



GENERAL QUALITY ASSURANCE REQUIREMENTS



These requirements shall be communicated to ALL appropriate personnel within Seller's organization, upon receipt of the Purchase Order.

1. Definitions

- The term "Purchase Order" refers to the Purchase Order, Subcontract, Request for Quote, or other written agreement between Buyer and Seller (Supplier), in which this document is incorporated by reference.
- The term "Buyer" shall mean the legal entity affiliate of Paligen Technologies, Inc. on the face of the Purchase Order.
- The term "Buyer's Authorized Procurement Representative" shall mean a person authorized by Buyer's cognizant procurement organization to administer and/or execute the Purchase Order.
- The term "Seller" refers to the legal entity that is the contracting party with Buyer with respect to the Purchase Order. Seller is the supplier to Buyer.

2. Purpose

This document establishes requirements applicable to items ordered under the Request for Quote or Purchase Order of which this document is a part. It contains General Requirements for quality assurance that is applicable, unless expressly excluded in the Purchase Order. Any Supplemental Quality Assurance Requirements (SQARs) specified on the Purchase Order shall also apply and if in conflict, shall supersede these requirements. Any other conflict of requirements shall be resolved in writing through Buyer's Authorized Procurement Representative.

3. Requirements for Systematic Control of Quality

A. Systematic Assurance of Conformance to Requirements:

Seller shall establish a system of internal quality controls sufficient to assure that all items, materials, and services submitted to Buyer conform to Purchase Order requirements, whether manufactured or processed by Seller, or procured from subcontractors or sub-tier suppliers. Seller shall perform any inspections and/or tests necessary to substantiate product conformance to drawing, specification, and Purchase Order requirements. Buyer encourages its suppliers to become compliant with the requirements of ISO-9001 (current revision) and to utilize those guidelines as the basis for their internal Quality Management System.

B. Records:

Seller shall maintain adequate records of all required certificates, inspections and tests, including such records or certifications provided to Seller by its suppliers, for at least 7 years after final payment, unless otherwise specified, and shall provide or make available for review all such documentation.

C. Drawing and Specification Control:

Seller's system shall assure that only correct, current drawings and specifications as detailed in the contract and/or Purchase Order are used for fabrication, processing, and inspection and testing.

For military and other standards and specifications, the latest revision at the time of Purchase Order issuance shall be used unless otherwise directed by the Purchase Order, drawing, or Buyer.

D. Measuring and Test Equipment:



Seller shall provide and maintain any measuring and test equipment necessary to assure that items and materials conform to requirements. To assure continued accuracy, such equipment shall be regularly checked for accuracy, and precision equipment shall be calibrated at established intervals against certified standards traceable to the National Institute of Standards and Technology (NIST). Buyer encourages its suppliers to utilize the guidelines of ISO 10012 (current revision) as a model for maintaining inspection equipment and tools.

E. Control of Nonconforming Material:

Seller shall establish and maintain an effective and positive system for identifying, segregating, and controlling material found not to conform to requirements. An initial report to Buyer of any material considered for MRB action is required within 2 business days of rejection. Seller is advised that the authority to make Material Review Board (MRB) dispositions for assemblies, sub-assemblies, or components that comprise items listed on the Purchase Order is not granted. Seller does not have the authority to perform any repairs or make substitutions. Seller does, however, have the authority to scrap product that doesn't use or contain Buyer supplied material. Any decisions to scrap any items made from Buyer supplied material must have the written consent of Buyer's Authorized Procurement Representative. Rework to drawing requirements is permitted unless otherwise noted. Seller may perform "Rework to Print", only after Buyer has been notified that such "Rework to Print" needs to be performed and only if a documented procedure is in place that has been approved by Buyer.

"Rework to Print" and "Repair" are defined as follows:

- Rework to Print: The reprocessing of nonconforming items, in the same manner as originally performed, to bring them completely into conformance with drawings, specifications, and/or Purchase Order requirements.
- Repair: The subjection of nonconforming material to an approved process designed to reduce but not completely eliminate the nonconformance. The purpose of repair is to bring nonconforming material into an acceptable condition. Repair is distinguished from rework in that the item after repair still does not completely conform to the applicable drawings, specifications, or contract requirements. Only Buyer's Authorized Procurement Representative can approve any repair activity.

