

QUALITY SYSTEM REQUIREMENTS FOR Manufacturer YFTFC001

PURPOSE:

This specification outlines the Quality System requirements for **Young & Franklin/Tactair Fluid Controls** suppliers. It is intended to assure that articles purchased from approved suppliers are as ordered and have been subjected to positive control during the supplier's handling and storage.

GENERAL:

The supplier's Quality System **shall** be documented in the form of a Quality Manual, supported by documented procedures as necessary. These documents **shall** be available for review by Young & Franklin/Tactair Fluid Controls.

Young & Franklin/Tactair Fluid Control approval of the supplier's Quality System is limited to the location shown on Young & Franklin/Tactair Fluid Controls Purchase Order and is not transferable to the supplier's other stocking locations or affiliated companies.

YFTFC001 QUALITY SYSTEM REQUIREMENTS

1.0 MANAGEMENT RESPONSIBILITY

Management **shall** immediately notify Young & Franklin/Tactair Fluid Controls of any significant changes in the Quality Program, leadership, procedures, or processes which would affect the quality of products.

1.1 Quality Policy

The supplier **shall** define and document its quality policy. The quality policy **shall** be relevant to the supplier's organizational goals, the expectations and needs of its customers. The supplier **shall** ensure that this policy is understood, implemented, and maintained at all levels of the organization.

1.2 Responsibility and Authority

The supplier's personnel performing quality functions **shall** have sufficient, well-defined responsibility, authority with the organizational freedom to identify and evaluate quality problems, and to initiate, recommend, or provide solutions.

1.3 Management Review

Management **shall** periodically review the status and adequacy of the quality system to ensure its continuing effectiveness in satisfying the supplier's stated quality policy and objectives. Records of such reviews **shall** be maintained.

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2.0 QUALITY SYSTEM

2.1 General

The supplier **shall** establish, document, implement, and maintain a quality system to assure product compliance to specified requirements.

The supplier **shall** maintain a quality manual that includes or makes reference to quality system procedures and outline the structure of the documentation used in the quality system.

2.2 Quality System Procedures

The supplier's procedures **shall** provide, review of all new project requirements during the earliest practical phase of a contract.

2.3 Quality Planning

Quality planning will identify and make timely provisions for the special controls, processes, IM&TE, fixtures, tooling and training required for assuring article quality.

3.0 CONTRACT REVIEW

3.1 Review

The supplier's quality function **shall** assure the supplier's procurement documents incorporate applicable quality, and technical requirements, and verifies that items are procured from approved sources when required by Young & Franklin/Tactair Fluid Controls purchase orders.

3.2 Amendment to Contract

The supplier **shall** identify how an amendment to a contract/purchase order is made and correctly transferred to the functions concerned within the supplier's organization.

3.3 Records

Records of contract reviews **shall** be maintained.

4.0 DESIGN REVIEW

4.1 General

The supplier **shall** establish and maintain documented procedures to control and verify the design of products in order to ensure that specified requirements are met.

4.2 Design and Development Planning

The supplier **shall** prepare plans for each design and development activity. The plans **shall** describe or reference these activities, and define responsibility for their implementation. The design and

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development activities **shall** be assigned to qualified personnel equipped with adequate resources. The plans **shall** be updated, as the design evolves.

4.3 Organizational and Technical Interfaces

Organizational and technical interfaces between different groups which have input into the design process **shall** be defined and the necessary information documented, transmitted, and regularly reviewed.

4.4 Design Input

Design-input requirements relating to the product, including applicable statutory and regulatory requirements, **shall** be identified, documented, and their selection reviewed by the supplier for adequacy. Incomplete, ambiguous, or conflicting requirements **shall** be resolved with those responsible for imposing these requirements.

Design input **shall** take into consideration the results of any contract/PO-review activities.

4.5 Design Output

Design output **shall** be documented and expressed in terms that can be verified against design-input requirements and validated.

4.6 Design Review

At appropriate stages of design, formal documented reviews of the design results **shall** be planned and conducted. Records of such reviews **shall** be maintained.

4.7 Design Verification

At appropriate stages of design, design verification **shall** be performed to ensure that the design-stage output meets the design-stage input requirements. The design-verification measures **shall** be recorded.

4.8 Design Validation

Design validation **shall** be performed to ensure that product conforms to defined user needs and/or requirements.

4.9 Design Changes

All design changes and modifications **shall** be identified, documented, reviewed, and approved by authorized personnel before their implementation.

