APPROVALS

Tim Holzschuh
Global Director of Quality
I approved this document
2020-07-09 11:38:25 AM -06:00
DocuSign

HISTORY OF CHANGES

Revision	Authored/ Revised by	Section number changed and summary of the changes, Reason for the change	Effective Date (YYYY-MM-DD)
0	John Gaspari	Initial release	2020-07-06

Creation Technologies

Supplier Quality Requirements

To our valued suppliers:

The purpose of this manual is to define the basic quality management system and procedures required of the suppliers and supplying organizations who manufacture and/or supply parts/materials or services to Creation or Creation customers. These requirements form part of the terms and conditions of our Purchase Orders. Acceptance of the Purchase Order constitutes acceptance of these requirements. The supplier's obligation to meet these requirements can only be waived by Creation in writing.

Whether your company is a new supplier to Creation Technologies, or a long-standing partner, the attached information will help you in better understanding Creations needs and expectations.

It is important that you read, interpret, and respond to these items if you have questions or concerns. Your Creation procurement specialist or Quality representative can provide additional information where you need clarification. They should be contacted immediately if you cannot or are unwilling to meet the requirements listed here. We also expect that this document will be shared to appropriate section/ personnel of your company so that they will be equally aware of these requirements.

We look forward to working with you.

SUPPLIER SELECTION PROCESS

Creation is constantly striving to partner with the best suppliers available. When Creation Commodity Management identifies a potential new supplier, this supplier is evaluated on their production capabilities, product quality, business model, pricing and several other important categories. The general requirements of any new supplier could include the following:

(i) Sign NDA
(ii) Quality Certifications
(iii) Payment terms
(iv) Supplier ley contact information (remit to, PO placement)
(v) Technology/Business/Pricing evaluation
(vi) Supplier financial assessment
(vii) Inbound packaging identification
(viii) Shipment capability
(ix) Supplier self-assessment
(x) Supplier quality audit (if applicable)

Creation selects the supplier on the basis of satisfactory results of the requirements listed above.

If the supplier qualifies, and meets any applicable regulatory compliance requirements, they are placed on Creation's approved vendor list.

TABLE OF CONTENTS

1.0 PURPOSE

- The purpose of this document is to formalize Creation Technologies Supplier Quality Requirements for our global supply chain. This document replaces all earlier documents.

2.0 SCOPE

- Clearly define the supplier quality requirement for Creation's production global supply chain for either new suppliers or current existing suppliers and their supply chains if applicable.

3.0 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 or Creation's customer procurement specification; as a minimum, every critical parameter is measured or tested.
ON-TIME DELIVERY (OTD)	Receipt of a PO line item by Creation within a specified window to the commit date.
PARTS PER MILLION DEFECTIVE (PPM)	PPM is the measure of supplier part quality and is the number of parts with one or more discrepancies per million of the same part. The calculation is performed by dividing the sum of the defective parts reported by the quantity of parts received from the supplier over that same period, multiplied by 1,000,000 to express PPM.
LOT ACCEPTANCE	This is a measure of the supplier part quality and is the number of lots accepted divided by the number of lots received.
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 issue by Creation.
SUPPLIER	Any organization that provides parts, materials or services purchased by Creation. This includes sub-contractors, distributors, brokers, original equipment manufacturers.

4.0 RESPONSIBILITIES

The functions listed below have responsibilities detailed in this procedure:

- **Procedure Owner**: Commodity Management or Supply Chain
- All the roles listed bellow should be trained on this procedure:
  - **Commodity Manager or Supply Chain Leader:** is **Responsible** - owns the task.
  - **Supply Chain Leader:** is **Accountable** - who must sign off (Approve) on work before it is effective.
  - **Quality Leader, Quality Engineer, Engineer Leader and Product Engineer:** to be **Consulted** – has information and/or capability necessary to complete the work.
  - **Commodity Manager and Supplier Quality:** can be **Supportive** - can provide resources or can play a supporting role in implementation.
  - **Procurement Specialist and Material Specialists:** to be **Informed** – must be notified of results but need not be consulted

5.0 TRAINING

- Review of SOP and acknowledgement in Creation University for Creation employees. For suppliers, acceptance of PO indicated acknowledgement and compliance to supplier quality requirements.

