GE - Aviation, Services Supplier Quality Specification

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Title: QUALITY SYSTEM STANDARD FOR MANUFACTURERS AND PROCESSORS

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Description of Changes:

REV#	DATE	DESCRIPTION
00	08 Sep 1999	Original Issue
01	15 Nov 2002	General Revision to split into Parts I, II, and III
02	03 May 2005	General Revision to incorporate new ISO 9001:2000 requirements, changed Author from Dave Bridge and Approved By from John Pina.
03	19 Apr 2007	Changes business name in accordance with corporate branding requirements.
04	19 Feb 2008	Incorporated latest regulatory requirements and record retention.
05	08 Feb 2012	Updated Issuing Function, Business Name, and Incorporated latest ISO9001/AS9100 requirements.

I. PURPOSE

To define the minimum quality program requirements for manufacturer and special process suppliers who provide material or services to meet GE - Aviation, Supply Chain, ISO9001, and AS9100 requirements.

II. DEFINITIONS

A. Abbreviations

PAH - Production Approval Holder

PC - Production Certificate

PMA - Part Manufacturer Approval

TC - Type Certificate

TSO - Technical Standard Order

- B. **Accountable Manager** The manager of an supplier with whom the ultimate responsibility of delivered product conformance and quality resides.
- C. First Article The first item being produced by a fixed process.

- D. **Manufacturer** A supplier that makes parts complete, or assembles parts into a subassembly (including suppliers of castings and forgings).
- E. **Parts Manufacturer Approval (PMA)** The system described in FAR 21.303 and in FAA Order 8110.42 whereby a company may obtain FAA approval for the design and production of replacement parts without the involvement of the original equipment manufacturer (OEM). In addition, the FAA PMA system provides for approval of parts designed and produced to support a modification approved under an FAA Supplemental Type Certificate (STC).
- F. **Processor** A supplier that performs operations, or processes, on hardware owned by other companies (including special processes and machining), but does not make the complete part for GE Transportation, Aircraft Engines Services.
- G. **Production Approval Holder (PAH)** The holder of an approval issued by the FAA for the production of aviation items. The approval must be for the manufacturer under a Type or Production Certificate, a Part Manufacturer Approval (PMA), or a Technical Standard Order (TSO).
- H. **Quality System** The total network of administrative and technical data and detailed procedures required to maintain the product and parts thereof to specified airworthiness standards. In addition, refers to the supplier's total network of administrative and detailed procedures implemented to ensure that the product satisfy the customer's aviation quality requirements and, in particular, that the parts documentation accurately reflects the criteria identified in the purchase order.
- I. **Quality System Standard** Criteria developed by various suppliers that provide a means to ensure that the supplier's quality system provides an acceptable level of control.
- J. Special processes Those processes which modify or change the inherent physical, chemical, electrical or metallurgical properties of an item; non-conventional methods which remove or deposit material on the item during or after fabrication which cannot be fully evaluated by nondestructive means; or those used to maintain process control such as nondestructive testing. These processes may require a demonstration of operator or equipment capability or proficiency and require special controls for monitoring per specification. Means for compliance are contained in individual specifications.
- K. **Supplier** Sources other than GE Aviation, Supply Chain, who supply material, parts, processes, or services for incorporation into GE Aviation products.

III. SCOPE

- A. This standard is in addition to or in conjunction with any other requirements that may be referenced in the purchase order. This standard specifies requirements for a quality management system where an supplier needs to demonstrate its ability to consistently provide product that meets customer and applicable regulatory requirements, and aims to enhance customer satisfaction though the effective application of the system, including processes for continual improvement of the system and the assurance of conformity to customer and applicable regulatory requirements. The term supplier used herein will refer to both subcontractors, direct materials and parts distributors.
 - 1. **Part I** of this standard applies to component repair and overhaul suppliers and can be applied independently of parts two and three.
 - 2. **Part II** applies to brokers and distributors of direct materials and new or surplus aircraft parts and industrial parts. This part can be applied independently of part one.

