



# Standard Guide for System-Based, Customer-Centered Quality Plan for Manufacturers<sup>1</sup>

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<sup>ε1</sup> NOTE—10.16 was editorially corrected in May 2016.

## 1. Scope

1.1 This guide establishes recommended system-based procedures to assist fastener manufacturers and alteration distributors in the development of process controls which are intended to produce quality products in a cost effective manner. These recommended system-based procedures allow an organization to continually improve operational effectiveness.

## 2. Referenced Documents

### 2.1 ASTM Standards:<sup>2</sup>

[F1469 Guide for Conducting a Repeatability and Reproducibility Study on Test Equipment for Nondestructive Testing](#)

[F1470 Practice for Fastener Sampling for Specified Mechanical Properties and Performance Inspection](#)

[F1503 Practice for Machine/Process Capability Study Procedure](#)

[F1789 Terminology for F16 Mechanical Fasteners](#)

[F2282 Specification for Quality Assurance Requirements for Carbon and Alloy Steel Wire, Rods, and Bars for Mechanical Fasteners](#)

### 2.2 ASTM Manual:

[Manual 22 Total Quality Management-Guiding Principles for Application<sup>2</sup>](#)

### 2.3 IFI Standard:

[IFI-139 Quality Assurance Requirements for Fastener Testing Laboratories](#)

### 2.4 ASME Standards:

[B18.18.1 Inspection and Quality Assurance for General Purpose Fasteners<sup>3</sup>](#)

[B18.18.2 Inspection and Quality Assurance for High-Volume Machine Assembly Fasteners<sup>3</sup>](#)

### 2.5 NIST Program:

[Malcolm Baldrige Criteria for Excellence \(www.nist.gov\)](#)

### 2.6 ISO Standard:

[ISO 16426 Fasteners—Quality Assurance System<sup>4</sup>](#)

NOTE 1—There is no direct relationship of this standard to an ISO counterpart. However, several elements of this guide may be found in ISO 16426.

## 3. Terminology

3.1 Terms shall be defined in accordance with Terminology [F1789](#).

## 4. Significance and Use

4.1 A need exists for a Quality Systems Guide that may be deployed by small to larger manufacturers that give direction on development of process-based systems that drive quality and continuous improvement. This guide does not require third party regulation, thus making it attractive to those manufacturers who are not required to have such certification.

## 5. Management's Role

5.1 Executive management shall be responsible for commitment to a company-wide quality policy. The Quality Policy shall be published, maintained, understood and implemented by all company operation groups.

<sup>1</sup> This guide is under the jurisdiction of ASTM Committee [F16](#) on Fasteners and is the direct responsibility of Subcommittee [F16.93](#) on Quality Assurance Provisions for Fasteners.

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<sup>2</sup> For referenced ASTM standards, visit the ASTM website, [www.astm.org](#), or contact ASTM Customer Service at [service@astm.org](#). For *Annual Book of ASTM Standards* volume information, refer to the standard's Document Summary page on the ASTM website.

<sup>3</sup> Available from American Society of Mechanical Engineers (ASME), ASME International Headquarters, Three Park Ave., New York, NY 10016-5990, [http://www.asme.org](#).

<sup>4</sup> Available from American National Standards Institute (ANSI), 25 W. 43rd St., 4th Floor, New York, NY 10036, [http://www.ansi.org](#).

5.2 *Quality Manual*—The management commitment shall be fully supported by a quality manual which shall be under periodic review.

5.3 *Personnel Training*—Management shall assume responsibility for providing appropriate training for all company personnel. Appropriate training shall include, but not be limited to, job skills, process knowledge, quality training, environmental issues, and safety skills for all organizational process streams.

## 6. Inquiries and Quotation

6.1 *Review of Drawings and Specifications*—All drawings and specifications that are applicable to a given inquiry shall be reviewed prior to issuance of a quotation. This review shall include engineering, manufacturing, production materials, processes, quality assurance, cost accounting and outside sourcing as applicable to ensure that all of the customer's requirements can be met.

