YOKOGAWA

QUALITY ASSURANCE MANUAL

ANNEX A

Additional Requirements for ATEX, IECEx, and INMETRO Certified Products

Yokogawa Corporation of America.

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ANNEX A to the Yokogawa Corporation of America Quality Assurance Manual For Additional Requirements selectively applied to ATEX and IECEx certified products

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ANNEX A to the Yokogawa Corporation of America Quality Assurance Manual For Additional Requirements selectively applied to ATEX or IECEx certified products

1. Scope

The scope of this addendum encompasses products provided to customers that are ATEX or IECEx certified. All such items are subject to the policies identified in this addendum and the Corporate Quality Manual.

2. Purpose

The purpose of this addendum is to provide explanation and description of quality processes, policies and procedures employed by Yokogawa Corporation of America to ensure the control and compliance of applicable ATEX and IECEx certified products to requirements set forth in ISO 9001:2008 and ISO/IEC 80079-34.

3. Normative Reference

This addendum was created based on the international standards ISO 9001:2008, Quality Management systems and ISO/IEC 80079-34, Explosive atmospheres – Part 34: Application of quality systems for equipment manufacture.

4. Quality Management System

4.1 General Requirements

Subclause 4.1 of ISO 9001:2008 applies, with the following addition:

Yokogawa's quality system ensures the control and compliance of applicable ATEX and IECEx certified products.

4.2 Documentation requirements

4.2.1 General

Subclause 4.2.1 of EN ISO 9001:2008 applies.

4.2.2 Quality manual

Subclause 4.2.2 of EN ISO 9001:2008 applies.

4.2.3 Control of Documents

Subclause 4.2.3 of EN ISO 9001:2008 applies with the following addition:

a) Technical documentation and Yokogawa's documentation shall be controlled,

b) Yokogawa's procedures ensure that information contained within Yokogawa's documentations is compatible with the technical documentation. Yokogawa shall not initially approve or subsequently amend related drawings unless they are in compliance with the schedule drawings,

c) Yokogawa's quality system ensures that no factor (type, characteristic, position etc.) defined within the Ex certificate and technical documentation (e.g. schedule drawings) is modified without Notified Body authorization.

In cases where Ex related drawing changes are necessary, the appointed management representative shall make application to the Notified Body and submit the drawing design change for revised certification,

d) Yokogawa has a documented system that refers all related drawings to the relevant schedule drawings,

e) Where there are common schedule drawings associated with more than one Ex certificate, Yokogawa has a documented system to ensure simultaneous supplementary action in the event of an amendment to such drawings,

f) Where Yokogawa also has drawings for equipment not intended for use in explosive atmospheres, Yokogawa has a system that enables both the related drawings and schedule drawings to be clearly identified,

g) Yokogawa shall document which notified body is responsible for the quality system of each Ex certificate.

h) Where technical documentation or Yokogawa's documentation are passed to a third party, they shall be provided in a way that is not misleading,

i) Yokogawa has a documented procedure to annually check the validity of all Ex related certificates, standards, regulations and other external specifications.

4.2.4 Control of Quality Records

Subclause 4.2.4 of ISO 9001:2008 applies, with the following addition:

a) Yokogawa retains adequate quality records to demonstrate conformity of the product. The quality records are retained for a period of a minimum of 10 years.

As a minimum, the list of documents requiring control and retention, as far as applicable, shall be:

those arising from regulatory requirements; customer order; contract review; training records; inspection and test data (per batch); calibration data; sub-contractor evaluation; delivery data (customer, delivery date and quantity, including serial numbers where available).

5 Management responsibility

5.1 Management commitment

Subclause 5.1 of ISO 9001:2008 applies.

5.2 Customer focus

Subclause 5.2 of ISO 9001:2008 applies.

5.3 Quality policy

Subclause 5.3 of ISO 9001:2008 applies.

5.4 Planning

5.4.1 Quality objectives

Subclause 5.4.1 of ISO 9001:2008 applies

5.4.2 Quality Management System Planning

Subclause 5.4.2 of ISO 9001:2008 applies, with the following addition:

a) Yokogawa documents all the elements, requirements and provisions we have adopted in order to ensure compliance of applicable products with their Ex certificates and technical documentation. They are documented in a systematic and orderly manner in the form of written policies, procedures and instructions. The quality system documentation permits a consistent interpretation of quality programs, plans, manuals and records.

