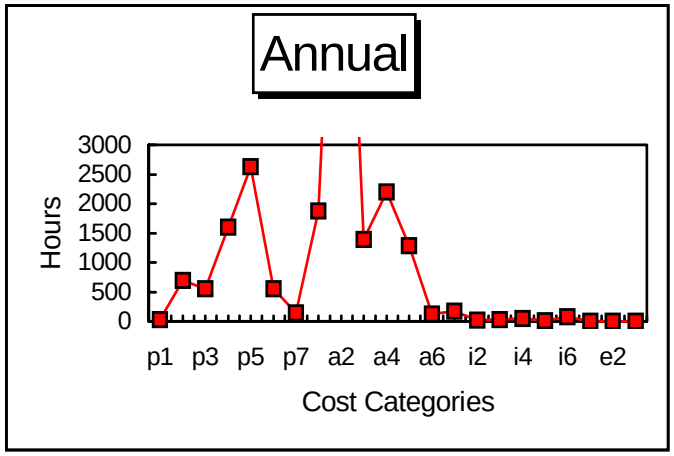
Appraisal Cost
- A1 R&I QC
- A2 QC
- A3 [redacted]
- A4 [redacted] n
- A5 [redacted]
- A6 [redacted]

Internal Failure
- I1 Failure Analysis
- I2 EP Scrap/Rework
- I3 R&I Scrap/Rework
- I4 [redacted]
- I5 [redacted]
- I6 [redacted]

External Failure
- E1 Warranty Repair
- E2 [redacted]
- E3 [redacted]

Cost of Quality Graphs

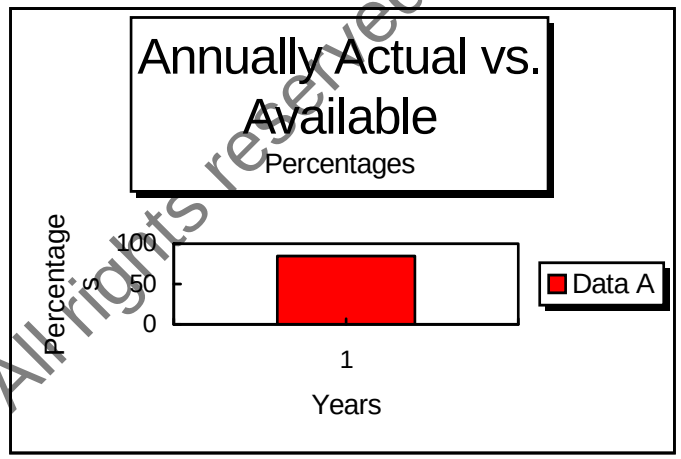
COST CATEGORIES



a2=10000 hrs

PERCENTAGES

Year1 85



Prevention Cost
- P1 Corrective Action
- P2 Quality Planning, PO's
- P3 Test Procedure Prep
- P4 [redacted]
- P5
- P6
- P7

Appraisal Cost
- A1 R&I QC
- A2 QC
- A3 [redacted]
- A4
- A5
- A6

Internal Failure
- I1 Failure Analysis
- I2 EP Scrap/Rework
- I3 R&I Scrap/Rework
- I4 [redacted]t
- I5
- I6

External Failure
- E1 Warranty Repair
- E2 [redacted]
- E3

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Continuous Improvement Metrics

(mo/yr)

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Used On	Contract#:		**Your Company**
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[redacted]:			
[redacted]:			**Your Procedure Name**
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Your Logo

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1.0 SCOPE

Explain the relationship between organizational objectives and metrics and provide some examples of the tools and techniques for collecting metric data.

2.0 THEORY

Nothing gets improved unless it is measured and a metric that is not tied to an objective is worthless.

3.0 OBJECTIVES

3.1 Focus on Customer requirements
3.2 Support goals and targets
3.3 Address the desired improvement
3.4 Stretch the organization
3.5 Allow for measurement

4.0 OVERVIEW

4.1 Measurements vs metrics
4.2 Tools for data collection
4.3 Attributes of a metric
4.4 Example of a metric
4.5 Metrics development worksheet

5.0 DEFINITIONS

5.1 Measurement

The act or process of quantitatively comparing results to requirements to arrive at a quantitative estimate of performance.

5.2 Metric

A measurement taken over a period of time that communicates vital information about a process or activity. A metric should drive appropriate leadership or management action.

6.0 TOOLS

6.1 Sampling

[redacted]

6.2 Check Sheet

The results of a measurement sample can be presented on a check sheet to establish a trend.
The check sheet can list attributes or variables type data:

Attributes type data		
Standard	Quantity	
Not…	𝍸 ||	
Not…	|||	
Should Be…	||	
Should Be…		
Not…		
Should Be…	𝍸 𝍸 𝍸	

Variables type data		
Time Study	Quantity	
1-4	𝍸 ||	
5-9	𝍸 𝍸	
10-14	𝍸	
15-19	||	
20-24	𝍸 𝍸 ||	
25-29	𝍸 𝍸	

6.3 Frequency Table

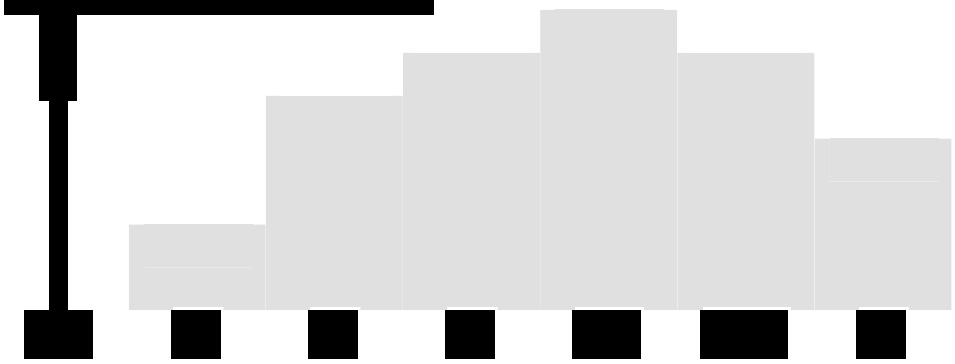
The check sheet is useful as a snapshot of the counts of an activity but it is not a metric.
The check sheet can be improved by converting it to a frequency table:

Attributes type data		
Standard	Quantity	Frequency
Not 1…	𝍸 ||	7
Not 2…	|||	3
Should Be 1 …	||	2
Should Be 2…		0
Not 3 …		0
Should Be 3…	𝍸 𝍸 𝍸	15

Variables type data		
Time Study	Quantity	Frequency
1-2	𝍸 ||	7
3-4	𝍸 𝍸	10
5-6	𝍸	5
7-8	||	2
9-10	𝍸 𝍸 ||	12
11-12	𝍸 𝍸	10

6.4 Histogram

The frequency table helps to quantify the cumulative number of recurring events but it is not a metric. Converting the frequency data to a Histogram is [redacted]:



6.5 Pareto Analysis

The frequency table helps to quantify the cumulative number of recurring events but it is not a metric. Converting the frequency data to a Pareto Chart is [redacted]:

Pareto Analysis of Attributes Data

6.6 Miscellaneous Charts, Diagrams and Statistics

Trend and control charts accumulate data over time so they are more than a snapshot of events but they are still not data that meets the attributes of a metric. A scatter diagram can be used to [redacted].

7.0 ATTRIBUTES OF A METRIC

7.1 Accepted as meaningful by the Customer

7.2 [redacted]

7.3 [redacted]

7.4 [redacted]

7.5 [redacted]

7.6 [redacted]

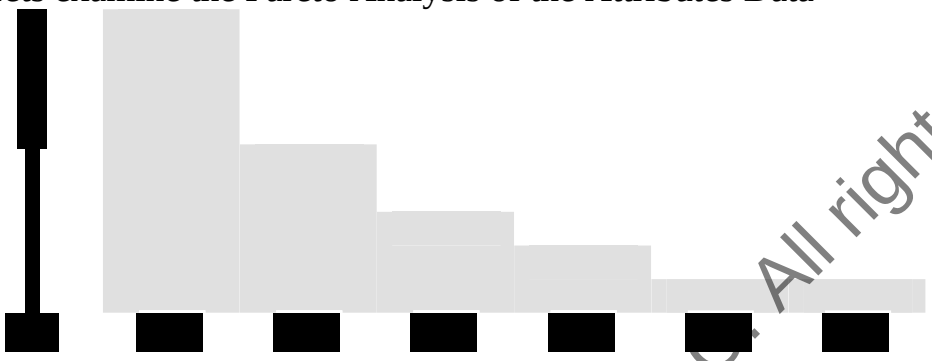
7.7 [redacted]

7.8 [redacted]

7.9 Metrics are not charts, schedules, goals or objectives, counts of activity or snapshots.

8.0 EXAMPLE OF A METRIC

Lets examine the Pareto Analysis of the Attributes Data

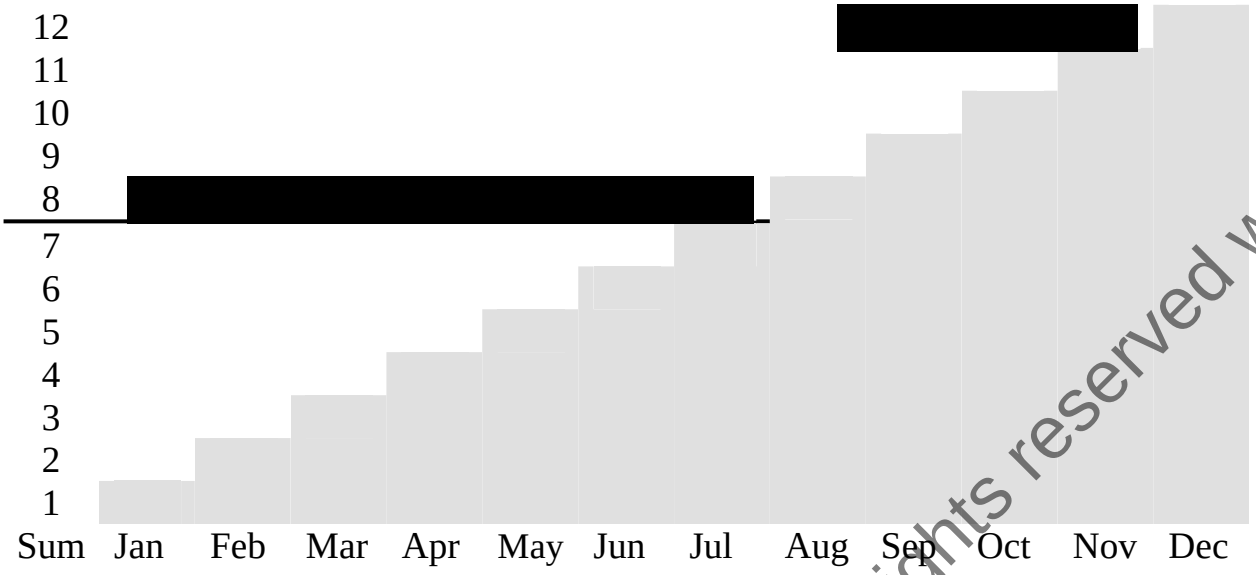


The chart has value because it identifies the <few> from the <many> but it is not a metric by itself unless [redacted]

The chart has been modified to define the [redacted]:

The modified chart is still not a metric because it [redacted].