6.2 *Ongoing Review*—The activity specified in 6.1 shall be subject to a periodic internal audit/review which will evaluate its ability to respond to the purchaser in a timely and accurate manner. Frequency of the internal audit/review shall be determined on past audit/reviews, but shall be conducted at least once a year. The results of the review shall be reported to and reviewed by management.

## 7. Engineering

7.1 *Specification Requirements*—For products defined by recognized standards, there shall be evidence that the applicable specifications for material, configuration, processing, finishing, inspection testing and packaging, were based upon established requirements specified in these standards and are related to fit, form, and function. Unless otherwise specified in the contract or purchase order, the latest revision of any cited or applicable specification shall be used.

7.2 *Drawing Requirements*—Drawings shall define all features and characteristics of the fastener. The use of informal sketches, uncontrolled drawings, and red lined changes to drawings, specifications, and process documents shall not be permitted in the purchasing, fabrication, process, test, or inspection operations.

7.3 *Design Change/Configuration Control*—A documented procedure shall exist for controlling and authorizing the development, release, change, use, and control of design documents. The procedure shall be adequate to prevent the use of obsolete design documents.

## 8. Procurement

8.1 *Responsibilities of Procurement*—The system and process for procurement of fastener materials, services, components, and assemblies shall be formally planned, documented, and controlled. The authority and responsibility of the organizations involved in interaction with the control of suppliers shall be established by management and documented. The fastener manufacturer and alteration distributor shall have an active documented system to verify the performance of suppliers.

8.2 *Supplier Evaluation*—The appropriate representatives from all segments of the organization shall participate, as needed, for approval of sources of materials and services.

8.3 *Source Approvals and Controls*—The organization shall formally audit on-site the supplier's or source's capability to furnish conforming materials and/or services relevant to supply, manufacture, processing, or alteration of fasteners. This audit shall be documented with procedures that include input as required, from quality assurance, engineering, materials, processing, and procurement. Subsequently, the suppliers or sources shall be evaluated on the basis of on-site surveys, physical audits, or current quality history. Such evaluations shall be conducted on an ongoing basis, but no less than annually. Evidence of evaluations shall be current and on-site audits shall be conducted at least once every four years.

8.4 *Technical Requirements*—Specifications, drawings, and purchase orders shall define and communicate applicable requirements to the supplier of materials and services.

## 9. Production

9.1 *Production Responsibilities*—A production procedure manual shall establish a controlled approach for product quality in production encouraging interaction with engineering, procurement, materials, processing, and quality assurance. The manufacturer or alteration distributor shall have in place a production procedures manual defining all elements of production which shall include as a minimum the elements listed under 9.2.

### 9.2 *Production and Planning Elements* :

9.2.1 *Capacity*—The manufacturer or alteration distributor shall have evidence that production is related to his manufacturing or alteration capacity.

9.2.2 *Equipment Capability*—The manufacturer or alteration distributor shall have evidence that capability studies have been conducted to verify ability to manufacture or alter and to process fasteners to specification requirements. Practice F1503 may be used for these studies.

9.2.3 *Tooling*—Evidence shall be present that a system exists for the design, purchase, inventory, and control of perishable and nonperishable tooling.

9.2.4 *Equipment Operators*—There shall be evidence that equipment operators have appropriate training in accordance with their specific responsibilities.

9.2.5 *Repair and Maintenance*—There shall be in place a program for preventative maintenance of manufacturing and processing equipment. Maintenance shall be performed at prescribed intervals. Records shall be maintained of maintenance and repair on manufacturing and processing equipment.

9.2.6 *Scheduling*—There shall be in place a system to evaluate and schedule the manufacturing or alteration capacity to meet stated customer requirements, including timeliness.

9.2.7 *Production Planning*—Production shall be carried out in accordance with a production plan of the process. This controlled approach should include tooling, material, processes, specifications, and the sequence of operations including outsource services. Process Flow Diagrams are helpful in documenting these requirements.

9.2.8 *Lot Control/Segregation*—There shall be in place a system to identify product in-process by lot identifiers traceable to the mill heat of raw material from which it is manufactured.

9.2.9 *Inspections*—In-process inspection, testing, and final verification shall be in place in accordance with requirements for in-process control (10.14.1), and verification (10.14.2).