- 3. **Part III** applies to manufacturers and processors. This part can be applied independently of part one or two. This part should be used in conjunction with the applicable special process checklists at special process suppliers.
- B. Suppliers are subject to a technical audit at any time during normal working hours. The audit may encompass the entire technical portion of the supplier's operation or any part thereof. The auditor will notify the supplier and arrange the audit so as to cause minimal interference with the supplier's operation and the supplier shall make accommodations for these audits.
- C. An acceptable audit result does not relieve the supplier of their duty to provide an acceptable product.

IV. PROCEDURE REQUIREMENTS

A. QUALITY MANAGEMENT SYSTEM

- 1. **General Requirements** [ISO9001/AS9100 paragraph 4.1]
 - a. The supplier shall establish, document, implement and maintain a quality management system and continually improve its effectiveness.
 - b. The supplier shall determine criteria and methods needed to ensure that both the operation and control of these processes are effective.
 - c. The supplier shall ensure the availability of resources and information necessary to support the operation and monitoring of these processes;
 - d. The supplier shall monitor, measure where applicable, and analyze these processes.
 - e. The supplier shall implement actions necessary to achieve planned results and continual improvement of these processes.
 - f. Where the supplier chooses to outsource any process that affects product conformity with requirements, the supplier shall ensure control over such processes. Control of such outsourced processes shall be identified within the quality management system.

2. General Documentation Requirements [ISO9001/AS9100 paragraph 4.2.1]

The quality management system documentation shall include documented statements of a quality policy and quality objectives, a quality manual, documented procedures, documents needed by the supplier to ensure the effective planning, operation and control of its processes, and records.

3. Quality Manual [ISO9001/AS9100 paragraph 4.2.2]

The supplier shall establish and maintain a quality manual that includes:

- a. the scope of the quality management system, including details of and justification for any exclusions,
- b. the documented procedures established for the quality management system, or reference to them, and
- c. a description of the interaction between the processes of the quality management system.

4. Control of Documents [ISO9001/AS9100 paragraph 4.2.3]

- a. The supplier shall establish and maintain documented procedures to control all documents and data and to ensure that only approved, released and pertinent revisions are available, including those in electronic format.
- b. The supplier shall establish a process to ensure the timely review, distribution, implementation, and maintenance of all authorized and released drawings, standards, specifications, planning and changes. The supplier shall maintain a record of change incorporation and, when required, shall coordinate these incorporations with the customer and/or regulatory authority.

5. Control of Quality Records ISO9001/AS9100 paragraph 4.2.4]

- a. A documented procedure shall be established to define the controls needed for the identification, storage, protection, retrieval, retention time and disposition of records.
- b. Records shall be established and maintained to provide evidence of conformity to requirements and of the effective operation of the quality management system. Records shall remain legible, readily identifiable and retrievable. Product/process records shall be retained for a minimum of five years after completion.

6. Control and Maintenance of Manufacturing Approvals

- a. Suppliers who are PAHs shall maintain all approvals (TC, PC, TSO, PMA) in current condition for approved products.
- b. Suppliers who are PAHs shall provide documents with each shipment of articles that attest that the articles were manufactured under the appropriate Production Approval (TC, PC, TSO, PMA).
- c. Any manufacturer that is a supplier to an PAH for a complete article shall not sell, or advertise for sale those products other than in compliance with a direct shipment agreement with the PAH.

B. MANAGEMENT RESPONSIBILITY

- 1. Top management shall provide evidence of its commitment to the development and implementation of the quality management system and continually improving its effectiveness by communicating to the supplier the importance of meeting customer as well as statutory and regulatory requirements. [ISO9001/AS9100 paragraph 5.1]
- 2. Top management shall ensure that customer requirements are determined and are met with the aim of enhancing customer satisfaction. [ISO9001/AS9100 paragraph 5.2]
- 3. Top management shall ensure that the quality policy is appropriate to the purpose of the supplier. [ISO9001/AS9100 paragraph 5.3]
- 4. Top management shall ensure that quality objectives, including those needed to meet requirements for product, are established at relevant functions and levels within the supplier. The quality objectives shall be measurable and consistent with the quality policy. [ISO9001/AS9100 paragraph 5.4.1]

