

PARMATECH CORPORATION QOP

PUR-303 Revision A Date 09/27/14

Supplier Quality Requirements

1. Purpose

Parmatech requires defect free product from our suppliers. The quality system fundamentals outlined within this document are considered a foundation for ensuring that Parmatech quality requirements are met.

This document further defines requirements that may or may not be covered by other procurement documentation. It is the responsibility of the supplier to understand and ensure compliance with these requirements.

It is Parmatech's desire to form long-term, mutually beneficial relationships with our suppliers with a common goal of repeatable product quality and continuous improvement. Parmatech requires it's suppliers to operate in full compliance with all applicable labor and environmental laws, as well as, provide for a safe work environment.

2. General Requirements

Suppliers must be capable of sending and receiving data, including purchase orders, invoices, drawings and specifications via email.

All Parmatech suppliers reviewing any data provided by Parmatech or visiting any Parmatech facility must sign a confidentiality agreement. Additionally, all Parmatech suppliers providing services or secondary operations related to product must complete a supplier questionnaire.

2. Quality System

At a minimum, suppliers are required to implement and maintain a quality system that adheres to the following requirements.

3. Process Change

Suppliers are required to notify Parmatech in advance of any planned change to the supplier's process, infrastructure, manufacturing location or key personnel that may impact the quality, or delivery, of Parmatech parts. Planned changes need to be reviewed to determine the qualification requirements of the change.

Additional changes that require notification of are as follows:

- Manufacturing Process Equipment changes
- Movement of machines in the factory
- Key process parameter changes
- Relocation or changes to manufacturing site
- Material changes
- End of life notification
- Packaging Changes

4. Purchase Order Review

Suppliers are required to review Parmatech purchase orders to ensure they are capable of meeting the purchase order requirements, including due date, quantity required, processing standards, and any regulatory standards required. Additionally, the supplier is responsible for ensuring any applicable Parmatech issued drawings in their possession match the part revision listed on the purchase order. Acceptance of a Parmatech Purchase Order constitutes acceptance of Parmatech Supplier Quality Requirements as defined in QOP-74-01 and all of the terms and conditions of the Purchase Order including the prices and the delivery dates. Delivery date is defined as the date it is due on Parmatech's dock. If the Supplier cannot meet the delivery dates stipulated in the Purchase Order, the Supplier shall immediately inform Parmatech of the Seller's best possible delivery date for Parmatech's consideration. Parmatech shall then have the right to accept or reject the proposed delivery date.

5. First Article Inspection Reports (must be provided in English)

First Article (FAI) or Delta First Article Inspections reports are required for first time build or first build against a new revision. The FAI requirements pertain only to those suppliers providing secondary machining operations and only for those dimensions achieved through the machining operation. A copy of the FAI dimensional report is to be sent with the shipment of parts. The FAI must include confirmed compliance to all notes on the part drawing as well as physical and/or chemical reports when specified.

6. Inspection Requirements

Supplier is required to have an inspection, or verification, process in place to ensure that product being manufactured and/or shipped to Parmatech is 100% compliant. Compliance may be achieved through capability studies, mistake proof gaging, lot inspection, process validation, etc. Supplier's product is also subject to inspection at Parmatech.

7. Nonconforming Product

Nonconforming product must be identified and immediately segregated from conforming product. Supplier must not knowingly ship nonconforming product to Parmatech unless supplier receives authorization in writing from an authorized Parmatech Quality representative (Parmatech Deviation or Variance form). If so authorized, nonconforming parts must be tagged as nonconforming and a copy of the Parmatech Deviation or Variance form must be included with the shipment. Failure to do so may result in a rejection of the product.

8. MRB

Suppliers are not allowed to disposition nonconforming material as "use as is" unless authorized by an authorized Parmatech Quality representative (see paragraph 7). Suppliers may disposition nonconforming product as "rework to print" or "scrap".

