

## Quality Manual TechnipFMC Measurement Solutions

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5.0	March 7, 2022	Andrea Feidler Senior Quality Analyst	Nicholas Heschke Quality Manager	QM reviewed no revisions necessary.
4.0	8 April, 2021	Andrea Feidler Senior Quality Analyst	Nicholas Heschke Quality Manager	Minor changes, Highlighted in Yellow
3.0	20 September 2019	Qaisar Bhat, Quality Manager, Measurement Solutions, Nor/Ellerbek	Ram Misra, Quality Assurance Manager, Erie	Removed reference to Bakersfield facility, no longer ISO certified. Added to TOC 4.4.3, 4.4.4 & 8.2.4(in manual but not TOC) Added Interested Parties Appendix I, revised section 4.1 to align with ISO, added methods of communications section 7.4.1, Added reference PP-QA-05 and VA-17-001-08 to section 4.4.4 and 7.5.3, Added reference to section 4.4.2 PP-QA-34, PP-QA-05 and VA-06-002-14 Reference PP-QA-10 in section 9.3.3. Revised reference to ISO/IEC 80079-34:2011 revised to current version ISO/IEC 80079-34: 2017
2.0	30 NOVEMBER 2017	Lise Wulfsberg, QAHSE Manager	Nicole Gailey, Quality Manager	Revised in its entirety to incorporate ISO 9001:2015 requirements, update IEC, ATEX, PED MID, and related requirements. Updated reference to scope for Ellerbek Operations. Reformatted to new standard.

**Effective Date:** March 7, 2022

**Process Owner**  
Quality Manager

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## 0 Measurement Solutions

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### 0.1 Introduction

TechnipFMC, Measurement Solutions Inc. is an operational business unit of TechnipFMC, London, England EC4M 8AP. The operations and locations named herein are business units of TechnipFMC.

Measurement Solutions is a worldwide leading manufacturer of liquid and gas flow meters, electronic and mechanical metering accessories, and custom-designed measuring systems for custody transfer applications, product distribution, and process control.

Product quality is one cornerstone of this success, a foundation of product reputation and the continued existence of Measurement Solutions. Therefore, the organization continuously strives to provide its customers with products and services that meet every expectation.

The management of Measurement Solutions accepts the responsibility for, and the commitment to, the Quality Policy as described in this manual, as well as the responsibility for its implementation at all levels within the organization.

The purpose of the Quality Manual is to document the quality system and policies and to inform Measurement Solutions customers of the controls implemented to assure product quality. The Quality Manual provides for a Quality Management System that:

- a) consistently provides products that meet customer, statutory, and regulatory requirements;
- b) enhances customer satisfaction through effective application of the quality system, including processes for continuous improvement of the system;
- c) addresses risks and opportunities associated with its context and objectives;
- d) demonstrates the ability to conform to specified Quality Management System requirements.

Measurement Solutions Quality Management System (QMS) meets the requirements of ISO 9001:2015, ISO/IEC 80079-34:2017 [ATEX], PED Directive 2014/68/EU, and MID Directive 2014/32/EU with applicable appendices.

### 0.2 Global Quality Policy

Reference POL-COR-010-Quality-Rev.0 – Jan. 2017.

The goal of TechnipFMC is to be viewed as the leader in our industry that contributes to our customers' success by continuously striving to meet requirements every time.

We will achieve this goal by:

- Clearly defining and agreeing with internal and external customers on requirements,
- Insisting on operational excellence in our facilities, sites and vessels,
- Supplying highly reliable systems, products, services, and

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- Delivering best-in-class project execution.

Our quality and business management systems will be firmly based on the following PRINCIPLES:

- Quality Leadership from the Top with ownership by all employees.
- Active Collaboration with internal/external suppliers and customers.
- A Prevention Mindset to focus on *Doing-it-right-the-first-time*.
- Processes that are waste-free and Zero Defect capable.
- Measurement Systems in place to drive Continuous Improvement.
- Best Practice and Problem Awareness systems in place to produce a rapid Learning Organization.
- Developing quality behaviors and competencies in all our people.

### 0.3 Quality Approach

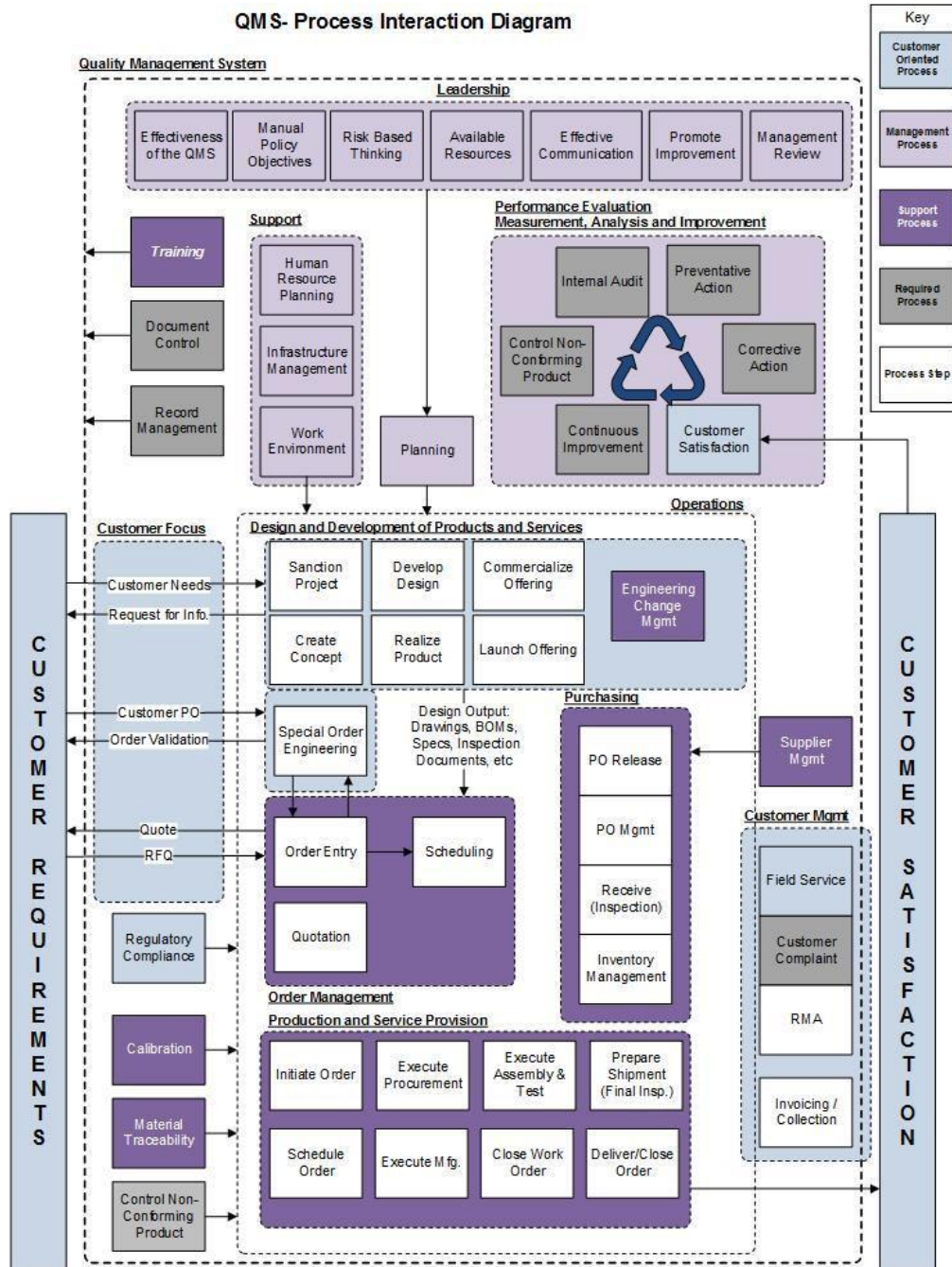
All employees are responsible for the quality of the product or service they provide to their customer. The formal organizational chart for the various operations that constitute TechnipFMC Measurement Solutions Inc. is available on request.