- 5. Top management shall ensure that responsibilities and authorities are defined and communicated within the supplier. [ISO9001/AS9100 paragraph 5.5.1]
- 6. Top management shall appoint a member of management who, irrespective of other responsibilities, has responsibility and authority that includes reporting to top management on the performance of the quality management system and any need for improvement. Also the organizational freedom and unrestricted access to top management to resolve quality management issues. [ISO9001/AS9100 paragraph 5.5.2]
- 7. Top management shall ensure that appropriate communication processes are established within the supplier and that communication takes place regarding the effectiveness of the quality management system. [ISO9001/AS9100 paragraph 5.5.3]
- 8. Top management shall review the supplier's quality management system, at planned intervals, to ensure its continuing suitability, adequacy and effectiveness. This review shall include assessing opportunities for improvement and the need for changes to the quality management system, including the quality policy and quality objectives. Records from management reviews shall be maintained. The management review shall be documented and include all the required Inputs and output.[ISO9001/AS91000 paragraph 5.6]

C. RESOURCE MANAGEMENT

- 1. The supplier shall determine and provide the resources needed to implement and maintain the quality management system, continually improve its effectiveness, and to enhance customer satisfaction by meeting customer requirements. [ISO9001/AS9100 paragraph 6.1]
- 2. Personnel performing work affecting product quality shall be competent on the basis of appropriate education, training, skills and experience. [ISO9001/AS9100 paragraph 6.2.1]
- 3. The supplier shall: [ISO9001/AS9100 paragraph 6.2.2]
 - a. determine the necessary competence for personnel performing work affecting product quality,
 - b. provide training or take other actions to satisfy these needs,
 - c. evaluate the effectiveness of the actions taken,
 - d. ensure that its personnel are aware of the relevance and importance of their activities and how they contribute to the achievement of the quality objectives, and
 - e. maintain appropriate records of education, training, skills and experience
- 4. The supplier shall determine, provide and maintain the infrastructure needed to achieve conformity to product requirements. Infrastructure includes, as applicable: [ISO9001/AS9100 paragraph 6.3]
 - a. buildings, workspace and associated utilities,
 - b. process equipment (both hardware and software), and
 - c. supporting services (such as transport or communication).
- 5. The supplier shall determine and manage the work environment needed to achieve conformity to product requirements. [ISO 9001:2000 paragraph 6.4]

D. PRODUCT REALIZATION

1. **Planning of Product Realization** [ISO9001/AS9100 paragraph 7.1]

- a. The supplier shall plan and develop the processes needed for product realization. Planning of product realization shall be consistent with the requirements of the other processes of the quality management system.
- b. In planning product realization, the supplier shall determine the following, as appropriate, quality objectives and requirements for the product, the need to establish processes and documents, and to provide resources specific to the product, required verification, validation, monitoring, measurement, inspection and test activities specific to the product and the criteria for product acceptance, configuration management appropriate to the product, resources to support the use and maintenance of the product, and records needed to provide evidence that the realization processes and resulting product meet requirements.
- c. The supplier shall establish, implement and maintain a process for managing risk to the achievement of applicable requirements, that includes as appropriate to the supplier and the product. [ISO9001/AS9100 paragraph 7.1.2]
- d. The supplier shall establish, implement and maintain a configuration management process that includes, as appropriate to the product. [ISO9001/AS9100 paragraph 7.1.3]
- e. The supplier shall establish,implement and maintain a process to plan and control the temporary or permanent transfer of work (e.g., from one supplier facility to another, from the supplier to a supplier, from one supplier to another supplier) and to verify the conformity of the work to requirements.. [ISO9001/AS9100 paragraph 7.1.4]