5.5 Responsibility, Authority and Communication

5.5.1 Responsibility and Authority

Subclause 5.5.1 of ISO 9001:2008 applies, with the following addition:

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 appointed Management Representative is responsible for interfacing with the approval organization for changes in the Quality system.

d) The Managers in charge of Engineering and Quality Assurance are responsible for 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

g) The Managers in charge of Engineering and Quality Assurance are responsible for reviewing Ex certificates and technical documentation and identifying any changes that effect product compliance with the certificate.

5.5.2 Management representative

Subclause 5.5.2 of ISO 9001:2008 applies.

5.5.3 Internal communication

Subclause 5.5.3 of ISO 9001:2008 applies

5.6 Quality Management Review

5.6.1 General

Subclause 5.6.1 of ISO 9001:2008 applies, with the following addition:

a) The maximum intervals between reviews should normally be 12 months and shall not exceed 14 months.

b) Top management shall chair the review.

c) The person(s) responsible for the activities detailed in 5.5.1 shall participate in the review.

5.6.2 Review Input

Subclause 5.6.2 of ISO 9001:2008 applies with the following addition:

a) The review shall include the overall effectiveness of the quality management system with respect to equipment intended for use in explosive atmospheres.]

5.6.3 Review output

Subclause 5.6.3 of ISO 9001:2008 applies.

6 Resource management

6.1 Provision of resources

Subclause 6.1 of ISO 9001:2008 applies.

6.2 Human resources

6.2.1 General

Subclause 6.2.1 of ISO 9001:2008 applies.

6.2.2 Competence, Awareness and Training

Subclause 6.2.2 of ISO 9001:2008 applies, with the following addition:

a) Yokogawa shall ensure that all persons having an impact on Ex compliance receive appropriate training.

6.3 Infrastructure

Subclause 6.3 of ISO 9001:2008 applies.

6.4 Work environment

Subclause 6.4 of ISO 9001:2008 applies.

7 Product realisation

7.1 Planning of product realization

Subclause 7.1 of ISO 9001:2008 applies.

7.2 Customer-related Processes

7.2.1 Determination of requirements related to the product

Subclause 7.2.1 of ISO 9001:2008 applies.

7.2.2 Review of Requirements Related to the Product

Subclause 7.2.2 of ISO 9001:2008 applies with the following addition:

a) The review shall ensure that any stated customer requirement is compatible with the Ex certificate e.g. equipment group, temperature class, type of protection, EPL and ambient temperature range.]

7.2.3 Customer communication

Subclause 7.2.3 of ISO 9001:2008 applies.

7.3 Design and Development

7.3.1 Design and development planning

Subclause 7.3.1 of ISO 9001:2008 is not within the scope of this standard.

7.3.2 Design and development inputs

Subclause 7.3.2 of ISO 9001:2008 is not within the scope of this standard.

7.3.3 Design and development outputs

Subclause 7.3.3 of ISO 9001:2008 is not within the scope of this standard

7.3.4 Design and development review

Subclause 7.3.4 of ISO 9001:2008 is not within the scope of this standard

7.3.5 Design and development verification

Subclause 7.3.5 of ISO 9001:2008 is not within the scope of this standard

7.3.6 Design and development validation

Subclause 7.3.6 of ISO 9001:2008 is not within the scope of this standard

7.3.7 Control of Design and Development Changes

Subclause 7.3.7 of ISO 9001:2008 applies with the following addition:

a) The Managers in charge of Engineering and Quality Assurance shall approve any changes that could compromise Ex compliance.

7.4 Purchasing

7.4.1 Purchasing Process

Subclause 7.4.1 of ISO 9001:2008 applies, with the following addition:

a) while manufacture, testing and final inspection may be sub-contracted, the responsibility for ensuring conformance with the Ex certificate shall not be sub-contracted;

b) suppliers that provide a product, process or service that can affect the product's compliance with the Ex certificate, shall only be selected after an evaluation has demonstrated that they have the capability of ensuring compliance with all specified requirements:

1) documented objective evidence that the supplier can provide a product, process, or service that is fit for its purpose shall be made by one or more of the following methods:

- the supplier has an acceptable Ex quality system,

- the supplier has a quality system certificate in accordance to the appropriate standard and with an acceptable scope,

- a documented site assessment to ensure that all relevant controls are available, documented, understood and effective.