Measurement Solutions employs a process approach to plan its processes and their interactions, which includes the Plan-Do-Check-Act (PDCA) cycle and risk-based thinking. This process approach is beneficial because:

- a) the PDCA cycle enables the organization to ensure that its processes are adequately resourced and managed, and that opportunities for improvement are determined and acted on;
- b) risk-based thinking enables an organization to determine the factors that could cause its processes and its Quality Management System to deviate from planned results. And, to place preventive controls, that minimize any negative effects and take advantage of opportunities as they arise.

### 0.4 Company Processes

Understanding and managing interrelated processes as a system contributes to the organization’s effectiveness and efficiency in achieving its intended results. This approach enables the organization to control the interrelationships and interdependencies among the processes of the system, so that the overall performance of the organization can be enhanced. Measurement Solutions has identified key company processes, and their interaction within the organization, and has fully integrated them into the Quality Management System.



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## 1 Scope & Exclusions

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### 1.1 Scope

This Quality Manual documents Measurement Solutions Quality Management System, which demonstrates the organization's pursuit to consistently provide a product that meets or exceeds customer, statutory, and regulatory requirements;

This Quality Manual establishes compliance to the ISO 9001:2015 standard and applies to Measurement Solutions business units.

A list of activities, by location, covered by this Quality Manual are found below:

- a) Erie Operation – Design, Manufacture and Sales of Measurement and other Control Equipment for the Petroleum, Gas, Chemical and Industrial Market Place.
- b) Ellerbek Operation -- Services, Design, Development, and Manufacture of Liquid and Gas Measuring Equipment, Accessories and Systems for the Petroleum, Gas, Chemical and Industrial Market Place.

Measurement Solutions produces product that is compliant to the following EU/EC Directives:

- Equipment intended for use in Potentially Explosive Atmospheres [ATEX] Directive ISO/IEC 80079-34:2017 (Module D) No concessions are allowed for EX-products
- Pressure Equipment Directive (PED) 2014/68/EU (Module D1) and
- Measuring Instruments Directive (MID) 2014/32/EU (Module F).

### 1.2 Exclusions

None

## 2 References

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Key for quality system requirements found in this Manual:

- ISO 9001:2015: Selections in regular type apply across the organization.
- ISO/IEC 80079-34:2017: Italicized and bracketed [*Abcdefg*] selections in this Manual are selectively applied to ATEX and/or IECEx products & processes.
- ISO 9000:2015: Quality Management Systems - Fundamentals and Vocabulary
- ISO 19011:2011: Guidelines for auditing management systems

### 3 Terms, Definitions & Acronyms

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#### 3.1 Terms & Definitions

For the purpose of this Quality Manual, additional terms and definitions may be obtained from ISO 9000.

ACCEPTANCE CRITERIA	Specified limits of acceptability applied to process or product characteristics.
AUTHORIZED REPRESENTATIVE	Individual, appointed by Top Management, that is responsible for ensuring the appropriate requirements are met for the identified authorizing agency.
ATEX	European Regulatory Framework for the Manufacture, Installation and Use of equipment in Explosive Atmospheres ( <b>AT</b> mospheres <b>EX</b> plosives).
CALIBRATION	Comparison and adjustment to a standard of known accuracy.
CONFORMANCE	Compliance with specified requirements.
CORRECTION	Any action that is taken to eliminate a nonconformity. Applied to products, corrections can include reworking and/or reprocessing products, regrading them, assigning them to a different use, or simply destroying them.
CORRECTIVE ACTION	Steps that are taken to eliminate the causes of existing nonconformities to prevent reoccurrence. The corrective action process endeavors to make certain that existing nonconformities and potential undesirable situations don't happen again.
DELIVERY	Point in time and physical location at which the agreed transfer of ownership takes place.
DESIGN ACCEPTANCE CRITERIA	Defined limits placed on characteristics of materials, products or services established by the organization, customer, and/or applicable specification to achieve conformity to the product design.
FORM	A document whose preset format for a record used to record evidence of activities performed while executing a process.
GUIDELINE	A document used for training/reference purposes. It provides step by step details to carry out an activity and is not subject to document control requirements.
MANAGEMENT REPRESENTATIVE	An individual, appointed by Top Management, that is responsible for ensuring the processes needed for the Quality Management System are established, implemented and maintained. This individual also has responsibilities for reporting on the effectiveness of the QMS, promoting customer awareness throughout the organization and serving as a liaison with external parties.

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MANUAL	A “manual” specifies Measurement Solutions Quality Management System requirements and interaction between processes.
OBJECTIVE EVIDENCE	Data supporting the existence or verity of something.
PART	The individual pieces used in the assembly of a single product or equipment units.
POLICY	A mandatory statement of position (the WHAT) that describes the intentions and directions of Measurement Solutions in key areas of business activities. A policy may reflect a published vision/mission, core values, long term goals, or specific prescribed rules that must be followed.
PREVENTATIVE ACTION	Steps that are taken to address the potential for a nonconformity to occur.
PRODUCT	The result of a process (For the purpose of this document, product refers to the physical product, system of products, and service-related product).
PROCESS FLOW	A set of interrelated activities which defines inputs and outputs for each activity.
QUALITY MANAGEMENT SYSTEM	A system by which an organization aims to promote conformance to specifications, standards, and customer expectations in the most cost effective and efficient manner. QMS consists of policies, manuals, processes, workflows, work instructions, standard operating procedures, templates/forms and records.
QUALITY OBJECTIVES	Measurables sought or aimed for, which affect product Quality.
RECORD	Documented and retrievable information stating results achieved or providing evidence of activities performed. Records can come in the form of hard-copy or electronic data.
REQUIREMENTS	Need or expectation that is stated, generally implied or obligatory.
SERVICE	Performance of an activity by one function or organization for another.
SERVICING	Product maintenance, adjustment, repair, and/or on-site installation when installation is required by applicable product specifications.
SHALL	To be obliged or bound-to by an imperative requirement.
SPECIAL PROCESS / PROCESS REQUIRING	Process where the conformity of the resulting product cannot be readily or economically verified by subsequent VALIDATION, monitoring or measurement, and the process requires validation.

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STANDARD OPERATING PROCEDURE	Specifies the requirements (the HOW), accountabilities and responsibilities (the WHO) to execute a single process step. It is used for a process operator role, and it should not be lengthy or complex and in many cases, can use a checklist format.
TENDER	Offer made by an organization in response to an invitation to provide a product.
TOP MANAGEMENT	Includes the Vice President and their direct reports who direct and control Measurement Solutions operations (MSLT and MSXLT).
TEMPLATE	A type of document whose preset format is used so that the format does not have to be recreated each time it is used.
TRACEABILITY	Ability to trace the history, application or location of an object.
WORKFLOW	Description of the sequence of activities, and the roles that support them, in a graphical or written representation.

### 3.2 Acronyms

ATEX	Atmospheres Explosives
CA/PA	Corrective Action / Preventative Action
CNQ	Cost of Non-Quality
ECN	Engineering Change Notice
IECEX	International Electrotechnical Commission Standard
IQ	Impact Quality
KPI	Key Performance Indicator
MID	Measuring Instruments Directive
PED	Pressure Equipment Directive
PO	Purchase Order
QM	Quality Manual
QMS	Quality Management System
TCE	Team Center Engineering
WO	Work Order
VOC	Voice of Customer
ZD	Zero Defect

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## 4 Measurement Solutions Incorporated

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### 4.1 Understanding of the Organization and its context

Measurement Solutions has determined those internal and external issues which have the potential to impact its purpose and strategic direction, and which may affect its ability to achieve the intended result(s) of its Quality Management System.

The Strategic points of the organization are as follows:

- Regain Customer Confidence
- Improve Market Position
- Capitalize on Competitive Advantages

Our foundational beliefs — safety, integrity, quality, respect and sustainability — are the cornerstone of our values. These beliefs reflect how we fundamentally do business and what we never compromise on, no matter the circumstances.