2. Customer-Related Processes (Contract Review) [ISO9001/AS9100 paragraph 7.2]

- a. The supplier shall determine requirements specified by the customer, including the requirements for delivery and post-delivery activities, requirements not stated by the customer but necessary for specified or intended use should be evaluated where known, statutory and regulatory requirements related to the product, and any additional requirements determined by the supplier should be reviewed.
- b. The supplier shall review review the requirements related to the product. This review shall be conducted prior to the supplier's commitment to supply a product to the customer (e.g. submission of tenders, acceptance of contracts or orders, acceptance of changes to contracts or orders) and shall ensure that product requirements are defined, contract or order requirements differing from those previously expressed are resolved, the supplier has the ability to meet the defined requirements, special requirements of the product are determined, and risks (e.g., new technology, short delivery time frame) have been identified. [ISO9001/AS9100 paragraph 7.2.2]
- c. Records of the results of the review and actions arising from the review shall be maintained.
- d. Where the customer provides no documented statement of requirement, the customer requirements shall be confirmed by the supplier before acceptance.
- e. Where product requirements are changed, the supplier shall ensure that relevant documents are amended and that relevant personnel are made aware of the changed requirements.
- f. The supplier shall determine and implement effective arrangements for communicating with

customers in relation to product information, inquiries, contracts or order handling, including amendments, and customer feedback, including customer complaints. [ISO9001/AS9100 paragraph 7.2.3]

3. **Design and Development** [ISO9001/AS9100 paragraph 7.3]

The supplier shall plan and control the design and development of the product (if applicable).

- 4. **Purchasing** [ISO9001/AS9100 paragraph 7.4]
 - a. The supplier shall ensure that purchased product conforms to specified purchase requirements. The type and extent of control applied to the supplier and the purchased product shall be dependent upon the effect of the purchased product on the final product.
 - b. The supplier shall be responsible for the conformity of all products purchased from suppliers, including product from sources defined by the customer.
 - c. The supplier shall evaluate and select suppliers based on their ability to supply product in accordance with the supplier's requirements. Criteria for selection, evaluation and reevaluation shall be established. Records of the results of evaluations and any necessary actions arising from the evaluation shall be maintained.
 - d. The supplier shall: [ISO9001/AS9100 paragraph 7.4.1]
 - 1. Maintain a register of approved suppliers that includes approval status (e.g., approved, conditional, disapproved) and the scope of the approval (e.g., product type, process family).
 - 2. Periodically review supplier performance. The results of these reviews shall be used as a basis for establishing the level of controls to be implemented.
 - 3. Define the necessary actions to take when dealing with suppliers that do not meet requirements.
 - 4. Ensure where required that both the supplier and all suppliers use customer-approved special process sources.
 - 5. Define the process, responsibilities and authority for the approval status decision, changes of the approval status and conditions for a controlled use of suppliers depending on the supplier's approval status.
 - 6. Determine and manage the risk when selecting and using suppliers.
 - e. Purchasing document shall describe the product to be purchased, including where appropriate: [ISO9001/AS9100 paragraph 7.4.2]
 - 1. Requirements for approval of product, procedures, processes and equipment.
 - 2. Requirements for qualification of personnel.
 - 3. Quality management system requirements.
 - 4. The identification and revision status of specifications, drawings, process requirements, inspection/verification instructions and other relevant technical data.

