Eclipse Engineering

Note: any reference within this manual to **the company** will apply to the entity you are working with.

Supplier Quality Manual QMSP-023 REV 2.0

Table of Contents

Quality Policy Statement	4
Scope	4
Definitions	5
Quality Requirements	6
Supplier Performance	12
TAR Compliance	17

Distribution: This manual is a Controlled Document within Eclipse Engineering's electronic system <u>only</u>. The copy a supplier receives, or downloads is for reference only. It is Eclipse Engineering's responsibility to maintain the most current revision on our website. IT IS THE VENDORS' RESPONSIBILITY TO ENSURE THEY ARE WORKING FROM THE MOST CURRENT POSTED REVISION.

Quality Policy Statement:

Policy Statement

It is the goal of Eclipse Engineering to provide our customers with products that meet or exceed the established requirements. Eclipse Engineering will strive to continually improve our processes, products, on-time delivery, and our customer satisfaction.

Scope

The Supplier Quality Manual defines the minimum requirements for suppliers doing business with Eclipse Engineering. Suppliers are expected to conform to requirements as listed out in the P.O. or referenced in this Supplier Quality Manual, part specific instructions and any regulatory or statutory requirements.

Definitions

- 1. Attribute Data Dimensional data reported as Pass/Fail, Go/No Go.
- Certification of Compliance: A document provided by the supplier that
 accompanies each lot, stating that the scope of work outlined on the part
 specific work instruction has been met. See clause 1.5 for complete list of Certification of
 Compliance requirements.
- 3. **Corrective Action** Action to eliminate the cause of a detected nonconformity or other undesirable situation.
- 4. **Deviation** A change or shift in the process from what is usual, accepted, expected, or planned. Supplier must request a deviation when processes or run failures require changes from the norm.
- 5. **Lot** Definite quantity of an item/part produced under uniform conditions and passing as a unit through the same series of operations.
- 6. **MRR** Material Rejection Report. Material is non-conforming to the applicable work instruction or regulatory requirements.
- 7. NDT Non-Destructive Testing
- 8. **Procedure** A documented way to carry out an activity or a process.
- Process Controls- The methods used to monitor and improve the quality output of a manufacturing process.
- 10. **Process Validation** means establishing by objective evidence that a process consistently produces a result or product meeting its predetermined specifications, when processed within the allowable window.
- 11. **Work Instruction** A document containing detailed instructions that specify exactly what steps to follow to carry out an activity.
- 12. **Record** document stating results achieved or providing evidence of activities performed.
- 13. **SCAR** Supplier Corrective Action Request. Method by which non-conforming quality conditions are documented and reported to the supplier. A corrective action is required as a component of the response.
- 14. Variable Data Dimensional data reported as exact measurement.
- 15. OASIS Online Aerospace Supplier Information System

- 16. **OSP** Outside Service provider
- 17. **FOD** -Foreign Object debris/damage. Contamination on surface of part (i.e. processing media, processing residue), handling, fixturing, or other objects which could potentially cause damage to parts.
- 18. **Cp** Measures how well the distribution of the data fits within the tolerance band (USL-LSL) regardless of how centered the data is.
- 19. **CpK** measures how well the distribution of the data fits between the specification's limits taking into consideration distribution and centering of the data.

Quality Requirements

1. Procedure

1.1.General

- **1.1.1.** It is the responsibility of the vendor to ensure all person and process are capable, have the required competencies including the required qualifications of persons performing Eclipse Engineering work.
- **1.1.2.** Lot integrity must be maintained throughout all processing steps.
- **1.1.3.** Parts must be handled in such a manner that dimensional and visual characteristics will not be affected.

1.2. Specification Flow down

- **1.2.1.** It is the responsibility of the supplier to flow down any applicable company requirements to sub suppliers of their process (i.e., raw material).
- **1.2.2.** If required vendors will use customer designated or approved external providers, including process sources (e.g., special processes)

1.3. Process Control

- Suppliers should have, and adhere to, a documented system of process controls (i.e., work instruction, FA direction). These controls form the basis for a quality plan that must be approved formalizing the process that must be adhered to until another plan is approved by the company.
- Suppliers are expected to record and hold data generated from these control measures as required in the Part Specific Work Instruction and section 1.9 of this Supplier Quality Manual.

When requested, the supplier will provide evidence of capability.

1.4. Non-Conforming Product

- **1.4.1.** Suppliers must request a deviation when processes or run failures requiring changes to an approved process.
 - Suspected Lots will be placed on hold Pending the company's response to the deviation request.
 - The company's initial response may begin via email to speed recovery or enhance throughput. Formal written documentation must follow.
 - Deviation requests are granted through Quality designee.
 - If parts are non-conforming, the company reserves the right to reject and return at the supplier's expense.
 - When requested by the company, non-conforming product, including NDT rejects, are to be returned to the company separate from conforming product and clearly identified with the company job number and reason for rejection.

