



CREATION TECHNOLOGIES
Core Procedure

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Supplier Quality Requirements

Creation Technologies

Supplier Quality Requirements

Valued suppliers:

The purpose of this document is to define the quality management system requirements for suppliers and supplying organizations who manufacture and/or supply parts/materials or services to Creation Technologies or Creation's customers.

These requirements form and support Creation's Terms and Conditions, which are agreed upon, when accepting Creation's Purchase Order.

The supplier's obligation to meet these requirements can only be waived by Creation in writing.

Questions or concerns can be directed to your Creation Supply Chain Representative.

Please contact Creation to report and discuss an exception to this document.

We look forward to working with you.





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1.0 PURPOSE

- This document defines the Supplier Quality Requirements for Creation’s global supply base.

2.0 SCOPE

- This document applies to suppliers providing product, materials, or services related to production for Creation Technologies.

3.0 DOCUMENT INFORMATION

- **Parent Document:** C-0002037 - Quality Management System Manual

4.0 DEFINITIONS

TERM	DEFINITION
FIRST ARTICLE INSPECTION (FAI)	A complete, in-depth inspection performed on one (or more) of the first part(s)/assemblies manufactured/purchased according to Creation’s customer procurement specification; as a minimum, every critical parameter is measured or tested. AS9102 is a type of FAI
COUNTERFEIT MATERIAL	Counterfeit material means material that is or contains items misrepresented as having been designed and/or produced under an approved system, or specific brand or other acceptable method and includes Counterfeit Work. Counterfeit material poses a significant risk to the supply chain, potentially resulting in loss of material, mission, or life. “Counterfeit Work” means Items, consisting of all Electronic Parts delivered under an Order that are in the lowest level of separately identifiable items (e.g., articles, components, goods, and assemblies) that are or contain Counterfeit Electronic Parts or suspect Counterfeit Electronic Parts. “Counterfeit Electronic Part” means an unlawful or unauthorized reproduction, substitution, or alteration that has been knowingly mismarked, misidentified, or otherwise misrepresented to be an authentic, unmodified electronic part from the original manufacturer, or a source with the express written authority of the original manufacturer or current design activity, including an authorized aftermarket manufacturer. Unlawful or unauthorized substitution includes used Electronic Parts represented as new, or the false identification of grade, serial number, lot number, date code, or performance characteristics.
END OF LIFE (EOL)	When a product enters the final stages it’s lifecycle or existence.
LAST TIME BUY (LTB)	Product identified as End-Of-Life may be available for a purchase prior to being made obsolete.
PRODUCTION PART APPROVAL PROCESS (PPAP)	A standardized form of documentation used primarily in manufacturing supply chains to establish confidence in suppliers and their production processes. Actual measurements are taken from the parts produced and are used to complete the various test sheets of PPAP.
ON-TIME DELIVERY (OTD)	Receipt of a PO line item by Creation within a specified window to the commit date.





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INCOMING LOT ACCEPTANCE RATE (ILAR)	This is a measure of the supplier part quality and is the number of lots accepted in a given period divided by the number of lots received in a given period x100.
PURCHASE ORDER (PO)	A written or electronic order (including attachments) containing the applicable terms and specifications for a particular part, material, or service.
SUPPLIER CORRECTIVE ACTION REQUEST (SCAR)	Formal request for corrective action for a specific non-conformance with supplier provided product, material, or service. The 8D methodology is preferred for SCAR response to Creation.
SUPPLIER	An organization that provides parts, materials, assemblies, systems, or services purchased by Creation. This includes sub-contractors, distributors, brokers, original equipment manufacturers, etc.
SUPPLIER BUSINESS REVIEW (SBR)	Periodic review with supplier to review performance, service, updates, quoting, financial etc.
VOE	Verification of Effectiveness

5.0 FUNCTIONS RESPONSIBLE FOR THIS PROCEDURE / ROLES

The functions listed below have responsibilities detailed in this procedure:

- **Process Owner:** Sr. Global Quality Director
- **Procedure User:**
 - Commodity Manager, Supplier Chain Leader, Buyer, Planner, Quality Leader, Quality Engineer, Supplier Quality Engineer, Engineering
- **Contributors:**
 - Commodity Management, Supply Chain, Quality, Global Quality Shared Services

6.0 TRAINING

Course Code: COM_SC_SOP_00033

The process owner and document author are considered trained by default because of their contribution in writing and reviewing/approving the document.


Procedure users must be trained on the major revisions of this procedure before executing their task.