- 5. Requirements for design, test, inspection, verification (including production process verification), use of statistical techniques for product acceptance, and related instructions for acceptance by the supplier, and as applicable critical items including key characteristics.
- 6. Requirements for test specimens (e.g., production method, number, storage conditions) for design approval, inspection/verification, investigation or auditing.
- 7. Requirements regarding the need for the supplier to notify the supplier nonconforming product, obtain supplier approval for nonconforming product disposition, notify the supplier of changes in product and/or process, changes of suppliers, changes of manufacturing facility location and, where required, obtain supplier approval, and flow down to the supply chain the applicable requirements including customer requirements.
- 8. Records retention requirements
- 9. Right of access by the supplier, their customer, and regulatory authorities (as applicable) to all facilities involved in the order and to all applicable records.
- 10. Requirements for the supplier to flow down to sub-tier suppliers applicable requirements in their purchasing documents.
- f. Verification of Purchased Product [ISO9001/AS9100 paragraph 7.4.3]
 - 1. The supplier shall shall establish and implement the inspection or other activities necessary for ensuring that purchased product meets specified purchase requirements.
 - 2. Verification activities can include, obtaining objective evidence of the conformity of the product from the supplier (e.g., accompanying documentation, certificate of conformity, test records, statistical records, process control records), review of the required documentation, inspection of products upon receipt, and delegation of verification to the supplier or supplier certification.
 - 3. Where purchased product is released for production use pending completion of all required verification activities, it shall be identified and recorded to allow recall and replacement if it is subsequently found that the product does not meet requirements.
 - 4. Where the supplier delegates verification activities to the supplier, the requirements for delegation shall be defined and a register of delegations maintained.
 - 5. Where the supplier or its customer intends to perform verification at the supplier's premises, the supplier shall state the intended verification arrangements and method of product release in the purchasing information.
- 5. Control of Production and Service Provision (Planning) [ISO9001/AS9100 paragraph 7.5.1]

The supplier shall plan and carry out production and service provision under controlled conditions. Controlled conditions shall include, as applicable.

- a. the availability of information that describes the characteristics of the product,
- b. the availability of work instructions, as necessary,

- c. the use of suitable equipment,
- d. the availability and use of monitoring and measuring equipment,
- e. the implementation of monitoring and measurement,
- f. the implementation of release, delivery and post-delivery activities,.
- g. accountability for all product during production (e.g., parts quantities, split orders, nonconforming product),
- h. evidence that all production and inspection/verification operations have been completed as planned, or as otherwise documented and authorized,
- i. provision for the prevention, detection, and removal of foreign objects.
- j. Monitoring and control of utilities and supplies (e.g., water, compressed air, electricity, chemical products) to the extent they affect conformity to product requirements, and,
- k. Criteria for workmanship, specified in the clearest practical way (e.g., written standards, representative samples, illustrations).

Planning shall consider, as appropriate, establishing, implementing and maintaining appropriate processes to manage critical items, including process controls where key characteristics have been identified, designing, manufacturing and using tooling to measure variable data, identifying inprocess inspection/verification points when adequate verification of conformance cannot be performed at later stages of realization, and special processes.

6. **Production Process Verification** [ISO9001/AS9100 paragraph 7.5.1.1]

The supplier shall use a representative item from the first production run of a new part or assembly to verify that the production processes, production documentation and tooling are capable of producing parts and assemblies that meet requirements. This process shall be repeated when changes occur that invalidate the original results (e.g., engineering changes, manufacturing process changes, tooling changes).

7. Control of Production Process Changes [ISO9001/AS9100 paragraph 7.5.1.2]

Personnel authorized to approve changes to production processes shall be identified. The supplier shall control and document changes affecting processes, production equipment, tools or software programs. The results of changes to production processes shall be assessed to confirm that the desired effect has been achieved without adverse effects to product conformity.

8. Control of Production Equipment, Tools and Software Programs [ISO9001/AS9100 paragraph 7.5.1.3]

Production equipment, tools and software programs used to automate and control/monitor product realization processes, shall be validated prior to release for production and shall be maintained. Storage requirements, including periodic preservation/condition checks, shall be defined for production equipment or tooling in storage.

9. **Post-Delivery Support** [ISO9001/AS9100 paragraph 7.5.1.4]

Post-delivery support shall provide as applicable for the:

- a. Collection and analysis of in-service data,
- b. actions to be taken, including investigation and reporting, when problems are detected after delivery,
- c. control and updating of technical documentation,
- d. approval, control and use of repair schemes, and
- e. controls required for off-site work (e.g., supplier's work undertaken at the customer's facilities).