COUNTERFEIT PARTS: For suppliers, the organization must plan, implement, and control processes, appropriate to the organization and the product for the prevention of counterfeit or suspect counterfeit part use and their inclusion in products delivered to the customer.

- **1.4.2** Suppliers ensure that counterfeit goods are not delivered. The purpose is to develop a robust process to prevent the delivery of counterfeit commodities and control commodities identified as counterfeit.
- 1.4.3 Suppliers purchase products to be delivered or incorporated as goods to the buyer directly from the authorized distributor chain or authorized reseller. These products are traceable to authorized distributor chain, aftermarket manufacturer, or authorized reseller that identifies the name and location of the supply chain to the direct source of the product. If goods can only be acquired from independent distributors or brokers in cases of diminishing material supply (DMS) or obsolescence, written notice shall be provided to this facility Quality Lead and Buyer prior to procurement of these goods. After written approval from this facility is received by supplier, goods may be subjected to testing and screening process appropriate to the commodity using an approved third-party laboratory. Records of evidentiary tests and

inspections performed that ensure verification of the goods are provided for review and approval from Quality prior to delivery. Written notice is not required for raw material purchased from independent distributors or brokers, but products must be able to provide commodity level traceability. The Supplier provides written notification to Quality and Buyer if the supplier becomes aware or suspects that it has furnished Counterfeit Goods within 24 hours. Supplier provides Quality and Buyer, upon request, the supply chain traceability to an Original Manufacturer or authorized distributor chain that identifies the name and location of the supply chain from the manufacturer to the direct source of the product. Suppliers have a process in place to ensure Counterfeit goods are contained and do not reenter the supplier chain.

1.5. Certification of Compliance

1.5.1. A certificate, to accompany each lot, stating that the parts supplied complies with the requirements of the part specific work instruction.

The certificate must include, but is not limited to the following items:

- The company purchase order number.
- The company drawing numbers and revision alpha identifier.
- Company Job number
- Quantity
- CpK data sheet if required by part specific work instruction.
- Ship Date
- Any additional documentation as out lined in the P.O.
- **1.5.2.** A hard copy shall be enclosed with the parts affixed to the outside of box one. The second copy if requested on the P.O. shall be emailed along with certs and data to karen@eclipseseal.com. Include Company Job number and part number in the subject line of this email.

Suppliers providing certificates of analysis will work with Eclipse Engineering periodically to obtain blind sampling of their material for compliance and traceability.

1.5.3. Suppliers who ship directly to the company's customers or drop ship

to another supplier must adhere to the requirements of 1.5.2. by providing documentation electronically to the email of the CSR the order came from. Once Eclipse has received the product in our system the CSR will email the required shipping documents to the vendor for inclusion in the shipment.

1.6. Calibration

- **1.6.1.** To ensure conformance to specifications of shipments to the company, only calibrated gages and equipment can be used to certify the product.
 - If calibration system does not exist, gages used to check product conformance shall be verified prior to use. The company may supply gages to check product conformance.
 - Records of calibration must be maintained as well as records showing compliance with measurement standards and traceability to NIST.

1.7. Change Control

- **1.7.1.** Suppliers are expected to maintain a process for change control.
 - The company must be notified of any changes that affect form, fit, or function including changes to the location of processing, major changes to the equipment used to process the parts, changes to qualification techniques or changes to suppliers of raw material or process media/chemicals. All changes must be denoted.
- **1.7.2** Approval by a company designee is required prior to implementing any changes.

1.8. Validation

- **1.8.1.** When required by the PO or part specific work instruction, suppliers are expected to submit Validation (IQ, OQ, PQ) of the process using the following guidelines.
- Note: Validation requirements, special requirements, critical items, or key characteristics that are required will be listed on the P.O.. But the vendor is required to follow the process steps included in this section.
 - **IQ Installation Qualification** Establishing by objective evidence that all key aspects of the process and ancillary system installation adhere to the manufacturer's approved specification and that the recommendations of the supplier of the equipment are

considered. *Items listed below are required for minimal compliancy.*

- Equipment/System Description
- Preventive Maintenance
- Equipment Calibration
- Calibrated Test Instruments
- Utilities
- Safety
- Equipment Functionality

OQ Operational Qualification- Establishing by objective evidence process control limits and action levels which result in product that meets all predetermined requirements. *Items listed below are required for minimal compliancy.*