### 4.2 Understanding the Needs and Expectations of Interested Parties

Due to their effect or potential effect on the organization's ability to consistently provide products and services that meet customer, statutory, and regulatory requirements; Measurement Solutions has 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.

Measurement Solutions monitors and reviews the information about these interested parties and their relevant requirements during the yearly [*not to exceed 14 months*] management review outlined in section 9.3.

Interested Parties and monitoring methods are listed on Appendix I of this manual.

### 4.3 Measurement Solutions QMS Scope

Measurement Solutions has determined the boundaries and applicability of the quality management system in establishing its scope.

When determining this scope, the organization has considered:

- a) the external and internal issues referred to in section 4.1;
- b) the requirements of relevant interested parties referred to in section 4.2;
- c) the products and services of the organization.

The scope of the organization's Quality Management system is available and maintained as documented information in section 1.1.

## 4.4 Measurement Solutions QMS Processes

Measurements Solutions has established, documented, implemented, and maintained a QMS which is continually improved for its effectiveness in accordance with customer, statutory, and regulatory requirements.

### 4.4.1 Measurements Solutions QMS Implementation & Sustainability

Measurement Solutions has determined the processes needed for the Quality Management System and their application throughout the organization, and has:

- 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 KPIs) needed to ensure the effective operation and control of these processes;
- d) determined the resources needed for these processes and ensure their availability;
- e) assigned the responsibilities and authorities for these processes;
- f) addressed the risks and opportunities as determined, outlined in section 6.1;
- g) evaluated these processes and implement any changes needed to ensure that these processes achieve their intended results;
- h) improved the processes and the quality management system.

### 4.4.2 Control of Documented Information

Documented information required by the QMS is controlled. Measurement Solutions has established a procedure to define document control methods for required documents including revisions, translations and updates. The procedure establishes the controls necessary to:

- a) maintain documented information to support the operation of its processes;
- b) retain documented information to have confidence that the processes are being carried out as planned.

Reference: PP-QA-34 Create, Revise, Release and Maintain Documents and PP-QA-05 Control of Records, VA-06-002-14 Managing Technical Documents.

The different types of organizational documents required by the QMS are controlled locally and/or globally.

### 4.4.3 Control of External Documents

Whenever other external specification requirements are used in the design and/or manufacture of product, the organization maintains documented information used for the integration of these requirements into product realization, and any other affected processes.

#### 4.4.4 Control of Records

Measurement Solutions maintains a relevant procedure for the control of records. These controls include: identification, storage, protection, retrieval, retention times and their disposition. The procedure also identifies the organizational functions responsible for the implementation of this procedure.

Reference PP-QA-05 Control of Records and VA-17-001-08 Issue a retention policy for QA records.

## 5 Leadership's Commitment to the QMS

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### 5.1 Leadership and Commitment

#### 5.1.1 General Statement

Top Management at Measurement Solutions continuously demonstrates its commitment to the development and implementation of the Quality Management System, and continually works to improve its effectiveness by:

- a) taking accountability for the effectiveness of the quality management system;
- b) ensuring that quality policy and objectives are established, including key performance indicators for use in data analysis, and are compatible with the context and strategic direction of the organization;
- c) ensuring integration of Quality Management System requirements into the organization's business processes;
- d) promoting the use of process-approach and risk-based thinking;
- e) ensuring that the resources needed for quality management systems 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) prompting improvement;
- j) supporting other relevant management roles to demonstrate their leadership as it applies to their areas of responsibilities.

Top Management at Measurement Solutions ensures that responsibilities, authorities and accountabilities are defined, documented and communicated within the organization.

The Quality Management Representative is a member of the Measurement Solutions management team and is designated by the title of Quality Manager (aka. Quality System Manager) unless otherwise appointed by Top Management. Note: The Quality Manager is understood to be the individual responsible for the management and maintenance of the Quality Management System.

The QMS Management Representative has the responsibility and authority to:

- a) ensure processes are established, implemented, maintained and delivering their intended output;
- b) ensure that the integrity of the Quality Management System is maintained when changes to the QMS are planned and implemented;
- c) engage, support and direct Measurement Employees to contribute to the effectiveness of the Quality Management System;
- d) promote the continuous improvement of the Quality Management System;
- e) report to Top Management at the organization on the performance of the QMS, including the need for improvement;
- f) ensure the timely initiation of actions; to minimize the likelihood of occurrence, or reoccurrence, of a nonconformity;
- g) ensure the promotion of the awareness of customer requirements throughout the organization.

### 5.1.2 Customer Focus

Top Management at Measurement Solutions ensures that customer requirements are first determined and then met with the aim of enhancing customer satisfaction outlined in section 9.1.2. Top Management demonstrates leadership and commitment with respect to customer focus by ensuring that:

- a) customer, 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 Measurement Solutions Global Quality Policy

### 5.2.1 Establishing the Quality Policy

The organization has established, implemented and maintained a Quality Policy that ensures the following requirements have been met:

- a) is appropriate to the purpose and context of the organization;
- b) includes a commitment to; support the requirements for, and continually improve the effectiveness of, the Quality Management System;
- c) provides a framework for establishing and reviewing quality objectives;

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- d) is communicated and understood within all Measurement Solutions facilities;
- e) is available to all interested parties, as appropriate;

### 5.2.2 Communicating the Quality Policy

Measurement Solutions ensures that the Global Quality Policy will:

- a) be available and be maintained as documented information;
- b) be communicated, understood and applied within the organization;
- c) be available to relevant interested parties, as appropriate;
- d) is reviewed at least annually by Top Global Management, to determine continued suitability;
- e) conveys the overall intentions and directions, related to quality, of Top Global Management;
- f) is documented and approved by TechnipFMC Chief Executive Officer, via a dated signature on the statement of the Global Quality Policy.

## 5.3 Measurement Solutions: Roles, Responsibilities & Authorities

Top Management at Measurement Solutions ensures that responsibilities and authorities are defined, assigned, communicated and understood throughout the organization.

Top Management at Measurement Solutions has appointed a Management Representative(s) for its business locations. The Management Representative(s) is a member of the company's management team who, irrespective of other responsibilities, has been assigned the responsibility and authority for:

- a) ensuring that the Quality Management system conforms to the requirements of Standards referred to in Section 1.1 Scope of this manual.
- 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 outlined in section 10.1, to Top Management;
- d) ensuring the promotion of customer focus throughout the organization;
- e) ensuring that the integrity of the Quality Management system is maintained when changes to the quality management system are planned and implemented.
- f) to serve as liaison with external parties on matters relating to the QMS;
- g) *[effectively coordinating activities with respect to products intended for use in potentially explosive atmospheres;*
- h) *the need to liaise with the notified body / ExCB responsible for the issue of the EC-type examination certificate / ExTR with respect to any proposed change to the design defined in the EC-type examination certificate / ExTR and technical documentation;*
- i) *the need to liaise with the notified body / ExCB responsible for the assessment of the quality system with respect to intended updating of the quality system; (see note for additional guidance)*

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- j) *the authorizing of initial approval and changes to related drawings, where appropriate;*
- k) *the authorizing of concessions*
  
- l) *informing its customers of any special conditions for safe use and any schedules of limitations by providing a manual for our equipment;*
- m) *issuing the Declaration of Conformity that the product fulfills all EU directives which comprises instructions for safe use, maintenance, etc.*

*In those facilities dealing with product manufactured to the requirements of an "Ex" type directive (e.g. ATEX or IECEx), an individual has been appointed as the "authorized representative" to interface with the Notified Body. This individual shall be responsible for communicating changes affecting compliance with the directive to the Notified Body prior to the implementation of those changes. The "Ex" representative has the following duties and is empowered to:*

- a) *ensure the implementation of the approved (by Notified Body) documents;*
- b) *ensure the implementation of Ex standards and guidelines of the Notified Body;*
- c) *participate in vendor evaluation;*
- d) *maintain approved documents;*
- e) *influence training activities;*
- f) *evaluate non-conformances, and*
- g) *perform audits.*

*NOTE: Certificates with a suffix X can contain special conditions for safe use. Component certificates with a suffix U can contain schedules of limitations.*

In those facilities dealing with product manufactured to the requirements of the Pressure Equipment Directive, PED, (2014/68/EU) or the Measuring Instrument Directive, MID, (2014/32/EU), an individual has been appointed as the "authorized representative" to interface with the Notified Body. This individual is responsible for communicating changes affecting compliance with the directive to the Notified Body prior to the implementation of those changes.

