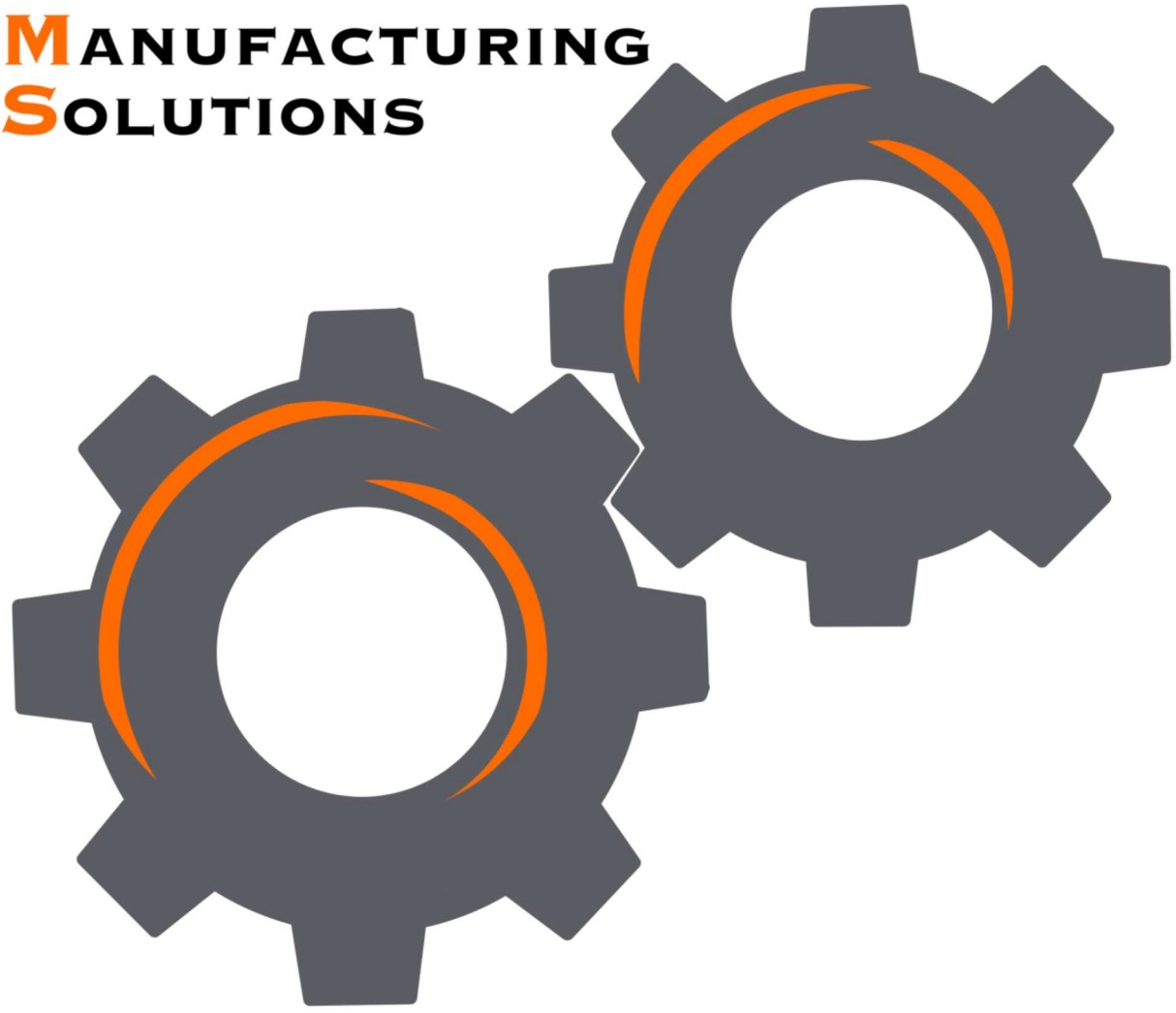
EMERGENT
MANUFACTURING
SOLUTIONS



EMERGENT MANUFACTURING SOLUTIONS

SUPPLIER QUALITY MANUAL

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0. INTRODUCTION

In today's manufacturing environment, products found to be non-conforming at receiving or during production cause serious disruptions of the production and shipping schedules, resulting in high production costs. Even the best Receiving Inspection program cannot detect all defective material. Emergent Manufacturing Solutions requires suppliers to control the quality of material shipped by managing and maintaining a robust Quality System.