- Equipment/System Description
- Training Records
- Equipment Calibration
- Test Materials
- Critical Process Parameters
- Challenge Limits (upper and lower)
- Acceptance Criteria
- Sampling Plan
- Calibrated Test Instruments

PQ Performance Qualification- Establishing by objective evidence that the process, under anticipated conditions, consistently produces a product which meets all the predetermined requirements. *Items listed below are required for minimal compliancy.*

- Equipment/System Description
- Training Records
- Equipment Calibration
- Test Materials
- Nominal Process Parameters
- Acceptance Criteria
- Sampling Plan
- Calibrated Test Instruments

Note: As deemed necessary by Eclipse Engineering some or all validation activities may be done at the supplier location and witnesses by an agent of Eclipse Engineering.

1.9. Record retention.

- **1.9.1.** Suppliers are required to have a documented record retention procedure. Retention requirements must meet the minimum requirements outlined in the table below unless otherwise specified in part specific work instructions per end customer requirements.
- **1.9.2.** Records must be maintained in either a hard copy or electronic copy and must be protected or electronically backed up to ensure they remain legible, identifiable, and retrievable.

Supplier Record Retention Matrix				
Document	Retention Time			
Control Charts (as applicable)	Indefinite			
Process Plan/ Item Master	Life of part + 1 year or 7			
	Year's minimum			
Tooling Records	Life of part + 1 year			
Work Instructions, Processing	Life of part + 1 year			
Documents (i.e., control charts				
process flow, programs, etc) not				
supplied by the company				
Certificate of Conformance	Indefinite			
Evidence of Processing History (i.e.,	Indefinite			
Job Routers/ Travelers)				
Lab Test Reports	7 Years			
Raw Material Certs	7 years			
Gage Records	7 years			

Inspection reports	Indefinite
Medical / Aerospace Records	50 years

1.10 Right of Access

1.10.1 Eclipse Engineering its customers and regulatory authorities, have the right of access to the supplier's facility/facilities and supply chain and to witness process, product, and records activities.

1.11 Related Documents

- Deviation request
- First Article/PPAP / AS9102

II. Supplier Performance

2.1 Procedure

2.1.1 Purchasing completes an on-site survey or requests that the supplier complete the survey. The form can be completed by either the supplier or an approved company auditor. The list of documents that will be requested prior to addition to the approved supplier list is as follows.

Note: The list below is not all inclusive and each item is not required from

• Non-disclosure Agreement (Required, for OSP. Tooling and Raw Material)

every supplier, items are requested based on the product or services being provided as well as the critical nature of the product or services.

- Insurance Certification
- Supplier Survey (Required, for OSP & Tooling)
- W-9 (Required)
- Quality Manual, Quality Management System, or other process validation evidence
- Certifications

2.2 Process Capability

- **2.2.1** When requested, the supplier will provide evidence of capability.
- **2.2.2** Process capability calculations are to use Cp and Cpk Process Capability Metrics

Cp, Cpk Formula (For Reference Only)

$$Cp = \frac{(USL - LSL)}{6\hat{\sigma}}$$

$$CpU = \frac{(USL - \overline{X})}{3\hat{\sigma}}$$

$$CpL = \frac{(\overline{X} - LSL)}{3\hat{\sigma}}$$

$$Cpk = Min(CpU, CpL)$$

Note: Eclipse Engineering will often refer to capability requirements in terms of Cpk values. If Minitab is used to calculate process capability on a lot-by-lot basis the Ppk value should be used. This is a calculation of the capability of the overall data set. The Cpk value is a view of what the process *may* be capable of based on the best-case subset of the data population and is therefore inappropriate to use for calculating the true process capability of a data set.

2.3 Supplier Expectations

- **2.3.1.** Process parts to comply with part specific work instructions, Supplier Quality Manual and any requirements as listed on the purchase order or required by the supplier Quality Management system.
- **2.3.2.** The company requires all suppliers to strictly adhere to the inventory practice of, FIFO (First In First Out).
- **2.3.3.** The supplier is expected to inform the company within 48 hours of any changes to the approved process.
 - Any changes to the supplier's certification status must be forwarded to the company within 24 hours and formal notification within 48 hours. Suppliers must stop all processes until further notice from the company Quality Manager.

