



Supplier Quality Requirements

creation
TECHNOLOGIES

Supplier Quality Requirements

- Supplier Letter

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 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.

Whether your company is a new supplier to Creation Technologies, or a long-standing partner, the information in this document will help you better understand Creation's needs and expectations.

It is important that you read, understand, and flow down these requirements. Questions or concerns can be directed to your Creation Buyer or Planner or Quality Representative. They can provide answers or additional information where you need clarification. Creation should be contacted immediately if you cannot or are unwilling to meet the requirements listed here. We expect this document will be shared to appropriate internal personnel of your company and flowed down to the respective sub-tier supplier personnel as required.

We look forward to working with you.

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SUPPLIER SELECTION PROCESS

Creation is constantly striving to partner with the best suppliers available. When Creation Supply Chain or Commodity Management identifies a potential new supplier, this supplier is evaluated based on 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 Key Contact information (remit to, PO placement)
- (v) Technology/Business/Pricing Evaluation
- (vi) Supplier Financial Assessment
- (vii) Inbound Packaging Identification
- (viii) Shipment Capability
- (ix) Supplier Questionnaire
- (x) Supplier Self Assessment/Audit Checklist (if applicable)
- (xi) Supplier Self Assessment/Requalification Audit Checklist (if applicable)

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

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

In accordance with FDA 820.50(b), Supplier agrees to provide Creation with prior written notification of any changes that are to be made to either the products or services provided hereunder and new specifications will be agreed to in advance of shipment or delivery of such products or services. Upon reasonable advance written notice by Creation, Supplier also agrees to provide to authorized representatives of Creation, its customers and/or any applicable regulatory agency (or agencies) full right of entry to all facilities that have been involved in Supplier's performance under this contract, including providing such parties access to all related records.

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1. PURPOSE

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

2. SCOPE

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

3. DEFINITIONS

4. RESPONSIBILITIES

The functions listed below have responsibilities detailed in this procedure:

- **Procedure Owner:** Supplier Quality
- All the roles listed below should be trained on this procedure:
 - **Commodity Manager or Supply Chain Leader:** is **Responsible** - communicates the task.
 - **Commodity Manager or Supply Chain Leader:** is **Accountable** – for supplier escalations.
 - **Quality Leader, Quality Engineer, Supplier Quality, Engineer Leader and Manufacturing Engineer:** to be **Consulted** – has information and/or capability necessary to complete the work.
 - **Quality or Supplier Quality:** can be **Supportive** - can provide resources or can play a supporting role in implementation.
 - **Buyer(s) and Planner(s):** to be **Informed** – inform suppliers of SQR requirements and must be notified if supplier cannot or will not meet the requirements of this document.

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5. TRAINING

- Review of SOP and acknowledgement in Creation University for Creation employees. For suppliers, acceptance of PO indicates acknowledgement and compliance to supplier quality requirements. Supplier training material is located on Creation's Supplier Website.

6. EQUIPMENT / MATERIALS / SUPPLIES

- Access to Creation's Supply Website, email, SupplyWin, specs and certifications.

7. CREATION POLICIES AND OBJECTIVES

Creation's policy requires that materials and services used to manufacture products for our global customers base, be procured in an ethical and professional manner that achieves a high-quality product, delivered on time, with the lowest total cost of ownership. All purchased material must be in compliance with the agreed procurement requirements, be delivered on time, and have competitive lead times and prices.

8. ORDER OF PRECEDENCE

In the event of conflict with the requirements of procurement documentation, the order of precedence is as follows:

- Purchase Order
- Creation Specifications
- Supplier Quality Requirements (this document)
- Industry or Regulatory Requirements

The requirements of this document are considered as accepted by the supplier when that supplier accepting a Creation Purchase Order.

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9. CODE OF CONDUCT AND CORPORATE SUSTAINABILITY

Creation's general requirements are defined within the Supplier Code of Conduct. [Creation will only utilize suppliers who embrace a similar level of compliance to standards of ethical conduct. Suppliers shall ensure that they have internal policies in place to promote ethical behavior and that all employees are aware of their obligations.](#) The full Supplier Code of Conduct and Corporate Responsibility are available under Important Downloads section on the Creation Supplier website.

10. ENVIRONMENTAL AND REGULATORY AGENCY COMPLIANCE

[It is the supplier's responsibility to ensure their part is in compliance with all applicable environmental, 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. Follow the Corporate Responsibility link under Important Downloads on the Creation Supplier website to access all relevant policies.

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11. CONFORMANCE TO REQUIREMENTS – NEEDED FOR PARTS

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 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.

A Certificate of Conformance shall be provided to Creation with every shipment when required.

Where required, Creation may request the following documentation:

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

Requirements will be communicated through the specific purchase order.

If sampling plans are used to perform part inspection, it should be based on an acceptable standard. Use of sampling plans in no way relieves the supplier of their responsibility to ship 100% conforming material.

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12. QUALITY MANAGEMENT SYSTEM REQUIREMENTS

Suppliers are required to have a quality management system in place. A 3rd party accreditation is preferred but not mandatory. QMS best practices should be adopted in compliance with industry standards such as ISO 9001, AS9100, ISO13485, IATF16949, etc. A successful QMS program should consistently meet or exceed customer expectations regarding on-time delivery, overall quality, and continuous improvement of material, product, or services.