## **6 Planning Focus at Measurement Solutions**

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

#### **6.1.1 Top Management's QMS Planning**

When planning for the Quality Management System, Top Management at Measurement Solutions ensures:

- a) that the Quality Management System can achieve its intended result(s);
- b) enhance desirable effects;



- c) prevent, or reduce, undesirable effects;
- d) achieve improvement
- e) criteria and methods needed for the operation and control of all Quality Management System process are determined, managed and effective;
- f) the quality objectives are carried out to meet customer, statutory and regulatory requirements;

### 6.1.2 Organizational Planning Risks and Opportunities

Measurement Solutions plans:

- a) actions to address risks and opportunities;
  - 1) how to integrate and implement the actions into its Quality Management System processes outlined in section 4.4.
  - 2) evaluate the effectiveness of these actions.

These actions taken to address risks and opportunities are proportionate to the potential impact on the conformity of products and services. Such actions include avoiding risk, taking risk to pursue an opportunity, eliminating the risk source, changing the likelihood or consequences, sharing the risk, or retaining risk by informed decision.

Measurement Solutions recognizes that this creates opportunities leading to the adoption of new practices, launching of new products, opening of new markets, addressing new customers, building strategic partnerships, using new technology and other desirable and viable possibilities to address the organization's or its customers' needs.

## 6.2 Quality Objectives and Planning How to Achieve Them

### 6.2.1 Establish Quality Objectives at Relevant Levels

Top Management at Measurement Solutions ensures the quality objectives are:

- a) consistent with the Global Quality Policy;
- b) applicable to and established at relevant function levels;
- c) measurable, monitored and reviewed [*not to exceed 14 months*] during Management Review Meetings outlined in section 9.3;
- d) documented, updated as necessary, and communicated to all relevant parties;
- e) considering applicable customer, statutory, and regulatory requirements;
- f) relevant to the conformity of products and services, and to the enhancement of customer satisfaction.

The organization maintains documented information on the quality objectives.

## 6.2.2 Achieving Quality Objectives

When planning how to achieve its quality objectives, the Measurement Solutions organization has determined:

- a) what will be done;
- b) what resources will be required;
- c) who will be responsible;
- d) when it will be completed;
- e) how the results will be evaluated.

## 6.3 Change Management

Top Management of Measurement Solutions ensures that the integrity of the Quality Management System continues to be maintained at times when changes to the Quality Management System are planned and implemented, in a manner consistent with section 4.4. Changes to the Quality Management System are approved to meet customer, statutory, and regulatory requirements, if required, prior to implementation.

The organization has considered:

- 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 and/or reallocation of responsibilities and authorities.

*[The quality system ensures that the product conforms to the type described in the EC-type examination certificate. All the elements, requirements and provisions adopted by TechnipFMC Measurement Solutions 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.]*

*The organization facilitates an arrangement whereby the notified body / ExCB may audit aspects of the supplier's operations that affect the type of protection.]*

# 7 Measurement Solutions Controls for QMS Support

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## 7.1 Resources

### 7.1.1 General

Measurement Solutions has determined and provided the resources needed for the establishment, implementation, maintenance and continual improvement of the quality management system.

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The resources provided:

- a) establish, implement and maintain the QMS, and continually improve its effectiveness;
- b) enhance customer satisfaction by consistently meeting or exceeding their requirements;

In achieving the above (b), Measurement Solutions considers:

- a) the capabilities of, and constraints on, existing internal resources;
- b) those resources need to be obtained from external sources.

### 7.1.2 Human Resource Management

Measurement Solutions has determined and provided the persons necessary for the effective implementation of its Quality Management System and for the operation and control of its processes.

Individuals performing work which has the potential to affect product conformity to product requirements, are competent, having the necessary education, training, skills and experience. Evidence of employee competence are assessed and maintained.

Identified training requirements include:

- a) Quality Management System training;
- b) customer-specified training and/or customer-provided training;
- c) on the job-specific training.

These training requirements are incorporated into a training plan, as appropriate, for each department or individual. The frequency of training is determined by Measurement Solutions. At a minimum, on the job training is given to any/all personnel, involved with a new or modified job, that affects product quality. Including all temporary-assignment, contract, and employment-agency-provided personnel. Training effectiveness is assessed to ensure employee competence. The organization maintains appropriate records on education, training, skill and experience.

### 7.1.3 Suitable Work Infrastructure

The organization has determined, provided and maintains the infrastructure necessary for the operation of its processes and to achieve conformity of products and services.

Suitable work infrastructure includes:

- a) buildings, individual workplaces, and associated utilities;
- b) equipment, including hardware and software;
- c) support services, including transportation, communication media, and information systems.

The above factors can differ substantially depending on location, products and services provided.

#### 7.1.4 Suitable Work Environment

Measurement Solutions has determined, provided and maintains the environment necessary for the operation of its processes and to achieve conformity of products and services. NOTE: A suitable environment can be a combination of human and physical factors, such as:

- 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).

The above factors can differ substantially depending on the locations, products and services provided.

#### 7.1.5 Monitoring and Measuring Resources

Measurement Solutions determines testing, monitoring and measurement requirements and the associated suitable equipment necessary to provide evidence of the conformity to those requirements. The organization also 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.

Measurement Solutions maintains documented information in order to ensure that, testing, measuring and monitoring equipment is calibrated and maintained, and that the equipment is used in a manner that is consistent with monitoring and measurement requirements. The relevant procedure includes requirements for specific equipment that addresses:

- a) a unique and discreet identifier;
- b) a calibration status which is readily identifiable;
- c) a frequency of calibration (specific intervals or prior to use);
- d) a calibration or verification method, including adjustments;
- e) a calibration acceptance criteria;
- f) a control for out-of-calibration equipment (to prevent unintended use);
- g) a calibration or verification to measurement standards through Measurement Solutions internal calibration laboratory, or contracted third-party calibration service;
- h) verification, on non-adjustable equipment, is performed against identified acceptance criteria;

When equipment is found to be out of calibration, the organization assesses the validity of previous measurements and takes the appropriate actions on the equipment and any potentially affected product. Measurement documents the occurrence as well as the customer-notification for suspect product that has already been shipped.

The organization maintains records of the results of calibration and verification in compliance with sections 4.4.4, and 7.5.1.e.

### 7.1.6 Measurement Traceability

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

- 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 to determine their status;
- c) safeguarded from adjustments, damage or deterioration that would invalidate the calibration status and subsequent measurement results;
- d) adjusted or re-adjusted as necessary; when measuring equipment is found not to conform to requirements, the organization assesses and records the validity of previous measuring results, and the organization takes appropriate action on the equipment and any product that is affected;
- e) protected from damage and deterioration during handling, maintenance and storage.

*[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:*

- *an unambiguous identification of the item calibrated;*
- *evidence that the measurements are traceable to international or national measurement standards;*
- *the method of calibration;*
- *a statement of compliance with any relevant specification;*
- *the calibration results;*
- *the uncertainty of measurement, where necessary;*
- *the environmental conditions, where relevant;*
- *the date of calibration;*
- *the signature of the person under whose authority the certificate was issued;*
- *the name and address of the issuing organization and the date of issue of the certificate;*
- *a unique identification of the calibration certificate.]*

The organization maintains records of the results of calibration and verification in compliance with sections 4.4.4, and 7.5.1.e.

### 7.1.7 Organizational Knowledge

Measurement Solutions has determined the knowledge necessary for the operation of its processes and to achieve conformity of products and services.

