



# QUALITY ASSURANCE MANUAL

**Revision H**

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## **1 Scope**

The scope of this manual encompasses all products and services provided to customers, specifically, the *Design, Manufacture, Distribution, Integration and Service of Industrial Instrumentation; Test & Measurement Equipment; and Digital Process Control Systems*. All such items are subject to the policies identified in this Quality Manual, addressed in annual Quality Plans, and controlled by our Quality Management System.

## **2 Purpose**

The purpose of this manual is to provide explanation and description of quality processes, policies and procedures employed by Yokogawa Corporation of America that assure adherence to quality standards consistent with certifications, approvals and contractual obligations.

Questions concerning this Quality Manual or the Quality Management System at Yokogawa Corporation of America should be directed to the Manager of Corporate Quality Assurance.

## **3 Normative Reference**

This Quality Management Manual was created based on the international standard ISO 9001:2000 Quality Management Systems – Requirements. If the international standard is modified, this Quality Management Manual will be revised accordingly.

## **4 Quality Management System**

### **4.1 General Requirements**

- (1) Yokogawa has established, documented, implemented and maintains a Quality Management System in compliance with ISO 9001:2000, and continually improves its effectiveness in accordance with the requirements of this International Standard.  
Yokogawa has:
  - a) Identified the processes needed for the Quality Management System and their application throughout the organization,
  - b) Clarified the order of these processes and the interaction between them,
  - c) Determined criteria and methods needed to ensure that both the operation and control of these processes are effective,
  - d) Ensured the availability of resources and information necessary to support the operation and monitoring of these processes,
  - e) Monitors, measures, and analyzes these processes,
  - f) Implements actions necessary to achieve planned results and continual improvement of these processes.
- (2) Yokogawa manages these processes in accordance with the requirements of this Quality Management Manual.
- (3) Further, this quality system ensures compliance of applicable products with the type described in the EC-Type Examination Certificate.

- (4) If processes that have an effect on product compliance with requirements are outsourced, the relevant department in charge of outsourcing manages the outsourcing in accordance with this Manual, to ensure the management of the process.

## **4.2 Documentation**

### **4.2.1 General**

The Quality Management System documentation issued by Yokogawa includes:

- (1) A Quality Policy and objectives,
- (2) A Quality Management Manual,
- (3) Documented procedures as required by ISO 9001:2000,
- (4) Documented procedures to ensure the effective planning, operation, and control of processes,
- (5) Records required by ISO 9001:2000.

### **4.2.2 Quality Management Manual**

Yokogawa has established and maintains a Quality Management Manual that includes the scope of the Quality Management System. The documented procedures established for the Quality Management System and a description of the interaction between the processes of the Quality Management System are referenced.

### **4.2.3 Control of Documents**

Documents required by the Quality Management System are under control by the appropriate department within Yokogawa.

A documented procedure (YQA-050) has been established by Corporate Quality Assurance to ensure:

- a) Approval of documents for adequacy prior to issue,
- b) Documents are reviewed and updated as necessary and re-approved,
- c) Changes and the current revision status of documents are identified,
- d) Relevant versions of applicable documents are easily available at points of use,
- e) Documents remain legible and readily identifiable,
- f) Documents of external origin are identified and their distribution controlled, whenever distribution is required,
- g) Prevention of unintended use of obsolete documents, and to apply suitable identification to them if they are retained for any purpose.
- h) Yokogawa to insure all documents that are passed on to a third party are not misleading (including documentation on the internet).

### **4.2.4 Control of Records**

Records have been established and are maintained by each relevant department to provide evidence of conformity to requirements and of the effective operation of this Quality Management System. Records are legible, readily identifiable, and can be easily retrieved. A documented procedure (YQA-160) has been established by Corporate Quality Assurance to ensure the identification, storage, protection, retrieval, retention time, and disposition of Records.

## **5 Management Responsibility**

### **5.1 Management Commitment**

The President, Executive Staff and Management team at Yokogawa have provided evidence of commitment to the development and implementation of the Quality Management System and continually improving its effectiveness by:

- (1) Communicating to the organization the importance of meeting customer as well as statutory and regulatory requirements,
- (2) Establishing and promoting the Quality Policy,
- (3) Ensuring that quality objectives are established, communicated, measured and met,
- (4) Conducting Quality Management Reviews,
- (5) Ensuring the availability of resources.

### **5.2 Customer Focus**

Yokogawa maintains a customer focused organization ensuring that customer requirements are determined and met with the aim of improving customer satisfaction. The needs and expectations of other interested parties are addressed on an “as needed” basis.