Contributors do not require formal training, but the procedure users are responsible for informing the contributor of their requirement when they are engaged in their contribution.

7.0 EQUIPMENT / MATERIALS / SUPPLIES

- Access to Creation’s Supplier Website, email, specifications, and certifications.



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8.0 CREATION REQUIREMENTS AND OBJECTIVES

Creation requires that materials and services used to manufacture products for our global customer base be of high-quality, procured in an ethical and professional manner, are delivered on time at competitive cost.

Parts, material, and services must be in compliance with the applicable procurement, regulatory, environmental, health & safety, as well as customer requirements.

The supplier is responsible to ensure that their organization is aware of the following:

1. Their contributions to product or service conformity
2. Their contribution to product compliance
3. The importance of ethical behavior

9.0 QUALITY MANAGEMENT SYSTEM REQUIREMENTS

Suppliers are required to have an established and effective quality management system (QMS) in place. A third-party accreditation such as ISO 9001, AS9100, ISO 13485, ISO 14001, IATF16949, etc., may be required depending on product and customer requirements.

Supplier organizations will ensure personnel working within manufacturing, testing, or inspection are competent, qualified, and trained; and are aware of their contribution to product conformity and the impact to the product if defects are produced.

10.0 EVIDENCE OF COMPLIANCE

It is the supplier’s responsibility to be prepared to substantiate compliance and / or authenticity by providing copies of C of C, Certifications, Regulatory documentation, test reports, etc. as applicable by making records available to Creation or its customers upon request. It is the supplier’s responsibility to ensure quality certifications are valid while manufacturing and shipping product to Creation. Creation reserves the right to request certification copies when required with a 24-hour response time.

Certificates of conformance (CofC) or analysis (CofA), will be provided as indicated by Creation. Certificates of Conformance will be in accordance with C-0003247 - Creation Suppliers Certificate of Conformance Requirements.

If approved by Creation, a blanket Certificate of Conformance (C of C) may be provided.

11.0 CONFORMANCE TO REQUIREMENTS – PARTS, MATERIALS, AND SERVICES

Supplier will ensure the conformance of parts and material delivered to Creation comply with requirements specified in prints, drawings, part specifications referenced on the Purchase Order, acceptability criteria, appearance standard / golden sample, or other requirements where applicable. In the event a waiver or deviation is needed, contact your Creation Supply Chain Representative.

Requirements are flowed down and communicated through the purchase order and procurement documentation. By accepting Creation’s purchase order, the supplier agrees to comply with the Creation Terms and Conditions and the requirements outlined in this document. The supplier is responsible to flow down requirements to sub-tier suppliers.

If sampling plans are used to determine product acceptance, including replacement or reworked product, it should be based on an applicable industry standard. The supplier will ensure that valid statistical techniques are used and samples are selected in a random manner that represent the batch population. Use of sampling plans does not relieve the supplier of the responsibility to ship 100% conforming material.

Creation interfaces with the direct supplier as documented on the PO. The supplier is responsible to coordinate resolution and correction with sub-tier suppliers when needed.





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The supplier is responsible to maintain capable processes, effective process controls, and effective verification activities, including sub-tier supply chain management. The supplier will maintain a system of material identification and segregation to ensure that non-conforming material is not intermingled with accepted material.

The supplier may be required to provide test specimens for design approval, inspection/verification, investigation, or auditing.

When Creation requests a Return Material Authorization (RMA) for defective parts, the RMA # should be provided within 3 business days and disposition concluded within 30 business days. The supplier will ensure replacement product is expedited, if needed, to reduce risk of downtime.

Creation or designee may, at its discretion, deploy personnel to perform inspection or testing at the supplier's facilities. Source Inspection does not guarantee acceptance.

If the supplier is in communication with the end customer, Creation must be included on the communication.

In the event that requirements are not clear, reach out to your Creation contact for assistance.

12.0 PRODUCTION PART APPROVAL PROCESS PPAP / FAI

Where required, Creation may request the following documentation associated with PPAP or FAI:

- Material analysis and validation reports
- PPAP or AS9102 or First Article report with verification of measurement and inspection
- Test and inspection reports
- Other validation documentation as needed.

Reference C-0003027 – Global Supplier PPAP Forms.

A new FAI/PPAP may be required when there is a qualifying change. (i.e., new revision, lapse of orders, change of manufacturing location, etc.)

13.0 COUNTERFEIT PREVENTION

Suppliers, including Sub-tier suppliers as applicable, are responsible to perform control and verification activities to prevent the use and introduction of counterfeit product, electronic or otherwise, in methods that align with standard industry guidelines.

