

Supplier Quality Assurance Requirements Manual



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Overview

Zot Engineering Ltd is committed to continually improve the quality level of products and services at our facilities. This document will define general and specific quality requirements to meet the needs and expectations of Zot Engineering Ltd and its customers.

The supplier is responsible for maintaining the current revision of this document when providing products and services to Zot Engineering Ltd

Any questions pertaining to this document should be address to the Quality Systems Manager. Please see our website for contact details www.zot.co.uk

Purpose

The purpose of this document is as a guide to our supplier in understanding the requirements and expectations of Zot Engineering Ltd and its customers. This document will form part of Zot Engineering Ltd purchase order process.

Scope

The scope of this document applies to suppliers who provide products and/or services used by Zot Engineering Ltd in relationship to our Aerospace and Medical Device Accreditation.

This document does not apply to products and services considered by Zot Engineering Ltd as non-medical or non-aerospace products and services. These products and services are used for commercial products and maintenance, such as office supplies and janitorial services.

Requirements listed in the engineering specification and on the purchase order shall take precedence over the requirements of the Supplier Quality Assurance Requirements Manual

1.0 Supplier Quality Assurance Requirements

1.1 General Quality Management System Requirements

The supplier shall maintain a quality management system which complies with industry standards and specification appropriate to the type of product or service provide.

Zot Engineering Ltd strongly recommends our suppliers to be certified or compliant with ISO9001 or BSEN9100. Supplier shall provide a current copy of their certifications to Zot Engineering Ltd.

Recommendations for Supplier Quality Management Systems by supplier type:

Calibration: BSEN ISO10012

Special Process: NADCAP, AC7004, BSEN9100

Manufacturer: ISO9001, BSEN9100, BSEN13485

Pass-Thru Distributor: ISO9001, AS9120

1.2 Changes in Quality Management System

The supplier shall promptly notify Zot Engineering Ltd within five business days of any change in management representation, company name change, ownership, quality system or manufacturing location, supplier or process and where required obtain approval.

The supplier shall submit written notification to Zot Engineering Ltd Quality Systems Manager.

1.3 Employee Awareness

The supplier shall ensure that employee are aware of their contribution to the product or service conformity, the product safety and the importance of conducting the duties inn ethical manor.

1.4 Sub-tier Control

The supplier shall flow down the requirements of Zot Engineering Ltd purchase orders and documented requirements to sub-tier suppliers who provide products and services which are subsequently delivered to Zot Engineering Ltd.

1.5 Right of Access

Zot Engineering reserves the right to perform initial and periodic review of the Suppliers quality system to obtain objective evidence of compliance to an acceptable quality system. Zot Engineering Ltd may honour qualified second and third part audits to provide evidence of compliance to the Suppliers quality system.

Suppliers shall provide Zot Engineering Ltd, Zot Engineering Ltd customers, third party of Zot Engineering Ltd or regulatory agencies access to Suppliers facility and records related to the verification of product conformity.

2.0 Document Control Requirements

2.1 Document Management Requirements

The Supplier shall maintain a document control process which ensures the latest technical data is easily identifiable and available at point of use. The document control system must include provisions for approval, review, update and re-approval. The distribution of documents must be controlled to prevent unintended use of obsolete technical data.

2.2 Revision Control

The supplier shall be responsible for obtaining the correct revision level of technical data as specified In Zot Engineering Ltd purchase orders

2.3 Document Control Audit

The supplier shall conduct an annual internal audit to ensure adequate control of engineering documentation, including drawings, specifications, datasets or other engineering media.

3.0 Control of non-conforming Material

3.1 Documented Nonconforming Material Procedure

The supplier shall have a documented procedure to systematically identify, segregate and disposition nonconforming material to prevent unintended use or release to Zot Engineering Ltd.

3.2 Dispositions

The supplier disposition authority is limited to: Rework to specification, Return to supplier or Scrap.

3.3 Internal Material Review

The supplier shall provide written notification to Zot Engineering Ltd Quality Systems Manager for dispositions which are not listed in this section. Disposition of product or services which affect form, fit, function, safety, weight interchangeability or unique key characteristics require written notification to be submitted on a Material Review document for Zot Engineering Ltd approval.

3.4 Disclosure/Notification of Nonconforming delivered product

The supplier shall provide immediate verbal and written notification to Zot Engineering Ltd.'s Quality Systems Manager and Buyer of nonconforming product released from the Suppliers facility or delivered to Zot Engineering Ltd. The supplier shall notify Zot Engineering Ltd within one business day when a non-conformance is determined to exist or is suspected to exist. Notification must include product name and number, quantity, clear description of discrepancy, release date, purchase order number, and provide root cause and prevention method to correct the process for subsequent shipments.

3.5 Foreign Object Damage (FOD) Prevention Program

The supplier shall promote the awareness of foreign object damage which includes prevention, detection, removal and reporting foreign objects. Zot Engineering Ltd reserves the right to obtain information regarding the FOD knowledge of affected personnel.

4.0 Material Identification and Part Marking Requirements

4.1 Product Identification – General Requirements

The supplier shall ensure all products to be delivered to Zot Engineering Ltd are identified in accordance with purchase order requirements and traceable to the supplier.