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

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

Organizational knowledge within Measurement Solutions is based on:

- a) internal sources (e.g. intellectual property; knowledge gained from experience; lessons learned from failures and successful projects; capturing and sharing undocumented knowledge and experience; the results of improvements in processes, products and services);
- b) external sources (e.g. standards; academia; conferences; gathering knowledge from customers or external providers).

## 7.2 Employee Competence

Personnel performing work affecting conformity to product requirements (directly or indirectly) are competent, having the appropriate education, training, skill, and experience. Measurement Solutions has:

- a) determined the necessary competence of person(s) doing work under its control that affects the performance and effectiveness of the Quality Management System;
- b) ensured that these persons are competent on the basis of appropriate education, training, or experience;
- c) where applicable, taken action to acquire the necessary competence, and evaluated the effectiveness of the actions taken;
- d) retained appropriate documented information as evidence of competence.

Measurement Solutions has identified training requirements that include:

- e) Quality Management System training;
- f) customer-specified training and/or customer-provided training;
- g) on the job-specific training.

At a minimum, on-the-job training is be given to all personnel involved in any new or modified job that affects product quality, including all temporary, contact, and agency -supplied personnel.

## 7.3 Organizational Awareness

Measurement Solutions ensures persons doing work under the organization's control are aware of:

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- 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 implications of not conforming with the Quality Management System requirements.
- e) All employee meetings, monthly huddles, quality policy posted and in shop floor binders and online GBPMS

## 7.4 Organizational Communication

Top Management at Measurement Solutions ensures that there are appropriate communication processes established throughout the organization. The organization's Top Management further ensures that communication takes place regarding the effectiveness of the Quality Management System.

The organization has determined the internal and external communications relevant to the Quality Management System.

### Internal Communication

The organization has established processes to ensure that the:

- a) communication occurs at relevant levels and functions within the organization regarding the effectiveness of the Quality Management System;
- b) importance of customer, statutory, and regulatory requirements, are communicated to all relevant functions within the organization;
- c) results of the analysis of data are communicated at relevant levels and functions within the organization.

The organization's communication modes are as follows:

- Weekly Safety Huddles
- Quarterly All Employee Meeting
- Monthly Hoshin Meetings

### 7.4.2 External Communication

The organization has established processes to ensure effective methods of customer communication:

- a) services and product information, including product nonconformities identified after delivery to the customer, through marketing or sales representatives, or specific meetings or presentations;
- b) inquiries, contracts, orders, and modifications through sale representatives and/or other established lines of communication;

- c) customer feedback and complaints through intercompany communications and customer meeting minutes relating (VOC) to products and services;
- d) any/all information regard changes with the potential to impact customer performance;
- e) when contractual: providing information required by product quality plans and any subsequent changes to those plans.

The organization remains in continuous contact with the customer during the entire Tender and Manufacturing process, to facilitate clarifications, exceptions, and to address unstated issues at the earliest possible point in the product-realization process.

## 7.5 Measurement Solutions Documentation Requirements

### 7.5.1 General

The documentation of the Measurement Solutions Quality Management System includes the following:

- a) the documented Quality Policy, as outlined in section 0.2 and the documented Quality Objectives of TechnipFMC Measurement Solutions Inc;
- b) this Quality Manual;
- c) the Quality Procedures are established to meet quality, customer, statutory, and regulatory requirements. These documented processes and workflows (showing complexity and interactions) are implemented and maintained;
- d) all such documents (including standard operating procedures and forms) that the organization needs to ensure the effective planning, operation and control of the processes;
- e) all records that are required by quality, customer, statutory, and regulatory requirements to provide objective evidence of policy, product or process compliance;

### 7.5.2 Creating and Updating

When creating and updating documented information, Measurement Solutions ensures the appropriate:

- a) identification and description (e.g. a 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 Documents

Measurement Solutions has established, documented, implemented and maintains a Quality Procedure for the control of documents. This procedure defines how the organization controls all documents required by the Quality Management System. Documented information required by the QMS are controlled to ensure availability and suitability for use where needed. Documentation

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is adequately protected from loss of confidentiality, improper use, and loss of integrity.

For the control of documented information, Measurement Solutions 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. revision control);
- d) retention and disposition.

Documented information of external origin determined by Measurement Solutions to be necessary for the planning and operation of the Quality Management System has been identified as appropriate, and is controlled.

*[Equipment documents and our documents are controlled;*

- a) documented procedures ensure that information contained within our documents is compatible with equipment documents. The organization shall not initially approve or subsequently amend related drawings unless they are in compliance with approved parts of the schedule drawings;*
- b) our quality system ensures that no factor (type, characteristic, position, etc.) defined within the EC type-examination certificate / ExTR and technical documentation (e.g. schedule drawings) is modified without approval of the Ex authorized representative;*
- c) our documented system refers all related drawings to the relevant schedule drawings;*
- d) where there are common schedule drawings associated with more than one EC type-examination certificate / ExTR, our documented system ensures simultaneous supplementary action in the event of an amendment to such drawings (see note for additional guidance);*
- e) where FMC also has drawings for products not intended for use in potentially explosive atmospheres then the manufacturer shall have a system that enables both the related drawings and schedule drawings to be clearly identified (see note for additional guidance);*
- f) FMC documents which notified body / ExCB is responsible for the quality system notification for each EC type-examination certificate / ExCoC;*
- g) where equipment documents or our documents are passed to a third party, they shall be provided in a way that is not misleading.]*

Measurement Solutions has established, documented, implemented and maintains a Quality Procedure for the control of records. This procedure defines how customer, statutory, and regulatory requirements, controls records to provide evidence of conformity to requirements and of the effective operation of the Quality Management System. All such records are kept legible, readily identifiable, retrievable and protected from unintended alterations.

The organization has defined its Records Retention Policy in Financial Standard G.270 and PP-QA-05 Control of records, and VA-17-001-08 Issue a retention policy for QA Records.

## 8 Measurement Solutions Operations (Planning & Controls)

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### 8.1 Operational Planning and Control

Measurement Solutions ensures that it is capable of planning, implementing and controlling the processes and documents throughout product realization necessary to achieve customer product requirements. Planning of product realization is consistent with all requirements of all processes within the QMS.

In particular, the organization has addressed:

- 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 resource requirements needed to achieve conformity to the requirements of products and services;
- d) product requirements of a customer's contract;
- e) applicable customer, statutory, and regulatory requirements;
- f) assess, manage and plan contingencies too control and mitigate the risks associated with product realization outlined in section 6.1;
- g) design and development activities in accordance with a documented process, including verification and validation of the design prior to release for manufacturing, and the design output from the process includes monitoring, measurement, inspection, test plans, and acceptance criteria to assure product integrity through the manufacturing/production process outlined in section 8.3.4;
- h) maintenance of records, including design and manufacturing, necessary to provide evidence that the product and services realization process, and resulting products and services, meet defined requirements;
- i) the use of only qualified suppliers and vendors to supply critical materials and services, ensuring control of outsourced processes outlined in section 8.4.

## 8.2 Requirements for Products and Services

### 8.2.1 Customer Communication

Measurement Solutions has identified and implemented effective methods of communication with regards to the customer:

- a) services and product information including nonconformities identified after delivery/provision to the customer, through marketing and/or sales representatives, or relevant meetings and presentations;
- b) inquiries, contracts, orders, and modifications via sale representatives and/or other established means of communication;
- c) obtaining customer feedback relating to products and services, including customer complaints;
- d) maintaining documented information for identifying, verifying, evaluating (suitability), safeguarding and controlling customer supplied property;
- e) contingency planning (based on assessed risks) including required actions and the assignment of responsibilities and authorities.