The following chart is the best representation of a metric:



The chart now meets the objectives of a metric because it [redacted]

METRICS DEVELOPMENT WORKSHEET

Organization Objective:

Customer(s):

Tips:
Double click grey area at top and bottom of page to edit header/footer
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Material Review Program

Mo/Yr

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

Used On	Contract#:		**Your Co**					
Prepared By:								
Your Dept:								
Your Dept:			**POLICIES AND PROCEDURES**					
Your Dept:			Your #					
Your Dept:			Size:	**A**	CAGE:		Form Rev: Orig	1 of 13

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1.0 SCOPE

These policies and procedures define the actions taken, and the documentation used when suspect material is detected in supplies produced for or manufactured by (Your Co).

2.0 APPLICABILITY

The following documents will serve as guidelines. This document will take precedence should a conflict arise concerning Material Review Procedure.

[redacted]

3.0 MATERIAL CONTROL

When a deliverable supply is suspected of noncompliance to applicable drawings, specifications, or other requirements, it is identified and segregated to the extent practicable, and held for review action.

3.1 Documentation

The Material Report (MR), (Your #), is used to document [redacted]

3.1.1 Material Report (MR)

(Your Co)'s reporting document for suspect material is provided to all necessary personnel. This document provides: [redacted]

3.1.2 Request for Corrective Action, (Your #)

This document, as well as the MR form, is used to request corrective [redacted]

3.1.3 Material Report, Purpose

The MRB checks a box at the top of the Material Report to identify the purpose of the MR.

[redacted]

3.1.4 Material Report, Change Implementation

"Conditional Acceptance" recommendations are [redacted]

3.2 Remedial and Preventive Action

The following MRB functions may be performed, but are not limited to:

a) [redacted]

b) [redacted]

c) [redacted]

d) [redacted]

e) [redacted];

f) [redacted];

g) [redacted];

h) [redacted];

i) [redacted]

3.3 Material Review Dispositions

3.3.1 Initial Review

An Initial Review of the prepared MR is conducted by QA to determine the adequacy and completeness of the record. Immediate action may include, but is not limited to:

a) [redacted];

b) [redacted]

c) [redacted]

A Material Report may not be voided by the Initial Review procedure since the MR may act as a [redacted].

3.3.2 Submit to MRB

Three qualified MRB signatures are required to implement MRB dispositions. Dispositions may include, but are not limited to: [redacted]

3.3.3 Return to Vendor (Receiving Inspection)

Receiving inspection initiates an MR for suspect material. After review of production schedules and contractual commitments, QA may request Receiving Inspection personnel to conduct a 100% inspection of the material to screen out all suspect material in order to obtain enough conforming material to maintain the production schedules.

Returned supplies are accompanied by an MR or Discrepancy Notice, or other suitable documentation in the event that the supplies are obviously unfit for use. If a (Your Co) Corrective Action is requested, the supplier is provided [redacted]

Corrective action may be requested based on the following criteria:

a) [redacted]
b) [redacted]
c) [redacted]
d) [redacted]

3.4 Material Review Board (MRB)

(Your Co) Material Review is conducted by a delegated board comprised of one (1) [redacted] one (1) [redacted] one

(1) [redacted]

Material Review Board members may consult with other (Your Co) Groups and personnel as required to arrive at optimum decisions. MRB decisions shall be determined by [redacted]

3.4.1 Responsibility

The Material Review Board:

a) [redacted]

b) [redacted]

c) [redacted] n;

d) [redacted]

e) [redacted]

f) [redacted]

At least two members of the (Your Co) Configuration Control Board (CCB) must [redacted]

3.4.2 Applicable Dispositions

MRB dispositions may include, but are not limited to:

[redacted]

Scrap

If the article or material is unfit for use it is dispositioned as Scrap. The MRB completes the Material Report. Imposed corrective action or comments are indicated on the Material Report. The material is tagged as "Reject" and segregated from the production flow.

The Material report is returned to the Quality Group for processing. This MRB disposition is not subject to [redacted]

3.4.2.1 Applicable Classifications

Major: [redacted]

Minor: [redacted]

None: [redacted]

3.4.2.2 Customer Disposition Authority

Major: [redacted]

Minor: [redacted]

None: [redacted]

3.4.3 Customer MRB Review

An incomplete MR is not subject to Customer review.

3.4.4 MRB Qualification

A Material Review Board member must:

1) [redacted]
2) [redacted] nd
3) [redacted]

3.5 Definitions

The following definitions apply:

a) Anomaly

A condition that is discovered during routine manufacturing or testing that is not specifically

prohibited, previously documented or practiced, but could affect product or process safety, reliability, durability, performance, interchangeability, or the basic objectives of a contract.

b) Continuous Improvement Opportunity

A tool to document conditions that do not conceivably affect product or process safety, reliability, durability, performance, interchangeability, safety, or the basic objectives of a contract. A metric for the Continuous Improvement Program.

c) Major Nonconformance

Any nonconformance that, after execution of the MRB disposition, will result in hazardous or unsafe conditions for individuals using or maintaining the affected product or process, or that may adversely affect safety, reliability, durability, performance, interchangeability of parts or assemblies, weight, or the basic objectives of the contract.

d) Minor Nonconformance

Any nonconformance that, after execution of the MRB disposition, will **not** result in hazardous or unsafe conditions for individuals using or maintaining the affected product, and will **not** adversely affect safety, reliability, durability, performance, interchangeability of parts or assemblies, weight, or the basic objectives of the contract.

e) None

Any nonconformance or condition that, after execution of the MRB disposition, will result in complete compliance with contractual requirements.

f) Repair

Any additional work performed to bring the supply to a condition that departs from one or more characteristics of the drawing, specification, or purchase order.

Repairs are accomplished with MRB and/or Customer approved procedures.

g) Rework

Correction of nonconforming supplies that results in complete compliance with contractual requirements.

h) Scrap

Obviously unfit for use. MRB is not required for Vendor supplied items that are obviously unfit for use as determined by the Purchasing Group.

i) Suspect

Any condition that deviates from standard practice or any alleged nonconformance

j) Technical Documents

Engineering Specifications, Purchase Orders, Procedures, Standards, Written Requirements, Material Notes, Bulletins, Contract Requirements, and Environmental, Health and Safety Directives

3.6 Corrective Action Board (CAB)

The CAB insures that causes of nonconformances are determined according to the "Applicable Classifications" paragraph herein, and responsible managers take appropriate corrective action. This function is performed by [redacted]

[redacted]

3.6.1 CAB Authority and Responsibilities:

a) [redacted]

b) [redacted]

c) [redacted]

d) [redacted]

3.6.2 SPC Data Review (Optional)

When process control techniques are used, and analysis of cumulative data for a targeted condition reveals that the established standards (yield requirements, etc.) are not being met, the CAB may [redacted]

3.6.2.1 Process Control (SPC is Optional)

When corrective action is required due to inadequate SPC process control, and until such time as it has been demonstrated that the corrective action has been effective, the CAB may request that the subject process include:

a) Monitoring:

1) [redacted]
2) [redacted]
3) [redacted]
4) [redacted]

b) [redacted]

3.6.3 Monitoring Effectivity

The CAB insures that reviews of MRB decisions are conducted periodically to determine that the MRB actions are effective and [redacted].

3.7 Disposition of Material

3.7.1 All Material Reports are disposed of by an MRB decision:

a) [redacted]

b) [redacted]

c) [redacted]

d) [redacted]

e) [redacted]

f) [redacted]

g) [redacted]

h) [redacted]
j) [redacted]
i) [redacted]
k) [redacted]
l) [redacted]
m) [redacted]

3.7.2 Reprocessing

Instructions for reprocessing material after repair are included in Standard Repair Procedures or other repair documentation. The instructions include [redacted]

3.7.3 Customer Repair/Rework Approval

Proposed repair/rework methods are submitted to the MRB and the Customer for review and approval prior to and/or during the repair/rework action. The act of approving the repair/rework method does not [redacted]

3.7.4 Repair Inspection

Material that has been satisfactorily repaired is subject to [redacted]

3.7.5 Scrap Identity

Scrapped material is conspicuously identified and controlled to preclude its subsequent use as other than scrap.

3.8 Material Report Documentation

3.8.1 Summary

The system maintains records of suspect material, dispositions, assignable causes, corrective actions, and effectiveness of corrective actions. The cycle time between Material Report (MR) preparation and completion is targeted at no more than [redacted]

Records are organized to permit efficient retrieval for:

a) [redacted]
b) [redacted]
c) [redacted]

3.8.2 MR Preparation

(Your Co) documents all suspect conditions. The Material Report includes:

a) [redacted]
b) [redacted]
c) [redacted]
d) [redacted]

e) [redacted]
f) [redacted]
g) [redacted]
h) [redacted]
i) [redacted]

3.8.3 MR Completion

The MRB adds the following information to the documentation:

a) [redacted]
b) [redacted]
c) [redacted]

Upon signature approval by all MRB members the MR is [redacted]

3.8.4 Request for Corrective Action [RFCA]

If the MRB requires corrective action according to the "Applicable Classification" paragraph herein, the following information is recorded on the MR or RFCA as appropriate to internal or external activities:

a) [redacted]
b) [redacted]
c) [redacted]
d) [redacted]

3.8.5 Analysis of Trends (Optional)

If corrective action is not warranted according to the "Applicable Classifications" paragraph herein, but corrective action is elected by the MRB, the CAB insures [redacted].

