

Objective and Scope

Product that is found to be non-conforming at receiving, or during production, causes serious disruptions of the production and shipping schedules, resulting in high production costs. Even the best Receiving Inspection program cannot detect all defective material. Empirical Technologies requires suppliers to control the quality of material shipped so that it meets the acceptance criteria when it is received. This manual describes Empirical Technologies expectations for its suppliers to ensure that purchased material meets the specified requirements.

Revision and Approval Table

Revision	Date of Change	Change Owner	Change Details
A	27-May-2020	Teresa Barnes	Create document for new QMS system from Form DC in old quality system.
B	05-Dec-2022	Randy Simons	Update document to meet current procedures. CR0021

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1. Classification levels

1.1. See Supplier Evaluation, Approval, and Maintenance procedure for details on classification levels.

2. Quality Management System Requirements

2.1. Quality Management System

2.1.1. Suppliers are required to maintain an effective quality management system, preferably one that conforms to ISO 9001 Quality Management System – requirements. In addition, the supplier must meet the requirements of this manual as directed by the PO.

2.2. Quality Manual and Procedures

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2.2.1. The supplier, as requested, will furnish a copy of their supplier's Quality Manual and supporting procedures. In addition, the supplier must complete Empirical's Supplier Questionnaire and submit it for review.

2.3. Control of Sub-tier Suppliers

2.3.1. Suppliers are responsible for the quality of materials and components provided by their sub-tier suppliers and sub-contractors.

2.3.2. Where appropriate, Empirical may specify the sub-tier suppliers that may be used, evaluate, and qualify the sub-tier supplier's facilities, and assist the supplier in controlling the sub-tier supplier. Typically, this occurs when the sub-tier supplier is an essential component of the supply-chain process. Empirical reserves the right to evaluate the quality system and records of such sub-tier suppliers as necessary. In the event of Empirical's involvement, it does not absolve suppliers of the ultimate responsibility for the quality performance of their sub-tier suppliers.

3. Part Qualification

- 3.1. The supplier is responsible for submitting all First Article data requested on the First Article requirements checklist (if requested).
- 3.2. Empirical and the supplier will agree on the number of the samples to be checked and submitted with the first article data.
- 3.3. Where possible, all First Article documents should be submitted to the Empirical's Quality Manager in electronic format.
- 3.4. In rare cases, Empirical personnel may wish to be present during the initial production run. This will allow Empirical to validate and verify the process before any product is shipped.

4. First Article Requirements Checklist

- 4.1. For each new or changed part, Empirical sends the supplier a First Article Requirements Checklist, listing the steps and information that must be submitted for qualification of the component or assembly for production.
- 4.2. The checklist items selected are based on the type of component or assembly to be supplied.
- 4.3. If a First Article checklist is not provided, then it is not necessary on the purchased component.

5. Dimensional Inspection Report

- 5.1. Empirical notifies the supplier of the quantity of parts to be inspected, when necessary.
- 5.2. The supplier inspects or tests each sample for all dimensions, drawing notes, and specification requirements listed on the current revision of the drawing and/or specification.
- 5.3. The supplier records the results on the First Article Report form or equivalent.
- 5.4. The supplier numbers a copy of the drawing and/or specification to correspond with the supplier's results.
- 5.5. The dimensional inspection report must include the specification number, specified requirements, and the inspection/test results.
- 5.6. Each report must be traceable to the supplier's material, through lot/heat/coil/batch numbers or, equivalent, and must be signed by the organization that performed the testing.
- 5.7. For any requirements that the supplier does not have the equipment to inspect or test, the supplier may obtain reports from their sub-supplier or other test agency.

- 5.8. Parts inspected for the dimensional inspection report are randomly selected from a production run of parts. The minimum quantity for the production run is agreed upon between the Supplier and Empirical.

6. Material Certification/Test Report

- 6.1. When requested, the supplier must provide a material certification/test report.
6.2. This report must include the specification number, specified material and/or physical requirements, and the inspection/test results.
6.3. Each report must be traceable to the supplier's materials and must be signed by the organization that performed the testing.

