AS-M-SQR01. Aerospace & Medical Device Provider Quality Requirements

1.0 Purpose

This specification defines the requirements for GPI Prototype & Manufacturing Services' Aerospace and Medical Device providers (subcontractors).

2.0 Scope

Applies to providers of materials, parts and services used in GPI Prototype & Manufacturing Services' Aerospace and Medical Device products.

3.0 Requirements

.1) All external providers must provide verification of the product including objective evidence of the product quality (e.g. certificate of compliance, test reports, statistical records, process control).

All certifications related to Special Processes (e.g. Plating, Anodizing, Heat Treat) must state the specification(s) including revision levels of the specification(s) to which the parts were processed.

All certifications related to Raw Materials must include a record of actual physical and chemical material analysis and a certificate of conformance to the applicable material specification(s). The certificate shall contain a list of the applicable specification(s), including revision levels and traceability by heat lot or melt numbers.

All certifications shall include:

A) Name of organization
B) GPI Prototype & Manufacturing Services Purchase Order Number
C) Drawing number and revision (if applicable)
D) If applicable, specification number(s) and latest revision(s)
E) Quantity
F) If applicable, serial numbers or lot numbers
G) Authentication by an authorized representative of the supplier's quality organization.

.2) Personnel performing work on product for GPI Prototype & Manufacturing Services must be qualified for the type of work being performed. (e.g. welder certification)

.3) Quality Management System requirements:
Provider is to maintain an effective quality system to ensure product and process integrity that is based on either AS9100 rev D for Aerospace, or ISO 13485 2016 for Medical.

.4) Nonconforming Material:
Nonconforming material will not be accepted by GPI Prototype & Manufacturing Services unless approved in advance in writing by the Quality Manager. Requests for authorization to ship nonconforming material should be addressed in writing GPI Prototype & Manufacturing Services' Quality Manager with a full explanation of the nonconformance.

.5) External Provider must notify GPI Prototype & Manufacturing Services in writing of any changes in product and/or process definition which could impact the form, fit or function and, where required, obtain GPI Prototype & Manufacturing Services approval.

.6) External providers are required to notify GPI Prototype & **Manufacturing** Services of any significant organizational or facility changes such as company name, location or senior management.

.7) GPI Prototype & Manufacturing Services, GPI Prototype & Manufacturing Services' customer and regulatory authorities are afforded the right of entry to all facilities involved in the order to determine and verify the quality of our products and to all applicable quality records.

8) External Provider must *flow down* to the sub-tier suppliers the applicable requirements in this document and the purchasing documents, including key characteristics where required and the use of approved sources for Special Processes as applicable to specific customer requirements.

.9) External Providers are required to maintain control of quality records for a minimum of 11 years unless otherwise specified on the purchase order. Examples of quality records are (but not limited to) Routers, Material Certifications, Purchase Orders.

.10) When indicated on a drawing the provider will monitor key characteristics using statistical process control (SPC). Key characteristics must be demonstrated to be in statistical control with a process capability (Cpk) > 1.33.

.11) Measuring and Test Equipment:
The provider shall provide and maintain measuring and test equipment (M&TE) necessary to assure conformance to purchase order requirements. All M&TE shall be calibrated for accuracy at established intervals against standards that have a known valid relationship to the National Institute of Standards and Technology (NIST). If production tooling, jigs or fixtures are used as a media of inspection, this equipment shall also be verified for accuracy at established intervals.

Calibration Systems shall meet the applicable requirements of ISO 10012, ISO 17025 or ANSI/NCSL Z540.3.

If ANSI/NCSL Z540.3 is applicable, the Handbook shall be used as the interpretive guide.
In accordance with the industry standards and guidance referenced above, stated reliability goals, accuracy ratios and significant out of tolerance condition criteria must be established.

1) The Calibration interval analysis methodology used to maintain the reliability of M&TE shall have a stated reliability goal to meet a minimum 95%> reliability target for M&TE in-tolerance at the end of their interval schedule.