3.8.6 Costs (Optional)

Data for costs associated with material reporting is collected to the extent specified by the CAB. A system using actual costs, relative cost constants, estimates by qualified personnel, or any combination thereof is used. [redacted] The cost data may include, but is not limited to the following:

a) [redacted]
b) [redacted]
c) [redacted]
d) [redacted]
e) [redacted]
f) [redacted]

g) [redacted]

h) [redacted]

j) [redacted]

3.9 Summary Report (Optional)

A Summary Report may include, but is not limited to:

a) [redacted]

b) [redacted]

c) [redacted]

d) [redacted]

e) [redacted] on

f) [redacted]

g) [redacted]

h) [redacted]

i) [redacted]

j) [redacted]

k) [redacted]

3.9.1 Data Availability (Optional)

This data is available for on-site review by the Customer unless it is defined as [redacted]

REQUEST FOR SUPPORT

☐**Nonconformance** ☐**Continuous Improvement Opportunity** ☐**Calculated Risk Release**

SUBCONTRACTOR: _____ DATE RECEIVED: _____

RFS#: SHEET _____ OF _____

Traveler#:		Op#:		Quantity Received:		Job Number:	
Item Name:		**Description: ID S/B Spec#, Para# & IS Condition w/Quantity &Dimension Affected**					**# Discrepant**
Dwg/Spec:							
Part#:							
Part# Rev:							
Lot or S/N:							
P.O.#:							
[redacted]							
[redacted]							
[redacted]							
[redacted]							
[redacted]							
[redacted]							
[redacted]							

Root Cause: [redacted]	
Affect on Supplies:	
Immediate Action, [redacted]	
Corrective Action Plan, [redacted]	
Actions Taken to [redacted]	
Trend? ☐NO ☐ YES *provide details:*	

ACN Orientation: ☐Yes ☐No	Suppl.: ☐Yes ☐No	ICAR: ☐Yes # ☐No	EO: ☐Yes # ☐No

CLASSIFICATION	Disposition - check all that apply
MAJOR	☐[redacted] ☐[redacted] ☐[redacted] ☐[redacted] ☐[redacted]
[redacted]	☐[redacted] ☐[redacted]
[redacted]	☐[redacted] ☐[redacted] ☐[redacted]

Approvals and Effectivity Verification

[redacted] :			
Responsible Engr. Authority – Date	Responsible Engr. Authority – Date	Quality - Date	Referee - Date
Rework/Repair Operator	Rework/Repair Date	Rework Inspector/Date	Customer/Date
[redacted]			

Your Logo **Shaded Area for Administrative Use** Form Rev: Orig

Your Co Name

Address
City - State - Zip
Phone: Fax:
Email:

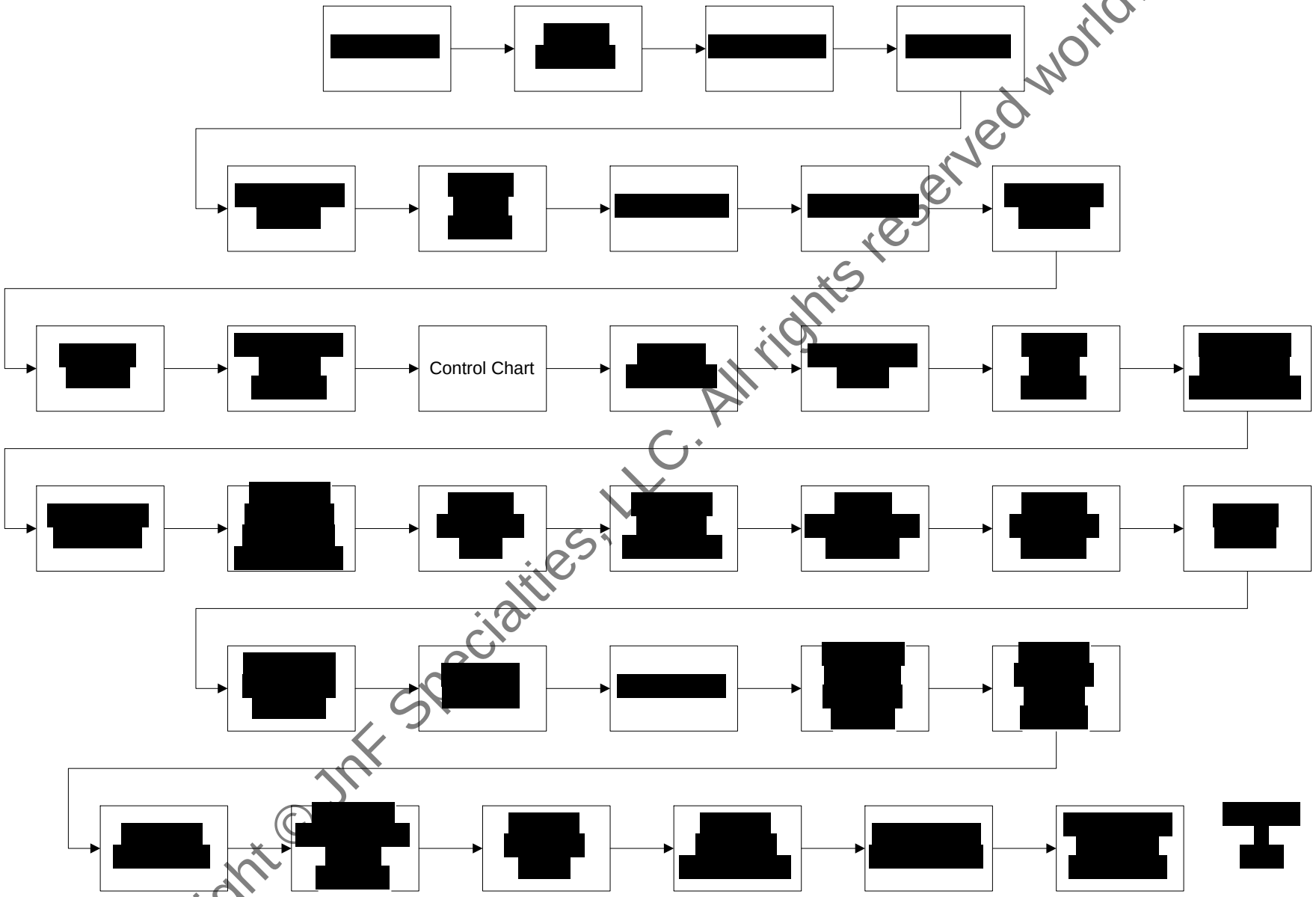
NON-CONFORMANCE REPORT

Control Number:		PO Number:	
[redacted]		[redacted]	
Description of Discrepancy:			
Disposition:	[redacted]	[redacted]	[redacted] ___
Supplier to provide documentation regarding [redacted].			Yes ____ No ____
Supplier Notification			
[redacted]		[redacted]	
Comments:			
[redacted]			
[redacted]			
[redacted]		[redacted]	
[redacted]		[redacted]	
[redacted]		[redacted]	

Your Form# (mo/yr)

Attach Tracking Information

Six Sigma Implementation



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Statistical Procedures

Mo/Yr

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

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 80% f >2	Maintenance schedules exist?	SPC impacts purchases?	Row 9 done?

Figure 2: Sample Statistical Process Plan

Tips:
Double click grey area at top and bottom of page to edit header/footer
Search for the word “your” throughout doc and replace as required

Validation Plan

(mo/yr)

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

Used On	Contract#:	**Your Company Name**
Prepared By: [redacted]		
		PROCEDURE
		Your #
	[redacted]	Form Rev: Orig 1 of 59

Your Logo

TABLE OF CONTENTS

1.0 Scope

Procedures in this standard may be used to validate conformance to requirements of the following:

a. [redacted]
b.
c.
d.
e.
f.
g.
h.

Note: use of the word "product" throughout this standard also refers to processes, services and other deliverables.

1.1 Product Requirements

The Company is required to produce and submit product that meets all contract and specification requirements. Each step of the manufacturing process must be controlled to maximize the probability that the finished product meets all quality and design specifications. The application of procedures from this standard does not relieve the Company of its responsibility for meeting all contract requirements. The Company's quality system must be established and operated to consistently produce products that meet all requirements. Absence of any inspection or process control requirement in the contract does not relieve the Company of its responsibility for assuring that all products submitted for acceptance conform to all requirements of the contract.

1.2 Limitations

The procedures of this standard are not intended for use with destructive tests or when product screening is not feasible or desirable and/or when end-product testing does not reveal all variations that may occur in the product that may impact on safety and effectiveness. In such cases, validation procedures will be defined in the product specification. There are too many products, devices, processes and manufacturing facilities to list all validation functions. Several broad concepts have general applicability that manufacturers can use successfully as a guide in validating a product. Although the particular requirements of validation will vary according to such factors as the nature of the product and the complexity of the process, the broad concepts stated in this standard have general applicability and provide an acceptable framework for building a comprehensive approach to the validation process.

2.0 Recommended Reading

2.1 Order of precedence

Nothing in this document supersedes applicable laws and regulations unless a specific exemption has been obtained.

3.0 Definitions

-Acceptance
The act of an authorized representative of the Customer by which the Customer, for itself or as agent of another, assumes ownership of supplies tendered or approves specific services rendered as partial or complete performance of the contract.
-Alpha risk (a)
This is also known as the producer's risk. When referring to lot acceptance sampling, it is the probability that an acceptable lot will be rejected. When applied to control charts, the alpha risk is the probability that an out-of-control signal will be observed when the process is actually in control.
-ANOVA (Analysis of Variance)
A technique that subdivides the total variation of a set of data into meaningful component parts associated with specific sources of variation for the purpose of testing some hypothesis on the parameters of the model or estimating variance components. The technique, in conjunction with the F ratio, is used to provide a test of significance for the effects of these sources of variation and/or to obtain estimates of the variances attributable to these sources. The basic assumptions are that the effects due to all the sources of variation are additive and that the experimental errors are independently and normally distributed with zero mean and have equal variances throughout all subdivisions of data.
-Benchmarking
A continuous, systematic process for evaluating the products, services and work processes of organizations that are recognized as representing best practices for the purpose of organizational improvement.
-Beta risk (b)
This is also known as the consumer's risk. When referring to lot acceptance sampling, it is the probability that a lot of rejectable quality will be accepted. When applied to control charts, the

beta risk is the probability that an out-of–control condition will not be observed when it actually exists.