6.0 EQUIPMENT / MATERIALS / SUPPLIES

- Access to email, SupplyWin, specs and certifications

7.0 CREATION POLICIES AND OBJECTIVES

Creation's policy requires that materials and services used in the products of our Customers be procured in an ethical and professional manner that results in achieving the lowest total cost of ownership. All purchased material must be in compliance with the agreed documented requirements, meet quality requirements, be delivered on time, and have competitive lead times and prices.

8.0 ORDER OF PRECEDENCE

In the event of conflict with the requirements of this document, the governing document shall be the part specification requirements as referenced on the Purchase Order, any MSA or Purchasing Agreement and then this document. The requirements of this document are considered as accepted by the supplier when that supplier accepts a Creation Purchase Order.

9.0 ENVIRONMENTAL LAWS AND REGULATION COMPLIANCE

Creation's general requirements are defined within the Supplier Code of Conduct. Creation will only utilize suppliers who embrace a similar level of compliance with applicable laws and regulations. Suppliers shall ensure that they have internal policies in place to promote ethical behavior and that all employees are aware of their obligations.

10.0 REGULATORY AGENCY COMPLIANCE

It is the supplier's responsibility to ensure their part is in compliance with all applicable regulatory agency and part safety requirements, and claims including those stated in supplier published part advertising, catalogues and data sheets. Additionally, the supplier must be prepared to substantiate compliance at any time by providing copies of test reports and making records available for review by Creation or its customers upon request.

11.0 CONFORMANCE TO REQUIREMENTS

It is the supplier's responsibility to ensure all requirements and part specifications are met before parts are shipped. Requirements include but are not limited to those defined by the Prints, Drawings, part specifications referenced on the Purchase Order or any appearance standard / golden sample. Also, where applicable by regulatory agencies or industry standards or supplier datasheets compliance is mandatory.

If Creation requires and provides information on sub-tier suppliers, including details of any special processes to be used, the supplier shall ensure that only these sub-tier suppliers and processes are used.

The supplier shall provide a Certificate of Compliance (C of C) as required. The C of C shall document compliance to part specifications and all applicable regulatory and environmental requirements. Further requirements may be included in specific procurement specifications and documentation. In addition to the C of C, with the first shipment of each revision, the supplier shall provide supporting data to demonstrate first article (FA) acceptance to verify compliance with the part specification. Unless otherwise indicated in the procurement specification, all dimensional measurements shall be provided in this FA report.

If sampling plans are used to perform part inspection, preferably based on ANSI Z1.4 and zero-defect acceptance criteria. However, use of sampling plans in no way relieves the supplier of their responsibility to ship 100% conforming material.

12.0 QUALITY MANAGEMENT SYSTEM REQUIREMENTS

- Suppliers are recommended to have a quality management system in place (not mandatory to be certified by 3rd party registrar but should be based on industry standard such as ISO 9001, AS9100, ISO13485, IATF16949, etc.) that assures consistent on-time delivery of conforming part.
- Suppliers are responsible for sending notification to their Creation purchasing contact and **pcn@creationtech.com** when any of their certifications become delinquent. It is the supplier's responsibility to ensure all quality certifications are valid while manufacturing and shipping parts to Creation.
- Problem Resolution and Escalation; The supplier is required to have created or provide Creation with their escalation process to next levels of management if a decision cannot be reached at any particular level of the organization.
- Suppliers will ensure that any persons working on parts or processes manufacturing parts shall be competent based on education, experience and or qualification.
- Design & Development Controls, Creation Technologies, is a "build to print and contract manufacturer" facility. However, if the supplier provides any level of design or development services to Creation as part of the PO, then they shall ensure that they follow their Design & Development Controls.
- Creation may request supplier for additional quality management procedures or documents to ensure parts are meeting requirements.