### 8.2.2 Determining the Requirements for Products and Services

Measurement Solutions has established documented information for the review of requirements related to provision of products and related servicing and has determined:

- a) requirements specified by the customer;
- b) applicable statutory and regulatory requirements;
- c) manufacturing requirements, not specified by the customer, that are required for form, fit and function to meet customer expectations;
- d) additional requirements that the organization considers necessary;
- e) if the organization can meet the claims for the products and services it offers.
- f) *[the product category and marking required by the EC type-examination certificate/ExTR are included.]*

### 8.2.3 Review of the Requirements for Products and Services

Ability to Meet Requirements; Sales, Operations and Engineering at Measurement Solutions collaborates, in regard to the Tender Review process, to ensure product and service requirements are identified as part of the tendering process. These reviews are conducted prior to Measurements Solutions commitment to supply its products and/or services, and to verify the following requirements:

- a) requirements specified by the customer, including the requirements for delivery and post-delivery activities;
- b) customer. Statutory, and regulatory requirements applicable to the products and services;
- c) contract or order requirements differing from those previously expressed;
- d) product and service requirements are clearly defined and documented, and that the organization has the ability to meet all of the defined requirements.

The organization ensures that contract or order requirements differing from those previously defined are resolved.

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

*[The review ensures that any stated customer requirement is compatible with the EC-type examination certificate/ExTR (e.g. ambient temperature range).]*

In situations in which it is impractical to formally review each individual order (e.g., in case of internet sales), the organization instead reviews the relevant product information such as catalogs or advertising materials.

Retention of Review Results as well as any subsequent actions, are documented and retained in accordance with section 4.4.4.

Where product and service requirements have changed, the contract and all other relevant documentation is amended, and all affected personnel are notified of the change in a timely manner.

## 8.3 Design and Development of Products and Services

### 8.3.1 General

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

#### 8.3.1 Design and Development Planning

In determining the stages and controls for design and development, the organization has considered:

- 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 effective assignment of resources, responsibilities and authorities, and their interactions, including communicating updates and/or changes to the design which may occur during any progression of the planning phase;
- d) the required design and development verification and validation activities;
- e) the responsibilities and authorities involved in the design and development process;
- f) the internal and external resource needs for the design and development of products and services;

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- g) the need to control interfaces between persons involved in the design and development process;
- h) the need for involvement of customers and users in the design and development process;
- i) the requirements for subsequent provision of products and services;
- j) the level of control expected for the design and development process by customers and other relevant interested parties;
- k) the documented information needed to demonstrate that design and development requirements have been met.

[Section 8.3 is not within the scope of standard ISO/IEC 80079-34:2017[ATEX].]

Measurement Solutions manages how the different groups that are involved in the design and development process interface with each other so that effective communication and clear assignment of responsibilities is ensured. The outputs of design and development planning is updated, as appropriate, as the design and development process progresses.

### 8.3.2 Design and Development Inputs

The organization has determined the requirements essential for the specific types of products and services to be designed and developed and has considered:

- a) functional and performance requirements;
- b) information derived from previous similar design and development activities;
- c) customer, statutory and regulatory requirements;
- d) standards or codes of practice that the organization has committed to implement;
- e) potential causes of failure due to the nature of the product and services.

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

Measurement Solutions retains documented information on design and development inputs outlined in section 4.4.2.

### 8.3.3 Design and Development Control (Reviews)

Measurement Solutions applies controls to the design and development process, with planned arrangements to:

- a) evaluate the suitability, adequacy and effectiveness of the results of design and development stage to meet specified requirements;
- b) identify any problems or risk, and propose appropriate action;
- c) initiate verification and a final review, performed in accordance with planned arrangements of section 8.3.2 to ensure that the Design and Development outputs correspond to the Design and Development inputs;
- d) initiate validation in accordance with planned arrangements section 8.3.2 to ensure the resulting products and services meet the requirements for the specified application and

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intended use. Validation activities are completed prior to delivery or implementation of the product, whenever possible;

- e) ensure any necessary actions are taken on problems determined during the reviews, or verification and validation activities.

The organization retains documented information on design and development inputs outlined in section 4.4.2.

Design and development reviews, verification and validation have distinct purposes. They can be conducted separately or in any combination, as is suitable for the products and services of the organization.

### 8.3.4 Design and Development Outputs

Design and Development outputs are in a form suitable for verification against the design and development inputs, and approved prior to release:

Design and development outputs will:

- a) correspond to the input requirements;
- b) provide appropriate information for purchasing, production, and servicing provision activities;
- c) contain or reference design acceptance criteria;
- d) include the identification of, or reference to, products and/or components deemed critical to the design;
- e) identify methods, assumptions, formulas, and calculations;
- f) specify the characteristics of the product and services that are essential for their intended purpose and their safe and proper use;

Measurement Solutions retains documented information on design and development inputs outlined in section 4.4.2.

### 8.3.5 Design and Development Changes

Measurement Solutions has identified, reviewed 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.

With regard to Design and Development change, Measurement Solutions will:

- a) review, verify and validate, as determined by the Engineering Change Process, and approve before implementation;
- b) perform an evaluation on the impact of changes on constituent/manufactured parts and product already delivered;
- c) be managed by Engineering and through the ECN procedure;
- d) ensure changes to design and development, including design documents, have the same controls as the original design and development, and design documentation.

Measurement Solutions retains documented information on design and development change outlined in section 4.4.2.

## 84 Measurement Solutions Purchasing Control

### 8.4.1 Activities & Information

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

Measurement Solutions maintains documented information to ensure that purchased products or outsourced activities conform to specified requirements.

The documented information addresses:

- a) determination of the criticality of the activities or products as they are applicable to conformance to product or customer specifications;
- b) type and extent of the control applied to the supplier based on the criticality of the product or activity;
- c) initial evaluation and selection of suppliers based on their ability to supply product or activities in accordance with Measurement Solutions' requirements;
- d) criteria, scope, frequency, and methods for reassessment of suppliers;
- e) maintaining a list of approved suppliers and scope for approval.
- f) *[while manufacture, test and final inspection may be sub-contracted, the responsibility for ensuring conformance with the EC type-examination certificate/ExTR will not be sub-contracted by Measurement Solutions;*
  - 1) *suppliers providing a product, process, or service that can affect the product's compliance with the EC type-examination certificate/ExTR shall only be selected after an evaluation by Measurement Solutions that the supplier demonstrated that they have the capability of ensuring compliance with all specified requirements. NOTE: The evaluation should take into account: criticality of the product, process or service; degree of difficulty or variability in the manufacturing process; location of the supplier and hence effectiveness of communications; does the supplier in turn sub-contract the product, process or service;*
  - 2) *suppliers not used for a period exceeding one year shall be re-evaluated by Measurement Solutions prior to the placing of the contract;*
  - 3) *requirements b), c) and f) are not mandatory for products, processes or services where the manufacturer fully verifies each item for conformance;*
  - 4) *the ongoing ability of the supplier to provide conforming product, process or service shall be reviewed at periods not exceeding one year;*
  - 5) *ExTAG DS 2004/06: the ExCB issuing a QAR should check to ensure that the end product manufacturer has a documented procedure for their checking, on a routine basis, that the IEC Ex CoC, covering the component, remains current.]*

Measurement Solutions maintains records of the results of the evaluations and of any necessary actions outlined in section 4.4.4.

#### 8.4.2 Type and Extent of Control

Measurement Solutions ensures that externally provided processes, products and services do not adversely affect the organization's ability to consistently deliver conforming products and services to its customers.

Measurement Solutions will:

- a) ensure that purchased products or activities meet specified requirements and remain within the control of its Quality Management System;
- b) state in the purchasing information the intended product verification arraignments and method of product release when verification activities occur at the supplier's location;
- c) hold the supplier accountable for the delivery of a product that satisfies the requirements of the purchase order.;
- d) hold the supplier accountable for the identification of nonconforming product which has not yet shipped, and for any/all resolution requirements;
- e) takes into consideration:
  - 1) the potential impact of the externally provided processes, products and services on the organization's ability to consistently meet customer and applicable statutory and regulatory requirements;
  - 2) the effectiveness of the controls applied by the external provider;
- f) determine the verification, or other activities, necessary to ensure that the externally provided processes, products, or services meet requirements.

#### 8.4.3 Information for External Providers

Measurement Solutions ensures the adequacy of purchase requirements prior to their communication to the external provider. Purchasing information is documented and includes a description of the processes, services and products to be purchased, including acceptance criteria.