-Bonus Tolerance (also known as “Increase in Positional Tolerance”)

Where the actual size of a feature is at maximum material condition (MMC), the geometric tolerance is zero. Where the actual size of the feature has departed from MMC, an increase in the geometric tolerance is allowed (bonus tolerance) equal to the amount of such departure. The total permissible variation is maximum at least material condition (LMC). Bonus tolerancing is applied on an MMC, LMC or ‘regardless of feature size” (RFS) basis. The bonus tolerance, datum and symbols are contained within feature control frames. This tolerance is in addition to the feature tolerance and permits the feature location and form to vary from true (theoretically exact) position. Basically, while maintaining the specified size limits of the feature, the center, axis or feature surface may not exceed the boundary established by the bonus tolerance. This may produce a distribution that is not centered on nominal and/or skewed. A detailed explanation is available in ASME Y14.5M, Dimensioning and Tolerancing.

-Cause and Effect Diagram

A method that graphically illustrates the factors (Causes) that impacts on a quality characteristic or contributes to some problem (the Effect). The causes are categorized under general headings that relate to the effect. Commonly used headings are; “Materials, Methods, People, Machines, Measurement and Environment”. This technique is used to aid in determining and ranking the severity or impact of the causes on the effect.

-Central tendency

Central tendency is the tendency of a set of measurement data to cluster or to center about certain numerical values.

-Check Sheets

A check sheet is a data collection sheet where categories or ranges of possible measurements are printed on the sheets. The data collector records tally or tick marks across from the appropriate category or measurement. It allows the user to systematically record and compile data from historical sources or observations as they happen so that patterns and trends can be clearly detected and shown.

-Chi-square test (goodness of fit test)

This is a statistical test that provides confidence levels and intervals to describe whether or not the data truly approximates a particular distribution such as the normal distribution.

-Common Cause

Factors that contribute to variation and are inherent to the process. When a process is in statistical control, the only variation existing comes from common causes. Common cause variation can only be reduced by management action on system components, e.g., improving equipment capability, better training, etc. (Also called chance cause).

-Continuous process improvement

This is a goal of quality driven organizations to continually improve and optimize their processes.

-Contract quality requirements

The technical requirements relating to the quality of the product - contract clauses prescribing inspection - other quality controls incumbent on the Company to assure that the product conforms to contractual requirements.

-Critical characteristic

A characteristic that experience and judgment indicate must be met to avoid hazardous or unsafe conditions for individuals using, maintaining or depending upon the product; or that experience and judgment indicate must be met to assure performance of the end product.

-Critical nonconforming unit

A unit of product that fails to conform to specified requirements for one or more critical characteristics.

-Customer quality assurance

The various functions performed by the Customer to determine whether a Company has fulfilled the contract obligations pertaining to quality and quantity.

-Cycle variation

This is the variation from piece to piece with no time element involved. The pieces could have been made in any time order.

-Histogram

A Histogram is plot of frequency distribution in the form of a bar chart whose bases are equal to the cell interval and whose areas are proportional to the frequencies. It is used to summarize data from a process that has been collected over a period of time and graphically presents its frequency distribution.

-Inspection

Examining and testing supplies or services including raw materials, components and intermediate assemblies to determine whether they conform to requirements.

- Installation qualification

Establishing confidence that process equipment and ancillary systems are capable of consistently operating within established limits and tolerances.

-Key characteristic

The feature of a material, part or process whose variation has a significant influence on product fit, performance, service life or manufacturability.

-Major characteristic

A characteristic, other than critical, that must be met to avoid failure or reduced usability of a product. Major characteristics will require more verification effort than minor characteristics. VL-VII requires the highest level of effort and the effort decreases as the VL decreases to the lowest level VL-I.

-Major nonconforming unit

A unit of product that fails to conform to specified requirements for one or more major characteristics but conforms to all critical characteristics.

-Minor characteristic

A characteristic, other than critical or major, whose departure from its specification requirement is not likely to reduce the usability of a product or whose departure from established standards has little bearing on the effective use or operation of the unit.

-Minor nonconforming unit

A unit of product that fails to conform to specified requirements of one or more minor characteristics but conforms to all critical and major characteristics.

-Nonconformance

A departure from a specified requirement for any characteristic.

-Nonconforming unit

A unit of product that has one or more nonconformances.

-Normal probability paper

Paper that is scaled to show graphically how close a variables data distribution approximates a normal distribution is called normal probability paper.

-Normality

This is the tendency of variables data to pattern itself in a bell shaped curve. Many processes innately behave in this manner. Some processes do not produce output whose measurements can be characterized by the normal distribution; therefore, before performing operations that depend on assumptions of normality, it is wise to test those assumptions.

-Pareto Analysis

A Pareto Analysis is used to graphically focus efforts on the problems that offer the greatest potential for improvement by showing their relative frequency, cost or other metric in a descending bar graph. It is based on the proven Pareto principle: approximately 20% of the sources cause approximately 80% of any problem.

-Poka-Yoke

Poka-Yoke is Japanese for “mistake proofing”. These devices are used either to prevent the special causes that result in defects or to inexpensively inspect each item that is produced to determine whether it is acceptable or defective. A Poka-Yoke device is any mechanism that either prevents a mistake from being made or makes the mistake obvious.

-Positional variation

This is the within piece variation. (e.g., measuring the paint thickness on the fender of a truck.)

-Process performance qualification

Establishing confidence that the process is effective and reproducible.

-Product performance qualification

Establishing confidence through appropriate testing that the finished product produced by a specified process meets all release requirements for functionality and safety.

-Production interval

A period of production under continuous sampling assumed to consist of essentially homogeneous quality. It is normally a single shift. It can be a day if it is reasonably certain that shift changes do not affect quality of product but shall not be longer than a day.

-Prospective validation
Validation conducted prior to the distribution of either a new product, or product made under a revised manufacturing process, where the revisions may affect the product's characteristics.
-Quality
The composite of material attributes including performance features and characteristics of a product to satisfy a given need.
-Quality assurance
A planned and systematic pattern of all actions necessary to provide adequate confidence that adequate technical requirements are established; products conform to established technical requirements and satisfactory performance is achieved.
-Quality audit
A systematic examination of the acts and decisions with respect to quality in order to independently verify or evaluate the operational requirements of the quality program or the specification or contract requirements of the product.
-Quality program
A program which is developed, planned and managed to cost effectively carry out all efforts to affect the quality of materials from concept through validation, full-scale development, production, deployment and disposal.
-Quality system
This is a documented procedure, written by the supplier explaining just how the organization will control quality in its processes and/or production of product.
-Rational subgroup
These are subgroups that are rationally or logically selected to only include common cause variability.
-Retrospective validation
Validation of a process for a product already in distribution based upon accumulated production, testing and control data.
-Run/Trend Charts
A run (or trend) chart is a line graph of the data, with time units represented on the x-axis and the data values on the y-axis. This type of chart is used to show visual signals in the ‘behavior’ of the process data with time; it is not a control chart per se and typically does not include any form of limits.
-Scatter Diagram
A scatter diagram is an X-Y plot of paired data from two variables. It is used to examine the strength of the relationship between a variable plotted on the horizontal axis and a second variable plotted on the vertical axis. A scatter diagram provides visual information that should be used in conjunction with investigations such as correlation analyses.
-Screening inspection
An inspection process whereby every unit is checked and all nonconforming units are removed; also referred to as 100 percent inspection.

-Shapes of distributions

These are the patterns formed by data when placed on a histogram.

-Shapiro-Wilk Test

The Shapiro-Wilk Test is a quantitative test for normality. It is designed for sample sizes less than or equal to 2000 and it computes the Shapiro-Wilk statistic (W). The statistic measures the strength of linear relationship between the set of data and the expected Normal distribution.

-Short run SPC

Short run SPC is a method for using control charts when a small number of items are manufactured; too few to use traditional control charts.

-Skewness

This is an indication of asymmetry of the data distribution. If skewed, a distribution is skewed to the right or left. If skewed to the right, the distribution has a long “tail” to the right and if skewed to the left, the distribution has a long “tail” to the left.

-Special Cause

A factor that contributes to variation and that is feasible to detect and identify. Examples are operator error or a faulty set-up.

-Stratified Sampling

The process of selecting units deliberately from various locations within a lot or batch or from various phases or periods of a process to obtain a sample. An attempt is made with stratified sampling to select known homogeneous areas within a lot that is not homogeneous - random samples are then taken from these various locations, usually proportional in number to the size of the strata. If the strata are known, stratified random sampling will reduce the sampling variability.

-Taguchi loss function

A formula that assigns a monetary value to the loss to society incurred due to a quality characteristic deviating from its optimum (target) value.

-Temporal variation

This is the measured piece to piece variation of a characteristic over time.

-Traceability

The ability to trace the history, application or location of an item or activity, or similar items or activities by means of recorded identification.

-Transformations

A mathematical process that changes data into a desired distribution (e.g., a normal distribution).

-Type I Error

The incorrect decision that a process is unacceptable when, in fact, perfect information would reveal that it is located within the zone of acceptable processes. (Ex. The decision to reject a lot of material that does not contain enough nonconformities to be classified as unacceptable).

-Type II Error

The incorrect decision that a process is acceptable when, in fact, perfect information would reveal that it is located within the zone of rejectable processes. (Ex. The decision to accept a lot of material that contains enough nonconformities to be classified as unacceptable).

-Validation

Establishing documented evidence which provides a high degree of assurance that a specific process will consistently produce a product meeting its pre-determined specifications and quality attributes.

-Validation protocol

A written plan stating how validation will be conducted, including test parameters, product characteristics, production equipment, and decision points on what constitutes acceptable test results.

-Verification level (VL)

Prescribes the level of significance or utility of a characteristic to the user. The amount of effort to assure conformance can be allocated on the basis of importance to the user.

-Worst case

A set of conditions encompassing upper and lower processing limits and circumstances, including those within standard operating procedures, which pose the greatest chance of process or product failure when compared to ideal conditions. Such conditions do not necessarily induce product or process failure.

-ZBA

Zero Based Acceptance (ZBA) plans are sampling plans in which the acceptance number is zero for any sample taken. They are also referred to as C=0 and Accept on Zero (AoZ) sampling plans.

