

Orbel Corporation

Quality Assurance Provisions (QAP) for Suppliers



A. PURPOSE

To define the Orbel quality assurance provisions for inventory materials received from strategic suppliers. This document is intended for use by Orbel strategic suppliers to aid in the quality assurance/control of incoming components.

B. SCOPE

This procedure applies to Purchase Orders (P.O.s) and Supply Contracts issued by the Orbel Purchasing Department. All revisions of this document must be approved by the Orbel Senior Management as part of the Orbel Document Control procedure.

C. REFERENCES (Use latest revision)

ANSI/ASQC Z1.4-1993	Sampling Procedures and Tables for Inspection by Attributes
ANSI/ASQC Z1.9-1993	Sampling Procedures and Tables for Inspection by Variables
DFARS	Defense Federal Acquisition Regulation Supplement
Directive 2011/65/EC	Restriction of Hazardous Substances Directive or RoHS
ISO-10012-1	Quality Assurance Requirements for Measuring Equipment
ITAR	International Traffic in Arms Regulations
NADCAP	National Aerospace and Defense Contractors Accreditation Program
MIL-STD 45662	Calibration System Requirements
Regulation (EC) No 1907/2006	Registration, Evaluation, Authorization and Restriction of Chemicals (REACH)

D. DEFINITIONS

Quality Assurance Provisions (QAP)	Requirements that are placed on the Purchase Order (P.O.) to communicate delivery or performance agreements to be met by the Supplier based on acceptance of the contract.
Strategic Supplier	Companies with whom Orbel has contracted with to deliver material for manufacture of products. Examples of Strategic Suppliers types are (but not limited to): <ul style="list-style-type: none"> Anodes Base Metal Suppliers

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D. DEFINITIONS (CONTINUED)

	<ul style="list-style-type: none"> • Calibration Services • Chemical Milling/Photo-Etching • Electroplaters/Coatings • Heat Treatment • Metal Formers/Stampers • Proprietary Process Chemical Suppliers (ex. Plating Baths) • Slitters • Tool/Die Suppliers
First Article Inspection Report (FAIR)	An inspection report completed by the supplier which conforms to AS9102

E. PROCEDURE

Quality Assurance Provisions (QAP) communicates to Suppliers additional requirements beyond those defined by the drawing and/or specification(s). Orbel uses QAPs as part of product acceptance and approval of Supplier's quality assurance processes. If the material is purchased through a distributor, the distributor remains responsible for flowing down the requirements to their suppliers.

- 1) QAPs will be communicated to suppliers on Orbel Purchase Orders (P.O.s), and detailed on the Orbel Website, www.orbel.com. If QAPs apply, QAP items will be displayed for each line item on the P.O. (Example QAP 1, 2, 4 will require that the supplier meet QAP 1, QAP 2 and QAP 4)
- 2) Suppliers must meet all QAPs as specified on the purchase order. Included in these requirements, all Suppliers must ensure that persons are aware of; their contribution to the product or service conformity, their contribution to product safety, and the importance of ethical behavior. If a supplier is unable to fulfill all QAPs as defined on the P.O., written approval is required from Orbel.

F. QUALITY ASSURANCE PROVISIONS

Quality Assurance Provisions (QAP) are additional requirements beyond those defined by the drawing and specification(s). If these QAPs apply to the purchase order you are fulfilling, the QAPs will be displayed for each line item on the Purchase Order.

All suppliers are required to meet and maintain the following;

On time delivery requirement will be Ten (10) days early and 0 (zero) late.

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Product quality requirement will be 100% lot acceptance. A lot is considered non-conforming if it fails to meet drawing, specification or lack of proper paperwork (incorrect packing slips, certifications and not including FAI documentation when requested).

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F. QUALITY ASSURANCE PROVISIONS (Continued)

QAP-1: QUALITY MANAGEMENT SYSTEM

Supplier shall, during performance of this P.O., maintain a Quality Management System acceptable to Orbel.

- a) Calibration Suppliers – Shall have a quality system that conforms to A2LA, ISO-17025 (Guide 25) or equivalent certifying body.
- b) Raw Material Suppliers – Shall have a Quality System that conforms to ISO-9001. This includes all metal and proprietary process chemical suppliers
- c) Special Process Suppliers – Shall have a Quality System that conforms to NADCAP (preferred), but at a minimum must conform to AS9100 or ISO 9001. This includes plating, coatings and heat treatment.
- d) Component Suppliers – Shall have a system that conforms to ISO-9001. This includes all Chemical Milling, Stamping and Forming, and Slitting suppliers.
- e) Tooling/Die Suppliers – Shall have a Quality System that conforms to ISO-9001.