## 10. Quality Assurance Program/System Elements

10.1 *Quality System Organization*—The organizational structure, functional responsibilities, levels of authority, and lines of communication for activities affecting quality shall be documented. Top management shall appoint a member of management who, is independent of other responsibilities and shall have responsibility and authority that includes:

10.1.1 Ensuring those processes needed for this standard are established, implemented and maintained,

10.1.2 Reporting to top management on the performance of the organization to this standard, and any need for improvement, and

10.1.3 Ensuring the promotion of awareness of customer requirements throughout the organization.

10.2 *Quality System Self Audit*—There shall be in place a system for internal audits to ensure compliance with this standard to verify the presence of, the adequacy of, and compliance with all aspects of the quality assurance system and to determine its effectiveness. These audits shall be performed in accordance with written procedures or checklists by personnel who do not have direct responsibility or involvement for performing the activities being audited. Audit results shall be documented, reported to, and reviewed by responsible management. These internal audits shall be conducted at least annually in accordance with the provisions of the Quality Assurance Manual. Documented corrective and preventive action shall be taken, where indicated, in a timely manner.

10.3 *Quality System Records*—Records that furnish documentary evidence of product conformance and traceability shall be specified, prepared, and maintained. Records shall be legible, identifiable, and retrievable. Records shall be protected against damage, alteration, deterioration, or loss. Requirements and responsibilities for record transmittal, distribution, retention, maintenance, and disposition shall be established and documented.

10.4 *Document Control*—The manufacturer or alteration distributor shall have in place a system governing the preparation, change and distribution, of documentation that specifies dimensions, mechanical, chemical, and performance requirements of the fastener. This system shall provide for the assignment of responsibility for preparing, reviewing, approving, and issuing documents. Persons other than those so designated shall make no changes to any documents.

10.5 *Testing Equipment, Measuring Devices, and Gages*—All testing equipment, measuring devices, and gages used to verify conformance to applicable standards and specifications shall be controlled and, at specified intervals, shall be calibrated to maintain accuracy within necessary limits. All calibrations shall be traceable to applicable national or interna-

tional standards or special certified masters if no international standard exists. Such equipment shall be uniquely numbered/identified and have a documented plan for maintenance, control, and repair actions. All testing equipment, measuring devices, and gages used in statistical quality control shall be qualified using Guide F1469. A system shall be in place that will, if necessary, identify and retrieve material or product found to be nonconforming because of equipment, measuring devices, or gages out of calibration. For fasteners that are subject to the FQA, laboratory accreditation by an independent third party shall serve as evidence of conformance.

10.6 *Raw Material Control and Traceability*—The raw material requirements shall be described by a document such as a recognized standard or specification such as Specification F2282. This description shall include size, type, chemistry, source, condition, and any other information deemed necessary to satisfy the product specification and manufacturing process. All raw materials shall be fully traceable and accompanied by a mill test report. A system shall be in place to control the identity, storage, and handling of raw material from receiving to the production operation.

10.7 *In-Process Material Control and Traceability*—A system shall be in place that maintains product traceability back to the original mill heat of raw material. This system shall be capable of maintaining lot identity with respect to factory order, part number, strength levels, manufacturing event, and all subsequent processing inspections and testing events.

10.8 *Finished Product Lot Control and Identification*—A system shall be in place for the handling, storage, and identification of finished products based on segregation by lot number. Distribution entities shall ensure lot control in their storage and movement operations from receipt of product to shipment of said product to their customer.

10.9 *Packaging and Inventory of Finished Product*—Lot purity, lot identity, and traceability shall be maintained throughout the entire operation in such manner to prevent commingling.

10.9.1 All products shall be packaged to prevent damage during storage and/or shipment. Containers shall be labeled to identify the contents, responsible party, country of origin, and lot number.

10.9.2 When required, the manufacturer or alteration distributor shall be able to issue a certified test report for each lot of fasteners in each respective container.

10.9.3 There shall be in place a system to accurately account for all products with respect to size, type, quantity, location, and lot number.