### **5.3 Quality Policy**

Based on corporate objectives and fundamental principles of quality control, Yokogawa establishes an appropriate Quality Policy as part of the annual Quality Plan. This Quality Policy includes a commitment both for products and employee behavior to meet statutory and regulatory requirements, as well as customer requirements and a commitment continual improvement.

The Quality Policy provides a framework for establishing and reviewing quality objectives, is communicated and understood within Yokogawa, and is reviewed for continuing suitability.

*The management team and employees of Yokogawa Corporation of America, together with our valued partners, pledge their commitment to working together as a team to deliver customer satisfaction first. Each employee is responsible for providing satisfaction to our customers at every opportunity demonstrating a personal commitment to professionalism and delivering consistently high levels of quality through understanding and commitment to quality systems, providing the products and services that consistently meets the expectations and needs of the customer, embracing a commitment to continual improvement, and complying with all statutory, regulatory requirements and recognized standards.*

### **5.4 Planning**

#### **5.4.1 Quality Objectives**

Yokogawa’s Quality Management Representative establishes quality objectives in the annual Quality Plan, and determines measures for achieving these objectives. These objectives are measurable and consistent with the Quality Policy, and include the objective of any legal or customer specific product requirements.

## **5.4.2 Quality Management System Planning**

Yokogawa has ensured that:

- (1) Proper planning is carried out as part of the Quality Management System in order to meet the requirements specified in section 4.1, as well as the quality objectives.
- (2) The integrity of the Quality Management System is maintained when changes are planned and implemented.

## **5.5 Responsibility, Authority and Communication**

### **5.5.1 Responsibility and Authority**

Yokogawa has defined responsibilities and authorities and communicated this to all employees. This is typically done through specific job descriptions and an organizational chart.

The following pertain to products requiring EC type certificates.

- a) The Managers in charge of Engineering and Quality Assurance are responsible for the activities associated with products intended for use in explosive atmospheres.
- b) These activities include interfacing with the approval organization for EC type certificates when changes in design require changes in the related drawings.
- c) The Management Representative is responsible for interfacing with the approval organization for changes in the Quality system.
- d) Procedure YQA-050 covers initial approval and changes to related drawing where appropriate.
- e) The Managers in charge of Engineering and Quality Assurance are responsible for any necessary concessions. For changes that impact the explosion proof design there are no concessions.
- f) The Managers in charge of Engineering and Quality Assurance are responsible for informing customers of special conditions for safe use and any limitations.

### **5.5.2 Management Representative**

Yokogawa has appointed the Manager of Corporate Quality Assurance as the Management Representative, with the responsibility and authority to ensure:

- (1) Processes for the Quality Management System are established, implemented and maintained,
- (2) The performance of the Quality Management System and any need for improvements are reported to the President and Executive Staff,
- (3) Awareness of customer requirements is promoted throughout the company.

The responsibilities of the Management Representative includes liaison with external parties on matters relating to the Quality Management System.

### **5.5.3 Internal Communication**

Yokogawa has established appropriate communication processes and communication takes place regarding the effectiveness of the Quality Management System.

## **5.6 Quality Management Review**

### **5.6.1 General (YQC-021)**

Yokogawa reviews the Quality Management System at planned intervals to ensure its continuing suitability, adequacy, and effectiveness. This review includes assessing opportunities for improvement and the need for changes to the Quality Management System, including the Quality Policy and quality objectives.

Records of these Reviews are maintained.

### **5.6.2 Review Input**

The inputs to Quality Management Review include information on:

- (1) Results of audits,
- (2) Customer feedback,
- (3) Process performance and product conformity,
- (4) Status of preventive and corrective actions,
- (5) Follow-up actions from previous Quality Management Reviews,
- (6) Changes that could affect the Quality Management System,
- (7) Recommendations for improvement.

### **5.6.3 Review Output**

The output from Quality Management Review includes any decisions and actions related to:

- (1) Improvement of the effectiveness of the quality management system and its processes,
- (2) Improvement of products related to customer requirements,
- (3) Resource needs.

## **6 Resource Management**

### **6.1 Provision of Resources**

Yokogawa has determined and is providing the resources needed to implement and maintain the Quality Management System and continually improve its effectiveness to enhance customer satisfaction by meeting customer requirements.

### **6.2 Human resources**

#### **6.2.1 General**

Personnel performing work affecting product quality are competent on the basis of appropriate education, training, skills, and experience.

#### **6.2.2 Competence, Awareness and Training**

Yokogawa has determined the necessary competence of personnel performing work affecting product quality and has taken actions to satisfy these requirements. Competence and the effectiveness of any actions taken to achieve competence are evaluated during the employee Performance Appraisal. Records of education, training, skills, and experience are maintained.