9. Nonconformance Notification and Request for Deviation

Suppliers are required to immediately notify Parmatech if they suspect that nonconforming product has been shipped to Parmatech. If it is determined that nonconforming product has been sent, the supplier is required to notify Parmatech within 24 hours, in writing, identifying the Parmatech PO number, date shipped, quantity shipped, and lot number if available.

Suppliers do not have the authority to disposition nonconforming product or product that has deviated from the intended process but may request deviation. Supplier requests for deviation from Purchase Order requirements and/or specifications shall be documented on form QA-432, Supplier Deviation Request form which will be directed to the Parmatech Corporation Purchasing or Engineering. Parmatech's Purchasing or Quality representative, shall consult with the appropriate personnel and communicate approval or disapproval to the Supplier. Approval or Disapproval shall be documented on Form QA-432. Without written notification of deviation approval from the Purchasing or Quality representative, the Supplier is to furnish material or service in compliance with all Purchase Order and/or drawing requirements.

10. Corrective Action

Parmatech will notify the supplier if nonconforming product has been received. The supplier is required to take immediate action to isolate any additional nonconforming product at their facility. The supplier is expected to implement corrective and preventive action(s). Parmatech may also require a written corrective action.

11. Traceability

Suppliers are required to have a system in place that provides product lot traceability. This includes traceability to raw materials used to manufacture product, lot traceability through the process, and traceability to the Parmatech purchase order.

12. Shipping Documents (must be provided in English)

Parmatech utilizes various suppliers. The documents required with each shipment to Parmatech depend on the product being purchased from the supplier. The following is an example of various that Parmatech may purchase product from and what type of document is required with each shipment:

Note: All Certificates of Conformance documents must be on official company letterhead and reference the Parmatech Purchase Order #, Part Number, Revision Level, and Part Description.

Machine Shop A Certificate of Conformance (inspection report or

evidence of inspection when required on PO)

Processors A Certificate of Conformance referencing process

specifications or standards

13. Shipping and Packaging Requirements

All parts shipped are to be packaged in a way to prevent damage during shipment. This may include double bagging or utilizing heavy gage plastic bags. Unless specific packaging requirements constitute a part of Parmatech's purchase order requirements, best practices shall apply. Cost associated with damage and/or loss incurred due to poor packaging shall be the responsibility of the supplier.

Partial Shipments of Material

Partial shipments of material represent additional cost to Parmatech, in the form of additional manufacturing setups and missed delivery dates to customers. Suppliers who must make shipments of material which represent less than the full quantity ordered by Parmatech shall notify the Purchasing representative in advance of the partial shipment, and shall indicate at that time the date and quantity of subsequent shipments to complete the order.

Packaging and Shipping

The Supplier shall maintain a system which ensures adequate control of the packaging and shipping phases of the process, in order to protect material in consideration of expected shipping and storage conditions. Any special Parmatech packaging requirements should be stated on the Purchase Order. Purchase Orders will state the method of shipment.

14. Quality Records

Supplier Quality Records serve as objective evidence that the purchase order requirements have been met. Supplier Quality Records must be legible and ultimately traceable to customer purchase orders. All records must be stored in a manner that ensures legibility and renders the records easily retrievable in the event of a customer recall.

15. Record Retention

Suppliers are required to retain all Quality Records (i.e. receiving documents, inspection records, material reports, purchase order, routers, etc) for a minimum of 7 years.

16. Shelf Life Requirements

Products with shelf life requirements must have, at a minimum, 80% of shelf life remaining.

17. Notification of Quality System Changes

Suppliers are required to notify Parmatech of any significant changes to their quality system.

18. Right of Entry Agreement

By accepting a purchase order from Parmatech, the Supplier agrees that Parmatech, its customers and regulatory agencies, may have access to the Supplier's facility, and all facilities involved in satisfying the order, for inspection and/or surveying purposes.

19. Related Documents

QOP-74-01 Supplier Management