10.10 *Product Conformance in Manufacturing, Processing and Alteration (ppm)*—In this standard, the quality of a manufacturing or shipping lot is defined in terms of ppm. This means that a lot may contain no more than a certain number of nonconformities per million to be acceptable. In this standard we define and control ppm through the use of process statistical control. See Appendix X1 for a further explanation of ppm.

10.10.1 Manufacturing shall apply such controls as necessary to assure a process capability:  $C_{pk} \geq 1.33$  for all significant design characteristics (see 10.16 for definition of significant

design characteristics). (This will yield at least 99.994 % acceptance rate to product specifications, and provide no more than between 0 and 60 ppm out of specification when the process is exactly centered.)

10.10.2 All post manufacturing operations (i.e., heat treat, coating, packaging) shall maintain a  $C_{pk} \geq 1.33$  for significant design characteristics.

10.11 *Control of Nonconforming Material and Product*—The manufacturer and alteration distributor shall have in place a documented system to facilitate an orderly and timely disposition of nonconforming material or product. See Guide F1470 for guidance on disposition of nonconforming fasteners. This system shall provide for identification, segregation, evaluation, documentation, and disposition of nonconforming material or products.

10.12 *Corrective Action*—There shall be a documented procedure established to define requirements for:

- 10.12.1 Identifying nonconforming conditions,
- 10.12.2 Reviewing nonconformities (including customer complaints),
- 10.12.3 Determining their causes,
- 10.12.4 Accessing the need for action to ensure that nonconformities do not recur,
- 10.12.5 Identifying and implementing action needed,
- 10.12.6 Evidence of results of action taken, and
- 10.12.7 Auditing corrective action taken.

10.13 *Preventive Action*—The organization shall take appropriate action to eliminate the causes of potential nonconformities. There shall be a documented procedure established to define requirements for:

- 10.13.1 Determining potential nonconformities and their causes,
- 10.13.2 Evaluating the need for action to prevent occurrence of nonconformities,
- 10.13.3 Identifying and implementing action needed,
- 10.13.4 Evidence of results of action taken, and
- 10.13.5 Auditing of preventive action taken.

10.14 *Inspection and Testing*—Inspections and tests required to verify conformance of a fastener to its specification requirements shall be planned, executed, and documented. A complete program outline may be found in IFI-139.

10.14.1 *In-Process Control*—At each machine or processing station, the part shall be checked during production for designated characteristics imparted to it by that machine or process. In-process control levels, frequency, and sample selection shall be planned, and documented.

10.14.2 *Verification*—There shall be a system in place for the verification of each lot of fasteners where applicable. The verification is to assure that the lot consists of the ordered parts, to check for mechanical property conformance, mixed stock, and to reinspect certain functionally important characteristics that may have been altered during heat treatment and/or finishing operations. Verification shall also include examination of any applicable characteristic not verified in-process. Verification records shall be maintained. Verification levels, frequency, and sample selection shall be in accordance with applicable standards or specifications.

10.15 *Control of Purchased Items and Services*—Purchased items and services shall be controlled by the applicable provisions of Section 8.

10.16 *Statistical Methods and Continuous Improvement*—Manufacturers and alteration distributors shall use statistical methods for process control and continuous improvement methods for operational performance. The minimum capability for significant design characteristics shall be  $C_{pk} \geq 1.33$ . Significant design characteristics are those characteristics that significantly influence the ability of a fastener to fulfill its fit, form, or function. Such characteristics are listed in Guide F1470, ASME B18.18.1, and ASME 18.18.2. Tables 1 and 2 of this standard are based on those documents and list specific characteristics that shall be selected by the purchaser based on intended application. The purchaser and the supplier shall agree on this selection of the significant design characteristics at the time of order.

10.16.1 There shall be evidence that management is committed to this operating practice. Statistical training, implementation of statistical methods and continuous improvement shall be supported by action plans. Suggested statistical and continuous improvement methodologies include Statistical Process Control, Statistical Sampling, FMEA (Failure Mode & Effects Analysis), and the criteria for business excellence described in the Malcolm Baldrige National Quality Program, and in Manual 22, Total Quality Management-Guiding Principles for Application.

