

# Quality Management Manual

Yokogawa Corporation of America.

## **INTRODUCTION**

### **Yokogawa North America**

#### **QUALITY, HEALTH & SAFETY and ENVIRONMENTAL MANAGEMENT (QHSE)**

Yokogawa is committed to providing sustainable solutions and services that meet the expectations of our customers.

The interests of our stakeholders, such as customers, employees, business partners, suppliers, governments and society, profoundly influence our business processes and practices.

Based on Yokogawa's *Co-inventing Tomorrow* direction, we will meet customer requirements for Quality, Health & Safety and Environmental Management in harmony with regulatory requirements. We actively foster the Continual Improvement of these management systems to empower each employee to practice this working philosophy.

At Yokogawa, QHSE responsibilities are integral to our management routines and employee behavior. Through observance of this Yokogawa participates in protecting the environment and the overall well-being of the community, our customers, employees and subcontractors. Our goal is Quality deliveries to our customer, minimize impact to the environment and prevent harm to our employees and others who are affected by our activities.

Yokogawa management recognizes their responsibility for creating and sustaining a culture that supports the implementation of QHSE standards. Management provides leadership and commitment to ensure that necessary resources to execute these standards are available and are in compliance with Yokogawa rules and guidelines.

The QHSE team has its prime focus to improve and assure Yokogawa business process performance to deliver products, projects and services compliant with customer expectations in North America, and projects all over the world. These are executed in a safe and healthy working environment embracing corporate social responsibilities of the communities where we operate.

We will continue to take a proactive approach towards quality and maintain a safe and healthy work environment with tools and methodologies for all employees and subcontractors to minimize health risks, reducing waste and using energy efficiently. We promote continued QHSE education and training for all employees and ensure a thorough evaluation of customer complaints, non-conformities, and incidents resulting in an effective improvement processes.

Our certified management systems integrate international standards and control measures regarding Quality, Health & Safety and Environmental Management into our business processes and verify our performance.

## **Quality Management Principles**

### **1. Customer Focus**

The primary focus of quality management is to meet customer requirements and strive to exceed customer expectations.

### **2. Leadership**

Leaders at all levels establish unity of purpose and direction and create conditions in which people are engaged in achieving the organization's quality objectives.

### **3. Engagement of people**

Competent, empowered and engaged people at all levels throughout the organization are essential to enhance our capability to create and deliver value.

### **4. Process approach**

Consistent and predictable results are achieved more effectively and efficiently when activities are understood and managed as interrelated processes that function as a coherent system.

### **5. Improvement**

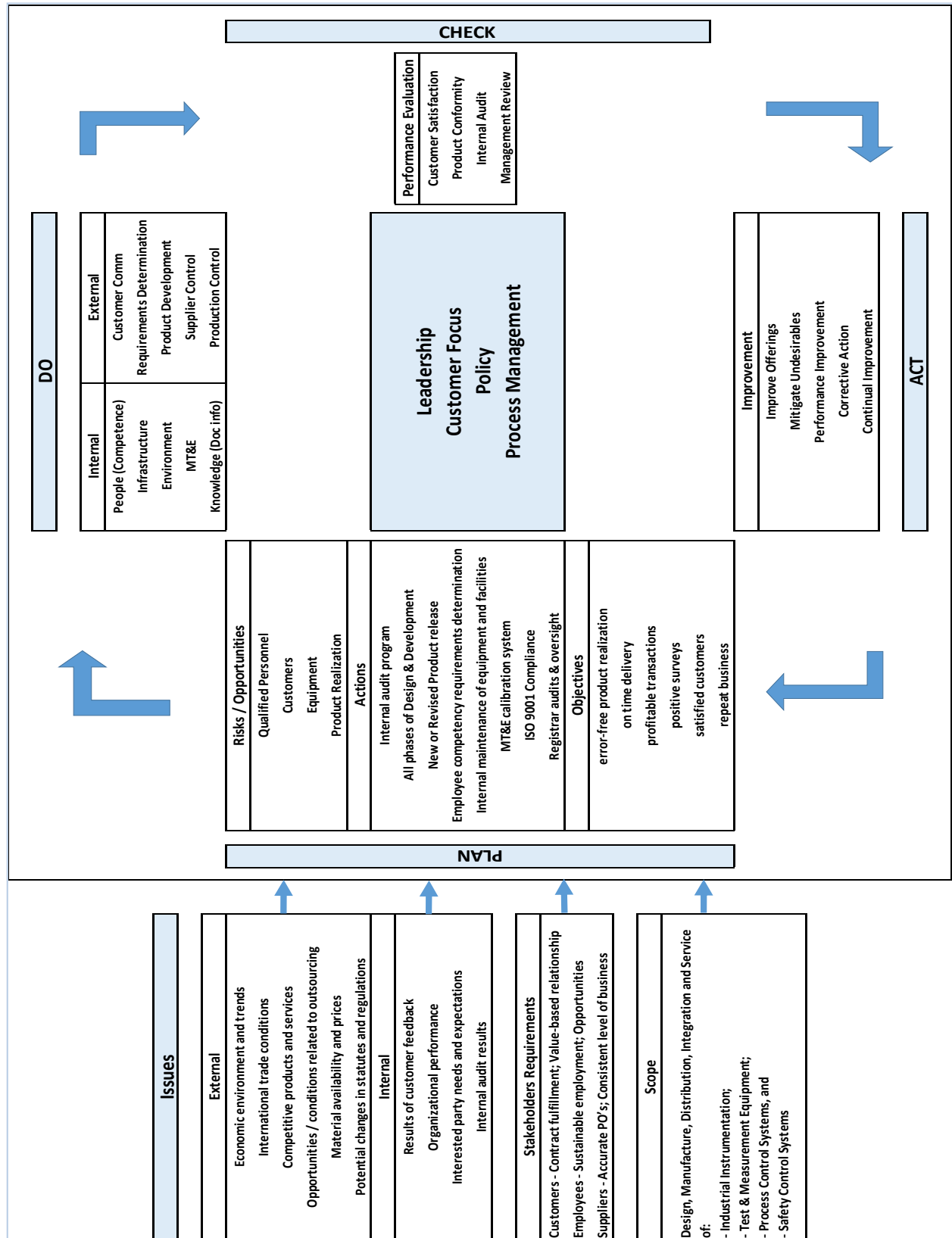
Successful organizations have an ongoing focus on improvement.

