

PARMATECH CORPORATION SOP

PUR-303 Revision F Date 4/21/21

Supplier Quality Requirements

1. Purpose

The purpose of this document is to clearly define Parmatech's supplier requirements. This document defines requirements that may be covered by other procurement documentation. It is the responsibility of the supplier to understand and ensure compliance with these requirements.

2. General Purchasing Provisions

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.

Parmatech requires its suppliers to operate in full compliance with all applicable labor and environmental laws, as well as, provide for a safe work environment. Suppliers are encouraged to implement environmentally friendly business practices.

Suppliers must be capable of sending and receiving data, including purchase orders, invoices, drawings and specifications via email. Additional correspondence may include conference calls with appropriate Parmatech personnel. All interactions between Parmatech personnel and customer representatives will be conducted professionally with the intent to develop a successful business partnership.

All Parmatech suppliers reviewing any specific information regarding product, or process, provided by Parmatech or visiting any Parmatech facility must sign a confidentiality and/or Non-Disclosure Agreement.

Parmatech suppliers providing services or secondary operations related to product must complete a supplier questionnaire. This questionnaire will be reviewed by authorized Parmatech personnel. If approved, the supplier's services are considered acceptable for the specific product requirements indicated on the Parmatech purchase order. Specific methods, processes and/or equipment used on first article parts may be approved via first article approval and/or site audits.

Except those requirements detailed in this document, requirements of each order will be flowed to the supplier in the Parmatech Purchase Order, including any Special Requirements. The supplier is required to review each Parmatech Purchase Order for details of the order and any Special Requirements.

When used, the supplier is responsible for applying appropriate controls, including flowing necessary Parmatech Purchase Order requirements, to their direct and sub tier external providers to ensure requirements are met.

Supplier is required to implement controls to prevent the purchase, and use, of counterfeit parts with regards to Parmatech orders.

3. Supplier Partnership

It is Parmatech's desire to form long-term, mutually beneficial relationships with our suppliers with a common goal of repeatable high product quality, continuous improvement, and equitable prosperity for all business partners with sustainable incremental growth. Interactions between Parmatech and supplier representatives will support this vision.

4. Purchasing Contact

Supplier contact for all matters related to purchased products and services, including quality and delivery, shall be Parmatech Corporation's Purchasing representative, or designee. See our website for contact information; www.parmatech.com (http://atwcompanies.com/parmatech)

Acceptance of the Parmatech Purchase Order constitutes acceptance of the Supplier Quality Requirements 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 goods or services are 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 Supplier's best possible delivery date for Parmatech's consideration.

Parmatech shall then have the right to accept or reject the proposed delivery date and contract of purchase. Packing List/ Shipping Documents Material and services received from Suppliers must be accompanied by a packing list and all relevant shipping documents. All documents must reference the Parmatech purchase order number.

5. Product Preservation in Packaging and Shipping

The Supplier shall maintain a system which ensures adequate control, and protection of product, during the packaging and shipping phases. Any special Parmatech packaging requirements are stated on the Purchase Order. Purchase Orders will state the method of preferred shipment.

6. 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.

7. Certification Requirements

Certificate of Analysis (CoA) Is Required for Raw Materials. All raw material Suppliers to Parmatech shall provide a CoA which must be received before the shipment of material if possible, if not when the shipment of material arrives.

The CoA requirement for raw materials is waived only when the Purchase Order specifically states that a CoA is not required

All other suppliers must provide a Certificate of Conformance (CoC) indicating that the service provided meets the requirements. If inspection reports or evidence of inspection are required that information will be indicated on the Purchase Order.

Both types of certifications must reference the Parmatech PO number/job number; indicate any requested specifications and the results of any required tests.

Failure to provide certifications with received material shall be cause for rejection of the material at receiving/inspection.

No invoice will be paid until certifications are received.