F. Request for Changes / Deviations / Waivers:

Seller shall not incorporate any change, deviation, or waiver which affects Buyer's, Seller's, or Government's specifications or drawings prior to receipt of written authorization from Buyer's Authorized Procurement Representative. This will also include any Acceptance Test Procedure (ATP) or process specification changes or other requirements imposed for the acceptance of the item as described in the Purchase Order.

Additionally, Seller is not authorized to process any items "at their risk" by incorporating the proposed change into deliverable items.

G. Rounding, and the Reporting of Inspection Data:

Unless otherwise specified, Seller shall, during the course of inspection of items under the Purchase Order, utilize the standard practice of ASTM E29 (latest revision) with respect to rounding of digits. The accuracy of acceptance is a ratio of 10:1 greater than the tolerance of the feature being inspected. It shall be this last digit that is employed to determine the rounding of the other significant digits. In the case of MAX callout for a feature, rounding shall not be utilized and the absolute method shall be employed.

Additionally, Seller shall report all inspection data, whether in their format or that of Buyer's format, to the same number of decimal places as shown on the drawing or within the specification.



H. Use of Controlled Shelf Life Materials:

Seller shall have and maintain an effective system for controlling items that have limited acceptability due to shelf life constraints. The system must include a method for identifying the age of such items and provide for the rotation of stock (FIFO) as well as provisions for any special storage and handling conditions required by the manufacturer of the controlled shelf life item. Seller shall not under any circumstances use or incorporate into any item materials that have lapsed beyond the shelf life expiration date.

I. Tooling and Tool Proofing:

Tooling required for items produced under the Purchase Order are subject to acceptance by Buyer. Seller shall notify Buyer when tooling is ready for inspection. Acceptance will be contingent upon a quantity of resultant dimensional samples inspected under surveillance of Buyer's delegated representative. In the case of multiple cavity tooling, the resultant samples must be from each cavity. Samples used for dimensional verification shall be identified with the tool number (and cavity number if applicable) used to produce them.

Seller shall notify Buyer prior to any rework, refurbishment, or replacement of any portion of the tooling used to produce items on the Purchase Order. Upon notification, Buyer shall advise Seller if there is a need for an updated (delta) First Article Data Package, or to perform a new mold, die, or tooling analysis.

J. Formation and Identification of Lot or Batches:

The product shall be assembled into identifiable lots, sub-lots, or batches. Each lot or batch shall consist of units or product of a single type, grade, class, size, and composition, manufactured under essentially the same conditions and at essentially the same time (MIL-STD-1916) unless stated otherwise in the Purchase Order or Quality Assurance Document (QAD).

K. Calibration System:

Seller shall maintain a calibration system using the guidelines of ISO-10012 (latest version).

4. Prohibited Practices

A. Unauthorized Repairs:

Seller may not repair parts damaged or found to be faulty during fabrication by means of welding, brazing, soldering, adhesives, or other means of adding material without the written consent of Buyer's Authorized Procurement Representative.

Defects in castings or forgings shall not be repaired by any method unless authorized in writing by Buyer's Authorized Procurement Representative.

B. Changes in Approved Systems, Processes, Materials, or Procedures:

Seller shall not change any process to include manufacturing methods or equipment, inspection methods or equipment, material, or procedure without prior written consent of Buyer's Authorized Procurement Representative. This specifically includes the Quality Management System. As to any product which has been subjected to Buyer or Government specified qualification procedures qualifying Seller's product or to permit Seller to become a qualified source for the product, Seller shall not change product design, composition, configuration (including form, fit, function, or interchangeability), materials, fabrication processes, Seller's subcontractors, facility of manufacture, or outside processing sources without prior notification and subsequent written approval by Buyer's Authorized Procurement Representative. All requests for change shall be submitted in writing.



Seller shall flow down this requirement to subcontractors as applicable.