Supplier will immediately notify Creation of issues related to counterfeit materials.

In the event that material delivered constitutes or includes counterfeit material, the supplier will, at their expense, promptly replace, remove, support field recall efforts, evaluate such material, or other action required to address and resolve the discrepancy and provide genuine conforming material to Creation. The measures contained in this paragraph are in addition to actions Creation may impose under the provisions of this document or the Terms and Conditions.

Parts provided by an independent distributor must be new, in original manufacturer's packaging, and have been stored according to manufacturer's recommendation(s).

14.0 FOREIGN OBJECT DEBRIS (FOD)

Supplier will implement and maintain part cleanliness and handling practices to prevent the introduction of debris and contaminants. Tooling, test and handling equipment, fixtures, and jigs are maintained in a state of cleanliness sufficient to prevent FOD.





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15.0 DFARS – SPECIALTY METALS

Components for defense industry defined with quality type AS9100 on the purchase order must comply with DFARS 252.225-7014, preference for domestic specialty metals, Alt I. Specialty metals is defined as including Titanium or Stainless Steel. Raw material must be melted in the United States (U.S.) or a Qualifying Country. Procuring raw material from a mill in the U.S. or Qualifying Country, does not guarantee its conformance to DFARS 252.225-7014. Supplier is to verify the sub-tier supplier’s conformance via their Raw Material C of C and/or C of A.

16.0 RIGHT TO ACCESS

The supplier will, with prior notice, grant Creation access to supplier facilities, documents, records, etc., including sub-tier facilities; for Creation, it’s customers or applicable regulatory authorities. The supplier will notify Creation of safety, documentation, or other requirements prior to arriving onsite.

17.0 TRACEABILITY AND IDENTIFICATION

The supplier will establish and maintain a system that provides traceability of raw materials, assembly components, and processes throughout product realization that can identify:

- raw material(s) composition or sourcing
- the material lot(s) used in the production or assembly of product.
- acceptance records of the production material
- Product manufactured from a given lot of material.
- Country/Countries of Origin

When required, traceability will maintain current revision, specification, and quality requirements from raw material through finalized product for materials, components and processes used by Creation, our customers, and its suppliers. Serialized parts / assemblies and detail parts used in assemblies will be traceable to the manufacturing lot(s) in which they were produced, as well as the material(s) used to produce them. Duplication of serial numbers for the same product supplied to Creation is prohibited.

18.0 RECORD RETENTION

The supplier will ensure records, including applicable sub-tier records, related to the design & procurement, manufacturing, services, and delivery of parts supplied to Creation will be maintained for a minimum of 3 years unless otherwise specified in regulatory or customer defined retention requirements.

- a. Supplier is responsible to properly dispose of obsolete or expired records in accordance with the supplier’s regulatory compliance or certifying body requirements.
- b. In the case where the supplier’s part is used to manufacture a medical/aerospace device, the supplier will retain records per the procurement specification after delivery to Creation.

19.0 SUPPLIER EVALUATION

Supplier evaluation assesses process management and controls, manufacturing capability, quality management system, risk, or other element to determine business system maturity and the supplier’s ability to meet Creation’s or it’s customer’s requirements. Evaluation results may include actions for the supplier to complete prior to approval or re-approval. A follow-up evaluation may be conducted as required by Creation.

Forms and resources are available on Creation's Supplier Website: <https://www.creationtech.com/suppliers/>





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20.0 SUPPLIER CORRECTIVE ACTION REQUEST (SCAR)

A SCAR is issued to resolve a non-conformance and to promote continuous improvement.

Root cause analysis tools such as 5 Why, 6M, etc., will be included in the supplier's response. Evidence will be provided to support containment, corrective, and preventative actions as well as verification of effectiveness. Reference the 8D Training Presentation available on the Creation Supplier website for guidance and C-0003031 is available for 8D SCAR responses.

Timely response to a SCAR is essential, the following targets are outlined to ensure that the situation is rectified in a timely manner:

- Acknowledgment of SCAR receipt, Initial Investigation, and Containment - Provided to Creation within 3 business days from SCAR receipt.
- Root Cause Analysis and Corrective/Preventive Action Plan target to be completed within 10 business days from SCAR receipt. Consultation of Corrective/Preventative Action Plan with Creation is recommended.
- Completed SCAR with VoE evidence that the issue was resolved – target to be provided to Creation within 30 calendar days from SCAR receipt.
 - Note: Response due dates may be adjusted if Creation returns product to the supplier for investigation or failure analysis.
 - Note: If further time is needed to implement and provide VoE, notify Creation of the requested commitment date.