10.17 *Training and Education*—There shall be evidence of continuous training and education in all phases of the manufacturer's operation. This program shall be documented with respect to subject, material, instructors, attendees, training materials, and length and frequency of the sessions. Management shall assure those personnel holding positions with critical job skills requiring government, industry, or professional society qualifications are certified.

10.18 *Change Control*—Any change that would affect the performance of a fastener, or otherwise deviates from the specification, shall be approved by the customer in writing prior to implementation. The manufacturer or alteration distributor shall have in place a documented system for describing the methods of obtaining approvals and lot identification from the customer for deviations on the product specification or customer requirements.

## 11. Document Management

11.1 *Retention and Disposition*—The manufacturer or alteration distributor shall develop and implement a program for the establishment of the retention period for records pertinent to product history and traceability and the method for retiring or disposing of these records. The retention and disposition program shall not violate or conflict with customer requirements stated in the purchase order. Identification of the records to be retained for each functional organization or operation shall be evident. Inspection and testing records shall demonstrate compliance with customer requirements relating to the required product and services quality. Records shall be protected from damage, deterioration, and loss.

**TABLE 1 Dimensional Characteristics**

NOTE 1—Legend: NA = not applicable; WA = when applicable

Characteristic		Internally Threaded	Externally Threaded	Non-Threaded
<b>Length</b>				
1	Shank diameter (body or shoulder) <sup>4</sup>	NA	WA	WA
2	Shank length (body or shoulder) <sup>4</sup>	NA	WA	WA
3	Grip length	NA	WA	WA
4	Total thread length	NA	WA	NA
5	Concentricity of shank to thread or pitch diameter	NA	WA	NA
6	Length-overall	WA	WA	NA
<b>Heads, Protrusions, or Nuts</b>				
7	Width across flats	WA	WA	WA
8	Width across corners	WA	WA	WA
9	Head height or nut thickness or head thickness	WA	WA	WA
10	Wrenching height	WA	WA	NA
11	Head or nut diameter	NA	WA	WA
12	Flange diameter	WA	WA	WA
13	Flange thickness	WA	WA	WA
14	Flange flatness	WA	WA	WA
15	Head and/or flange location	WA	WA	WA
16	Chamfer or radius, top or bottom of head or nut	NA	WA	WA
<b>Bearing/Head to Shank/Runout/Protrusion</b>				
17	Mandrel protrusion	NA	NA	WA
18	Blind side protrusion	NA	NA	WA
19	Mandrel diameter	NA	NA	WA
20	Location between thread and shank	NA	WA	NA
21	Location between head and shank	NA	WA	WA
22	Bearing surface diameter (washer face diameter)	WA	WA	WA
23	Bearing surface (washer face) thickness	WA	WA	WA
24	Location between thread and outside dimension for nuts	WA	NA	NA
25	Angularity of bearing surface	WA	WA	WA
26	Diameter of undercut	NA	WA	WA
27	Depth of undercut	NA	WA	WA
28	Width of undercut	NA	WA	WA
29	Radius or fillet under head	NA	WA	WA
30	Underhead fillet transition diameter	NA	WA	WA
31	Underhead fillet transition length	NA	WA	WA
32	Shoulder chamfer	NA	WA	WA
33	Thread neck fillet	NA	WA	WA
34	Thread neck width	NA	WA	NA
35	Head countersunk angle	NA	WA	WA
36	Runout of the bearing surface with respect to the shank or thread	WA	WA	WA
37	Head protrusion/flushness	NA	WA	WA
<b>Point</b>				
38	Point diameter	NA	WA	WA
39	Point length	NA	WA	WA
40	Dog point diameter	NA	WA	WA
41	Dog point length	NA	WA	WA
42	Dog point concentricity	NA	WA	WA
43	Oval point radius	NA	WA	WA
44	Angles-all points-all set screw configurations	NA	WA	WA
45	Corner radius	NA	WA	WA
<b>Drive/Cross Drill</b>				
46	Recess or socket depth penetration	NA	WA	NA
47	Angle, bottom of socket	NA	WA	NA
48	Wall thickness	NA	WA	NA
49	Location of recess	NA	WA	NA
50	Location of hole or socket	WA	NA	NA
51	Socket or hole size	NA	WA	NA
52	Countersink diameter and depth	WA	NA	WA
53	Angularity of tapping by tapping screws	NA	WA	NA
54	Slot width	WA	WA	WA
55	Slot depth	WA	WA	WA
56	Slot alignments and location	WA	WA	WA
57	Cross-drilled holes-location	NA	WA	WA
58	Cross-drilled holes-diameter	NA	WA	WA
59	Cross-drilled holes-chamfers or burrs	NA	WA	WA
60	Cross-drilled holes-hole alignment	NA	WA	WA
<b>Washers for Assembly</b>				
61	Type of washer(s)	NA	NA	WA
62	Washer outside diameter	NA	NA	WA
63	Washer inside diameter	NA	NA	WA
64	Washer thickness	NA	NA	WA