4.2 Hardware

Hardware shall be identified by manufacturer, date of manufacture or date control number, such as the batch number, lot number, eat lot number, or serial number for traceability purposes. When size of hardware prevents individual identification, identification shall be placed on bags, tags or labels as applicable.

4.3 Raw Material

The supplier shall provide certifications of metal materials which include the mill certificate or material test report. Test reports must include the chemical and physical analysis for product shipped to Zot Engineering Ltd.

4.4 Shelf Life Materials

The supplier shall provide certification which indicates the manufacture date, lot number, expiration date or length of shelf life and storage requirements. No more than 20% of shelf life shall have expired for any item of product requested on the purchase order. Zot Engineering Ltd shall reject items where the shelf life has expired by more than 20%.

4.5 Counterfeit Parts

The supplier shall plan, implement, and control processes for the prevention of counterfeit or suspect counterfeit part use and their inclusion in products supplied.

5.0 Inspection Requirements

5.1 First Article Report and Approval Requirement

Where specified on the purchase order, the supplier shall perform first article inspection (FAI) and provide documentation of manufactured product in accordance with the requirements of BSEN9102 First Article Inspection Report on the sae.org website. Supplier shall obtain approval on first article inspections from Zot Engineering Ltd Buyer, prior to subsequent shipments to Zot Engineering Ltd.

5.2 Release of Products and Services

The supplier is responsible for the conformity and required documentation of products released to Zot Engineering Ltd. The supplier shall perform appropriate inspection activities to ensure product conforms to specified requirements. If the supplier does not perform 100% inspection prior to release, the inspection sample plan must be approved by Zot Engineering Ltd.

Product will be released to requirements specified on our purchase order as follows:

Product to be released to requirements of BS EN ISO 9001

Product to be released to requirements of BS EN 9100

Product to be released to requirements of BS EN 13485

Appropriate certification i.e. C of C must accompany release and where specified test/ inspection reports.

5.3 Source Inspection

Zot Engineering reserves the right to perform source inspection activities at the Supplier's facility. The Supplier shall ensure product is not released to Zot Engineering if source inspection is required by Zot Engineering Ltd.

5.4 Tooling Inspection Requirements

The Supplier shall ensure tooling, used for inspection purpose, are included in the Supplier's periodic calibration program. Suppliers shall provide evidence of periodic tool inspection activities to Zot Engineering Ltd on request.

6.0 Shipping Documentation Requirements

6.1 Shipping Document

The supplier shall provide shipping documents including a delivery note, a certificate of conformance and applicable documentation to support product conformity

6.2 Packaging Method

The supplier shall ensure product is packaged in accordance with industry standards to prevent damage and deterioration through the delivery process.

7.0 Quality Records Requirements

7.1 Quality Records Maintenance Process

The supplier shall maintain quality records which provide evidence that processes meet requirements or conformity to requirements is evident. Quality records must be in English, legible, identifiable, appropriately stored to protect from damage, deterioration or loss and easily retrievable for review.

7.2 Type of Records.

Records include but are not limited to:

- Test Results
- Inspection Reports
- Raw Material Certificates
- Special Process Certificates
- Certificate of Conformance
- Material Review Reports
- Calibration Records
- Control Charts
- Traceability Records
- Education, training and skills records

7.3 Record Retention

The supplier shall retain Quality Records for a period of not less than ten (10) years or as required by the relevant quality standard from fulfilment of the purchase order. Supplier shall flow down this requirement to sub-tier suppliers.

8.0 Corrective and Preventive Action

8.1 Correction and Preventive Action Process

The supplier shall complete and submit a corrective action report by the due date indicated on the request. The due date may be extended upon request to allow the supplier to effectively respond, but the supplier must request an extension prior to the initial due date. Zot Engineering Ltd reserves the right to verify corrective action has been implemented to ensure the root cause has been eliminated. Zot Engineering Ltd may perform verification at the supplier's facility or the supplier shall submit objective evidence as requested.

9.0 Special Process Requirements

9.1 Special Processes

At a minimum Zot Engineering Ltd require and Quality Program compliant to the requirements of the applicable section of the ISO9001 with process controls in place according to the governing process specification

While NADCAP (National Aerospace and Defence Contractors Accreditation Program) accreditation (SAE AS7003) is not required as a prerequisite for business, it does benefit the supplier's rating from which procurement decisions are made.

9.2 Approval of Special Process Suppliers

Suppliers shall use special process sources approved by Zot Engineering Ltd. Approved is indicated when the special process source is listed on a Zot Engineering Ltd purchase order.

Special Processes are:

Brazing and Welding
Calibration
Chemical Film
Electroplated Coatings, Alochrom, Passivation, Anodising
Heat Treatment
Non- destructive Testing

9.3 Special Process Certificate

Supplier shall provide as part of the shipping documentation a special process certificate(s) which contains:

Specification Number
Revision Level
Test Results

For processes performed under the NADCAP certification, the NADCAP process statement, accreditation number and expiration date must be included in the certification provided to Zot Engineering Ltd.

9.4 Calibration Service Providers

Calibration Service providers will immediately notify Zot Engineering Ltd Quality Management of any out of tolerance conditions during calibration or servicing. Immediate notification will be verbal, followed by written notification.