Employees are aware of the relevance and importance of their activities and how they contribute to the achievement of the quality objectives.

### **6.3 Infrastructure**

Yokogawa has determined and provides a maintained infrastructure necessary to achieve conformity to product requirements.

### **6.4 Work environment**

Yokogawa has determined and manages the required work environment specific to the given process in order to ensure conformity to product requirements.

## **7 Product Realization**

### **7.1 Planning of Product Realization**

Yokogawa has planned and developed the processes needed for product realization and they are consistent with other processes in the Quality Management System.

In planning product realization, Yokogawa has determined the following:

- a) Quality objectives and requirements for the product
- b) The need for product-specific processes, documents, and resources
- c) Required verification, validation, monitoring, inspection, and test activities specific to the product and the criteria for product acceptance
- d) Records needed to provide evidence that the realization processes and resulting product meet requirements

### **7.2 Customer-related Processes**

#### **7.2.1 Determination of Requirements Related to the Product**

Yokogawa has determined the product related requirements, whether customer specified or not, including delivery and after-sales support. This includes statutory and regulatory requirements.

#### **7.2.2 Review of Requirements Related to the Product**

Yokogawa has implemented a contract review process, which is implemented prior to acceptance of a customer order. This process ensures product requirements are defined, order requirements are defined, and we are confident of our ability to meet these requirements. For catalog products, there is no external record of this review.

For Projects, as defined by inclusion of non-catalog products, non-standard product features or delivery requirements, a Tender Review is conducted prior to issuing an offer. Tenders which result in customer orders will have a Contract Review ensuring any discrepancies are mutually resolved and accepted by both parties. When disparities results in negotiations a record of the review, actions, and agreements will be maintained.

Any changes to contracts will be managed using the above processes ensuring all parties are aware of the changes.

#### **7.2.3 Customer Communication**

Yokogawa has determined and implemented effective arrangements for communicating with customers with respect to product information through our web site and printed information (catalogs, brochures, etc). Customer contacts are identified and made known in the Customer Master database and through

our Sales channels.

Yokogawa maintains communications links for customer feedback via:

- a) Published telephone and fax numbers,
- b) Our website (info@ Yokogawa.com/us),
- c) Our web-based complaint and information system (Customer Concerns),
- d) Customer satisfaction transaction surveys for products, Service, and Training,
- e) Project completion surveys for Systems and Measurement.

### **7.3 Design and Development**

#### **7.3.1 Design and Development Planning**

Yokogawa controls the design and development of product by planning and defining the responsibilities and authorities needed. All design and development projects require management approval prior to commencing and a Project Manager is assigned. The Project Manager determines the project stages and the review, verification and validation milestones. The Project Manager is also responsible for effective communications with all interested parties, including maintaining project documentation.

#### **7.3.2 Design and Development Inputs**

It is the responsibility of the Project Manager to ensure all design input criteria has been identified prior to commencing the design. This criteria includes all functional and performance requirements and applicable statutory and regulatory requirements. A review of these requirements will be conducted either by peer or committee to ensure all requirements are clarified and adequately addressed without conflict.

#### **7.3.3 Design and Development Outputs**

It is the responsibility of the Project Manager to provide design and development outputs in a form that enables verification against the design and development input, and approve them prior to release. This ensures design and development outputs:

- a) Meet the input requirements for design and development
- b) Provide appropriate information for purchasing, production, and service provision
- c) Contain or reference product acceptance criteria
- d) Specify the characteristics of the product that are essential for its safe and proper use

#### **7.3.4 Design and Development Review**

It is the responsibility of the Project Manager to perform systematic reviews of design and development at suitable stages in accordance with planned arrangements. This is done to evaluate the ability of the results of design and development to meet requirements and to identify any problems and propose necessary actions. This review will include as necessary, the representatives of functions concerned with the design and development stage(s) under review. Records of the results of the reviews and any necessary actions are maintained.

### **7.3.5 Design and Development Verifications**

It is the responsibility of the Project Manager to perform verification in accordance with planned arrangements to ensure that the design and development outputs have met the design and development input requirements.

Records of the results of the verification and any necessary actions are maintained.

### **7.3.6 Design and Development Validation**

It is the responsibility of the Project Manager to perform design and development validation in accordance with planned arrangements to ensure that the resulting product is capable of meeting the requirements for the specified application or intended use, where known. Wherever practical, validation is completed prior to the implementation or delivery of the product. Records of the results of the validation and any necessary actions are maintained.