C. Improper Resubmittal:

Items rejected by Buyer and subsequently resubmitted to Buyer shall be clearly and properly identified as resubmitted. Seller's shipping documents shall state that the items are replacements or reworked items and shall also reference, by number, Buyer's rejection document.

D. Unauthorized Subcontracting:

Seller shall not subcontract work, or processing (including that required by drawing or specification), or procure materials to be supplied to Buyer (other than raw materials or catalog items), or release technical information included with the Request for Quotation or Purchase Order, to other subcontractors or sub-tier suppliers without specific written approval of Buyer's Authorized Procurement Representative. (Buyer may have Customer requirements to control special process sources.)

E. Unauthorized Facility Change:

Seller shall not relocate any production, manufacturing, and/or processing facilities during performance of the Purchase Order without prior notification of such relocation to Buyer, and affording Buyer or Buyer's delegated representative an opportunity to examine such facilities for compliance with Quality Assurance requirements, including any necessary approvals.

F. Counterfeit Parts:

Purchased parts must be obtained by the Original Component Manufacturer (OCM)/Original Equipment Manufacturer (OEM), or through an OCM/OEM authorized distributor chain. "Counterfeit Work" means Work that is or contains items misrepresented as having been designed and/or produced under an approved system or other acceptable method. Seller must immediately notify Buyer with the pertinent facts, if Seller becomes aware or suspects that it has furnished Counterfeit Work. When requested by Buyer, Seller shall provide OCM/OEM documentation that authenticates traceability of the affected items to the applicable OCM/OEM.

5. Responsibility for Conformance

Neither surveillance inspection and/or tests performed by Buyer, or their representative, at either Seller's or Buyer's facility, or Seller's compliance with all applicable Quality Assurance Requirements shall relieve Seller of the responsibility to furnish items that fully conform to the provisions of the Purchase Order in its entirety.

Product found to be nonconforming after source inspection or source surveillance does not relieve Seller's responsibility of their product. Product will have to be replaced or reworked as appropriate.

6. Documentation

Buyer may refuse to accept items delivered under the Purchase Order if Seller fails to submit the certification documentation, test data, inspection documentation, or reports specified in the Purchase Order. Documentation includes source inspection records when such source inspection is performed.



7. Lot Sampling

Buyer reserves the right to use statistically valid sampling plans, including Zero Defect plans, for the acceptance or rejection of items, and to return items rejected by such means to Seller for correction or replacement. Final acceptance shall be at Buyer's location, or if drop shipped, at the final destination.

8. Corrective Action Requests

When Buyer determines that an issue exists, Seller shall provide a formal response to any Supplier Corrective Action Request (SCAR) issued by Buyer within the following timeframe.

A. Initial response:

Seller shall provide to Buyer an initial response within 48 hours (2 business days if the 48 hours timeframe falls during a weekend or holiday). Extensions to the initial response due date may be granted at the discretion of Buyer, but shall not exceed an additional 48 hours. Seller Point of Contact (POC) shall provide an initial response which shall include at a minimum:

- Acknowledgement that the SCAR has been received and understood.
- A simple statement of the condition without placing blame or attempting to solve the issue.
- A short term containment effort to prevent the condition from getting to the next step or the customer. This should include the name of the person responsible (POC) and the date of implementation.
- An initial data gathering plan – this plan may not be fully realized at this stage of the process, but may be used as a starting point which may be modified and updated as the process develops. Again, this should include the name of the person responsible (POC) and the date of initiation and projected dates of additional events.

B. Interim response(s):

Seller shall frequently generate and provide Buyer updates to either the containment action or to the initial data gathering plan as necessary. Seller shall provide updates no less frequently than weekly unless agreed to by Buyer.

C. Final response:

Seller shall provide a final response to Buyer within 14 calendar days of initial receipt of the SCAR. Extensions to the final response due date may be granted at the discretion of Buyer, but only in the event that the need for extension is justified and is evidenced by a plan of action with dates extending beyond the original final response due date. The final response shall include at a minimum:

- The completed fully executed data gathering plan with analysis/interpretation of data.
- A determination of the root cause for the condition.
- A determination of actions needed to prevent recurrence of the condition.
- A corrective action implementation plan including the name of the person responsible and the date of implementation.
- A plan for future monitoring of the implemented actions to determine effectiveness.
- All objective evidence of actions taken to support the root cause and corrective actions implemented.
- Signature of the highest authority within Seller's facility responsible for the overall execution of the corrective action process.

