



QUALITY ASSURANCE REQUIREMENTS FOR SUPPLIERS

Creation Technologies
6300 Merrill Creek Pkwy, A100
Everett, Washington 98203

PURPOSE

This document establishes Quality Assurance Requirements for suppliers.

APPLICABILITY – The general requirements shall apply to CREATION suppliers whenever this document is invoked by CREATION Purchase Order.

I. DEFINITIONS

- A. “Supplier” means the vendor/supplier performing the work/supplying materials, parts, assemblies, subassemblies, systems, subsystems, or services pursuant to the CREATION purchase order.

II. GENERAL REQUIREMENTS

- A. **QUALITY SYSTEM** - The Supplier shall notify CREATION in writing whenever there is a significant change to the Supplier’s Quality Assurance System, that results in a revision to the Quality System’s Manual, personnel change of the Quality Manager or top management level, gaining or losing any Quality System recognized registration or certification.
- B. **SPECIFICATIONS** – Specifications apply when referenced on drawings or the Purchase Order. The applicable revision status of such specifications shall be the revision in effect on date of Purchase Order, unless otherwise specified on the Purchase Order.
- C. **TO OBTAIN SPECIFICATIONS** – When required, the Supplier may obtain copies of pertinent specifications through CREATION’ Global Supplier Management.
- D. **SUPPLIER ASSISTANCE** – In the event that requirements are not completely clear, or where special assistance is needed, CREATION will provide qualified personnel to consult with Supplier. Requests for assistance shall be made via CREATION’ Global Supplier Management.
- E. **SUPPLIER’S QUALITY ASSURANCE SYSTEM** – The Supplier’s Quality Assurance System shall conform to, at a minimum, the intent of ISO-9001 series, ISO-13485, TS16949 or AS9100 Quality System requirements.
 - 1. **Organization** – Quality Assurance responsibility shall be clearly designated within the Supplier’s organization. Personnel having the responsibility shall have sufficient authority to assure that quality is not compromised.
 - 2. **Procedures** – The Supplier’s Quality Assurance System shall be implemented by written procedures, which adequately provide for compliance with the requirements of the Purchase Order.
- F. **AUDITS** – CREATION may conduct an onsite audit of the supplier’s Quality Assurance system and any sub-tier supplier’s system to evaluate the

degree of ability to comply with these and other applicable requirements or assist in the resolution of quality problems. As necessary, CREATION's Customers may accompany CREATION's Representatives.

- G. RECORDS – The Supplier shall maintain adequate records of inspection, tests and other Quality Assurance activities. Records shall provide objective evidence of the Quality Assurance operations performed, the results obtained, and corrective actions taken. Such records shall be available to CREATION. Where such records are traceable by serial or lot designation to material supplied to CREATION, they shall be retained by the supplier for a period of not less than seven (7) years after the completion of the purchase order unless a longer period is specified on the CREATION purchase order. If a supplier subcontracts the record retention (for example: the supplier is sending a part out for painting) the supplier shall impose the same record retention requirement on their subcontractor.
- H. SOURCE INSPECTION – Inspection/test acceptance at the Supplier's facilities does not guarantee acceptance. Acceptance shall be at the CREATION facility unless otherwise specified in the Purchase Order.
- I. CONFORMANCE RESPONSIBILITY – Surveillance, inspection and/or test conducted by CREATION or its representative of any customer at the Supplier or CREATION facility shall not relieve Suppliers of their responsibility in meeting the quality requirements of the Purchase Order.
- J. SAMPLING – CREATION reserves the right to use ANSI/ASQC Z1.4-2003 or equivalent sampling plans for the acceptance or rejection of supplies. If a lot is rejected by the sampling procedure, the entire lot may be returned to the Supplier for screening at the Supplier's expense, or the rejected lot may be screened by CREATION or a third-party inspection company at the Supplier's expense (if agreed to by the Supplier.)
- K. CERTIFICATE OF CONFORMITY – Supplier shall provide Certification of Conformity with each shipment. This Certificate shall stipulate that the Supplier certifies the material referenced on this certification has been manufactured and inspected in conformance with all applicable drawings and specifications; any exceptions shall be only as per Purchase Order. The Certificate of Conformance will contain each of the following: Part Number, Revision Level, Purchase Order Number, under certain circumstances and if approved by CREATION, a blanket Certificate of Conformance may be submitted. All the Supplier's sub-tier vendors must be identified on the certificate by name, process (es) provided and unique identifier. If the above blanket certificate is not utilized, then copies of all certificates of conformance from all sub-tiers must accompany the product. First Article Inspections require all sub-tier vendor certificates of conformance accompany the product.
- L. CREATION QUALITY ASSURANCE REPRESENTATIVE – CREATION may, at its discretion, provide resident or itinerant Quality Assurance personnel whose function shall be to survey Supplier operations, assist the