8. Supplier Quality Management System Requirements

At a minimum, suppliers are required to implement and maintain a quality system that is capable of accurately tracing separate parts, lots, and all documentation through their processes, as well as facilitate accurate change control. Suppliers with 3rd party certification to a recognized management system such as AS9100 or ISO 9001 will be given priority as a business partner over those that cannot demonstrate that they have a reliable quality management system in place.

9. Traceability – labeling and containers

All material shipped to Parmatech must be identified with the part number and Parmatech order number to ensure appropriate traceability. Suppliers utilizing subcontractors must obtain Parmatech approval and shall retain traceability markings on containers, forms and tags, so as to assure traceability from Parmatech to the Subcontractor, and back to Parmatech.

10. Verification of Product/Service Conformance

Parmatech shall perform a receiving inspection of materials or services as determined necessary by Engineering and/or Quality.

Material found to be discrepant at receiving inspection shall be rejected, and handled in accordance with Control of Nonconforming Product procedure QOP-83-01.

Rejected items, which are returned by a Supplier to Parmatech after sorting or rework shall be kept separate from other material, and clearly identified.

11. Deviations from Purchase Order Requirements

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 representative, or designee.

Parmatech's purchasing representative, or designee, shall consult with the appropriate personnel and communicate approval or disapproval to the Supplier in writing.

Approval or Disapproval shall be documented on form QA-432.

Without written approval of the deviation from the Purchasing representative or designee the may not submit the deviated parts and is expected to furnish materials or services in compliance with all Purchase Order requirements.

12. Purchase Order Review Requirements

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, Parmatech customer requirements and any regulatory standards required.

Each supplier is responsible for ensuring that 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, delivery dates, and any processing instructions. This requirement is noted on the Purchase Order.

Delivery date is defined as the date parts are due at the Parmatech facility.

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. Suppliers are expected to have contract review procedures in place to ensure that any special instructions on the PO will be recognized and effectively communicated throughout the production cycle, and that there is a closed loop to ensure that the instructions have been successfully followed prior to returning the parts to Parmatech.

Applicable requirements must be flowed down to supplier's supply chain. Requirements include, and are not limited to, ITAR, DFARs, DPAS, RoHS, Right of Entry, State and Federal Regulatory requirements, part specific requirements as specified on PO and/or part drawing.

13. First Article Inspection Reporting (Secondary Operations) and Test Specimens

First Article Inspection (FAI) or Delta First Article Inspections reports are required for first time machined operations and new drawing revisions, where the revision changes involve the suppliers process. Parmatech's preferred format is AS9102 <u>Aerospace First Article Inspection Requirement</u>, or QA-411 Parmatech <u>First Article Inspection Report Template</u>. Inspection results may be documented on the supplier's own inspection form providing the information documented is traceable to the First Article purchase order and all requirements/samples are captured as reflected in Parmatech QA-411.

Parmatech will coordinate with the supplier on inspection methodology and the number of inspection articles to be measured. 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.

Test specimens may be required maybe required fir special inspection verifications, investigations and for auditing purposes.

14. Supplier Inspection Capability Requirements

All suppliers are 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.

15. Training, Awareness and Competence

Supplier is expected to ensure appropriate training is provided to employees that directly affect Parmatech product or service requirements. Services conducted for Parmatech that require certification to a required Standard such as penetrant testing, heat treating, surface treatment, etc. shall been verified by certified personnel.

Additionally, Supplier organization must ensure their employees are aware of:

- Their contribution to product or service conformity;
- Their contribution to product safety;
- The importance of ethical behavior.

16. Approval of Product

Parmatech will determine approval and acceptability of product or services at incoming inspection. Exceptions to this will be those suppliers who have achieved a dock to stock or skip lot status. Parmatech engineering, and/or Quality representatives will communicate critical items, key characteristics, statistical requirements and inspection methodologies where necessary or where the method is not apparent. Acceptance and release of the product is based on lot sampling, C=0 methodology. On-site inspection may be conducted by Parmatech or its customers and will be communicated to the supplier in a reasonable fashion.