All Suppliers are responsible for communicating to their respective Creation purchasing contact or Supply Chain contact and email:

- pcn@creationtech.com for any catalog or off the shelf product.
- MaketoPrintPCN@creationtech.com for any custom or build to print product or certification expiration or delinquency.

New email address added for make to print supplier communications.

It is the supplier's responsibility to ensure all quality certifications are valid while manufacturing and shipping product to Creation.

Problem Resolution and Escalation; The supplier may be required to provide Creation with their escalation process to next levels of management if a decision cannot be reached within the supplying organization.

Suppliers will ensure that any personnel working within any manufacturing process, testing or inspection station, or performing external services directly related to production product, shall be competent based on education, training, experience 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 additional quality management procedures, inspection reports or documents from suppliers to confirm the supplied product meets specification.

Supplier shall assign a Quality Management Representative (QMR) to be the key contact point for Creation on any quality issues, audit, customer support, and process insights. QMR will be responsible to respond 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.

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13. ACCESS

Creation Technologies, with appropriate prior notice, shall have the right of access to the applicable areas of all supplier 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 as needed. This access will be required from time to time to facilitate verification or validation activities, including test, inspection, supplier assessment or audit, risk, development activities, and production process verification, which may be required and support or prove conformance activities.

14. PART QUALITY REQUIREMENTS

It is the responsibility of the supplier to assure the conformance of all parts and material delivered to Creation meet all 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 supply Chain, ensuring all requirements are flowed down to all levels of the supply chain. Supplier shall perform control and verification activities to prevent the use and introduction of any counterfeit product, electronic or other.

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 product, a deviation must be submitted for Creation's approval. Submission must include all supporting documentation and evidence as to why the supplier believes Creation can use the product. Under no circumstances can the supplier ship the non-conforming part without prior written authorization and approval from Creation.

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

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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, contract a 3rd party contractor to perform 100% inspection/verification or rework as needed or be liable for the cost of inspection or rework by Creation to avoid line down.

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. They must also certify and identify the product(s) that were determined to be non-conforming for easy identification at Creation.

When Creation requests a Return Material Authorization (RMA) for defective parts, the supplier is required to issue an RMA #, preferably within a single business day. The supplier shall ensure replacement product is expedited, if needed, to reduce risk of downtime.

Field returned Non-conformance failures currently under investigation/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.

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15. 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)

- AS9102 FAIR, full or partial, may be required from custom or build to print suppliers for new product or revision change.

PPAP (Production Part Approval Process)

- PPAP may be required if Creation customer mandated.

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.

Costs associated with FAIs and PPAPs shall not be charged to Creation. [Any FAI and PPAP charges must be negotiated with Creation.](#)

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16. TRACEABILITY AND IDENTIFICATION

The organization shall establish and maintain a system that provides traceability of all 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
- all product manufactured from a given lot of material
- duplication of serial numbers for the same product supplied to Creation is prohibited
- Country/Countries of Origin

The traceability system shall maintain current revision, specification, and quality requirements from raw material through finalized product for all materials, components 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. This may also include any specific customer traceability requirements.

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17. 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, virtual, or 3rd party) is deemed satisfactory.

Corrective actions from the assessments have been identified, implemented, and found acceptable, as required.

First Article or PPAP samples & inspection reports, if applicable, as acceptable.

If the above requirements have been satisfied and C-0002594 Supplier Status Change Signoff is completed, the supplier is identified or is changed to "approved" status.

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18. 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

Supplier Corrective Action Request (SCAR)

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 Creation Supplier Requalification Audit (C-0003005) to suppliers to complete and return.

19. SUPPLIER SCORECARD

Supplier Scorecards can be used to communicate the supplier's performance. Creation Supply Chain, Supplier Quality, or Quality will review supplier scorecard data quarterly. Creation may decide to communicate to supplier and request further action based on supplier performance. Reference C-0002929 Supplier Scorecard Performance Metrics.

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20. 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, 5 Why, etc. *Creation strongly urges the supplier use Creation's 8D SCAR format, which should be provided upon SCAR issuance or is available on the Creation Supplier Website, to document supplier's problem-solving responses back to Creation.*

A SCAR is designed as a two-way communication vehicle to foster *continuous improvement* at the supplier and at Creation if needed. In the event that material from a supplier is found to be non-conforming anywhere at, or downstream from Creation, a SCAR may be initiated with the supplier being solely responsible for addressing the non-conformance. The suppliers then must 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 actually incurred by Creation as a result of supplier-responsible SCARs, will be required to be reimbursed to Creation by the supplier.

Depending on the severity of the non-conformance and the impact to Creation's or its customers' production schedule, Creation may require compensation for customer charge backs and down time directly related to the non-conformance, refer to Section 28.

A SCAR should be generated when Creation's customer or Creation is impacted by any of the following events:

- Supplier defect results in Production Line Down
- Major rework or repair is required to return the product to conformance
- Shipment stopped
- Repeat occurrence
- Safety Risk
- Part criticality and risk level warrants a SCAR
- Major Creation supplier audit findings

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A SCAR may be issued for any other reason, subject to the local BU determination based on risk.