### **6. Evidence-based decision making**

Decisions based on the analysis and evaluation of data and information are more likely to produce desired results.

### **7. Relationship management**

For sustained success, organizations manage their relationships with interested parties, such as suppliers.



# Yokogawa Quality Policy

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 and providing our customers quality products and services, on time, every time, everywhere. 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 meet the expectations and needs of the customer, embracing a commitment to continual improvement, and complying with all statutory and regulatory requirements, and recognized standards.

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## **1 Purpose and Scope**

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.

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 Process & Safety 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.

*ANNEX A to this Quality Manual lists additional requirements, supplemental to the ISO 9001 requirements listed herein, that are selectively applied to ATEX or IECEx certified products.*

*ANNEX B to this Quality Manual is a stand-alone manual that lists technical competence requirements for testing and calibration laboratories per ISO/IEC 17025.*

## **2 Normative Reference**

This Quality Management Manual was created based on the international standard ISO 9001 Quality Management Systems – Requirements.

Annex A was created based on ISO/IEC 80079-34, Explosive atmospheres – Part 34: Application of quality systems for equipment manufacture.

Annex B was created based on ISO/IEC 17025, General requirements for the competence of testing and calibration laboratories.

If the international standards are modified, this Quality Management Manual and/or Annexes will be revised accordingly.

## **3 Terms and definitions**

For the purposes of this document, the terms and definitions given in ISO 9000 apply.

## **4 Context of the Organization**

### **4.1 Understanding the Organization and its Context**

The context of Yokogawa is defined in our scope of registration:

*Manufacture, Distribution, Integration, Assembly and Service of: Industrial Instrumentation, Analyzers and Packaging, Test and Measurement Equipment, Process & Safety Control Systems.*

Yokogawa has determined external and internal issues that are relevant to our purpose and strategic direction and that affect our ability to achieve the intended result(s) of our quality management system.

The external issues that affect our organization include:

1. Economic environment and trends;
2. International trade conditions;
3. Competitive products and services;
4. Opportunities and conditions related to outsourcing;
5. Material availability and prices;
6. Potential changes in statutes and regulations.

The internal issues that affect our organization include:

1. Results of customer reviews, audits, complaints and feedback;
2. Organizational performance;
3. Interested party needs and expectations;
4. Internal audit results.

Yokogawa uses the SWOT analysis framework for identifying and analyzing the external issues that can have an impact on the company.

Context		External Issues:					
		Economic Environment & Trends	International Trade Conditions	Competitive Products & Services	Outsourcing Conditions & Opportunities	Material Availability & Prices	Statute Changes
strengths	Quality reputation in marketplace			x			
	Member of Global Yokogawa network		x	x	x	x	
	Easy access to capital	x				x	
	Disciplines: J-Ethic, 4-ISO, FSM						x
	Customer Satisfaction high			x			
weaknesses	Lack of market share (new to US)			x			
	Aging workforce (Knowledge Management)	x					
	Competition entrenched			x			
	Narrow portfolio - Energy focus	x		x			
	Product delivery (competitor stocking)	x		x			
opportunities	Territory (USA) is a strong market	x					
	Major Energy accounts in territory	x					
	Potential for growth (steal market share)			x			
	Many GMA's are in Territory		x	x			
	EPA mandates may increase	x					x
threats	Competitive pressure at key customers	x		x		x	
	Competitors / Retaining key personnel	x		x			
	Supply Chain Disruptions		x				
	Volatility of Energy Market	x					

## 4.2 Understanding the Needs and Expectations of Interested Parties

Due to their effect or potential effect on Yokogawa's ability to consistently provide products and services that meet customer and applicable statutory and regulatory requirements, we determined:

- a) The interested parties that are relevant to the quality management system;



- b) The requirements of these interested parties that are relevant to the quality management system.

