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Standard Guide for System-Based, Customer-Centered Quality Plan for Manufacturers[1]

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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:*[2]

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[2]

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[3]

B18.18.2 Inspection and Quality Assurance for High-Volume Machine Assembly Fasteners[3]

2.5 *NIST Program:*

Malcolm Baldrige Criteria for Excellence (www.nist.gov)

2.6 *ISO Standard:*

ISO 16426 Fasteners—Quality Assurance System[4]

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.

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.

[1] 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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[2] 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.

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

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

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 international 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, and 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.

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.