This manual describes Emergent Manufacturing Solutions' expectations for its suppliers to ensure purchased material meets requirements.

Emergent Manufacturing Solutions specializes in providing custom fabrication, manufacturing, and assembly services to end users in the Aerospace, Automotive, and Power Generation sectors.

0.1 Emergent Manufacturing Solutions Quality Policy

EMS is committed to exceeding customer expectations on quality, delivery, and cost through continuous improvement and customer interaction.

0.2 Scope

This manual applies to all suppliers who have an interest in doing business with Emergent Manufacturing Solutions. It also applies to Emergent Manufacturing Solutions' outsourced partners and subsidiaries.

1. QUALITY MANAGEMENT SYSTEM REQUIREMENTS

1.1 Quality Management System

Each supplier is required to maintain an effective quality management system. At a minimum, the quality system must conform to ISO 9001:2015 Quality Management System – Requirements. In addition, the supplier must meet all other requirements of this manual.

1.2 Quality Manual and Procedures

The supplier, as requested, will furnish Emergent Manufacturing Solutions with a copy of the supplier's Quality Manual and supporting procedures. This includes detailed documents and work instructions specific to material(s), process(es), service(s), and product(s) produced for Emergent Manufacturing Solutions.

1.3 Control of Sub-tier Suppliers

Suppliers are responsible for the quality of materials and components provided by their sub-tier suppliers and sub-contractors. Emergent Manufacturing Solutions suppliers must impose controls on their sub-tier suppliers that provide quality results and documentation comparable to the controls applied to suppliers by Emergent Manufacturing Solutions. The extent of the controls may vary, depending on the nature and complexity of the product and processes, but should normally include:

- Evaluation and qualification of sub-tier supplier facilities
- Control to ensure that raw materials used meets Emergent Manufacturing Solutions' requirements
- Controls to ensure that the sub-tier suppliers of components used are those approved by Emergent Manufacturing Solutions, where applicable
- Part qualification, including first article inspection and process capability studies, as applicable

- Control of drawings and revisions
- Control of nonconforming material
- Corrective action and preventive action programs
- A continuous quality improvement program

Where appropriate, Emergent Manufacturing Solutions 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.

Emergent Manufacturing Solutions reserves the prerogative to evaluate the quality system and records of such sub-tier suppliers as necessary. In the event of EMS involvement, it does not absolve suppliers of the ultimate responsibility for the quality performance of their sub-tier suppliers.

1.4 Document Retention Periods

Unless otherwise specified on the purchase order, suppliers shall keep documents for 15 years beyond the project's life.

1.5 Required Minimum Flow Downs

At a minimum, all suppliers must adhere to the following, and flow down the following to their sub-tier suppliers:

1. System(s), process(es), and/or procedure(s) to prevent the use of counterfeit parts;
2. All applicable flow downs from EMS to the supplier, including customer requirements;
3. Ensuring all persons within the organization are aware of
    a. Their contribution to product and service conformity;
    b. Their contribution to product safety;
    c. The importance of ethical behavior.

1.6 Right of Access

At a minimum, all suppliers must grant Right of Access to Emergent Manufacturing Solutions, our customers, and all regulatory authorities, to the applicable areas of facilities and to applicated documented information. This Right if Access must be applicable to all levels of the supply chain. It is the responsibility of the supplier to ensure all sub-tier suppliers are aware of and agree to this requirement.

2. SUPPLIER QUALIFICATION PROCESS

All suppliers of production materials to Emergent Manufacturing Solutions must be qualified suppliers. The extent of the qualification process is dependent upon the criticality of product purchased and other factors determined by Emergent Manufacturing Top Management. The qualification process in its most complete form consists of three parts:

- A questionnaire completed by the supplier
- A quality management system self-assessment completed by the supplier, using the supplier assessment survey form. This is returned, along with the supplier's quality manual and documentation for review
- An on-site assessment by Emergent Manufacturing Solutions

Emergent Manufacturing Solutions periodically reevaluates suppliers using quality performance data and/or on-site assessments.