When failure or destructive analysis is required to determine point of failure, product may be returned to the supplier and is managed through the Return Material Authorization (RMA) process. Additional support may also be requested to facilitate production needs, including replacement product, sorting support, onsite investigation support, etc.

21.0 PERFORMANCE MEASUREMENT AND SUPPLIER SCORECARD

Supplier Scorecards are used to monitor supplier performance. Poor supplier performance may trigger additional action including but not limited to; development plan, supplier audit, Focus Supplier Improvement Program, and / or other actions as applicable.

Supplier performance data will be a factor in calculating supplier score.

Primary supplier performance metrics are:

Primary Metrics	Goal
Supplier Corrective Action Request (SCAR)	0 SCARs in a quarter
Incoming Lot Rate Acceptance (iLAR)	99.6% quarterly average.
On Time Delivery (OTD)	85% quarterly average





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22.0 SUPPLIER COPSQ AND CHARGEBACK

Creation reserves the right to recover costs incurred by Creation, or Creation's customer, as a result of supplier provided product that is non-conforming or fails to meet requirements.

Costs incurred may include, but are not limited to, the following items:

- Sorting, testing or rework labor costs.
- Production line down time (Creation or Customer)
- Containment costs
- Recall of material
- Storage
- Administrative costs
- Components
- WIP
- Costs associated with counterfeit parts / material

Creation will summarize the information and evidence of the actual costs incurred by Creation. Unless otherwise agreed by Creation and supplier, credit is the preferred method for reimbursement. See C-0003263 – Cost of Poor Supplier Quality Matrix and C-0003621 – Cost of Poor Supplier Quality Chargeback Notice.

Creation reserves the right to pursue additional action if chargeback is declined.

23.0 SUPPLIER BUSINESS REVIEWS

Depending on historical performance, Creation may schedule periodic meetings with the supplier to review performance (OTD, SCAR, ILAR), escalations, operational updates, org structure, quote activity, quoting performance, financial update, bond performance, site feedback, or other related topics.

24.0 PRODUCT CHANGE NOTIFICATION

Suppliers will notify Creation immediately of changes that may impact fit, form, function, quality, reliability, or regulatory requirements. Creation will determine if the change impacts the customer's finished product. Supplier PCNs and/or ECNs will be submitted to the applicable email address below unless otherwise specified.

pcn@creationtech.com for any catalog or off the shelf product.

MakeToPrintPCN@creationtech.com for any custom or build to print product.

A PCN is required for the following scenarios:

1. Make change in supplier's processing or composition of part specifications, formulation, part, changes made by sub-tier vendor, equipment / process location change, manufacturing processes, or performance characteristics of part thereof (including labeling, packaging, shipping method, etc.).
2. Use temporary deviation or permanent change that affects the product including manufacturing process, cosmetic, dimensional specification, or tolerance, handling, or sterility of the part; or in the event product does not meet requirements but the defect does not affect fit, form or function, a temporary deviation could be issued.
3. Changes, including loss, to the supplier's certification standings (including, ISO, AS, UL, ITAR, CGD, FDA, CSA, CE, VDE, TUV, or others).

Written notice, including the details regarding such proposed change or action, and a sample of the affected part and other information, will be provided as requested by Creation. A change may not be implemented without Creation's written approval.





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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 or it’s Customers.
2. Discard of Approvals – Change in process of Quality Assurance procedure that is subject to specific approval by Creation, or it’s Customers, without proper notification and re-approval.

25.0 END OF LIFE NOTIFICATION

If a supplier intends to end the production life of a part (LTB) or becomes aware of an End-of-Life Notification (EOL) notice to a subcomponent, this change will be communicated to Creation Technologies immediately. An End-of-Life notification, with details for last time buy opportunities, will be sent to the applicable email address below unless otherwise specified.

pcn@creationtech.com for any catalog or off the shelf product.

MakeToPrintPCN@creationtech.com for any custom or build to print product.

26.0 BUSINESS CONTINUITY PLANNING

Labor Disputes

The supplier will notify Creation in writing at least six (6) months in advance of the expiration of a labor contract(s).

The supplier will notify Creation of an actual or potential labor dispute or disruption that will delay, or threaten to delay, timely delivery.

Contingency Plan

The supplier must have a Disaster Recovery/Contingency plan, including backup capabilities, for quality, delivery, utility interruptions, labor shortage, succession planning for key executives, natural disasters, catastrophic events, facets of the manufacturing process, key equipment failure, field returns, legal issues, business disruption, or other circumstance that could affect production flow of material to Creation.