Supplier in the resolution of quality problems, and witness at any stage (subject to proprietary considerations) the manufacture, processing, test and operations, as well as the volume of CREATION work being produced, will determine in part the need for surveillance and a resident or itinerant Quality Assurance representative. Copies of applicable specifications and documents shall be made available to the CREATION Quality Assurance Representative.

- M. DRAWING AND CHANGE CONTROL – The Supplier’s system shall assure that the latest applicable drawings, specifications, technical requirements, Purchase Order information and changes thereto will be available at the time and place of Supplier’s acceptance of material. All changes shall be processed in a manner which will ensure incorporation on the affected supplies at specified effectivity points.
- N. PROCUREMENT BY THE SUPPLIER – The Supplier shall maintain a system to assure that Supplier-procured supplies and services conform to drawing and specification requirements. Applicable Quality Assurance requirements shall be conveyed to Suppliers in every tier. The implementation of such controls shall be subject to surveillance by CREATION.
- O. PROCESSING – The Supplier shall establish a system to assure that thermal, chemical, metallurgical, or other critical processes, the control of which cannot be readily determined by inspection of the part, will be performed in accordance with specification requirements in adequate facilities by competent personnel using proper procedures. The Supplier is also responsible for using the appropriate SQC/SPC methods to control the manufacturing processes including secondary operations and assembly.
- P. INSPECTION – The Supplier shall perform inspection and/or test on end items covered by the Purchase order prior to submission to CREATION or prior to delivery. Inspection/test of supplies or raw materials, which cannot be readily examined on the completed products, must be performed at the appropriate in-process stages of manufacturing. Adequate records of inspection/tests must be maintained by the Supplier. Any statistical sampling procedures used in final inspection/test may be subject to disapproval by CREATION.
- Q. INSPECTION STATUS – The Supplier shall maintain a system for identifying inspection status of supplies. Identification may be accomplished by means of stamps, tags, routing cards, labels, bar codes, electronic databases, or other control devices. Final acceptance stamps must be provided for Supplier identification unless identification is provided on the product by other acceptable means.
- R. MATERIAL REVIEW – The Supplier shall not exercise discrepant material review authority without written approval by CREATION Procurement Management or the Quality Assurance Organization. (This applies only to

material that is CREATION -designated and/or design controlled to CREATION specification.)

- S. PRESERVATION AND PACKAGING (The following applies only when specified packaging and preservation instructions are not invoked in the Purchase Order.)
1. All material intended for CREATION shall be packed with suitable protection to prevent damage through handling, during storage at the Supplier's, in transit, and during storage at CREATION before use.
 2. All material intended for CREATION shall be protected against the usual hazards of corrosion, contamination, deterioration, or other spoilage at the Supplier's facility and in transit.
 3. For electronic components packaging requirements see CREATION Procedure 221-009 Supplier Packaging & Delivery Requirements.
 4. All packaging must be marked with the manufacturer or distributor's name, part number, quantity and any date code or lot number identification.
 5. Packing slips – All packing slips must be placed within a packing envelope and should be easily accessible. There should be one packing slip per purchase order number. The following information is required on all packing slips.

Purchase Order Number
Purchased Part Number
Quantity matching the Purchasing Part Number
Certificate of Conformance (See section K)

- T. TOOLS AND TEST EQUIPMENT CONTROL (CREATION OWNED) – All tooling and test equipment fabrication by the Supplier at CREATION' expense, or supplied by CREATION for Supplier use, shall be considered property of CREATION. Such tooling and test equipment shall be inspected, calibrated, and controlled as outlined in the following paragraphs. Tool and test equipment controls shall be accomplished by the Supplier with review and approval at CREATION' option.
1. All tools and test equipment, unless size or use prohibits, shall be identified with a tag permanently attached, which contains the following information: Data that identifies CREATION as the owner, Part number of tool/test equipment and recalibration date.
 2. If not otherwise specified, all equipment that is used to determine acceptance of material will be subject to, as a minimum, an initial inspection and calibration, and a re-inspection and recalibration every year thereafter.