2.1 New Supplier Questionnaire

In the early stages of the supplier selection process, potential suppliers are sent a questionnaire. This questionnaire solicits general information about the company such as location(s), size, capabilities, and financial stability as well as detailed questions regarding the Company's quality management system and quality history.

2.2 New Supplier Self-assessment

When a new supplier is being considered, they are sent a quality management system self-assessment survey form. The supplier completes the self-assessment and returns it along with a copy of their quality manual and supporting documents. Emergent Manufacturing Solutions' quality group will review the quality manual, procedures, and survey to determine if the documented quality system meets requirements.

2.3 On-Site Assessment

For suppliers of critical components, an on-site assessment of the supplier's facility is performed. The on-site assessment includes three components:

- A quality assessment to determine whether the supplier's quality management system is in place and functioning effectively
- A business assessment to determine whether the supplier has financial resources, production capacity, and other business resources needed to fulfill production needs
- A technology assessment to determine whether the supplier has the needed technical resources, including production and inspection equipment, facilities, engineering resources, etc.
- In some cases, the technology assessment will include assessing the health of information security to determine whether a potential supplier can comply with ITAR and/or EAR regulations

If the assessment team determines that the supplier meets requirements, Emergent Manufacturing Solutions qualifies the supplier to bid on new business and supply production materials.

2.4 Periodic Re-evaluation

Emergent Manufacturing Solutions periodically reevaluates current production suppliers through the use of quality performance data and/or on-site assessments. If requested, the supplier shall make their facility available for on-site process verification by Emergent Manufacturing Solutions personnel, with reasonable notice.

3. PART QUALIFICATION

The supplier is responsible for submitting all First Article data requested on the first article requirements checklist. Emergent Manufacturing Solutions and the supplier will agree on the number of the samples to be checked and submitted with the first article data. Where possible, all First Article documents should be submitted to the supplier quality engineer in electronic format (preferably Adobe Acrobat or Microsoft Office).

Emergent Manufacturing Solutions personnel may wish to be present during the initial production run. This will allow validation and verification of the process before any product is shipped.

3.1 First Article Requirements Checklist

For each new or changed part, Emergent Manufacturing Solutions 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. The checklist items selected are based on the type of component or assembly to be supplied.

3.2 Dimensional Inspection Report

Emergent Manufacturing Solutions notifies the supplier of the quantity of parts to be inspected, typically five from each tool or cavity. 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. The supplier records the results on the First Article Report form or equivalent. The supplier numbers a copy of the current drawing and/or specification to correspond with the supplier's results.

The dimensional inspection report must include the specification number, specified requirements, and the inspection/test results. A simple statement that the material meets the requirements is not acceptable. 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. 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.

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 Emergent Manufacturing Solutions. The parts must be produced under volume-production conditions, including material, machines, tooling, processing parameters, cycle times, etc. Any exceptions to the volume-production conditions must be approved in writing by Emergent Manufacturing Solutions and be included in the submitted data package.

3.3 Material Certification and Test Reports

When requested, the supplier must provide a material certification/test report. This report must include the specification number, specified material and/or physical requirements, and the inspection/test results. A simple statement that the material meets the requirements is not acceptable. Each report must be traceable to the supplier's material and must be signed by the organization that performed the testing.

3.4 Gauge Repeatability and Reproducibility Studies

For characteristics specified by Emergent Manufacturing Solutions, the supplier must perform Gauge R&R studies using procedures described in Measurement Systems Analysis published by AIAG. Emergent Manufacturing Solutions must approve R&R values greater than 10 percent of the tolerance.

Normally for variable gages, three different operators measure ten samples three times each. For attribute gages, an Attribute Gauge Study (long method) is required. Emergent Manufacturing Solutions must approve any alternative methods.

3.5 Gauge Correlation Studies

For characteristics specified by Emergent Manufacturing Solutions, the supplier must perform a gauge correlation study. This consists of the supplier identifying, measuring and recording a specified number of production parts. The supplier then sends the parts to Emergent Manufacturing Solutions for measurement. Emergent Manufacturing Solutions compares their

measurements with the supplier's measurements to determine the correlation between the gages.

3.6 Process Capability Studies

Process Capability (Cpk) is a comparison of the inherent variability of a process output to specification limits *under statistically stable conditions*. There are several techniques for assessing the capability of processes. Emergent Manufacturing Solutions suppliers must use methods defined in Statistical Process Control (SPC) published by AIAG for determining process capability and process performance, unless an alternate method is approved in writing.