Relevant interested parties include:

Stakeholders	Requirements
Customers	Contract fulfillment; Value-based relationship;
Employees	Sustainable employment; Opportunities;
Suppliers	Accurate PO's; Consistent level of business;

Yokogawa monitors and reviews the information about these interested parties and their relevant requirements.

#### 4.3 Determining the Scope of the Quality Management System

4.3.1 Yokogawa has determined the boundaries and applicability of the quality management system to establish its scope.

When determining this scope, we considered:

- a) The external and internal issues referred to in 4.1;
- b) The requirements of relevant interested parties referred to in 4.2;
- c) The products and services we offer.

Yokogawa applies all the requirements of this International Standard as they are applicable within the determined scope of our quality management system.

The scope of our quality management system, as detailed below, is available and maintained as documented information.

*Design, Manufacture, Distribution, Integration and Service of Industrial Instrumentation; Test & Measurement Equipment; and Process & Safety Control Systems.*

4.3.2 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.

#### 4.4 Quality Management System and its Processes (PIT)

4.4.1 Yokogawa has established, implemented, maintains, and continually improves a quality management system, including the processes needed and their interactions, in accordance with the requirements of ISO 9001.

We have determined the processes needed for the quality management system and their application throughout Yokogawa, and:

- a) Determined the inputs required and the outputs expected from these processes;
- b) Determined the sequence and interaction of these processes;
- c) Determined and applied the criteria and methods (including monitoring, measurements and related performance indicators) needed to ensure the effective operation and control of these processes;

- d) Determined the resources needed for these processes and ensured their availability;
- e) Assigned the responsibilities and authorities for these processes;
- f) Addressed the risks and opportunities as determined in accordance with the requirements of 6.1;
- g) Evaluate these processes and implement any changes needed to ensure that these processes achieve their intended results.
- h) Improve the processes and the quality management system.

Yokogawa manages these processes in accordance with the requirements of this Quality Management Manual.

4.4.2 To the extent necessary, we:

- a) Maintain documented information to support the operation of our processes;
- b) Retain documented information to have confidence that the processes are being carried out as planned.

## **5 Leadership**

### **5.1 Leadership and Commitment**

#### **5.1.1 General**

Top management demonstrates leadership and commitment with respect to the quality management system by:

- a) Taking accountability for the effectiveness of the quality management system;
- b) Ensuring that the quality policy and quality objectiveness are established for the quality management system and are compatible with the context and strategic direction of Yokogawa;
- c) Ensuring the integration of the quality management system requirements into our business process;
- d) Promoting the use of the process approach and risk-based thinking;
- e) Ensuring that the resources needed for the quality management system are available;
- f) Communicating the importance of effective quality management and of conforming to the quality management system requirements;
- g) Ensuring that the quality management system achieves its intended results;
- h) Engaging, directing and supporting persons to contribute to the effectiveness of the quality management system;
- i) Promoting improvement;
- j) Supporting other relevant management roles to demonstrate their leadership as it applies to their areas of responsibility.

#### **5.1.2 Customer Focus**

Yokogawa maintains a customer focused organization ensuring that customer requirements are determined and met with the aim of improving customer satisfaction. Our mission statement is: *“Yokogawa Corporation of*

*America, the most trusted automation solutions partner for operational excellence & a sustainable future.”*

Top management demonstrates leadership and commitment with respect to customer focus by ensuring that:

- a) Customer and applicable statutory and regulatory requirements are determined, understood and consistently met;
- b) The risks and opportunities that can affect conformity of products and services and the ability to enhance customer satisfaction are determined and addressed;
- c) The focus on enhancing customer satisfaction is maintained.

## **5.2 Policy**

### **5.2.1 Developing the 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 to continual improvement. The Quality Policy provides a framework for establishing and reviewing quality objectives, and is communicated and understood within Yokogawa.

It is endorsed by top management and is reviewed annually for continued suitability by them through the Quality Management Review process.

Top management has established, implemented and maintains a quality policy that:

- a) Is appropriate to the purpose and context of Yokogawa and supports our strategic direction;
- b) Provides a framework for setting quality objectives;
- c) Includes a commitment to satisfy applicable requirements;
- d) Includes a commitment to continual improvement of the quality management system.

### **5.2.2 Communicating the Quality Policy**

The Quality Policy:

- a) is available and maintained as documented information;
- b) is communicated, understood and applied within the organization; and
- c) is available to relevant interested parties, as appropriate.

#### **Quality Policy:**

*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 and providing our customers quality products and services, on time, every time, everywhere. 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 meet the expectations and needs of the customer, embracing a commitment to continual improvement, and complying with all statutory and regulatory requirements, and recognized standards.*

### **5.3 Organizational Roles, Responsibilities, and Authorities**

Top management ensures that the responsibilities and authorities for relevant roles are assigned, communicated and understood. This is typically done through specific job descriptions and an organizational chart.