5.0 DOCUMENT AND DATA CONTROL

5.1 General

The supplier **shall** establish and maintain documented procedures to control all documents and data

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that relate to the requirements of this standard including, to the extent applicable, documents of external origin such as standards and customer drawings. In essence a system is maintained to control the initiation, revision, issue, and distribution of all Quality related documents.

5.2 Document and Data Approval and Issue

The documents and data **shall** be reviewed and approved for adequacy by authorized personnel prior to issue. A master list or equivalent document-control procedure identifying the current revision status of documents **shall** be established and be readily available to preclude the use of invalid and/or obsolete documents. Obsolete documents **shall** be recalled from use or destroyed.

5.3 Document and Data Changes

Changes to documents and data **shall** be reviewed and approved by the same functions or organizations that performed the original review and approval, unless specifically designated otherwise. The designated functions or organizations **shall** have access to pertinent background information upon which to base their review and approval

6.0 PURCHASING

6.1 General

The supplier **shall** establish and maintain documented procedures to ensure that purchased product conforms to specified requirements.

6.2 Evaluation of Subcontractors

The supplier **shall** evaluate and select subcontractors on the basis of their ability to meet subcontract requirements, define the type and extent of control exercised by the supplier over subcontractors, and establish and maintain quality records of acceptable subcontractors.

6.3 Verification of Purchased Product

Where Young & Franklin/Tactair Fluid Controls proposes to verify purchased products at the supplier's or subcontractors' premises, Young & Franklin/Tactair Fluid Controls **shall** specify verification arrangements and the method of product release in the purchasing documents.

7.0 CONTROL OF CUSTOMER-SUPPLIED PRODUCT

The supplier **shall** establish and maintain documented procedures for the control of verification, storage, and maintenance of Young & Franklin/Tactair Fluid Controls supplied product. Any such product that is lost, damaged, or is otherwise unsuitable for use **shall** be recorded and reported to Young & Franklin/Tactair Fluid Controls.

8.0 PRODUCT IDENTIFICATION AND TRACEABILITY

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The supplier **shall** establish and maintain documented procedures for identifying products by suitable means from receipt and during all stages of production, delivery, and installation.

The supplier **shall** establish and maintain documented procedures for unique identification of individual products or batches. This identification **shall** be recorded.

9.0 PROCESS CONTROL

The Supplier **shall** identify and plan the production, installation, and servicing processes which directly affect quality and **shall** ensure that these processes are carried out under controlled conditions.

Controlled conditions **shall** include the following:

- Documented procedures defining the manner of production, installation, and servicing, where the absence of such procedures could adversely affect quality:

- Use of suitable production, installation, and servicing equipment, and a suitable working environment;

- Compliance with reference standards/codes, quality plans, and/or documented procedures:

- Monitoring and control of suitable process parameters and product characteristics;

- Approval of processes, equipment and personnel as appropriate:

- Criteria for workmanship, **shall** be stipulated in the clearest practical manner (e.g., written standards, representative samples, or illustrations);

- Suitable maintenance of equipment to ensure continuing process capability.

Where the results of processes cannot be fully verified by subsequent inspection and testing of the product and where, for example, processing deficiencies may become apparent only after the product is in use, the processes **shall** be carried out by qualified operators and/or **shall** require continuous monitoring and control of process parameters to ensure that the specified requirements are met.

The requirements for any qualification of process operations, including associated equipment and personnel **shall** be specified.

Records **shall** be maintained for qualified processes, equipment, and personnel, as appropriate.

10. INSPECTION AND TESTING

The supplier **shall** establish and maintain documented procedures for inspection and testing activities in order to verify that the specified requirements for the product are met. The required inspection and testing, and the records to be established, **shall** be detailed in the quality plan or documented procedures.

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10.1 Receiving Inspection and Testing

The supplier **shall** ensure that incoming product is not used or processed until it has been inspected or otherwise verified as conforming to specified requirements. Verification of the specified requirements **shall** be in accordance with the quality plan or documented procedures.

10.2 In-process Inspection and Testing

The supplier **shall**:

Inspect and test the product as required by the quality plan and/or documented procedures;
Hold a product until the required inspection and tests have been completed or necessary reports have been received and verified, except when products are released under positive-recall procedures **shall** not preclude the activities.