Supplier shall assign a Quality Management Representative (QMR) to be the key contact point for Creation for any quality issues and processes. QMR will be responsible for responding to any quality inquiries as well as providing regular quality reporting. The supplier shall notify Creation in writing if there is any change to the QMR.

13.0 ACCESS

Creation Technologies, with appropriate prior notice, shall have the right of access to the applicable areas of all facilities at any level within the supply chain, involved in the purchase order and to all applicable records. This right of access shall also be granted to Creation's customers and any applicable regulatory authority. This access will be required from time to time to facilitate verification or validation activities, including test, inspection and production process verification, which may be required.

14.0 PART QUALITY REQUIREMENTS

It is the responsibility of the supplier to assure the conformance of all parts and material delivered to Creation to requirements specified in the procurement specification, drawings, or other provided documents. Supplier shall maintain capable processes, effective process controls and effective verification activities, including appropriate controls to the direct and sub-tier providers, ensuring all requirements are flowing down to all the levels of the supply chain. Supplier shall perform control and verification activities to prevent the use of counterfeit electronic parts.

Quality records shall be made available for review if required. Examples of these records are final QC results, in-process results, test results and final inspection / quality audit results.

In the event the supplier discovers a non-conforming condition with their part and have reasons to believe that Creation can use the part, the supplier shall request Creation's written approval. Under no circumstances can the supplier ship the non-conforming part without prior written authorization from Creation.

Supplier to provide test specimens for design approval, inspection/verification, investigation, or auditing. Document such as raw material certificate of origin shall also be provided if requested.

The supplier is responsible for reworking or replacing all non-conforming parts/material to comply with the procurement specification(s) defined in the PO. In the event 100% inspection is required as a result of a rejected batch, the supplier has the option to provide onsite inspection services within 24 hours or be liable for the cost of inspection by Creation.

When 100% inspection is not used for product acceptance of replacement or reworked products, supplier shall ensure that valid statistical techniques are used, and samples are selected in a random manner, representing the batch being shipped.

When Creation requests a Return Material Authorization (RMA) for defective parts, the supplier is required to issue an RMA # preferably within 24 hours.

Field returned Non-Conformance failures currently under warranty are subject to return or repair under warranty. In the case of repair, a newly established buyback purchase order will be created to allow for the repaired unit to be brought back into Creation.

15.0 PART APPROVAL PROCESS

Based on the level of risk for a particular part, combined with whether that item has critical to quality attributes requiring tightened variation control, one of two different validation processes may be utilized if required:

- FAI (First Article Inspection)
- PPAP (Production Part Approval Process)

For high risk items that have critical to quality attributes and require variation control, PPAP may be required.

As a potential supplier of high-risk items and products, you may be required to meet the PPAP requirements to begin shipment.

Your supplier, design, and quality contacts at Creation will notify you well in advance of the quoting stage as to what level of compliance you need to submit based on risk assessment activities internal to Creation or from Creation customers.

Supplier quote should reflect these additional steps and timelines to comply, as all suppliers quoting on high risk items will be under the same approval criteria.

16.0 TRACEABILITY AND IDENTIFICATION

The organization shall establish and maintain a system that provides traceability of material and processes throughout product realization that is capable of identifying:

- the material lot(s) used in the production of product
- acceptance records of the production material
- all product manufactured from a given lot of material
- duplication of serial numbers for the same product supplied to Creation is prohibited

The traceability system shall provide sufficient means to maintain current revision, specification, and quality requirements from raw material through finished product for all materials and processes used by Creation, our customers and its suppliers. Serialized parts / assemblies and detail parts used in assemblies shall be traceable to the manufacturing lot(s) in which they were produced, as well as the material(s) used to produce them.

17.0 SUPPLIER ASSESSMENT & APPROVAL

The objective of a supplier assessment & approval is to thoroughly evaluate a supplier's facility, manufacturing capability, quality management system and business system maturity on the basis of their ability to meet specified requirements, including quality requirements. The supplier assessment is intended to be comprehensive and inclusive of all major facets of a business relationship with a supplier and indicate expected levels for continuous improvement.