Measurement Solutions communicates to external providers its 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;

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- d) the external providers' interactions with the organization;
- e) control and monitoring of the external providers' performance to be applied by the organization;
- f) verification or validation activities that the organization, or its customer, intends to perform at the external providers' premises.
  - 1) *[the purchasing documents shall clearly describe the specific requirements pertaining to subcontracted product set out in the EC type-examination certificate / ExTR and the equipment documents (e.g. for process control, testing or inspection);*
  - 2) *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;*
  - 3) *measurement Solutions defines the method by which documents (e.g. Technical specifications), stated in a particular purchase order remain traceable to the order.*
  - 4) *requirement is for IECEx only (does not appear in ISO/IEC 80079-34:2017[ATEX]): Where Measurement Solutions does not provide such documents with subsequent orders, then Measurement Solutions shall have procedures for ensuring that suppliers have current copies of documents, and that they remain in good condition.*
  - 5) *for purchased products that can compromise the type of protection Measurement Solutions determines and implements verification arrangements which demonstrate the product's compliance with the EC type-examination certificate/ExTR, taking into account the nature of the product and the nature of the supplier;*
  - 6) *when deciding what type of verification is required for a purchased product, Measurement Solutions considers the nature of the purchased product, the supplier, and how critical it is to the type of protection. (see note for additional guidance)*
  - 7) *where the supplier has been evaluated and documented objective evidence demonstrate the supplier to be fully capable of producing and verifying the product or service, no further verification of the product or service is required, if a declaration of conformity according to EN 45014 is supplied with each batch or product;*
  - 8) *where the EC type-examination certificate/ExCoC specifies routine tests or inspections these shall be carried out on each and every product. Either the supplier or the manufacturer may carry them out. When carried out by the supplier they shall be specified on the purchasing documents (e.g. by a quality plan) and confirmed by the supplier (e.g. declaration of conformity according to EN 45014);*
  - 9) *where verification of a product cannot be carried out after manufacture (e.g. internal parts of an encapsulated intrinsically safe circuit), then the product shall only be accepted if supplied with a declaration of conformity according to EN 45014. 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;*
  - 10) *when sample inspections or tests are permitted they shall be conducted in a manner which demonstrates conformity of the entire batch;*
  - 11) *when sample inspections or tests are permitted they shall be conducted in a manner which demonstrates conformity of the entire batch;*

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- 12) *when sample inspections or tests are permitted they shall be conducted in a manner which demonstrates conformity of the entire batch;*
- 13) *when the supplier of Measurement Solutions requires training or specialist skill or knowledge to carry out a verification they shall be documented, and training records maintained;*
- 14) *when Measurement Solutions chooses not to carry out inspections and tests at its own premises, then inspections and tests shall be performed on the supplier's premises under the responsibility of Measurement Solutions;*
- 15) *where a supplier provides product with evidence of conformity, (e.g. Declaration of Conformity/ExTR, quality assurance notification), then further verification is not required unless Measurement Solutions considers it necessary.]*

## 85 Measurement Solutions Provisions for Production & Service

### 8.5.1 Control of Production and Service Provision

Measurement Solutions has implemented production and service provisions 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.

*[ISO/IEC 80079-34:2017[ATEX]: Measurement Solutions considers the requirements contained in the EC type-examination certificate.*

*OD/005: Measurement Solutions provides 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 ExTR and with the requirements of the ExTR.]*

### 8.5.2 Identification and Traceability

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

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

Measurement Solutions controls the unique identification of the outputs when traceability is a requirement and retains the documented information necessary to enable traceability outlined in section 4.4.3.

- a) *[Measurement Solutions establishes and maintains 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.*

*NOTE: Significant parts are, for example, a printed circuit board (PCB) of an intrinsically safe circuit, but not each electronic component on a PCB.]*

### 8.5.3 External Property Provisions

Measurement Solutions exercises care with property belonging to customers or other external providers while it is under the organization's control or being used by the organization. This can include but not limited to materials, components, tools and equipment, premises, intellectual property and personal data.

Measurement Solutions identifies, verifies, protects and safeguards customers' 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, Measurement Solutions will report this to the customer or external provider and retain documented information on what has occurred.

*[Measurement Solutions is responsible for verifying the compatibility of customer-supplied product with the requirements of the EC type-examination certificate / ExTR.]*

### 8.5.4 Product & Service Preservation

Measurement Solutions preserves the outputs during production and service provision, to the extent necessary to ensure conformity to requirements. This can include but is not limited to identification, handling, contamination control, packaging, storage, transmission or transportation, and protection.

*[ISO/IEC 80079-34:2017[ATEX]: Measurement Solutions provides its customer with the instructions as described in Annex II of the Directive. These instructions must be translated into the national language where the product will be placed in use.*

*OD/005: Measurement Solutions provides its customer with the instructions to enable the safe use of the product. If deemed necessary by Measurement Solutions, such instructions shall contain special requirements for product maintenance. These may be specified in the ExTR.*

*NOTE: Procedures may be required for products with limited life if they affect the type of protection, e.g. batteries.]*

### **8.5.5 Post-Delivery Activities Provision**

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

In determining the extent of post-delivery activities that are required, Measurement Solutions considers the following:

- a) statutory and regulatory requirements;
- b) any potential undesired consequences associated with its products and services;
- c) the nature, use and intended lifetime of its products and services;
- d) customer requirements;
- e) customer feedback.

These Post-delivery activities can include actions under warranty provisions, contractual obligations such as maintenance services, and supplementary services such as recycling or final disposal.

### **8.5.6 Change Control Provision (MOC; Management of Change)**

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

Measurement Solutions 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.

## **86 Release of Products and Services**

Measurement Solutions implements 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 does not proceed until the planned arrangements have been satisfactorily completed, unless otherwise approved by a relevant authority and, as applicable, by the customer.

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

- a) evidence of conformity with the acceptance criteria;

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- b) traceability to the person(s) authorizing the release.
- c) *[for purchased products that can compromise the type of protection Measurement Solutions determines and implements verification arrangements which demonstrate the product's compliance with the EC type-examination certificate/ExTR, taking into account the nature of the product and the nature of the supplier;*
- d) *when deciding what type of verification is required for a particular purchased product, the Measurement Solutions considers the nature of the purchased product, the supplier, and how critical it is to the type of protection (see note for additional guidance);*
- e) *where the supplier has been evaluated and documented objective evidence demonstrate the supplier to be fully capable of producing and verifying the product or service, no further verification of the product or service is required, if a declaration of conformity according to EN 45014 is supplied with each batch or product;*
- f) *where the EC type-examination certificate/ExCoC specifies routine tests or inspections these shall be carried out on each and every product. Either the supplier or the manufacturer may carry them out. When carried out by the supplier they shall be specified on the purchasing documents (e.g. by a quality plan) and confirmed by the supplier (e.g. declaration of conformity according to EN 45014);*
- g) *where verification of a product cannot be carried out after manufacture (e.g. internal parts of an encapsulated intrinsically safe circuit), then the product shall only be accepted if supplied with a declaration of conformity according to EN 45014. 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;*
- h) *when sample inspections or tests are permitted they shall be conducted in a manner which demonstrates conformity of the entire batch;*
- i) *when the supplier of Measurement Solutions requires training or specialist skill or knowledge to carry out a verification they shall be documented, and training records maintained;*
- j) *when Measurement Solutions chooses not to carry out inspections and tests at its own premises, then inspections and tests shall be performed on the supplier's premises under the responsibility of Measurement Solutions;*
- k) *where a supplier provides product with evidence of conformity, (e.g. Declaration of Conformity /ExTR, quality assurance notification), then further verification is not required unless Measurement Solutions considers it necessary.*

*Where routine tests are required by the EC type-examination certificate / ExTR and the equipment documents, then those tests shall be performed as specified with no sampling techniques being permitted.*

*Where practical, the label bearing the marking data shall not be affixed until the final inspection and testing has been satisfactorily completed.]*

## 87 Control of Non-Conforming Outputs

### 8.7.1 Preventing the Unintended Use of Non-Conforming Material

Measurement Solutions ensures that products and services that do not conform to requirements are identified and controlled to prevent their unintended use or delivery.