### **7.3.7 Control of Design and Development Changes**

Yokogawa controls the design and development change process by:

- (1) Thorough identification of design and development changes and record retention,
- (2) Reviewing, verifying, and validating the changes to approve their appropriateness before implementation,
- (3) Including in the review of design and development changes the evaluation of the effect of the changes on constituent parts and products already delivered,
- (4) Maintaining records of the results of the review of changes and any necessary actions.

## **7.4 Purchasing**

### **7.4.1 Purchasing Process**

Yokogawa has made provisions to ensure that purchased materials conform to specified purchase requirements. The type and extent of control applied to our suppliers and materials is dependent upon the effect of the materials on the final product.

We evaluate and select suppliers based on their ability to supply in accordance with our stated requirements. Criteria for selection, evaluation and reevaluation have been established. Records of the results of evaluations and any necessary actions arising from the evaluation are maintained.

### **7.4.2 Purchasing Information**

Yokogawa purchase orders describe the material to be purchased, including where appropriate:

- a) Requirements for approval of product, procedures, processes and equipment,
- b) Requirements for qualification of personnel,
- c) Quality management system requirements.

Yokogawa ensures the adequacy of specified purchase requirements prior to communication to the supplier.

### **7.4.3 Verification of Purchased Product**

(1) Yokogawa has established and implemented formal incoming inspection and other similar activities necessary for ensuring that purchased materials meet specified purchase requirements. When Yokogawa (or our customer) intends to perform verification qualification at the supplier's premises, it will state the intended verification arrangements and method of material release in the purchasing information.

## **7.5 Production and Service Provision**

### **7.5.1 Control of Production and Service Provision**

Yokogawa has established plans and executes production and service provisions under controlled conditions. These provisions include:

- a) The availability of information that describes the characteristics of the product,
- b) The availability of work instructions, as necessary,
- c) The use of suitable equipment,
- d) The availability and use of monitoring and measuring devices,
- e) The implementation of monitoring and measurement,
- f) The implementation of release, delivery and post-delivery activities.

### **7.5.2 Validation of Processes for Production and Service Provision**

Yokogawa validates special processes for production and service provision where the resulting output cannot be verified by subsequent monitoring or measurement. This includes any processes where deficiencies become apparent only after the product is in use or the service has been delivered. We ensure that validation demonstrates the ability of these processes to achieve the planned results by establishing arrangements for these processes including, as applicable:

- a) Defined criteria for review and approval of the processes,
- b) Approval of equipment and qualification of personnel,
- c) Use of specific methods and procedures,
- d) Requirements for records,
- e) Revalidation of important changes in facilities, personnel, and procedures affecting the product quality.

### **7.5.3 Identification Codes and Traceability**

Where appropriate, Yokogawa identifies product by suitable means throughout realization, including status with respect to monitoring and measurement requirements. Where traceability is a requirement, there is a unique identification of the product.

### **7.5.4 Customer Property**

(1) Yokogawa exercises due care with customer property while it is under our control or being used by us. We identify, verify, protect, and safeguard customer property provided for our use or incorporated into the product. If any customer property is lost, damaged, or otherwise found to be unsuitable for use, we report this fact to the customer and maintain records.

### **7.5.5 Preservation of Product**

Yokogawa has taken steps maintain the conformity of product during internal processing and delivery to the intended destination. This preservation includes identification, handling, packaging, storage and protection.

### **7.6 Control of Monitoring and Measuring Devices**

Yokogawa has determined the monitoring and measurement required and the monitoring and measuring devices needed to provide evidence of conformity of product to determined requirements.

Yokogawa has established processes to ensure that monitoring and measurement is carried out in a manner that is consistent with the monitoring and measurement requirements.

Where necessary to ensure valid results, measuring equipment is calibrated or verified at specified intervals, or prior to use, against measurement standards traceable to international or national measurement standards. Where no such standards exist, the basis used for calibration or verification is recorded.

Measurement equipment is:

- (1) Adjusted or readjusted as necessary,
- (2) Identified to enable the calibration status to be determined,
- (3) Safeguarded from adjustments that would invalidate the measurement result,
- (4) Protected from damage and deterioration during handling, maintenance, and storage.

When the equipment is found not to conform to requirements, Yokogawa will assess and record the validity of the previous measuring results and take appropriate action on the equipment and any product affected.

Yokogawa maintains records of the results of calibration and verification.

When used in the monitoring and measurement of specified requirements, we confirm the ability of computer software to satisfy the intended application. This is undertaken prior to initial use and reconfirmed as necessary.

## **8 Measurement, Analysis and Improvement**

### **8.1 General**

Yokogawa has planned and implemented the monitoring, measurement, analysis, and improvement processes needed to demonstrate conformity of the product and to ensure conformity of the Quality Management System. Yokogawa continually improves the effectiveness of the Quality Management System.