Top management assigns the responsibility and authority for:

- a) Ensuring that the quality management system conforms to the requirements of ISO 9001;
- b) Ensuring that the processes are delivering their intended outputs;
- c) Reporting on the performance of the quality management system and on opportunities for improvement (10.1), in particular to top management;
- d) Ensuring the promotion of customer focus throughout;
- e) Ensuring that the integrity of the quality management system is maintained when changes to the quality management system are planned and implemented.

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

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

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

## **6 Planning**

### **6.1 Actions to Address Risks and Opportunities**

- 6.1.1** When planning for the quality management system, Yokogawa considered the issues referred to in 4.1 and the requirements referred to in 4.2 and determined the risks and opportunities that need to be addressed to:

- a) Give assurance that the quality management system can achieve its intended results;
- b) Enhance desirable effects;
- c) Prevent, or reduce, undesired effects;
- d) Achieve improvement.

Categories include:

- a) Qualified Personnel
- b) Customers
- c) Equipment
- d) Product Realization

#### **6.1.2 Yokogawa plans:**

- a) Actions to address these risks and opportunities;
- b) How to:
  - 1) Integrate and implement the actions into our quality management system processes (4.4)
  - 2) Evaluate the effectiveness of these actions.

Actions to address risks and opportunities include:

- Internal audit program;
- All phases of Design & Development;
- New or Revised Product release;
- Employee competency requirements determination;
- Internal maintenance of equipment and facilities;
- MT&E calibration system and components, including ISO 17025 accreditation;
- ISO 9001 Compliance;
- Registrar audits & oversight

Actions taken to address risks and opportunities are proportionate to the potential impact on the conformity of products and services.

## **6.2 Quality Objectives and Planning to Achieve Them**

Yokogawa 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.

### **6.2.1 Yokogawa has established quality objectives at relevant functions, levels and processes needed for the quality management system.**

The quality objectives are:

- a) Consistent with the quality policy;
- b) Measurable;
- c) Taken into account applicable requirements;

- d) Relevant to conformity of products and services and to enhancement of customer satisfaction;
- e) Monitored;
- f) Communicated;
- g) Updated as appropriate.

Objectives include:

- error-free product realization
- on time delivery
- profitable transactions
- positive surveys
- satisfied customers
- repeat business

Yokogawa maintains documented information on the quality objectives.

**6.2.2** When planning how to achieve our quality objectives, Yokogawa has determined:

- a) What will be done;
- b) What resources will be required;
- c) Who will be responsible;
- d) When it will be completed; and
- e) How the results will be evaluated.

### **6.3 Planning of Changes**

When Yokogawa determines the need for changes to the quality management system, the changes are carried out in a planned manner.

Yokogawa considers:

- a) The purpose of the changes and their potential consequences;
- b) The integrity of the quality management system;
- c) The availability of resources;
- d) The allocation or reallocation of responsibilities and authorities.

## **7 Support**

### **7.1 Resources**

#### **7.1.1 General**

Yokogawa determines and provides the resources needed for the establishment, implementation, maintenance and continual improvement of the quality management system.

Yokogawa considers:

- a) The capabilities of, and constraints on, existing internal resources;

- b) What needs to be obtained from the external providers.

### **7.1.2 People**

Yokogawa determines and provides the persons necessary for the effective implementation of our quality management system and for the operation and control of our processes.

### **7.1.3 Infrastructure**

Yokogawa determines, provides, and maintains the environment necessary for the operation of our processes and to achieve conformity of products and services.

- a) Buildings and associated utilities;
- b) Equipment, including hardware and software;
- c) Transportation resources;
- d) Information and communication technology.

### **7.1.4 Environment for the Operation of Processes**

Yokogawa determines, provides and maintains the environment necessary for the operation of our processes and to achieve conformity of products and services.

- a) Social (e.g. non-discriminatory, calm, non-confrontational);
- b) Psychological (e.g. stress reducing, burnout prevention, emotionally protective);
- c) Physical (e.g. temperature, heat, humidity, light, airflow, hygiene, noise).

These factors can differ substantially depending on the products and services provided.

### **7.1.5 Monitoring and Measuring Resources**

#### **7.1.5.1 General**

Yokogawa determines and provides the resources needed to ensure valid and reliable results when monitoring or measuring is used to verify the conformity of products and services to requirements.

Yokogawa ensures that the resources provided:

- a) Are suitable for the specific type of monitoring and measurement activities being undertaken;
- b) Are maintained to ensure their continuing fitness for their purpose.

We retain appropriate documented information as evidence of fitness for purpose of the monitoring and measurement resources.

#### **7.1.5.2 Measurement Traceability**

When measurement traceability is a requirement, or is considered by Yokogawa to be an essential part of providing confidence in the validity of measurement results, measuring equipment are:

- a) Calibrated or verified, or both, at specified intervals, or prior to use, against measurement standards traceable to international or national measurement standards; when no such standards exist, the basis used for calibration or verification is retained as documented information;
- b) Identified in order to determine their status;
- c) Safeguarded from adjustments, damage or deterioration that would invalidate the calibration status and subsequent measurement results.