For suppliers that are not certified to the Quality System requirements required above, Orbel reserves to the right to perform an on-site audit to verify conformance. This will be communicated and scheduled with the supplier in advance. Corrective Action will be required for any items found not in conformance, and depending upon severity may include temporary hold on materials and/or services until the actions have been resolved and approved.

Suppliers are expected to ship product that conforms to the P.O. issued. Written approval by Orbel is required prior to shipment of any non-conforming goods. In addition, the Supplier shall include a copy of the deviation documenting the non-conformance with the shipment. Written notification is required within 2 business days of non-conforming discovery, if found after shipment.

Supplier is expected to inform Orbel within ten (10) business days of any major change in the Supplier's Quality management System when Supplier is fulfilling open P.O.s, and before accepting any new P.O.s.

Orbel may request a Supplier Corrective Action (SCAR) and root cause analysis upon receipt of nonconforming material or deviation request. The Supplier is expected to complete the SCAR in a timely manner and return completed report to the respective Orbel purchasing agent or Quality Management representative.

QAP-2: SAFETY DATA SHEET (SDS)

All products containing hazardous substances must be labeled in accordance with applicable regulations and have the necessary Safety Data Sheet included with the shipment or immediately available for downloading on the company website.

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QAP-3: CERTIFICATE OF ANALYSIS

A Certificate of Analysis (C of A) must be included with the shipment specifying, at a minimum, the data/results for the critical dimensions or aspects listed on the Orbel-supplied drawing and/or specifications. Records showing these controls shall be on file at the Supplier's facility for eleven (11) years. At a minimum, the C of A shall include the Orbel part number/revision, P.O. number, ship date, quantity of items, serial number and/or lot/batch code, Supplier part number/revision (if applicable) and signature of authorized supplier's representative. Any discrepancy or waiver that applies must be noted on C of A.

QAP-4: CERTIFICATE OF CONFORMANCE

A Certificate of Conformance (C of C) must be included with the shipment specifying that all materials, processes and finished item inspections were controlled in accordance with P. O. requirements. Records showing these controls shall be on file at the Supplier's facility for

eleven (11) years. At a minimum, the C of C shall include the Orbel part number/revision, P.O. number, ship date, quantity of items, serial number and/or lot/batch code, Supplier part number/revision (if applicable) and signature of authorized supplier's representative. Any discrepancy or waiver that applies must be noted on C of C.

QAP-5: CONTROL OF RECORDS/DOCUMENTATION

The Supplier shall generate and maintain records and data for all inspections and tests performed. The records and data generated shall be appropriate to the inspection and test operations performed and in sufficient detail to provide for complete verification and evaluation of operations. On request the records will be supplied to the Purchaser and no records will be destroyed without prior permission of Orbel. These records may include, but are not limited to;

Product Release certification:

- a) Records of testing or inspection such as test certificates, route cards, or hatch records that detail product serial numbers and are required for traceability purposes.
- b) The Supplier shall retain records for a minimum of seven years unless otherwise agreed in writing by Purchaser. This time period shall be valid from the date of completion of the record.

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QAP-6: RIGHT OF ACCESS

Upon the Purchaser providing reasonable notice, the Supplier shall (and procure that its sub-contractors shall):

- a) Allow the Purchaser and persons authorized by the Purchaser (which may include the Purchaser's Customer) access to the Supplier's premises (and those of its sub tier Suppliers) as are being used to carry out work on the Goods and Services in order to inspect and audit the facilities, processes, and procedures used in manufacturing the Goods
- b) Provide adequate data to the Purchaser relating to progress of work on the Goods and their quality
- c) Provide all necessary assistance (including, where appropriate, access to office, accommodation, telephone and fax facilities) to enable the rights set out in purchase order to be exercised fully.

QAP-7: PACKAGING

All material shipped to Orbel is to be packed in containers that will prevent damage during the shipping and receiving process. Material is to be packaged in the container in a manner and method that will prevent damage during the shipping and receiving process.

QAP-8: PACKAGING IDENTIFICATION

Supplier shall identify all containers, packing lists and/or certifications with supplier Name; PO Number; Item/Line Number; Orbel part number and revision; supplier's part number (if applicable), lot/batch number, date code or serial number (if required); and any waivers/deviations that apply.

QAP-9: INDIVIDUAL PART IDENTIFICATION

Each item is to be individually packaged. Packaging label for each item shall include serial number, PO number, Orbel part number and revision, supplier's part number (if applicable) and any waivers/deviations that apply.

QAP-10: LOT/BATCH PART IDENTIFICATION

Items are to be shipped in batches, with a maximum of one lot per package. Packaging label for items shall include lot/batch number or date code in package, number of items in lot/batch, PO number, Orbel part number and revision, supplier's part number (if applicable) and any waivers/deviations that apply

Supplier shall be responsible for defining the lot/batch. An individual lot/batch is expected to be determined by the process step with the minimum number of items. Supplier shall furnish lot definition to Orbel upon request. Items will be inspected at incoming inspection on a lot/batch basis.