A C_{pk} value of at least 1.50 is required for critical dimensions.

3.7 Failure Modes and Effects Analysis

When requested, the supplier must perform a Process Failure Modes and Effects Analysis (PFMEA) and submit it for approval. For parts and assemblies designed by the supplier, the supplier should also perform a Design Failure Modes and Effects Analysis. The PFMEA considers all reasonably foreseeable potential failure modes of each process. Based on the potential seriousness and likelihood of the problem, the supplier develops manufacturing controls. The PFMEA should be a living document, and should be updated when process changes occur, or when defective material is produced. PFMEA methods and examples can be found in Potential Failure Mode and Effects Analysis published by AIAG.

3.8 Control Plan

When requested, the supplier must develop a control plan, and submit it for approval. The control plan is a detailed description of the supplier's proposed processing steps required to produce the part, and the controls that are put into place to control the quality at each step. The control plan must include all in-house processing, external processing, inspection, packaging, and shipping. Suppliers may use their own format. Measuring devices and fixtures designed and built to check Emergent Manufacturing Solutions' parts must be identified with a gage number and drawing and must be listed on the control plan.

The control plan must include all critical characteristics. Where detailed instructions are required, the supplier details those instructions in a work instruction, or equivalent, which must be listed in the control plan. Inspection methods, sample sizes, and sampling frequencies should be based on the process capabilities, seriousness and likelihood of potential non-conformances, and process stability. Critical characteristics that do not meet process capability requirements must be inspected 100%, unless alternate control methods are approved in writing.

3.9 Material Safety Data Sheets and IMDS Submission

As applicable, Material Safety Data Sheets (MSDS) must be provided during the First Article Inspection process. Additionally, IMDS submission must be complete before sample parts are sent to Emergent Manufacturing Solutions, if required.

3.10 Agency Approvals and Compatibility Reports

The supplier is responsible for providing the proper agency approval test reports per requirements. Examples are UL, CE, FCC, TUV, etc. The supplier is also responsible for agency test reports from their sub-supplier or other outside test agencies, as required.

The suppler is responsible for submitting test results that verify compatibility as required (USB,

1394 etc.). Testing may be done by the supplier or by a test facility certified by the supplier.

3.11 Packaging and Labeling

The supplier must adequately plan for packaging of material shipped to Emergent Manufacturing Solutions. The supplier will provide a documented packaging plan including container size, number of parts per container, packaging configuration, etc. Packaging will be designed to provide protection from any damage that may occur. Packaging, labeling, and shipping materials must comply with the requirements of common carriers to secure the least amount of transportation costs.

3.12 Traceability

The supplier must plan for traceability of components. The supplier will provide a written plan specifying how components will be marked with serial or lot numbers and date codes if required, or how containers will be identified with lot numbers or date codes if component marking is not required. The plan will also include sizes of lots or batches. Where possible, batch sizes should be minimized to aid in containment should quality problems be found.

4. MANUFACTURING CONTROL

4.1 Process Control

All Emergent Manufacturing Solutions suppliers are required to control all manufacturing processes in accordance with the control plan, which is approved during part qualification.

4.2 Statistical Process Control

Where specified in the control plan, the supplier is required to apply effective statistical process controls. Effective controls must include:

- The control chart displays control limits that are correctly calculated (specification limits may not be used as control limits)
- The control chart is at the process area, visible to the operator, or persons who are responsible for controlling the process
- For each out-of-control condition, actions are taken to bring the process back into control. Actions taken to bring the process back under control are recorded.
- Product produced during any out-of-control condition is sorted, scrapped, reworked or dispositioned through the supplier's material review process

4.3 Process Performance Requirements

Process Performance (Ppk) is the comparison of the actual process variation to the specification limits. When required to submit process performance data, the supplier must report process performance using the Emergent Manufacturing Solutions provided calculations sheet. Any other method must be approved in writing by the Emergent Manufacturing Solutions Engineering Services team.

A P_{pk} value of at least 1.33 is required for critical characteristics. Failure to meet the minimum requirement requires both containment and improvement plans.