2) suppliers providing calibration services (including verification on measuring devices by comparison with calibrated equipment) shall be evaluated on their ability to meet stated requirements, in addition to 7.6;

3) where the features affecting the type of protection cannot be verified at a later stage, e.g. encapsulated intrinsically safe circuits, then the product, process or service shall only be accepted by one of the following methods:

- Yokogawa can demonstrate that the control process implemented by the subcontractor ensures Ex compliance,

– the body responsible for the verification of the quality system performs periodic audits at the sub-contractors.

c) suppliers not used for a period exceeding one year shall be re-evaluated in accordance with 7.4.1 b) prior to the placing of a contract or a purchase order;

d) requirements b) and c) are not mandatory for products, processes or services where Yokogawa verifies conformance in accordance with 7.4.3;

e) the ongoing ability of the supplier to provide conforming product, process or service shall be reviewed at periods not exceeding one year;

f) Yokogawa shall facilitate an arrangement whereby the body responsible for the verification of the Ex quality system may also verify aspects of any supplier's operation that affects the type of protection.

7.4.2 Purchasing Information

Subclause 7.4.2 of ISO 9001:2008 applies, with the following addition:

a) the purchasing documents shall clearly describe the specific requirements pertaining to subcontracted product set out in the Ex certificate and the technical documentation (e.g. for process control, testing or inspection);

b) for items where conformance cannot be verified after manufacture (e.g. encapsulated intrinsically safe circuits), the purchasing information shall set out the specific quality procedures, resources and sequence of activities relevant to the particular item;

c) Yokogawa shall define the method by which documents, e.g. technical specifications, stated in a particular purchase order remain traceable to the order;

d) where Yokogawa does not provide such documents with subsequent orders, then Yokogawa shall have procedures for ensuring that suppliers have current copies of documents and that their integrity be maintained.

7.4.3 Verification of Purchased Product

Subclause 7.4.3 of ISO 9001:2008 applies, with the following addition:

a) for purchased products that can compromise the type of protection the manufacturer shall determine and implement verification arrangements which demonstrate the product's compliance with the Ex certificate, taking into account the nature of the product and the nature of the supplier;

b) when deciding what type of verification is required for a particular purchased product, the manufacturer shall consider the nature of the purchased product, the supplier and how critical it is to the type of protection.

c) where the supplier has been evaluated, and documented objective evidence has been obtained to demonstrate that the supplier is fully capable of producing and verifying the product or service, no further verification of the product or service is required, provided a declaration of conformity according to ISO/IEC 17050-1 is supplied with each batch or product;

d) where the Ex certificate specifies routine tests or inspections, these shall be carried out on each product. They may be carried out by either the supplier or the manufacturer. When carried out by the supplier, this shall be specified on the purchasing documents, e.g. by a quality plan, and confirmed by the supplier, e.g. by a declaration of conformity according to ISO/IEC 17050-1 including test results, if required;

e) where verification of a purchased product cannot be carried out after manufacture, e.g. the internal parts of encapsulated intrinsically safe circuits, then the product shall only be accepted if supplied with a declaration of conformity according to ISO/IEC 17050-1. This shall specifically state compliance to the purchase documents, e.g. a quality plan that lists the factors that together demonstrate conformity of the product;

f) where sample inspections or tests are permitted they shall be conducted in a manner which demonstrates conformity of the entire batch;

g) where either the supplier or the manufacturer requires training or specialist skills or knowledge to carry out a verification, then the training material, specialist skill, knowledge or background shall be documented and training records maintained;

h) where the manufacturer chooses not to carry out inspections and tests on his own premises, then inspections and tests shall be performed on the supplier's premises under the responsibility of the manufacturer;

i) where a supplier provides product with evidence of conformity applicable to use in a explosive atmosphere (e.g. Ex certificate), then further verification is not required unless the manufacturer considers it necessary;

j) where verification of a purchased product relates to the material (metals, alloys, non metallic parts, resins and similar), a specific analysis certificate or declaration shall be supplied.

7.5 Production and Service Provision

7.5.1 Control of Production and Service Provision

Subclause 7.5.1 of ISO 9001:2008 applies, with the following addition:

a) Yokogawa shall provide procedures, production equipment, working environments and inspection/testing facilities that together provide assurance with respect to the compliance of the product with the type as described in the Ex certificate.

7.5.2 Validation of Processes for Production and Service Provision

Subclause 7.5.2 of ISO 9001:2008 applies, with the following addition:

a) Where a process can affect the integrity of a type of protection, and where the resulting integrity cannot be verified after manufacture (e.g. the environmental conditions required for curing an encapsulant), that specific process shall be measured or monitored and documentary evidence shall be maintained to demonstrate compliance with required parameters.

7.5.3 Identification Codes and Traceability

Subclause 7.5.3 of ISO 9001:2008 applies, with the following addition:

a) Yokogawa shall establish and maintain procedures for product identification during all stages of production, testing, final inspection and placing on the market;

b) traceability is required with respect to the final product and its significant parts. Traceability can be achieved using serial number, batch or other acceptable method.