10.3 Final Inspection and Testing

The supplier **shall** carry out all final inspection and testing in accordance with the quality plan and/or documented procedures to complete the evidence of conformance of the finished product to the specified requirements.

10.4 Inspection and Test Records

The supplier **shall** establish and maintain records which provide evidence that the product has been inspected and/or tested. These records **shall** show clearly whether the product has passed or failed the inspections and/or tests according to defined acceptance criteria. Where the product fails to pass any inspection and/or test, the procedures for control of nonconforming products **shall** apply.

Records **shall** identify the inspection authority responsible for the release of the product.

11. CONTROL OF INSPECTION, MEASURING, AND TEST EQUIPMENT

Control and calibration of instrumentation and calibration standards **shall** be in accordance with the requirements of ISO-10012-1 and/or ANSI/ASQ Z 540-1. The supplier **shall** establish and maintain documented procedures to control, calibrate, and maintain inspection, measuring, and test equipment (including test software) used by the supplier to demonstrate the conformance of a product to the specified requirements. Inspection, measuring, and test equipment **shall** be used in a manner which ensures that the measurement uncertainty is known and is consistent with the required measurement capability.

Where test software or comparative references such as test hardware are used as suitable forms of inspection, they **shall** be checked to prove that they are capable of verifying the acceptability of the product, prior to release for use during production, installation, or servicing and **shall** be rechecked at prescribed intervals. The supplier **shall** establish the extent and frequency of such checks and **shall** maintain records as evidence of control.

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Where the availability of technical data pertaining to the measurement equipment is a specified requirement, such data **shall** be made available, when required by the customer or customer's representative, for verification that the measuring equipment is functionally adequate.

11.1 Control Procedure

The supplier **shall**:

Determine the measurements to be made and the accuracy required, and select the appropriate inspection, measuring, and test equipment that is capable of the necessary accuracy and precision;

Identify all inspection, measuring, and test equipment that can affect product quality, and calibrate and adjust them at prescribed intervals, or prior to use, against certified equipment having a known valid relationship to internationally or nationally recognized standards. Where no such standards exist, the basis used for the calibration **shall** be documented;

Define the process employed for the calibration of inspection, measuring, and test equipment, including details of equipment type, unique identification, location, frequency of checks, check method, acceptance criteria, and the action to be taken when results are unsatisfactory;

Identify inspection, measuring, and test equipment with a suitable indicator or approved identification record to show the calibration status;

Maintain calibration records for inspection, measuring, and test equipment;

Assess and document the validity of previous inspection and test results when inspection, measuring, and test equipment is found to be out of calibration;

Ensure that the environmental conditions are suitable for the calibrations, inspections, measurements, and tests being carried out;

Ensure that the handling, preservation, and storage of inspection, measuring, and test equipment are such that the accuracy and fitness for use are maintained;

Safeguard inspection, measuring, and test facilities, including both test hardware and test software, from adjustments which would invalidate the calibration setting.

12.0 INSPECTION AND TEST STATUS

The inspection and test status of a product will be identified by suitable means, which indicate the conformance or non-conformance of the product with regard to inspection and tests performed. The identification of inspection and test status will be maintained, as defined in the quality plan and/or documented procedures, throughout production, installation, and servicing of the product to ensure that only product that has passed the required inspections and tests or released under an authorized concession is dispatched, used, or installed.

13.0 CONTROL OF NONCONFORMING PRODUCT

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The supplier will establish and maintain documented procedures to ensure that product that does not conform to specified requirements is prevented from unintended use or installation. This control **shall** provide for identification, documentation, evaluation, segregation (when practical), disposition of non-conforming products, and for notification to the functions concerned.

13.1 Review and Disposition of Nonconforming product

The responsibility for review and authority for the disposition of non-conforming products **shall** be defined.

Non-conforming products **shall** be reviewed in accordance with documented procedures. It may be:

- reworked to meet specified requirements,
- accepted with or without repair by concession (when approved by customer),
- re-graded for alternative applications, or
- rejected and/or scrapped

Where required by the contract, the proposed use or repair of a product which does not conform to specified requirements **shall** be reported for concession to the customer or customer's representative. The description of the non-conformity that has been accepted, and of repairs, **shall** be recorded to denote the actual condition.

Repaired and/or reworked products **shall** be **100%** reinspected in accordance with the quality plan and/or documented procedures.

14.0 CORRECTIVE AND PREVENTIVE ACTION

14.1 General

The supplier **shall** establish and maintain documented procedures for implementing corrective and preventive action.