**TABLE 1** *Continued*

Characteristic		Internally Threaded	Externally Threaded	Non-Threaded
65	Bearing width	NA	NA	WA
66	Section width	NA	NA	WA
Other				
67	Thread acceptability <sup>B</sup>	WA	WA	NA
68	Visual inspection <sup>C</sup>	WA	WA	WA
69	Straightness	NA	WA	WA

<sup>A</sup> The term shank includes body diameter, shoulder diameter, and any length of unthreaded cylinder whose diameter is approximately pitch diameter.

<sup>B</sup> Refer to ASME B1.3M, or other applicable standards.

<sup>C</sup> Visual inspection for grade and source identification, presence of finish, duds, head and/or flange eccentricity, flange flatness, radius under head, type of washer, presence of locking features, closeness of thread to head, and general workmanship.

**TABLE 2 Performance and Mechanical Characteristics**

NOTE 1—Legend: NA = not applicable; WA = where applicable

Characteristic	Description of Control			
	Internally Threaded Parts	Externally Threaded Parts	Non-Threaded	Washers
Adhesion (coating)	WA	WA	WA	WA
Assembly tension test	NA	WA	NA	NA
Bend, body (nails)	NA	NA	WA	NA
Bend, notched (bolts)	NA	WA	NA	NA
Bend, body (track spikes)	NA	NA	WA	NA
Breaking strength (eyebolts)	NA	WA	NA	NA
Carbide precipitation	WA	WA	WA	WA
Case depth/decarburization	WA	WA	WA	WA
Chemistry <sup>A</sup>	WA	WA	WA	WA
Compression (washer direct tension)	NA	NA	NA	WA
Cone proof	WA	NA	NA	NA
Drive test	WA	WA	NA	NA
Elongation—Machined specimen	NA	WA	WA	NA
Extension at failure	NA	WA	WA	NA
Grain size <sup>B</sup>	WA	WA	WA	WA
Hardness <sup>C</sup>	WA	WA	WA	WA
Bend, head (track spikes)	NA	NA	WA	NA
Humidity	WA	WA	WA	WA
Hydrogen embrittlement	WA	WA	WA	WA
Impact	NA	WA	WA	NA
Lubrication	WA	WA	WA	WA
Magnetic permeability	WA	WA	WA	WA
Packaging <sup>D</sup>	WA	WA	WA	WA
Plating/coating thickness (weight)	WA	WA	WA	WA
Product identification marking <sup>E</sup>	WA	WA	WA	WA
Proof load—Full size	WA	WA	NA	NA
Reduction of area—Machined specimen	NA	WA	WA	NA
Bend, rivet	NA	NA	WA	NA
Flattening, rivet	NA	NA	WA	NA
Rotational capacity	WA	WA	NA	WA
Salt spray <sup>F</sup>	WA	WA	WA	WA
Shear strength	NA	WA	WA	NA
Stress corrosion	WA	WA	WA	WA
Surface discontinuities	WA	WA	WA	WA
Surface roughness	WA	WA	WA	WA
Tensile strength—Full size <sup>G</sup>	NA	WA	WA	NA
Tensile strength—Machined specimen	NA	WA	WA	NA
Torque <sup>H</sup> (prevailing)	WA	WA	NA	NA
Torque (torsional strength)	WA	WA	NA	NA
Yield strength—Full size	NA	WA	NA	NA
Yield strength—Machined specimen	NA	WA	NA	NA

<sup>A</sup> A certified copy of the material's chemical or product analysis shall be furnished with each shipping lot, and the shipping lot shall have documentation providing traceability to this chemical analysis. It is required that the purchaser of the raw material (used to manufacture) shall verify that the material is the material specified on the purchase order.