A P_{pk} value of at least 1.00 is required for all other characteristics. Suppliers are not required to calculate and report process performance for non-critical characteristics, unless specifically requested by Emergent Manufacturing Solutions. When specified, other characteristics failing to meet the minimum requirement also require containment and

improvement plans.

4.4 Process Improvement

Out-of-control or unstable processes (which have assignable causes) and processes that do not meet the minimum C_{pk}/ P_{pk} requirements must be identified and corrected. The Supplier must also improve processes with low yield rates.

4.5 Lot Control

A lot consists of product of one part number and revision that are made at the same time, under the same processing conditions, from the same lot of raw materials. The primary purpose for identifying lots is to determine the scope of actions that must be taken when problems arise during further manufacturing or with customers. Each container of material shipped to Emergent Manufacturing Solutions must be identified with the Supplier's lot number. Inspection records must be traceable to lot numbers.

The following are typical conditions that result in a change of lot numbers:

- Change of part number or revision
- Change of part number or revision of components
- Interruption of continuous production (typically for more than a few hours)
- Repairs or modification to the tooling or equipment
- Tooling changes (other than minor adjustment or replacement of consumable tooling)
- Change to a different lot of raw materials
- Process changes

4.6 Traceability

Traceability ties the finished product back to the components used in production. When individual unit traceability is specified, the traceability marking should be effective down to the individual component (lot code, batch, and serial number) and traceability must be provided in a manner that stays with the unit through additional processing. For example, the component should be marked in such a way that it is affixed to the part through ink or other suitable marking means as opposed to an external sticker on a box, bag, or carton.

4.7 Workmanship

When workmanship standards are not referenced on supplied drawings or specifications, the supplier is expected to follow industry-accepted standards (e.g. ANSI, IPC, MIL). When in doubt, consult with Emergent Manufacturing Solutions for clarification.

4.8 Safety

At no time should any customer, or person at an Emergent Manufacturing Solutions facility, be exposed to hazardous material or situations that are not inherent in a component's structure. Residues, films, out-gassing products and packaging materials should comply with OSHA (Occupational Safety & Health Association) standards. For items with inherent hazards, safety notices must be clearly observable. As applicable, MSDS sheets must be provided during the First Article process.

4.9 Maintenance

The supplier must maintain all facilities, manufacturing machines, tools, measuring devices, and other equipment in such a manner that the supplier can support Emergent Manufacturing Solutions' production requirements, and the quality of parts manufactured is not degraded in any way.

5. DRAWINGS AND CHANGES

5.1 Drawing and Change Control

The supplier must have a documented system for assuring that the latest drawings are in effect at their facility. 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. In addition, the procedure must address control of obsolete drawings and specifications. A documented procedure should also detail the method used to contain new or modified parts until approved by the customer.

5.2 Process AND Engineering Changes

Suppliers must have systems in place to control changes to drawings, specifications, processes, or produced parts. Systems should be able to handle changes requested by the customer and supplier.

NOTE:The First Article approval process is directed at a given part number for a specified revision level produced in a specific area of the manufacturer's facility. Suppliers may not make any changes in their process, location, material, or to the part without written approval from Emergent Manufacturing Solutions.

5.3 Supplier Process Change Request

A Supplier Process Change Request is used to request a change to a released part, process, drawing, or specification. Emergent Manufacturing Solutions encourages use for process improvement with the stipulation that before an SPCR is submitted, the supplier thoroughly reviews their FMEA and control plan to assure that all process-related issues have been addressed and resolved.

The originator of an SPCR includes the following information:

- Drawing or part number
- Drawing or part title
- Description of problem or recommended change
- Reason for change or "rationale"
- Proposed effective date

The supplier submits the SPCR with the revised FMEA and control plan (if applicable) to the Emergent Manufacturing Solutions Engineering Services team for evaluation of the following:

- Supplier-demonstrated process capability and stability
- Comparison to First Article data
- Industry standards
- Supplier process engineering capabilities
- Supplier's adherence to control plan

After review, Emergent Manufacturing Solutions will notify the supplier as to the final disposition of the SPCR and part submittal requirements and dates.

When monitoring is required, the appropriate markings must be identified on the parts for a specified time frame as decided jointly with Emergent Manufacturing Solutions and the supplier.

