

# AcuCut Purchasing Quality Requirements

## Form QF 7.4-5

### 1. CERTIFICATE OF CONFORMANCE

When indicated on the purchase order, a certificate of conformance, indicating parts meet all applicable specifications, is required for each shipment. This certificate must be signed or stamped by an authorized company representative. It must contain as a minimum, supplier name and address, AcuCut's part number and revision level, purchase order number, quantity and date shipped.

### 2. AUTHORITY

Decisions between the supplier and AcuCut's coordinating personnel shall not be binding upon either party unless authorized by purchase order or amendment thereto.

### 3. SUPPLIER QUALITY SYSTEM

The supplier shall maintain an effective written quality control system which ensures compliance with the purchase order requirements. This system shall provide for the control of incoming material, manufactured material, special processes and outgoing product. Responsibility for the control of quality shall be clearly designated within the supplier's organization. The supplier shall utilize drawing specifications and other data supplied by AcuCut in the performance of this order. The quality system must utilize written records which indicate conformance to all contractual requirements. Upon request, supplier shall make available to AcuCut's personnel, drawings, processing descriptions and inspection plans. If such information is considered proprietary, the availability may be at the supplier's site, or as such other arrangements as may be made between AcuCut and the supplier.

### 4. WRITTEN NOTIFICATION OF CHANGES

The supplier shall notify AcuCut's Quality Assurance Department, in writing, of any changes that may impact product quality. Changes that may affect product quality include, but are not limited to, use of new procurement sources, new part numbers or materials, personnel changes in manufacturing and quality assurance management or certified areas, significant changes within the supplier's facilities or those of their subcontractors, and new source or location changes.

### 5. SURVEY AND SURVEILLANCE

AcuCut and its customers shall have the right to conduct surveys and perform surveillance of the supplier's and supplier's subcontractor's operations in order to evaluate their capability to comply with contractual requirements.

### 6. CONTROL OF SUBCONTRACTORS

Suppliers are forbidden to subcontract this order unless authorized in writing by AcuCut's Purchasing. If allowed, the supplier shall be responsible to ensure that their subcontractors (down to the lowest tier) comply with all of the requirements set forth in this purchase order. AcuCut's Quality Department reserves the right to disallow work being performed by any subcontractor.

### 7. SUPPLIER'S INCOMING MATERIAL

Parts and material procured for use on items supplied by AcuCut shall be subject to a system that will assure compliance to all contractual requirements. The system will utilize test reports, specifications, and inspection verification, as appropriate, of the physical and chemical properties of materials. Raw material shall be clearly identified as to the composition and heat treatment and shall be stored in the proper manner. Supplier will provide to AcuCut complete material certification from the material's source.

### 8. CONTROL OF QUALITY RECORDS

Records of inspections, tests, purchased materials, special processing, engineering changes, serial numbers and other quality assurance activities shall be maintained and available for review by AcuCut's personnel. Such records shall be maintained for seven years or as specified on the purchase order.

### 9. SAMPLING PROCEDURES

When performing less than 100% inspection, sampling procedures must be approved by AcuCut's Quality Department prior to use. Regardless of any sampling plans used, items found to be nonconforming as a result of inspection at AcuCut may be cause for rejection of the entire lot.

### 10. DOCUMENT AND DATA CONTROL

The supplier shall maintain a change control system to ensure that all changes to drawings, specifications and other technical data are incorporated in the documentation, processing system, and the product at the points defined in the change document. All products must conform to the change level shown on the purchase order. Supplier requested changes to drawings and specifications must be submitted to AcuCut with sufficient data to evaluate the request. These changes shall not be incorporated until written approval from AcuCut has been obtained.

### 11. CONTROL OF INSPECTION MEASURING AND TEST EQUIPMENT

The supplier shall provide suitable tools, gauges and test equipment for the purpose of evaluating product conformance to specified requirements. The supplier shall maintain a system for the purpose of periodic evaluation and calibration of this equipment per ANSI Z540-1 or equivalent, traceable to the National Institute of Standards and Technology. Evidence of evaluation and calibration shall be recorded and made available to AcuCut upon request.

### 12. PRODUCT IDENTIFICATION AND TRACEABILITY

The supplier shall establish and maintain documented procedures for unique identification of individual product or batches. This identification must be recorded, and those records must be made available to AcuCut's personnel upon request.

### 13. HANDLING, STORAGE, PACKAGING, PRESERVATION AND DELIVERY

The supplier shall establish controls to ensure that product is not damaged during manufacture or transportation to AcuCut. The supplier shall comply with special packaging and/or preservation requirements that may be included in purchase order specifications or drawings.

### 14. ACCEPTANCE

Acceptance of product will be at AcuCut or by source inspection, or as otherwise specified on the purchase order. Product found to be non-conforming may be returned to the supplier. AcuCut shall not be required to submit suspect product to 100% inspection. When returning product to AcuCut that has been reworked as a result of nonconformance, supplier shall note on the pack slip that the material has been reworked. The pack slip must also include the rejection number and debit memo number (if applicable) under which the material was returned to the supplier by AcuCut. Acceptance by AcuCut or source inspection does not relieve the supplier of responsibility for anomalies later detected.

### 15. VERIFICATION OF PURCHASED PRODUCT

AcuCut's customer or the customer's representative shall be afforded the right to verify at the supplier's premises and AcuCut's premises that subcontracted product conforms to specified requirements.

### 16. CONTROL OF NONCONFORMING MATERIAL

The supplier shall establish a system for the control, identification and segregation of non-conforming material. Product returned to the supplier due to nonconformances must be controlled under this system. Any requests for corrective action must be completed and returned to AcuCut by the date specified on the request. No repair or use as is dispositions shall be made by the supplier without the written approval of AcuCut.

### 17. SOFTWARE CONTROL

The supplier must establish a Software Quality Assurance Plan for non-deliverable software. This plan must address, as a minimum, software development, test criteria, documentation, library control and subcontractor control.

### 18. PROCESS CONTROL

Specific controls shall be established, defined in writing, maintained and recorded by the supplier on all manufacturing processes. Where specific customer approval of manufacturing processes is required, these processes must not be altered or changed without prior written approval from the customer.

### 19. EXCEPTIONS

When the parts or services provided are for AcuCut's end use, exceptions to these requirements may be granted by AcuCut's Quality Assurance Manager.

### 20. RIGHT OF ACCESS

The supplier shall grant AcuCut, our customer, and regulatory authorities to the applicable areas of all facilities at any level of the supply chain involved in the in the order and to all applicable records.

### 21. FOREIGN OBJECT DETECTION/ELIMINATION

Removal of all foreign objects/materials (chips, stains, etc) that could result in damage or failure is required.

### 22. PERSONNEL QUALIFICATION

None unless required by specification, AcuCut, and/or the suppliers requirements to ensure product conformity. Workers shall be competent

### 23. CONFLICT MINERALS

All Material must be Conflict Free according to DODD FRANK Act.

### 24. CODE OF CONDUCT

All suppliers shall comply with the Supplier's Code of Conduct QF 7.4-6.

### 25. COUNTERFEIT MATERIAL/PARTS

Supplier must provide only authentic and conforming product and material that is procured from legally authorized sources and ensure that counterfeit product or material is not used in fulfillment of AcuCut PO.

Approvals	Approvals	Revision/Date	Reason For Change
<b>Scott Barmore</b>	<b>Jack Provenzano</b>	<b>06 08/03/17</b>	<b>See QF 4-2 dated 07/31/17</b>