17. Supplier Requirements for Managing Nonconforming Product

Nonconforming product must be identified and immediately segregated from conforming product.

Suppliers must not knowingly ship nonconforming product to Parmatech unless supplier receives authorization in writing from an authorized Parmatech Quality representative using Parmatech's Supplier Deviation Form QA-432.

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. 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.

18. Requirements for Disposition of Non-Conforming Parmatech Owned Parts

Suppliers may not disposition nonconforming Parmatech product in their possession with a disposition of "use as is" or "rework to print" or "scrap" unless formally approved in writing by an authorized Parmatech Quality representative.

19. 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 report and in repeat situations may request reimbursement for damaged product as a result of a nonconforming event during secondary operations processing by the supplier.

20. Traceability - General Requirements

Suppliers are required to have a system in place that provides product lot traceability through the secondary operation process, and traceability to the Parmatech purchase order.

Parmatech parts may not be mixed across lot numbers including batches of the same part number.

For raw material suppliers each unique batch is required to have traceability back to the key ingredients.

21. 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.

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

Table One is a list of common types of supplier services and the various types of documentation that Parmatech requires with each shipment. Additional requirements may be included on the Purchase Order.

22. Supplier Process Change Notification Requirements

Parmatech recognizes that it is common for businesses to implement change, whether it involves process changes, infrastructure changes, or changes with key personnel.

Our request, and requirement, is that your company's representative notifies Parmatech of any change that may impact the quality, or delivery, of our parts and awaits Parmatech approval PRIOR to processing Parmatech parts.

Planned changes need to be reviewed internally by Parmatech QA department and other interested parties in advance of implementation to determine the qualification requirements of the change per our customer specifications and agreements.

To facilitate this communication please utilize form QA-432 available via the Supplier Portal on our website. Changes that require prior notification include but are not limited to the following:

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

Should any of these changes occur please provide <u>prior</u> written email notification to Parmatech staff listed below and do not process Parmatech parts without written approval of the change from the Parmatech Operations Manager or Quality Manager.

Please note that parts processed without prior Parmatech notification and approval will be considered nonconforming and payment will be withheld. It is important to note that such actions will cause delays in our production and will negatively impact our Customer commitments. This is certainly not an action we want to take, however, many of our Customers strictly demand change notification from us.

To satisfy our Customers' request for prior change notification Parmatech requires compliance from our Suppliers. Disregarding this request may require us to replace your services and terminate our business relationship.

Table One

SERVICE	SHIPPING DOCUMENTATION EXAMPLES		
	Certificate of Conformance		
Machine Shop	Statement of conformance to drawing specifications		
	An inspection report or evidence of inspection as required on PO		
Processors	Certificate of Conformance		
	Method used per a published standard* (MIL, ASME, etc.)		
	Process specifications and statement of conformance to specification		
	*Proprietary Processes are excluded		
	Certificate of Conformance		
Coatings/Plating	Method used per a published standard (MIL, ASME, etc.)		
	Process specifications and statement of conformance to specification		
	Certificate of Analysis		
Raw Materials	Method processed per a published standard (MIL, ASME, etc.)		
Raw ivialerials	Process specifications and statement of conformance to specification		
	SDS Document		

23. 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.

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 are stated on the Purchase Order. 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.

24. Supplier Quality Records Regarding Parmatech Product

Supplier Quality Records serve as objective evidence that the purchase order requirements have been met. Supplier Quality Records must be legible and traceable to Parmatech purchase orders.

All records must be stored in a manner that ensures legibility and renders the records easily retrievable upon request.

25. Supplier Record Retention Regarding Parmatech Products

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

26. Shelf Life Requirements

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

27. Right of Entry Agreement

By accepting a purchase order from Parmatech, the Supplier agrees that Parmatech (and its customers, and regulatory agencies, etc.) are allowed access for inspection, surveying purposes, compliance to stated services, etc.