A SCAR may not be closed until all actions have been implemented. Failure by Seller to adhere to the response requirements shall reflect on Seller's performance rating and their ability to quote future business.



When corrective action is required for Government Source inspected items, Seller shall coordinate such actions with the Government Quality Assurance Representative assigned to their facility.

9. Workmanship

Products delivered to Buyer are representative of Seller's quality of work and shall be free of defects, sharp edges, burrs, dents, folds, dirt, and oil.

A. Surface Finish, Plated, & Surfaces:

Machined, plated, and painted surfaces shall be smooth and uniform. Free from blisters, pits with depth exceeding surface finish specifications, and other defects visible without magnification. Paint and plating shall be uniform in color. Scratches shall not expose base material.

B. Forgings & Castings:

Forging and castings shall be free of slivers, laps, cracks, checks, seams, cold shunts, inclusions, scale, burning, and lamination.

C. Welding:

All welds are to be free of slag, spatter, inclusions, and porosity. Weld beads are to be uniform and consistent.

D. Threaded Features:

Screws, nuts, bolts, and threaded holes shall show no evidence of cross threading, mutilation, or detrimental burrs.

E. Cleaning:

Machined parts and assemblies shall be cleaned free of dirt, oil, machining residues, smudges, metal chips, mold release agents, finger prints, or any other contaminant that detracts from the appearance of the item. Care should be taken in process to avoid staining and absorption of contaminant such as cutting fluid into porous material. Lubricants containing silicone should be avoided as silicone is nearly impossible to remove. Buyer's components are frequently assembled into items containing explosives. Chemical residues can cause a hazardous reaction.

F. Item Identification:

When required item identification shall be clearly legible without magnification using a color contrasting in color to the surface. Do not metal stamp, engrave, or otherwise alter surface in excess of surface finish requirements unless explicitly stated in applicable Purchase Order or drawing. Do not use graphite pencils to identify metal parts (corrosion).

10. Packaging for Shipment

Seller shall package all items for shipment or transport to Buyer, or other destinations as may be designated by Buyer, in accordance with good commercial practices or as otherwise specified, assuring that the items are sufficiently protected so as to preclude damage such as abrasion, scratching, and denting due to contact between the items themselves and/or external damage in the course of normal commercial transport.



11. Right of Access

Seller shall grant Buyer and Buyer's authorized customer / Government representatives and regulatory authorities right of access to all applicable records and areas of all facilities, at any level of the supply chain, involved with the products and/or services delivered under this Purchase Order for the purpose of inspection or verification of materials, processes, procedures, tooling, and equipment during performance of the Purchase Order.

12. Contract Change Approval

Buyer's Authorized Procurement Representative has sole authority to invoke contract changes, such as engineering changes. No other Buyer representative, whether in the act of technical supervision, administration, or any other functional group is authorized to make any commitment to Seller, to perform or terminate any work, or to incur obligation. Project Engineers, Technical Supervisors, Quality Engineers, and any other groups within Buyer (or as an agent thereof), are not authorized to make or otherwise direct changes that in any way affect the contractual relationship of Seller and Buyer.

13. Flow Down of Requirements

Seller's Purchase Orders must flow down all applicable Quality Assurance Requirements of Buyer's Purchase Order/Subcontract including, but not limited to, Federal Acquisition Regulations (FAR) / Defense FAR Supplement (DFARS) / Department of Energy Acquisition Regulation (DEAR) clauses, material certification, traceability of raw material during processing and delivery, documentation and control of processes, record retention, and a requirement for the appropriate inspection/quality system.

Seller's system shall assure the flow down of all applicable quality and technical requirements that are part of the Purchase Order, and shall verify the subcontractor's capability to produce items and methods for assuring compliance to requirements. Seller's subcontractors shall be required to flow down and verify requirements of supplies and services to their suppliers.