<sup>B</sup> Steel making practice (course or fine grain) shall be included with the material producer's chemical analysis report.

<sup>C</sup> Surface, core, or both, as applicable.

<sup>D</sup> All packaging requirements shall be in conformance with the applicable packaging standard.

<sup>E</sup> Visual inspection for conformance.

<sup>F</sup> Continuous monitoring of salt spray performance in accordance with the recommendation of Control Check 18 in Appendix III of ASME B18.18.2 constitutes compliance with the requirements for salt spray testing outlined in this table.

<sup>G</sup> Wedge angle or axial test as applicable.

<sup>H</sup> Prevailing torque test includes thread start, all specified torque requirements, and retention of locking feature, when applicable.

11.2 *Security and Authentication*—Evidence shall exist to ensure that prudent steps have been taken to ensure authenticity and controlled reproduction of certificates of conformance, laboratory test reports, mill certifications, certified test reports, and other relevant documents to prevent unauthorized use, copying, alteration, counterfeiting, or distribution of these documents.

11.3 *Document Quality*—Evidence shall exist that all original and reproduced documents are fully legible to the unaided eye with the exception of corrective lenses.

11.4 *Control*—A system shall be in place for recording the receipt, identification of document number, revision level, and distribution of documents within the facilities. The system shall provide for the retrieval and/or replacement of documents made obsolete by recall, revision, mutilation, marking, obsolescence or wear. Assurance shall exist that the appropriate revision level of documents is used in the purchase, receipt, fabrication, verification, and delivery of products.

## 12. Servicing

12.1 The supplier shall establish and maintain procedures for performing and verifying that any agreed service requirement is fulfilled.

## 13. Quality Performance

13.1 A system shall be in place to measure/determine the quality performance of the manufacturer or alteration distributor on an ongoing basis.

13.2 The quality performance data shall be made known to all employees of the organization.

13.3 The measure of quality performance shall be ppm.

13.4 The quality performance data shall be presented to management for review on a regular basis.

## 14. Contingency Plan

14.1 A written plan should exist to deal with unforeseen work interruptions. This plan would outline steps to be followed for given unforeseen interruptions in production. Exceptions may exist for catastrophic occurrences.

## 15. Keywords

15.1 continuous improvement; customer centered quality plan; distributor quality; Malcolm Baldrige National Quality Program Criteria for Excellence; manufacturing quality; quality plans; quality systems

# APPENDIXES

## (Nonmandatory Information)

### X1. PARTS PER MILLION (PPM)

#### X1.1 Introduction

X1.1.1 This concept, parts per million (ppm), was introduced in the late 1980's to establish goals which are desirable quality objectives for the manufacturer of mechanical fasteners by cold forming. The ppm measurement has become a method to evaluate existing processes and suppliers. When ppm is plotted against cost, a logarithmic curve is produced as the ppm target is moved towards zero. The last stages in the concept of moving towards zero ppm are the most costly to achieve and must be considered in terms of cost versus value. Much depends upon the means used to measure the ppm and exactly what is included in that measurement.

#### X1.2 Definition

X1.2.1 Parts per million (ppm) is the number of mechanical fasteners which have one or more nonconforming significant design characteristic(s) in a theoretical one million piece lot.

#### X1.3 Contributing Factors

X1.3.1 *In Plant*—Depending upon the complexity of the fastener geometry, mechanical and performance properties, and type of corrosion protection, the fasteners in a given lot may be moved several times within the manufacturing plant. The movements may involve several changes in container(s) and

thus afford opportunity for lot contamination in addition to thread nicks and other surface imperfections which may impact fastener function.

X1.3.2 *Out of Plant Processing*—Many producers subcontract heat treating, plating, and/or other process operations that offer additional opportunities for lot contamination and surface discontinuities.