The Supplier Assessment is utilized as needed to evaluate the supplier's current quality system, as well as their overall capability and relative to the needs of Creation. This is a comprehensive self assessment takes between one to two full days on-site (depending on suppliers' physical size). A supplier report will be created and reviewed within Creation, once content is agreed upon, it will be sent to the supplier with next steps. A non-qualified supplier may be placed on restricted status and is expected to develop and implement an improvement plan if they wish to continue to do business with Creation. This plan and its status will be communicated to Creation as defined in the improvement plan until a follow up assessment is conducted and deemed acceptable. A non-qualified supplier can request a follow-up assessment after corrective actions and improvements are implemented.

The assessment & approval process has several steps:

- Recommended to have an acceptable Quality Management System in place, as defined in section 12.0.
- Creation's review of Supplier Assessments (self, site, or 3rd party) is satisfactory.
- Corrective actions from the assessments have been planned and found acceptable, as required.
- First Article samples & inspection reports if applicable as acceptable.

If the above requirements have been satisfied, the supplier is identified as "approved" status.

18.0 PERFORMANCE MEASUREMENT

Creation and our suppliers must agree to work together to achieve continuous improvements in the following areas;

Primary performance metrics may include but are not limited to:

- Quality levels – PPM
- Incoming Inspection Lot Acceptance
- On Time Delivery
- Quoting Performance
- Customer Service including, responsiveness to requests for information
- Cost reductions

Creation may monitor certain supplier's performance and meet periodically with those suppliers to review the progress made on performance metrics. On a periodic basis, Creation conducts Supplier re-evaluations by sending the Supplier QMS Approval Questionnaire to suppliers to be completed and returned.

19.0 SUPPLIER SCORECARD

Supplier Scorecards can be used to communicate the supplier's performance.

20.0 SUPPLIER CORRECTIVE ACTION REQUEST (SCAR)

Major or repeat occurrences of non-conformances indicate that the supplier's process is out of control. If requested by Creation, effective and timely corrective & preventative action is required and documented in the form of a SCAR. The supplier shall analyze the problem, implement containment action(s), determine the root cause(s), define corrective and preventive actions and verify the effectiveness of those actions. The supplier is expected to follow a recognized problem-solving methodology such as the 8D process.

A SCAR is designed as two-way communication vehicles to foster *continuous improvement* at the supplier and at Creation if needed. Incoming inspection ensures that suppliers are sending the highest quality materials to Creation. In the event that material from a supplier is found to be non-conforming either at Incoming Inspection, In-process. Final inspection or field usage, a SCAR will be initiated with the supplier being solely responsible for addressing the non-conformance. The suppliers then need to respond to these issues via SCAR, evidencing both internal improvements in their own companies and externally helping their suppliers or Creation identify where it needs to make changes/ improvements related to the issue if needed. In addition, all rework/sorting and/or freight costs for all supplier responsibility SCARs will be required to be at the supplier's expense.

In the event that supplier corrective action attempts have not been successful in eliminating non-conformances, Creation reserves the right to invoke additional process control measures to drive process improvement and ensure product conformance. If and when necessary, additional process controls can be specified on the purchase order.

21.0 FAILURE ANALYSIS

When requested by Creation or their customer, Supplier agrees to timely failure analysis of the non-conforming part(s) and root cause analysis and corresponding corrective & preventive actions. Creation will return suspect piece parts or materials for analysis when possible. These returns shall be managed through a Return Material Authorization process.

22.0 PRODUCT CHANGE NOTIFICATION

Suppliers must notify Creation immediately of any changes that may impact form, fit, function, quality, reliability, or regulatory requirements. Creation will determine if these changes have any impact to their customers finished product. Supplier PCNs shall be sent to the Creation email address **pcn@creationtech.com** for proper tracking and Customer notification.