4.0 General

4.1 Quality System

The Company shall establish and implement an internal prevention-based quality system as a means of ensuring that all products conform to requirements specified by the contract and associated specifications and standards. The acceptability of the quality system is dependent on compliance with ISO 9001 or equivalent - demonstration of its process focus - and the availability of objective evidence of its implementation and effectiveness. Using ISO 9001 will not in itself assure quality products; however, it will assure that if the organization is using its quality system appropriately, it has in place the necessary mechanisms for corrective and preventive action.

4.1.1 Quality system plan

The quality system shall be documented and shall be subject to on-site Customer review throughout the contract. It shall include, at a minimum, a description of the organizational structure, responsibilities, procedures, processes and resources. The Company shall maintain,

disseminate, update and improve the quality system plan in order to ensure its continued use and accuracy. The design and documentation of the quality system plan shall allow for ease of use, review and audit by internal as well as Customer personnel.

4.1.2 Prevention-based quality system

The quality system shall demonstrate its prevention-based outlook by meeting the following objectives throughout all areas of contract performance:

a. [redacted]

b. [redacted]

c. [redacted]

d. [redacted]

e. [redacted]

f. [redacted]

g. [redacted]

4.1.3 Process focus of quality system

To demonstrate a process focus, the Company shall demonstrate that the manufacturing process and its related processes have been studied and are understood, controlled and documented to show that they are:

a. [redacted]

b. [redacted] and other process inputs, and designed to [redacted]

[redacted]

4.1.4.2 Examples of evidence regarding process control.

[redacted]

4.1.4.3 Examples of evidence regarding product conformance

[redacted]

4.2 Validation Overview

It is recognized that sampling inspection alone does not control or improve quality. Product quality comes from [redacted]
When such activities are effective, sampling inspection is a redundant effort and an unnecessary cost. This standard provides a selection of tools that can be used to determine if a process will consistently meet its pre-determined specifications and quality attributes in a predictable way. Tools in this standard must be selected and used according to the technical requirements of the product – not all tools are applicable to every project but their use will give more meaningful results than just determining if all test results fall within specifications. [redacted]

4.3 Elements of a Validation Program

A typical validation program includes [redacted]

[redacted]

A. Prospective Validation

Prospective validation includes [redacted]

A.1 Equipment and Process

The equipment and process(es) should be designed and/or selected so that product specifications are consistently achieved. This should be done with the participation of all appropriate groups that are concerned with assuring a quality product, e.g., engineering design, production operations and quality assurance personnel.

A.1.a Equipment - Installation Qualification

Installation qualification studies establish confidence that the process equipment and ancillary systems are capable of consistently operating within established limits and tolerances. After process equipment is designed or selected, it should be evaluated and tested to verify that it is capable of operating satisfactorily within the operating limits required by the process.

This phase of validation includes [redacted]

[redacted]

A.1.b Process: Performance Qualification

The purpose of performance qualification is to provide rigorous testing to demonstrate the effectiveness and reproducibility of the process. In entering the performance qualification phase of validation, it is understood that the process specifications have been established and essentially proven acceptable through laboratory or other trial methods and that the equipment has been judged acceptable on the basis of suitable installation studies. Each process should be defined and described with sufficient specificity so that employees understand what is required. Parts of the process that may vary so as to affect important product quality should be challenged. In challenging a process to assess its adequacy, it is important that challenge conditions simulate those that will be encountered during actual production, including "worst case" conditions. The challenges should be repeated enough times to assure that the results are meaningful and consistent.

[redacted]

A.1.c Product - Performance Qualification

These steps should be viewed as pre-production quality assurance activities. Before reaching the conclusion that a process has been successfully validated, it is necessary to [redacted]

[redacted]

A.2 System to Assure Timely Revalidation

There should be a quality assurance system in place that requires revalidation whenever there are changes in packaging, formulation, equipment or processes that could impact on product effectiveness or product characteristics, and whenever there are changes in product characteristics. Furthermore, when a change is made in raw material supplier, the manufacturer should consider subtle, potentially adverse differences in the raw material characteristics.

[redacted]

A.3 Documentation

The validation program must be documented and properly maintained. Approval and release of the process for use in routine manufacturing should be based upon [redacted]

B. Retrospective Process Validation

In some cases a product may have been on the market without sufficient pre-market process validation. In these cases, it may be possible to [redacted]

4.4 Factors that affect product quality

All factors that affect product quality should be evaluated when designing and undertaking a process validation study. These factors may [redacted]

4.4.1 R&D

During the research and development (R&D) phase, the desired product should be carefully defined in terms of its characteristics, such as [redacted]

4.4.2 Changes

Documentation of changes made during development help to provide traceability to information that can later be used to pinpoint solutions to future problems. Once a specification is demonstrated as acceptable, it is important that any changes to the specification be made according to documented change control procedures.

4.4.3 End Use

The product's end use should be a determining factor in the development of product (and component) characteristics and specifications. All pertinent aspects of the product that impact on safety and effectiveness should be considered. These aspects include [redacted]

[redacted]

4.4.4 Acceptance Specifications

The validity of acceptance specifications should [redacted]

4.4.5 Operator Control

It is highly desirable that production operators should make decisions on conformance. They are already in the mainstream of the product flow and are most familiar with the nature of the product characteristics. To require others to make measurements and judge conformance adds costs and delays and reduces the sense of responsibility of the operators. When work is organized in a way that enables a person to have full mastery over the attainment of planned results, that person is [redacted] the operator must be provided with:

a. [redacted].
b. [redacted]
c. [redacted]

If all the parameters have been met, the person is said to be in a state of self-control and can [redacted]

5.0 Process Validation Tools

5.1 Process Improvement

5.1.1 Design of experiments

[redacted]

5.1.2 Determining optimum process settings

[redacted]

[redacted]

5.1.3 Quality Function Deployment

[redacted]

5.1.4 Failure Mode and Effects Analysis

[redacted]

[redacted]

5.2 SPC

a. [redacted]

b. [redacted]

c. [redacted]

d. [redacted].

e. [redacted]

f. [redacted]

5.2.1 Service and administrative SPC

SPC for service and administrative processes refers to the application of statistical techniques to [redacted]

5.2.2 Customer requirements

“Customer” in this document includes both internal and external Customers.

a. [redacted]

b. [redacted].

c. [redacted]:

(1) [redacted]?

(2) [redacted]

(3) [redacted]?

d. [redacted]

[redacted]

To achieve a state of self-control, the operator must be provided with:

a. [redacted]
b. [redacted].
c. [redacted]

5.3 SPC Planning

5.3.1 Approach

Knowledge of statistical procedures alone is not sufficient to ensure improvements in product quality and process productivity. A structured approach for implementing SPC is needed. Organizational team structures, such as self-managed work teams, cross-functional teams and project teams will facilitate and enhance the use of SPC with its many internal and external benefits. [redacted]

5.3.2. Preliminary planning

The following factors contribute significantly to effective SPC implementation:

[redacted]

[redacted]

5.3.2.8 SPC plan

A written SPC implementation plan (SPC Plan) should be developed which does the following:

a. [redacted];

b. [redacted];

c. [redacted]

d. [redacted]

[redacted]

5.3.2.9 SPC verification

The verification of effective internal and vendor SPC programs has its basis in an effective SPC audit program. Once an effective SPC plan has been established, it is recognized that the full implementation of the events defined in the plan may take a long time. Therefore, at various times during this implementation and practice of SPC, the SPC program should be reviewed for compliance. Some of the more important aspects of SPC practices to be evaluated during an audit will be:

a. [redacted]
b. [redacted]
c. [redacted]

A typical audit checklist for a production operation:

DATE/SHIFT:							
The operator has provided date, time and initials.							
[redacted]							
[redacted]							
[redacted]							
[redacted]							
[redacted]							
[redacted]							
[redacted]							
[redacted]							
[redacted]							
[redacted]							
[redacted]							
[redacted]							

5.3.3 Training

Initial SPC training should be provided for all supplier personnel who will be involved in the program to impart knowledge of the philosophy and concepts of SPC. Visiting similar facilities that exemplify the type of commitment required can be beneficial. An overall training strategy should be developed and included in the SPC plan. The strategy should consider and account for the needs of all personnel levels and responsibilities. It should draw from a mixture of resources including trade journals, books, videos, in-house and outside experts. A training plan should consider:

a. [redacted]?

b. [redacted]

c. [redacted]?

[redacted]

5.4 Process knowledge

5.4.1 Flow diagramming

In order to optimize and control a process and maximize the benefits from SPC implementation, a thorough knowledge of the process is of paramount importance; therefore, prior to implementing SPC, it is very helpful to [redacted]. Flow diagrams may consider:

a. [redacted]
b. [redacted]
c. [redacted]
d. [redacted]
e. [redacted]
f. [redacted]
g. [redacted]

5.4.2 Additional tools and techniques to gain knowledge of the process

Upon completion of flow diagramming, several other problem solving tools and techniques may also be used to analyze, study, control and optimize the processes. These techniques, described in Appendix C, include:

[redacted]

Inputs for the above techniques may be data from [redacted]

5.4.3 Characterizing variation

There are, in general, three main mechanisms of variation:

a. [redacted]
b. [redacted]
c. [redacted]

It is important that the relative contribution of these sources is investigated - SPC control charting, subgroup formulation and sampling procedures are based on this information. The use of multi-vari charts is very beneficial in tracking down the sources of variation. Multi-Vari charts use vertical lines to represent the range of variation of one unit of product. The resulting

vertical lines are plotted against the tolerance limits to visually show the amount of variation that is using up the tolerance. By using this chart over a series of units, [redacted]

5.5 What to measure

5.5.1 Key characteristics to control

[redacted]

5.5.2 Process variables to control product characteristics

[redacted] Common process variables to consider include:

a. [redacted]

b. [redacted]

5.6 Normality

5.6.1 When and why normality is important

[redacted]

5.6.2 Tests for normality

Methods of testing for normality include:

a. [redacted]
b.
c.
d.

It is recommended that the first three tests be used when reasonably large amounts of data are available. The Shapiro-Wilk test is recommended for small data sets.

5.6.3 Transformations/Curve-fitting

[redacted] Some types of transformations that may be used are:

a.
b.
c.

5.7 Control charting

The control chart has been utilized to enhance process control and process improvement capabilities since its introduction in the late 1920's by W.A. Shewhart. It has become the cornerstone of the time proven methods and practices of SPC.