X1.3.3 *OEM Plant Procedures*—While some OEM plants employ procedures to avoid conditions which may create further contamination, many may not. Open boxes, moisture, mixing lots in bins and multiple same part suppliers may contribute to further lot contamination, corrosion or part damage.

#### X1.4 Measurement of ppm

X1.4.1 To evaluate a mechanical fastener, the numerous characteristics that may be applicable to determine its fit, form and function must be established for inspection purposes.

X1.4.2 **Tables 1 and 2** list those characteristics for a wide range of mechanical fasteners.

X1.4.3 **Table 1** deals with dimensional characteristics, and **Table 2** with mechanical and performance characteristics. The user must select the applicable characteristics from these tables

that determine the fit, form and function of a given lot of fasteners. These would then become the basis for establishing a ppm target.

### X1.5 ppm Calculations

X1.5.1 Historically, manufacturers of fasteners have used two basic measurements. Namely the number of pieces and/or weight in pounds. At cold forming machines a piece count is generally used, while in further processing during plating or heat treating a common unit of measurement is weight. There are several methods to calculate ppm, and all of them are subject to error in interpretation. Therefore, caution must be exercised when using this measurement.

X1.5.1.1 *Actual Count*— A lot of fasteners (or other attribute) is inspected 100 %, and then a calculation is made by relating the number of nonconforming pieces in the given lot to the number of nonconforming pieces in a theoretical 1 000 000-piece lot having the same % nonconforming. Example: A 100 000-piece lot is 100 % inspected, and 20 nonconforming fasteners are detected. Therefore a 1 000 000-piece lot would be expected to contain  $10 \times 20$ , or 200 nonconforming parts equating to 200 ppm.

X1.5.1.2 *Sampling*—A 100 000-piece lot of fasteners (or other attribute) is sampled. The sample size is 100, and 5 nonconforming parts are detected. To take 100 to 1 000 000, one multiplies by 1000. Therefore, we multiply  $5 \times 1000$  to get 5000 ppm. If one is using a zero defects sampling plan such as

Guide F1470, and achieves 0 nonconforming in your sample, you must assume a 5 % risk of accepting a nonconforming lot. Therefore, it may be possible to have nonconforming parts in the lot, but the calculation of ppm is not possible.

X1.5.1.3 *Statistical Analysis*—One needs only to convert the  $C_{pk}$  for a given process characteristic, and convert that to ppm. This method considers all available variances that influence a process over time, therefore it is considered highly accurate.

### X1.6 State-of-the-Art

X1.6.1 Fastener manufacturers employ all prudent and economic steps to reduce the typical ppm values for their product shipments to the minimum value. In many cases these values are less than 100 ppm. To achieve lowest values, often inspection may be carried out using state-of-the-art laser sensing devices that may actually examine multiple characteristics at one time. Most of these are dimensional fit and form characteristics, however, and do not lend themselves to the mechanical and performance characteristics for function found in Table 2. These characteristics require actual destructive evaluation and the inspection level may be reduced by the establishment of in-process controls. While the goal of zero ppm is highly desirable, it awaits the development of new, state-of-the-art technology to bring about the economics to reach this objective for mass produced high-volume fasteners.

## X2. GUIDANCE TO OPERATIONAL EFFECTIVENESS AND CONTINUOUS IMPROVEMENT

X2.1 In order for an organization to improve, it must have a complete understanding of where they currently are in relation to where they wish to be. They also must have a clearly defined understanding of the internal and external factors that shape their operating environment.

X2.2 Therefore, what your organizational profile does is to address your operating environment, your key organizational relationships, your competitive environment and strategic challenges, and your approach to performance improvement. It gives a critical insight into the key internal and external factors that shape your operating environment. These factors, such as

the mission, vision, values, competitive environment, and strategic challenges, impact the way your organization is run and the decisions you make.

X2.3 To determine your organization's profile, please acquire a copy of the criteria from the Baldrige National Quality Program, and simply follow the guidelines for completing your profile. The profile may be downloaded from [www.baldrige.nist.gov/eBaldrige/Step\\_One.htm](http://www.baldrige.nist.gov/eBaldrige/Step_One.htm), and it is free. This could be one of the more important and cost effective things you can do to improve your business operations.



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