5.4 Supplier Deviation Request

A supplier is never permitted to knowingly ship product that deviates from the print, specification limits, or design intent without written authorization from Emergent Manufacturing Solutions. If such a condition exists, the supplier may request to allow shipment of the product. This is accomplished by initiating a Deviation Request.

If directed, the supplier must send samples of non-conforming items for evaluation. The cost of testing required to determine the product's acceptability will be charged to the supplier. Emergent Manufacturing Solutions will determine the item's acceptability and what corrective actions (if any) are required beyond the deviation. If approved, written deviation approval will be sent to the supplier.

The deviation is only intended to be an interim action and **is not** to be construed as an engineering change. The supplier must begin work immediately to correct the condition in question. This must be accomplished within the time frame stated on the deviation. Failure to comply with the mutually agreed upon closure date for the deviation may result in the supplier's rating being affected.

In all cases, the supplier must fully contain all product suspected of being non-conforming at their facility. In addition, the supplier may be required to sort any suspect already received by or in transit to Emergent Manufacturing Solutions, including on-site sorting at an Emergent Manufacturing Solutions customer if required. Costs and/or charges incurred by the supplier for sorting, disposal, or transporting of suspect or non-conforming goods are the responsibility of the supplier and not transferrable to Emergent Manufacturing Solutions. Refer to §8.3 Non-Conformances for additional information.

Any parts shipped on an approved Deviation must be clearly identified on the box, container, or other packaging method with the appropriate markings decided jointly by Emergent Manufacturing Solutions and the supplier.

6. PACKAGING AND LABELING

6.1 Packaging

Each supplier must adequately plan for packaging. Suppliers will provide packaging that provides protection from any damage that may occur. Packaging must protect the components from contamination, including fibers from the packaging materials. Packaging, labeling, and shipping materials must comply with the requirements of common carriers, in a manner to secure the lowest transportation costs.

Expendable materials and packaging must be legal and safe for standard "light industry" disposal. The preferred maximum weight of manually handled packs is 40 lbs. The maximum acceptable weight is 45 pounds, unless approved in writing.

Only one part number and one supplier lot are to be packaged per container. When more than one part number or lot number is packaged in a crate or on a skid, each part number and/or lot number must be separately packaged inside the container, with each labeled as to the contents. A Master Label specifying the part number(s), lot number(s), and quantities of each part must be affixed to the crate or skid exterior and must be clearly marked "MASTER SKID LABEL".

6.2 Labeling

Each shipping container or inside package must contain the following information:

- Part Number
- Quantity
- Supplier's Name
- Purchase Order Number
- Lot identification
- Deviation number, PPAP approval number, sample approval number, or other identifying lot traceability reference(s) as required

Labels may be color coded at supplier's discretion except RED and NEON ORANGE. Red and neon orange labels may never be used to label conforming product shipped to Emergent Manufacturing solutions.

7. CORRECTIVE ACTION SYSTEM

Suppliers are required to utilize a closed-loop corrective action system when problems are encountered in their manufacturing facility, or after nonconforming product has been shipped to Emergent Manufacturing Solutions.

7.1 Corrective Action Process Approach

The corrective action system utilized should be similar to the process outlined below. The focus should be on identifying the root cause(s) of the problem and preventing its recurrence.

- Use a team approach
- Describe the problem
- Contain the problem
- Identify and verify root causes(s)
- Implement permanent corrective actions
- Verify corrective action effectiveness
- Close the corrective action

7.2 Supplier Corrective Action

Emergent Manufacturing Solutions issues a Corrective Action Request (CAR) to a supplier when non-conforming parts are found at incoming inspection, in production, in test, or by an Emergent Manufacturing Solutions customer. They may also be issued because of a supplier audit. The supplier must respond by returning the CAR back to Emergent Manufacturing Solutions by the agreed date. The following provides a brief outline of the CAR procedure that suppliers should comply with:

- Company XX requires that the supplier take immediate containment action upon notification of the nonconformance. The supplier must submit a written response to Company XX, reporting 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.
- The containment plan must clearly define the containment actions at the supplier's facility to assure that no nonconforming product is shipped to Emergent Manufacturing Solutions. If suspect product has already been shipped, the supplier must address all suspect stock in transit and any stock at Emergent Manufacturing Solutions. The supplier will assist Emergent Manufacturing Solutions in identifying customer risk by identifying all suspect lot numbers and associated quantities involved.
- Within 2 weeks after the original notification, the supplier must report the results of the Supplier's investigation into the cause of the problem.