Yokogawa determines if the validity of previous measurement results has been adversely affected when measuring equipment is found to be unfit for its intended purpose, and takes appropriate action as necessary.

#### **7.1.6 Organizational Knowledge**

Yokogawa determines the knowledge necessary for the operation of our processes and to achieve conformity of products and services.

This knowledge is maintained and made available to the extent necessary.

Retention methods include:

- Succession Planning;
- Cross-training;
- Lessons Learned;
- Procedures, Work Instructions, documented information;
- Standardized Work processes.

When addressing changing needs and trends, Yokogawa considers our current knowledge and determines how to acquire or access any necessary additional knowledge and required updates.

### **7.2 Competence**

Yokogawa:

- a) Determines the competence of person(s) doing work under our control that affect the performance and effectiveness of the quality management system;
- b) Ensures that these persons are competent on the basis of appropriate education, training, or experience;
- c) Where applicable, take actions to acquire the necessary competence, and evaluate the effectiveness of the actions taken;
- d) Retain appropriate documented information as evidence of competence.

### **7.3 Awareness**

Yokogawa ensures that persons doing work under Yokogawa's control are aware of:



- a) The quality policy;
- b) Relevant quality objectives;
- c) Their contribution to the effectiveness of the quality management system, including the benefits of improved performance;
- d) The implication of not conforming to quality management system requirements.

#### **7.4 Communication**

Yokogawa determined the internal and external communications relevant to the quality management system, including:

- a) On what it will communicate;
- b) When to communicate;
- c) With whom to communicate;
- d) How to communicate;
- e) Who communicates.

#### **7.5 Documented Information**

##### **7.5.1 General**

The Quality Management System documentation issued by Yokogawa includes:

- a) A Quality Policy and objectives;
- b) A Quality Management Manual;
- c) Documented procedures and records as required by ISO 9001;
- d) Documents, including records, determined to be necessary to ensure the effective planning, operation, and control of processes.

##### **7.5.2 Creating and Updating (QA-80-0050)**

When creating an updating documented information, Yokogawa ensures appropriate:

- a) Identification and description (e.g. title, date, author, or reference number);
- b) Format (e.g. language, software version, graphics) and media (e.g. paper, electronic);
- c) Review and approval for suitability and adequacy.

##### **7.5.3 Control of Documented Information**

7.5.3.1 Documents required by the Quality Management System are under control by the appropriate department within Yokogawa. A documented procedure (QA-80-0050) has been established by Corporate Quality Assurance to ensure:

- a) availability and suitable for use, where and when it is needed;
- b) adequate protection (e.g. from loss of confidentiality, improper use, or loss of integrity).

7.5.3.2 For the control of documented information, Yokogawa has addressed the following activities, as applicable:

- a) Distribution, access, retrieval and use;
- b) Storage and preservation, including preservation of legibility;
- c) Control of changes (e.g. version control);
- d) Retention and disposition.

Documented information of external origin determined by Yokogawa to be necessary for the planning and operation of the quality management system is identified as appropriate and controlled.

Documented information retained as evidence of conformity are protected from unintended alterations.

#### 7.5.3.3 Control of Records (QA-80-0160)

Records established by each relevant department to provide evidence of conformity to requirements and of the effective operation of this Quality Management System shall be controlled. Records are legible, readily identifiable, and can be easily retrieved. A documented procedure (QA-80-0160) has been established by Corporate Quality Assurance to ensure the controls necessary for the identification, storage, protection, retrieval, retention, and disposition of Records.

## **8 Operation**

### **8.1 Operational Planning and Control**

Yokogawa planned, implemented and controls the processes (4.4) needed to meet the requirements for the provision of products and services, and implemented the actions determined in Clause 6, by:

- a) Determining the requirements for the products and services;
- b) Establishing criteria for:
  - 1) The processes;
  - 2) The acceptance of products and services;
- c) Determining the resources needed to achieve conformity to the product and service requirements;
- d) Implementing control of the processes in accordance with the criteria;
- e) Determining and keeping documented information to the extent necessary:
  - 1) To have confidence that the processes have been carried out as planned;
  - 2) To demonstrate the conformity of products and services to their requirements.

The output of this planning is in a form suitable to Yokogawa's method of operations. Yokogawa ensures that outsourced processes are controlled (8.4).

## **8.2 Requirements for Products and Services**

### **8.2.1 Customer Communication**

Communication with Customers includes:

- a) Providing information relating to products and services;
- b) Handling inquiries, contracts or orders, including changes;
- c) Obtaining customer feedback relating to products and services, including customer complaints;
- d) Handling or controlling customer property;
- e) Establishing specific requirements for contingency actions, when relevant.

### **8.2.2 Determining the Requirements Related to Products and Services**

When determining the requirements for the product and services to be offered to customers, Yokogawa ensures that:

- a) The requirements for the product and services are defined, including:
  - 1) Any applicable statutory and regulatory requirements;
  - 2) Those considered necessary by Yokogawa;
- b) Yokogawa can meet the claims for the product and services it offers.

