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SUPPLIER QUALITY MANUAL

Supplier Quality Manual

1. Purpose

1.1 This document describes actions expected to be performed by Suppliers to ensure that all AMC expectations are met. AMC requires that all suppliers be approved prior to issuance of purchase orders.

2. Scope

2.1 These requirements apply to all Suppliers of Production Material or service critical to AMC performance.

3. Order of Precedence

3.1 In the event of a conflict between the text of this document, any references cited herein, or in the purchase order requirements, the following order of precedence shall apply:

1. The purchase order
2. The controlled drawing
3. Documents listed on the controlled drawings
4. This document
5. Documents listed in this document

4. Definitions

4.1 Quality System – A set of interrelated or interacting processes with regard to quality, accomplished by the management of an organization by establishing policy and objectives, and by achieving those objectives.

4.2 Material Review Board (MRB) – A management team usually consisting of Purchasing, Quality, Manufacturing and Engineering which tracks reviews and dispositions non-conforming material in a timely manner.

4.3 Material Traceability – The ability to trace the history, application or location of an item or activity by means of recorded identification.

4.4 Certificate of Conformance (COC) – A formal documented statement, issued by an authorizing individual, stating that the delivered product meets all standards and requirements.

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5. General Requirements

5.1 Quality System Requirements – Suppliers shall maintain a Quality Management System (QMS) suitable to the products and services provided to AMC which is certified by an accredited third-party certification body to the latest version of one or more of the following, as applicable:

- ISO 9001 – Quality Management System Requirements
- ISO 13485 – Quality Management System Requirements (Medical)

In the absence of third party certification, depending on the product, its application, value, and criticality, of other evidence of Quality Management System may be accepted. This may include On-Site Audit or First-Party (self) assessment to the applicable criteria above, or to a set of alternative basic quality requirements.

5.2 Procedures and Work Instructions – The supplier shall develop, implement and maintain procedures that define quality practices and work instructions for all manufacturing processes. All inspection operations must include accept/reject criteria.

5.3 Revision Control – Unless otherwise specified, the revision of all drawings and specifications in effect at the time of issuance of a Purchase Order is applicable to the order.

5.4 Flow-Down Requirements – Unless otherwise specified, the requirements specified on drawings, specifications or purchase order are applicable to sub-tier suppliers.

5.5 Material Traceability – The supplier is required to maintain traceability of all materials when products are manufactured to a drawing. Distributors are required to maintain traceability to vendor lot numbers or purchase order numbers.

5.6 AMC Supplied Material – The supplier is required to segregate and protect all material provided by AMC. Receipt shortages, material which is lost or damaged during processing shall be reported to the buyer for further disposition. The AMC lot number (when available) shall be recorded on internal processing records.

5.7 Supplied Equipment – The supplier is required to identify, segregate, protect and maintain all fixtures, molds or other equipment provided by AMC. AMC supplied equipment shall only be used for the fabrication of products. Any damage to equipment should be reported to the buyer.

5.8 Record Retention – Unless otherwise specified, the manufacturer shall have available for review for six (6) years minimum from the end of the contracts or purchase orders, all records applicable to each order. The requirement includes but is not limited to purchasing records, device history records, process validations, inspections and test records, equipment calibration records, non-conforming material reports and quality system certificates.

5.9 No Changes – Supplier shall make no change to design, material, manufacturing location, manufacturing processes, or sources of supply, after AMC acceptance of the first Article/First Piece test parts, without the written approval of AMC. Historically, unauthorized Supplier changes after First Piece Acceptance or Process Validation have been prominent trend in non-conformances. Undisclosed changes by Suppliers and/or their sub-tiers can cause quality and performance issues. The Supply Chain Manager & Quality Director must be notified in writing of any potential changes that may affect the ability of purchased product to meet specified purchase requirements.

5.10 Corrective Action System – The supplier shall have a system in place to respond to corrective action requests within 15 days of receipt. If the supplier cannot respond by the due date an extension may be requested. Failure to respond to corrective action requests may result in the loss of future orders.

5.11 Inspection and Test – The supplier shall have an effective inspection and test system in place to assure that all material delivered to AMC complies with the purchase order, drawings and specifications.

5.12 Test/Inspection Equipment – All equipment used to evaluate product acceptance shall be calibrated with a source know to be traceable to NIST.

5.13 Non-Conforming Material – The supplier may not ship any non-conforming material without written authorization by AMC Quality Assurance.