- Within 3 weeks from the initial notification date, the supplier must submit the corrective action to be taken to prevent recurrence of the problem, and the effectivity date (the date the corrective action will be implemented.). Actions such as “train the operator,” “discipline the operator,” or “increase inspection,” are typically not acceptable corrective actions.
- The supplier is required to keep Emergent Manufacturing Solutions informed of progress towards implementing the corrective action. When corrective action implementation is complete, the supplier and Emergent Manufacturing Solutions verify that the corrective action is effective in preventing the problem’s recurrence.

8. DOCK-TO-STOCK (DTS)

Emergent Manufacturing Solutions utilizes a Dock-to-Stock (DTS) policy to reduce the problems associated with receiving nonconforming product from suppliers, while minimizing incoming inspection and speeding up the process of moving product to production.

Suppliers with all parts on DTS and high ongoing quality performance are Preferred Suppliers. Preferred Suppliers are given first opportunity to quote for new business and are given preference for increased volumes when consolidating suppliers for multiple-source items.

Emergent Manufacturing Solutions administers the DTS program on a part-by-part basis. DTS applies to all material and components purchased for use in released product. It does not include pre-released parts, samples, prototypes, pilot runs, First Articles for new tooling, and other low volume applications. DTS material will be moved directly into production, bypassing incoming inspection.

8.1 Dock-to-Stock Requirements

The supplier attains Dock-to-Stock status with each proposed part by meeting the following criteria:

- For non-critical parts, the part achieves DTS status upon First Article qualification, assuming all other requirements are met as detailed below
- For critical parts, the supplier must be qualified through an on-site quality management system assessment. At Emergent Manufacturing Solutions’ discretion, the formal on-site assessment may be waived with a fully completed supplier self-assessment.
- For critical parts, the most recent three lots received must have passed all incoming inspections
- The part must have no outstanding corrective action requests (CARs) for issues affecting form, fit, function, reliability, or customer acceptance
- The 3-lot requirement may be waived on critical parts if the supplier can show Ppk values of 1.67 or higher on three consecutive runs

For products shipped as complete, sealed, point-of-sale items from the supplier, Emergent Manufacturing Solutions will determine if that product may be placed on DTS immediately. This decision is based on the supplier test and manufacturing process/capability and availability of equipment to do meaningful testing.

If a supplier produces a part in more than one facility, each facility must qualify individually for DTS.

8.2 Dock-to-Stock Suspension

The supplier is placed on DTS suspension when any of the following conditions occur:

- A lot fails an incoming inspection audit.
- A supplier-caused CAR is initiated for an issue affecting form, fit, function, reliability, or customer acceptance
- The supplier fails a quality management system assessment
- A control plan audit shows the supplier is not following their approved control plan

If DTS is suspended, Emergent Manufacturing Solutions personnel investigate and determine whether the suspension extends to other part numbers/tools furnished by that supplier, issues a Corrective Action Request (CAR) if a CAR has not already been issued, and works with the supplier to correct the problem.

When the supplier's DTS status is returned to good standing, Emergent Manufacturing Solutions notifies the supplier of the change in status.

If a supplier does not implement effective corrective action, or if the supplier is put on suspension repeatedly, Emergent Manufacturing Solutions determines whether the supplier's DTS status should be discontinued. This decision may also include a decision to move the business to an alternate supplier.

8.3 Non-Conformance

In the event non-conforming material is shipped to Emergent Manufacturing Solutions, the supplier is solely responsible for remedying the situation. This may include, but is not limited to, sorting product at an Emergent Manufacuring Solutions facility, sorting product at an Emergent Manufacturing Solutions' customer facility, or arranging and paying for return shipment to the supplier facility to sort and/or dispose of non-conforming material. At the supplier's discretion, a third party may be hired to sort product at an Emergent Manufacturing Solutions facility. Where personnel for sorting activities come from the supplier's own site or are higher through a third-party, all representatives must be able to furnish ITAR compliance documentation upon arrival.