2) Significant out of tolerance conditions are defined as any M&TE out-of-tolerance condition exceeding 25% of the product tolerance. These conditions require documented review of impact on quality and notification to GPI Prototype & Manufacturing Services if product received by GPI Prototype & Manufacturing Services has been affected.

.12) Providers must certify compliance with DFARS Clause 252.225-7014, Preference for Domestic Specialty Metals, and Alternate 1, with each shipment. Providers are required to flow this clause down to all levels of the supply chain. Evidence of compliance must be kept on file per Requirement Q9 and submitted to GPI Prototype & Manufacturing Services upon request.

.13) Much of the technical data is export controlled under ITAR (International Traffic in Arms Regulations) or EAR (Export Administration Regulations). Export of this information in any form is restricted. Providers shall not disclose this information in any form to a foreign person entity, or export it from the United States without US Government authority and the express written authorization of GPI Prototype & Manufacturing Services or our customer. In addition- any provider accepting such work certifies that they are not on the Denied Persons List or any other list of companies restricted from working on export controlled product. You shall *flow down* the substance of this notice to all lower tier external providers where export controlled technical data is involved. It may be necessary for you to return all copies of the technical data provided or certify in writing that the data has been destroyed.

.14) A First Article Inspection Report (FAIR), in compliance with AS9102 requirements, is required on one (1) part randomly selected from a production lot for each part number. The FAIR must accompany the part with the shipment. The part which the FAIR was performed on must be tagged as "First Article".
The documentation shall include the drawing with numbered (ballooned) characteristics corresponding to the itemized FAIR report.

FULL FAIR:
A Full FAIR will be required for all incoming parts that meet all of the following criteria:

1) The part is a GPI Prototype & Manufacturing Services designed part or a GPI Prototype & Manufacturing Services Customer designed part.
2) The part is NOT a MIL-SPEC part or a catalog item (e.g. AS, MS or NAS items).
3) The part is the first production lot to be produced for GPI Prototype & Manufacturing Services by the external providers or a period of 24 months has elapsed since the previous delivery of the part to GPI Prototype & Manufacturing Services.

"DELTA" FAIR:
A "Delta" FAIR (a limited scope FAIR of a part which had already previously passed a Full FAIR) will be required when one (1) of the following criteria is met:

1) A design or process change has been made that affects the form, fit or function of the part upon which the previous FAIR was performed.
2) The drawing revision level, manufacturing process or tooling has changed.
3) A change in the manufacturing location.

.15) Parts received from GPI Prototype & Manufacturing Services tagged with a FAIR tag must be kept identified throughout the manufacturing process and returned to GPI Prototype & Manufacturing Services with the tag attached.

.16) FOD (Foreign Object Debris) Control – Providers shall have a FOD control plan for the organization and shall define areas where FOD controls are necessary to ensure FOD free products are delivery to GPI Prototype & Manufacturing Services. Providers shall ensure that appropriate personnel have received FOD awareness training.

For additional information regarding FOD prevention, refer to *National Aerospace Standard NAS 412- Foreign Object Damage/Foreign Object Debris (FOD) Prevention.*

.17) If an item on this Purchase Order invokes by reference military specifications, military standards, or other revision controlled requirement documents, the revisions in effect are as of the date of this Purchase Order. The provider may contact GPI Prototype & Manufacturing Services for the current revision level.

.18) Counterfeit part avoidance- Providers shall implement and enforce a written Counterfeit Parts Prevention and Control Plan designed to prelude, detect, and remove any counterfeit components or non-compliant material from all GPI Prototype & Manufacturing Services deliveries. Providers shall provide certification showing un-broken traceability from all intermediaries back to the OCM (Original Component Manufacturer) or OEM (Original Equipment Manufacturer).

For additional information regarding counterfeit part avoidance, refer to *AS5553 Counterfeit Electronic Parts; Avoidance, Detection, Mitigation, and Disposition.*