If Supplier desires to:

1. make any change in supplier's processing or composition of part, specifications, processing, composition, formulation, part or supplier of any materials, or the manufacturing processes or for performance characteristics of any part or any part thereof (including labeling, etc.);
2. use any nonconforming materials in the manufacturing of the part;
3. use any temporary or permanent deviation that affects the product (including manufacturing process), handling or sterility of the part; or
4. implement any corrective or preventative action that could affect the safety or efficacy of the part;
5. changes to the supplier's certification standings (including, ISO, UL, ITAR, CGD, FDA, CSA, CE, VDE, TUV, or others).

Supplier shall provide prior written notice to Creation, including the details regarding such proposed change or action, a sample of the affected part and such other information requested by Creation.

The supplier should maintain a history file of changes and these files are to be made available for review if requested by Creation or their customers. Refer to retention requirements.

In addition to the foregoing, if a supplier desires to make any change in the location of manufacturing, the supplier shall provide prior written notice to Creation; including the details regarding such proposed changes. All such changes shall be submitted to Creation at the earliest time possible of the proposed date of implementation. The Supplier shall not implement any change in the location of manufacturing of any part without Creation's prior written approval. These change notifications shall be in writing by the QMR, as identified in section 12.0.

23.0 HANDLING, PACKAGING, STORAGE & SHIPPING

All material, parts, and assemblies shall be packaged and shipped so that both the packaging and their contents arrive at their destination damage free. All material, parts, and assemblies shall be packaged so that they are protected from any moisture, abrasion, nicks, dents, scratches or other damage. Where applicable, the use of protective ESD materials shall be used. Proper restraining and/or cell packaging shall be used to prevent any shifting or movement that may induce damage.

Shipping documents shall be clearly marked, and may include Packing list, Certificate of Conformance, RoHS Compliance Certificate and other related documents including test/inspection records. Parts and assemblies shall be protected from contamination, corrosion or tarnish where applicable.

Parts or materials that require special storage or handling conditions as defined by the specification, Customer, industry standards, or by the manufacturer's specification shall be stored, handled, and shipped accordingly.

The organization is required to incorporate good commercial standard practices and methods for the preservation, packaging, and shipment to preclude damage to products during shipment to Creation Technologies or our Customers or deterioration while in storage at the supplying organization or Requested Creation BU.

Appropriate protective wear such as gloves, finger cots, barrier creams, etc., shall be used to prevent damage resulting from staining or rusting.

24.0 BUSINESS UNIT REVIEWS

Supplier Business Unit Reviews (BURs) may be conducted when deemed necessary. The topics covered in a BUR could include a supplier's performance, operational updates, org structure, quote activity, Quoting performance, financial update, bond performance, BU feedback, recent scorecards, Lean, OTD and a categorized list of recent SCARs. This is not a comprehensive list of all the topics that will be discussed in a BUR, but rather, it is an example of the basic subjects that will be reviewed.

25.0 RECORDS

- The supplier shall ensure all records related to the design & procurement, manufacturing, services and delivery of parts supplied to Creation and (if applicable) the material certificate of origin will be maintained for a minimum of 3 years unless otherwise specified.
    a. In the case where the supplier's part is used to manufacture a **medical device**, the supplier shall retain all records for a time period specified within the procurement specification after delivery to Creation.
    b. Supplier will contact Creation upon expiration of the said time period to discuss proper disposition of such records.
- Supplier shall provide Creation a copy of such records without charge upon Creation's request.
- All records shall be signed or marked in a traceable manner to authorized supplier representative.

26.0 BUSINESS CONTINUITY PLANNING

It is the goal of Creation that every vendor has a robust Disaster Recovery Plan with a business resiliency plan. Supplier's Business Continuity Planning shall be made available upon request to Creation as needed.

27.0 END OF LIFE NOTIFICATION

If 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 shall be communicated to Creation Technologies ASAP. Any End of Life Notification will be sent to Creation at least six months or more in advance with a sufficient explanation to Creation. Supplier will notify Creation by sending EOL and LTB notifications to their Creation purchasing contact and **pcn@creationtech.com**