Reference C-0003171 – Disaster Recovery Template on the Supplier Website.

27.0 HANDLING, LABELING, PACKAGING, STORAGE & SHIPPING

Material, parts, and assemblies will be packaged, stored, and transported as defined in specifications, standards, or industry best practices to prevent excess moisture, abrasion, nicks, dents, scratches, or other damage resulting in cosmetic or dimensional deformities or contamination. The supplier is responsible to ensure responsible handling and ESD practices are used to prevent damage or failure.

Shipping documents will be clearly marked, including Packing list, C of C / C of A, Validation documentation, and RoHS Compliance Certificate as required. Parts and assemblies will be protected from contamination, corrosion, or tarnish where applicable.

If packaging is customer owned or reusable packaging or crating, it is to be cleaned, previous labeling is to be removed and inspected for overall condition or wear. If reusable packaging is found to be damaged or unusable, the Creation Supply Chain Representative must be notified.

Carton shipment greater than 40 pounds, must be marked with the Gross, Tare Weight, and Net Weight.





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Materials requiring shelf-life monitoring must be delivered with a minimum of 80% of the total specified shelf life and the is documented on the supplier’s packing slip and / or C of C. If circumstances, such as transportation delays, shortages, etc., will impact delivery and shelf-life acceptance, Creation must be notified.

Shipment labeling requirements are in accordance with C-0003229 – Supplier Shipment Label Requirement.

28.0 RISK AND OPPORTUNITIES

Risks

1. Supplier does not review and / or adhere to the Supplier Quality Requirements as noted per the PO and T’s and C’s
2. Supplier takes exception to clauses in the SQR but does not obtain approval from Creation to deviate from the stated requirements.

Opportunities

1. Standardized SQR provides a unified message to suppliers.
2. Suppliers are informed and aware of requirements and are equipped to meet expectations.
3. Suppliers take guidance from the SQR to initiate improvement activities.

29.0 REFERENCED DOCUMENTS

Procedure/Standard #	Section # and Name	Document Category	Name of the Procedure
C-0003247	All Sections	SOP	Supplier C of C Requirements
C-0002929	All Sections	SOP	Supplier Scorecard Performance
C-0003229	All Sections	SOP	Supplier Shipment Label Requirement
C-0003171	All Sections	Template	Disaster Recovery Template
C-0003263	All Sections	Form	Cost of Poor Supplier Quality Matrix
C-0003621	All Sections	Form	Cost of Poor Supplier Quality Chargeback Notice
C-0003027	All Sections	Form	Global Supplier PPAP Forms
C-0003031	All Sections	Form	Creation Supplier Corrective Action request 8D Report





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HISTORY OF CHANGES

Revision	Authored/ Revised by	Section # Changed	Summary of the Changes	Reason for the Change	Issue Date (YYYY MM DD)	Effective Date (YYY MM DD)
0	John Gaspari	N/A	Initial Release	N/A	2020 07 20	See DocBank
A	John Gaspari	15, 20, 21, 22, 26, 28	Added FDA compliance statement, clarified order of precedence, Updated the SCAR section with updated requirements and guidelines, added information around FAIR and PPAP, added Section 28, other general updates	General Improvement	2021 04 19	See DocBank
B	Kelly Menze	8,11, 20, 23	Clarified Certificate of Conformance requirements, SCAR final response time, revised order of precedence, indicated latest directive of RoHs.	General Improvement	2021 06 11	See DocBank
C	Kelly Menze	2-5, 7-28	Updated several sections to integrate and align non-legacy supplier requirements. Removed sections that are covered in the T's and C's	Integrate legacy and non-legacy supplier quality requirements.	2023 03 02	See DocBank
D	Kelly Menze	5.0, 18.0	Corrected a typo in section 5, Updated the paragraph in section 18 to make it more general so all evaluation requirements can be encompassed.	Make a correction and update section 18 to clarify and communicate evaluation requirements.	2023 03 30	2023 04 17
D.1	Kelly Menze	20.0	Added SCAR response targets.	Minor change to insert specific requirements for SCAR response timing that aligns with 8D Report and training on SCAR response.	2024 03 08	2024 03 11
E	Emmanuel Garcia Madrid / Kelly Menze	All Sections	Reorganized entire document, revised, and combined sections for better flow and clarity	Overall Improvement, reduce redundant sections and text.	2024 06 28	2024 07 05