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QAP-11: FIRST ARTICLE INSPECTION. SUPPLIER

First article inspection is required preferably per AS9102. Supplier shall provide a First Article report using a suitable AS9102 format. A first article inspection report shall be supplied with the initial shipment of a part number or if a part number has not been delivered in the previous 24 months. A FAI will be required for all changes in an Orbel part number revision unless an exemption has been approved by the Orbel Quality Management.

QAP-12: SUPPLIER INSPECTION – 100% INSPECTION

Inspection by attributes or variables (conforming to ANSI/ASQC Z1.4-1993 or ANSI/ASQC Z1.9-1993) is required using a sampling plan of 100%. Quality Records are to be retained by supplier and available for review by Orbel when required. Retention time shall be 11 years.

QAP-13: SUPPLIER INSPECTION – AQL 1.0%

Inspection by attributes or variables (conforming to ANSI/ASQC Z1.4-1993 or ANSI/ASQC Z1.9-1993) is required using a sampling plan of AQL 1.0% Level II or an approved alternate. Quality Records are to be retained by supplier and available for review by Orbel when required. Retention time shall be 11 years.

QAP-14 TEST DATA SHEETS

Each shipment shall include appropriate test data sheet as applicable for each part number, lot number, batch specific material types, or heat-treat, as specified on the Orbel drawing and/or specification. Test data sheets shall reference the P.O. number, Orbel part number/revision and suppliers part number/revisions.

QAP-15: SUPPLY CHAIN CONTROL OF SUB-TIER SUPPLIERS / SPECIAL PROCESSES

Suppliers using sub-tier Suppliers shall either have their systems to control sub-tier Suppliers approved by the Purchaser or an external certification body. Should the Supplier's system be approved to control the sub-tier Suppliers, the Supplier shall have records of this approval on file and available for review by the Purchaser's Quality Representative(s). Approval of sub-tier Suppliers by the Purchaser does not relieve the Supplier of the responsibility for assuring that work performed by sub-tier Suppliers is in accordance with specification requirements. When Special Processes are required by Purchase Order, Drawing, or other Specification, Special Processes shall be performed by an Orbel or other end-user Approved Source and Certifications shall accompany each shipment of product or good to Orbel.

QAP-16: MATERIAL TRACEABILITY

Goods and Services supplied against this Order require full traceability of parts/materials from the time of receipt through delivery of the finished article. Raw material traceability is required to the physical and chemical analysis. If the Supplier is not the original manufacturer of the Goods and Services, the Supplier shall also provide with the delivery of each consignment, copies of the original manufacturers certificates of conformity/compliance together with test results etc., where applicable.

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QAP-17: WAIVERS / DEVIATIONS / CONCESSIONS

All deviations from drawings/specifications/ requirements/statements of work or other documents incorporated into the Order by reference are to be referred to the Purchaser's Procurement Department for approval, and shall be authorized by the Purchaser in the form of an order amendment prior to delivery of the Goods and Services. Suppliers must demonstrate the requirements for managing Product Non-Conformances (this includes all hardware and software items where the product item does not conform to the specified requirements) within the business. It is essential that pre-approved Waivers/Deviations/Concessions are recorded on all delivery paperwork. Written Waivers/Deviations/Concessions are deemed to be sufficient and formal order amendments thus obviating unnecessary redrafting of said Order(s). As such, in being order amendments, they are by definition of limited time and/or duration and do not constitute a permanent change to aforementioned drawings/specification/requirements/statement of work or other documents unless otherwise agreed in writing by Purchaser.

QAP-18: CONFIGURATION MANAGEMENT

The Supplier will establish and control the configuration of their documents such as drawings, specifications, plans and procedures necessary to design, manufacture, test, inspect and deliver Goods to the configuration package supplied by the Purchaser. Where the Supplier is designing or supplying systems or sub-systems a configuration management plan may be required by The Purchaser. There shall be no changes or deviations to the contractually agreed purchaser configuration package without written approval by Order amendment from Purchaser.

QAP-19: CONTROL AND MONITORING OF DEVICES (CALIBRATION)

The supplier shall maintain a system for calibration that:

- a) Calibration Service Suppliers: Conforms to A2LA, ISO-17025 (Guide 25) or an equivalent certification.
- b) All other suppliers: Conforms to MIL-STD-45662

Test equipment shall have its performance and calibration verified for all parameters detailed in its manufacture's published performance/calibration specification, against measurement standards traceable to National or International Standards (NIST). At the request of the Purchaser the Supplier or the Supplier's sub-tier Suppliers shall provide calibration certificate and test report showing all test results including an estimate of the uncertainty of measurement.