Measurement Solutions 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. Measurement Solutions deals with nonconforming outputs in one or more of the following ways:

- a) correction of the nonconformity by appropriate means;
- b) identification, containment, segregation, return authorization, suspension of provision;
- c) timely notification of actual or potential impact to the customer;
- d) obtaining authorization for acceptance under concession (deviation);

*[Measurement Solutions maintains a system such that in the event of product not complying with the EC type-examination certificate / ExTR and having been supplied, then Measurement Solutions customer can be identified;*

*Measurement Solutions takes action, appropriate to the degree of risk;*

- a) *where non-conforming product has been supplied to a customer;*
- b) *where unsafe, non-conforming product has been supplied to a customer, Measurement Solutions informs, in writing, its customer and the notified body / ExCB responsible for the quality system notification;*
- c) *where it is not possible to trace unsafe 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;*

*For all non-conforming products that has been supplied to a customer, Measurement Solutions maintains, for a minimum period of 10 years, records of;*

- a) *serial numbers or identification of products supplied;*
- b) *the customer who received the product;*
- c) *the action taken to inform customers and the relevant notified body / ExCB in the case of unsafe non-conforming product;*
- d) *the action taken to implement corrective and preventative action;*
- e) *concessions for product that take the product outside the design as defined in the EC type-examination certificate / ExTR and technical documentation are not permitted.]*

Measurement Solution ensures conformity to requirements are verified when nonconforming outputs are corrected.

### 8.7.2 Retaining Non-Conformance Documentation

Measurement Solutions 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 with respect to the nonconformity.

## 9 Measurement Solutions Performance Controls

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### 9.1 Monitoring, Measurement, Analysis and Evaluation

#### 9.1.1 General

Measurement Solutions plans and implements the monitoring, measurement, analysis, and improvement processes needed to ensure adherence to this specification and to continuously improve the effectiveness of the QMS.

Measurement Solutions has determined:

- a) what needs to be monitored and measured;
- b) applicable methods for monitoring, measurement, analysis and evaluation needed to ensure valid results;
- c) when the monitoring and measuring need to be performed;
- d) when the results from monitoring and measurement need to be analyzed and evaluated.

Measurement Solutions evaluates the performance and the effectiveness of the Quality Management System.

Measurement Solutions retains appropriate documented information as evidence of the results. These records are a considered a special type of document and are controlled according to the requirements outlined in section 4.4.4.

*[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.]*

#### 9.1.2 Customer Satisfaction

Measurement Solutions monitors customers' perceptions to determine the degree to which their needs and expectations have been fulfilled. Measurement Solutions determines the methods for obtaining, monitoring and reviewing this information. Such methods include but are not limited to customer surveys, customer feedback on delivered products and services, VOC meetings, market-share analysis, compliments, warranty claims and service reports.

[For purposes of the ExTR standard, “customer satisfaction” shall be in relation to the product’s compliance with the EC type-examination certificate / ExTR.]

### 9.1.3 Analysis and Evaluation

Measurement Solutions 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.

## 92 Measurement Solutions Internal Auditing: Controls, Responsibilities & Authorities

### 9.2.1 Conduct Internal Audits

Measurement Solutions conducts internal audits at planned intervals to provide information on whether the Quality Management System:

- a) conforms to:
  - 1) the organization’s own requirements for its Quality Management System;
  - 2) the requirements of this International Standard.
- b) is effectively implemented and maintained.

### 9.2.2 Audit Planning, Results, and Actions

Measurement Solutions has:

- a) planned, established, implemented and maintains an audit program including the frequency, methods, responsibilities, planning requirements and reporting, and has taken into consideration the importance of the processes concerned, changes affecting the organization, and the results of previous audits;
- b) defined the audit criteria and scope for each audit;
- c) selected auditors and conduct audits to ensure objectivity and the impartiality of the audit process;
- d) ensured that the results of the audits are reported to relevant management;

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- e) taken appropriate correction and corrective actions without undue delay;
- f) outsourced activities performed on Measurement Solutions' premises, which impact product quality, are included in the scope of the audit program.

*[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 EC type-examination certificate/ExTR. The maximum period between the Ex audits should normally be 12 months and not exceed 14 months.]*

*Measurement Solutions may employ vertical auditing and/or checklist audits to validate effectiveness of the Quality Management System.]*

Measurement Solutions retains documented information as evidence of the implementation of the audit and audit results.

## 93 Measurement Solutions Management Review Requirements

### 9.3.1 General

Top Management at Measurement Solutions reviews the organization's Quality Management System, at planned intervals [*not to exceed 14 months*]. Top Management and (the person(s) responsible for the activities as detailed in 5.3) ensures by means of the review that the QMS continues to be suitable, adequate, effective and in alignment with the strategic direction of the organization.

### 9.3.2 Management Review Inputs

Measurement Solutions management includes, at a minimum, the following inputs:

- a) 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 [*Results of audits should include both internal audits and those conducted by other parties (e.g. the notified body / ExCB).*];
  - 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 improvements;
- g) *[overall effectiveness of the Quality Management System with respect to products intended for use in potentially explosive atmospheres.]*

### 9.3.3 Management Review Outputs

The outputs of the management review include, at a minimum, the decisions and actions related to:

- a) opportunities for improvement;
- b) any need for changes to the Quality Management System;
  
- c) resource needs.

Measurement Solutions retains documented information as evidence of the results of management reviews outlined in section 7.5.3.

Reference PP-QA-10- Management Review

## 10 Measurement Solutions Focus on Improvement

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### 10.1 General

Measurement Solutions has determined and selected opportunities for improvement and implements, in a timely fashion, those actions necessary to meet customer requirements and enhance customer satisfaction.

### 10.2 Nonconformity and Corrective Action

#### 10.2.1 Incidence of Nonconformity and Complaints

Measurement Solutions has maintained documented information to correct nonconformities and to take appropriate action to eliminate the causes of nonconformance, internally and within the supply chain, to minimize the impacts of the nonconformance, as well as its likelihood of recurrence. Corrective Actions are appropriate to the magnitude of the effects caused by the nonconformance.

The procedure will, at a minimum, address then following:

- a) review of the nonconformity, including customer complaint;
- b) identify the root cause(s) of the nonconformance and assess the need for a corrective action;
- c) implement the corrective action with the intent to reduce likelihood of recurrence;
- d) establish a timeframe and responsible “owner” for addressing corrections and corrective action;
- e) review the effectiveness of any corrective action taken;

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- f) update risks and opportunities determined during planning;
- g) manage change, when corrective action requires changes to the QMS outlined in section 6.3;
- h) *[maintain a system such that in the event of product not complying with the EC type-examination certificate / ExTR and having been supplied, then Measurement Solutions customer can be identified;*
- i) *take actions, appropriate to the degree of risk, where non-conforming product has been supplied to a customer;*
- j) *ensure, where unsafe and/or non-conforming product has been supplied to a customer, informs, in writing, its customer and the notified body / ExCB responsible for the quality system notification;*
- k) *ensure, where it is not possible to trace unsafe product (e.g. product supplied via a distributor, or for high volume products such as cable glands), a notice shall be placed in appropriate publications providing recommended action to be taken;*
- l) *for all non-conforming products that has been supplied to a customer, Measurement Solutions maintains, for a minimum period of 10 years, 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 relevant notified body / ExCB in the case of unsafe non-conforming product;*
  - 4) *the action taken to implement corrective and preventative action.*
- m) *concessions for product that take the product outside the design as defined in the EC type-examination certificate / ExTR and technical documentation are not permitted.]*

Measurement Solutions' retains documented information as evidence of the implementation of the procedure and performs reviews to determine the effectiveness of actions taken.

### 10.3 Continual improvement

Measurement Solutions has ensured the Quality Management System is continually improved for its effectiveness, using the Global Quality Policy, IQ leadership program, quality objectives, internal and supplier audit Results, analysis of data, corrective and preventative actions, and Management Review.

**"End of Document"**