3. The Supplier shall be responsible for maintaining adequate records of all tooling and test equipment including procedures for control of all tooling and test equipment.
 4. Any tooling or test equipment furnished to the Supplier by CREATION shall not be reworked or modified without prior written approval of CREATION.
 5. Tooling or test equipment shall be properly maintained and preserved at Suppliers expense.
- U. MEASURING AND TEST EQUIPMENT CALIBRATION SYSTEM – The Supplier shall provide and maintain suitable gages, instruments, and test equipment to measure and test all supplies for conformance to CREATION requirements. The Supplier shall also provide a system, including written procedures, to assure inspection and evaluation of measuring and test equipment, whether Supplier-owned or supplied by CREATION or another agency. This system shall ensure that the inherent accuracy of equipment is comparable with the requirements of units being tested, and that required measurements are adequately performed. The system shall include appropriate calibration schedules and records per paragraphs T2 and T3.
- V. MEASUREMENT STANDARDS CONTROLS – The Supplier’s working standards used for calibration of tooling, measuring, and testing equipment shall be checked at established intervals by reference to the National Bureau of Standards or equivalent certified standards. The Supplier shall maintain records or other conclusive evidence that proper control is being provided. CREATION may conduct, in the Supplier’s facility, an evaluation of the Supplier’s standards, measuring/testing devices, and calibration/maintenance personnel and methods to establish correlation between CREATION’ and the Supplier’s measurements.
- W. CORRECTIVE ACTION – The Supplier’s Quality Assurance system shall provide means for ready detection of discrepancies and for prompt and effective corrective action. Corrective action must be positive and specific, including firm effectivity points by lot number, part number, date, or other agreed methods. Corrective action records and information, such as pertinent data on defects and failures, shall be available.

The Supplier is responsible for initiation of prompt replies to CREATION Nonconforming Material Reports and CREATION -initiated Supplier Corrective Action Requests (SCAR) and implementation of required corrective action. In the event the Supplier is issued a CREATION’ SCAR, Supplier must provide the following information.

1. Containment plan: Address any containment at the supplier site, parts in transit and/or at CREATION site(s).

2. Recovery Plan: Schedule for recovery, expedition of part shipments, replacement parts to CREATION facilities to support assembly lines and rework/sort plan where applicable.
 3. Identify Causes - Root Cause analysis, which documents the following:
 - Actions taken to identify and confirm the root cause of the problem.
 - Supporting data
 4. Develop/Implement Solutions - Corrective Action plan which includes the following:
 - Permanent Corrective Action plan to avoid reoccurrence.
 - Systemic fixes to be employed to address the root cause.
 - Schedule for implementation and completion
 - Documented verification that the action plan was completed (e.g., updated work instructions, training record)
 5. Validate Solutions - Supporting data that validates corrective actions. May include the following:
 - Process control data
 - Outgoing Quality Assurance data
 - Incoming raw material data
- X. AGE CONTROL – The Supplier shall have an approved system of age control for items where acceptability is limited by maximum age. The system shall ensure that items past useful age are not available for use.
- Y. CHANGE CONTROL – Supplier must get written authorization from CREATION prior to making CLASS A or CLASS B process changes on any custom CREATION product. See [Appendix A](#) for more details regarding process change classifications. Examples of CLASS A and CLASS B process changes include, but are not limited to, changes to the following items:

CLASS A

1. Design change – size, features, material, color, artwork, etc
2. Manufacturing process change – this includes significant changes to the machine set up or moving a tool to an unqualified machine.
3. Manufacturing facility change – moving a tool from one plant to another.

CLASS B

Change to tool function – moving or modifying injection gate location, adding undercuts.

Major tooling repair – welding, replacing a component that affects fit/form/function.

Inspection plan changes

Packaging changes

Tool maintenance change – frequency, procedure

Secondary operation equipment changes.

Manufacturing location within a facility – moving machines that require recalibration.

Subcontractor change

Major environmental change –
temp, humidity

Supplier must notify CREATION SQE of any CLASS C Process changes.
Examples of CLASS C process changes include changes to the following:

CLASS C

1. Process flow changes
2. Internal material handling changes
3. Work Instructions changes

Z. PROHIBITED PRACTICES – The following actions are prohibited:

1. Unauthorized Processing – Addition, revision, or deletion of thermal, chemical, or electrochemical processes in manufacturing when processes are subject to specification control by CREATION.
2. Discard of Approvals – Change in any process of Quality Assurance procedure that is subject to specific approval by CREATION without proper notification and re-approval.
3. Improper Material Submittal – Submission of material having known defects/problems to CREATION without notification and written approval from CREATION.