5.7.1 The basic control chart and its use

[redacted]

5.7.2 Types of control chart

There are two major types of control charts:

a. [redacted]

b. [redacted]

5.7.2.1 Variable chart

Variable charts are concerned with three characteristics:

a. [redacted].

b. [redacted].

c. [redacted]

Table A – Sample size rules for variables control charts

Control Chart Type	Sample Size (n)
[redacted]	[redacted]
[redacted]	[redacted]
[redacted]	[redacted]
[redacted]	[redacted]

[redacted]

[redacted]

5.7.2.2 Attributes charts

Attribute control charts may be applied to quality characteristics that can be observed only as attributes or those that are actually recorded as attributes even though they might have been measured as variables. Attributes charts are concerned with:

a. [redacted]

b. [redacted]

Table B – Sample size rules for attributes control charts

Control Chart Type	Sample Size
[redacted]	[redacted]
[redacted]	[redacted]
[redacted]	[redacted]
[redacted]	[redacted]

5.7.3 Rationale for subgroup size

The following points should be considered in selecting the subgroup size.

a. [redacted]

b. [redacted]

c. [redacted]

d. [redacted]

e. [redacted]

5.7.4 Rationale for sampling frequency

Selecting the appropriate sampling frequency (i.e., the interval between subgroups) is as important a decision as selecting the subgroup size. Sampling frequency may be expressed in terms of time or as a proportion of units produced, such as one subgroup after every 200 units produced. Sampling frequency influences the speed with which process changes are detected and also affects the cost of sampling. The following factors should be considered:

a. [redacted]

b. [redacted]

c. [redacted]

d. [redacted]

5.7.5 SPC for short run production

[redacted]

[redacted]

5.7.5.1 Control charts for short run production - variables data

a. [redacted]

b. [redacted]

c. [redacted]

d. [redacted]

e. [redacted]

5.7.5.2 Control charts for short run production - attribute data

[redacted]

5.7.6 Control chart auditing

a. [redacted]

b. [redacted]

5.8 Assess stability, capability and performance

5.8.1 Stability

5.8.1.1 Introduction

A process is said to be operating in a stable manner (that is, in statistical control) when all special causes have [redacted]

[redacted]

5.8.1.2 Criteria (interpretation)

Interpreting control charts involves [redacted]

Other criteria may also be used.

Test 1. [redacted]

Test 2.

Test 3.

Test 4.

Test 5.

Test 6.

Test 7.

Test 8.

5.8.1.3 Verification

[redacted]

5.8.2 Capability

[redacted]

5.8.2.1 Introduction

[redacted]

[redacted]

5.8.2.2 Process capability index = Cp = (USL-LSL)/(6 sigma)

[redacted]

5.8.2.3 Capability of non-normal distributions

[redacted]

5.8.2.4 Capability for one-sided specifications

[redacted]

[redacted]

5.8.2.5 Verification

[redacted]

5.8.3 Performance

5.8.3.1 Introduction. The performance index determines how well the process is actually performing relative to the specification limits.

5.8.3.2 Index

[redacted]

5.8.3.3 Performance for non-normal data distributions

Method 1. [redacted]

Method 2. [redacted]

Method 3. [redacted]

5.8.3.4 Verification

[redacted]

5.8.3.5 Economic positioning of process

[redacted]

5.8.3.6 Continuous improvement prioritization

[redacted]

5.8.4 Other measures

[redacted]

5.9 Gaging and measurement

It is very important to have valid measurement studies to ensure that the data and measurements collected are accurate and precise. There are a number of methods used to determine validation of the measuring system. Some of the commonly used techniques are:

a. [redacted]
b. [redacted]
c. [redacted]
d. [redacted]

[redacted]

5.10 Final Acceptance using SPC

5.10.1 Requirements for acceptance

Prior to utilization of SPC for Final Acceptance of a characteristic, the controlling process(es) should [redacted].

5.10.2 Actions for acceptance by SPC

a. [redacted].

5.10.3 Customer report generation

A myriad number of SPC activities can be tracked to develop internal metrics and generate statistical reports. Internal metrics are typically calculated and published on a monthly basis. This data is then accumulated into a statistical report and attached to the validation report. Examples of validation reports are as follows:

a. [redacted].

b. [redacted].

[redacted]

6.0 Alternate Methods for Process Validation

This standard focuses on statistical process control and acceptance by the AoZ Tables.
When SPC is not possible, it is recognized that other product acceptance methodologies are also viable. Examples of these other acceptance techniques include Poka-Yoke, calibrated fixtures as a media of inspection, 100% automated inspection, tool control, etc. Any validation plan must demonstrate that it provides [redacted]

6.1 Poka-Yoke or mistake-proofing

[redacted]. The types of Poka-Yoke devices are:

a. [redacted]

b. [redacted]

c. [redacted].

6.2 Calibrated fixtures as a media of inspection - Production Tooling Used as Media of Inspection

When production jigs, fixtures, tooling masters, templates, patterns and such other devices are used as media of inspection, they shall be proved for accuracy prior to release for use.
These devices shall [redacted]

6.3 100% automated inspection

This system must be verified as to the accuracy of the inspection and its fail-safe feature.

7.0 Sampling Inspection

7.1 Sampling

It is through careful design and validation of both the process and process controls that the Company can establish a high degree of confidence that all manufactured units from successive lots will be acceptable. Successfully validating a process may reduce the dependence upon intensive in-process and finished product testing. It should be noted that in most all cases, end-product testing plays a major role in assuring that quality assurance goals are met; i.e., validation and end-product testing are not mutually exclusive.

7.1.1 Preferred sampling plans

[redacted]

7.1.2 Formation and identification of lots or batches

[redacted]

7.1.3 Determination of sampling plan

A sampling plan is determined by:

a. [redacted].
b. [redacted].
c. [redacted]
d. [redacted]

For lot acceptance situations (attributes or variables), the occurrence of one or more nonconformances shall result in [redacted]

7.1.4 Sampling of lots or batches

7.1.4.1 Selection of units

Units of product drawn from a lot for a sample shall be selected at random from the lot without regard to [redacted]

7.1.4.2 Representative (stratified) sampling

When appropriate, the number of units in the sample shall be selected in proportion to the size of sublots or sub-batches, or parts of the lot or batch identified by some rational criterion. When representative sampling is used, the units from each sublot, sub-batch or part shall be selected at random.

7.1.4.3 Process of sampling

[redacted].

7.1.4.4 Non-conforming product

When sample units are drawn during lot or batch assembly and nonconforming units are found, the Company shall withhold from acceptance that portion of the lot completed and all additional production occurring prior to the initiation and verification of corrective action. For lots or batches withheld from acceptance, the Company shall take the following actions:

a. [redacted]

b. [redacted]

c. [redacted]

d. [redacted].

7.2 Acceptance using Sampling

7.2.1 Sampling inspection

[redacted]

TABLE I. Code letters (CL) for entry into the sampling tables

Lot or production interval size	Verification Levels						
	VII	VI	V	IV	III	II	I
2–170	A	A	A	A	A	A	A
[redacted]							

7.2.1.2 Sampling procedures

Sampling is performed at one of three stages called normal, tightened and reduced. [redacted]

7.2.1.3 Switching procedures

The procedures for switching among normal, tightened and reduced inspection are given as Note (2) in Tables II, III and IV. The switching procedures are [redacted]

7.2.1.3.1 Normal to tightened

When normal inspection is in effect, tightened inspection shall be instituted when [redacted]

[redacted]

7.2.1.3.2 Tightened to normal

When tightened inspection is in effect, normal inspection may be instituted when the following conditions are both satisfied:

a. [redacted].

b. [redacted].

7.2.1.3.3 Normal to reduced

When normal inspection is in effect, reduced inspection may be instituted when the following conditions are all satisfied:

a. [redacted].

b. [redacted]

c. [redacted]

d. [redacted]

7.2.1.3.4 Reduced to normal

When reduced inspection is in effect, normal inspection shall be instituted when one of the following conditions occur.

a. [redacted]

b. [redacted]

c. [redacted].

d. [redacted].

7.2.1.4 Discontinuation of acceptance

If sampling inspection of lots or batches remains in tightened inspection due to discovery of nonconformances or when, on continuous sampling plans, there are long periods of screening due to discovery of nonconformances, the Company must discontinue acceptance of the product until the causes of nonconformances are eliminated or other acceptable means have been

instituted. When sampling inspection is restarted after discontinuation of acceptance, it shall be at the tightened inspection stage.

7.2.2 Preferred sampling inspection tables

[redacted].

7.2.2.1 Attributes sampling plans for lot or batch inspection

[redacted]

7.2.2.1.1 Acceptability criterion

[redacted]

TABLE II - Attributes sampling plans

Code letter	Verification levels								
	T	VII	VI	V	IV	III	II	I	R
	Sample size (n_a)								
A	3072	1280	512	192	80	32	12	5	3

NOTES:

(1) [redacted]

(2) [redacted]

7.2.2.2 Variables sampling plans for lot or batch inspection

[redacted]

7.2.2.2.1 Limitations on use

[redacted]

7.2.2.2.2 Nonconforming unit

[redacted]

7.2.2.2.3 Acceptability criteria

[redacted]