10. Validation of Processes (Special Processes) [ISO9001/AS9100 paragraph 7.5.2]

The supplier shall validate any processes for production and service provision where the resulting output cannot be verified by subsequent monitoring or measurement and, as a consequence, deficiencies become apparent only after the product is in use or the service has been delivered. The supplier shall establish arrangements for these processes including, as applicable,

- a. defined criteria for review and approval of the processes,
- b. approval of equipment and qualification of personnel,
- c. use of specific methods and procedures,
- d. requirements for records, and
- e. revalidation

11. **Identification and Traceability** [ISO9001/AS9100 paragraph 7.5.3]

- a. Where appropriate, the supplier shall identify the product by suitable means throughout product realization.
- b. The supplier shall maintain the identification of the configuration of the product in order to identify any differences between the actual configuration and the agreed configuration.
- c. The supplier shall identify the product status with respect to monitoring and measurement requirements throughout product realization.
- d. When acceptance authority media are used (e.g., stamps, electronic signatures, passwords), the supplier shall establish appropriate controls for the media.
- e. Where traceability is a requirement, the supplier shall control and record the unique identification of the product and maintain records.

12. Customer Property [ISO 9001:2000 paragraph 7.5.4]

The supplier shall exercise care with customer property while it is under the supplier's control or being used by the supplier. The supplier shall identify, verify, protect and safeguard customer property provided for use or incorporation into the product. If any customer property is lost, damaged or otherwise found to be unsuitable for use, the supplier shall be report this to the customer and maintain records.

13. **Preservation of Product** [ISO9001/AS9100 paragraph 7.5.5]

- a. The supplier shall preserve the product during internal processing and delivery to the intended destination in order to maintain conformity to requirements. As applicable, preservation shall include identification, handling, packaging, storage and protection. Preservation shall also apply to the constituent parts of a product.
- b. Preservation Preservation of product shall also include, where applicable in accordance with product specifications and applicable statutory and regulatory requirements, provisions for:
 - 1. Cleaning,
 - 2. prevention, detection and removal of foreign objects,
 - 3. special handling for sensitive products,
 - 4. marking and labeling including safety warnings,
 - 5. shelf life control and stock rotation, and
 - 6. special handling for hazardous materials.

14. Control of Monitoring and Measuring Devices [ISO9001/AS9100 paragraph 7.6]

- a. The supplier shall determine the monitoring and measurement to be undertaken and the monitoring and measuring equipment needed to provide evidence of conformity of product to determined requirements.
- b. The supplier shall maintain a register of the monitoring and measuring equipment and define the process employed for their calibration/verification including details of equipment type, unique identification, location, frequency of checks, check method and acceptance criteria.
- c. The supplier shall establish processes to ensure that monitoring and measurement can be carried out and are carried out in a manner that is consistent with the monitoring and measurement requirements.
- d. The supplier shall ensure that environmental conditions are suitable for the calibration, inspection, measurement and testing being carried out.
- e. Where necessary to ensure valid results, measuring equipment shall:
 - 1. Be calibrated or verified, or both, at specified intervals, or prior to use, against measurement standards traceable to international or national measurement standards; where no such standards exist, the basis used for calibration or verification shall be recorded.
 - 2. be adjusted or re-adjusted as necessary;
 - 3. have identification in order to determine its calibration status;
 - 4. be safeguarded from adjustments that would invalidate the measurement result;
 - 5. be protected from damage and deterioration during handling, maintenance and storage.

- f. The supplier shall establish, implement and maintain a process for the recall of monitoring and measuring equipment requiring calibration or verification.
- g. Records of the results of calibration and verification shall be maintained.
- h. Calibration records shall:
 - 1. Show the date the item was calibrated or checked.
 - 2. Show the date the next calibration is due.
 - 3. Where an outside source accomplished the calibration or check, identify that individual or supplier
 - 4. Contain a certificate of calibration for each item calibrated by an outside agency.
 - 5. Record the details of any required adjustment or repair.
 - 6. Identify the standard, including the part number, serial number, and calibration due date, used to calibrate the tool.
- i. When used in the monitoring and measurement of specified requirements, the ability of computer software to satisfy the intended application shall be confirmed. This shall be undertaken prior to initial use and reconfirmed as necessary.