This provision applies to the Supplier's facility and all facilities involved in satisfying the order.

Whenever possible, Parmatech will provide supplier with reasonable advanced notice when access is required by Parmatech, it's customer or a regulatory agency.

28. Natural Rubber Latex Disclosure Requirement

Parmatech customers in the medical device markets are now requiring that their suppliers be free of natural rubber latex in the processes and materials used to manufacture and to handle their components. This is a requirement driven by potential patient and clinician allergic sensitivity to latex.

As part of Parmatech's obligation to our customers we have been asked to flow this same requirement down to our suppliers.

Parmatech now distributes a detailed letter which requires a signed acknowledgement be returned to us in which our suppliers agree to eliminate all sources of natural rubber latex that could come into contact with the components sent to us or returned to us after secondary operations. The signing and retuning of this acknowledgement letter is required.

29. Rating Criteria

Rating of suppliers and subcontractors shall be based on their ability to meet quality and delivery requirements, as outlined on the Purchase Order.

30. Quality Rating

Quality rating for a supplier shall be calculated by the following formula: (number of lots accepted at Receiving Inspection) / (total number of lots received from supplier) x 100

31. Delivery Rating

On-time delivery is defined as the condition whereby all material ordered on a Purchase Order is received at the Parmatech Corporation receiving dock by the Promise Date shown on the Purchase Order.

If a Promise Date is not entered on the Purchase Order the system will calculate on-time delivery based on the Due Date. Promise Dates can be adjusted by the Parmatech staff if this delay does not create delivery issues for Parmatech's customer and the supplier has given sufficient explanation of the reason for the delay.

Early deliveries are acceptable within 5 days of the Due Date, unless otherwise approved by Parmatech, and shall be designated on-time for the purposes of this Procedure. Delivery rating for a supplier shall be calculated by the following formula: (number of lots received on-time) / (total number of lots received from supplier) x 100

32. Supplier Performance Reporting

Supplier Rating reports are sent to Category-A1 suppliers with a minimum estimated average yearly delivery rate of 10 or greater purchase order lines, regardless of quantity delivered per line. The Supplier Performance Rating report shall, at a minimum, consist of the following items:

- Delivery Rating
- Quality Rating
- Overall Score
- The Supplier Rating is a calculated by the following formula: (Quality Rating x 0.65) + (Delivery Rating x 0.35)
- Scorecards routinely are expected to be generated and sent quarterly per the calendar year, but can be sent once per six months or longer if necessary due to business circumstances or labor constraints.

33. Score Card Rating Categories and Corresponding Action

Rating of 90-100; Outstanding – No action

Rating of 80 - 89; Good - No action

Rating of 70 - 79; Concerning - Discussions with supplier to improve rating

Rating of 50 - 69; Needs Improvement - CAR needed detailing plan to improve

Rating of 49 – 00; Probation – CAR needed detailing plan to improve and supplier must show improvement during next re-evaluation cycle (90 days for all suppliers other than suppliers with minimal annual shipments –see section 31 of this document)

34. Outsourcing

Any processes that require outsourcing must be approved by Parmatech including special processes.

35. Related Documents

AS9102, Aerospace First Article Inspection Report

QA-411, First Article Inspection Report

QA-432, Supplier Deviation Request Form

QA-502, First Article Inspection Report

QOP-74-01, Supplier Management Requirements

QOP-83-01, Control of Nonconforming Material

REVISION HISTORY			
Rev	Rev Description of Change		Rev Date
В	Updated to current processes & improved formatting	P. Brown	07/7/17
С	Added natural latex rubber requirement as section #24	P. Brown	08/11/17
D	Updated to ISO 9001:2015 reqs and added Approval process	S. Stites	10/24/17
Е	Amended and highlighted focus on attending to COA approval	T. Field	1/21/21
F	Updated to include AS9100 requirements and clarification	S. Stites	4/21/21