2.4 Supplier **Evaluation Summary**

2.4.1. Annually, active suppliers will be evaluated by the Vendor Review

Board (VRB) consisting of representatives from Purchasing, Planning & Quality. The VRB will assess each supplier's rating based on items listed and may issue a Supplier Score Card to active vendors on the Approved Supplier List. If the vendor was not used in the recent quarter, they will not be scored. VRB meetings will address:

- Delivered product quality.
- Adherence to the requirements of the P.O. (i.e. Eclipse's ability to receive at receipt, all documentation and other requirements delivered on time)
- Process Control
- Customer disruptions (SCARs, RMAs, and Quality Alerts)
- Schedule attainment
- Delivery schedule performance (including premium freight)
- Pricing
- Special status customer notifications related to quality or delivery issues.
- Suppliers certified to AS9100 are expected to utilize the OASIS database. The company shall be granted access to view the supplier's assessment details.

Suppliers should communicate the requirements by ensuring that persons are aware of

- Their contribution to product or service conformity
- o Their contribution to product safety
- o The importance of ethical behavior

Appendix

Reference Documents:

- Revision History
- Deviation Report (sample attached)
- C=0 Sampling Plan (Use most current revision)
- ANSI Z14 Sampling Plan (use most current revision)
- Supplier Corrective Action (Any excepted format will be accepted; QA can provide a copy of the document if needed).
- ITAR

Revision History

Revision	Rev Date	Change Description	Author /
			Approver
1.0	09/28/2021	Released as new.	Quality Lead
1.5	10-30-2023	Updated distribution requirement, Removed acknowledgement page.	Quality Lead
2.0	05/15/2024	Updated 2.1 record retention times to include Aerospace records. Made minor edits for typos and grammar.	Quality Lead

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Deviation Report

Issued By:	Date Issued:
Supplier:	Company Item # / Tracker #:
Process:	Company P.O. #:
Quantity:	Company Work Instruction #, Rev Letter

Description of Deviation:

Cause:

Action Taken:

<u>Customer's Response:</u>

<u>Note:</u> Product will be placed on HOLD pending customer's instructions

ITAR Compliance

The International Traffic in Arms Regulations (ITAR) and the Export Administration Regulations (EAR) are two important United States export control laws that affect the manufacturing, sales and distribution of technology.

The legislation seeks to control access to specific types of technology and the associated data. Its goal is to prevent the disclosure or transfer of sensitive information to a foreign national. Export control laws provide for substantial penalties, both civil and criminal.

ITAR covers military items or defense articles. It regulates goods and technology designed to defend against death in a military setting. It includes space related technology because of applications to missile technology. It also includes technical data related to defense articles and services.

EAR regulates items designed for commercial purposes which could have military applications such as computers or software. It covers both the goods and the technology. Licensing addresses competing interests and foreign availability. Combines commercial and research objectives with national security.

Due to the nature of some of Eclipse Engineering's business, Eclipse operates under ITAR and EAR regulations. Eclipse Engineering is registered with the US Department of State, Directorate of Defense Trade Controls.

As such Eclipse Engineering requires the following:

All new vendors, customers, and visitors, both US citizens and Foreign Nationals to sign a bilateral non-disclosure agreement before any prints, drawings, or models can be shared between parties. A license may also be necessary upon further review. Eclipse Engineering will check all new vendors and customers against the Compliance and Enforcement lists on OCR Software to make sure that we will be conducting business in a legal manner as required by the US Government.

Any vendor that process parts, tools, or does any other outside work must employ US Citizens. They will be expected to read prints and models of parts that may be sensitive and under ITAR/EAR guidelines.

As for cell phones in the facility the following guidelines apply:

1 Employees: Eclipse Engineering is aware of the rules regarding the export of technical information, and we relay that to our employees. Essentially, we make them aware that

- they're not allowed to take pictures for personal use or to share with anyone for any reason, without going through your facilities documented compliance procedure.
- **2 Foreign National Visitors:** Foreign national visitors should not be allowed the use of cell phones or other photographic or recording equipment while touring a facility. More importantly, foreign national visitors shouldn't even be exposed to export restricted items, much less have the opportunity to photograph them. Certain areas of the facility are off limits to all foreign national visitors. Your Eclipse Engineering guide will be aware of these areas.
- 3 Other Visitors: Eclipse Engineering has sensitive goods that are subject to export controls, therefore all guests are expected to check-in at the front desk, this is part of our compliance program. Eclipse Engineering can either take this opportunity to simply make guests aware that photography is prohibited. All guests will need to be escorted by Eclipse Engineering employees; we make sure the employee is aware that the guests aren't allowed to take pictures. Remember that even though guests may be US citizens, it's best to error on the side of caution by not exposing them to export restricted material.

Note: Supplier that handle ITAR sensitive materials directly will be given a copy of Eclipse Engineering's ITAR Supplier / Customer Questionnaire that goes into greater detail then the general requirements in this Supplier Quality Manual.