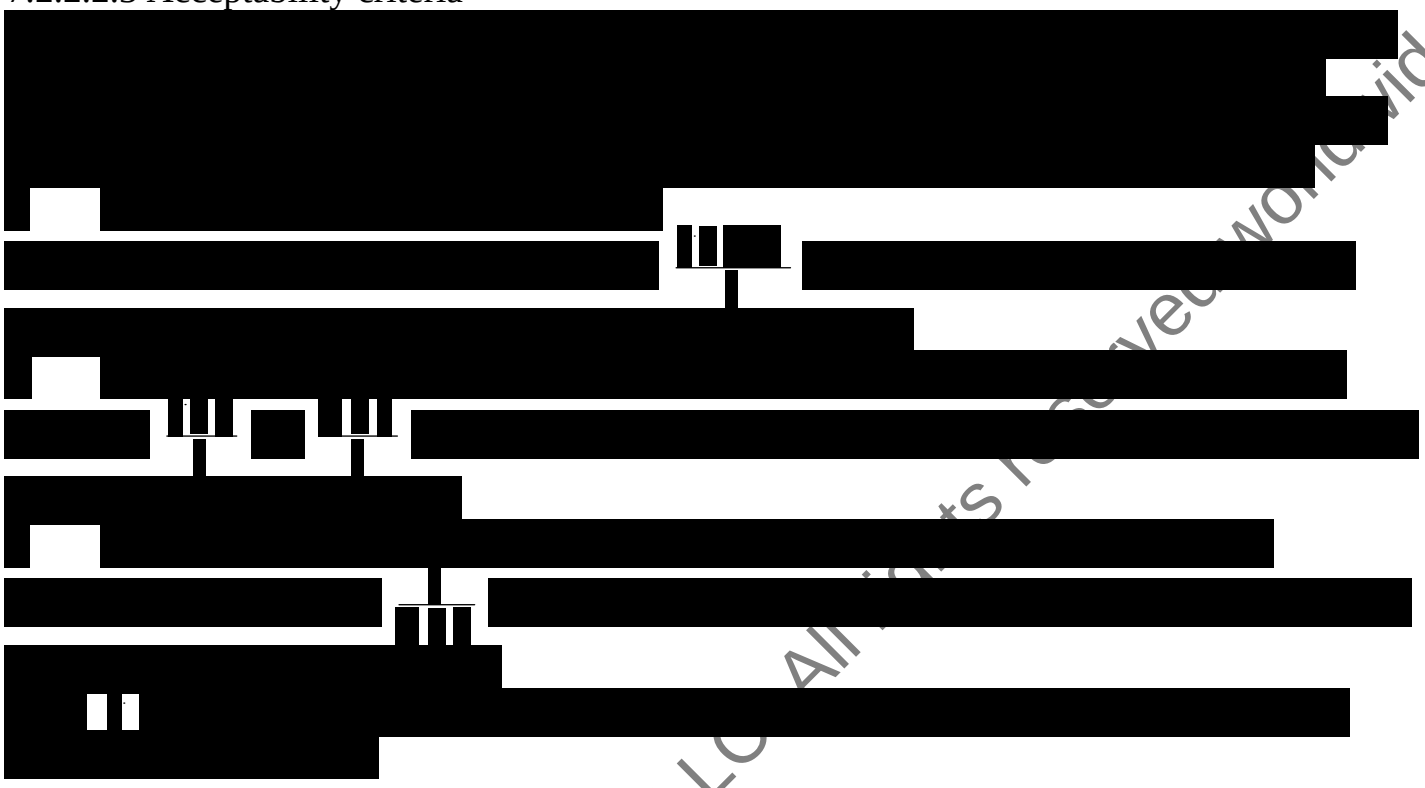

TABLE III - Variables sampling plans

Code Letter	Verification Levels								R
	T	VII	VI	V	IV	III	II	I	
A	113	87	64	44	29	18	9	4	2
	[redacted]								
	K values (one- or two-sided)								
A	3.51	3.27	3.00	2.69	2.40	2.05	1.64	1.21	1.20
	[redacted]								
	F values (two-sided)								
A	.136	.145	.157	.174	.193	.222	.271	.370	.707
	[redacted]								

NOTES:
(1) [redacted]
(2) [redacted]

7.2.2.3 Continuous attributes sampling inspection plans
The preferred continuous sampling plans for inspection by attributes are described in Table IV for normal, tightened and reduced inspection.

TABLE IV - Continuous sampling plans

Code Letter	T	Verification Levels VII	VI	V	IV	III	II	I	R
	Screening Phase: clearance number (*i*)								
A	3867	2207	1134	527	264	125	55	27	*NA*
[redacted]									

NOTES:

[redacted]

7.2.2.3.1 Conditions for continuous sampling procedures

The following conditions must exist before the continuous attributes sampling procedures of this section may be used for inspection.

a. [redacted]

b. [redacted]

c. [redacted]

7.2.2.3.2 Continuous sampling inspection procedure

At the start of production, all units are inspected. Sampling inspection may be initiated at frequency "*f*" when the following conditions are satisfied:

a. [redacted]

b. [redacted]

a. [redacted]

7.2.2.3.3 Acceptability criterion

[redacted]

7.2.2.3.3.1 Special reservation for critical nonconforming unit

[redacted]

7.3 Disposition of nonconforming product

All units of product found to be nonconforming shall be removed and kept apart from the flow of production or otherwise identified or segregated to preclude submission to the Customer. The Company may [redacted]

7.4 Critical characteristics

Unless otherwise specified in the contract or product specifications, the Company is required to implement an automated screening or a fail safe manufacturing operation and apply sampling plan VL-VII to verify the performance of the screening operation. The occurrence of one or more critical nonconformances requires corrective action as specified in paragraph 7.5.

7.5 Special reservations for critical nonconformance

When a critical nonconformance is discovered at any phase of production or during any inspection, the following immediate actions are required:

a. [redacted]
b. [redacted].
c. [redacted]
d. [redacted]
e. [redacted]

Records of corrective actions shall be maintained and made available to the Customer representative.

APPENDIX A - EXAMPLES OF SAMPLING PLAN USE

A.1 SCOPE

A.2 General

This Appendix is not a mandatory part of the standard. The information contained herein is intended for guidance only.

A.3 Purpose

This Appendix illustrates how to implement the three types of sampling plans described in paragraphs 4 and 5 of this standard. The examples explain how to use the four tables, how to apply the switching rules and how to do some of the requisite calculations. In addition, this Appendix explains how the Company can modify Table IV to some extent by calculating and using other "*i*" and "*f*" values.

A.4 APPLICABLE DOCUMENTS

This section is not applicable to this Appendix.

A.5 EXAMPLES

A.5.1 Attributes sampling

Wing nuts are to be inspected for missing thread. A verification level IV (VL-IV) has been specified. The producer chooses to use attributes sampling plans from Table II. Lot sizes may vary as a result of production decisions. A segment of the producer's experience is shown in figure 1.

Lot #	Lot Size	Code Letter	Sample Size	Non-conform-ances	Lot Disposition	Stage T/N/R	Action
1	5000	D	160	2	Withhold Acceptance	N	Begin with normal sampling, VL-IV.
[redacted]							

FIGURE 1 - Attributes sampling inspection log

A.5.2 Variables sampling (single-sided specification limit case)

The maximum temperature of operation for a certain device is specified as 209 (measured in degrees F). Verification level I (VL-I) has been specified. A lot of 40 items is submitted for inspection according to variables sampling. Table III requires a sample size of $n_v = 4$ for code letter A. Suppose the measurements obtained are as follows: 197, 188, 184, and 205; and compliance with the acceptability criteria is to be determined. Computations are shown in figure 2. The lot is accepted since it meets all applicable acceptability criteria.

Line	Information Needed	Symbol	Formula	Result	Explanation
1	Sample size	n_v		4	See Table III
2	Sum of measurements		$\sum x$	774	

FIGURE 2 - Computations for single specification limit case

A.5.3 Variables sampling (double-sided specification limit case)

[redacted]

Line	Information Needed	Symbol	Formula	Result	Explanation
1	Sample size	n_v		4	See Table III
2	Sum of measurements		$\sum x$	774	
[redacted]					

FIGURE 3 - Computations for double specification limit case

A.5.4 Continuous sampling

A visual inspection of stamped metal parts for the presence of a spot weld will be performed immediately after units pass through a spot welding station. Verification level II (VL-II) has been specified. The product will be submitted for continuous attributes sampling inspection. The production interval size is an 8-hour shift, which initially will consist of between 700 to 800 welded parts. With VL-II and code letter C (CL-C) from Table I, the "*i*" and "*f*" values (Table IV) are found to be 116 and 1/48, respectively. A segment of sampling experience is shown in figure 4.

Product Item Number	Code Letter	Frequency or 100%	Stage T/N/R	Event/Action
1	C	100%	N	Start production: Begin screening phase with *i* = 116.
8	C	100%	N	Find a defective unit: Reset counter.
[redacted]				

FIGURE 4 - Continuous sampling inspection log

A.5.5 Continuous sampling - plan tailoring

The Company may opt to use another continuous sampling plan instead of the one specified in Table IV. The only restrictions are that such a change is not allowed while inside a screening sequence and the new plan must be derived according to [redacted]

[redacted] The procedure to determine a valid *f* is as shown in figure 5.

Line	Information Needed	Symbol	Formula	Result	Explanation
1	Clearance number	i		116	Table IV
2	Target *i* number	i_t	$i_t < i$?	Yes	50 < 116
[redacted]					

FIGURE 5 - Procedure to determine a valid *f*

Therefore, an *i* of 50 may be used in lieu of 116 if *f* is increased [redacted]

APPENDIX B - SPC SOFTWARE CONSIDERATIONS

B.1 SCOPE

This appendix provides some factors that should be considered in the acquisition of SPC software.

B.2 PURPOSE OF SPC SOFTWARE.

B.2.1 Software and management objectives

SPC Software should support the objectives management establishes for the quality and production systems.

B.2.2 Assessing effectiveness

No matter what SPC software a organization uses, the key to assessing its effectiveness is objective evidence that the software supports the organization's management system.

B.2.3 Convenience

SPC software is used for convenience factors, speed, and accuracy.

B.2.4 Successful usage

The key to successful SPC software usage is real time data gathering, analysis, and action. Ultimately, reliance should be placed upon the people and systems which drive quality.

B.3 SOFTWARE EVALUATION

B.3.1 End user. Who will be using it?

B.3.2 End use. How will it be used?

a. Data entry/input
b. Plotting, charting, analysis
c. Recalculating limits
d. Response to process condition
e. Summary reports
f. Overall system (SPC) monitoring/maintenance

B.4 SUGGESTED MINIMUM FEATURES

An excellent reference is the annual software issue of “Quality Progress” magazine.

B.4.1 Control charts

As a minimum, the SPC software should be able to produce these control charts:

a. Variable charts, such as: X-bar and R, X-bar and S, X and moving R
b. Attribute charts, such as: u, c, p, np

B.4.2 Out-of-control conditions

As a minimum, the SPC software should automatically detect out-of-control conditions using common conventions or rules.

B.4.3 Variable size subgroups

The SPC software should have subgroup sizes which are user configurable.

B.4.4 Control limits

Control limits should be calculated using accepted statistical methods and centerline values should be clearly displayed. The user should specify when (and if) to recalculate the limits.

B.4.5 Subgroups used

User should define what subgroups to use and when to perform calculations.

B.4.6 Out-of control conditions

The software should require that Out-of-control conditions be acknowledged by someone.

B.4.7 Histogram

Software should generate histograms using individual data.

B.4.8 Process capability

During a capability study, the system should warn the user if the process is not stable or not normally distributed.