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QAP-20: FOREIGN OBJECT DAMAGE

The Supplier shall develop and maintain a Foreign Object Debris/Damage ("FOD") prevention program for manufacturing areas. The intention is to prevent introduction of foreign objects into any item delivered under this purchase order (PO). National Aerospace Standard 412 (NAS 412) is available as a guideline.

The Supplier shall employ appropriate housekeeping practices to assure timely removal of residue/debris generated, if any, during manufacturing operations and/or normal daily tasks. The Supplier's FOD program shall be proportional to the sensitivity of the design of the product(s) to FOD, as well as, to the FOD generating potential of the manufacturing methods.

QAP-21: ROHS / REACH COMPLIANCE

Supplier shall develop and document a program complying with the latest iterations of RoHS and REACH. All certifications must reference RoHS/ REACH compliance if the QAP is required. Records are to be retained by the supplier and available for review by Orbel when required. Retention time shall be 11 years. Certification of product conformance must be provided with the material certification, as a corporate declaration or available on the company website for immediate downloading.

QAP-22: DFAR – PREFERENCE FOR DOMESTIC SPECIALTY METALS

Where required on the P.O., DFAR requirements will apply. Any specialty metals incorporated in articles delivered to Orbel shall be melted in the United States, its possessions, Puerto Rico or a qualifying country (reference DFARS for a complete listing). Certification of product conformance must be provided with the material certification, as a corporate declaration or available on the company website for immediate downloading.

- a) This requirement shall be flowed down to all sub-tier raw material sources.
- b) Prior Orbel approval is required if specialty metals not meeting the DFAR requirements are planned for use.

Any Orbel approved exceptions to this requirement shall be noted on the Certifications and/or Test Data Sheets.

QAP-23: ITAR REQUIREMENTS

Where required by the P.O., the supplier shall maintain a system to adhere to ITAR requirements.

- a) This requirement shall be flowed down to all sub-tier suppliers that will be used in the supply chain.
- b) If this requirement cannot be met, the supplier must inform Orbel's purchasing agent upon receipt so that proper actions can be taken.

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QAP-24: CONFLICT METALS

Based on unique requirements, products purchased by Orbel Corporation may contain one or more conflict minerals, tantalum, tin, tungsten or gold, and these minerals are necessary to the functionality of the products manufactured. Suppliers of these products must declare that all conflict minerals used in Orbel Corporation products do not originate in the Democratic Republic of the Congo or an adjoining country or come from a recycler or scrap supplier.

- a) This requirement shall be flowed down to all sub-tier suppliers that will be used in the supply chain.
- b) If this requirement cannot be met, the supplier must inform Orbel's purchasing agent upon receipt so that proper actions can be taken.

QAP-25: COUNTERFEIT PARTS PREVENTION

When required by the purchase order, Suppliers must have developed a counterfeit electronic parts detection and avoidance program to ensure parts provided are authentic. These requirements must flow down to their suppliers as well.

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G. DEFAULT QAP REQUIREMENTS BY STRATEGIC SUPPLIER TYPE

This section is for reference purposes only; the actual QAPs will be listed on the Purchase Order and may include the addition or removal of clauses listed below.

Supplier Type >		Anodes	Base Metal	Calibration	Chem. Milling / Etchers	Electroplaters / Coatings	Heat Treat	Prop. Process Chemicals	Slitters	Stampers / Formers	Tool / Die
QAP	Description										
1	Quality System	X	X	X	X	X	X	X	X	X	X
2	MSDS	X	X					X			
3	Cert. of Analysis	X			X	X	X	X			
4	Cert. of Compliance								X	X	
5	Control of Records	X	X	X	X	X	X	X	X	X	X
6	Right of Access	X	X	X	X	X	X	X	X	X	X
7	Packaging	X	X	X	X	X	X	X	X	X	X
8	Pack. Identification	X	X		X	X	X		X	X	
9	Individual Packaging										
10	Lot Identification	X	X		X	X	X	X	X	X	
11	FAI				X					X	
12	100% Inspection										
13	AQL 1.0%		X		X	X	X		X	X	
14	Test Data Sheets		X	X							
15	Supply Chain	X	X	X	X	X	X	X	X	X	X
16	Material Traceability	X	X	X	X	X		X	X	X	X
17	Waivers/Deviations	X	X	X	X	X	X	X	X	X	X
18	Configuration Mgmt.	X	X	X	X	X	X	X	X	X	X
19	Calibration	X	X	X	X	X	X	X	X	X	X
20	FOD	X	X		X	X	X	X	X	X	X
21	RoHS / REACH	X	X		X	X		X		X	
22	DFARS	X	X								
23	ITAR	X	X								
24	Conflict Metals	X	X			X		X			
25	Counterfeit Parts				X				X	X	X