7.5.4 Customer Property

Subclause 7.5.4 of ISO 9001:2008 applies, with the following addition:

a) It is the responsibility of Yokogawa to verify the compatibility of the customer supplied product with the requirements of the Ex certificate.

b) It is Yokogawa policy to not fit customer supplied product to our Ex type products. If customer needs required such fit, Yokogawa would seek approval from the notified body or documented review by Engineering.

7.5.5 Preservation of Product

Subclause 7.5.5 of ISO 9001:2008 applies, with the following addition:

a) Yokogawa shall provide customers with instructions prepared in accordance with the relevant standards or statutory and regulatory requirements.

7.6 Control of Monitoring and Measuring Devices

Subclause 7.6 of ISO 9001:2008 applies, with the following addition:

a) Where a calibration certificate does not bear the accreditation logo of a national accreditation authority, each calibration certificate shall include at least the following information:

1) an unambiguous identification of the item calibrated;

2) evidence that the measurements are traceable to international or national measurement standards;

3) the method of calibration;

4) a statement of compliance with any relevant specification;

5) the calibration results;

6) the uncertainty of measurement, where necessary;

7) the environmental conditions, where relevant;

8) the date of calibration;

9) the signature of the person under whose authority the certificate was issued;

10) the name and address of the issuing organization and the date of issue of the certificate;

11) a unique identification of the calibration certificate.

b) Where a calibration certificate does not bear the accreditation logo of a national accreditation authority or does not contain the information listed in 7.6 a) of ISO 9001:2008, the manufacturer shall demonstrate a valid relationship to international or national measurement standards by other means (e.g. a documented site assessment).

8 Measurement, analysis and improvement

8.1 General

Subclause 8.1 of ISO 9001:2008 applies.

8.2 Monitoring and Measurement

8.2.1 Customer satisfaction

Subclause 8.2.1 of ISO 9001:2008 applies.

8.2.2 Internal Audit

Subclause 8.2.2 of ISO 9001:2008 applies, with the following addition:

a) The audit program shall address the effectiveness of the elements of the quality system as described in this standard to ensure that the products are in conformity with the Ex certificate.

b) The maximum period between audits should normally be 12 months and shall not exceed 14 months.

8.2.3 Monitoring and measurement of processes

Subclause 8.2.3 of ISO 9001:2008 applies.

8.2.4 Monitoring and Measurement of Product

Subclause 8.2.4 of ISO 9001:2008 applies, with the following addition:

a) Where routine tests are required by the Ex certificate and by the technical documentation, these tests shall be performed as specified. Unless specifically permitted by the Ex certificate and the technical documentation, statistical methods shall not be used.

b) Where practicable, the label bearing the marking data shall not be affixed until the final inspection and testing has been satisfactorily completed.

8.3 Control of Nonconforming Product

Subclause 8.3 of ISO 9001:2008 applies, with the following addition:

a) Yokogawa shall maintain a system such that in the event of the product not complying with the Ex certificate, and having been supplied, then Yokogawa's customer can be identified;

b) Yokogawa shall take action, appropriate to the degree of risk, where a nonconforming product has been supplied to a customer;

c) where an unsafe nonconforming product has been supplied to a customer, Yokogawa shall inform the customer, in writing as well as the body responsible for the verification of the quality system, and the issuer of the Ex certificate; In the case of INMETRO Certified Product, if unsafe or non-compliant product has been supplied to a client, Yokogawa must inform in writing the Brazilian Product Certification Body (OCP) responsible for issuance of the Ex certificate.

d) where it is not possible to trace the unsafe, nonconforming product (e.g. product supplied via a distributor, or for high volume products such as cable glands) then a notice shall be placed in appropriate publications providing recommended action to be taken;

e) for all nonconforming product that has been supplied to a customer, Yokogawa shall maintain, for a minimum period of 10 years after the last product shipped, records of:

1) serial numbers or identification of products supplied;

2) the customer who received the product;

3) the action taken to inform customers and the body responsible for the verification of the quality system in the case of unsafe nonconforming product;

4) the action taken to implement corrective and preventative action;

f) concessions for the product that take it outside the design, as defined in the Ex certificate and technical documentation, are not permitted.

8.4 Analysis of data

Subclause 8.4 of ISO 9001:2008 applies.

8.5 Improvement

8.5.1 Continual improvement

Subclause 8.5.1 of ISO 9001:2008 applies.

8.5.2 Corrective action

Subclause 8.5.2 of ISO 9001:2008 applies.

8.5.3 Preventive action

Subclause 8.5.3 of ISO 9001:2008 applies.