7. Gage Repeatability and Reproducibility (R&R) Studies

- 7.1. Empirical will indicate on the PO if R&R studies are required.
7.2. For those characteristics specified by Empirical, the supplier must perform gage R&R studies using procedures described in Measurement Systems Analysis published by an acceptable source.
7.3. Empirical must approve R&R values greater than 10 percent of the tolerance.
7.4. Normally for variable gages, three different operators measure ten samples three times each.
7.5. For attribute gages, the Attribute Gage Study (long method) is required. Empirical must approve any alternative methods.

8. Drawings/Changes

- 8.1. Drawing and Change Control
8.1.1. The supplier must have a documented system for assuring that the latest drawings are in effect at their facility.
8.1.2. The supplier's quality management system must contain a documented procedure that describes the method used for the receipt, review, distribution, and implementation of all changes to drawings and specifications.
8.1.3. In addition, the procedure must address control of obsolete drawings and specifications.
8.2. Process Changes, Engineering Changes
8.2.1. Suppliers must have systems in place to control changes to drawings, specifications, processes, or produced parts.
8.2.2. Systems should be capable of handling changes being requested by the customer and also changes requested by the supplier.

9. Corrective Action System

- 9.1. Empirical Technologies requires suppliers to utilize a closed-loop corrective action system when problems are encountered in their manufacturing facility, or after nonconforming product has been shipped to Empirical Technologies.
9.2. Supplier Corrective Action - Empirical issues a Supplier Corrective Action Request (SCAR) to a supplier when non-conforming parts are found at incoming inspection. They can also be issued as a result of a supplier audit. The supplier is required to respond by returning the SCAR back to Empirical. The following provides a brief outline of the SCAR procedure that suppliers to Empirical Technologies should comply with:
9.2.1. Empirical requires that the supplier take immediate containment action upon notification of the nonconformance. The supplier must submit a written response to Empirical Technologies, reporting

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the Supplier's initial observation and defining the interim containment plan within 48 hours of notification. The Supplier's Initial Observation is an acknowledgement that the Supplier has been informed of the problem and has begun to gather information about the problem.

9.2.2. Within 2 weeks after the original notification, the supplier must report the results of the Supplier's investigation into the cause of the problem.

9.2.3. The supplier is required to keep Empirical informed of progress towards implementing the corrective action. When corrective action implementation is complete, the supplier and Empirical **will** verify that the corrective action is effective in preventing the problem's recurrence.

10. Supplier Monitoring

10.1. Empirical Technologies continually monitors its suppliers to ensure they continue to meet Empirical Technologies requirements, and to ensure that the supplier continues to ship acceptable parts. This may consist of:

10.1.1. A quality management system surveillance audit at the supplier's facility

10.1.2. A random incoming inspection audit of a batch of product

10.2. Supplier Audits (If directed by PO)

10.2.1. Periodically, Empirical may audit the supplier's quality management system.

10.2.2. The supplier must make their facility available for on-site process verification by Empirical Technologies personnel at any time, with reasonable notice. This may be a full or abbreviated documentation and on-site audit.

10.2.3. The purpose is to evaluate any changes that may have occurred in the supplier's quality management system, and to assess the supplier's continuing commitment to quality improvement.

10.3. Supplier-Furnished Lot Documentation (If directed by PO)

10.3.1. Empirical may require the supplier to furnish inspection, test, process performance, or other quality data with each shipment to ensure that the product meets requirements. When data submission is required, the data must accompany each shipment, or be e-mailed at the same time the lot is shipped.

References

Name
Supplier Evaluation, Approval and Maintenance, Counterfeit Parts, Supplier Questionnaire,

Internal and external references, forms, and templates:

Definitions

- ISO – International Organization for Standardization
- ASTM – American Society for Testing and Materials
- R & R – Gage Repeatability and Reproducibility

Responsibilities

- Services and Solutions Specialist
- Quality Manager
- Deputy Quality Manager