E. MEASUREMENT, ANALYSIS AND IMPROVEMENT

1. **General** [ISO9001/AS9100 paragraph 8.1]

The supplier shall plan and implement the monitoring, measurement, analysis and improvement processes needed to demonstrate conformity to product requirements, to ensure conformity of the quality management system, and to continually improve the effectiveness of the quality management system. This shall include determination of applicable methods, including statistical techniques, and the extent of their use.

2. Customer Satisfaction [ISO9001/AS9100 paragraph 8.2.1]

As one of the measurements of the performance of the quality management system, the supplier shall monitor information relating to customer perception as to whether the supplier has met customer requirements. The methods for obtaining and using this information shall be determined.

Information to be monitored and used for the evaluation of customer satisfaction shall include, but is not limited to, product conformity, on-time delivery performance, customer complaints and corrective action requests. suppliers shall develop and implement plans for customer satisfaction improvement that address deficiencies identified by these evaluations, and assess the effectiveness of the results.

- 3. **Internal Audits** [ISO9001/AS9100 paragraph 8.2.2]
 - a. The supplier shall conduct internal audits at planned intervals to determine whether the quality management system conforms to the planned arrangements, to the requirements of this International Standard and to the quality management system requirements established by the supplier, and is effectively implemented and maintained.

- b. An audit program shall be planned, taking into consideration the status and importance of the processes and areas to be audited, as well as the results of previous audits. The audit criteria, scope, frequency and methods shall be defined. The selection of auditors and conduct of audits shall ensure objectivity and impartiality of the audit process. Auditors shall not audit their own work.
- c. A documented procedure shall be established to define the responsibilities and requirements for planning and conducting audits, establishing records and reporting results.
- d. Records of the audits and their results shall be maintained.
- e. The management responsible for the area being audited shall ensure that any necessary corrections and corrective actions are taken without undue delay to eliminate detected nonconformities and their causes. Follow-up activities shall include the verification of the actions taken and the reporting of verification results.

4. Monitoring and Measurement of Processes [ISO9001/AS9100 paragraph 8.2.3]

The supplier shall apply suitable methods for monitoring and, where applicable, measurement of the quality management system processes. These methods shall demonstrate the ability of the processes to achieve planned results. When planned results are not achieved, correction and corrective action shall be taken, as appropriate.

In the event of process nonconformity, the supplier shall:

- a. take appropriate action to correct the nonconforming process,
- b. evaluate whether the process nonconformity has resulted in product nonconformity,
- c. determine if the process nonconformity is limited to a specific case or whether it could have affected other
 - processes or products, and
- d. identify and control any nonconforming product

5. Monitoring and Measurement of Product ISO9001/AS9100 paragraph 8.2.4]

- a. The supplier shall monitor and measure the characteristics of the product to verify that product requirements have been met. This shall be carried out at appropriate stages of the product realization process in accordance with the planned arrangements.
- b. Measurement requirements for product acceptance shall be documented and shall include:
 - 1. criteria for acceptance and/or rejection,
 - 2. where in the sequence measurement and testing operations are to be performed,
 - 3. required records of the measurement results (at a minimum, indication of acceptance or rejection), and
 - 4. any specific measurement instruments required and any specific instructions associated with their use.

- c. When critical items, including key characteristics, have been identified the supplier shall ensure they are controlled and monitored in accordance with the established processes.
- d. When the supplier uses sampling inspection as a means of product acceptance, the sampling plan shall be justified on the basis of recognized statistical principles and appropriate for use (i.e., matching the sampling plan to the criticality of the product and to the process capability).
- e. Where product is released for production use pending completion of all required measurement and monitoring activities, it shall be identified and recorded to allow recall and replacement if it is subsequently found that the product does not meet requirements.
- f. Records shall indicate the person(s) authorizing release of product for delivery to the customer.
- g. Where required to demonstrate product qualification, the supplier shall ensure that records provide evidence that the product meets the defined requirements.
- h. The release of product and delivery of service to the customer shall not proceed until the planned arrangements have been satisfactorily completed, unless otherwise approved by a relevant authority and, where applicable, by the customer.
- i. The supplier shall ensure that all documents required to accompany the product are present at delivery.