AA. NOTIFICATION OF PROBLEMS – The Supplier shall notify CREATION if there may be a form, fit, function, usability, or reliability problem with parts or assemblies that have already been delivered.

BB. FIRST ARTICLE INSPECTION REQUIRED – When defined on Purchase Orders that a First Article Inspection is required, a complete First Article Inspection shall be performed by the Supplier. Reports for each specified feature, dimension, material callout, process, etc., shall be documented in report form. This report may be documented on CREATION Form 42-010 or equivalent and must accompany the product to the CREATION location. A copy of the FAI shall be maintained by the Supplier at the Supplier's location.

CC. NON-FRANCHISED DISTRIBUTOR / Prevention of Counterfeit Parts –

1. Parts provided must be new, in the original manufacturer's packaging and have been stored according to manufacturer's recommendation(s).
2. Packaging is confirmed as either reels or trays unless specified otherwise on the purchase order.
3. The seller will handle parts in compliance with all manufacturers' specifications.
4. The seller will handle parts in compliance with manufacturer's moisture sensitivity requirements.
5. Date codes more than 2 years will be solderability tested per EIA/JESD22-B102-C test method by the seller or CREATION. If solderability is to be performed by CREATION, the seller must provide one sample part per date code for those lots that exceed the 2-year requirement.
6. Parts which do not meet the above criteria are returnable for a full refund.
7. Seller acknowledges that he/she is liable for any consequential damages, including but not limited to rework material and labor costs, arising from use of Product described in this Purchase Order that is determined to be counterfeit (non-authentic) manufacturer's product.

APPENDIX A – PROCESS CHANGE CLASSIFICATIONS

CLASS A: Will have significant impact on Fit, Form, Function or Reliability of product.

- Requires CREATION to test the changed material before the supplier can make the change.
- May require that CREATION customers also test and/or approve the change before the supplier may make the change.

CLASS B: May have a significant or minor impact on Fit, Form, Function or Reliability, but will be visible during CREATION inspection.

- CREATION may allow implementation only after reviewing and approving the supplier's qualification.
- May need to be tested at CREATION to insure no negative effect on CREATION process
- May require CREATION to notify its customers before the supplier can make the change.

CLASS C: Will have no significant impact on Form, Fit, Function or Reliability, and will not be visible to CREATION inspection.

- Supplier must notify CREATION prior to making the change to confirm change will not have any impact.
- CREATION may require copies of supplier's qualification test results.

NOTE: Classification occurs before the change is made

MATERIAL CHANGE CHECKLIST

YES	NO	Does Your Change Meet Any of The Following Criteria? If Yes, You Must Classify the Change And Notify CREATION SQE.
		KEY/CRITICAL PARAMETERS
		(1) Change is visually or functionally obvious to CREATION
		(2) Change could cause CREATION concern (manufacturability, reliability, or performance)
		(3) Change to internal part dimensions or design
		(4) Change in key process parameter, targets, or control limits
		(5) Changes in environmental requirements
		INSPECTION/MONITORS
		(6) Changes to incoming, in process, or out going sampling plan (frequency, sample size)
		(7) Change in inspection criteria
		(8) New inspection/monitoring equipment
		(9) Change in inspection equipment calibration – method or frequency
		REWORK
		(10) Implementation of a rework step
		(11) Change to a rework procedure
		PROCESS FLOW
		(12) Addition/deletion of a process step in the process flow
		(13) Change in sequence of steps in the process flow
		PRODUCT/SITE TRANSFER
		(14) Move of a production site or the transfer of a CREATION buy item to another production site
		(15) Begin use of, or change sub-contractors
		RAW MATERIALS
		(16) Change of raw material
		(19) Addition or change of supplier for raw materials
		SHIPPING MATERIAL
		(20) Any change to packaging or shipping materials
		(21) Any change to labels
		PROCESS METHOD
		(22) Change in process technology (i.e., Spot weld vs laser weld, or pad print vs screen print)
		(23) Change in key equipment setup procedures
		(24) Change to critical aspect of preventative maintenance procedure
		OTHER
		(25) Has a problem ever resulted from such a change in the past?