APPENDIX C - SELECTED PROCESS IMPROVEMENT TOOLS

C.1 Scope

This appendix lists some tools that are useful for process improvement.

[redacted]

[redacted]

[redacted]

APPENDIX D – PROCESS MODELING

D.1 Process Qualification Sequence

D1.1 Acceptance Criteria

Develop acceptance criteria such as the maximum allowable nonconformance probability and the net sensitivity.

D1.2 Confidence Limit

Base the acceptance criteria on the 90% upper confidence limit for the fraction nonconforming (tail probabilities).

[redacted]

[redacted]

$$NS = \frac{1}{\sigma\sqrt{2\pi}}(e^{-.5(LSL-\mu)^2/\sigma^2} - e^{-.5(USL-\mu)^2/\sigma^2})$$

[redacted]

Tips:
Double click grey area at top and bottom of page to edit header/footer
Search for the word “your” throughout doc and replace as required

Variation Management of Key Characteristics

Mo/Yr

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

Used On	Contract#:	**Your Company Name**	
Prepared By:		Date	
[redacted]		[redacted]	**YOUR PROGRAM**
			Your Procedure #
		[redacted]	Form Rev: Orig 1 of 16

Your Company Logo

TABLE OF CONTENTS

1.0 Scope

This procedure shall be applicable to all production processes that influence the variation of Key Characteristics. This procedure applies to assemblies and all levels of parts within an assembly, including castings and forgings.

2.0 Applicable Documents

Process Control Document (PCD)
First Article Inspection (FAI)

3.0 Requirements

3.1 Variation management activities must be performed on identified Key Characteristics and processes until they are in control and process capability has been established. Appropriate monitoring methodology should then be implemented to ensure continued performance.
3.2 Appropriate documentation of Key Characteristics and manufacturing process elements that influence variation in Key Characteristics shall [redacted]. Documentation shall be developed when any of the following occurs:
a. [redacted]eter.
b. [redacted]
c. [redacted].
3.3 The following requirements must be met if statistical process control is chosen as the method of control for the Key Characteristic:
a. [redacted]
b. [redacted].
c. [redacted]).
d. [redacted]
e. [redacted]

3.4 The use of other variation control methods to ensure process stability and capability may be used, such as [redacted].

3.5 Achieving stable and capable Key Characteristics does not relieve compliance to all drawing characteristics, specifications and other Customer requirements and/or invoked standards.

3.6 Exceptions shall [redacted]

3.7 Process Model

The management of Key Characteristics shall begin with [redacted]

APPENDIX A: Variation Management of Key Characteristics

1.0 Understand Key Characteristics and Required Performance

1.1 Establish an appropriate cross-functional team that has an understanding of the Customer's requirements and the affected manufacturing processes. Review Customer defined Key Characteristic requirements (if any).

1.2 [redacted]

1.3 [redacted]

2.0 Plan a Manufacturing Process to Produce Acceptable Performance

2.1 Define the affected manufacturing process by using a new or existing manufacturing process flowchart. Include the identification of key elements that influence variation of Key Characteristics. Consider existing process capability and Customer capability requirements.

2.2 [redacted]

2.3 [redacted]

2.4 [redacted]

2.5 [redacted]

2.6 [redacted]

2.7 Outputs from planning the manufacturing process

- [redacted]
- [redacted]
- [redacted]

- [redacted]

3.0 Operate the Process on a Trial-Basis to Generate Data

3.1 Create a data collection plan for all Key Characteristics that reflects the sources of variations. [redacted]

3.2 [redacted]

3.3 [redacted]

3.4 [redacted]

3.5 [redacted]

3.6 [redacted]

4.0 Analyze Data to Identify Appropriate Action

4.1 Review control charts to determine if the process is stable. Calculate process capability and provide evidence to demonstrate statistical reasoning and justification in addition to the calculation method. The process capability index (e.g., Cp. and Cpk.) shall be calculated only when the process is stable.

4.2 [redacted]

4.3 [redacted]

4.4 [redacted]

4.5 [redacted]tion.

4.6 [redacted]

5.0 Take Action from Studying the Performance of Key Characteristics

5.1 Take corrective action to permanently remove or minimize the cause, and verify the effectiveness of the corrective action when a process is not stable and the special cause is known.

5.2 [redacted]

5.3 [redacted].

5.4 [redacted]

5.5 [redacted]

5.6 A first article inspection (FAI) may be performed unless it has been performed previously and the process is unchanged.

5.7 Take appropriate action whenever actions are taken that change the manufacturing process.

5.8 Finalize the Process Control Document (PCD) as soon as the process is stable and capable.

5.9 Outputs from study of the performance of Key Characteristics

- [redacted]ts
- [redacted]
- [redacted]
- [redacted]
- [redacted]

[redacted]

6.0 Continue to Monitor the Performance

6.1 [redacted]

6.2 [redacted]

6.3 Outputs from continuing to monitor the process

- [redacted]
- [redacted]
- [redacted]

[redacted]

7.0 Process Change Management

7.1 [redacted].

7.2 [redacted]

7.3 Outputs from process change management

- [redacted]
- [redacted]

[redacted]

APPENDIX B: Process Control Document

Note: Any equivalent method of documentation is acceptable.

Instructions for completing the form:

[redacted]

APPENDIX C

Definitions

ATTRIBUTE DATA
A result from a characteristic or property that is appraised only as to whether it does or does not conform to a given requirement (for example, go/no-go, accept/reject, pass/fail, etc.).

CUSTOMER
An organization that provides Part or System Key Characteristics via engineering drawings, specifications or purchase order/contract requirements. A Customer may be an internal engineering department for a company that has design authority in addition to the external Customer who specifies system Key Characteristics.

DESIGN CHARACTERISTICS
Those dimensional, visual, functional, mechanical and material features or properties that describe and constitute the design of the article as specified by Drawing Requirements Dimensional features include in-process locating features such as target machined (or forged/cast) dimensions on forgings and castings and weld/braze joint preparation necessary for acceptance of finished joint. Material features or properties may include processing variables and sequences, which are specified by the drawing (e.g., heat treat temperature, fluorescent penetrant class, ultrasonic scans, and sequence of welding and heat treat). These provide assurance of intended characteristics that could not be otherwise defined.

DRAWING REQUIREMENTS
Requirements of the drawing (including Parts Lists), specification or purchasing document to which the article is to be made. These include any notes, specifications and lower-level drawings invoked.

EXAMPLE
Guidance Only

FIRST ARTICLE INSPECTION (FAI)
A complete, independent and documented physical and functional inspection process to verify that prescribed production methods have produced an acceptable item as specified by engineering drawings, planning, purchase order, engineering specifications and/or other applicable design documents.

FIRST ARTICLE INSPECTION REPORT (FAIR)
The forms and package of documentation for a part number or assembly, including FAI results.

FIRST PRODUCTION RUN PARTS
The first group of one or more parts that are the result of a planned process designed to be used for future production of these same parts. Prototype parts or parts built using methods different from those intended for the normal production process shall not be considered as part of the first production run.

KEY CHARACTERISTIC (KC):
AS9100/EN-9100/JISQ 9100 definition: The features of a material or part whose variation has a significant influence on product fit, performance, service life or manufacturability.
This definition is further explained as follows:
• Key Characteristics for a part, subassembly or system are those selected geometrical, material properties, functional and/or cosmetic features, which are measurable, whose variation control is necessary in meeting Customer requirements and enhancing Customer Satisfaction.
• Key Characteristics for a process are those selected measurable parameters of a process whose control is essential to manage variation of part or system Key Characteristics.
• Substitute Key Characteristics may be identified when a Customer-defined Key Characteristic is not readily measurable within the production setting and other characteristics may need to be controlled to ensure conformance.

KEY CHARACTERISTIC OWNER
The person or function that defines the Key Characteristics and recognizes the reasons for the selection of the Key Characteristic. Typically, the responsibility is held by Internal or External Customer Design, Quality or Manufacturing Engineering and should be identified by a cross-functional team.

KEY CHARACTERISTIC PROCESS OWNER
The person or function that uses Key Characteristic data to maintain and improve the process.

MULTIPLE CHARACTERISTICS
Identical characteristics that occur at more than one location (e.g., —4 Places“) but are established by a single set of drawing requirements (e.g., rivet hole size, dovetail slots, corner radii, chemical milling pocket thickness).

MUST
Mandatory requirement

PROCESS CONTROL DOCUMENT (PCD)
A written description of a manufacturing plan developed to control variation in Key Characteristics that is updated to reflect the addition / deletion of Key Characteristics.

PRODUCER
An organization that performs any process affecting the manufacture of the part.

PRODUCT
The result of a process that includes finished detailed parts and assemblies and forgings and castings.

REFERENCE CHARACTERISTICS
The characteristics that are used “for information only” or to show relationship. These are dimensions without tolerances and refer to other dimensions on the drawing.

SHALL
Mandatory requirement

SHOULD
Mandatory requirement with some flexibility allowed to exhibit conformance to the intent of this procedure.

SPECIAL CAUSE
The term can be substituted by ‘assignable cause’ and both terms have their usual meanings relative to Statistical Process Control methodology..

STANDARD CATALOG HARDWARE
A part or material that conforms to an established industry or national authority published specification having all characteristics identified by text description, National/Military Standard Drawing or catalog item.

TYPICAL
Guidance Only

VARIABLES DATA
Quantitative measurements taken on a continuous scale. For example, the diameter of a cylinder or the gap between mating parts.

Appendix D: Process Control Document

PROCESS CONTROL DOCUMENT				1 of 2
1. Document Number	6. Process Owner	10. Date (Orig)	11. Date (Rev)	7. Flowchart Created ☐Yes ☐No

2. Part Number / Part Family / Latest Change Level		8. Approval and Date	9. Customer Approval and Date
[redacted]		[redacted]	[redacted]
[redacted]	[redacted]	[redacted]	[redacted]

[redacted]

[redacted]	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]		[redacted]	☐[redacted] ☐[redacted]	☐[redacted] ☐[redacted]
					Cp	Cpk		☐Yes ☐No	☐Yes ☐No
								☐Yes ☐No	☐Yes ☐No
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Form # (mo/yr)

Process Control Document continued…

PROCESS CONTROL DOCUMENT				2 of 2
1. Doc No.	2. P/N – Latest Change	10. Date (Orig)	11. Date (Rev)	

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Form # (mo/yr)