In the event a supplier does not respond to an escape notification within two business days, Emergent Manufacturing Solutions reserves the right to sort product in-house and charge back the supplier at a rate of $100 per hour, per person. If Emergent Manufacturing Solutions must sort product at a customer facility due to supplier non-response, Emergent Manufacturing Solutions reserves the right to charge back the supplier at a rate of $150 per hour, per person, plus associated travel costs at $30 per hour, per person, plus actual mileage at the IRS currently established rate for mileage reimbursement.

9. SUPPLIER MONITORING

Emergent Manufacturing Solutions continually monitors its suppliers to ensure they continue to meet requirements and to ensure that the supplier continues to ship acceptable parts. This may consist of:

- A quality management system surveillance audit at the supplier's facility
- An on-site audit of the supplier's control plan
- A random incoming inspection audit of a batch of product
- Source inspection of product at the supplier's facility
- Nth Article Inspection
- Review of supplier-furnished data packages
- A supplier progress review meeting conducted periodically at the supplier's site or Emergent Manufacturing Solutions to review supplier performance and progress

9.1 Supplier Audits

Periodically, Emergent Manufacturing Solutions may audit the supplier's quality management

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

Periodically, Emergent Manufacturing Solutions may also audit the supplier's continuing conformance to the control plan approved in the First Article process.

9.2 Inspection Audits

Emergent Manufacturing Solutions expects its suppliers to furnish material that conforms to all requirements, and that does not need to be inspected when received. Material that has not achieved Dock-to-Stock status, or that is on DTS suspension, is inspected on a lot-by-lot basis. Emergent uses a C=0 sampling plan that rejects the entire lot when a single non-conforming part is found in the sample. At Emergent Manufacturing Solutions' discretion, to meet production requirements, 100% sorting may be done as necessary at the supplier's expense. Refer to §8.3 of this manual for more information.

Emergent Manufacturing Solutions may inspect product at the supplier's facility to detect potential problems prior to shipment. Emergent may also inspect product at sub-tier suppliers.

9.3 N^{th} Article Inspection

The supplier must perform **annual** Nth Article Inspection of critical parts to verify continuing conformance of the part to the specification. This is also required if an engineering change affecting form, fit, or function occurs.

The supplier must perform a **semi-annual** (once every two years) Nth Article Inspection of each non-critical part and is also required if an engineering change affecting fit, form, or function occurs.

Nth Article Inspection must also occur any time there is a manufacturing lapse of one year or greater. This requirement is for both critical and non-critical parts.

For all sub-components, the manufacturing supplier is responsible for ensuring that the components that make up each assembly are qualified and monitored through the supplier's own part qualification system.

At the discretion of Emergent Manufacturing Solutions, Nth Article Inspection can be postponed beyond, or required prior to, the annual expiration. Considerations such as component volume, program life cycle and supplier/part performance are used in the decision to pull in or extend the requirement for Nth Article.

9.4 Supplier-Furnished Lot Documentation

Emergent Manufacturing Solutions 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 time the lot is shipped. All documentation must be attached in password protected file(s) or folder(s) and passwords, if emailed, must be sent in a separate email with a different subject line.

When specified, the supplier must submit monthly data packages. Data packages typically consist of copies of control charts and process capability calculations for specified characteristics.

Once the supplier has completed two consecutive quarters of data submissions, the supplier may request elimination of the data submission if records show that the characteristic consistently satisfies requirements for process stability and process performance, and if the characteristic has caused no problems in subsequent production processing. Emergent Manufacturing Solutions will notify the supplier in writing if the data submission may be discontinued.

10. NOTES

10.1 Revision Indicator

Revision information is available in the revision table at the end of this document. No revision indicators are embedded in the document itself; previous revisions of this or any other document are archived in the QMS and available upon request.

11. REVISION HISTORY

Document Name	Supplier Quality Manual
Document Owner	Quality Manager or Delegate
Document Level	Level 0 - Manuals

Rev	Date	Section	Add Remove Update	Revised By:	Approved By:
Original	9/11/2023	All	Add	JF	SC; JR
A	10/3/2023	Header 1.4	Remove Add	JF	SC; JR
B	05/03/2024	Footer All	Update: Controlled copies on BLUE General grammar updates throughout document	JF	SC; JR
C	06/03/2024	§1.5 §1.6	Add Add Changes made to satisfy audit finding TNR-451966	JF	JR; SC