6. Control of Nonconforming Product [ISO9001/AS9100 paragraph 8.3]

- a. The supplier shall ensure that product which does not conform to product requirements is identified and controlled to prevent its unintended use or delivery. A documented procedure shall be established to define the controls and related responsibilities and authorities for dealing with nonconforming product.
- b. The supplier's documented procedure shall define the responsibility and authority for the review and disposition of nonconforming product, and the process for approving personnel making these decisions.
- c. The supplier shall deal with nonconforming product by one or more of the following ways:
 - 1. by taking action to eliminate the detected nonconformity;
 - 2. by authorizing its use, release or acceptance under concession by a relevant authority and, where applicable, by the customer;
 - 3. by taking action to preclude its original intended use or application.
 - 4. by taking action appropriate to the effects, or potential effects, of the nonconformity when nonconforming product is detected after delivery or use has started.
 - 5. by taking actions necessary to contain the effect of the nonconformity on other processes or product.
- d. Dispositions of use-as-is or repair shall only be used after approval by an authorized representative of the supplier responsible for design.
- e. The supplier shall not use dispositions of use-as-is or repair, unless specifically authorized by

the customer, if the nonconformity results in a departure from the contract requirements.

- f. Product dispositioned for scrap shall be conspicuously and permanently marked, or positively controlled, until physically rendered unusable.
- g. When nonconforming product is corrected it shall be subject to re-verification to demonstrate conformity to the requirements.
- h. Records of the nature of nonconformities and any subsequent actions taken, including concessions obtained, shall be maintained.

7. Analysis of Data [ISO9001/AS91000 paragraph 8.4]

- a. The supplier shall determine, collect and analyze appropriate data to demonstrate the suitability and effectiveness of the quality management system and to evaluate where continual improvement of the effectiveness of the quality management system can be made. This shall include data generated as a result of monitoring and measurement and from other relevant sources.
- b. The analysis of data shall provide information relating to customer satisfaction, conformity to product requirements, characteristics and trends of processes and products including opportunities for preventive action, and suppliers.

8. **Continual Improvement** [ISO9001/AS9100 paragraph 8.5.1]

The supplier shall continually improve the effectiveness of the quality management system through the use of the quality policy, quality objectives, audit results, analysis of data, corrective and preventive actions and management review.

The supplier shall monitor the implementation of improvement activities and evaluate the effectiveness of the results.

9. Corrective Action [ISO9001/AS9100 paragraph 8.5.2]

- a. The supplier shall take action to eliminate the cause of nonconformities in order to prevent recurrence. Corrective actions shall be appropriate to the effects of the nonconformities encountered.
- b. A documented procedure shall be established to define requirements for:
 - 1. reviewing nonconformities (including customer complaints),
 - 2. determining the causes of nonconformities,
 - 3. evaluating the need for action to ensure that nonconformities do not recur,
 - 4. determining and implementing action needed,
 - 5. records of the results of action taken,
 - 6. reviewing the effectiveness of the corrective action taken,
 - 7. flowing down corrective action requirements to a supplier when it is determined that the supplier is responsible for the nonconformity,

- 8. specific actions where timely and/or effective corrective actions are not achieved, and
- 9. determining if additional nonconforming product exists based on the causes of the nonconformities and taking further action when required.

10. **Preventive Action** [ISO9001/AS9100 paragraph 8.5.3]

- a. The supplier shall determine action to eliminate the causes of potential nonconformities in order to prevent their occurrence. Preventive actions shall be appropriate to the effects of the potential problems.
- b. A documented procedure shall be established to define requirements for:
 - 1. determining potential nonconformities and their causes,
 - 2. evaluating the need for action to prevent occurrence of nonconformities,
 - 3. determining and implementing action needed,
 - 4. records of results of action taken, and
 - 5. reviewing the effectiveness of the preventive action taken.

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