### **8.2.3 Review of Requirements Related to Products and Services**

8.2.3.1 Yokogawa ensures that it has the ability to meet the requirements for products and services offered to customers. Yokogawa conducts a review before committing to supply products and services to a customer, to include:

- a) Requirements specified by customer, including the requirements for delivery and post-delivery activities;
- b) Requirements not stated by the customer, but necessary for the specified intended use, when known;
- c) Requirements specified by Yokogawa;
- d) Statutory and regulatory requirements applicable to the products and services;
- e) Contract or order requirements differing from those previously expressed.

Yokogawa ensures that the contract or order requirements differing from those previously defined are resolved.

The customer's requirements are confirmed by Yokogawa before acceptance, when the customer does not provide a documented statement of their requirements.

8.2.3.2 Yokogawa retains documented information, as applicable:

- a) On the results of the review;
- b) On any new requirements for the products and services.

#### **8.2.4 Changes to Requirements for Products and Services**

Yokogawa ensures that relevant documented information is amended, and that relevant persons are made aware of the changed requirements, when the requirements for products and services are changed.

### **8.3 Design and Development of Products and Services**

#### **8.3.1 General**

Yokogawa has established, implemented, and maintains a design and development process that is appropriate to ensure the subsequent provision of products and services.

#### **8.3.2 Design and Development Planning**

In determining the stages and controls for design and development, Yokogawa considers:

- a) The nature, duration, and complexity of the design and development activities;
- b) The required process stages, including applicable design and development reviews;
- c) The required design and development verification and validation activities;
- d) The responsibilities and authorities involved in the design and development process;
- e) The internal and external resource needs for the design and development of products and services;
- f) The need to control interfaces between persons involved in the design and development process;
- g) The need for involvement of customers and users in the design and development process;
- h) The requirements for subsequent provisions of products and services;
- i) The level of control expected for the design and development process by customer and other relevant interested parties;
- j) The documented information needed to demonstrate that design and development requirements have been met.

#### **8.3.3 Design and Development Inputs**

Yokogawa determines the requirements essential for the specific types of products and services to be designed and developed. Yokogawa considers:

- a) Functional and performance requirements;
- b) Information derived from previous similar design and development activities;
- c) Statutory and regulatory requirements;
- d) Standards or codes of practice that Yokogawa has committed to implement;
- e) Potential consequences of failure due to the nature of the products and services.

Inputs are adequate for design and development purposes, complete, and unambiguous. Conflicting design and development inputs are resolved.

Yokogawa retains documented information on design and development inputs.

#### **8.3.4 Design and Development Controls**

Yokogawa applies controls to the design and development process to ensure that:

- a) The results achieved are defined,
- b) Reviews are conducted to evaluate the ability of the results of design and development to meet requirements;
- c) Verification activities are conducted to ensure that the design and development outputs meet the input requirements;
- d) Validation activities are conducted to ensure that the resulting products and services meet the requirements for the specified application or intended use;
- e) Any necessary actions are taken on problems determined during the reviews, or verification and validation activities;
- f) Documented information of these activities is retained.

#### **8.3.5 Design and Development Outputs**

Yokogawa ensures that design and development outputs:

- a) meet the input requirements;
- b) are adequate for the subsequent processes for the provision of products and services;
- c) include or reference monitoring and measuring requirements, as appropriate, and acceptance criteria;
- d) specify the characteristics of the products and services that are essential for their intended purpose and their safe and proper provision.

Yokogawa retains documented information on design and development outputs.

#### **8.3.6 Design and development changes**

Yokogawa identifies, reviews, and controls changes made during, or subsequent to, the design and development of products and services, to the extent necessary to ensure that there is no adverse impact on conformity to requirements.

Yokogawa retains documented information on:

- a) Design and development changes;
- b) The results of reviews;
- c) The authorization of the changes;
- d) The actions taken to prevent adverse impacts.

## **8.4 Control of Externally Provided Processes, Products, and Services**

### **8.4.1 General**

Yokogawa ensures that externally provided processes, products, and services conform to requirements.

Yokogawa determines the control applied to externally provided processes, products, and services when:

- a) Products and services from external providers are intended for incorporation into Yokogawa's own products and services;
- b) Products and services are provided directly to the customer(s) by external providers on behalf of Yokogawa;
- c) A process, or part of a process, is provided by an external provider as a result of a decision by Yokogawa.

Yokogawa determines and applies criteria for the evaluation, selection, monitoring of performance, and re-evaluation of external providers, based on their ability to provide processes or products and services in accordance with requirements. Yokogawa retains documented information of these activities and any necessary actions arising from the evaluations.

### **8.4.2 Type of Extent Control (QC-80-0016)**

Yokogawa ensures that externally provided processes, products and services do not adversely affect Yokogawa's ability to consistently deliver conforming products and services to our customers.