Time expectations

- Creation expects the supplier to provide acknowledgment and completed containment action(s) is within **3 business days** of Creation communicating Creation's complaint.
- Creation expects the supplier to provide the defined root cause(s) and corrective action plan within **10 business days**.
- The supplier will provide the final problem solving (i.e., "8D") report, including effectiveness validation, within **30 calendar days** of Creation communicating Creation's complaint.

If the supplier will not be able to make the SCAR due date, the supplier should request an extension from Creation.

Reference the 8D Training Presentation available on the Creation Supplier website.

Creation expects supplier problem solving to be *thorough*. For example, Creation won't accept retraining or other personnel-focused actions as the only root causes/corrective actions.

If 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. When necessary, additional process controls can be specified on the purchase order. Such additional measures could include, among other things, requiring the supplier (at supplier's sole cost and expense) to install additional testing, install additional inspection, contract a secondary testing/inspection service, being audited by Creation, etc. until the issue has been proven to be resolved permanently.

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21. FAILURE ANALYSIS

When requested by Creation or any Creation customer, Build-to-Print Suppliers agree to failure analysis, in addition to, root cause analysis and corresponding corrective & preventive actions of the non-conforming part(s) if data, information, or specification is available for the customer to support analysis. Reference Section 20 of this document for Corrective Action guidelines. Creation will send photos, documentation or suspect pieces, parts, product, or materials for analysis when possible. These returns shall be managed through a Return Material Authorization process.

22. PRODUCT CHANGE NOTIFICATION

Suppliers must notify Creation immediately of any changes that may impact fit, form, function, quality, reliability, or regulatory requirements. Creation will determine if these changes have any impact to their customer's finished product. Supplier PCNs and/or ECNs shall be sent to the applicable Creation email address:

- pcn@creationtech.com for any catalog or off the shelf product.
- MaketoPrintPCN@creationtech.com for any custom or build to print product. ***New Email Address***

If Supplier desires to:

make any change in supplier's processing or composition of part, specifications, processing, composition, formulation, part or supplier of any materials, equipment or process location change, or the manufacturing processes or for performance characteristics of any part or any part thereof (including labeling, etc.);

use any temporary or permanent deviation 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.

implement any corrective or preventative action that could affect the safety or efficacy of the part;

changes to the supplier's certification standings (including, ISO, AS, 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.

If supplier is a make to print or a custom build supplier, any changes to the custom product, material, location of equipment, location of manufacturing, or any change that could affect fit, form or function, 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 least six (6) months (or earliest time possible) before 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 and / or option for safety stock purchase. This change notification shall be communicated in writing by the QMR, or designated contact, as identified in section 12.0.

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23. 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 any other damage resulting in cosmetic or dimensional deformities. 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, RoHS Compliance Certificate (to the latest directive), Conformance or Validation documentation as per Section 11. 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 requesting Creation BU.

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

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

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24. 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 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 could be reviewed.

25. 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.

- 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.
- Supplier is responsible to properly dispose of obsolete or expired records in accordance with the supplier's regulatory compliance or certifying body requirements.

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. BUSINESS CONTINUITY PLANNING

It is the goal of Creation that every vendor has a robust Disaster Recovery Plan which should include succession planning for key executives, natural disasters, catastrophic events, in all facets of the manufacturing process etc. The Disaster Recovery plan should include backup of all customer, manufacturing and supplier data, prints, drawings, designs, equipment and tooling, every facet of the process, in redundant locations in the event of loss. The supplier's Business Continuity or Disaster Recovery Plan shall be made available upon request to Creation as needed.

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27. 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 immediately. Any End of Life or Obsolescence Notification will be sent to Creation at least **six (6)** months or more in advance with a sufficient explanation to Creation and an opportunity to place a last time buy. Supplier will notify Creation by sending EOL and LTB notifications to their Creation purchasing contact and

- pcn@creationtech.com for any catalog or off the shelf product.
- MaketoPrintPCN@creationtech.com for any custom or build to print product.* **New Email Address***

28. SUPPLIER CHARGEBACKS – New Section

Creation reserves the right to recover costs incurred by Creation due to non-conforming materials or late delivery.

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

- Any sorting, testing or rework costs incurred by Creation or a contracted third party at its direction
- Replacement of material
- Recall of material
- Creation's customer's charges for removal, replacement, or return
- Late delivery penalties from Creation's customers
- Travel expenses
- Source inspection costs as a result of non-conformance
- Additional inspect costs at Creation
- Containment costs

In instances of non-conformance, refer to Section 20 for SCAR requirements. Creation will summarize the basic information and evidence of the actual costs incurred by Creation. [These chargebacks are not meant to be punitive, only to remedy instances in which Creation has incurred notable costs for non-conforming products or late deliveries, in each case, due to the fault of the supplier.](#) The preferred method of cost recovery is to debit the supplier's account unless an alternative agreement is reached through review with the supplier. The charge back will be initiated after 10 working days or completion of the review process.



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