STERITOOL™
The Global Source for Stainless Steel Tools

Supplier Quality Requirements Manual

1. PURPOSE: This manual establishes the minimum elements of a Supplier's Quality Assurance System required for STERITOOL Inc. deliverable material and special process suppliers.
1.1 The supplier's quality system shall provide for the control of quality throughout the procurement, Manufacturing, inspection, and delivery processes. Supporting documentation shall be maintained and made available upon request. Suppliers shall flow down requirements to all sub-tier suppliers.
1.2 The requirements of this document must be complied with when specified on STERITOOL purchase order.
1.3 The use of customer approved sources does not relieve the user of the responsibility for subcontractor controls, including verifying current approval status and process compliance.

2. SCOPE: This document is not intended to supersede any contractual or specification requirement. If a conflict occurs, the Purchase Order requirement shall take precedence.

3. RESPONSIBILITY AND AUTHORITY: Quality, Operations, and/or Engineering are responsible for the control of this document.

4. KEY PERFORMANCE INDICATORS (KPI):

- Material Acceptance Rate >98%
- On-Time Delivery >98%

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6. STERITOOL QUALITY SYSTEM REQUIREMENTS FOR SUPPLIERS:
6.1 It is the supplier's responsibility to meet all requirements of the STERITOOL Purchase Order.

- Material Specifications (Type, Heat, Weight)
- Processes, equipment, service, and work instruction requirements, as applicable
- Quality Requirements (KPI's)
- Marking requirements, as needed
- Certificate of Conformance (CoC) / Packing List (PL), and Material Certifications with complete traceability of material.

6.2 Questions or conflicts regarding engineering issues shall be documented and provided to STERITOOL via the e-mail address at steritool@steritool.com.
6.3 For all raw materials, the latest version of material specification shall be used, unless otherwise specified on the Purchase Order.
6.4 Inspection is required on all deliverable items to STERITOOL.

7. CONTROL OF DOCUMENTS
7.1 All applicable records need to be retained for at least 10 years.

7.2 Supplier shall maintain a work instruction or equivalent document for the control of product processing, quality, and configuration for each part number through all stages of production.
7.3 Material certifications, CoC/PL, and any other inspection documentation shall be maintained and retrieved as requested by STERITOOL.
7.4 Corrections to work instructions or documents shall be in ink, recorded, dated and traceable to the originator (e.g., signature, stamp, etc.) with the original data remaining legible after the correction.

8. RESOURCE MANAGEMENT – COMPETENCE, AWARENESS & TRAINING
8.1 Supplier Management shall facilitate all necessary training and maintain reports / certifications to ensure employee skill levels meet the scope of work being performed.
8.2 All training shall be documented and maintained.

9. VERIFICATION OF PURCHASED PRODUCTS
9.1 ***All incoming raw material is considered 'received only' until business allows for full material and document review. Raw material is not fully accepted until all inspection and testing of material has been completed.***
9.2 Suppliers shall provide raw material test reports / certification results / lab analysis data (e.g., tensile, hardness, chemical composition, mechanical properties etc.) as defined by the product definition data and/or Purchase Order requirements.

10. CONTROL OF MONITORING AND MEASURING DEVICES
10.1 Gauges, measuring and test equipment, (M&TE) used for acceptance purposes shall be calibrated to standards traceable to the National Institute of Standards and Technology (NIST). If such standards are not available at NIST, industry standards may be used.
10.2 Visual examinations for damage or wear shall be performed before each use.

11. INTERNAL AUDITS
11.1 The supplier should conduct Quality Management System (QMS) style internal audits to encompass the entire QMS, including any customer unique requirements, at a minimum, every three years.
11.2 Internal audit results shall be retained and be available for review.

12. INSPECTION SYSTEM REQUIREMENTS
12.1 Supplier shall perform receiving inspection on all production materials, as necessary to ensure conformance to contract requirements.
12.2 When sub-tier supplier certifications / test reports are used as a basis for material acceptance purposes, supplier shall independently validate accuracy of certification data on a periodic basis.
12.3 All Supplier and sub-tier supplier certifications should provide the specifications used and revision status, as applicable.
12.4 Certifications and document packages are to be legible and maintained on file at the supplier's facility and are to be made available to STERITOOL within twenty-four hours, when requested.

13. PRESERVATION, PACKAGING, STORAGE AND SPECIAL HANDLING

13.1 Supplier shall provide necessary protection of all articles to prevent damage, loss, deterioration, or degradation in accordance with requirements contained in Purchase Order, or when not specified in the Purchase Order, good commercial practices shall be used.

14. SUPPLIER NOTIFICATION OF DELIVERED NONCONFORMING PRODUCTS TO STERITOOL

14.1 When suspect or known nonconforming product has been delivered to STERITOOL, the Supplier shall notify STERITOOL Quality Management at steritool@steritool.com within 24 hours of the initial discovery. The Supplier shall use receipt acknowledged e-mail or other positive notification method.

15. SERIALIZATION & IDENTIFICATION

15.1 Traceability shall be maintained through the supplier's system for lot control and serialization subject to approval by STERITOOL for material, parts, and assemblies when required by purchase order.

15.2 Mill supplied heat numbers shall not be duplicated and shall provide full traceability to all material, fabrication, assembly, inspection, and test documentation.

15.3 Identification and inspection status shall be maintained during all phases of fabrication, denoting the inspection, change and/or time limited status of the supplies. This identification may be accomplished by means of tags, routing cards, move tickets, tote box cards, stamps, or other normal controls.

15.4 Inspection, serialization, identification, or acceptance marking shall be placed on the output in accordance with STERITOOL requirements and in a manner which will not damage the output or assembly.

16. CONTROL OF NONCONFORMING OUTPUT & MATERIAL REVIEW

16.1 Suppliers shall establish and maintain procedures for the identification, segregation, and control of nonconforming products. Outputs found to be nonconforming to STERITOOL drawings, specifications, contract, or other design requirements shall be identified, segregated, reworked, or replaced with conforming products prior to delivery to STERITOOL.

16.2 *ALL nonconforming parts/materials shall be reworked and/or returned at* ***Suppliers*** *expense. This will include time used to review and inspect, as well as all shipping related costs.*

17. NONCONFORMANCE REPORT (NCR)

17.1 Nonconforming outputs that are the responsibility of supplier require:

a. A Root Cause & Corrective Action (RCCA)

b. RCCA to be submitted to STERITOOL Quality within 20 business days of notification.

18. CORRECTIVE ACTION REQUIRED (CAR) NOTICE

18.1 CAR responses shall be submitted to the STERITOOL Quality Management at steritool@steritool.com.

18.2 The corrective action response must contain:
a. Containment of nonconforming material
b. Root Cause of the nonconformance
c. Corrective Action to prevent a recurrence of the nonconformance
18.3 When a corrective action cannot be completed within 30 calendar days for Internal (STERITOOL) Rejections, the supplier may request extension. A current status of the corrective action investigation and plan for completion is required.
18.4 Supporting documentation for corrective actions shall be submitted (e.g., manufacturing work instruction changes, tool orders, engineering changes, training records, etc.).
18.5 STERITOOL Quality rating is a factoring system based on part acceptance / parts received ratio, NCR activity is also included. STERITOOL has established a supplier performance rating of not less than 98% Quality and 98% for Delivery.

19. COUNTERFEIT PARTS PROGRAM
19.1 All material must be procured from an authorized distributor/manufacturer.
19.2 Under no circumstances, should any defective or counterfeit part/material be provided to STERITOOL.