Yokogawa:

- a) Ensures that externally provided processes remain within the control of our quality management system;
- b) Defines both the controls that it intends to apply to an external provider and those it intends to apply to the resulting output;
- c) Takes into consideration:
  - 1. The potential impact of the externally provided processes, products and services on Yokogawa's ability to consistently meet customer and applicable statutory and regulatory requirements;
  - 2. The effectiveness of the controls applied by the external provider.
- d) Determines the verification, or other activities, necessary to ensure that the externally provided processes, products and services meet requirements.

### **8.4.3 Information for External Providers**

Yokogawa ensures the adequacy of requirements prior to their communication to the external provider.

Yokogawa communicates to external providers our requirements for:

- a) The processes, products and services to be provided;
- b) The approval of:
  - 1. Products and services;
  - 2. Methods, processes and equipment;
  - 3. The release of products and services;
- c) Competence, including any required qualification of persons;
- d) The external providers' interactions with Yokogawa;
- e) Control and monitoring of the external providers' performance to be applied by Yokogawa;
- f) Verification or validation activities that Yokogawa, or our customer, intends to perform at the external providers' premises.

## **8.5 Production and Service Provision**

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

Yokogawa implements production and service provision under controlled conditions. Controlled conditions include, as applicable:

- a) The availability of documented information that defines:
  - 1. The characteristics of the products to be produced, the services to be provided, or the activities to be performed;
  - 2. The results to be achieved;
- b) The availability and use of suitable monitoring and measuring resources;
- c) The implementation of monitoring and measurement activities at appropriate stages to verify that criteria for control of processes or outputs, and acceptance criteria for products and services have been met;
- d) The use of suitable infrastructure and environment for the operation of processes;
- e) The appointment of competent persons, including any required qualification;
- f) The validation and periodic revalidation, of the ability to achieve planned results of the processes for production and service provision, where the resulting output cannot be verified by subsequent monitoring or measurement;
- g) The implementation of actions to prevent human error;
- h) The implementation of release, delivery and post-delivery activities.

### **8.5.2 Identification and Traceability**

Yokogawa uses suitable means to identify outputs when it is necessary to ensure the conformity of products and services.

Yokogawa identifies the status of outputs with respect to monitoring and measurement requirements throughout production and service provision.

Yokogawa controls the unique identification of the outputs when traceability is a requirement and retains the documented information necessary to enable traceability.

### **8.5.3 Property Belonging to Customers or External Providers**

Yokogawa exercises care with property belonging to customer or external providers while it is under Yokogawa's control or being used by Yokogawa.

Yokogawa identifies, verifies, protects and safeguards customer or external providers' property provided for use or incorporation into the products and services.

When the property of a customer or external provider is lost, damaged or otherwise found to be unsuitable for use, Yokogawa reports this to the customer or external provider and retains documented information on what has occurred.

### **8.5.4 Preservation**

Yokogawa preserves the outputs during production and service provision, to the extent necessary to ensure conformity to requirements.

### **8.5.5 Post-delivery Activities**

Yokogawa meets requirements for post-delivery activities associated with the products and services.

In determining the extent of post-delivery activities that are required, Yokogawa considers:

- a) Statutory and regulatory requirements;
- b) The potential undesired consequences associated with our products and services;
- c) The nature, use and intended lifetime of our products and services;
- d) Customer requirements;
- e) Customer Feedback.

### **8.5.6 Control of Changes**

Yokogawa reviews and controls changes for production or service provision, to the extent necessary to ensure continuing conformity with requirements.

Yokogawa retains documented information describing the results of the review of changes, the person(s) authorizing the change, and any necessary actions arising from the review.

## **8.6 Release of Products and Service (QC-80-0026)**

Yokogawa has implemented planned arrangements, at appropriate stages, to verify that the product and service requirements have been met.



The release of products and services to the customer, do not proceed until the planned arrangements have been satisfactorily completed, unless otherwise approved by a relevant authority and, as applicable, by the customer.

Yokogawa retains documented information on the release of products and services. The documented information includes:

- a) Evidence of conformity with the acceptance criteria;
- b) Traceability to the person(s) authorizing the release.

## **8.7 Control of Nonconforming Outputs**

**8.7.1** Yokogawa ensures that outputs that do not conform to their requirements are identified and controlled to prevent their unintended use or delivery.

Yokogawa takes appropriate action based on the nature of the nonconformity and its effect on the conformity of products and services. This also applies to nonconforming products and services detected after delivery of products, during or after the provision of services.

Yokogawa deals with nonconforming outputs in one or more of the following ways:

- a) Correction;
- b) Segregation, containment, return or suspension of provision of products and services;
- c) Informing the customer;
- d) Obtaining authorization for acceptance under concession.

Conformity to the requirements are verified when nonconforming outputs are corrected.

**8.7.2** Yokogawa retains documented information that:

- a) Describes the nonconformity;
- b) Describes the actions taken;
- c) Describes any concessions obtained;
- d) Identifies the authority deciding the action in respect of the nonconformity.