### **8.2 Monitoring and Measurement**

#### **8.2.1 Customer Satisfaction**

As one of the measurements of the performance of our Quality Management System, Yokogawa monitors information relating to customer perception to determine whether we are meeting customer requirements.

#### **8.2.2 Internal Audit**

Yokogawa conducts internal audits at planned intervals to verify the Quality Management System:

- a) Conforms to planned arrangements,
- b) Conforms to ISO 9001:2000 requirements and to the regulations prescribed in this Quality Management System,
- c) Is effectively implemented and maintained.

The Yokogawa audit program takes into consideration the status and importance of the processes and areas to be audited, as well as the results of previous audits. The audit criteria, scope, frequency and methods are defined in the audit schedule and audit plans. Internal Audits are conducted by Quality Assurance personnel and never by the personnel performing the work being audited. This ensures audits are objective and impartial.

The responsibility and requirements for planning and conducting audits, and for reporting results and maintaining records, is defined in documented procedure YQA-170.

The manager responsible for the area audited takes immediate actions to eliminate detected nonconformities and their causes. Quality Assurance verifies actions taken and the reporting of verification results.

### **8.2.3 Monitoring and Measurement of Processes**

Yokogawa has developed methods for monitoring and measurement of the Quality Management System processes, and these methods demonstrate the ability of the processes to achieve planned results.

When planned results are not achieved, correction and corrective actions are taken to ensure conformity of the product.

### **8.2.4 Monitoring and Measurement of Product**

Yokogawa monitors and measures the characteristics of our products verifying that requirements are met. This verification is carried out at appropriate stages in the product realization process in accordance with the planned arrangements. Yokogawa maintains evidence of conformity using acceptance criteria. Records indicate the person(s) authorizing release of product.

Yokogawa does not proceed with product release and service delivery until the planned arrangements have been satisfactorily completed, unless otherwise approved by a relevant authority and, where applicable, by the customer.

### **8.3 Control of Nonconforming Product**

Yokogawa has taken precautions to ensure that product which does not conform to requirements is identified and controlled to prevent its unintended use or delivery. The controls and related responsibilities and authorities for dealing with nonconforming product are defined in documented procedure YMQA-13-001. Yokogawa deals with nonconforming product by one or more of the following ways:

- a) by taking action to eliminate the detected nonconformity
- b) by authorizing its use, release, or acceptance under concession by a relevant authority and, where applicable, by the customer
- c) by taking action to preclude its original intended use or application

Records of the nature of nonconformities and any subsequent actions taken,

including concessions obtained, are maintained.

When a nonconforming product is corrected, it is subject to re-verification to demonstrate conformity to the requirements.

When a nonconforming product is detected after delivery or after use, appropriate actions are taken based on the effects, or potential effects, of the nonconformity.

#### **8.4 Analysis of Data**

Yokogawa determines, collects, and analyzes appropriate data to demonstrate the suitability and effectiveness of the Quality Management System and to evaluate where continual improvement can be made. This includes data generated as a result of monitoring and measurement and from other relevant sources.

The analysis of this data provides information relating to:

- a) Customer satisfaction,
- b) Conformance to product requirements,
- c) Characteristics and trends of processes and products including opportunities for preventive action,
- d) Suppliers.

#### **8.5 Improvement**

##### **8.5.1 Continual Improvement**

Yokogawa continually improves the effectiveness of the Quality Management System through the use of the quality policy, quality objectives, audit results, analysis of data, corrective and preventive actions and management review.

##### **8.5.2 Corrective Action**

Yokogawa takes actions to eliminate the cause of nonconformities in order to prevent recurrence. Corrective actions are appropriate to the effects of the nonconformities encountered.

Yokogawa has documented procedure YQA-140 defining requirements for:

- a) Reviewing nonconformities (including customer complaints),
- b) Determining the causes of nonconformities,
- c) Evaluating the need for action to ensure that nonconformities do not recur,
- d) Determining and implementing action needed,
- e) Records of the results of action taken,
- f) Reviewing corrective action taken.

##### **8.5.3 Preventive Action**

Yokogawa determines actions to eliminate the causes of potential nonconformities in order to prevent their occurrence. These preventive actions are appropriate to the effects of the potential problems.

Yokogawa has documented procedure YQA-140 defining requirements for:

- a) Determining potential nonconformities and their causes,
- b) Evaluating the need for action to prevent occurrence of nonconformities,
- c) Determining and implementing action needed,
- d) Records of results of action taken,
- e) Reviewing preventive action taken.

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