Any corrective or preventive action taken to eliminate the causes of actual or potential non-conformities **shall** be to a degree appropriate to the magnitude of problems and commensurate with the risks encountered.

The supplier **shall** implement and record any changes to the documented procedures resulting from corrective and preventive action

14.2 Responding to Corrective Action Requests.

The supplier **shall** respond to a corrective action request in a timely manner. A letter sent to the supplier from Young & Franklin/Tactair Fluid Controls gives a description of non-conformities along

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with a due date that the supplier **shall** respond by. If the supplier does not respond to the corrective action by the due date, their approved supplier status may be revoked and payment of products may be withheld.

15.0 HANDLING, STORAGE, PACKAGING, PRESERVATION, AND DELIVERY

The supplier will establish and maintain documented procedures for handling, storage, packaging, preservation, and delivery of a product.

15.1 Handling

The supplier **shall** provide methods of handling products that prevent damage or deterioration.

15.2 Storage

The supplier **shall** use designated storage areas or stock rooms to prevent damage or deterioration of products, pending use or delivery. Appropriate methods for authorizing receipt to and dispatch from such areas **shall** be stipulated.

In order to detect deterioration, the condition of products in stock **shall** be assessed at appropriate intervals.

15.3 Packaging

The supplier **shall** control packing, packaging, and marking processes (including materials used) to the extent necessary to ensure conformance to specified requirements.

15.4 Preservation

The supplier **shall** apply appropriate methods for preservation and segregation of products when the product is under the supplier's control.

15.5 Delivery

The supplier **shall** arrange for the protection of the quality of a product after final inspection and test. Where contractually specified, this protection shall be extended to include delivery to a destination.

16.0 CONTROL OF QUALITY RECORDS

The supplier **shall** establish and maintain documented procedures for identification, collection, indexing, access, filing, storage, maintenance, and disposition of quality records.

The supplier **shall** maintain adequate records of all inspections and tests. The records **shall** indicate the nature and number of observations made, the number and type of deficiencies found, the quantities approved and rejected and the nature of corrective action taken as appropriate. Such records **shall** be made available to Young & Franklin/Tactair Fluid Controls upon request, and **shall** be retained for

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eight years after final payment under the related Purchase Order or for an additional period as imposed in the Purchase Order.

All quality records **shall** be legible and **shall** be stored and retained in such a way that they are readily retrievable in facilities that provide a suitable environment to prevent damage or deterioration and to prevent loss.

Records may be in the form of any type of media, such as hard copy or electronic media.

17.0 INTERNAL QUALITY AUDITS

The supplier **shall** establish and maintain documented procedures for planning and implementing internal quality audits to verify whether quality activities and related results comply with planned arrangements and to determine the effectiveness of the quality system.

Internal quality audits **shall** be scheduled on the basis of the status and importance of the activity to be audited and **shall** be carried out by personnel independent of those having direct responsibility for the activity being audited.

The results of the audits **shall** be recorded and brought to the attention of the personnel having responsibility in the area audited. The management personnel responsible for the area **shall** take timely corrective action on deficiencies found during the audit.

Follow-up audit activities **shall** verify and record the implementation and effectiveness of the corrective action taken.

The results of internal quality audits form an integral part of the input to management review activities.

18.0 TRAINING

The supplier **shall** establish and maintain documented procedures for identifying training needs and provide for the training of all personnel performing activities affecting quality. Personnel performing specific assigned tasks **shall** be qualified on the basis of appropriate education, training and/or experience, as required. Appropriate records of training **shall** be maintained.

Training certification or qualification of individuals performing processes ie: X-ray, fluorescent penetrant, welding magnetic particle, ultrasonic inspection **shall** be documented. Any approval where the Level III individual does not possess a current Professional Level III Certification **shall** use the words Internal Support Only on that approval.

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For Non-Destructive Inspection (NDT) Level III inspectors or any Level III acting as a consultant for multiple processors must have a current Professional Level III Certification.

19.0 SERVICING

Where servicing is a specified requirement, the supplier **shall** establish and maintain documented procedures for performing, verifying, and reporting that the servicing meets the specified requirements.

20.0 STATISTICAL TECHNIQUES

The supplier **shall** identify the need for statistical techniques required for establishing controlling and verifying process capability and product characteristics.

The supplier **shall** establish and maintain documented procedures to implement and control the application of the statistical techniques identified.