## **9 Performance Evaluation**

### **9.1 Monitoring, Measurement, Analysis and Evaluation**

#### **9.1.1 General**

Yokogawa determines:

- a) What needs to be monitored and measured;

- b) The methods for monitoring, measurement, analysis and evaluation needed to ensure valid results;
- c) When the monitoring and measuring is performed;
- d) When the results from monitoring and measurement are analyzed and evaluated.

Yokogawa evaluates the performance and the effectiveness of the quality management system.

Yokogawa retains appropriate documented information as evidence of the results.

#### **9.1.2 Customer Satisfaction (QC-80-0018) (QC-80-0049)**

Yokogawa monitors customers' perceptions of the degree to which their needs and expectation have been fulfilled. Yokogawa determines the methods for obtaining, monitoring and reviewing this information.

#### **9.1.3 Analysis and Evaluation**

Yokogawa analyzes and evaluates appropriate data and information arising from monitoring and measurement.

The results of analysis are used to evaluate:

- a) Conformity of products and services;
- b) The degree of customer satisfaction;
- c) The performance and effectiveness of the quality management system;
- d) If planning has been implemented effectively;
- e) The effectiveness of actions taken to address risks and opportunities;
- f) The performance of external providers;
- g) The need for improvements to the quality management system.

### **9.2 Internal Audit (QA-80-0170)**

#### **9.2.1 Yokogawa conducts internal audits at planned intervals to provide information on whether the quality management system:**

- a) Conforms to:
  - 1. Yokogawa's own requirements for our quality management system;
  - 2. The requirements of ISO 9001.
- b) Is effectively implemented and maintained.

#### **9.2.2 Yokogawa has:**

- a) Planned, established, implemented and maintains an audit program including the frequency, methods, responsibilities, planning requirements and reporting, which is taken into consideration the importance of the processes concerned, changes affecting Yokogawa, and the results of previous audits;
- b) Defined the audit criteria and scope of each audit;

- c) Selected auditors and conducts audits to ensure objectively and the impartiality of the audit process (QC-80-0048);
- d) Ensured that the results of the audits are reported to relevant management;
- e) Take appropriate correction and corrective actions without undue delay;
- f) Retained documented information as evidence of the implementation of the audit program and the audit results.

### **9.3 Management Review (QC-80-0021)**

#### **9.3.1 General**

A documented procedure (QC-80-0021) has been established by Corporate Quality Assurance to ensure Yokogawa conducts Management Reviews of 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.

#### **9.3.2 Management Review Inputs**

Management review is planned and carried out taking into consideration:

- a) The status of actions from previous management reviews;
- b) Changes in external and internal issues that are relevant to the quality management system;
- c) Information on the performance and effectiveness of the quality management system, including trends in:
  1. Customer satisfaction and feedback from relevant interested parties;
  2. The extent to which quality objectives have been met;
  3. Process performance and conformity of products and services;
  4. Nonconformities and corrective actions;
  5. Monitoring and measurement results;
  6. Audit results;
  7. The performance of external providers;
- d) The adequacy of resources;
- e) The effectiveness of actions taken to address risks and opportunities;
- f) Opportunities for improvement.

#### **9.3.3 Management Review Outputs**

The outputs of the management review include decisions and actions related to:

- a) Opportunities for improvement;
- b) Any need for changes to the quality management system;
- c) Resource needs.

Yokogawa retains documented information as evidence of the results of management reviews.

## **10 Improvement**

### **10.1 General**

Yokogawa determines and selects opportunities for improvement and implements any necessary actions to meet customer requirements and enhance customer satisfaction.

These include:

- a) Improving products and services to meet requirements as well as to address future needs and expectations;
- b) Correcting, preventing or reducing undesired effects;
- c) Improving the performance and effectiveness of the quality management system.

### **10.2 Nonconformity and Corrective Action (QA-80-0140)**

**10.2.1** When a nonconformity occurs, including any arising from complaints, Yokogawa:

- a) Reacts to the nonconformity and, as applicable:
  - 1. Takes action to control and correct it;
  - 2. Deals with the consequences;
- b) Evaluates the need for action to eliminate the cause(s) of the nonconformity, in order that it does not recur or occur elsewhere, by:
  - 1. Reviewing and analyzing the nonconformity;
  - 2. Determining the causes of the nonconformity;
  - 3. Determining if similar nonconformities exist, or could potentially occur;
- c) Implements any action needed;
- d) Reviews the effectiveness of any corrective action taken;
- e) Updates risks and opportunities determined during planning, if necessary;
- f) Makes changes to the quality management system, if necessary. Corrective actions are appropriate to the effects of the nonconformities encountered.

**10.2.2** Yokogawa retains documented information as evidence of:

- a) The nature of the nonconformities and any subsequent actions taken;
- b) The results of any corrective action.

### **10.3 Continual Improvement**

Yokogawa continually improves the suitability, adequacy and effectiveness of the quality management system.

Yokogawa considers the results of analysis and evaluations, and the outputs from the management review, to determine if there are needs or opportunities that are addressed as part of the continual improvement.

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