5.14 Certificate of Conformance – Unless otherwise specified, all shipments of material shall be accompanied by a Certificate of Conformance (COC), signed by

an authorized supplier representative, stating that the material conforms to the purchase order, applicable drawings and specifications. At a minimum the COC shall include the purchase order, drawing number and revision, internal lot number, quantity, or any other information required for material/lot identification. Material shipped to without a COC will not be received.

5.15 Test Data – When required by the AMC purchase order, drawing or specification the supplier shall provide test data with the material.

5.16 Limited Shelf Life Material – The supplier shall provide expiration dates on all materials (adhesive materials, chemicals, etc.) which have a limited shelf life. No material shall be shipped which has less than 75% of its available shelf life remaining. Products which require refrigeration shall be marked on the exterior of the shipping container.

5.17 Cleanliness – AMC expects that the supplier shall deliver product free of dirt, grease, etc. in compliance with Good Manufacturing Practices (GMP).

5.18 Packaging – Unless otherwise specified, the supplier shall take reasonable precautions to insure that all material is protected against contamination, deterioration, damage, corrosion or any other detriment that may adversely affect the quality or application of the material.

6. Initial Part Qualification

This section defines the generic requirements for production part qualification and approval. The purpose is to determine if all design and specification requirements are properly understood by the Supplier and that the manufacturing processes have the capability to consistently meet these requirements. Part qualifications approval mut be obtained prior to any production part shipments.

6.1 First Article Inspection – As a minimum, a First Article Inspection (FAI) is required to initially qualify a part/process for Supplier approval. Furthermore, a new FAI may be requested if there is an extended gap of time since the last production. The FAI requires that all features and characteristics on the design specification and control plan be inspected and verified prior to production. Actual measured values shall be recorded as opposed to general statements of conformance or other notations simply indicating acceptance.

6.2 Supplier Readiness – *When required by AMC*, the Supplier shall submit a more comprehensive qualification package, referred to as a Supplier Readiness Package. The extent of this package will be documented on an AMC Supplier Readiness form, F7.4-07 and acknowledged by representatives from AMC and the Supplier. Typical Supplier Readiness packages may include, but are not limited to, process flow diagrams, validation and/or verification plans, Measurement System Analysis (MSA), design and/or process FMEA, etc.

- Process Flow Diagrams
  The Supplier shall have a visual diagram of the proposed or current process. This diagram shall clearly describe the production process steps and sequence, and meet the specified AMC needs, requirements and expectations.

- Failure Mode and Effects Analysis

Suppliers with product design responsibility shall develop a Design FMEA in accordance with, and compliant to, AMC specified requirements. A single Design FMEA may be applied to a family of similar parts or materials. Suppliers with process validation responsibility develop a Process FMEA in accordance with, and compliance to, AMC specified requirements. Where appropriate AMC may require the Supplier to develop a Process FMEA where processes do not require validation but require specific consideration of risk.

- Measurement System Analysis
  The Supplier must develop or obtain gages and standards to control their process and to determine product conformance to specifications. Variable gages and measurements are preferred. Alternative methods, gages or standards may be used. AMC may request the Supplier to participate in a correlation study to compare Supplier measurement results against results obtained by AMC gages and methods. Gage studies may include analysis for repeatability, bias, linearity, and stability.
- Control Plan
  The Supplier shall have a Control Plan that takes into account the output from the FMEA and defines all methods used for process monitoring and control of special product / process characteristics. A single control plan may apply to a group or family of products that are produced by the same process at the same source.

- Process Capability Study
  Process Capability Index (Cpk) is a comparison of the inherent variability of a process output to specification limits under statistically stable conditions. Most methods for estimating capability require that the characteristic being evaluated is approximately normal in distribution, and in statistical control. The distribution should be determined prior to estimating capability. If the process is not in statistical control, all assignable causes must first be identified and remove or mitigated. Special techniques are available for calculating capability when inherent assignable causes, such as tool wear, are present. Cpk expectations may be specified by AMC on specific contracts or items.

7. Supplier Guidance

7.1 AMC utilizes a C = O sampling plan. Any nonconformity may result in the material being returned to the supplier for further screening.

7.2 AMC evaluates all of it suppliers based on quality (including required paperwork) and delivery. If a supplier's rating falls to an unacceptable level AMC may initiate supplier corrective action request, place the supplier on limited approval or proceed with termination.

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Document Revision Status

Revision	Date	Abstract of Revision	Approval
Orig	10-21-15	creation of QSP	J. Shepherd
A	9-27-18	#5, (5.9) rewrite; rename document Supplier Quality Manual	J. Shepherd
B	1-18-2023	Remove signature page, change retention from 3 years to 6 years, post to our web site vs. send.	J. Lee